Mt Washington Pediatric Hospital_FAV_SB 879

Uploaded by: Ajayi-Akintade, Dr Ajoke

Position: FAV

Mt. Washington Pediatric Hospital
Where Children Go to Heal and Grow

An affiliate of University of Maryland Medical System and Johns Hopkins Medicine

Maryland Infant Lifetime Care Trust
Senate Bill 879

Before the Senate Finance Committee

March 5, 2020
Position: Support

Good Afternoon, my name is Dr. Ajoke Ajayi-Akintade.

I am a board-certified neurodevelopmental pediatrician and the Assistant Medical Director at Mt. Washington Pediatric Hospital in Baltimore, Maryland. I am also the Director of the Pediatric Complex Care Program (PCCP), a program that transitions children with complex medical diagnoses including severe neurological impairment to home, ensuring that all needed medical and health support are in place to promote ongoing developmental growth and stability. I earned a Master's degree of Occupational Health from Harvard University and completed my pediatric residency at Howard University Hospital, followed by a Neurodevelopmental Disabilities fellowship at Johns Hopkins University.

As a neurodevelopmental pediatrician with more than 20 years of experience I am an untiring advocate of medically fragile children. As such, I know firsthand the unique needs of these children with neurological injuries, genetic birth defects and complex medical conditions. As the director of the Pediatric Complex Care Program, my team and I care for the most medically complex and fragile newborns and children in Maryland, each and every day.

I am here in support of SB 879 - the Maryland Infant Lifetime Care Trust. Less than 1 % of children in the US have such complex medical diagnoses--approximately seven children per year in the state of Maryland. As the neurodevelopment pediatrician at MWPH, I receive about five of these seven cases each year so I know what it takes to care for a child with such disabilities. The child's pediatrician is in the best position to plan for the course of treatment because they interact with the child on a routine basis and monitor the child's improvements and regressions.

This Trust and the mechanics of determining the child's needs by the treating physician and making the monies available for the care or necessary accommodations when they are needed is the best course of action. This Trust would ensure that the child receives the best quality of care by providing adequate funds, when needed, to support the development of the child throughout their entire lifetime, and ensuring that the course of treatment is determined by an unbiased expert who actually treats the child during the course of the child's life.

Mt. Washington Pediatric Hospital
Where Children Go to Heal and Grow

An affiliate of University of Maryland Medical System and Johns Hopkins Medicine

The Infant Lifetime Care Trust is a just and equitable plan of action for Maryland. I urge a favorable vote on SB 879.

Sincerely,

Ajoke Ajayi-Akintade, MD, FAAP, MOH
Assistant Medical Director
Neurodevelopmental Pediatrician
Mount Washington Pediatric Hospital

Mercy Health Services_FAV_SB 879
Uploaded by: Amos, Sister Helen
Position: FAV

Mercy
HEALTH SERVICES

University Affiliated

Sponsored by the Sisters of Mercy

March 6, 2020

Chair Delores G. Kelley
Maryland Senate Finance Committee
3 East Miller Senate Office Building
Annapolis, Maryland 21401

RE: SUPPORT FOR SB0879: PUBLIC HEALTH – MARYLAND INFANT LIFETIME CARE TRUST FUNDED BY HSCRC AND MARYLAND PATIENT SAFETY CENTER DUTIES

Dear Chairwoman Kelley & Committee Members:

On behalf of Mercy Medical Center, I am writing to express strong support for SB0879: Public Health – Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties. In a small number of complex cases, an infant may require long-term medical care as a result of neurological injuries that occur at birth. The Maryland Lifetime Infant Care trust would provide guaranteed lifetime care for these infants and would be funded entirely by Maryland hospitals through Maryland's unique all-payor rate-setting system.

Medical liability risk related to birth injury cases has been a looming crisis that Mercy has been warning about for the past several years. Mercy's liability expense and hospital reinsurance costs have more than tripled since 2012 and two of Mercy's reinsurers have either stopped providing or scaled back coverage since that time.

Since the $229 million Byrom vs. Hopkins Bayview award in July 2019—the largest medical malpractice jury award in the history of the United States—the medical liability environment has worsened significantly. The future availability and affordability of hospital reinsurance has become highly uncertain. A recent Baltimore Sun Editorial endorsing the Maryland Infant Lifetime Care Trust described the situation as *"a genuine health care emergency"*. Indeed, the only way to reverse this alarming trend is legislative reform, which we believe would safeguard Mercy's and other hospitals' ability to secure affordable reinsurance in the future.

Mercy is Baltimore City's largest birthing hospital, delivering roughly 3000 babies each year. The overwhelming majority of our mothers are Medicaid-insured and many come from Baltimore's poorest and most challenged neighborhoods. It's been our mission to provide access to high-quality

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TTY 410-332-9888 *http://www.MDMERCY.com*

maternity care for this vulnerable population. We fully intend to continue our mission but we need your help now to address this worsening crisis.

Thank you for your consideration and we urge a favorable report for SB0879: Public Health – Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties. If you have any questions regarding Mercy's position in support of this important legislation, please contact Ryan O'Doherty, Vice President External Affairs, Mercy Medical Center at 410-456-0892 or rodohert@mdmercy.com.

Sincerely,

Sister Helen Amos, RSM
Executive Chair, Board of Trustees
Mercy Health Services

Kennedy Krieger Institute_FAV_SB 879
Uploaded by: Burton, Dr Joanna
Position: FAV

Kennedy Krieger Institute

DATE: **March 5, 2020** **COMMITTEE: Senate Finance**
BILL NO: **Senate Bill 879**
BILL TITLE: **Public Health – Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties**
POSITION: **Support**

Kennedy Krieger Institute supports Senate Bill 879 - Public Health – Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties

Bill Summary:
This legislation establishes the Infant Lifetime Care Trust. The trust will be funded by hospitals who deliver babies and would provide guaranteed lifetime care for infants injured at birth.

Background:
Kennedy Krieger Institute is an internationally recognized institution dedicated to improving the lives of children and adults with developmental disabilities and disorders of the brain, spinal cord and musculoskeletal system. KKI serves over 24,000 patients per year throughout their life spans, many of whom have a history of perinatal brain injury.

The Infant Neurodevelopment Center at Kennedy Krieger specializes on follow-up of high risk infants including those with devastating brain injury in the perinatal period. We see around 500 children a year, following them from hospital discharge through preschool years, and provide neurodevelopmental consults in the Neonatal Intensive Care Units at Johns Hopkins.

A key piece of our practice is guiding parents through appropriate support as new developmental concerns arise. We provide comprehensive, multi-disciplinary assessments at key points when best prognostication is available for disability such as cerebral palsy, intellectual disability, cortical vision impairment, autism, learning disability and ADHD.

Infants with severe perinatal brain injury can require a number of specialized services for ongoing medical and developmental care:

- Gastrostomy tubes (for problems of the mouth, stomach, esophagus or intestines)
- Supplemental oxygen
- Durable medical equipment, braces, wheelchairs and augmentative communication devices
- Targeted therapies, most commonly physical therapy, occupational therapy and speech language therapy
- Supports and accommodations including nursing care and school accommodations.

Each of these supports is targeted to a particular need and those needs change over time, requiring ongoing, serial assessment to tailor the child's treatment plan.

Rationale:
The Maryland Infant Lifetime Care Trust is important for the overall health of the children it would serve because it allows for the family and treating physician to provide appropriate support to the children when they need it based on thorough individualized assessment rather than on prognostication of the future.

Children's needs change as they grow and age. Support needs that are appropriate at younger ages may not be appropriate at older ages. Similarly, additional needs may surface throughout a patient's life that may require new therapies unforeseen at infancy or childhood.

Finally, we are at an exciting time in perinatal brain injury medicine with new targeted therapies for complications of perinatal brain injury such as cerebral palsy that are changing outcomes, which makes it increasingly difficult to predict outcomes at a single point in time; the pace of change requires ongoing, lifelong evaluations to determine appropriate care. Treating physicians and families need a reasonable way forward that allows children with severe perinatal brain injury to receive fully-compensated, targeted, timely and individualized lifetime care to address the children's ever-changing needs. The Infant Lifetime Care Trust would guarantee that care.

Kennedy Krieger Institute requests a favorable report on Senate Bill 879.

SB 879_FAV_Medical Mutual_DeLong
Uploaded by: DeLong, Ashton
Position: FAV

MEDICAL MUTUAL

Liability Insurance Society of Maryland

Bill: Senate Bill 879 – Public Health – Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties

Date: March 5, 2020

Position: ***SUPPORT***

Bill Summary

Senate Bill 879 establishes the Maryland Infant Lifetime Care Trust (the "Trust") to provide payment for economic and health care services to infants who experience a birth-related neurological injury. First, the bill creates a seven-member Board of Trustees to oversee the Trust, and a Trust Administrator, appointed by the Board of Trustees, to serve as the administrative head of the Trust. Second, Maryland hospitals providing obstetrical services fund the Trust, and one million dollars will be allocated each year to study improving maternal and fetal outcomes in Maryland. Third, Senate Bill 879 does not alter a claimant's access to the courts and instead imposes a system where a claimant's eligibility for the Trust is determined after settlement or judgment. After a settlement or judgment, the Trust then ascertains whether an injury qualifies as a birth-related neurological injury, and once confirmed that the injury does qualify, the Trust disperses compensation for services needed for a claimant's lifetime care.

Medical Mutual's Position

Medical Mutual supports Senate Bill 879. Currently, there are three birth-related injury funds that operate in the United States: the Florida Birth-Related Neurological Injury Compensation Association, the Virginia Birth-Related Neurological Injury Compensation Program, and the New York State Medical Indemnity Fund. Senate Bill 879 incorporates the system set forth in the New York State Medical Indemnity Fund by creating the Trust and also allowing claimants to litigate an alleged medical malpractice claim in the court system. If a judgment or settlement is entered in favor of a claimant and the Trust determines that the claimant is eligible for payments from the Trust, the Trust provides compensation for the remainder of the claimant's lifetime.

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As a mutual company, Medical Mutual is owned by its physician policyholders, and we strive to offer affordable medical professional liability insurance. Medical Mutual supports Senate Bill 879, because it creates a system that balances the need to control medical malpractice costs to ensure that Maryland women continue to have access to quality obstetrical services in all regions of the State with the need to provide lifetime care to infants who experience a birth-related neurological injury.

For the reasons contained herein, Medical Mutual respectfully requests a ***FAVORABLE*** report of ***SENATE BILL 879.***

For more information contact:
Cheryl F. Matricciani / cmatricciani@weinsuredocs.com
Ashton DeLong / adelong@weinsuredocs.com
(410) 785-0050

APCIA_FAV_SB879
Uploaded by: Egan, Nancy
Position: FAV

American Property Casualty Insurance Association
INSURING AMERICA apci.org
Nancy J. Egan, State Government Relations Counsel
Nancy.egan@APCIA.org Cell: 443-841-4174

Testimony of American Property Casualty Insurance Association (APCIA)

Senate Finance Committee and Judicial Proceedings Committee

Senate Bill 879 Public Health – Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties

March 5, 2020

Letter of Support

The American Property Casualty Insurance Association (APCIA) represents more than 1200 insurers and reinsurers that provide critically important insurance protection throughout the U.S. and world. In combination, our members write 60% of the U.S. property casualty market. APCIA members represent all sizes, structures, and regions—protecting families, communities, and businesses in the U.S. and across the globe. APCIA appreciates the opportunity to provide written comments in support of Senate Bill 879.

Senate Bill 879 seeks to stabilize and reduce medical liability risk in order to preserve essential access to obstetric services by creating a fund, underwritten by a fee assessed against hospitals providing those services, that would pay for all future medical expenses in jury awards and settlements relating to birth-related neurological injuries that result in unusually high costs for lifetime care and rehabilitation. The astronomical costs of providing this care warrant adoption of this type of risk-spreading mechanism, which has been operational for decades in Florida and Virginia.

For these reasons, APCIA urges the Committee to provide a favorable report on Senate Bill 879.

ACNM_FAV_SB 879
Uploaded by: Elliott, Robyn
Position: FAV

AFFILIATE OF
AMERICAN COLLEGE of NURSE-MIDWIVES
With women, for a lifetime®

Committee:	**Senate Finance Committee**
Bill number:	**SB 879**
Title:	**Public Health – Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties**
Hearing Date:	**March 5, 2020**
Position:	**Support**

The Maryland Affiliate of the American College of Nurse Midwives (ACNM) supports *Senate Bill 879 – Public Health – Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties.* This bill would create a trust, supported by an assessment on hospital obstetric units, that would pay for medical and supportive care for individuals who suffer a neurological injury during birth.

ACNM supports policy to stabilize what has become a liability crisis for hospitals and families that have a child who has suffered neurological injury during birth. Under the current system, juries award a lump sum to a family for an infant's future care. This is difficult to estimate, as has been demonstrated by awards that have been insufficient to cover future costs to others that have been so high they have led to drastic cost of care increases and impacted the ability of providers to provide maternity care.

This bill would pay medical and supportive expenses, which would include transportation and home modifications, as needed throughout the life of the injured individual, offering peace of mind to the family that their expenses is this regard will always be covered. Hospitals will still be responsible for all other costs associated with litigation, such as non-economic damages, pain and suffering, lost earnings, and attorney's fees.

We believe this bill is a way forward to ensure coverage for affected families while maintaining access to maternity care, and we ask for a favorable report. If we can provide any further information, please contact Robyn Elliott at relliott@policypartners.net or (443) 926-3443.

MNA_FAV_SB 879
Uploaded by: Elliott, Robyn
Position: FAV

Committee: **Senate Finance Committee**

Bill Number: **Senate Bill 879**

Title: **Public Health – Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties**

Hearing Date: **March 5, 2020**

Position: **Support**

The Maryland Nurses Association (MNA) supports *Senate Bill 879 – Public Health – Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties.* This bill would create a trust, supported by an assessment on hospital obstetric units, that would pay for medical and supportive care for individuals who suffer a neurological injury during birth.

After a traumatic event where an infant suffers a neurological injury during childbirth, families often turn to the courts to cover expenses relating to the newborn's care. However, the current system does not consistently meet families' needs and has destabilized the healthcare system. Currently, juries award a lump sum to a family for an infant's future care following a neurological birth injury. This is difficult to estimate, and has resulted in awards that have been insufficient to cover future costs to others that have been so high, such as the recent verdict of over $2 million against Johns Hopkins, that they have impacted the ability of providers to provide maternity care.

This bill would pay medical and supportive expenses from the trust as needed throughout the life of the injured individual, rather than trying to estimate the lifetime costs at the outset. We believe this will offer peace of mind to the families that their expenses related to the birth injury will always be covered. Hospitals will still be responsible for all other costs associated with litigation, such as non-economic damages, pain and suffering, lost earnings, and attorney's fees. In addition, we strongly support the bill's provision requiring that the trust devote $1 million annually to address health disparities and improve maternal and fetal outcomes across Maryland.

We believe this bill is a way forward to ensure coverage for affected families while maintaining access to maternity care, and we ask for a favorable report. If we can provide any further information, please contact Robyn Elliott at relliott@policypartners.net or (443) 926-3443.

Maryland Patient Safety Center_FAV_SB 879
Uploaded by: Epke, Barbara
Position: FAV

6820 Deerpath Road
Elkridge, MD 21075

MARYLAND Patient Safety CENTER

410.540.9210 (Phone)
410.540.9139 (Fax)

March 4, 2020

To: The Honorable Delores G. Kelley, Chairman
Senate Finance Committee

From: Barbara Epke
Interim President and CEO
Maryland Patient Safety Center

RE: Letter of Support---Senate Bill 879—Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties

Thank you for the opportunity to express support of Senate Bill 879 on behalf of the Maryland Patient Safety Center. The MPSC is an independent organization, and our reputation has shown us to be effective as a convener of healthcare providers without institutional bias to disseminate best practices, educate and train allied healthcare workers, and facilitate discussion in order to improve patient safety. MPSC has been engaged in infant and maternal health initiatives since 2006, working on improving outcomes related to OB Hemorrhage, NEC (necrotizing enterocolitis), Early Elective Deliveries and "Golden Hour" protocols for infants in distress. More recently, we have seen significant success from our collaborative initiatives with Maryland hospitals focused on the reduction of first time C-sections and Neonatal Abstinence Syndrome—establishing standardized treatment protocols for substance addicted infants. I believe the MPSC is uniquely qualified to conduct the duties as outlined in HB 879, specifically, to convene a certain Perinatal Clinical Advisory Committee, which will take certain actions and report annually to the Board of Trustees of the Maryland Infant Lifetime Care Trust.

The MPSC has long been familiar with the incidence of risk and injury at hospitals that deliver babies, as well as care needs of infants who suffer a neurological injury at birth. While it is understood that families may still hold hospitals and physicians accountable, the enormous resources required to adequately care for an infant sustaining an injury must be assured, and the fact that the proposed Trust will cover medical and supportive care for anyone receiving a court approved settlement or verdict for a birth-related neurological injury is progress indeed. It should be noted that because of our extensive experience in maternal and infant health related initiatives, the MPSC was chosen to participate in the Maryland Maternal Health Innovation Program, a five-year initiative that began in October of 2019 and aims to improve maternal health across the state of Maryland.

The Maryland Patient Safety Center strongly supports Senate Bill 879—Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties. The focus of the bill is clearly in line with our mission to promote safety and safe care in and beyond the hospital setting in the state of Maryland. Because of our existing relationships with hospitals and hospital appointed Patient Safety Officers, and because of our extensive experience in gathering, reviewing, and trending outcome data, MPSC is uniquely qualified to convene and lead a group to study and address disparities in care and to improve maternal and fetal outcomes across the state. In addition to identifying risks and obstacles to care, MPSC is experienced in working with hospitals on the next step in managing such issues, including establishing or proposing protocols, procedures and policies for improvement.

The horizon for risk has expanded to include healthcare disparities and implicit bias, an area now receiving attention in the aforementioned Maryland Maternal Health Innovation Program, funded by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS). The MPSC welcomes this opportunity to move safe infant care to a new level and is grateful to be able to devote resources to the education, analysis, and collaboration with hospitals and local agencies to foster the actual improvement. The MPSC is prepared to both report routinely to the Board of Trustees of the Maryland Infant Lifetime Care Trust as well as to submit a written report of progress.

In conclusion, the MPSC is in complete support of Senate Bill 879 and we are excited to assist the State with the initiative proposed, so that together we can improve the quality of care received by infants in Maryland. Should you wish to discuss further, please do not hesitate to contact me.

For more information, please contact:
Barbara Epke
bepke@marylandpatientsafety.org
410-540-9210

Donald Fry_FAV_SB879
Uploaded by: Fry, Donald
Position: FAV

gbc POSITION STATEMENT

TESTIMONY PRESENTED TO THE SENATE FINANCE COMMITTEE AND SENATE JUDICIAL PROCEEDINGS COMMITTEE

SENATE BILL 879 -- PUBLIC HEALTH – MARYLAND INFANT LIFETIME CARE TRUST FUNDED BY HSCRC AND MARYLAND PATIENT SAFETY CENTER DUTIES

March 5, 2020

DONALD C. FRY
PRESIDENT & CEO
GREATER BALTIMORE COMMITTEE

Position: Support

Senate Bill 879 establishes the Maryland Infant Lifetime Care Trust (Trust) to pay for the costs of medical and supportive care for individuals who suffer a neurological injury during birth. The bill provides guaranteed coverage for the lifetime care needs as determined by their physician to be paid for by the Trust, which would be funded by Maryland hospitals that deliver babies. The bill would also allocate $1 million annually to improve fetal outcomes in Maryland.

The GBC supports Senate Bill 879 because it provides a common sense solution for the needs of the families of children who suffer a neurological injury during birth. Additionally, the bill acknowledges the importance of one of the leading employment sectors in the Greater Baltimore region. Hospitals are one of Maryland's most important economic drivers, providing not only jobs and economic activity, but the ability to deliver some of the best health care in the world. According to the Maryland Hospital Association, Maryland hospitals account for nearly eight percent of the State's gross domestic product, employ nearly 108,000 people and indirectly support an additional 120,000 non-hospital jobs, accounting for eight percent of the State's total employment in Maryland.

The GBC believes that an important priority for policymakers is enhancing the ability of hospitals to compete in an increasingly competitive health care market. Passage of Senate Bill 879 would be an important step to ensuring Maryland's hospitals are able to stay competitive and continue providing their vital services to Marylanders.

Hospitals have been increasingly concerned with the liability climate in Maryland and its potential impact on access to care. Recent events, such as a $229.6 million medical malpractice verdict against Johns Hopkins, and the decision of some liability insurers to exit Maryland, have brought this issue to the forefront. Under Maryland's current system, when infants are injured at birth, families may turn to the courts to ensure coverage of their child's future medical costs and hold doctors and hospitals accountable. However, families have to rely on whatever amount juries determine will be needed to care for the complex, lifelong health challenges of an infant with birth injuries. In some cases the amount may be insufficient while in other cases there are awards that could potentially destabilize the healthcare system in Maryland, leading to higher costs and impacting the availability of maternity care.

Senate Bill 879 is consistent with a key tenet in *Gaining the Competitive Edge: Keys to Economic Growth and Job Creation in Maryland,* a report published by the GBC that identifies eight core pillars for a competitive business environment and job growth:

> **Competitive costs of doing business.** Public policies must reflect a government predisposition to nurture business growth and to avoid arbitrarily or disproportionately imposing additional overhead upon the business sector.

For these reasons, the Greater Baltimore Committee urges a favorable report on Senate Bill 879.

The Greater Baltimore Committee (GBC) is a non-partisan, independent, regional business advocacy organization comprised of hundreds of businesses -- large, medium and small -- educational institutions, nonprofit organizations and foundations located in Anne Arundel, Baltimore, Carroll, Harford, and Howard counties as well as Baltimore City. The GBC is a 65-year-old, private-sector membership organization with a rich legacy of working with government to find solutions to problems that negatively affect our competitiveness and viability.

GREATER BALTIMORE COMMITTEE
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MedChi, MDACOG_Pam Kasemeyer_FAV_SB0879
Uploaded by: Kasemeyer, Pam
Position: FAV

MedChi

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ACOG
The American College of Obstetricians and Gynecologists
Maryland Section

TO: The Honorable Delores G. Kelley, Chair
The Honorable William C. Smith, Jr.
Members, Senate Finance Committee
Members, Senate Judicial Proceedings Committee

FROM: J. Steven Wise
Pamela Metz Kasemeyer
Danna L. Kauffman
Richard A. Tabuteau

DATE: March 5, 2020

RE: **SUPPORT** – Senate Bill 879 – *Public Health – Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties*

On behalf of the Maryland State Medical Society (MedChi) and the Maryland Section of the American College of Obstetricians and Gynecologists (MDACOG), we submit this letter of **support** for Senate Bill 879.

Senate Bill 879 establishes a Trust that will provide compensation and benefits for claims asserted against health care practitioners or hospitals in connection with birth injuries, where an infant is permanently neurologically and physically impaired. These injuries can be devastating to the infant and their family or caregiver and require health care and other resources be made available to them, in amounts often running into the millions of dollars. The awards or settlements for these costs are borne by the hospital, the providers and their insurers, driving up their liability costs and the cost of health care generally.

The Trust established under Senate Bill 879 will help ensure that the infant and caregivers are given the resources they need to provide proper care for the injured party. At the same time, the Trust helps the hospitals and providers manage the costs of damage awards stemming from these cases. The Trust is funded through an assessment on those hospitals that provide acute obstetrics, neonatal intensive care, newborn and premature nursery, normal newborn or labor and delivery services. It can be accessed on application to the Trust by any qualifying party.

Considering the recent $220 million verdict against Johns Hopkins, MedChi and MDACOG believe this legislation is a necessary step to ensure that birth-related health care services remain available in our State, and that injured claimants are assured of proper care resulting from birth injuries.

For these reasons, MedChi and MDACOG support Senate Bill 879.

For more information call:
J. Steven Wise
Pamela Metz Kasemeyer
Danna L. Kauffman
Richard A. Tabuteau
410-244-7000

JohnsHopkins_FAV_SB879_Kohn
Uploaded by: Kohn, MD,MPH, Jaden R.
Position: FAV

Department of Gynecology and Obstetrics
600 N. Wolfe Street / Phipps 264
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JOHNS HOPKINS
MEDICINE

SB 879: Favorable

To: The Honorable Delores G. Kelley, Chair
Senate Finance Committee

The Honorable Williams C. Smith, Jr., Chair
Senate Judicial Proceedings Committee

From: Jaden R. Kohn, MD, MPH
Resident Physician in Gynecology & Obstetrics
Johns Hopkins Medicine

Date: March 5, 2020

As a Resident Physician in Gynecology & Obstetrics at Johns Hopkins Medicine, I strongly support **Senate Bill 879 – Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties**. In addition to my medical doctorate, I have a Master's degree in Public Health, focusing on Health Services Research and Healthcare Management. I also have extensive training in safety and quality, and I am the Gynecology & Obstetrics departmental representative for the Housestaff Patient Safety and Quality Council at Hopkins.

I am driven by a passion to provide high-quality care to women and their families, each of whom deserve access to healthcare that is safe, dependable, and equitable. The current legal environment jeopardizes access to that care for women throughout the state of Maryland. Nationally, an increasing number of Labor and Delivery units are closing, in part, due to non-sustainable financial structures resulting from malpractice premiums – and Labor and Delivery units in Maryland are not exempt from these threats. Senate Bill 879 is a necessary and important step to ensure that the women of Maryland will continue to have access to obstetric care.

Furthermore, my colleagues share my sentiment that, as resident physicians, we have two obligations to our patients: 1) to invest ourselves in our training such that we are prepared to provide the high-quality medical care that Marylanders deserve, and 2) to give back to the women who have contributed to our education by devoting our careers to clinical excellence. Thus, it is crucial to ensure that Labor and Delivery units have the necessary support to provide high-quality education to obstetricians-in-training, while also providing exceptional care for women. Unfortunately, if the trends in our liability system continue unabated without SB879, it will become increasingly difficult to attract and to retain both obstetricians-in-training and experienced obstetricians in the state of Maryland, jeopardizing the future of healthcare for the women in our local communities.

This bill is an opportunity for change. SB879 offers a straightforward solution to the existing system – a financially-sustainable strategy to pay for the costs of a lifetime of care, while still holding hospitals accountable. Maryland families are asking for our support; their beloved children are some of our

communities' most vulnerable. SB879 is one means to create a just and equitable system that helps to secure their future.

Historically, Maryland has been a national leader in innovative payment reform; Senate Bill 879 provides our state the opportunity to continue to be a leader, by 1) addressing current malpractice concerns that jeopardize the future of hospitals and obstetricians, 2) preserving access to high-quality obstetric care for all women, and 3) creating a commitment to families that financial resources will exist to provide for their children's future.

For these reasons, I urge a favorable report on **Senate Bill 879 – Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties**.

Johns Hopkins Health System_FAV_SB 879
Uploaded by: Miller, Dr Redonda
Position: FAV

JOHNS HOPKINS
UNIVERSITY & MEDICINE
Government and Community Affairs

SB 879
SUPPORT

TO: The Honorable Delores G. Kelley, Chair
Senate Finance Committee

The Honorable William C. Smith, Jr., Chair
Senate Judicial Proceedings Committee

FROM: Kevin Sowers, M.S.N, R.N., F.A.A.N.
President, Johns Hopkins Health System
Executive Vice President, Johns Hopkins Medicine

DATE: March 5, 2020

INTRODUCTION

The Maryland General Assembly has the opportunity to provide urgently needed stability to Maryland's healthcare system and to secure a common sense, common-ground approach to a long-intractable problem. **Most importantly, however, legislators have the opportunity to establish a mechanism by which Maryland's most vulnerable infants are guaranteed the medical care and supportive services that they will need for life.** Therefore, on behalf of the Johns Hopkins Health System, I offer the following testimony in strong support of **Senate Bill 879, Public Health – Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties**

A NEW, COMMON-SENSE PROPOSAL: SENATE BILL 879

The approach proposed by SB 879 is simple, straightforward and would benefit everyone. Families would still be able to hold hospitals and doctors accountable and would still receive direct compensation for non-economic damages, past medical expenses, legal fees, and lost earnings. None of that would change.

Instead, the bill creates the Infant Lifetime Care Trust, which would assume the payment responsibilities for all future medical expenses for infants who suffer birth injuries. The Trust would be funded by an annual assessment on Maryland's hospitals that deliver babies and would be required to cover all costs of care as determined solely by the patients' own physicians in perpetuity.

Through this one change, Senate Bill 879 provides certainty to what is today uncertain. It provides certainty to families that their loved ones will receive the care they need for life. It provides certainty to insurers that hospitals won't receive astronomic verdicts that will drive up premiums to unsustainable levels. And it provides certainty to Marylanders that they will be able to access high quality maternity care when and where they need it.

In addition, the Trust would commit $1 million each year to study maternal and fetal health disparities through the Office of Minority Health and Health Disparities. This investment nearly doubles the current budget and sends a clear signal that Maryland is committed to making sure that every mother – regardless of race or socioeconomic status – is able to access high quality pre-natal care.

Finally, by designating the Infant Lifetime Care Trust as the party responsible for paying for medical care, Senate Bill 879 would relieve Maryland's Medicaid system of paying for this care. Under current law, when a plaintiff obtains a settlement or wins a jury verdict for medical liability, the proceeds generally go into a 'Special Needs Trust' (SNT). That SNT allows the family to protect those proceeds and still qualify for medical care from the Maryland Medicaid Program. Initially under this new Infant Lifetime Care Trust, the costs for Medicaid will increase by a small amount because of the hospital rate adjustment to fund the Trust. However, it is estimated that funding a child's lifetime care through the Infant Lifetime Care Trust rather than from the state Medicaid program will produce significant annual savings to the state general fund after the first few years.

MARYLAND'S STATUS QUO

Tens of thousands of babies are born in Maryland each year, and Johns Hopkins Health System is a leader in providing world-class obstetric care to Marylanders. Our hospitals deliver more than 7,200 babies each year, and we receive more than 350 high-risk transfers from around the state. The Johns Hopkins Hospital and Johns Hopkins Bayview Medical Center are two of a limited number of Maryland hospitals with level III and level IV neonatal intensive care units (NICU) that are equipped to handle the most complex births. As a result, we frequently receive patients – transferred from other hospitals throughout the state – whom our physicians and nurses have never treated before and with whom we have no prior relationship. Our clinical teams care for these patients – as we do all our patients – with expertise, compassion, and a single goal: ensuring their safety and wellbeing.

Though extremely rare, in a very small number of complex cases, an infant may require long-term medical care and specialized support services as a result of neurological injuries that occur at birth. It is these cases, and the lifelong health of the infants in question as well as the broader impact on the health system, that are the focal points of this testimony.

Maryland has the second highest quality hospitals in the country according to independent rankings, and the Johns Hopkins Hospital is nationally recognized as one of the top three hospitals in the country. Yet despite the exceptional care provided by the state's hospitals -- Maryland has half the national average of medical liability claims – Maryland hospital payouts are double the national average. This is one indication of a long-term trend that has destabilized the liability insurance market in Maryland. Another is that over the last 12 years as claim amounts in all other states went up by 50 percent, claim amounts in Maryland surged by more than 300 percent.

Let me be clear at the outset that infants who have suffered injuries at birth should be guaranteed the care they need for life. And it is equally clear that if a mistake has been made, those responsible should be held accountable. But in Maryland today a jury can only guess at how much a child's future medical care will cost, and an attorney is incentivized to inflate that number, because he or she gets a large percentage of the total amount awarded (usually 40 percent). Whereas other parts of a jury award are capped by law (such as non-economic or "pain and suffering" damages), this part is completely open-ended.

THE PROBLEMS WITH MARYLAND'S STATUS QUO

The current system has a critical flaw: future medical expenses are impossible to accurately predict. The needs of a critically ill patient from birth to childhood to adolescence and adulthood are unknowable. At the same time, the pace of technological and clinical change increases seemingly every day, with new and potentially expensive therapies that cannot today be imagined becoming available in future years and decades. Juries are ill-equipped to provide accurate estimates of the cost of care over the full lifetime of an infant.

As a result, in some cases their estimate may be too little, leaving families unable to pay for a lifetime of expensive medical care without the necessary funds to do so. No family should have to hold fundraisers to raise money to care for their child. Yet today's system offers no guarantee against such an outcome.

Conversely, in other cases, the estimate may be too much, stretching the ability of hospitals and their liability insurance companies to pay. **As one example, a recent high-profile medical malpractice case against Johns Hopkins resulted in a $229 million verdict -- the largest medical malpractice verdict in US history -- after a Maryland jury awarded the plaintiff more than five times what the plaintiff's own attorney claimed would be necessary to provide for future medical expenses.** Although this case is clearly an outlier, it illustrates a volatility that fundamentally destabilizes the healthcare system in Maryland. Claims exceeding $10 million appeared for the first time ten years ago and the frequency of their occurrence in Maryland has risen sharply since.

The uncertainty of this environment, and the potential for juries to estimate an astronomical amount to cover the care of the infant, has led to a crisis for Maryland's hospitals.

Insurance companies abhor uncertainty. That is as true for automobile insurance as it is for hospital liability insurance. In a market where risk is uncertain, as in Maryland's current hospital liability market, insurers may choose to simply leave the market rather than provide coverage. In fact, this has already happened and some of the nation's largest malpractice insurers are now declining to cover hospitals in Maryland.

As a result, insurance rates continue to rise for Maryland's hospitals. At Johns Hopkins Health System, which, with four Maryland hospitals employing nearly 30,000 Marylanders, is among the state's largest private employers, **in 2012, our insurance liability costs were $39 million. Today, less than ten years later, they have risen to $151 million. On January 1, our insurance premium went up by $40 million.** To put this new, $40 million insurance increase in context, the average Hopkins compensation of salary plus benefits in Baltimore City is about $80,000. **A $40 million charge is equivalent to 500 good-paying Johns Hopkins jobs in Baltimore City.**

Adding to the pressure facing our health system, our hospital revenues are capped by agreement between Maryland and the federal government. As part of Maryland's unique All Payer agreement with the federal government, Maryland hospitals must adhere to a global budget, which requires them to operate under a fixed annual revenue cap. That revenue cap means Johns Hopkins Health System, or any other hospital in Maryland, is unable to simply 'see more patients' or 'just increase prices' to cover the cost of higher malpractice insurance.

This environment has left Johns Hopkins Health System in an unsustainable position: our fixed costs are ballooning due to higher liability premiums while our revenue is limited. Put

simply, this environment is making it increasingly urgent that to continue our core mission of caring for communities across Maryland, we will have to make a series of difficult choices as we work to reconcile our financial and budgetary realities.

This unsustainable trend in Maryland's liability system makes it increasingly challenging to attract obstetricians to practice in Maryland, and maternity program closures are now more likely. Due in part to the rising costs of delivering obstetrical care, **several hospitals in Maryland have significantly reduced or eliminated their obstetrics programs in recent years and similar closures in Washington, DC further threaten access for Marylanders.**

We cannot wait for this crisis to deepen. The Johns Hopkins Health System – along with a broad coalition of Maryland hospitals, physicians, nurses, and patient safety advocates – believes there is a better way to ensure that infants with birth injuries are provided the care they need for life, while simultaneously creating a sustainable liability environment that holds hospitals and doctors accountable. Senate Bill 879 offers such a solution.

CONCLUSION

With Senate Bill 879, the Maryland Senate has the opportunity to put our state's most vulnerable infants first while taking an important step to stabilize and secure the state's healthcare system. The Infant Lifetime Care Trust is a smart approach to addressing a pressing issue facing the state. It is also **an approach strongly favored by Maryland's voters.** In a recent survey conducted by Braun Research Incorporated, **Marylanders supported a new approach that would provide guaranteed lifetime care for infants over the status quo by overwhelming margins: 85 percent to 15 percent.** Support is bipartisan and comes from every corner of the state. The message from Maryland voters is clear: the status quo no longer works. The state needs a new approach, like the Infant Lifetime Care Trust, to provide guaranteed care to infants.

For the above reasons we strongly urge a **favorable report on Senate Bill 879**.

cc: Members, Senate Finance Committee
Members, Senate Judicial Proceedings Committee

MCIC
VERMONT
A RECIPROCAL RISK RETENTION GROUP

Chris Smith
Chief Executive Officer

February 25, 2020

To whom it may concern,

I am writing on behalf of MCIC Vermont, a Vermont Risk Retention reciprocal, that insures Johns Hopkins Medicine for its medical malpractice risk. MCIC insures over 4,000 physicians and approximately 25,000 employees in the state of Maryland.

We believe it is imperative that the Maryland legislature pass some form of tort reform in the state to mitigate runaway medical malpractice costs. Baltimore, along with Cook County, Illinois, Philadelphia and Miami, is now one of the worst cities/counties in the U.S. for large medical malpractice lawsuits. This status is verified by Willis Towers Watson, the leading actuarial firm in the country.

These results are driving medical malpractice premiums to unsustainable levels and has most insurers considering not writing this business in Baltimore in the future. Several important insurance companies, including Berkshire Hathaway and CNA, have already declined to write in the city of Baltimore or have significantly reduced the amount of coverage they will provide. MCIC utilizes many of these companies for reinsurance purposes and without such insurance being available brings into question the viability of companies like ours.

Medical malpractice coverage is critical for large healthcare systems in Maryland to operate effectively. The potential risks to healthcare in the state are significant as certain healthcare services may become unsustainable from a cost perspective. In addition, these cost increases have made national news in many medical communities, which may also affect physicians' views of Maryland as a state in which to practice. Patient care could suffer significantly as a result.

We urge you to please pass significant tort reform as quickly as possible before these dramatically rising claim costs negatively impact provider services and patient care.

Sincerely,

Christopher D. Smith
Chief Executive Officer

Two Ravinia Drive, Suite 400, Atlanta, Georgia 30346

Tel: 770-551-5060 • Fax: 770-551-5061

UMD School of Medicine_FAV_SB 879
Uploaded by: Reece, Dr E. Albert
Position: FAV

UNIVERSITY *of* MARYLAND
SCHOOL OF MEDICINE

E. ALBERT REECE, MD, PhD, MBA Executive Vice President for Medical Affairs, UM Baltimore John Z. and Akiko K. Bowers Distinguished Professor and Dean, University of Maryland School of Medicine

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March 5, 2020

Senator Delores G. Kelley
Chair, Finance Committee
11 Bladen Street Annapolis,
Maryland 21401

Maryland Infant Lifetime Care Trust
Senate Bill 879
Position: Support

Dear Chairperson Kelley:

Good afternoon, my name is Dr. E. Albert Reece, and I am the Executive Vice President for Medical Affairs, University of Maryland Baltimore, and Dean of the School of Medicine. I am also an obstetrician-gynecologist, with sub-specialty training in high-risk obstetrics. In addition, I also serve as Co-chair of the Maryland Medicine Comprehensive Insurance Program, a joint venture self-insurance program of the clinical faculty organization of the School of Medicine and the University of Maryland Medical System.

I have committed my career to caring for patients and educating the next generation of physicians in Maryland and the nation. I testify today in strong support of SB 879.

Marylanders deserve high-quality obstetric care, yet the medical liability environment in the state has produced a profound chilling effect on the ability of our hospitals and universities to retain top talent, particularly in this critically important field.

It's important to note, despite what some may contend, that most adverse outcomes at delivery are NOT caused by specific and preventable actions by a physician. Adverse birth outcomes cannot just be labeled bad medicine.

The bottom line is this---it is simplistic, and simply wrong, to think that the external, indirect, and often subjective means of assessing fetal health and well-being will pick up the precise fetal condition, and that intervention can avoid injury 100% of the time.

Our medical students and physicians in training have options for where to practice, and it should be our shared goal to ensure that they stay and care for patients here in our state.

A 2017 report surveyed more than 4,000 Ob-Gyns and found:

- 85% of them had been named in a lawsuit
- 44% of those ob-gyns indicated that the threat of malpractice influences their actions ALL or MOST of the time

All of these issues cause extreme difficulty for those of us encouraging medical students to go into obstetrics, and to recruit and retain doctors in the field of obstetrics.

SB 879 is a common-sense proposal that brings rationality to this issue.

Under this bill, families may still hold hospitals accountable. At the same time, this bill provides reassurance to hospitals and providers that they will not face skyrocketing, career-ending insurance premiums. Most importantly, it provides guaranteed lifetime care to patients who need it most.

On behalf of the University of Maryland School of Medicine, I strongly support Senate Bill 879.

Sincerely yours,

E. Albert *Reece,* **MD, Ph , IGIBA**
Executive Vice President 1'
Medical Affairs, UM Baltimore John Z. and Akiko K. Bowers
Distinguished Professor and Dean, University of Maryland
School of Medicine

SenKelley_FAV_SB879
Uploaded by: Senator Kelley, Senator Kelley
Position: FAV

SENATOR DELORES G. KELLEY
Legislative District 10
Baltimore County

Chair
Finance Committee

Executive Nominations Committee
Rules Committee
Legislative Policy Committee

THE SENATE OF MARYLAND
ANNAPOLIS, MARYLAND 21401

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TESTIMONY OF SENATOR DELORES G. KELLEY

REGARDING SENATE BILL 879 - PUBLIC HEALTH - MARYLAND INFANT LIFETIME CARE TRUST FUNDED BY HSCRC AND MARYLAND PATIENT SAFETY CENTER DUTIES

BEFORE THE SENATE FINANCE COMMITTEE

ON MARCH 5, 2020

Good afternoon fellow Members, I am here to introduce Senate Bill 879 Public Health - Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties. This is a new, common-sense approach that is right for the families, for infants, and for Maryland. Permanently funded through assessments on hospitals, the Trust would provide guaranteed lifetime care for infants born with neurological injuries, and this is a better way than our current system. Our current system fails to guarantee care for the most vulnerable infants and leads to rising health care costs that impact all Marylanders. The Trust turns today's guess—a lump sum payment that may or

may not be sufficient—into a guarantee of lifetime care directed by the family's own chosen physician. If a mistake has been made, hospitals remain accountable to those families. A family's right to a jury trial would remain unchanged.

The Trust would pay not only for medical treatment but also for other expenses necessary for the lifetime care of the child. It would pay for transportation costs, physical, behavioral and specialty therapies, and other services that a family and their chosen doctor deem is necessary. And it would also pay for vehicles or home modifications. And, the Trust would lead to savings in Maryland's Medicaid system. Maryland's Medicaid system would no longer be responsible for paying for the care of these children. Under the current system, Medicaid is often financially responsible for the medical care of children born with neurological injuries. Under this proposal, the Trust would pay for all care currently covered by Medicaid, and would cover care and services that are currently not allowed to be paid for by Medicaid. Benefits from the trust

include:

- Lifetime expenses for qualified health care costs; and
- Reasonable expenses connected with adjudication of disputed matters.

SB 879 includes numerous qualifiers for the use of Trust funds for a qualified plaintiff but the Bill specifies that attorney's fees may not be paid from the Trust. The Trust will be managed by a Board, and it is separate and distinct from State Government. Most of the money for the Trust will come from an assessment determined by the HSCRC and will be charged only to hospitals that charge for acute obstetrics, neonatal ICU, newborn nursery, premature nursery, normal newborn, or labor and delivery services. The HSCRC may periodically assess the stability of the Trust and may make additional assessment to assure that the Trust can meet its obligations. SB 879 focuses on the problem of birth-related injuries by establishing a Birth-Related Injury Prevention program in the Maryland Patient Safety Center.

The program will:

- review Trust fund claims and processes;

- formulate best practices for prenatal care and deliveries; and
- develop and implement programs to improve OB outcomes. The program will receive $1 million annually from the Trust.

SB 879 sets up a situation during a court proceeding on a birth-related neurological injury whereby all payments for future medical expenses of the qualified plaintiff will be paid by the Trust. The intent is to take lifetime health care costs of the qualified patient out of a settlement agreement or jury or court award to an eligible claimant, by designating the claimant as a qualified plaintiff.

You are going to hear today from several experts regarding:

- rising medical liability costs and the serious destabilization of the hospital reinsurance market;
- concerns about the training, recruitment, and retention of OB doctors and access to critical OB services;
- how it is very difficult to accurately predict future care costs in these rare, complex cases;

- the mechanics of the Bill, how it works to provide guaranteed lifetime care without major changes to the tort system; and
- how the State of New York has successfully enacted and implemented a similar model.

I am passionate about this Bill, and I urge a favorable report on Senate Bill 879.

Maryland Hospital Assocaition_Stallings_FAV_SB 879
Uploaded by: Stallings, Nicole
Position: FAV

Maryland
Hospital Association

Senate Bill 879 - Public Health - Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties

Position: *Support*
March 5, 2020
Senate Finance Committee

MHA Position

Maryland's 61 nonprofit hospitals and health systems care for 5 million people each year, treating 2.3 million in emergency departments and delivering more than 67,000 babies.

The birth of a child is one of the most joyous moments in a family's life. However, in a small number of complex cases, an infant may require long-term medical care as a result of neurological injuries that occur at birth. These incidents are tragic and devastating for everyone involved.

That is why Maryland hospitals want to guarantee these vulnerable infants receive the care they need—for life. That is the goal of SB 879, which would establish a fund paid for by hospitals to ensure families receive the resources to provide the care patients' personal physicians recommend.

This is a common-sense solution to rescue Maryland's medical liability climate.

While our state has half the number of medical liability claims as the national average, our payouts are double the national average.[1] In fact, payouts for claims above $10 million increased by 2,179% from 2016-2018 compared to the previous nine years.[2] As a result of these dramatic spikes in payouts, Maryland is now considered one of the four worst venues for medical malpractice in the country.

Maryland is seeing an exodus of reinsurers willing to write policies in our state. Reinsurers who have remained in the market are requiring far greater risk retention (essentially a deductible), dramatically increasing premiums, and imposing extensive coverage exclusions and restrictions. Maryland hospitals operate under fixed global budgets and are then forced to consider reductions to programs, service lines, and/or staffing to address these rising costs.

Maryland hospitals support SB 879, to provide comprehensive and as-needed relief to families who suffer an injury during childbirth and stabilize Maryland's medical liability climate. The Maryland Infant Lifetime Care Trust ensures families have guaranteed medical care prescribed by their own physician throughout the course of the injured child's lifetime. This system better serves these families, who currently receive a lump-sum payment based on a jury's best estimate

[1] Aon/ASHRM Hospital and Physician Professional Liability Benchmark Analysis, October 2018
[2] Willis Towers Watson analysis

of the future medical needs of an injured child. The legislation simply changes the mechanism for how future medical expenses are paid.

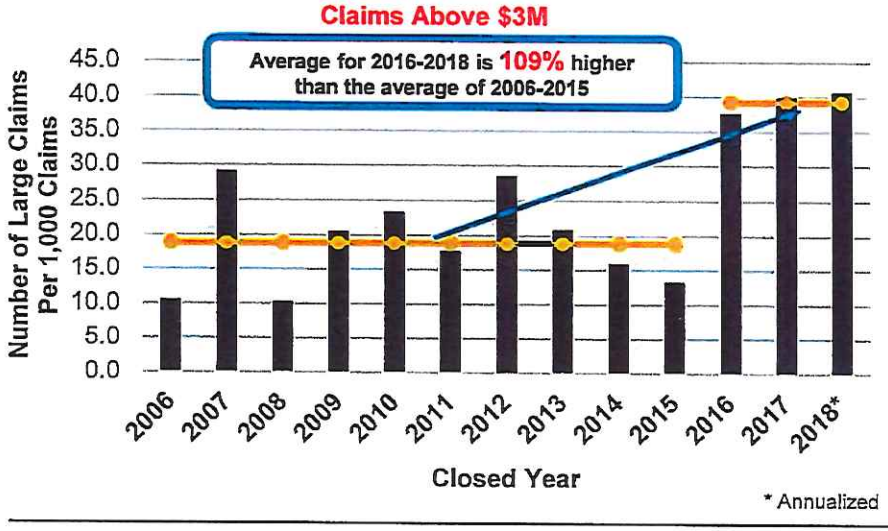
There are no changes to the existing legal process—families can still hold providers accountable in court and attorneys still receive contingency fees.

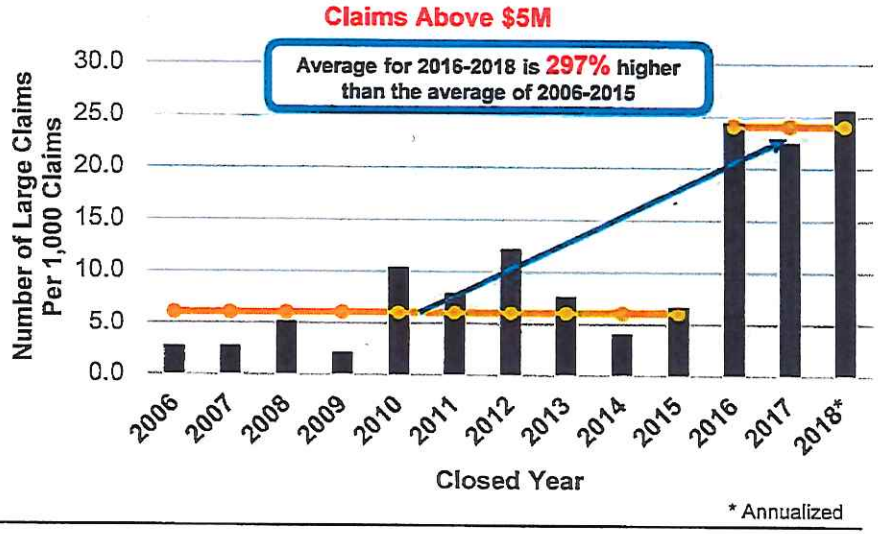
This proposal better serves families while also taking a significant step to improve a medical liability climate under which hospitals struggle to access and maintain reinsurance. The new approach is right for families, right for infants, and right for Maryland.

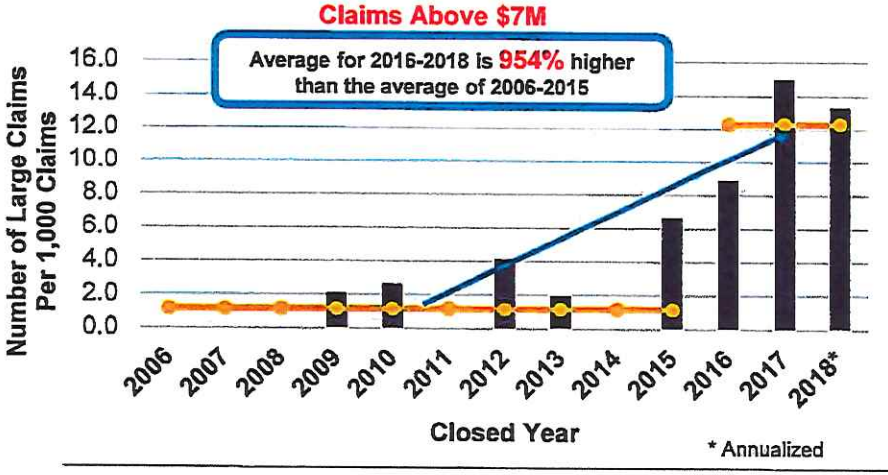
For these reasons, we urge a ***favorable*** report.

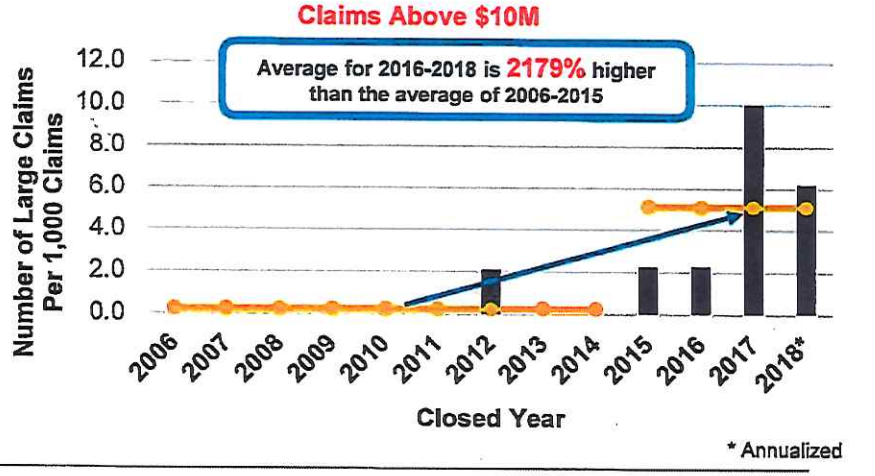
For more information, please contact:
Nicole Stallings
Nstallings@mhaonline.org

Maryland closed claim data shows an even more dramatic spike and the same increase at higher layers









Willis Towers Watson

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06 February 2020

To whom it may concern

Medical Malpractice Insurance coverage in Maryland

The recent spate of high value Medical Malpractice settlements and verdicts in Maryland - and in particular Baltimore City - is making the procurement of Insurance and Reinsurance protection extremely challenging.

Insurers and Reinsurers are withdrawing &/or are reducing the amount of limits (capacity) that they are willing to provide to Healthcare providers based in the State. Zurich Insurance have withdrawn and other significant US Domestic Insurance carriers namely Berkshire Hathaway , W R Berkley, C N A, and Chubb have either declined to participate on certain risks based in this jurisdiction or have markedly reduced capacity. The market for USA Medical Malpractice insurance is a global one; The Bermuda and London Insurance markets are important providers of capacity and major carriers such as Sompo, and AXA, have materially cut back the amount of capacity that they are willing to provide, London Insurers particularly based in Lloyd's have followed suit.

The insurers and reinsurers that are still willing to take on Baltimore based risks are requiring

- Far greater risk retention (Self insurance) by the Healthcare Providers
- Dramatically increased premiums
- The imposition of coverage exclusions and restrictions.

A recent settlement of $190 million and verdict of $229 million in Maryland has caused considerable concern within the specialist US Medical Malpractice insurance industry; these widely publicized values engender fear within the healthcare provider community that has the effect of driving up settlement values. These increased values in combination with $100 million plus verdicts make the provision of insurance in Maryland commercially unsustainable.

Yours Sincerely

Charles F Pearch
Managing Director

UNIVERSITY of MARYLAND
SCHOOL OF MEDICINE

E. ALBERT REECE, MD, PhD, MBA
Executive Vice President for Medical Affairs, UM Baltimore
John Z. and Akiko K. Bowers Distinguished Professor and
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March 5, 2020

Senator Delores G. Kelley
Chair, Finance Committee
11 Bladen Street
Annapolis, Maryland 21401

Dear Chairperson Kelley:

Good afternoon, my name is Dr. E. Albert Reece, and I am the Executive Vice President for Medical Affairs, University of Maryland Baltimore, and Dean of the School of Medicine. I am also an obstetrician-gynecologist, with sub-specialty training in high-risk obstetrics. In addition, I also serve as Co-chair of the Maryland Medicine Comprehensive Insurance Program, a joint venture self-insurance program of the clinical faculty organization of the School of Medicine and the University of Maryland Medical System.

I have committed my career to caring for patients and educating the next generation of physicians in Maryland and the nation. I testify today in strong support of SB 879.

Marylanders deserve high-quality obstetric care, yet the medical liability environment in the state has produced a profound chilling effect on the ability of our hospitals and universities to retain top talent, particularly in this critically important field.

It's important to note, despite what some may contend, that most adverse outcomes at delivery are NOT caused by specific and preventable actions by a physician. Adverse birth outcomes cannot just be labeled bad medicine.

The bottom line is this---it is simplistic, and simply wrong, to think that the external, indirect, and often subjective means of assessing fetal health and well-being will pick up the precise fetal condition, and that intervention can avoid injury 100% of the time.

Our medical students and physicians in training have options for where to practice, and it should be our shared goal to ensure that they stay and care for patients here in our state.

A 2017 report surveyed more than 4,000 Ob-Gyns and found:

- 85% of them had been named in a lawsuit
- 44% of those ob-gyns indicated that the threat of malpractice influences their actions ALL or MOST of the time

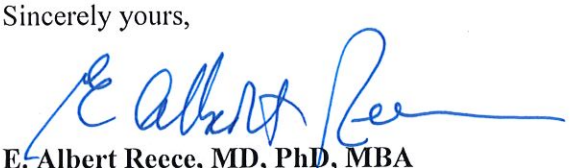
All of these issues cause extreme difficulty for those of us encouraging medical students to go into obstetrics, and to recruit and retain doctors in the field of obstetrics.

SB 879 is a common-sense proposal that brings rationality to this issue.

Under this bill, families may still hold hospitals accountable. At the same time, this bill provides reassurance to hospitals and providers that they will not face skyrocketing, career-ending insurance premiums. Most importantly, it provides guaranteed lifetime care to patients who need it most.

On behalf of the University of Maryland School of Medicine, I strongly support Senate Bill 879.

Sincerely yours,



E. Albert Reece, MD, PhD, MBA
Executive Vice President for Medical Affairs, UM Baltimore
John Z. and Akiko K. Bowers Distinguished Professor and
Dean, University of Maryland School of Medicine

SOMPO INTERNATIONAL

March 4, 2020

Susan Durbin Kinter
Vice President Claims, Litigation & Risk Management
Maryland Medicine Comprehensive Insurance Program
250 West Pratt Street
Suite 1200
Baltimore, MD 21201

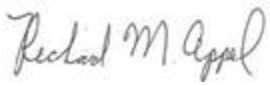
Re: Maryland Tort Reform

Dear Ms. Kinter,

Sompo International writes concerning the increasingly hostile legal environment in Maryland and the critical need for meaningful tort reform in the state. Sompo International is particularly concerned about the increasing severity of non-economic damage awards and the impact it has on (re)insurers ability to do business in the state going forward. Sompo International proffers its full endorsement of significant tort reform legislation to address this growing problem. We believe such legislation is necessary in order to stabilize the Maryland (re)insurance market and to stem the tide of (re)insurers pulling their business from the state.

Should you have any questions or need any additional information I may be reached at 212-209-6508 or rappel@sompo-intl.com. Thank you.

Sincerely,



Richard M. Appel
Senior Counsel

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MARYLAND'S LIABILITY CLIMATE: A HOSPITAL PROFESSIONAL LIABILITY (RE)INSURER PERSPECTIVE

From: Nat Cross <[redacted]>
Sent: Friday, February 7, 2020 11:52 AM
To: Smith, Larry L <[redacted]>
Cc: Leyko, Rachel A <[redacted]>
Subject: Beazley Healthcare - US Hospitals Focus Group - Current Perception of Maryland including Baltimore City and Baltimore County

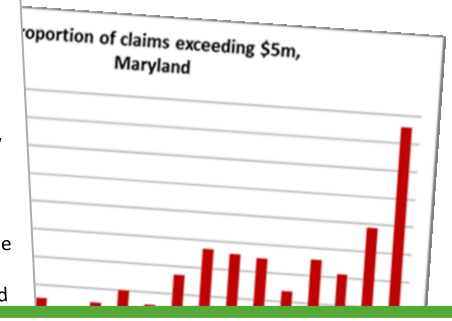
Dear Larry,

You have asked me to provide an excess Hospital Professional Liability (re)insurer's perspective of Maryland including the City and County of Baltimore given local, as well as national, trends of increasing medical malpractice ("medmal") severity.

largely caught up, and the insurance press is awash with
om our perspective we first noticed this increasing
to provide bespoke analytical reports to our insureds
ch as Philadelphia. With the benefit of hindsight, the
ar: the suppression of the medmal plaintiff's bar in the
rm, patient safety and quality, and increased risk
other vehicles), and the undermining (through
global economic downturn) of their attempts to
is in the latter part of the decade. However, come
increased liquidity, and a new strategy finalised, they

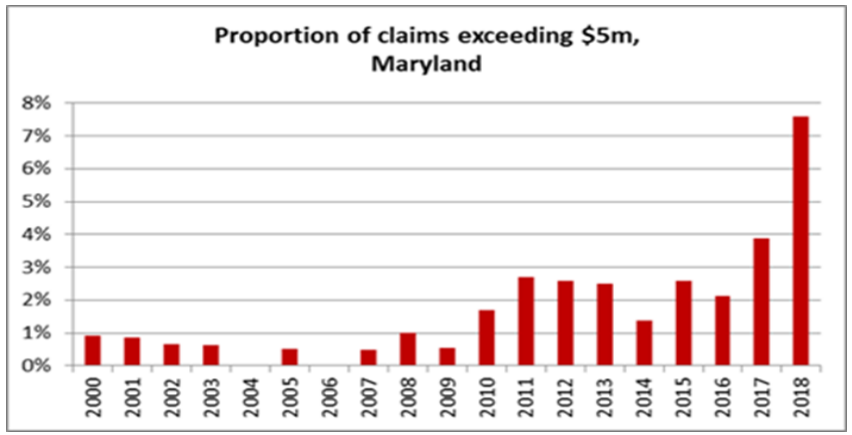
firstly bypass the impact of damage caps by
on-economic damages, and focus on claims with the
(cases involving high earners with the

n in the following chart where the number of non-zero cases
r $5m has risen in the region of 300% in recent years (c. 2.5%

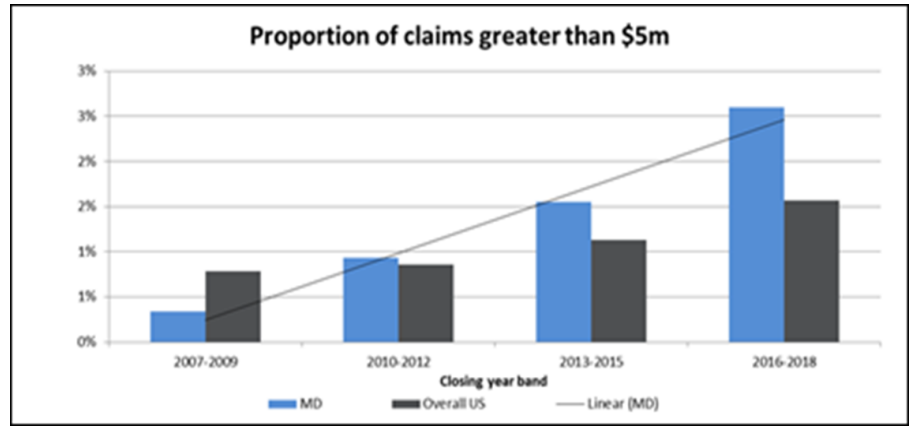


requency) of claims. Pleasingly, actuarially we have been able
Unfortunately, our analysis has further indicated that
lity have no bearing whatsoever on the value or quantum
of course has meant that Beazley and Medstar have held
tions over recent annual renewals as we as (re)insurers
ntegrity of our book, and you as steward of malpractice
d for recognition of your efforts. My understanding is that
ent renewal for your overall programme were particularly
wal of carriers that had historically provided
ll as the actions of others to
as (re)insurers

300% Increase in Claims over $5m



Maryland is outstripping the US nationwide



From: Nat Cross <[redacted]>
Sent: Friday, February 7, 2020 11:52 AM
To: Smith, Larry L <[redacted]>
Cc: Leyko, Rachel A <[redacted]>
Subject: Beazley Healthcare - US Hospitals Focus Group - Current Perception of Maryland including Baltimore City and Baltimore County

Dear Larry,

You have asked me to provide an excess Hospital Professional Liability (re)insurer's perspective of Maryland including [redacted] and County of Baltimore given local, as well as national, trends of increasing [redacted] severity.

By way of background, as you kn[ow] offices throughout the globe, em[ploying] writings we own two licensed U[K] European Insurer, BIDAC. In 201[9] $3b, $0.9b of which was writte[n] risk, and of which the Healthca[re] $235m of premium, substanti[al] East, and Australasia, and we [have] London, and European insura[nce]

Of this $235m, approximatel[y] This book has shrunk considerably (21%) from [its] Although this can be attributed to a number of different factors (inc[luding] consolidation brought about by the Affordable Care Act), **from my perspective the largest single determining factor has been the effect of increasing severity**, and the need to re-underwrite our portfolio (through amending programme structure and pricing) to protect the profitability of the portfolio. We believe that through our expert team of former medmal defence attorneys claims managers, and our deep analytical bench strength (founded upon our 800,000 HPL claim record HealthRate database), Beazley Healthcare was one of the entities to identify the worsening environment early on, a fact that you have been gracious enough to acknowledge. From a practical standpoint, however, it led our team to lose business, as our efforts to improve the terms on placements were undermined by other markets, ignorant of the worsening environment around them, who were prepared to match or often improve our expiring terms.

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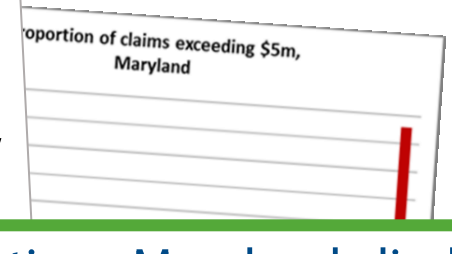

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Maryland is a tort reform state… But over time, Maryland climbed the ladder, from the lowest [severity] category to the highest, **and now has the unfortunate accolade of being one of the 4 worst venues for medical malpractice in the nation alongside New York City, Philadelphia, and Cook County (Chicago).**

[O]ur analysis has further indicated that **outstanding safety and quality have no bearing whatsoever on the value or quantum (i.e. severity) of claims**. . . [I]t is not hard to envisage a scenario where Baltimore City / County **hospitals are unable to procure sufficient capacity – regardless of cost – for their needs.**

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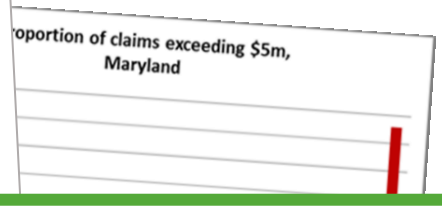

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the information that you require.

I regret to inform you that we have now made the decision to include new risks with exposures in Baltimore City and County in this cohort (where Beazley is not writing policies).

Maryland Hospital Association_FAV_SB 879
Uploaded by: Stallings, Nicole
Position: FAV

The Infant Lifetime Care Trust

Care for Infants. Justice for Families.

March 2020

ACOG The American College of Obstetricians and Gynecologists

Affiliate of American College of Nurse-Midwives

GBMC HEALTHCARE

Johns Hopkins Medicine

Kennedy Krieger Institute

Maryland Hospital Association

MNA Maryland Nurses Association

Maryland Patient Safety Center

MedChi The Maryland State Medical Society

MedStar Health

Mercy Medical Center

Mt. Washington Pediatric Hospital

Total Health Care You're Covered.

University of Maryland Medical System

THE ALLIANCE FOR INFANT LIFETIME CARE

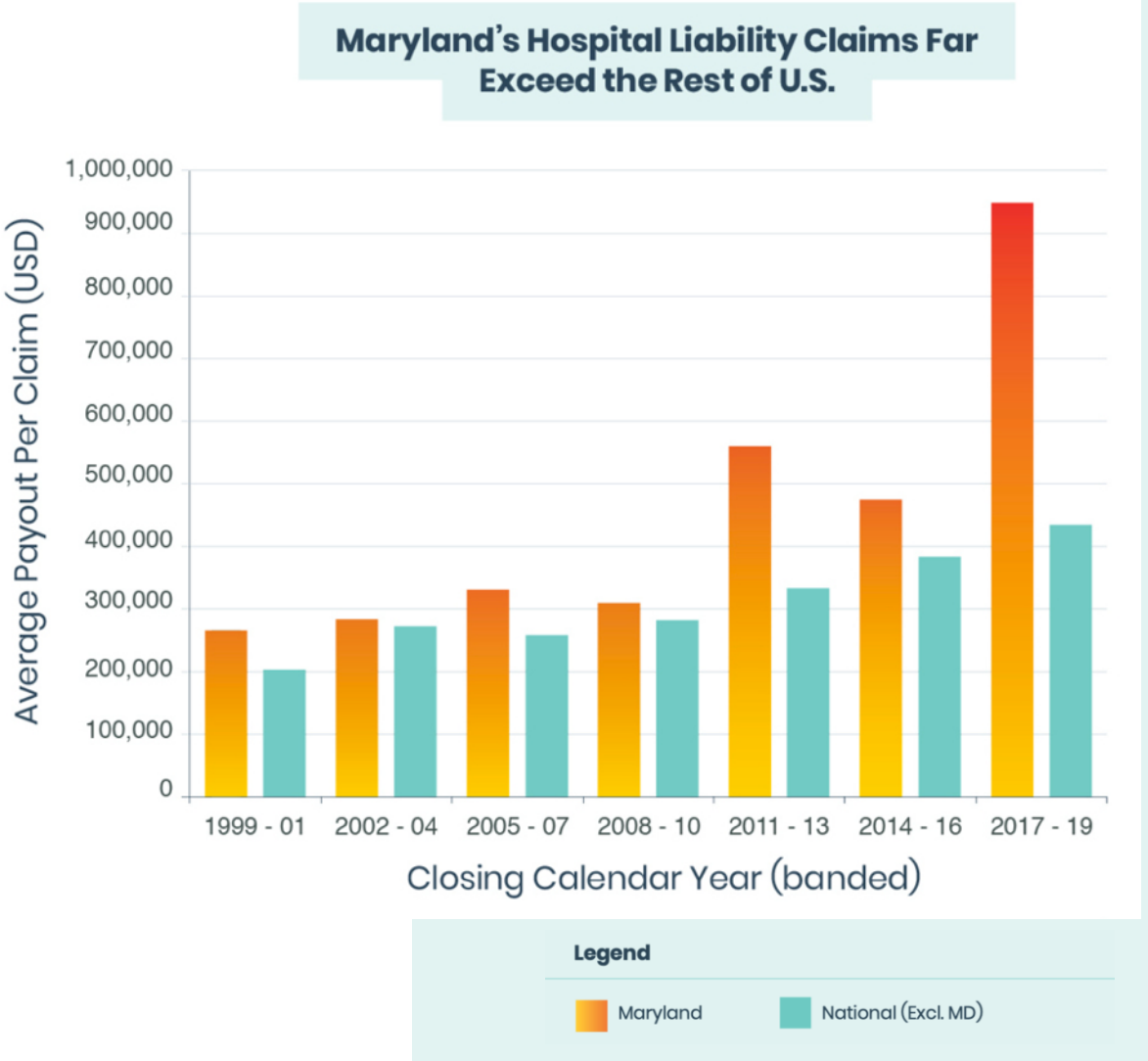
The Facts About Maryland's Medical Liability System

The current medical liability system is unsustainable

Today's system **fails to guarantee care** for the state's most vulnerable infants and leads to rising health care costs.

Claims associated with Maryland liability cases significantly and **consistently exceed national averages.**

Worse still, over the last 12 years, Maryland **claims increased by more than 300%,** while claims in all other states went up by 50%

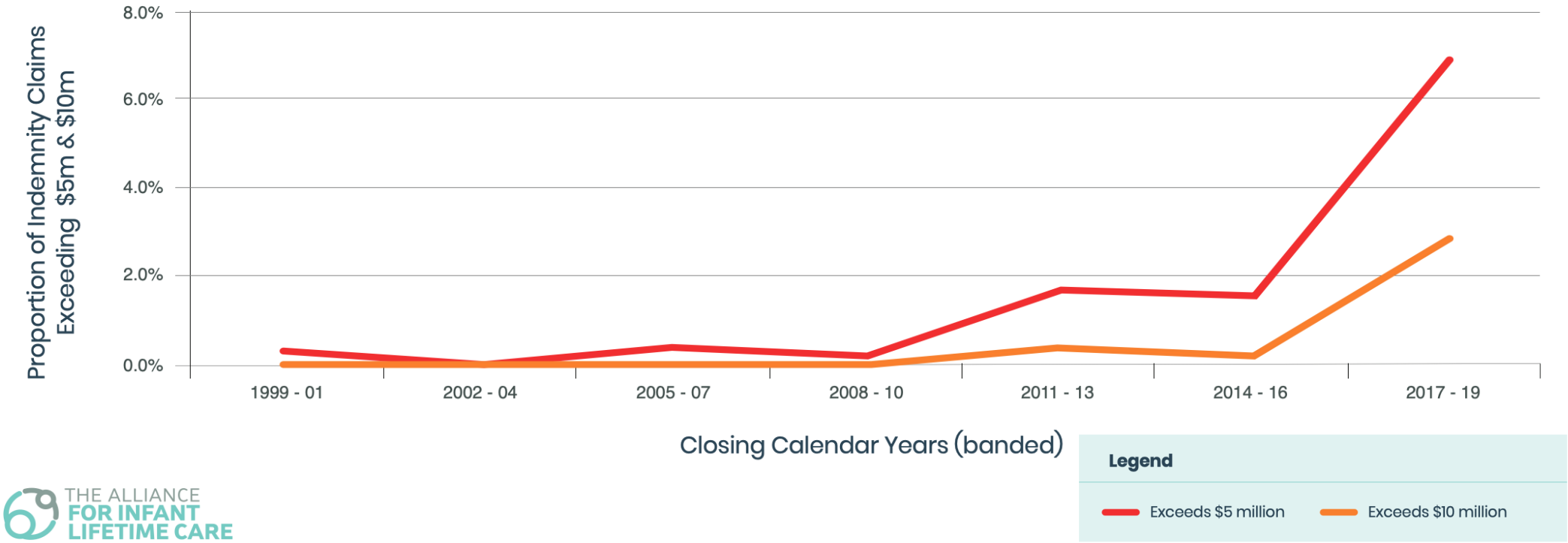


THE ALLIANCE FOR INFANT LIFETIME CARE

Rising claims are destabilizing the state's health care system

Claims exceeding $10 million appeared for the first time ten years ago and have risen sharply since.

Maryland has half the national average of medical liability claims, yet the state's payouts are double the national average.



Rising health care costs fall on all Marylanders

As hospitals face rising liability costs, they may have to shutter services, end community programs, or reduce maternity care throughout the state.

Four hospitals in Maryland have significantly reduced their obstetrics programs, and three counties in Maryland have only one OB/GYN to provide maternity care.

Three Maryland hospitals have ceased offering obstetric care since 2012, and similar closures in DC further threaten access for Marylanders.

A Common-Sense Solution

The Infant Lifetime Care Trust

To guarantee care and address a medical liability crisis, the Trust would cover the lifetime cost of care for infants who suffer a neurological injury at birth.

Families would still be able to hold hospitals and doctors accountable – their right to a jury trial would remain unchanged.

Maryland hospitals that deliver babies would pay an estimated $30 million annually to fund the Trust.

How the Trust Would Work

The Trust would cover medical and supportive care for anyone receiving a court approved settlement or verdict for a birth-related neurological injury.

Injured infants would have access to guaranteed lifetime care, instead of lump sum payments that may or may not be sufficient.

Patients' personal physicians would determine the care they need – and the Trust would be required to pay the costs of this care.

Holding Hospitals Accountable

Hospitals would still be held accountable in court if a mistake has been made, and may be liable for damages, plaintiff legal fees, and loss of income.

The Trust would be overseen by a state agency, and an administrative appeals process would address any disputes regarding payments.

A Single, Common-Sense Adjustment

DAMAGES	CURRENT SYSTEM	INFANT LIFETIME CARE TRUST
Future Medical Expenses	**Lump sum estimated by jury or settlement process; no guarantee that care will be covered for life.**	**The Infant Lifetime Care Trust guarantees coverage for lifetime care, as determined by patients' own physicians**
Non-Economic Damages (e.g. compensation for pain and suffering)	Lump sum (Determined by jury or settlement)	No change
Lost Earnings	Lump sum (Determined by jury or settlement)	No change
Past Medical Expenses	Lump sum (Determined by jury or settlement)	No change
Legal Fees	30–40% of lump sum (Determined by plaintiff and lawyer)	No change

Thank You

Robert Walling_FAV_SB 879
Uploaded by: Walling, Robert
Position: FAV

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Robert J. Walling III, FCAS, MAAA, CERA
Principal and Consulting Actuary
rwalling@pinnacleactuaries.com

March 4, 2020

Chair Delores G. Kelley
Maryland Senate Finance Committee
3 East Miller Senate Office Building
Annapolis, Maryland 21401

RE: SUPPORT FOR SB0879: Public Health - Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties

Dear Chair Kelley:

My name is Robert James Walling III. I have been asked to present testimony in support of SB0879 related to the establishment of the Maryland Infant Lifetime Care Trust. I am a Fellow of the Casualty Actuarial Society (FCAS) and a member of the American Academy of Actuaries (MAAA). I am also a Chartered Enterprise Risk Analyst (CERA). I am currently a Principal and Consulting Actuary with Pinnacle Actuarial Resources, Inc. I have served the Casualty Actuarial Society in a number of roles including chairing several professional committees and recently completed my three year term as a member of the CAS Board of Directors. I have also recently been named to the 2019 Captive Review Power 50 most influential professionals in captive insurance for the fourth consecutive year.

My practice has focused on commercial lines ratemaking and product development, captive insurance companies, self-insurance programs, loss reserving, legislative costing, litigation support and regulatory assistance. One area of particular focus has been regulatory work related to medical professional liability insurance including government insurance programs, including patient compensation funds and birth funds. I have served the Virginia Birth Related Neurological Injury Compensation Program in various capacities since 2003. I have served the New York Medical Indemnity Fund since before it was enacted in October of 2011. I have also served patient compensation funds in New Mexico and Wisconsin since 2002 and 2007 respectively. Pinnacle has also served the Florida Birth-Related Neurological Injury Compensation Association (NICA) since 2008.

Support for Maryland Infant Lifetime Care Trust

The first key point I want to make about the proposed Maryland Infant Lifetime Care Trust is that **under the proposed system more benefits, in fact lifetime benefits, are paid than under**

the current system. This is because there is no limitation on the amount of coverage related to the solvency of the insurance company or the limits of coverage purchased by the health care provider. The Virginia birth fund pays over 90% of the funds they receive out in benefits to program participants. The compares to efficiency of 35% in the medical professional liability insurance industry. This difference is dramatic. Commercial medical professional liability insurance only delivers about a third of their total revenues to claimants, whereas a birth fund's frictional costs represent only 10% of total revenues that don't go to paying benefits to participants.

What does this mean in Maryland? Out of all of the current birth fund participants in Virginia, 60 of those families receive more $100,000 in benefits annually. Most of this group are expected to receive more than $10 million in total benefits over their child's lifetime. Neither of the following issues influenced whether the families received benefits or how much of a benefit they will receive:

- the quality of the health insurance of the impacted family
- the insurance coverage available from the healthcare providers and facilities involved

Birth funds substantially increase the fairness and equity for families dealing with birth injuries because eligible families receive the much needed support they deserve for these often severe, lifelong injuries regardless of these factors.

Expected Cost of Maryland Infant Lifetime Care Trust

Enclosed is Pinnacle Actuarial Resource's report providing information on design and funding features of other birth-related neurological injury compensation funds as well as the estimated benefit costs and funding levels developed by the current version of the proposed birth fund legislation in Maryland contained in SB0879. In summary, Pinnacle's analysis of the frequency of covered birth-related neurological injuries in Florida and Virginia suggests that Maryland can expect that between 0.9 and 1.0 claims per 10,000 live births, or a total of about 6.8 qualifying births, occur in Maryland annually. The basis for this actuarially assumed number of eligible births is almost thirty years of experience in the Virginia and Florida birth funds.

The experience of the existing birth funds suggests that the expected present value of lifetime benefits in Maryland would be between $2.87 million and $3.27 million per claim. Based on these assumptions, **the Maryland Infant Lifetime Care Trust would incur accrued benefits costs of between $18.4 million and $23.2 million annually**. Overall operational expenses are estimated at $750,000 annually, and an additional $1 million grant from the Trust is designated for improving maternal and fetal outcomes. Total expected costs for the Maryland Infant Lifetime Care Trust under the current bill are therefore $22.5 million.

The proposed approach to funding the proposed Maryland Infant Lifetime Care Trust is premiums assessed from Maryland hospitals through the Maryland Health Services Cost Review Commission (HSCRC). This approach is responsive to program experience, which helps assure the long-term viability of the Trust. **The legislation represents a reasonable, appropriate and actuarially sound approach to funding the Trust on an accrual basis.**

This funding approach results in an increase to Medicaid funding as a result of higher hospital premiums, but the Trust will remove future medical expenses from the Medicaid system. Based on the Virginia, Florida, and New York birth funds, approximately 60% of expenses paid by the Maryland Infant Lifetime Care Trust will otherwise be paid by Medicaid. **The indicated increase in Medicaid funding of $4.5 million is more than offset by the Trust removing $40.5 million in future medical expenses from Medicaid**.

Virginia Funding Status

Finally, it is important to have an accurate portrayal of the financial condition of the Virginia birth fund. Claims regarding the impaired financial condition of the Virginia program are greatly exaggerated and simply inaccurate. Last year, I performed an analysis of the Virginia birth fund based on data as of December 31, 2018. Pinnacle's report found that **the Virginia birth fund had assets of over $462 million available to pay future benefits** to the estimated 279 participants born on or before December 31, 2018. This compares to expected future benefits and administrative expenses of about $539 million, resulting in a forecasted deficit of $76.8 million. However, this does not consider future assessment income or the possibility of better than expected investment returns which the Virginia program often experiences. In short, **the Virginia program is as financially strong as it has been in years and capable of paying benefits to participants for many years into the future.**

I, Robert J. Walling III, FCAS, MAAA, CERA am a member in good standing of the American Academy of Actuaries and meet its qualification standards to render this actuarial opinion. If you have any questions, comments, or if you require anything further, please call me at 309.807.2320.

Sincerely,

Robert J. Walling III, FCAS, MAAA, CERA
Principal & Consulting Actuary
Pinnacle Actuarial Resources, Inc.

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Principal and Consulting Actuary
rwalling@pinnacleactuaries.com

February 26, 2020

Alliance for Lifetime Infant Care
c/o Ryan O'Doherty
Mercy Health Services
Director of External Affairs and Strategic Communications
[Delivered via email to RODohert@mdmercy.com]

Dear Mr. O'Doherty:

Enclosed is Pinnacle Actuarial Resource's (Pinnacle's) report to the Alliance for Lifetime Infant Care and other interested parties providing information on design and funding features of other birth-related neurological injury compensation funds (birth funds) as well as the estimated benefit costs and funding levels developed by the current version of the proposed birth fund legislation in Maryland contained in SB0879.

I, Robert J. Walling III, FCAS, MAAA, CERA am a member in good standing of the American Academy of Actuaries and meet its qualification standards to render this actuarial opinion.

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Report on the Maryland SB0879

and the Feasibility, Design and Funding of

The Maryland Infant Lifetime Care Trust

February 2020

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Commitment Beyond Numbers

Table of Contents

Maryland SB0879 and the Feasibility, Design and Funding of The Maryland Infant Lifetime Care Trust

Purpose & Scope

Pinnacle Actuarial Resources, Inc. (Pinnacle) has been retained by the Alliance for Lifetime Infant Care and other interested parties to provide an overview of the important design features of a potential birth-related neurological injury compensation fund (birth fund) in Maryland. In addition, Pinnacle has also been tasked with developing an estimate of expected annual benefits obligations of the final version of the proposed Maryland Infant Lifetime Care Trust legislation as contained in Maryland SB0879 and the expected revenue produced to fund these benefits. Pinnacle has relied heavily on available information regarding existing birth funds in Virginia and Florida, and to a lesser extent New York.

Executive Summary

There are several key elements about the design of a birth fund that can be determined by examining similar programs in Virginia and Florida. These include:

- Carefully defined benefits and eligibility requirements are an important feature of birth funds. Changes as simple as changing the phrase "physical and mental" to "physical or mental" can result in differences in benefits of millions of dollars.
- Formation as a segregated trust account, rather than a state agency, is the preferred organizational form.
- Birth funds are typically governed by a Board of Directors with representation by the various stakeholders including participating physicians, hospitals, non-participating physicians, liability insurers, and public citizens.
- Involvement of relevant state agencies, medical associations and medical schools can bring existing skills and expertise and ensure the development of strong program fundamental processes.
- An executive director, hired by the Board of Directors, and supporting staff are recommended to manage the day-to-day operations of a birth fund. Certain services requiring technical expertise, such as investment, legal and actuarial work, should be outsourced.
- Appropriate financial controls are imperative to the soundness of a birth fund.
- The proposed final legislation contains additional legislative features including requirements regarding the actuarial soundness of the unpaid benefits reserves and premium levels that

appear to strengthen the financial soundness of the proposed Maryland Infant Lifetime Care Trust.

- The proposed use of the existing Maryland Hospital Services Cost Review Commission (HSCRC or the Commission) to collect the premiums of the proposed Maryland Infant Lifetime Care Trust should prove to be an efficient and easy to implement administrative approach.

Pinnacle's analysis of the frequency of covered birth-related neurological injuries in Florida and Virginia suggests that Maryland can expect that between 0.9 and 1.0 claims per 10,000 live births, or a total of about 6.8 qualifying births, occur in Maryland annually. The experience of the existing birth funds suggests that the expected present value of lifetime benefits in Maryland as currently proposed would be between $2.87 million and $3.27 million per claim. Based on these assumptions, a Maryland birth fund would incur accrued benefits costs of between $18.4 million and $23.2 million annually. Overall operational expenses were estimated at $750,000 annually. In addition, the current bill proposes $1.0 million per year as a grant designated for improving maternal and fetal outcomes in the state. Total expected costs for the Infant Lifetime Care Trust under the current bill are therefore $22.5 million.

The proposed approach to funding the proposed Maryland Infant Lifetime Care Trust are premiums assessed from Maryland hospitals through the Maryland Hospital Services Cost Review Commission. Under the legislation, the HSCRC would be authorized to assess and collect premiums by establishing regulations to assess an annual premium on hospitals to fully account for the annual actuarial funding need of the birth injury fund based on an annual certified report. This approach has been used historically to fund other programs as well. In the following table, we show a few of these assessments and their size to the prior overall HSCRC revenue[1]:

[1] Table data provided by Mercy Health Services staff

Assessment	Payment	% of Revenue
Medicaid Expansion	193,914,773	1.07%
HSCRC User Fees	15,000,000	0.08%
Medicaid Deficit	309,000,000	1.70%
Maryland Health Care Commission	5,679,756	0.03%
Nurse Support Program 1	17,472,274	0.10%
Nurse Support Program 2	17,186,577	0.09%
Maryland Patient Safety Center	369,056	0.00%
Total Assessments	558,622,435	3.07%
Total Assessments with Markup	614,484,679	3.38%
Total Revenue	18,200,000,000	
Maryland Infant Lifetime Care Trust	24,728,530	0.14%

In comparison, the total cost of the Maryland Infant Lifetime Care Trust (including a 10% markup for nonpayment) would be only 0.14% of total revenue or 2.6% of obstetrics related revenue (see Exhibit 3, Page 1).

The HSCRC would be granted statutory authority to establish a hospital premium methodology that accounts for: geographic differences among hospitals, differences in historical birth-related claims experience among hospitals, and differences between hospitals that provide obstetrical care and those that do not. This represents a reasonable, appropriate and actuarially sound approach to funding the fund on an accrual basis. This approach should also help the proposed Maryland Infant Lifetime Care Trust avoid some of the pitfalls the Virginia birth fund has experienced in the past.

Birth Fund Background

General

It may be useful to define birth funds in general terms before describing specific features and options. Birth funds are a specialized form of patient compensation funds (PCFs). Patient compensation funds are medical malpractice government insurance programs, created by state law, designed to increase professional liability coverage availability and/or affordability primarily by providing coverage for a specific type of injury or an excess layer of coverage. In the case of birth funds, both the type of injury (birth-related neurological injuries) and the benefits are very precisely defined. To date, there are three birth funds (in Florida, New York and Virginia). There is also the National Vaccine Injury Compensation Program (VICP). VICP is a national program for individuals found to be injured by

certain vaccines. VICP has many of the same design features and benefits of a birth fund, but covers a different type of medical incident.

Three of these funds, other than New York's, were formed in the 1980's in response to severe crisis conditions in the healthcare industry and specifically medical professional liability. The most severe of these conditions related to birth-related neurological injuries which have very high claim severities, often in the tens of millions of dollars. The large claim severities and highly emotional nature of the claims presented significant challenges to the tort system. Similarly, the high claim costs also led directly to very high medical professional liability insurance premiums for hospitals and OB/GYNs. These costs were high enough that access to available and affordable healthcare became a material issue. The essential nature of obstetrics services makes the access to birth-related care particularly important. The New York program was established in late 2011 based on similar concerns as well as the additional incentive of removing future medical expenses for injured infants out of the Medicaid system. Currently Maryland is facing a similar crisis in the wake of a recent birth-related injury award totaling over $200 million.

We will focus on the Virginia and Florida programs as they are most similar to the type of program being considered in Maryland.

Benefits Provided

The nature of the coverage and benefits of the Florida and Virginia birth funds are somewhat similar to those proposed in Maryland. They provide unlimited and broad medical and economic benefits to qualifying program participants. The economic benefits are quite extensive and commonly extend beyond medical care (physicians, hospital, on-site nursing care, physical therapy, prescription drugs and medical equipment) to include housing and transportation accommodations, legal expenses and lost wages. There is no deductible or any other limitation of benefits. However, collateral sources such as health insurance and other sources of benefits, including state and federal health insurance programs, can provide primary compensation before the birth funds in some cases. In Virginia, the birth fund purchases health insurance for participants to deliver some of their benefits. These unlimited benefits do not include non-economic damages.

The general theory of the birth fund mechanisms is that all stakeholders in the medical professional liability system benefit from the fund. Injured infants and their families benefit by receiving much broader, unlimited benefits than they would receive in the tort system. Families benefit by receiving the guarantee of unlimited future medical payments instead of relying on a lump sum or periodic payments. Physicians and hospitals also benefit by often having lower overall insurance costs. Medical professional liability insurers benefit by not having to bear the risk and volatility associated with these

very low frequency/high severity claims. This often leads to greater availability and affordability of coverage and increased competition in the medical professional liability insurance sector.

In addition, a birth injury fund facilitates better cooperation between healthcare providers and patients and their families by allowing them to focus on developing and implementing treatment plans, rather than worrying about potential liability.

Virginia Birth-Related Neurological Injury Compensation Program

The Virginia Birth-Related Neurological Injury Compensation Program (VABRNICP or the Program) was created in 1987 to provide the exclusive remedy for covered birth-related neurological injuries in Virginia. Injury must have resulted from oxygen deprivation or mechanical injury during labor, delivery, or immediately post-delivery. The injury must result in both physical and mental impairment. Participation is voluntary for physicians, registered nurses, midwives and hospitals. A ten-year statute of limitations applies to all claims for Program benefits.

The Virginia Workers' Compensation Commission is the exclusive venue for hearings to determine whether a claimant will be admitted to the Program. The Virginia Office of the Attorney General supports the Program by providing requested legal services.

The process for filing a claim is as follows:

- The claimant submits a petition containing a specific list of required information and documentation.
- The Virginia Department of Health Professions, Board of Medicine and Department of Health all investigate the claim.
- The Program responds to the claim petition.
- The Virginia Workers' Compensation Commission holds a hearing to determine
    - whether the injury claimed is a birth-related neurological injury (based on the opinion of a panel of three qualified and impartial physicians with pertinent expertise and a plan developed by the deans of three medical schools in the state),
    - whether the obstetrical services were delivered by a participating physician
    - whether the birth occurred in a participating hospital, and
    - how much compensation is awardable.
- Subject to an appeals process for rehearings within a specified time frame, the findings of the Commission are conclusive and binding.

Benefits provided include:

- Unlimited actual, necessary medical expenses including physicians, nursing, hospital, rehabilitation and therapy, prescription medications, medical equipment and appliances and related travel expenses. This includes certain housing and transportation expenses.
- Loss of earnings from the age of 18 to age 65 based on 50% of the average weekly wage in the Commonwealth for workers in the private, non-farm sector.
- Reasonable attorney fees and other expenses associated with the application for admittance.
- As previously mentioned, several collateral sources offset Program benefits costs.

The birth fund legislation in Virginia also explicitly states several expenses that are not covered.

The Program is governed by a nine-member board of directors. The board is appointed by the Governor with six citizen representatives and one representative each of participating physicians, participating hospitals, and liability insurers. The board's powers are clearly delineated in the Program's enabling legislation. Day to day operations are managed by an Executive Director hired by the Board. The executive director is supported by additional staff as needed.

The Program is funded through the Virginia Birth-Related Neurological Injury Compensation Fund (the Fund), which is organized as a segregated account trust fund. The assets of the Fund are administered by the board of directors of the Program. The Board has retained investment advisors to manage the Program's assets.

The Program uses a variety of funding approaches and is intended to provide accrual based funding. First, participating physicians are required to pay a premium. The current assessment is $6,200. In addition, all licensed physicians, including non-OB/GYNs, that do not participate in the Program are required to pay a fee of $300 annually as a condition of being licensed in Virginia. Hospitals pay a premium of $55 per live birth to participate, subject to a maximum of $200,000 in premiums annually. A number of exclusions to the premiums apply for physicians with extenuating circumstances. Finally, if and only if the Program is determined to be actuarially unsound, a premium of up to 0.25% of all "net direct premiums written" by liability insurers in Virginia may be charged. These premiums of liability insurers have been charged at the maximum amount for many years. All changes in premium levels require legislative action.

Medical professional liability insurers in the Commonwealth of Virginia are <u>required</u> by law to provide a discount for hospitals and healthcare providers that participate in the Program. These discounts typically range from 15% to 20% of otherwise indicated premiums.

An annual audit by a certified public accountant selected by the board is a required element of the Program's financial controls. In addition, a biennial actuarial study on the financial soundness of the program and recommended premium rates is required. The actuarial study is funded and directed by the Virginia State Corporation Commission.

The current financial condition of the Program has been a subject of much discussion. The Fund currently shows an unfunded deficit on an accrual basis of approximately $76.8 million as of December 31, 2018. This deficit has grown substantially in recent years as the Fund's liabilities have shifted due to a 2018 court judgment. Previous deficits were the result of two historical issues. First, the Program initially significantly underestimated the life expectancy for Program participants. Essentially, the participants are living longer than expected. Over the last decade, the Program has steadily revised their life expectancies. This led to material adverse development of the unpaid benefits liability of the Fund which has resulted in previous revenues being inadequate to fund the ultimate benefits liabilities. Second, the requirements regarding revisions to Program premium levels made it extremely difficult to react to the higher expected loss estimates. However, it must be noted that on a cash flow basis the Fund appears to have the ability to pay benefits going forward for many years and holds sufficient assets to meet all expected future benefit obligations for current participants. The benefits paying ability and solvency of the Program will not be a concern for several decades and a variety of stakeholders are working diligently to further continue reducing and ultimately eliminate the Fund deficit.

Florida Birth-Related Neurological Injury Compensation Association (NICA)

The Florida Birth-Related Neurological Injury Compensation Association (NICA) was created in 1988 to provide an exclusive no-fault remedy for birth-related neurological injury claims in Florida. Injury must be a brain or spinal cord injury caused by oxygen deprivation or mechanical injury during labor, delivery, or immediately post-delivery. The injury must result in both physical and mental impairment. Florida also has a requirement that the weight at birth must exceed 2,500 grams, 2,000 for multiple gestations. The Plan also does not apply to genetic or congenital abnormalities. Participation is voluntary for physicians.

The Florida Division of Administrative Hearings is the exclusive venue for hearings to determine whether a claimant will be admitted to NICA.

The process for filing a claim is as follows:

- The claimant submits a petition containing a specific list of required information and documentation. (The required information is quite similar to Virginia's.)

- The Florida Division of Medical Quality Assurance and the Florida Agency for Health Care Administration both investigate the claim.
- NICA responds to the claim petition.
- The administrative law judge holds a hearing to determine:
    - whether the injury claimed is a birth-related neurological injury,
    - whether the obstetrical services were delivered by a participating physician
    - how much compensation is awardable.

The applicable statute of limitations for a birth-related neurological injury shall be tolled by the filing of a claim with NICA and the time that the claim to NICA is pending shall not be computed as part of the period within which a civil action may be brought. In addition, a claim must be made to NICA within five years of the birth.

Benefits provided include:

- Unlimited actual, necessary medical expenses including:
    - Medical
    - Hospital
    - Rehabilitation/therapy/training
    - Family or professional residential or custodial care
    - Prescription medications
    - Special equipment or facilities
    - Related travel expenses.
- Reasonable attorney fees and other expenses associated with the application for admittance.

The NICA legislation also explicitly states several expenses that are not covered and notes that collateral sources may offset NICA benefits.

The Program is governed by a five-member board of directors. The board is appointed by NICA's Chief Financial Officer. The board will be composed of one citizen representative, one representative of participating physicians, one hospital representative, one representative of liability insurers, and one representative of non-participating physicians. The board's powers are clearly delineated in the Program's enabling legislation. Day to day operations are managed by an executive team, including the Chief Financial Officer hired by the Board. The executive team is supported by additional staff as needed.

NICA is organized as a non-governmental association whose assets are treated as a segregated association fund. NICA is “not a state agency, board, or commission”, but may use the state seal.

NICA uses a variety of funding approaches intended to provide for benefits on an accrual basis. First, participating physicians are required to pay a premium of $6,200. In addition, all licensed physicians, including non-OB/GYNs, that do not participate in the Program are required to pay a fee of $300 annually as a condition of being licensed in Florida. Hospitals pay a premium of $55 per live birth. A number of exclusions to the premiums apply for physicians with extenuating circumstances. Finally, if and only if the above premiums are “insufficient to maintain the plan on an actuarially sound basis” two additional revenue sources are available. The first of these is a transfer of $20 million from the Insurance Regulatory Trust Fund. Further, a premium of up to 0.25% of all “net direct premiums written” by casualty insurers in Florida may be assessed. These insurers are also explicitly permitted to recoup these premiums via surcharges in future policy premiums. In addition, “if the Office of Insurance Regulation finds that the plan cannot be maintained on an actuarially sound basis…the office shall increase the premiums … on a proportional basis as needed.”

An annual audit by a certified public accountant selected by the board is required to be provided to the Office of Insurance Regulation. An annual actuarial study on the financial soundness of the program is also conducted. NICA also has a unique additional protection in their enabling legislation. It states that “in the event that the total of all current (claims) estimates equals 80% of the funds on hand and the funds that will become available to the association within the next 12 months from all sources…, the association shall not accept any new claims without express authority from the Legislature.”
NICA is currently in excellent financial condition, having avoided some of the problems experienced by the Virginia Program.

New York Medical Indemnity Fund (MIF)

“The Medical Indemnity Fund ("Fund") was established by Chapter 69 of the 2011 Session Laws of the State of New York. The Fund is designed to pay all future costs necessary to meet the health care needs of plaintiffs in medical malpractice actions who have received either court-approved settlements or judgments deeming the plaintiffs' neurological impairments to be birth-related.” More specifically, a “birth-related neurological injury” is “an injury to the brain or spinal cord as the result of a deprivation of oxygen or mechanical injury that occurred in the course of labor, delivery or resuscitation, or by the provision or non-provision of other medical services during the delivery admission.” The law in New York currently states that these injuries need to have “rendered the infant with a permanent and substantial motor impairment or with a developmental disability.” This change from requiring both physical and mental injuries to one or the other or both is a subtle but very important difference from Virginia and Florida. As a result, participation rates in New York are currently about five times the rates

in the other states as a large number of participants that would not be eligible in either other state are being accepted into the MIF. Another major difference between the MIF and the Florida and Virginia birth funds is that claims are still pursued through the tort system and the determination of birth fund coverage is made by the judge responsible for the case.

Benefits provided by the Fund include:

- Medical, Dental, Surgical and Hospital Care
- Nursing and Custodial Care
- Prescription and Non-Prescription Drugs
- Rehabilitation Services
- Durable Medical Equipment and Assistive Technology
- Certain Home and Vehicle Modifications
- Other Health Care Costs for Medical Services and Supplies for Participants

The New York State Department of Health (NYS DOH) serves as the current administrator of the Fund. Three different third party administrators (TPA) have been involved in the MIF.

The Fund currently is financed through a budget allocation from the state of New York and is indirectly funded by "a quality contribution … imposed on the inpatient revenue of each general hospital that is received for the provision of inpatient obstetrical patient care services in an amount equal to 1.6% of such revenue, as defined in § 2807-d(3)(a) of the Public Health Law." Participation in the fund is triggered by an application by any party to a medical professional liability claim to have the judgment reflect that the judgment should provide that the portion of the judgment related to benefits covered by the Fund should be paid by the Fund.

Birth Fund Design Features

In evaluating program features for a potential birth fund in Maryland, the lessons learned in Florida and Virginia can be instructive in replicating successes and assist in avoiding repetition of mistakes.

Benefits Provided

The benefits covered by both the Florida and Virginia birth funds are fairly similar with the exception of the wage loss benefit.

An additional feature associated with providing birth fund medical benefits that is worthy of consideration is the use of managed care networks and/or the application of fee schedules to provide medical benefits, particularly nursing care. Significant cost savings may be realized through the use of

these cost controlling mechanisms to provide these benefits. Both the Virginia and Florida programs also coordinate benefits with private insurance and Social Security.

The benefits contained in the final version of the proposed Maryland Infant Lifetime Care Trust legislation as contained in Maryland SB0879 include reasonable expenses of:

- "Actual lifetime expenses for qualifying health care costs, limited to reasonable charges prevailing in the same community for similar treatment of injured individuals when the treatment is paid for by the injured individual" including
  - Medical care provided by physicians, surgeons and other health care providers
  - Hospital
  - Rehabilitative care
  - Nursing, family residential or custodial care
  - Durable medical equipment
  - Assistive technology
  - Medically necessary drugs
- Travel expenses or vehicle modifications that are necessary to meet the participant's health care needs
- Modification of the residential housing environment
- Reasonable expenses associated with "the adjudication of any disputed matters under this subtitle"

The benefits in the legislation are generally in line with the Florida and Virginia funds but exclude any loss of earnings benefit.

In addition, "a heath care cost that a qualified plaintiff's treating physician, physician's assistant, or nurse practitioner determines to be reasonable and necessary is presumed to be a qualifying health care cost unless there is clear and convincing evidence that the cost is not a qualifying health care cost." This provision ultimately gives the determination of benefits into the hands of the participant's health care provider rather than the Fund administrator.

Participation and Eligibility

A key issue in the area of participation and eligibility is whether participation in the birth fund is mandatory or not. Mandatory participation, as the final version of the proposed Maryland Infant Lifetime Care Trust contains, would appear to be a superior design feature. Making participation mandatory for both hospitals and OB/GYNs avoids a common situation in Virginia where either the hospital or the OB/GYN is a participant, but not both. In this scenario, only one of the parties has paid a premium but the child is eligible nonetheless. In this case, mandatory participation would increase

funds, but not add to the expected number of claims. The current Maryland bill proposes a mandatory birth fund. A detailed comparison of the birth fund eligibility criteria between the proposed Maryland legislation and the eligibility of the Florida and Virginia birth funds is attached as Exhibit 4.

Governance

In viewing patient compensation funds in general, two governance approaches are predominant: department of insurance administration and Board of Directors governance. Both birth funds use a board of directors approach, with some form of insurance department oversight. While Virginia authorizes the governor to have authority to appoint members to the Board, the Chief Financial Officer makes the appointments in Florida. The proposed Maryland Infant Lifetime Care Trust would follow form with Virginia and have the Governor make the Board appointments. The representation of the key birth fund stakeholders on the Florida Board (participating physicians, hospitals, non- participating physicians, and casualty insurers) is also quite appealing. The proposed Maryland Infant Lifetime Care Trust proposes a seven member Board comprised of:

- One obstetrician
- One pediatric neurologist
- One representative of the Maryland Hospital Association
- One attorney
- Two citizen representatives
- One expert in disability care

The proposed Maryland Infant Lifetime Care Trust would also be expected to have staff to handle day-to-day operations in a manner similar to the Florida and Virginia funds. Some staffing functions could also be accomplished through third party service providers. The currently proposed Maryland Infant Lifetime Care Trust bill would create the position of Trust Administrator and empower the administrator to administer the fund at the direction of the Board.

Administration

Once the decisions as to the overall governance and administration of the birth fund have been made, a number of specific tactical decisions need to be made about the fund's day-to-day operations. The most significant of these relate to compliance and policy management, billings and collections, claims administration, asset management, and actuarial services.

Services requiring technical expertise, such as legal and actuarial, tend to be outsourced more often than some other services. Virginia's approach of using other state agencies for certain services, such as legal services, may reduce costs and be intuitively appealing. Other PCFs utilize their State Investment

Board to manage investments; however, this raises potential risks which will be discussed later in the report. The use of a dedicated venue for establishing eligibility and participation of claimants is used by both the Florida and Virginia birth funds. It is important to select this venue so as to ensure that they have the requisite expertise and consistently apply the eligibility criteria.

The proposed Maryland Infant Lifetime Care Trust proposes that the Board oversee the investments of the fund, likely in partnership with professional investment managers. The proposed Maryland Infant Lifetime Care Trust also requires the engagement of a qualified actuary to be an advisor on appropriate funding levels and estimating unpaid benefits for the fund. These are both common and generally accepted approaches.

One innovative use of existing governmental agencies and processes in the current legislation is utilizing the existing Maryland Hospital Services Cost Review Commission (Commission) to collect the premiums of the proposed Maryland Infant Lifetime Care Trust. Because the Commission already has the statutory authority to collect certain other hospital assessments and the infrastructure to administer these assessments, utilizing it to also collect Fund premiums should prove an efficient and easy to implement approach.

Control of Funds and Investments

In terms of financial structure, two approaches are common for PCFs generally: a separate trust fund or a state agency. The trust fund approach has the advantage of independence from state government. The state agency approach allows the opportunity for better organizational controls, more access to other state agencies that can provide valuable services, a somewhat different position in claims negotiations, and independence from the influence of special interests.

In our opinion, it is absolutely imperative that birth fund assets be established in such a way that they are kept at arm's length from the funds of the state. Lessons learned in New Hampshire and Wisconsin, where government insurance program funds were taken in an effort to balance state budgets or fund other programs, made this abundantly clear. While the use of state investment managers has some appealing cost savings, it may lead to a co-mingling of funds that is not intended. There are usually controls on the percentage or amounts of funds that can be invested in different types of securities. These types of controls are also prudent for a fund that may hold premiums for decades before benefits are paid. The current Maryland bill addresses this concern.

Financial Oversight

Both birth funds require annual audits and financial reporting. We view this as absolutely essential. In addition, periodic actuarial studies to evaluate the soundness of the birth fund are also very important, especially in the early years of a birth fund. The birth funds use this actuarial review as an opportunity to review indicated premium rates. The New York Medical Indemnity Fund goes so far as to produce quarterly actuarial reports. The final version of the proposed Maryland Infant Lifetime Care Trust legislation requires both annual audits and actuarial reviews.

Other Legislative Features

Based on the experience of the Virginia fund, it appears that requiring a legislative action to achieve changes in premium levels is too restrictive and does not allow a birth fund to react to changing experience trends. The Florida legislation allowing the state's insurance regulators to intervene and increase premiums appears much more flexible and a reasonable measure to ensure program financial soundness. The additional Florida legislative features allowing access to additional state funds, if necessary, as well as the temporary discontinuation of accepting new claimants also appear to have merits. The Virginia legislative feature requiring discounts for participating hospitals and physicians also appears to be a reasonable control to ensure the overall economic soundness of the birth funds. The final version of the Maryland Infant Lifetime Care Trust bill requires the premium levels charged to hospitals in Maryland to be actuarially determined. In addition, the assessments of premiums are required to:

- Reflect geographic differences among hospitals
- Account for differences in historical experience by hospital
- Distinguish between hospitals that provide obstetrical services and those that do not.

This approach should help the proposed Maryland Infant Lifetime Care Trust avoid some of the pitfalls the Virginia birth fund has experienced.

Approaches to Funding

The Florida and Virginia birth funds both rely on some common funding approaches: premiums of participating physicians, non-participating physicians (including non-OB/GYNs) and hospitals. Both funds use an accrual based approach to funding in an effort to avoid large, unfunded, future benefits obligations. They both also have the means to assess liability insurers in the state. The New York Fund, on the other hand, is funded on a fiscal year basis with no accrual for future benefits payments.

Basis of Funding

Benefits are carried by the Virginia and Florida birth funds on an occurrence basis intended to cover all benefits accrued during that period. That is, unpaid benefits liabilities are accrued by the funds when the births occur, not when the petition for participation is made or when a participant is deemed eligible for participation in the birth fund. This would strongly suggest that the premiums paid by participants be developed on the same basis. The New York Medical Indemnity Fund is funded on a cash flow or "pay as you go" basis as a budget allocation from the state budget. This is likely to result in a significant unfunded liability for future benefits payments to current program participants as the MIF adds additional participants in future years. This was demonstrated in legislative costing studies produced by Pinnacle during the 2017 legislative session in New York. The proposed Maryland Infant Lifetime Care Trust legislation appears to be consistent with the approach in Florida and Virginia.

Hospital Premiums

Both the Florida and Virginia funds assess hospitals on a per live birth basis. This appears to be a sound approach. The proposed Maryland Infant Lifetime Care Trust legislation goes one step further and makes hospital assessments the sole funding source. The Virginia feature capping a hospital's annual premium may be a reasonable approach to recognize the important role of women's and infant's hospitals and other centers of excellence for difficult births.

Neither Florida nor Virginia differentiates the premiums of participants according to geographic differences. Some argument could be made that a flat premium fails to recognize differences in both physician revenues and medical professional liability premiums between participants in urban areas (e.g., Miami, Fairfax, VA or Baltimore) and participants in rural areas. The proposed requirement in Maryland that the premium assessment methodology "account for geographic differences" appears both reasonable and actuarially sound.

Health Care Provider Premiums

The impact of birth funds on the total medical professional liability insurance costs of OB/GYNs is an essential consideration of any birth fund. It is actuarially reasonable for future rates to reflect the lower expected losses due to implementation of the Trust. An exhibit showing potential impact to OB/GYN premiums is shown in Exhibit 5. The current OB/GYN rates for four of the leading medical professional liability insurers in the state, Medical Liability Mutual Insurance Society of Maryland, The Doctors Company, ProAssurance, and Medical Protective are shown by territory. There is a significant difference in premium rates by territory for each company. It is our understanding that premium discounts for birth fund participants in other states are commonly at least 10% to 15%. Based on this assumption, the premium savings for participating OB/GYNs would be typically between $10,000 and $20,000. In fact, this range of expected premium savings may be somewhat conservative. This is

based on the fact that the discount provided by the Medical Liability Mutual Insurance Society of Maryland to OB/GYNs that participate in the Virginia Birth Fund is currently 17%.

The Virginia birth fund also charges a lesser assessment to non-participating physicians, including non-OB/GYNs. This revenue generation approach has two desirable characteristics: first, it spreads some portion of the birth fund's costs across a broader premium base (i.e., all licensed healthcare providers in the state), and second, it encourages a higher rate of participation by OB/GYNs. This approach is not part of the current Maryland legislation.

Some PCFs charge premiums as a percentage of underlying insurance premiums. This approach has the desirable feature that the premium is adjusted for the insured's experience to the same extent as the underlying premium has been adjusted explicitly or implicitly for the insured's experience. The potentially undesirable feature of this approach is that comparable providers with different carriers would pay different premiums purely based on their primary carrier's expense loadings or rate adequacy level. This does not appear to be an attractive approach for birth funds.

Insurance Premium Taxes

Virginia's birth fund charges a premium tax of up to 0.25% on all liability premiums in the state. The logic behind the premium taxes on liability insurers is that the removal of birth injuries from the tort system removes a group of catastrophic injuries from the tort system and benefits liability insurers in total. While this logic may apply more fully to some liability coverages than others, it serves to spread the birth fund's costs across a broader segment of the interested parties in the state. It is important to realize that insurers are not only permitted, but expected, to recoup these premium taxes by reflecting their premium taxes in their filed rates. This type of special purpose tax on insurance premiums is quite common in almost every state and is recouped by the expense provision in insurers' rates. It is also noteworthy that the premium taxes can only be assessed when the Virginia birth fund is not "actuarially sound," that is physician and hospital premiums have not been sufficient to fund for all program benefits. This approach is not part of the proposed Maryland Infant Lifetime Care Trust legislation.

Premium Collection

The most common premium collection technique used by PCFs is requiring the primary insurer to collect the funds and serve as a "pass-through" to the PCF or birth fund. This approach to collection is well suited to premiums based on fixed dollar amounts. This approach has the benefit that the number of revenue sources is greatly reduced from having each hospital and provider pay the birth fund directly. Conversely, adding a layer of bureaucracy increases the potential for error. We find the proposed use of the existing Maryland Hospital Services Cost Review Commission to collect the

premiums of the proposed Maryland Infant Lifetime Care Trust to be an appealing and efficient approach.

Expected Funding Need and Benefits of the Maryland Infant Lifetime Care Trust

Expected Funding Need

The first step in developing a financial model of a potential birth fund in Maryland is an estimate of the expected annual benefits such a program would incur. Pinnacle's estimate is contained in attached Exhibit 2. We have assumed that the Maryland birth fund would be designed with similar benefits structures to those of the Virginia and Florida funds. Based on available information from those programs, we estimate that the frequency of qualifying claims would be between 0.9 and 1.0 claims per 10,000 live births. This estimate does not contemplate any impact on the number of participants in the Maryland Infant Lifetime Care Trust due to the changes in the definition of "birth-related neurological injury" in the final version of the legislation. It also does not assume a greater frequency of eligible births in Maryland due to differences in eligibility wording to Florida, that describes "substantial" impairments, or Virginia that describes specific characteristics of an eligible participant. In addition, the difference in the Maryland birth fund (allowing actions to proceed under the tort system) will also not materially change the number of admitted participants annually. A hospital that believes a child is eligible for birth fund benefits will in all likelihood offer birth fund participation as an early settlement offer. It is difficult to envision a scenario where a child that would have been admitted to the program under the originally proposed no-fault approach would somehow not be admitted under the tort approach. Based on this assumption, we estimate that a total of about 6.80 qualifying births occur in Maryland annually.

Similarly, a review of Florida and Virginia benefits payments and unpaid benefits estimates suggests that lifetime claims benefits in Maryland for benefits similar to those in the Virginia and Florida birth funds and adjusted for unique benefits elements in Maryland would have a present value of between $2.87 million and $3.27 million. These present values assume a discount rate of 4%, which provides a reasonable estimate of a conservative investment return for birth fund invested assets. These estimates also make necessary cost of living adjustments to reflect medical, housing, and other cost differences in Maryland. Based on these assumptions, a Maryland birth fund would incur benefits costs of between $18.4 million and $23.2 million annually. This calculation is documented in Exhibit 2.

The next consideration is the means of funding the birth fund's benefit obligations. In the proposed legislation, the HSCRC, in conjunction with a qualified actuary, will develop a hospital premium methodology that accounts for: geographic differences among hospitals, differences in historical birth-

related claims experience among hospitals, differences between hospitals that provide obstetrical care and those that do not. This represents a reasonable, appropriate and actuarially sound approach to funding the fund on an accrual basis. This approach should also help the proposed Maryland Infant Lifetime Care Trust avoid some of the pitfalls the Virginia birth fund has experienced in the past.

This funding mechanism is a valid approach to fully funding the proposed Maryland Infant Lifetime Care Trust's expected benefits.

More detail is provided in the attached exhibits.

Expected Benefits

Funding for the Maryland Infant Lifetime Care Trust initially causes higher costs for Medicaid based on increased reimbursement rates. We estimate that rates for obstetric services would increase by approximately 2.6% (see Exhibit 3, Page 1). However, these costs are more than offset by the Trust removing medical expenses from Medicaid for decades into the future. Based on the Virginia, Florida, and New York birth funds, approximately 60% of expenses paid by the Maryland Infant Lifetime Care Trust would otherwise have been paid by Medicaid. We estimate that the ultimate saving to Medicaid far exceeds the additional costs to the state general fund. Exhibit 3, Page 2 shows the benefit payment streams for Trust participants born in 2020 compared to the initial cost to Medicaid due to the rate increase. Exhibit 3, Page 3 further generalizes this result by looking at five birth years of participants expected to be placed in the Trust.

Distribution & Use

This Report has been prepared in support of the Alliance for Lifetime Infant Care and the other members of the group working to develop this legislation and for their internal use only. It is understood that the Alliance for Lifetime Infant Care may also wish to distribute this report to the various policymakers and stakeholders in the state, potentially including the Governor and the Legislature, as well as the general public via their website. This distribution as well as any further distribution to the makers of public policy and the various stakeholders in the healthcare industry in the State of Maryland is hereby granted.

When this report is distributed, it should be distributed in its entirety. All recipients of this report should be aware that Pinnacle is available to answer any questions regarding the report. These third parties should recognize that the furnishing of this report is not a substitute for their own due diligence and should place no reliance on this report or the data, computations, and interpretations contained herein that would result in the creation of any duty or liability by Pinnacle to the third party.

Pinnacle consents to reference by the Alliance for Lifetime Infant Care to Pinnacle's reports, opinions, advice and firm name in documents released by or at the direction of the Alliance for Lifetime Infant Care concerning our findings.

The exhibits attached in support of our findings are an integral part of this Report. These sections have been prepared so that our actuarial assumptions and judgments are documented. Judgments about the conclusions drawn in this Report should be made only after considering the Report in its entirety. We remain available to answer any questions that may arise regarding this Report. We assume that the user of this Report will seek such explanation on any matter in question.

Our conclusions are predicated on a number of assumptions as to future conditions and events. Those assumptions, which are documented in subsequent sections of this report, must be understood in order to place our conclusions in their appropriate context. In addition, our work is subject to inherent limitations, which are also discussed in this Report.

Reliances & Limitations

We have prepared this Report in conformity with its intended use by persons technically competent in the areas addressed and for the stated purposes only.

Throughout our analysis we have, without audit or verification, relied on historical data and qualitative information provided by the American Medical Association, the Florida Birth-Related Neurological Injury Compensation Association, the Virginia Birth-Related Neurological Injury Compensation Program and other publicly available sources. The accuracy of our results is dependent upon the accuracy and completeness of this underlying data. However, we did review as many elements of this data and information as practical for reasonableness and consistency with our knowledge of the insurance industry. We have not anticipated any extraordinary changes to the legal, social, or economic environment.

Judgments as to conclusions, recommendations, methods, and data contained in this report should be made only after studying the report in its entirety. Furthermore, Pinnacle is available to explain any matter presented herein, and it is assumed that the user of this report will seek such explanation as to any matter in question. It should be understood that the exhibits, graphs, and figures are integral elements of the report.

Pinnacle is expressing no opinion on the appropriateness of the 4% interest rate used in the discounting calculations.

Estimates discounted for the time value of money can be more uncertain than those on an undiscounted basis. In addition to the usual uncertainty in projecting unpaid claims obligations and benefits, discounted estimates are also influenced by:

- Variations in the timing of actual benefit payments versus the rate of payment assumed in discounting estimates to present value
- Variation in the actual investment yield on the assets underlying the liabilities versus the assumed interest rate used in discounting.

While an explicit risk margin may be applied to account for this additional uncertainty, we have not incorporated an explicit risk margin in our analysis.

Pinnacle is not qualified to provide formal legal interpretations of current or proposed state legislation. The elements of this report that require legal interpretation should be recognized as reasonable interpretations of the available statutes, regulations, and administrative rules. State governments and courts are also constantly changing and reinterpreting these statutes.

There is a limitation upon the accuracy of these estimates in that there is inherent uncertainty in any estimate of future claims benefits. This is due to the fact that the ultimate liability for claims is subject to the outcome of events yet to occur, e.g., the likelihood of claimants bringing suit, the size of jury awards, changes in the standards of liability and the attitudes of claimants toward settlement of their claims. We have employed generally accepted actuarial techniques and assumptions that we believe are reasonable and appropriate. Further, the conclusions presented herein are reasonable and appropriate and supported by our analysis, given the information currently available. However, it should be recognized that future loss emergence will likely deviate, perhaps materially, from our estimates.

INDEX OF EXHIBITS

Maryland Infant Lifetime Care Trust

Exhibit 1

Projected Birth Fund Costs and Revenues

		Expected Costs
(1)	Central Expected Benefits Paid	20,730,482
(2)	Operating Expenses	750,000
(3)	Maternal and Fetal Outcomes Grant	1,000,000
(4)	Total Program Costs	22,480,482

Footnotes

(1) From Exhibit 2
(2) Based on review of comparable programs in Florida and Virginia
(3) Grant allocated by legislation to improve maternal and fetal health outcomes
(4) = (1) + (2) + (3)

Maryland Infant Lifetime Care Trust

Exhibit 2

Projected Birth Fund Benefits

	Low	Central	High
(1) Expected Number of Live Births	71,080	71,080	71,080
(2) Expected Frequency of Claimants per 10,000 Live Births	0.90	0.95	1.00
(3) Expected Number of Claimants Admitted to the Program	6.4	6.8	7.1
(4) Expected Average Benefits Paid to Admitted Claimants (Present Value Basis)	2,870,000	3,070,000	3,270,000
(5) Expected Birth Fund Benefits	18,359,964	20,730,482	23,243,160

Footnotes

(1) 2018 live birth data from National Center for Health Statistics (www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_13-508.pdf)

(2), (4) Based on review of comparable programs in Florida and Virginia

(3) = (1) x (2) / 10,000

(5) = (3) x (4)

Maryland Infant Lifetime Care Trust

Projected Impact to Medicaid

Rate Center	Center Code	Hospital Count	Average Rate	Statewide Volume	Expected Total Charges
(1)	(2)	(3)	(4)	(5)	(6)
Obstetrics Acute	OBS	32	1,221.73	168,211	205,508,430
Neonatal ICU	NEO	16	1,729.50	111,254	192,414,355
Newborn Nursery	NUR	32	723.11	150,694	108,967,914
Premature Nursery	PRE	1	1,239.48	1,129	1,399,894
Labor & Delivery Services	DEL	32	124.59	3,510,572	437,382,133
					945,672,726

(7)	Total Infant Care Trust Annual Cost	22,480,482
(8)	Markup for underpayment (estimated)	1.10
(9)	Hospital Rate Revenue Increase Required	24,728,530
(10)	Percentage of Charges to Medicaid	45%
(11)	Incremental Medicaid Charges	11,127,839
(12)	% of Federal Match	40%
(13)	**Annual Program Cost to State General Fund**	4,451,135
(14)	Rate Increase to Obstetrics Services	2.6%

Footnotes

(1) - (5) Rate Center data from HSCRC FY 2020 rates (obtained from https://hscrc.state.md.us/Pages/hsp_rates2.aspx)
(6) = (4) x (5)
(7) = Exhibit 1, Item 4
(8), (10), (12) Estimates based on publicly available HSCRC data
(9) = (7) x (8)
(11) = (9) x (10)
(13) = (11) x (12)
(14) = (9) / (6) Total

Maryland Infant Lifetime Care Trust

Projected Trust Benefits to Medicaid
Payment Streams for 2020 Birth Year Participants Only

Trust Payments	**2020**	**2021**	**2022**	**2023**	**2024**	**2025 - 2029**	**2030 - 2034**	**2035 - 2039**	**2040 - 2044**	**2045 - 2049**	**2050 - 2054**	**2055 and beyond**
(1) Estimated Trust Benefits	434,549	541,107	573,237	646,979	657,131	3,063,312	2,238,120	2,434,176	2,475,977	2,476,057	2,478,473	22,523,863

Medicaid Cost	**2020**	**2021**	**2022**	**2023**	**2024**	**2025 - 2029**	**2030 - 2034**	**2035 - 2039**	**2040 - 2044**	**2045 - 2049**	**2050 - 2054**	**2055 and beyond**
(2) Program Cost to State General Fund	4,451,135											

Net Benefit Position	**2020**	**2021**	**2022**	**2023**	**2024**	**2025 - 2029**	**2030 - 2034**	**2035 - 2039**	**2040 - 2044**	**2045 - 2049**	**2050 - 2054**	**2055 and beyond**
(3) Projected Benefit to Medicaid	-4,016,586	-3,475,479	-2,902,241	-2,255,262	-1,598,131	1,465,181	3,703,301	6,137,477	8,613,453	11,089,510	13,567,983	36,091,846

Footnotes
(1) Based on Trust analysis central estimate on a nominal basis for expected 6.8 participants born in 2020
Assumes approximately 60% of future payments would otherwise be covered by Medicaid
Payment pattern estimated from Virginia program
(2) Projected Cost to Medicaid estimated on Exhibit 3, Page 1
(3) = (1) - (2)

Maryland Infant Lifetime Care Trust

Exhibit 3

Projected Trust Benefits to Medicaid

Page 3

Payment Streams for 2020 through 2024 Birth Year Participants Only

Trust Payments		**2020**	**2021**	**2022**	**2023**	**2024**	**2025 - 2029**	**2030 - 2034**	**2035 - 2039**	**2040 - 2044**	**2045 - 2049**	**2050 - 2054**	**2055 and beyond**
(1) Estimated Trust Benefits													
	Year 1	434,549	541,107	573,237	646,979	657,131	3,063,312	2,238,120	2,434,176	2,475,977	2,476,057	2,478,473	22,523,863
	Year 2		434,549	541,107	573,237	646,979	3,158,379	2,354,607	2,387,697	2,478,368	2,467,772	2,476,005	23,024,281
	Year 3			434,549	541,107	573,237	3,209,723	2,514,199	2,332,268	2,472,233	2,467,560	2,474,557	23,523,546
	Year 4				434,549	541,107	3,170,593	2,694,969	2,262,659	2,475,453	2,468,556	2,476,878	24,018,217
	Year 5					434,549	3,088,279	2,877,033	2,220,352	2,461,499	2,473,768	2,476,436	24,511,065

Medicaid Cost	**2020**	**2021**	**2022**	**2023**	**2024**	**2025 - 2029**	**2030 - 2034**	**2035 - 2039**	**2040 - 2044**	**2045 - 2049**	**2050 - 2054**	**2055 and beyond**
(2) Program Cost to State General Fund	4,451,135	4,451,135	4,451,135	4,451,135	4,451,135							

Net Benefit Position	**2020**	**2021**	**2022**	**2023**	**2024**	**2025 - 2029**	**2030 - 2034**	**2035 - 2039**	**2040 - 2044**	**2045 - 2049**	**2050 - 2054**	**2055 and beyond**
(3) Projected Benefit to Medicaid	-4,016,586	-7,492,065	-10,394,306	-12,649,568	-14,247,699	1,442,586	14,121,514	25,758,666	38,122,196	50,475,909	62,858,257	180,459,228

Footnotes

(1) Based on Trust analysis central estimate on a nominal basis for expected 6.8 participants per birth year
Assumes approximately 60% of future payments would otherwise be covered by Medicaid
Payment pattern estimated from Virginia program

(2) Projected Cost to Medicaid estimated on Exhibit 3, Page 1

(3) = (1) - (2)

Maryland Infant Lifetime Care Trust

Exhibit 4

Comparison of Birth-Related Neurological Injury Definitions

Maryland Proposed	Florida [s. 766.302(2)]	Virginia (§ 38.2-5001)
"Birth-related neurological injury" means	Identical	Identical
an injury to the brain or spinal cord of a live infant that:	Identical	Omits “live” due to death benefit
is caused by oxygen deprivation or other injury	Replaces “other” with “mechanical”	Replaces “other” with “mechanical”
Omitted entirely	weighing at least 2,500 grams for a single gestation; or in the case on multiple gestation, weighing at least 2,000 grams at birth;	Omitted entirely
that occurred or could have occurred during labor, during delivery, or in the resuscitative period after delivery; and	occurring in the course of labor, delivery, or resuscitation in the immediate postdelivery period in a hospital, which	that occurred in the course of labor or delivery, in a hospital which
renders the infant permanently neurologically and physically impaired.	renders the infant permanently and substantially mentally and physically impaired.	renders the infant permanently motorically disabled and (i) developmentally disabled or (ii) for infants sufficiently developed to be cognitively evaluated, cognitively disabled.
Additional language not included in Maryland.	Additional language not included in Florida.	In order to constitute a "birth-related neurological injury" within the meaning of this chapter, such disability shall cause the infant to be permanently in need of assistance in all activities of daily living.
<u>Additional Clarifications</u> includes only injuries involving live infants born in a Maryland hospital.	Addressed elsewhere in definition.	Addressed elsewhere in definition.
does not include disability or death caused by genetic or congenital abnormality.	shall not include disability or death caused by genetic or congenital abnormality.	shall not include disability or death caused by genetic or congenital abnormality, degenerative neurological disease, or maternal substance abuse.

*New York not shown due to significant definition difference from other three funds.

Maryland Infant Lifetime Care Trust

Exhibit 5

Projected Obstetrician Medical Professional Liability Insurance Premium Savings

Mature Claims-Made Coverage, $1 Million per Occurrence Limit/$3 Million Aggregate

Company/ Est. Market Share	Territory	Manual Premium	10% Decrease	15% Decrease
Medical Liability Mutual Insurance Society of MD	Baltimore City and County	116,378	11,638	17,457
	Montgomery, Prince Georges, Howard, and Anne Arundel Counties	105,787	10,579	15,868
55%	Remainder of State	93,102	9,310	13,965
The Doctors Company (TDC)	Baltimore City and County	152,989	15,299	22,948
	Montgomery, Prince Georges, Howard, and Anne Arundel Counties	140,391	14,039	21,059
14%	Remainder of State	113,991	11,399	17,099
ProAssurance	Baltimore County	158,317	15,832	23,748
	D.C. Beltway	143,969	14,397	21,595
6%	Remainder of State	127,126	12,713	19,069
Medical Protective (Med Pro)	Baltimore City and County	113,558	11,356	17,034
	Montgomery, Prince Georges, Howard, and Anne Arundel Counties	100,931	10,093	15,140
3%	Remainder of State	84,111	8,411	12,617

Source: Medical Liability Monitor, October 2019, Annual Rate Survey Issue

Robert Walling_FAV_SB 879
Uploaded by: Walling, Robert
Position: FAV

Report on the Maryland SB0879 and the Feasibility, Design and Funding of The Maryland Infant Lifetime Care Trust

For the Maryland State Senate Finance Committee

Commitment Beyond Numbers

PINNACLE
ACTUARIAL RESOURCES, INC.

Robert J. Walling III, FCAS, MAAA, CERA
Principal and Consulting Actuary

March 5, 2020

Pinnacle Introduction & Background

- Fellow of the Casualty Actuarial Society (FCAS)
- Member of the American Academy of Actuaries (MAAA)
- Former member of the CAS Board of Directors

Pinnacle Actuarial Resources has served:

- ✓ **New York** Medical Indemnity Fund since before it was enacted in October of 2011
- ✓ **Florida** Birth-Related Neurological Injury Compensation Association (NICA) since 2008
- ✓ **Virginia** Birth-Related Neurological Injury Compensation Program in various capacities since 2003
- ✓ Patient compensation funds in **New Mexico** and **Wisconsin** since 2002 and 2007, respectively.

Robert J. Walling III
Principal and Consulting Actuary
Pinnacle Actuarial Resources, Inc.

Key Findings: Expected Cost of the Trust

- Maryland can expect between 0.9 and 1.0 claims per 10,000 live births, or a total of about 6.8 qualifying births annually.

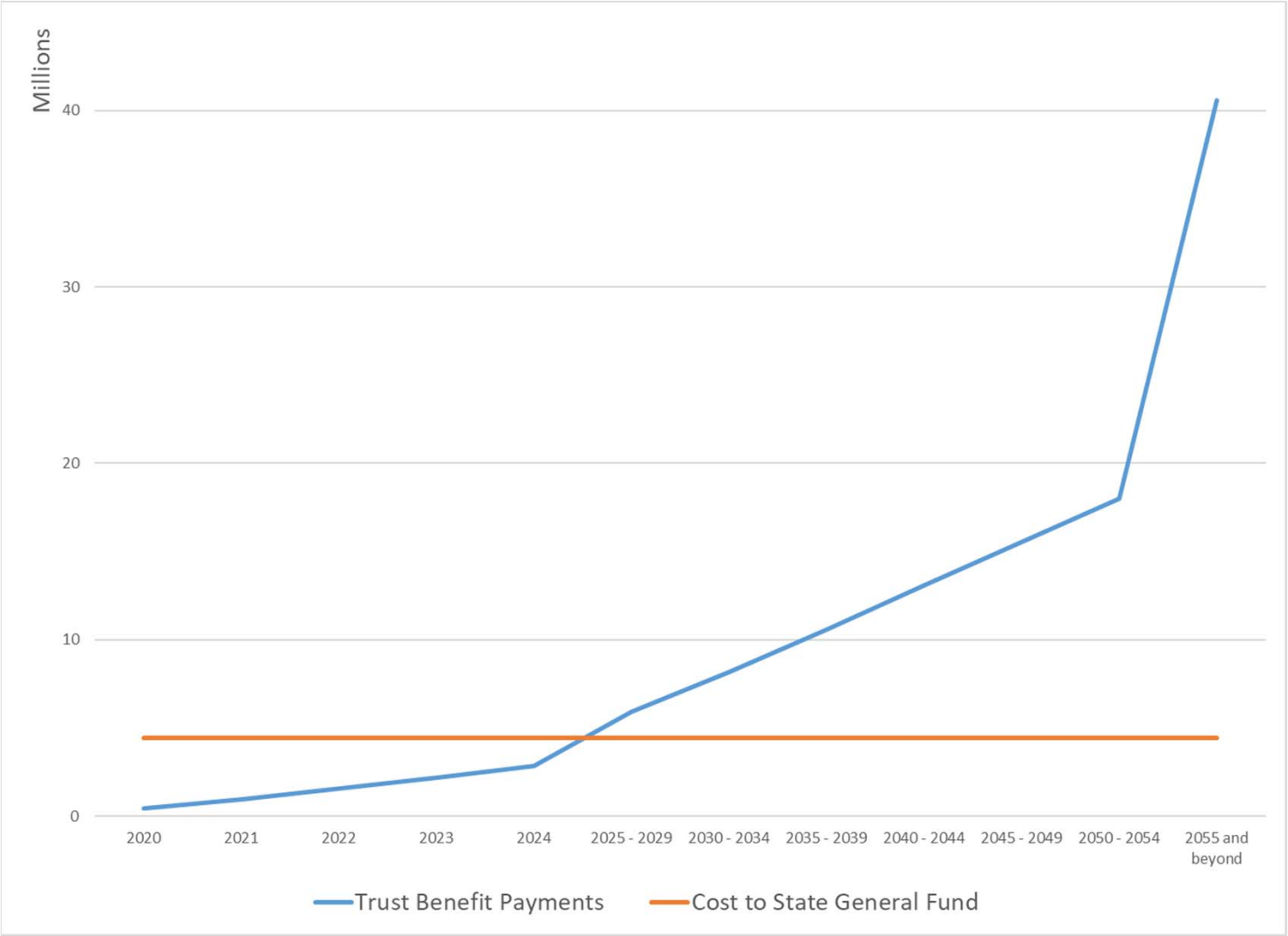
- Present value of lifetime benefits in Maryland as currently proposed would be between $2.87 million and $3.27 million per claim.

- **Total expected costs for the Infant Lifetime Care Trust under the current bill are therefore $22.5 million:**
  - Accrued annual benefits costs of $18.4 - 23.2 million
  - Overall operational expenses estimated at $750,000 annually
  - $1.0 million per year as a grant designated for improving maternal and fetal outcomes in the state

Key Findings: Funding the Trust

- The Trust is funded on accrual basis by an estimated $22.5 million HSCRC assessment on hospital rates, based on an annual actuarial report evaluating projected liabilities.
- The total cost of the Maryland Infant Lifetime Care would be only 0.14% of total hospital revenue (or 2.6% of OB revenue).
- The Trust will generate significant savings for Maryland's overall healthcare system over time.

Impact on Medicaid



Conclusion

- Bill SB0879 provides a reasonable, appropriate and actuarially sound approach to funding the Trust on an accrual basis.
- State General Fund Medicaid will be minimally impacted in early years and ultimately accrue savings in the long term.
- Trust benefits will paid as incurred, not estimated as part of a one-time lump sum.
- Guaranteed lifetime care will be provided to families once enrolled in the Trust.

Thank You for Your Attention

Robert J. Walling III, FCAS, MAAA, CERA

309-807-2320

rwalling@pinnacleactuaries.com

PINNACLE
ACTUARIAL RESOURCES, INC.

Appendices

Projected Annual Impact to Medicaid

Rate Center	Center Code	Hospital Count	Average Rate	Statewide Volume	Expected Total Charges
(1)	(2)	(3)	(4)	(5)	(6)
Obstetrics Acute	OBS	32	1,221.73	168,211	205,508,430
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Labor & Delivery Services	DEL	32	124.59	3,510,572	437,382,133
					945,672,726

(7)	Total Infant Care Trust Annual Cost	22,480,482
(8)	Markup for underpayment (estimated)	1.10
(9)	Hospital Rate Revenue Increase Required	24,728,530
(10)	Percentage of Charges to Medicaid	45%
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(13)	**Annual Program Cost to State General Fund**	4,451,135
(14)	Rate Increase to Obstetrics Services	2.6%

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(8), (10), (12) Estimates based on publicly available HSCRC data
(9) = (7) x (8)
(11) = (9) x (10)
(13) = (11) x (12)
(14) = (9) / (6) Total

Payment Streams for Participants Born in 2020

Trust Payments	2020	2021	2022	2023	2024	2025 - 2029	2030 - 2034	2035 - 2039	2040 - 2044	2045 - 2049	2050 - 2054	2055 and beyond
(1) Estimated Trust Benefits	434,549	541,107	573,237	646,979	657,131	3,063,312	2,238,120	2,434,176	2,475,977	2,476,057	2,478,473	22,523,863

Medicaid Cost	2020	2021	2022	2023	2024	2025 - 2029	2030 - 2034	2035 - 2039	2040 - 2044	2045 - 2049	2050 - 2054	2055 and beyond
(2) Program Cost to State General Fund	4,451,135											

Net Benefit Position	2020	2021	2022	2023	2024	2025 - 2029	2030 - 2034	2035 - 2039	2040 - 2044	2045 - 2049	2050 - 2054	2055 and beyond
(3) Projected Benefit to Medicaid	-4,016,586	-3,475,479	-2,902,241	-2,255,262	-1,598,131	1,465,181	3,703,301	6,137,477	8,613,453	11,089,510	13,567,983	36,091,846

Footnotes

(1) Based on Trust analysis central estimate on a nominal basis for expected 6.8 participants born in 2020
Assumes approximately 60% of future payments would otherwise be covered by Medicaid
Payment pattern estimated from Virginia program

(2) Projected Cost to Medicaid estimated on Exhibit 3, Page 1

(3) = (1) - (2)

Payment Streams for Multiple Birth Years

Trust Payments	2020	2021	2022	2023	2024	2025 - 2029	2030 - 2034	2035 - 2039	2040 - 2044	2045 - 2049	2050 - 2054	2055 and beyond
(1) Estimated Trust Benefits												
Year 1	434,549	541,107	573,237	646,979	657,131	3,063,312	2,238,120	2,434,176	2,475,977	2,476,057	2,478,473	22,523,863
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Medicaid Cost	2020	2021	2022	2023	2024	2025 - 2029	2030 - 2034	2035 - 2039	2040 - 2044	2045 - 2049	2050 - 2054	2055 and beyond
(2) Program Cost to State General Fund	4,451,135	4,451,135	4,451,135	4,451,135	4,451,135							

Net Benefit Position	2020	2021	2022	2023	2024	2025 - 2029	2030 - 2034	2035 - 2039	2040 - 2044	2045 - 2049	2050 - 2054	2055 and beyond
(3) Projected Benefit to Medicaid	-4,016,586	-7,492,065	-10,394,306	-12,649,568	-14,247,699	1,442,586	14,121,514	25,758,666	38,122,196	50,475,909	62,858,257	180,459,228

Footnotes

(1) Based on Trust analysis central estimate on a nominal basis for expected 6.8 participants per birth year
Assumes approximately 60% of future payments would otherwise be covered by Medicaid
Payment pattern estimated from Virginia program

(2) Projected Cost to Medicaid estimated on Exhibit 3, Page 1

(3) = (1) - (2)

Paige Barocca _unf_SB879
Uploaded by: Barocco, Paige
Position: UNF

Chairs, Vice Chairs and Members of the Senate Finance Committee. **OPPOSE SB879**

My name is Paige Barocca. I am writing today as parent and a citizen to express my serious concern for the medical freedoms of parents and children in Maryland. I stand strongly against the Infant Lifetime Care Trust bill, as I feel that will limit choices for parents of children with birth injuries. New treatments come on the market every day. Medicine is improving at a rapid rate. Parents of severely disabled children are often more up to date on the newest research and experimental treatments then even the doctors are. If you force victims into this pubic fund it takes away the parents decision-making power about what kinds of treatments their children need. In addition, they could be putting potentially gruesome waits on these vulnerable victims. How often will the board meet to approve or deny treatments? In other states it is once a month, if that, as it is within their power to reschedule. These incredibly sick children deserve the best treatment, they do not have the time to wait for some board's approval.

The bill is leaving decisions out of the hands of parents and into the hands of vaguely defined medical staff. On page 10, line 9: "qualifying health care costs" are defined as "REASONABLE" expenses of medical, hospital and rehabilitative care, family residential services, custodial care, professional residential care, durable medical equipment, assistive technology, medically necessary drugs, and related travel, and residential or vehicle modifications that are necessary to meet the QUALIFIED PLANTIFF'S HEALTH CARE NEED AS DETERMINED BY THE QUALIFIED PLAINTIFF'S TREATING PHYSICIANS, PHYSICIANS ASSISTANTS, OR NURSE PRACTITIONER'S, AND AS OTHERWISE DEFINED BY STATUTE OR REGULATION.

WHAT IS REASONABLE? WHO DECIDES WHO IS A QUALIFIED PHYSICIAN? What does it mean otherwise defined by statute or regulation? I interpret that to mean that the overseeing body can create regulation not in statute to limit the potential definition of qualified healthcare costs. What about my child's acupuncture, which has proven incredibly helpful? What about chiropractic care? What about art therapy? Or any other issue that our doctor may not be familiar with? Each time I would like to add something to my child's care, I would need to come to the board and beg for coverage that can be denied.

Furthermore, this fund will not be treating communities in need with the equal value given in richer neighborhoods. On page 18, line 21, it states that only "reasonable charges prevailing in the same community for similar treatment" So if you live in Ellicott City you may get more money, because the care in your area costs more simply because you live in an affluent area. But if you live in rural counties or in Baltimore City your child is entitled to lower valued care, as your community practioners cannot charge more merely because of who the local clients are? Care in being rationed before the Board is even in place.

I'd like to end with a reflection of who this bill benefits. The people? Surely not. It seems as though we are supporting hospitals who are hoping to avoid large settlements for their neglect. Do we really want to live within a system that allows for excuses and funds to cover up poorly managed care? Why don't we, instead, spend a million dollars finding out why we are injuring and killing so many babies, especially black babies? As Maya Angelou said, "do the best you can until you know better. Then when you know better, do better!"

An Infant Lifetime Care Trust would be a step backwards, away from progress. We should be moving forward to provide more options for parents and children, along with safer and more accountable care. This bill is offensive and a grotesque violation of the rights of the most vulnerable among us.

Thank you for your time and consideration,

Paige Barocca, RN, LDEM, CPM
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443.907.3705

Brandon_UNF_SB879
Uploaded by: Brandon, Dr. Kirra
Position: UNF

Maryland Families for Safe Birth, Inc.

SB 879
UNF

The Honorable Delores Kelley
Chair, Senate Finance Committee
Miller Senate Office Building, 3 East Wing
11 Bladen St., Annapolis, MD 21401

March 5, 2020

Dear Chair Kelley and Members of the Senate Finance Committee:

Maryland Families for Safe Birth is a grassroots, consumer based organization dedicated to improving maternity care in the state of Maryland. We represent all families in Maryland, with the support of over 1500 active members. We are writing in opposition to Senate Bill 879.

The Maryland Infant Lifetime Care Trust is an effort to minimize the financial impact of birth injury lawsuits on hospitals. That may well be an effort that is worthwhile, but only if it were limited to situations in which negligence did not occur. Giving hospitals financial immunity from negligence related to birth outcomes is not going to improve maternity care overall.

Simply put, this bill provides little, if any, protection for consumers of maternity care.

Imagine that your baby suffers a severe birth injury requiring lifetime care. Imagine that every time you need to access funds to take care of your injured child, you must appeal to a board that manages your ability to access the monetary resources necessary to care for your child. Suppose an experimental treatment becomes available. It is very likely that it will not be approved by the board. The bill, in fact, states that someone other than you, the parent, will decide what care is appropriate for your child. In an already incredibly difficult situation, are we really asking parents to hand over control of the medical care their child can receive?

PO Box 204
Myersville, MD 21773

408-MYBIRTH
408-692-4784

info@marylandfamiliesforsafebirth.org

www.marylandfamiliesforsafebirth.org
www.MFSB.me

Imagine that you have a perfectly normal birth and your baby is fine. According to this bill, the hospital will be allowed to increase their maternity care fees in order to offset the costs of their required contribution to the fund. As a result, your completely normal birth will cost even more.

This bill will hurt every single consumer of maternity care in Maryland. We represent those families, and strongly urge you to oppose SB 879.

If a solution to mitigate costs for hospitals is deemed necessary, it must be structured differently than is conveyed in this bill. It must be structured in a way that is not harmful to your constituents.

Sincerely,

Dr. Kirra L Brandon
President, Maryland Families for Safe Birth

PO Box 203
Boonsboro, MD 21713

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Sarah Cusack_unf_SB879
Uploaded by: Cusack, Sarah
Position: UNF

SB 879 Testimony – oppose

Sarah Cusack

I strongly oppose SB 879. While I do not understand the intricacies of this particular piece of legislation, I am familiar with another health fund, the Federal VICP, Vaccine Injury Compensation Fund.
The VICP fund was created in coordination with parents of injured and deceased children and was supposed to provide swift compensation to individuals with a documented vaccine injury. Instead it has turned into a nightmare. Families that file can expect 8-10 grueling years fighting for what they are rightly owed and may or may not be compensated at the end.
The fund is not well publicized. Most families of injured people have no idea that the fund exists, or how to file.
There are very strict conditions and time limits to file.
It is not a real court.
There is no precedent set. Each family has to start over with their own experts, scientist, and doctors.
There is a paltry maximum compensation for a deceased family member of only $250,000.
The incentive for vaccine makers (Big Pharma) to keep their products safe has literally been removed. Innovation has been lost. It has clearly left an open door for this particular industry to behave poorly.
I am a pediatric Physical Therapist and worked for 10 years at the Kennedy Krieger Institute in Baltimore. I am familiar with how catastrophic birth injuries can be to a child and their family. The right to be able to sue is an important one. Please do not protect hospitals over our children.
Thank You for reading and considering. I appreciate it.
Sarah Cusack, MPT

Joshua Dixon._unf_SB979
Uploaded by: Dixon, Joshua
Position: UNF

SB 879 Testimony – oppose

My name is Joshua Dixon. I oppose SB0879.

In December 2008, my wife and I transferred to Johns Hopkins Bayview ER for our birth. We were told our baby was dead and begged for emergency c-section or any help. For three hours we received none. By the grace of god we finally delivered a healthy baby.

Page 11 line 3 of this bill puts the onus of solving medical malpractice on the state. Why would we no longer make hospitals responsible for the damage they cause to women and babies?

On line 12 it states states the General Assembly would "...study trust claims and other data to develop best practices in perinatal care. Are hospitals incapable of doing this themselves without governments help?

Some suggestions for future perinatal care:
1. When a licensed and certified nurse midwife brings in a transfer patient and states that the women requires an immediate cesarean, I suggest you give the woman an immediate cesarean and not wait three hours.
2. If you have erroneously offered a woman a midterm abortion and then discovered her baby is healthy and not eligible. I highly suggest you tell the mother that information and then you monitor the baby's heartrate during her 60 hour long induction.

I provide those suggestions to hospitals free and at no cost to the state.

Thank you,

--
Joshua E. Dixon

UMBC Mechanical Engineering '18

Deirdre Elvis-Peterson_unf_SB879
Uploaded by: Elvis-Peterson, Deidre
Position: UNF

SB 879 Testimony – oppose

Good afternoon, I'd like to express my opposition to SB 879. This bill takes AWAY the right of a victim to hold the offender accountable. This bill makes hospitals and their staff FREE FROM LIABILITY in the care of pregnant/laboring women. A pregnant/laboring woman is in the most vulnerable state she will ever be in her life. Labor and delivery is a time when women go inside themselves and seek comfort from those surrounding them.

The fact that hospital staff commit errors that result in the injury to babies and their mothers, NOW, WHILE they are liable, should inform everyone that taking liability AWAY will only worsen these problems.

Right now maternal and fetal mortality in Maryland are increasing in the black community only…no others have seen an increase. How many ways can you find to victimize African Americans as a group?

The single and only reputable part of this bill is the allocation of the million dollar grant to study AND address disparities in maternal and fetal outcomes across the state. Sad they're only willing to allocate a million dollars to this important issue. Why are these injuries occurring at the rates they are? That is the crux of the problem. Victim's rights should not be infringed upon because of repeated medical negligence. The medical negligence is what needs to be addressed.

Taking liability away from the body that is being paid quite well to care for women in a vulnerable state is not wise. Without liability, without their malpractice insurance premiums, without the knowledge that their negligence can result in a lawsuit, what is the incentive to improve on their performance? There would be no incentive direct to the care provider.

Many women find contentious situations as it is when laboring in hospitals. This legislation will not improve upon that. This legislation also succeeds in stripping victims' parents of their right to pursue medical treatments they deem fit for their child following the injuries they sustain. The parents of the victim would have to beg a board, which would have no concept of what it is to raise their now injured child. This board consisting heavily (57%) of medical professionals would have a STRONG medical bias toward any alternative treatments parents may seek to create comfort or improvement for their injured child. Therefore I ask that you not support SB 879. Thank you. Deirdre Elvis-Peterson 4123 Bedford Road Pikesville District 43B

Deirdre Elvis-Peterson
Primerica Independent Representative
"Freedom lives here."

KaraFisher_Oppose_SB0879
Uploaded by: Fisher, Kara
Position: UNF

SB 879: Public Health – Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties

Kara Fisher

Oppose

Senate Finance Committee members:

I ask you to oppose SB 879/HB 1563. Although I support the intentions in which this bill was written, I believe it is harmful overall.

My cousin suffered a birth injury due to physician negligence and spent two years requiring daily medical care before she passed away. My family had the ability to pursue litigation directly with those responsible – the physician and hospital. I do not support a law that removes liability from providers and expects citizens to fund a trust to pay for the care of the injured.

Thank you,

Kara Fisher

District 19

KaraFisher_unf_SB0879
Uploaded by: Fisher, Kara
Position: UNF

SB 879: Public Health – Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties

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Thank you,

Kara Fisher

District 19

Kessler_SB879_OPP
Uploaded by: Garagiola, Rob
Position: UNF

ARTICLES

THE NEW YORK STATE MEDICAL INDEMNITY FUND: REWARDING TORTFEASORS WHO CAUSE BIRTH INJURIES BY RATIONING CARE TO THEIR VICTIMS

Michael W. Kessler &*
*Matthew Fahrenkopf***

TABLE OF CONTENTS

* Michael W. Kessler received his J.D from Albany Law School in 1972. He is Board Certified in Medical Negligence Law by the American Board of Professional Liability Attorneys and is a partner in the Albany, New York personal injury law firm of Rosenblum, Ronan, Kessler & Sarachan, LLP. He limits his practice to the representation of catastrophically injured plaintiffs.
**Matthew Fahrenkopf received his J.D. from Albany Law School in 2012. He currently works as a law clerk in the Albany, New York personal injury law firm of Rosenblum, Ronan, Kessler & Sarachan, LLP. In 2009, he received his B.A. in History/Political Science from the College of Saint Rose.

I. INTRODUCTION

For many years New York's medical community has asserted that increased medical malpractice insurance premiums have contributed to driving up the cost of medical care.[1] Whether or not this is true,[2] it is unquestioned that when a child suffers a severe neurologic injury at birth, the cost of caring for that child (who will eventually become an adult and may live for fifty years or more) can be enormous. It has been argued, that because of this enormous cost, malpractice verdicts and settlements arising from birth trauma, as compared to other causes of medical malpractice, contributes disproportionally to "high" malpractice costs paid by hospitals and obstetricians.[3]

It would seem that the most obvious way to decrease the cost of obstetric malpractice (and simultaneously improving patient outcome) would be to reduce the incidence of malpractice and the

[1] *See* GREATER N.Y. HOSP. ASS'N, OVERVIEW OF THE NEW YORK STATE MEDICAL INDEMNITY FUND FOR NEUROLOGICALLY IMPAIRED NEWBORNS (March 2011), *available at* www.gnyha.org/10711/File.aspx; Amos Grunebaum et al., *Effect of a Comprehensive Obstetric Patient Safety Program on Compensation Payments and Sentinel Events*, 204 AM. J. OBSTETRICS & GYNECOLOGY 97, 102–03 (2011).

[2] It was recently reported that medical malpractice insurance is, by a wide margin, the most profitable line of property and casualty insurance. "The medical professional liability insurance (MPLI) sector continues to stand out among insurance sectors for its ability to garner profits and generate returns far in excess of the composite averages of its property/casualty peers, according to a recently released A.M. Best Co. special report." *A.M. Best Special Report: Medical Professional Liability Outperforms, But is This Sustainable?*, BUSINESS WIRE (May 2, 2012, 10:41 AM), http://www.businesswire.com/news/home/20120502006132/en/A.M.-Special-Report-Medical-Professional-Liability-Outperforms.

[3] *See* GREATER N.Y. HOSP. ASS'N., *supra* note 1. It is beyond the scope of this article to address, much less resolve, any argument as to the extent of malpractice premium cost increases, the causes of any such increases, or whether such increases are justified.

severity of the injuries that occur, as some leading hospitals have done.[4] Another possibility, as some states have tried, would be to create a type of "no fault" system similar to workers compensation—all birth injured children would have certain but reduced compensation, in exchange for eliminating the need to establish that their injury was the result of malpractice, though they may still have to prove causation.[5]

Instead of adopting these approaches, effective April 1, 2011, New York took the unprecedented step of rationing care to children who had *proven* that they were injured at birth by the negligence of a hospital, physician, or other health care professional. The Legislature and the Governor did this by preventing these children from recovering their court determined damages for future care costs from the tortfeasor who caused their injuries, and forcing them into the state administered New York State Medical Indemnity Fund. The Fund is entitled to completely ignore the findings of the court as to the future care required by the child. Rather, the Fund will exclusively determine the nature and extent of the care that the malpractice victim will get and how much it will pay for such services.[6]

Ironically, instead of controlling health care costs by reducing the incidence of obstetric malpractice (and the legal and care costs associated with it), the Fund may actually wind up increasing both the number of birth related injuries and costs. There are two reasons for this: first, since the cost of their negligence is no longer born by the wrongdoer, there will be less incentive to practice sound medicine;[7] second, because the Fund applies to settlements as well as judgments, and the tortfeasor is unconcerned with the actual cost of care, there may be an incentive to settle less meritorious cases without regard to its total cost to the Fund.[8] Nor does the Fund reduce the number of what may be asserted to be "frivolous" or unmeritorious claims. To the contrary, the Fund *only* applies to cases in which the

[4] Grunebaum, *supra* note 1, at 97, 102–104.

[5] *See* VA. CODE ANN. § 38.2-5002 (West 2011); FLA. STAT. ANN. § 766.303 (West, 2011). The success or failure of these measures is beyond the scope of this article.

[6] *See* Thomas A. Moore & Matthew Gaier, *Budget Bill's 'Tort Reform' Targets Rights of Injured Children*, N.Y. L.J., April 5, 2011, at 3.

[7] *See* Lawrence Knipel, *Diverse Consequences Arising From State Medical Indemnity Fund*, N.Y. L.J., Nov. 15, 2011, at 7.

[8] *See id.*

injured child has already established liability and causation to the satisfaction of the court, or to cases that the defendant has deemed sufficiently meritorious by agreeing to settle it.[9]

Entirely aside from the potential adverse health consequences that are likely to result from the limitations to care that are inherent in the bureaucratic determination of indispensable care services to the most catastrophically injured malpractice victims, the manner in which the Fund is set up to operate creates a host of logistical and legal issues for the enrollee. Perhaps more important, there are a number of serious questions concerning whether the Fund, and the way it is designed and operates, is constitutional.

Despite a long tradition of tort law that allows a worthy plaintiff the right to recover sufficient damages from a negligent defendant to provide for the future care necessitated by the tortfeasor's wrongdoing, the Fund makes no such provision. Instead, the Fund treats the successful plaintiff in a manner that is essentially no different than if he were receiving Medicaid—though ironically in some ways a Medicaid recipient has greater legal rights than someone forced into the Fund.[10] Although it would seem only reasonable that someone who was harmed by the negligence of another should at least be entitled to a recovery that provides for care needs beyond the often inadequate minimal care provided by Medicaid, such is not the case under the Fund.[11] This article will initially focus on the consequences that will occur to the families of children enrolled in the Fund. It will then examine the federal and New York State Constitutional issues that are raised by (1) the creation of the Fund, (2) the manner in which the Fund operates, and (3) the Fund's impact on the rights of the children who are forced into it and thus deprived of the right to enforce their judgment against the tortfeasor who caused the need for future care.

Part II of this article provides a general background to the Fund and compares it to the manner in which damages in medical malpractice cases are traditionally determined in New York. Part III explains how the Fund will function under the "emergency regulations" promulgated by the Department of

[9] *See* Moore & Gaier, *supra* note 6.
[10] *Id.*
[11] *Id.*

Health as of March, 13, 2012,[12] and how these regulations may ultimately impact the quality of care provided to Fund enrollees. Part IV discusses the practical difficulties that the Fund will present to both enrollees and the state, and how it may impact the care received by these children—who of course will eventually become adults. Finally, Part V considers the various constitutional issues that are implicated by the Fund. These include possible violations of the separation of powers, the right to a jury trial, the appropriation of public monies for private purposes, and the denial of due process and equal protection.

II. BACKGROUND

A. The Medical Indemnity Fund

Effective April 1, 2011 the Legislature created the New York Medical Indemnity Fund, with the stated goal of controlling the costs of malpractice insurance for obstetricians and hospitals providing obstetric services.[13] It is critical to note that participation in the Fund is mandatory, and is applicable only after the plaintiff receives a judgment or settlement that includes the tortfeasor's liability for future medical care arising from medical malpractice that causes a birth related neurological injury.[14] Therefore, the Fund has nothing to do with reducing "frivolous" or "unmeritorious" claims, since it only applies to

[12] The Fund's "emergency regulations" were adopted on September 15, 2011, have been readopted as "emergency regulations" several times, and remain in force as of June 1, 2012, the date of the submission of this article. As a result, there have never been any public hearings on the Fund regulations, nor have any public hearings been noticed as of this time. Thus, there has been no opportunity for the public to submit comments on the regulations, even though it is more than one year after the Fund was enacted and more than seven months after applications for enrollment have been accepted. After this article was submitted for publication, the Fund readopted "emergency regulations" effective June 15, 2012. Although there are slight changes in the "new" emergency regulations, they do not change the discussion contained in this article as submitted. However, some of the changes further demonstrate a violation of the separation of powers and also further impair an enrollee's access to care. Moreover, the authority cited for enacting "emergency regulations" indefinitely is the initial budget bill which created the Fund. 2011 N.Y. Sess. Laws ch. 59, Part H, §§ 52, 111, 111(q) (McKinney). This is a further illustration of the unconstitutional enactment of changes in substantive law in a budget bill which is prohibited by Article VII, Section 6. *See infra* Part V.F.

[13] 2011 N.Y. Sess. Laws ch. 59, Part H, §§ 52, 111, 111(q) (McKinney).

[14] N.Y. PUB. HEALTH LAW § 2999(j)(6)(7) (McKinney Supp. 2012); Knipel, *supra* note 7; Moore & Gaier, *supra* note 6.

plaintiffs who have either successfully won their cases at trial, or persuaded the defendant to settle their claims because of the defendant's concern that the plaintiff will succeed at trial. The Fund transfers the financial obligation of the defendant and/or his insurer to pay for future care costs as determined by the court, to the state and its taxpayers. This has significant ramifications to each of these parties. The restrictions on recovery for future care costs only apply to a small subclass of medical malpractice victims: those who have suffered neurologic impairment that occurred during (1) labor, (2) delivery, or (3) any period of resuscitation after birth.[15]

The Fund therefore serves as a mandatory alternative to a money judgment for future medical care that was determined by the jury.[16] The Fund does not automatically take effect simply because an infant has suffered a birth related neurological injury and asserts that it is a result of medical malpractice. In order to be covered, a child who has suffered a neurologic impairment at birth must initiate a lawsuit against the defendants and then either (1) receive a judgment of damages based upon a jury verdict, just as in any other malpractice case or (2) reach a settlement agreement with the defendants.[17] In either instance, it must be recognized that a portion of the damages relate to the future care needs of the infant.[18] The Fund has no effect with regard to any pain and suffering damages or economic damages that are not attributable to future medical care.[19] However, once the birth injured child is accepted into the Fund, the defendant is completely relieved of the obligation to pay any portion of the settlement or judgment attributable to any aspect of future care costs, whether or not the Fund actually pays for or provides the services determined to be necessary by the court.[20] The Fund, therefore, does not provide payments to anyone except those who have already successfully won or settled a malpractice case.[21]

As noted, the Fund is mandatory for any malpractice victim who has suffered a birth-related neurological injury. The plaintiff cannot choose to simply recover his damages from the defendant

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15 PUB. HEALTH § 2999-h(1).
16 *Id.* § 2999-j(6)(b); Knipel, *supra* note 7.
17 PUB. HEALTH § 2999-j(6).
18 *Id.*
19 *Id.* Moore & Gaier, *supra* note 6.
20 PUB. HEALTH § 2999-j(6).
21 *Id.*

or opt out of the Fund. Thus, regardless of any adverse consequences to the plaintiff, he is stuck with all of the restrictions and limitations that the Fund imposes.[22] The statute requires that any judgment made in favor of any plaintiff for future care damages resulting from such injury must decree "the future medical expenses of the plaintiff shall be paid out of the fund."[23] After a judgment or settlement where a finding that future care will be required for a birth related neurological injury, either the plaintiff *must*, *or the defendant* may, make an application to place the infant plaintiff into the Fund.[24] Therefore, the *defendant* has the right to be relieved from paying that portion of the judgment relating to future care costs by placing the plaintiff into the Fund, thereby imposing future care costs on the state.

The Commissioner of Taxation and Finance serves as the custodian of the Fund and it is to be administered by the Superintendent of Financial Services or her designee.[25] It appears that the Fund is to be financed by a combination of general appropriations as well as a "quality contribution" collected by the state from general hospitals.[26] The "quality contribution" is based on a tax of 1.6 percent on impatient revenue of the general hospital derived from "inpatient obstetrical patient care services."[27] The legislative appropriation for the first year of the Fund came from the Health Care Reform Act Fund and amounted to $30 million.[28] The amount that is

[22] *Id.* § 2999-j(6)–(7); Knipel, *supra* note 7.

[23] PUB. HEALTH § 2999-j(6)(b). Even though this statement is made, the Fund regulations, as described below, place significant limitations on the types and the extent of care that will provided, how much they will pay for it, and even if such care will in fact be provided.

[24] *Id.* § 2999-j(7).

[25] *Id.* § 2999-i(1)–(2).

[26] *Id.* §§ 2807-d-1, 2999-i(5); THOMAS A. MOORE & KEVIN P. MCMULLEN, MEDICAL MALPRACTICE: DISCOVERY & TRIAL § 17:2.4[B][1] (7th ed. 2012). The term "contribution" is a euphemism since the funding source is neither a "contribution" nor related in any way to the improvement of the quality medical services. In fact it is a tax on obstetrical services, and this may have significant legal consequences. *See infra* Part V.C. Moreover, by eliminating the responsibility of the tortfeasor to pay for the damages caused by his or her negligence it is hard to see how this will in any way lead to an improved "quality" of services. Knipel, *supra* note 7.

[27] PUB. HEALTH § 2807-d-1; MOORE & MCMULLEN, *supra* note 26, § 17:2.4[B][1].

[28] PUB. HEALTH § 2807-d-1; Joel Stashenko, *Lawyers Await Specific Regulations on Infant Medical Malpractice Fund*, N.Y. L.J., April 20, 2011, at 1.

supposed to be appropriated by the Legislature will be increased each year based on the increase in the consumer price index published by the U.S. Department of Labor.[29]

The tax ("quality contribution") rate is fixed, and the number of births in New York is relatively constant. The number of children covered by the Fund, however, will inevitably increase each year for several decades as more children are enrolled, but before a significant number of enrollees die and exit the plan. Therefore, there can be no assurance as to how long the tax will raise enough money for the Fund to remain solvent and either continue to accept new enrollees or pay care promised to those already accepted into the Fund. Perhaps for this reason, the Legislature specifically provided that when 80 percent of the Fund's resources are already allocated to "beneficiaries," enrollment will be suspended and the Fund will no longer accept new applicants until the Fund's liabilities are below 80 percent of its resources.[30] During the period of suspension judgments and settlements would be satisfied as if the Fund did not exist.[31] The appropriation to the Fund must, in addition to paying for care to enrollees, bear the cost of administering the Fund, thereby further reducing the amount available for care, and increasing the risk of insolvency.[32]

Instead of the plaintiff having the resources to pay for the future care from her recovery determined by the court, the plaintiff would have to apply anew to the Fund Administrator to seek payment for future care services. Because such care could be denied by the Fund, the very care to which the infant plaintiff was already found entitled by a court, after a full hearing on the merits, may forever be in jeopardy.[33] Since, as noted above, it was recognized that the appropriation by the Legislature may not be sufficient to pay all the potential claims of birth injury malpractice victims, the Administrator would have every

[29] PUB. HEALTH §§ 2807-d-1(2), 2999-i(5), (7).

[30] *Id.* § 2999-i(6)(a). This has potential constitutional ramifications because it clearly envisions a scenario in which two identically injured children, with identical judgments for future care costs, could wind up with vastly different recoveries based solely upon the timing of whether the Fund was exhausted by the time of the year that their individual judgments were obtained. *See infra* Part V.B.

[31] PUB. HEALTH § 2999-i(6)(b).

[32] *Id.* § 2999-i(3).

[33] N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.6 (2012); *see id.* §§ 69.7–69.13 (explaining the prior approval requests process for future services).

motivation to deny the care to which the child was already found entitled.[34] In addition, the Fund legislation provides that the Fund Administrator will be appointed by the Superintendent of the Department of Financial Services.[35] Thus, any political appointee who assumes this position will be beholden to the state and its finances and not to the plaintiff or the judgment rendered by the court.

The ultimate impact to those children who "qualify" for payment by the Fund is to remove both the court and the child's caregivers as the final arbiter of health care decisions, even though there was already a previous jury verdict determining future care damages. Instead, the Fund would decide what type of care is appropriate for the infant victim, the quality of that care, and how much they will pay for it, without any regard whatsoever to the jury's finding. [36] As a consequence, at least with respect to future care, the child is in no significantly better position than if he had no claim for malpractice at all, and had to rely solely upon Medicaid.[37] Moreover, without control of the assets from a recovery for future care costs, the child's family will be unable to plan for or assure essential care for their child after they are no longer able to do so.[38]

B. Malpractice Judgments in New York: Article 50-A

It is important to understand the manner in which damages for medical malpractice plaintiffs are determined in New York. Since its revision in 2003, Civil Practice Law and Rules (CPLR) Article 50-A specifies how damages are to be computed and paid

[34] *See supra* notes 25–32 and accompanying text.

[35] PUB. HEALTH §§ 2999-i(2)(a).

[36] *Id.* § 2999-j(2), (6); Moore & Gaier, *supra* note 6.

[37] Moore & Gaier, *supra* note 6.

[38] Some have argued that because of the prevalence of Supplemental Needs Trusts, the Fund avoids the potential of a double payment for future care costs to the birth injured child. GREATER N.Y. HOSP. ASS'N., *supra* note 1. This argument is without basis because to the extent that a Supplemental Needs Trust pays for items that are not covered by Medicaid, there is obviously no "double" payment. *See* LEE S. KREINDLER ET AL., 16 NEW YORK PRACTICE SERIES—NEW YORK LAW OF TORTS § 21:44 (2011). For items that would otherwise be paid by Medicaid for the child's care costs, under a Supplemental Needs Trust these payments must be repaid to Medicaid at the time of the death of the child. N.Y. SOC. SERV. LAW § 366(2)(b)(2)(iii)(A) (McKinney 1971 & Supp. 2012); KREINDLER ET AL., *supra* note 38, at § 21.44. Accordingly, there would not be a situation where there would have been a "double" payment.

in all medical negligence cases, including birth injury cases.[39] As will be seen, the interplay between the Fund and Article 50-A will create an additional subclass of birth injury plaintiffs who are treated differently, not only from other tort victims, but also from other malpractice victims with the exact same injury.[40]

Article 50-A and CPLR section 4111 form the basis for assessing damages for future care expenses.[41] In summary, the statutes require that the jury make a finding of (1) the annual cost of care; (2) whether the condition is permanent (which in these cases it almost always is); and (3) a rate of inflation applicable to future care costs.[42] Future costs are established by expert testimony, usually by a life care planner, by physicians, or some combination of both.[43] Medical inflation is usually proven by an economist, and has averaged around 5.75 percent since 1950, depending on how it is measured.[44] Assuming a life expectancy of at least seventy years, a present value cost of care at $150,000 per year at current market rates going up even only 4 percent per year would greatly exceed a present value of $10 million per case.

After the jury makes the findings required by statute, the Judge then takes the annual cost of care, applies the jury determined inflation rate, and arrives at a total, which for purposes of entering a judgment, computing attorney's fees and interest, is discounted to present value using the appropriate investment discount rate.[45]

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[39] N.Y. C.P.L.R. § 5031 (McKinney 2007).

[40] C.P.L.R. § 4111 (McKinney Supp. 2012); C.P.L.R. § 5031; *see infra* Part V.B.

[41] C.P.L.R. §§ 4111, 5031.

[42] C.P.L.R. §§ 4111(d), 5031(d).

[43] Michael W. Kessler, *Critical Analysis of the Life Expectancy Research from an Attorney's Perspective*, *in* PEDIATRIC LIFE CARE PLANNING AND CASE MANAGEMENT 797–799 (Susan Riddick-Grisham ed., 2004); Michael W. Kessler, *Defeating the Reduced Life Expectancy Defense*, *in* 2 ASS'N TRIAL LAW AM. ANN. CONVENTION REFERENCE MATERIALS: TRAUMATIC BRAIN INJURIES 2283 (2004).

[44] Robert W. Johnson, *Presenting Damages for Earning Capacity and Future Medical Expense Damages: An Economists Perspective*, *in* 1 ASS'N TRIAL LAW AM. ANN. CONVENTION REFERENCE MATERIALS: TRAUMATIC BRAIN INJURIES 1277 (2005).

[45] C.P.L.R. § 5031(d), (f).

C. The Impact of the Fund on Article 50-A in Birth Injury Malpractice Cases

As discussed above, the substantive law of damages in *all* medical malpractice cases and how they are paid is governed by CPLR Article 50-A, and in particular section 5031 and its counterpart section 4111, detailing the findings to be made by the jury.[46] These provisions of law—which also direct the court how to compute and enter judgment in a malpractice case—were not repealed or amended by the Fund statute, and therefore remain in force.[47] Some of the provisions of section 5031 would appear to inherently conflict with the Fund legislation, and some of the Article 50-A provisions could—and section 4111 *would*—still be applied even if it was determined that the Fund statute takes precedence.[48] These conflicts would seem to be a consideration with respect to several of the constitutional arguments discussed below—separation of powers, the right to a jury trial, equal protection, and due process.

By its terms, the application of section 5031 is just as obligatory as is the Fund legislation. It commands, among other things that "the court *shall* proceed as follows" and "the court *shall* apply to the findings of past and future damages."[49] It would appear that nothing in the Fund legislation eliminates the defendant's obligations pursuant to CPLR section 5031(h). That section mandates that "judgment shall be entered on the lump sum payments and the present value of the streams of payments required to be made by the defendants under this section."[50]

Section 5031(b) provides that "all damages for future loss of services . . . of five hundred thousand dollars or less shall be paid

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[46] *Id.* §§ 4111(d), 5031. Section § 4111 enumerates the specific findings required by the jury to provide the basis for the court to enter Judgment under Article 50-A. *Id.* § 4111(d).

[47] 2011 N.Y. Sess. Laws ch. 59 (McKinney).

[48] Since by its own terms the Fund legislation only applies after the jury has fulfilled its fact finding role, the requirements of section 4111 will necessarily still apply. N.Y. PUB. HEALTH LAW § 2999-j (McKinney Supp. 2012).

[49] C.P.L.R. § 5031, (a) (emphasis added).

[50] *Id.* § 5031(h). This is required even under the Fund, because without this component of the judgment, there would be no means of computing attorney's fees or interest. N.Y. PUB. HEALTH LAW § 2999-j. Similarly, because the Fund will cease to take enrollees after it is 80 percent exhausted, it can never be known at trial whether the plaintiff will be enrolled. As a result there can be no alternative but to compute the judgment in accordance with Article 50-A and C.P.L.R. section 4111. PUB. HEALTH § 2999-i(6).

in a lump sum."[51] This is inherently contradictory to the Fund legislation, which provides that portion of the judgment related to future care is carved out of the judgment and such services are to be paid by the Fund as they are approved and incurred.[52] Although it could be argued that the more specific birth injury case legislation trumps section 5031(b), it is equally likely that by leaving this section intact and by failing to except birth injury cases from its application, the Legislature intended to require that for cases under $500,000 the Fund would not apply, and that the defendant would have to pay that sum in cash. Similarly if the Fund statutory scheme does or does not apply to these cases, a conundrum is created: either the court's independence to fashion a judgment under section 5031 is impaired, or, if section 5031 takes precedence, a discriminatory "subclass" and "taking" has been created.[53] In that instance, birth injury victims with future damages less than $500,000 are treated differently not only from other malpractice victims (because they are enrolled in the Fund), but from birth injury victims with damages greater than $500,000 (because they are entitled to a lump sum payment). These issues raise additional significant equal protection arguments.

A similar and perhaps even more vexing issue is created by CPLR section 5031(g), which mandates that "[t]he defendants and their insurance carriers shall be required to offer and to guarantee the purchase and payment of an annuity contract to make annual payments in equal monthly installments of the remaining streams of payments specified in such subdivisions (c) and (d). . . ."[54]

In the first place, with respect to the taking of a property right determined by the court and the denial of a jury trial, nothing could better demonstrate the differences between this annuity requirement and care being provided by the Fund instead. Under section 5031(g), the defendant must offer an annuity to guarantee payments of the sums for future care as determined by the jury, whereas under the Fund, there is no lifetime reserve. To the contrary, it is purely "pay as you go," as long as the Fund has

[51] C.P.L.R. § 5031(b).

[52] PUB. HEALTH § 2999-j.

[53] The Fund creates a cornucopia of different subclasses of tort victims that it discriminates against, as this article will point out below.

[54] C.P.L.R. 5031(g).

assets.[55] There is nothing to back the "promise" of future care or assure that it will be paid, even if it were to duplicate the care that the jury found to be required. Similarly, there would appear to be no reason why the annuity requirement cannot be applied even if the Fund statute was determined to be applicable. This section still requires that "defendants and their insurance carriers," offer an annuity to the plaintiff to guarantee payments.[56] One can only presume that the Legislature's failure to repeal or amend section 5031 as applied to birth injury cases meant, at a minimum, those portions of that section that can be applied consistent with the Fund must still be applied. Section 5031(f) would appear to fall into this category. To the extent that it is asserted the Fund legislation effectively superseded section 5031(f), it would appear to demonstrate the Fund's infringement of the separation of powers, a taking without compensation, a denial of equal protection, and interference with the right to a jury trial.[57]

By leaving Article 50-A intact when the Fund was created, it is certainly reasonable to argue that the Legislature fully intended at least portions of it would continue to be applied, even in birth injury malpractice cases, and there is little basis to conclude otherwise.

III. HOW THE FUND OPERATES: THE REGULATIONS

Without the opportunity for any significant public comment, effective September 15, 2011, emergency regulations to effectuate the New York State Medical Indemnity Fund were adopted by the New York State Department of Health.[58] These regulations were adopted pursuant to Public Health Law Section 2999-j(15).[59] They have been readopted, apparently as "emergency regulations"—and therefore without public hearings—again in December 2011 and March 2012. This analysis of how the Fund is designed to actually operate will follow the sequence of the Regulations themselves.

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[55] Stashenko, *supra* note 28.

[56] C.P.L.R. 5031(g).

[57] *Id.* C.P.L.R. 5031(f); *see infra* Part V.

[58] 33 N.Y. Reg. 25–26 (Sept. 28, 2011).

[59] N.Y. PUB. HEALTH LAW § 2999-j(15) (McKinney Supp. 2012); N.Y. COMP. CODES R. REGS. tit. 10, § 69-10 (2012); *id.*

A. Definitions

It is important to have an understanding of certain definitions in the regulations have a grasp of the various problems and issues that the Fund is going to have in trying to provide care to children who have suffered neurologic impairment from an injury at birth.

Assistive Technology

"Assistive technology (AT) means an item, piece of equipment or product system, whether purchased ready to use or needing modification or customization, ordered by a physician, that is used to maintain, increase or improve the functional capacities of the user."[60] Notably it must be "ordered by a physician."[61] This would seem to preclude assistive technology equipment recommended by other providers such as physician's assistants, nurse practitioners, physical, occupational, or speech therapists.[62] More importantly, the assistive technology that is approved may be entirely inconsistent with the "assistive technology" found by the jury or court to be necessary.

Birth-related injury

> Birth-related neurological injury means an injury to the brain or spinal cord of a live infant caused by the deprivation of oxygen or mechanical injury that occurred in the course of labor, delivery or resuscitation or by other medical services provided or not provided during delivery admission that rendered the infant with a permanent and substantial motor impairment or with a developmental disability . . . .[63]

This definition would not appear to include birth trauma that relates either to disfigurement or nerve damage, facial palsy, or other motor damage that does not result from an injury "to the brain or spinal cord."[64] The definition would also seem to be broad enough to include even neurologic injuries that have nothing to do with the birthing process or resuscitation after delivery, because it covers anything caused by a medical service "provided or not provided during the delivery admission." What if

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[60] N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.1(b).
[61] *Id.*
[62] *Id.*
[63] *Id.* § 69-10.1(c).
[64] *Id.* Knipel, *supra* note 7.

a child does not leave the hospital from the delivery admission but suffers a hypoxic brain injury as a result of an unrelated anesthesia error surgery to correct a congenital defect?[65] There may well also be an attempt by some enterprising attorneys to bring autism under the auspices of the Fund.[66]

Durable Medical Equipment

"Durable medical equipment" must also be "ordered by a physician," in contrast to other providers. It must meet the following criteria: (1) "withstand repeated use for a protracted period of time," (2) be primarily used for medical purposes, (3) cannot be useful without an injury, (4) is "not usually fitted, designed, or fashioned for a particular individual's use;" and, (5) if equipment is "intended for use only by one patient, it may be either custom-made or customized."[67] The definition seems to be self-contradictory, since it would appear that criteria (4) and (5) conflict with each other.

Environmental Modification

> Environmental modification (Emod) means an interior or exterior physical adaptation to the residence in which an enrollee lives that is necessary to ensure the health, welfare, and safety of the enrollee and enables him or her to function with greater independence in the community and/or helps avoid institutionalization and has been ordered by a physician. Emods include but are not limited to: ramps, widened doorways and handrails, roll-in showers, vertical lifts, and cabinet and shelving adaptations.[68]

Environmental modification requires an order by a physician, and not by any other type of provider.[69] This may also conflict with the jury's findings.

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[65] N.Y. PUB. HEALTH LAW § 2999-h(1) (McKinney Supp. 2012); N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.1(b). The author was recently consulted in a case where there was a failure to diagnose and treat a condition unrelated to delivery or resuscitation but which occurred before the child was discharged home after birth. Is this covered under the Fund? If so the number of potential Fund enrollees could greatly exceed the number of children the Fund can sustain.

[66] Knipel, *supra* note 7.

[67] N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.1(j).

[68] *Id.* § 69-10.1(m).

[69] It is unclear how a physician is qualified to determine the nature of environmental modification that is required.

Fund Administrator

"Fund Administrator means the Superintendent of Financial Services or any person or entity designated by the Superintendent for purposes of administering the Fund, if any."[70] Since the statute specifically authorizes the Superintendent to contract with a private entity to administer the Fund (and such contractor is paid out of the Fund) this could mean that instead of a jury, the court, the victim's family, or even an agency of government making health care decisions for these children, a private company will be deciding what health care services will be approved or denied.[71]

Habilitation Services

"Habilitation means assisting a child to achieve developmental skills involving mobility, communication, and the activities of daily living when impairments have caused the delay or have blocked initial acquisition of the skills."[72] The plaintiff may not, and at some point inevitably will not be a "child." It is unclear whether such services will be provided to an adult, though presumably they will.

Physician and Physician Assistant

"Physician" and "Physician Assistant" refers only to persons licensed to practice as such in New York State, another state, or the District of Columbia.[73] This leaves out a physician from another country, and perhaps even U.S. territories.

Qualified Plaintiff

> Qualified plaintiff means every plaintiff or claimant who (i) has been found by a jury or court to have sustained a birth-related neurological injury as the result of medical malpractice, or (ii) has sustained a birth-related neurological injury as the result of alleged medical malpractice and has settled his or her lawsuit or claim therefor.[74]

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[70] N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.1(o).
[71] N.Y. PUB. HEALTH LAW § 2999-i(2)–(3) (McKinney Supp. 2012).
[72] N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.1(p).
[73] *Id.* § 69-10.1(v)–(w).
[74] *Id.* § 69-10.1(y).

Qualifying Health Care Costs

The definition of "qualifying health care costs" is very broad. It does include "custodial" care and "nursing" care, but it is unclear as to whether this definition includes services such as home health aides or licensed practical nursing services.[75] Although respite care is not specified in the definition, it is referred to elsewhere in the regulations and is limited to no more than 45 days a year (less than one day per week) without prior approval.[76] Transportation costs are limited to "health care related appointments."[77] Other unenumerated health care costs are covered if a physician, physician assistant, or nurse practitioner has justified them in writing.[78] Qualifying health care costs do not include anything "provided or available" by a school IEP or Early Intervention Program, or "through any commercial insurance under which the enrollee is covered."[79]

The Fund will, therefore, not make payments for care items that may be paid by school districts or private insurance companies.[80] Any amount of money paid by the Fund is reduced by the collateral source rule, and this would include care provided by school districts or private insurance.[81] Several groups that provide services to disabled children have raised concerns that the interplay between different government programs and health care providers, as well as payment at Medicaid rates, will ultimately inhibit access to care by either complicating the payment system, limiting providers who will accept these low rates, or by giving private insurance an incentive to drop coverage for their services.[82]

Two other critical issues are presented. First, with regard to services provided by a school district, a plaintiff could be bound by a school district's finding of what services it will provide. This is because "qualifying health care costs" excludes anything

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[75] *Id.* § 69-10.1(z).
[76] *Id.* § 69-10.6(a).
[77] *Id.* § 69-10.1(z).
[78] *Id.*
[79] *Id.*
[80] *Id. See* N.Y. PUB. HEALTH LAW § 2999-j(3) (McKinney Supp. 2012) (stating that the Fund will not pay for qualifying health care costs that are paid for by "collateral source[s]").
[81] PUB. HEALTH § 2999-j(3); N.Y. C.P.L.R. § 4545 (McKinney Supp. 2012).
[82] Michael Bergen, Matthew Hyland & Izel Obermeyer, *Important Movement of Our Association*, N.Y. PHYSICAL THERAPY ASS'N (July 11, 2011, 11:03 AM), http://nypta.blogspot.com/2011/07/important-movement-of-our-association.html.

provided by a school district.[83] For example, the school district may have found—over the plaintiff's objection—that a child does not require a one-to-one aide, even though the family and/or the court in the malpractice action may have determined otherwise. Therefore, even though these services were found to be necessary by a jury, neither the defendant nor the Fund may be required to provide such care; under these circumstances, the plaintiff would have to do without it. The Fund leaves what has the potential to be a huge gap with regard to certain types of developmental care by merely assuming that school districts will gladly provide and pay for such services. Second, the interplay between the Fund, a school district or other governmental entity such as Medicaid, and a commercial payer will likely result in disputes between the three with respect to what entity has to pay for what service. This would leave the plaintiff caught in the middle. In the meantime, she will be left waiting for care to be provided—if indeed it is ever provided at all.

B. Application and Enrollment Process

Section 69-10.2 provides for the application and the process to become enrolled in the Fund.

> An application for enrollment . . . may be submitted by [either]: (1) a qualified plaintiff; (2) a person authorized to act on . . . [the] behalf [of a qualified plaintiff]; or (3) [*by*] *a defendant* in a medical malpractice . . . action that results in a court-approved settlement or judgment issued on or after April 1, 2011, [that includes a] finding that the plaintiff sustained a 'birth related neurological injury.'[84]

Section 69-10.2(b) requires that an application to the Fund be on the form provided, as set forth on the Fund's website.[85] The Application must include a medical release form to the Fund. *Thus a Fund recipient must surrender a lifetime of medical privacy merely to try to get the services to which he was found entitled by a court.*[86] The application also requires "a certified

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[83] N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.1(z).

[84] *Id.* § 69-10.2(a) (emphasis added).

[85] *Id.* § 69-10.2(b).

[86] *Id.* § 69-10.2(b)(1). Another serious question that is raised by this requirement to provide a lifetime waiver of medical privacy is whether it violates HIPPA. Health Insurance Portability and Accountability Act of 1996, Pub. L. 104–191, 110 Stat. 1936 (1996); *see* discussion *infra* notes 393, 597.

copy of the court-approved settlement or judgment."[87] This provision assumes that a settlement would require judicial approval. There may be circumstances in which a settlement may not have to be approved, such as where the injured child is legally competent and has reached majority.

This provision requires that the plaintiff provide extensive documentation of the "specific nature and degree" of the applicant's injury, including its "impact on . . . activities of daily living."[88] The Fund will accept a sufficiently detailed life care plan prepared for litigation, a summary provided by the child's physician, or other materials provided to the court to support the settlement or to enroll in other health related programs, as long as they "accurately reflect[] the applicant's condition . . . ."[89]

Subparagraph (4) also requires that the applicant provide the names, addresses and phone numbers of "all providers," of services at the time of the application.[90] There may be dozens of providers and it would be a very burdensome process to gather and continue to update this material.

Subparagraph (5) requires documentation of "all other present sources of health care coverage . . . . "[91] Private health coverage must be used before the Fund will pay.[92] Private insurance, however, may indeed provide better coverage than the Fund. More importantly, under a private health insurance policy, contractual legal rights to enforce policy benefits may be more favorable than the remedies and burden of proof necessary to reverse a Fund decision. This creates another discriminatory subclass of birth injury victims—those who have private insurance versus those who do not.

Paragraph (c) permits the use of documentation submitted for enrollment in "another health related program" to be utilized in the Fund application, provided that it is still current.[93] It is questionable whether any such information will either suffice under the requirements of the Fund application, or be sufficiently

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87 N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.2(b)(2).

88 *Id.* § 69-10.2(b)(3).

89 *Id.*

90 *Id.* § 69-10.2(b)(4).

91 *Id.* § 69-10.2(b)(5).

92 N.Y. PUB. HEALTH LAW § 2999-j(3) (McKinney Supp. 2012); N.Y. C.P.L.R. § 4545(a) (McKinney Supp. 2012); N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.1(z).

93 N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.2(c).

current for the Fund's application process.

Paragraph (d) requires the Fund Administrator to review the "court approved settlement or judgment" to ensure it states the Plaintiff has sustained an injury making her eligible for Fund benefits.[94] It further provides—in a stunning invasion of the separation of powers—that "[i]f the [required] language . . . is missing or is not clear, the Fund Administrator shall refer the settlement or judgment back to the court that approved the settlement or issued the judgment to add clarifying language, if appropriate."[95] *The Fund Administrator, therefore, can order the court what to put in a judgment.*

Paragraph (e) requires the Fund Administrator to review all of the submitted documentation within fifteen business days of submission and notify the applicant of any missing information necessary to complete the application.[96] If all the paperwork is found to be in order, the plaintiff shall be enrolled in the Fund within another fifteen business days.[97] Thus the enrollment process, assuming that everything was timely submitted and is found to be acceptable, will take thirty business days, or approximately forty days. In the meantime, the plaintiff receives no benefits, and may be deprived of care.

Paragraph (g) provides for the Fund Administrator to assign a Fund "case manager" to the enrollee within seven business days of receipt of all the necessary paperwork.[98]

C. Claims Assistance Manager

Section 69-10.3 provides for a claims assistance manager whose duties include (a) "answering questions regarding the information and documentation [necessary to complete] the application process;" (b) investigating any claimed delays in either the application process, claims, claims denials, prior approvals, or reviews; and (c) "assisting in resolving any issues [between] enrollees and case managers or the assignment of case managers."[99] It does not explain what, if any, authority that the claims assistance manager has to resolve these issues, or how

[94] *Id.* § 69-10.2(d).
[95] *Id.*
[96] *Id.* § 69-10.2(e).
[97] *Id.* § 69-10.2(f).
[98] *Id.* § 69-10.2(g).
[99] *Id.* § 69-10.3.

this person is assigned to assist an enrollee.[100]

D. Case Management

Section 69-10.4 is a critical section of the regulations referring to the plaintiff's case management. As a practical matter, this section transfers health care decisions from the plaintiff and his or her family, to the Fund. A "case manager" designated by the Fund is assigned to each plaintiff.[101] The case manager will not be beholden to the client, but rather to the Fund, in order to get paid and receive assignments.[102]

Paragraph (a) defines case management functions and makes it clear that the Fund appointed case manager will be expected to insert themselves into every intimate detail of the plaintiff's life *forever*.[103] It should be kept in mind that the state appointed case manager will play a major role in all care decisions, despite the fact that the enrollee has already been determined to be a victim of malpractice and entitled to various health care services by the jury or a court.[104] The enrollee is being *forced* to completely surrender to the Fund case manager, any medical or personal privacy, her fundamental family intimacy, and more importantly, the right to make primary decisions concerning critical medical issues.

The case manager is charged with the following:

> (1) [making] an initial assessment and periodic reassessments of the enrollee's medical needs; (2) evaluating the enrollee's strengths, informal support system and environmental factors relevant to . . . care;[105] (3) reviewing information [from] the enrollee, [his or her] informal support system, and current

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[100] *Id.*

[101] *Id.* § 69-10.2(g).

[102] *Id.* § 69-10.1(d), -10.5(a).

[103] *Id.* § 69-10.4(a).

[104] N.Y. PUB. HEALTH LAW § 2999-j(6)–(7) (McKinney Supp. 2012).

[105] This is another way of saying that the case manager can consider but not pay for the care provided by the family—presumably to avoid paying for outside care. The family is not obligated to provide free "custodial" care beyond normal parenting duties, and if they do, they are entitled to be compensated for it. *See* Schultz v. Harrison Radiator Div. General Motors Corp., 683 N.E.2d 307, 311 (1997); Auer v. New York, 733 N.Y.S.2d 784, 787 (App. Div. 3d Dep't 2001); King v. New York, 393 N.Y.S.2d 93, 94 (App. Div. 3d Dep't 1977); 1B ASS'N OF JUSTICES OF THE SUPREME COURT OF THE STATE OF N.Y., COMM. ON PATTERN JURY INSTRUCTIONS, N.Y. PATTERN JURY INSTRUCTIONS: CIVIL § 2:280 (West 2012). The case manager should not be entitled to consider the "informal support system" to limit what the Fund will pay for.

> providers (including [the school system]) regarding . . . services . . . [currently] provided . . . and any . . . gaps in the services . . . ;[106] (4) establishing a comprehensive, written case management plan to provide for coordinated delivery of all qualified health care services [necessary];[107] (5) securing services determined in the case management plan . . . through referral to agencies or persons qualified to provide those services;[108] (6) assisting the enrollee with any forms necessary [to receive services or getting those services paid for]; (7) providing crisis intervention [for] . . . emergency service needs; (8) developing alternative provider sources . . . in the event of service disruption;[109] and (9) monitoring and providing follow up services . . . (A) [to] verif[y] that [the] quality of services provided [are received at the amount and frequency specified in the plan as well as] (B) documenting . . . the [enrollee's] medical condition and progress made; and (10) . . . coordinat[ing] . . . [with any] other case manager [in another health related program].[110]

Paragraph (b) describes the qualifications for a case manager.[111] It does not require any expertise other than training or experience in "the performance of assessments and the development of case management plans."[112] Significantly, it requires absolutely no expertise or experience in dealing with the assessment or the care needs of neurologically impaired children

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106 This further highlights the invasive nature of the duties and powers by the Fund and its case managers. Even if the case manager is well-meaning and properly motivated, she is not responsible solely to the plaintiff.

107 This does not account for services that may not be covered under "qualified health care services." Moreover there is no requirement as to how frequently the plan must be reviewed, nor is it specified what services would be included as "qualified health care services," and these could change over time. *See* N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.4. For example, certain services provided by a school district might become "qualified health care services" after the enrollee reaches majority. *See id.* § 69-10.1(z).

108 This is a critical provision since it reinforces the fact that it is the Fund appointed manager, and not the family, the jury, or court, who will initially determine what services will be provided. Then, having been free to ignore the jury or the family, the Fund case manager will play a major role in determining who provides such services and how much they will be paid. This may work out fine, but then again, there is significant potential that it will not.

109 Although this is a worthy goal, it is significantly impaired by the reimbursement of services at Medicaid rates. Moore & Gaier, *supra* note 6. The case manager has no power to get emergency services at higher rates if that would be necessary in order to avoid disruption of even "critical" services. *See* PUB. HEALTH § 2999-j(4); N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.4, .20.

110 N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.4(a).

111 *Id.* § 69-10.4(b).

112 *Id.*

or adults.[113]

Paragraph (c) provides that an enrollee may request a change in case managers by written request.[114] There is no assurance that there will be a reassignment.[115] Reassignments, if they do occur, will only be made "as promptly as possible based on case manager availability and existing caseloads," or in other words, solely at the convenience of the Fund.[116]

There is no description or limitation as to the number of enrollees who can be assigned to a case manager, or how available the case manager must be to the plaintiff.[117]

E. Claims Submission Process

Section 69-10.5 describes the claims submission process.[118] Paragraph (a) is critical, since it requires that "[a]ll providers providing services to an enrollee must accept assignment of payment from the Fund."[119] This not only means that all providers other than physicians will be reimbursed at Medicaid rates, but it also compels such providers to agree to the payment submission and approval process. This alone, even without the Medicaid reimbursement rate limitations, will undoubtedly limit access to care.[120] Moreover, there is no way for residents of states other than New York, or other countries, to compel their providers to accept Fund assignment, or the Medicaid level rates that will be paid by the Fund. As discussed below, this may impair the constitutional right of freedom to travel.[121]

Paragraph (d) provides that claims for services submitted within ninety days will be paid within forty-five days of receipt, thus compelling a provider to wait a significant time to be reimbursed.[122] It provides no remedy to the provider if the bill is not accepted or not paid within forty-five days.[123] The paragraph also provides that claims submitted after ninety days may not be paid at all, unless the provider can show good cause for the

113 *Id.*
114 *Id.* § 69-10.4(c).
115 *Id.*
116 *Id.*
117 *Id.* § 69-10.4.
118 *Id.* § 69-10.5.
119 *Id.* § 69-10.5(a).
120 *See* Moore & Gaier, *supra* note 6; Bergen, *supra* note 82.
121 *See infra* Part V.B, V.D.2.
122 *Id.* § 69-10.5(d).
123 *Id.*

delayed billing. The finding of good cause would presumably be made by the Fund Administrator.[124]

F. Prior Approval Request Process

Section 69-10.6 describes the items that require prior approval by the Fund before they will be provided. Essentially anything that is expensive will require "prior" Fund approval. This section prescribes the procedures that must be followed in order to obtain such approval.[125] The concept of "prior approval" itself is contradictory to the way the statute was written and promoted. The prior approval process was supposed to be the exception rather than the rule.[126]

Under paragraph (a) some of the more common and significant items that require prior approval are (1) assistive technology, such as augmentative communication devices; (2) handicapped modifications for vehicles and the home; (3) private duty nursing;[127] (4) "custom made durable medical equipment;" (5) hearing aids; (6) enteral formula (i.e. tube feeding nutrition);[128] (7) planned specialist or hospital visits requiring "travel involving overnight accommodations;"[129] (8) experimental treatment; and (9) respite care for more than 45 days in a calendar year.[130]

Paragraph (b) provides that other than for emergency requests, prior approval requests should be determined within thirty days from the time necessary documentation to support it has been received by the Fund.[131]

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[124] *Id.*

[125] *Id.* § 69-10.6.

[126] N.Y. PUB. HEALTH LAW § 2999-j(2) (McKinney Supp. 2012).

[127] Depending on what is meant by "private duty nursing," this could be an enormous concern. Nursing type care at various levels is a significant, and is usually the single largest component in each of these cases. ROBERT J. WALLING & DEREK W. FREIHAUT, COMMONWEALTH OF VIRGINIA STATE CORP. COMMISSION, 2011 ANALYSIS OF THE VIRGINIA BIRTH-RELATED NEUROLOGICAL INJURY COMPENSATION PROGRAM 21–23 (2011).

[128] However the regulations state that no prior approval is required where the enrollee has documentation that he or she is fed by feeding tube, gastrostomy, or J-tube. N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.11(a). It appears that if a new mode of feeding is initiated the Fund must give "prior approval."

[129] This definition is inconsistent with the definition of "prior approval," which does not refer to overnight accommodation. *Id.* § 69-10.1(x).

[130] *Id.* § 69-10.6(a).

[131] *Id.* § 69-10.6(b).

Paragraph (c) relates to documentation for all expenses other than private duty nursing, which is treated separately and discussed below.[132] In order to obtain prior approval, the request must be accompanied by a written justification from the enrollee's treating physician stating why the service, equipment, or treatment is necessary, and "what other alternatives have been tried or explored."[133] This again gives the Fund the right to second guess both the physician's determination concerning the necessary health care for the plaintiff, as well as the right to ignore the findings that have already been determined in court.

The prior approval process creates an inherent conflict of interest for any professional charged with making these determinations on behalf of the Fund. This is inevitable, because the financial well-being of the Fund will necessarily be balanced against the best possible care that the plaintiff could receive. Instead of the plaintiff using the recovery to make her own health care determinations in her own best interest, such care will now be determined by the Fund Administrator or its contractor—essentially its own HMO. This is important because, unlike contractual and legal limitations that constrain restrictions on care by an HMO or insurer, the Fund can change the rules during the process, without limitation, and decide what services are "necessary" and which will be paid. Since the Fund Administrator has an incentive to preserve its funds, there is every motivation to deny payments for services, even those that a court has already determined are justified and appropriate.

A course of care or treatment that the child's family believes is in her best interest may be subject to prior approval by the Fund and denied. "Prior Approval" refers to the requirement that the Fund Administrator must approve many aspects of care and equipment in advance.[134] This substitutes the Fund's determination for that of the child's family and the court. It may result in delay and possible additional expense to secure care. Although the statute provides that the payment of qualifying health care costs "shall not be subject to prior authorization, except as described by the commissioner in regulation," the regulations essentially reverse this presumption, and require virtually any significant category of expenditure to have prior

[132] *Id.* § 69-10.6(c).
[133] *Id.*
[134] *Id.* § 69-10.1(x).

approval.[135] Despite the statute's purported intent to provide seamless care with a minimum of bureaucratic involvement it is apparent that a substantial amount of the most essential and costly services needed by an enrollee's care will require the Fund's prior blessing.[136]

Similarly, the plaintiff may well simultaneously have a private case manager, a case manager from a private insurance company, a Medicaid case manager, as well as one appointed by the Fund. This will inevitably lead to conflicts between them concerning what benefits will be received, who will provide them, and how much the providers will be paid. Although independent "case management" is inevitably a component of future care costs, there does not appear to be a provision under either the statute or the regulations to provide for such services, except for the state designated and paid "case manager" whose loyalties are divided, and who certainly is not chosen by the enrollee. This is no different than if the Fund decided which doctors or therapists could treat the plaintiff. In fact, to a certain extent they have done so, both by inserting their own case manager and by limiting the reimbursement to most providers at Medicaid rates.

G. Prior Approval Requests for Environmental Modifications

Section 69-10.7 specifies the requirements to obtain prior approval for environmental modifications.[137] This section, and a similar provision for vehicle modifications, clearly illustrates the differences between what the plaintiff would be entitled to under a jury's finding, and what the Fund may or may not allow.[138]

Paragraph (a) requires that home modifications can only be made to the "enrollee's primary residence."[139] This by itself creates numerous potential problems. Many of these plaintiffs do not own residences, and because they are limited to future care costs from the Fund, as compared to collecting damages from a

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[135] N.Y. PUB. HEALTH LAW § 2999-j(2) (McKinney Supp. 2012).

[136] *Compare id.* ("The provision of qualifying health care costs to qualified plaintiffs shall not be subject to prior authorization, except as described by the commissioner in regulation . . . ."), *with* N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.6–.13 (describing the various medical requests that need to be preapproved in order to receive coverage, including expensive needs such as private duty nursing and nonemergency ambulance transportation).

[137] N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.7.

[138] *Id.* § 69-10.7–.8.

[139] *Id.* § 69-10.7(a).

tortfeasor, they will not likely have sufficient funds to purchase a residence. Paragraph (a) does provide, however, that if the "family does not own [a] residence, [that] written permission of the property owner must be [obtained]."[140] It is unclear how readily agreeable a landlord would be to making handicapped accessible modifications to a rental property.

Paragraph (b) requires the enrollee to provide written documentation of the assessed value of the residence and proof of adequate homeowners or rental insurance.[141] Paragraph (c) requires that any modification "must meet applicable State and local building codes."[142]

Paragraph (d) provides that the Fund administrator will not approve any home improvement "that is not medically necessary to ensure the health, welfare and safety of the enrollee by enabling him or her to function with greater independence in the community and/or by helping him or her to avoid institutionalization."[143] Apparently no consideration is given to the family's needs if they are caring for an enrollee at home, or whether such care would be made easier, less burdensome for them, or provide a better quality of life for the injured Fund enrollee.

Paragraph (e) sets forth the documentation necessary to support an application for home modification "prior approval."[144] It requires a written statement from the treating physician "on the physician's letterhead" stating why the modification is medically necessary.[145]

Subparagraph (2) is extremely burdensome to the enrollee. It requires "a comprehensive evaluation of the proposed project by a rehabilitative evaluation agency or an independent building contractor who has significant experience working with ADA building standards."[146] The "comprehensive evaluation" must include "pictures of the specific location" as well as specifying the need for the modification, the reason why the proposed modification was selected, whether it is the most cost effective

140 *Id.*
141 *Id.* § 69-10.7(b).
142 *Id.* § 69-10.7(c).
143 *Id.* § 69-10.7(d).
144 *Id.* § 69-10.7(e).
145 *Id.* § 69-10.7(e)(1). Again, it is unclear how a physician is qualified to make these determinations.
146 *Id.* § 69-10.7(e)(2).

means of meeting the plaintiff's needs, and any safety concerns associated with the modification and how they will be met.[147] There are no standards by which the Fund will evaluate the project.[148]

Prior approval requests must also contain "a minimum of three acceptable bids from qualified contractors" who "have no outstanding judgments against [them] and/or . . . [the] business on file with the New York State Department of Law or the Better Business Bureau."[149] The requirement to obtain three bids in many geographic areas is not only time consuming to families who are attempting to provide full time care to a severely disabled child, but may be expensive as well.

Paragraph (g) provides that where less than three bids are submitted, a written explanation must be provided detailing (1) why additional bids were not submitted and (2) how it was determined that the considered bids are reasonably priced.[150]

Paragraph (f) requires the bid to describe the scope of the work and its specifications, proof of adequate insurance, and "a statement signed by the contractor . . . that the work will be done in a workmanlike manner . . . and will comply with all applicable building and zoning laws."[151]

Paragraph (h) describes how the Fund will evaluate the bids.[152] It goes into an involved description that "[i]f the two lowest comparable bids are within 10 percent of each other, the enrollee . . . may choose the contractor."[153] However, "[i]f there is more than a 10 percent difference between the two lowest comparable bids," the Fund will choose the lowest bid, unless "the higher bid reflects higher quality, longer durability or a higher degree of safety."[154] In that case—and this is quite revealing—"the Fund shall choose the bid that represents the best value for the *Fund* and the enrollee."[155] Thus, the Fund will not solely consider the enrollee's interests. After a winning bidder is chosen, the Fund will pay one-third of the total bid

147 *Id.*

148 *See id.* § 69-10.7 (disclosing the procedure but setting no standards as to review).

149 *Id.* § 69-10.7(e)(3).

150 *Id.* § 69-10.7(g).

151 *Id.* § 69-10.7(f).

152 *Id.* § 69-10.7(h).

153 *Id.*

154 *Id.*

155 *Id.* (emphasis added).

amount to the contractor at that time.[156]

Subparagraph (i) requires that any change in specifications that increases the price of the modification requires Fund approval.[157] Subparagraph (j) provides that no further payment (i.e., the remaining two-thirds of the cost) will be paid until the Fund receives an undefined "evaluation," confirming that the project meets the plaintiff's "functional needs" and "is in compliance with the initial evaluation."[158] It is possible, therefore, that although an approved modification could be done properly, it may not meet the enrollee's functional needs once it is completed, in which case payment may not be forthcoming. In that case, there may be a mechanic's lien on the premises that would be the obligation of the enrollee to satisfy.[159]

Subparagraph (k) does provide that the Fund will pay for the cost of evaluating the pre- and post-project modification, as well as the cost of the project.[160] However, it does not say when such payment will be made, thus possibly requiring the family to advance it and hope that they will be paid back.

Subparagraph (l) provides for repairs to modification projects, but requires prior approval for modifications that have worn out.[161] As noted, there does not appear to be any thought concerning payment for modifications if the enrollee moves, or how many times in a lifetime modifications will be paid for.[162] This may be even more relevant in premises that are rented by the enrollee.

The potential effect of the rigorous nature of these provisions is twofold. First, the neurologically impaired child and his family may be deprived of home modifications essential to making care less onerous and improving life quality. Second, ironically, the more challenging it becomes to obtain an appropriate home environment, the more likely it will be that an increased number of these individuals may be forced to be institutionalized, leading to even higher possible costs to the Fund.

Moreover, the Fund fails to adequately take into consideration some of the most common situations that will likely be

156 *Id.*
157 *Id.* § 69-10.7(i).
158 *Id.* § 69-10.7(j).
159 *See id.*
160 *Id.* § 69-10.7(k).
161 *Id.* § 69-10.7(l).
162 *Id.* § 69-10.7.

encountered. For example, if a landlord denies permission to an enrollee for an environmental modification it will be unlikely that the family will be able to secure housing appropriate to enable the plaintiff to be cared for at home.[163] When the family is in control of making home modifications, the process may become more feasible, quicker, less expensive, and better meet the family's needs. It also must be noted that the Fund permits payment only for environmental modifications, and not for new housing, which may be more cost effective and which the enrollee may need in many instances.[164]

In addition to these problems, the overbearing bureaucratic procedures required for environmental modifications necessarily discourage potential providers of care and services from undertaking this work.[165] The most disturbing aspect of the complicated application process is that the Fund is not making its determination based on what may best fit the enrollee's situation, would make the plaintiff the most comfortable, or would maximize the quality of her life. Rather, the Fund's decision is required to be based on whether the modification allows for an *appropriate balance between the injured enrollee's minimum needs and the best value provided to the Fund*.[166] These regulations, therefore, do not exist to assure quality of life care, but rather to limit what the Fund is obligated to pay. The enrollee does not care about the best value to the Fund, only the service that best meets his needs.

The Fund only allows for repairs to the modifications if they are "cost effective."[167] The regulations do not state how cost effectiveness is to be measured or provide any procedure with regard to necessary repairs.[168] If a repair is not deemed to be cost effective, apparently the recourse for the plaintiff is to seek prior approval for an entirely new modification. When modifications are worn out through normal use, the Fund requires the enrollee to reapply for approval for a new modification.[169] The regulations are silent however, to what happens if the modification is

163 *Id.* § 69-10.7(a).
164 *Id.* § 69-10.7.
165 *See id.*
166 *Id.* § 69-10.7(h).
167 *Id.* § 69-10.7(l).
168 *Id.* § 69-10.7.
169 *Id.* § 69-10.7(l).

damaged or destroyed by something other than normal use.[170] This implies that the Fund might not be obliged to accept an application for a modification that was damaged or destroyed in a fire or simply failed to function to meet the family's needs.

H. Prior Approval Requests for Vehicle Modifications

Section 69-10.8 provides prior approval requirements for vehicle modifications, such as handicapped accessible vans.[171] These requirements are similar, but perhaps even more burdensome, than are the regulations applicable to home modifications.[172] In the first place, the Fund will only pay for modifications to "a vehicle owned by the enrollee or a member of the enrollee's household who has consistent and ongoing contact with the enrollee and provides *unpaid* primary, long term support to the enrollee."[173] This will present a major obstacle to many enrollees. The Fund will not pay for the vehicle itself, but rather only for the modification.[174]

Paragraph (b) specifies the requirements to support an application for vehicle modification including an evaluation of the modification by "a Driver Rehabilitation Specialist who has been certified by the Association of Driver Rehabilitation Specialists and approved by New York State Adult Career and Continuing Education Services-Vocational Rehabilitation (Acces-VR)."[175] The evaluation must specify the most cost effective means of meeting the enrollee's needs, and a detailed specification of the work required.[176]

Paragraph (c) limits vehicle "[m]odifications . . . to vehicles that are registered, insured and meet New York State inspection

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[170] *See id.* § 69-10.7 (failing to specifically identify how modifications damaged by other than normal use should be handled). Even if someone else causes damage, should the innocent child/enrollee be penalized?

[171] *Id.* § 69-10.8.

[172] *Compare id.* § 69-10.7 (allowing modifications are only if to the enrollee's primary residence or written permission if not owned by enrollee), *with id.* § 69-10.8 (allowing modifications to a vehicle if owned by enrollee *or a person that provides unpaid, primary long term support to the enrollee*, and if the vehicle is providing access to services or supports in the community, which increase their independence).

[173] *Id.* § 69-10.8(a).

[174] *Id.* §§ 69-10.8(a), (d), (l).

[175] *Id.* § 69-10.8(b), (k). One can imagine how difficult it might be to find one of these specialists in a rural county.

[176] *Id.*

standards."[177] This would preclude vehicles that are registered, insured or meet the standards of other states or countries where the enrollee might reside. This would seem to interfere with the constitutional right of freedom to travel or live in other states or countries.[178]

Paragraphs (d) and (e) and (f) impose even greater restrictions on the ability of many, if not most enrollees to get vehicle modifications, and certainly more than if the plaintiff could recover damages for vehicle modifications from the defendant, as other tort victims can. Paragraph (d) limits "[m]odifications . . . to (1) a new vehicle . . . purchased by the enrollee or a member of the enrollee's household or (2) [a] structurally sound [vehicle], not in need of . . . repair [that is] less than 5 years old or [with] less than 50.000 miles" on it.[179] Without significant cash funds from the judgment, it is unlikely that the plaintiff or his family will be able to access sufficient funds to buy a new or low mileage van for modification. If this were not bad enough, pursuant to Paragraph (f) the cost of modifications cannot exceed the Blue Book value of the vehicle.[180] These provisions essentially eliminate poor or lower socioeconomic group plaintiffs from having a handicapped accessible van. Many enrollees will not be able to afford a used van with less than fifty thousand miles. The Fund would thereby deprive these families from any accessible transportation at all.

Paragraph (e) limits modifications for wheelchair accessible vans to those necessary to assure "safe transportation and safe access into and out of the vehicle."[181] The comfort of the enrollee or ease of use of the modification is apparently not a consideration.[182]

Paragraph (h) requires three bids for modifications,[183] and paragraph (g) limits bids only to those "that meet Acces-VR's qualifications for performing vehicle modifications."[184] If fewer

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177 *Id.* § 69-10.8(c).

178 *See infra* Part V.

179 *Id.* § 69-10.8(d). Many people in New York do not own and cannot afford a new or low mileage used vehicle. No alternative means of generally available handicapped transportation service is provided for by the Fund Regulations.

180 *Id.* § 69-10.8(f).

181 *Id.* § 69-10.8(e).

182 *See id.*

183 *Id.* § 69-10.8(h).

184 *Id.* § 69-10.8(g). Again, in most counties it will be difficult to find three bidders and, even if they can be found, this is a major and unnecessary

than three bids are submitted a written explanation must be submitted as to why.[185]

Subparagraph (j) requires that any change in specifications that increases the price of the modification requires Fund approval.[186] Similar to home modifications, subparagraph (k) provides that complete payment will not be made until the Fund receives an evaluation confirming that the project meets the enrollee's "functional needs" and is in compliance with the initial evaluation.[187] Again, it is possible that an approved modification could be done properly, but after it is completed not meet the enrollee's functional needs, in which case payment may not be forthcoming.

Subparagraph (l) does provide that the Fund will pay for the cost of the pre- and post-project evaluation, as well as the cost of the modification and, in limited circumstances, travel costs.[188]

The problems that these Fund regulations present with respect to vehicle modifications are similar to those that have been discussed with regard to home modifications. A jury may well have found that a handicapped accessible van would have been included in the plaintiff's future care costs as part of a reasonably considered life care plan. Under the Fund, however, an injured enrollee is not entitled to the cost of a new or even low mileage used van equipped for her disabilities.[189] The Fund will only provide for vehicle modifications, not the purchase of a vehicle.[190] Therefore, if the enrollee does not already have a vehicle—most usually a van that is suitable for modification to fit the plaintiff's needs—the enrollee will simply not get accessible transportation from the Fund at all.

Although the regulations allow for modifications for vehicles that the plaintiff's family currently owns, this too is subject to limitations. The owner of the van must be the person who provides the "*unpaid* primary, long-term support to the enrollee" and "has consistent and ongoing contact with the enrollee."[191] This indicates that a handicap accessible van modification is not

imposition on families.

185 *Id.* § 69-10.8(h).

186 *Id.* § 69-10.8(j).

187 *Id.* § 69-10.8(k).

188 *Id.* § 69-10.8(l).

189 *Id.* § 69-10.8.

190 *Id.*

191 *Id.* § 69-10.8(a).

available under the Fund in any circumstance where the injured enrollee is institutionalized or where the family member would get paid for the care of the child even if they had to give up another paying job to do so. Moreover, the Fund will only pay for a modification if the vehicle is the enrollee's "primary source of transportation."[192] Without the full recovery of a judgment many, if not most, urban dwellers will not be able to afford a van. Most enrollees in New York City, for example, will essentially be deprived of a handicapped accessible van, even for outings to other parts of the state.

The regulations further restrict the availability of modifications by requiring that (1) modifications can only be made on new vehicles, vehicles less than five years old, or vehicles with less than 50,000 miles on them; and (2) "[t]he cost of the modification[ ] may not exceed the Blue Book . . . value [for] the vehicle.[193] This significantly limits the opportunity for those who cannot afford a new van to be able to modify an older one, which they might be able to afford. In order for the Fund to pay for modifications a potential van, therefore, must fall within the small window of being new enough to qualify as being less than five years old or having 50,000 miles, and simultaneously be old enough to be affordable for the family to purchase, and still be sufficiently expensive to possess a Blue Book value that exceeds the cost of the modifications that must be made to it.[194]

These problems are in addition to similar constraints that vehicle modifications share with the prior approval for environmental modifications described above. The process is long and protracted, requires evaluations by independent parties, and requires at least three bids.[195] Again, if the difference between the two lowest bids be greater than 10 percent, the Fund is to pick the bid that it feels provides the best value to the Fund, and not what best meets the plaintiff's needs.[196] Finally, the regulations make absolutely no provision for maintaining the modified van and how that will be paid for.[197] Presumably that burden would fall onto the enrollee, even though she likely lacks the ability to pay for it because she has been prevented from

192 *Id.*
193 *Id.* § 69-10.8(d), (f).
194 *Id.*
195 *Id.* §§ 69-10.7(e), (g), (j), 69-10.8(b), (h), (k).
196 *Id.* § 69-10.8(i).
197 *Id.* § 69-10.8.

recovering this sum from the defendant-tortfeasor.

I. Prior Approval Requests for Assistive Technology

Section 69-10.9 provides for prior approval requests for Assistive Technology.[198] Essentially the bidding process for this service restates the bidding requirements for home and vehicular modifications.[199] The differences will be highlighted below.

Paragraph (a) provides that a request for an assistive technology device shall also "be considered to include a request for AT services."[200] This is assistance from the Fund "to the enrollee in the selection, acquisition, and use of the appropriate AT device and necessary training."[201] Although this paragraph may sound benign, what it really does is supplant the decision of the family's physician and other providers, who answer solely to the family in choosing assistive devices. The decision on equipment may be based on *the Fund's assessment and motivations in keeping cost low*, rather than the enrollee's needs, preferences, or choices.[202] For example, insurance companies and government programs may refuse to pay for electric wheelchairs because they claim that the patient was not an appropriate candidate, even though her doctors, teachers, or family felt otherwise. It is a further example of the Fund inserting itself where a court, a jury, the family, or a health care professional disagrees with the Fund's assessment.

Paragraph (b) describes the requirements to be a provider of Assistive Technology Equipment.[203] A provider must either (1) be approved under 18 N.Y.C.R.R. Part 504, (2) be a provider under the New York State Office for Persons with Developmental Disabilities Community Based Waiver Program, (3) be a licensed pharmacist, or (4) be a Durable Medical Equipment provider.[204] For Personal Emergency Response Systems, the provider must be approved under an existing contract with a local Social Services District or a similar agency in another state.[205] No provision is

198 *Id.* § 69-10.9.
199 *Compare id.* § 69-10.9, *with id.* § 69-10.7, *and id.* § 69-10.8.
200 *Id.* § 69-10.9(a).
201 *Id.*
202 *Id.* § 69-10.9(a), (e), (g)–(i).
203 *Id.* § 69-10.9(b).
204 *Id.*
205 *Id.*

made for providers outside the United States.[206]

Similarly, under paragraph (c) anyone making an assistive technology assessment must be either (1) "a New York State Acces-VR approved provider" (or equivalent in another state—but not outside the United States), (2) an "Independent Living Skills trainer" (past or present under the New York State Community Waiver program, but apparently not another state or country), or (3) a "professional who is knowledgeable about the full range of devices and/or technology available to assist individuals with disabilities."[207] This latter catchall would seem to include almost anyone, or perhaps no one.

Paragraph (d) requires that AT devices requested from the Fund must meet Underwriters Laboratory standards or comply with any applicable Federal Communications Commission requirements.[208]

The process for requesting AT is quite detailed and extensive. It "must include . . . justification for . . . how the [requested] equipment . . . will meet the needs and goals of the enrollee in . . . improving . . . functional capacities in an efficient and cost effective manner."[209] It also "must include . . . all assessments made to determine the necessary AT, including [(1)] . . . information [regarding] the [enrollee's unique] needs and preferences, . . . limitations and prognosis; [(2)] . . . the environment [for where the equipment] will be used; [(3)] the basis for selecting the particular AT [and its] advantages over other options. . . ; and" (4) *any information regarding at least three alternatives considered.*[210] If there are less than three options considered, that fact must be justified to the Fund.[211]

Under paragraph (f) if any AT equipment requires home modification, information and permission of the landlord must be provided if the home is not owned.[212]

Paragraph (g) requires written explanation justifying the

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206 *Id.*

207 *Id.* § 69-10.9(c).

208 *Id.* § 69-10.9(d).

209 *Id.* § 69-10.9(e)(1). This again places cost efficiency at the top of the list, above the needs of the plaintiff, or whether the court found that certain equipment was warranted.

210 *Id.* § 69-10.9(e)(2).

211 *Id.* § 69-10.9 (e)(2)(D). All of this creates a major burden on families, when in fact the court, the family, or a health professional has likely already made a direct or indirect finding that such equipment was justified.

212 *Id.* § 69-10.9(f).

choice of AT equipment and, as noted above, if less than three alternatives were considered, an explanation as to why there were less than three.[213] As with vehicular and home modifications, under Paragraph (h) if the two lowest bids are within ten percent of each other the enrollee may choose between the providers, but if there is more than a ten percent difference, the Fund will pick the lowest bidder, unless one provides "higher quality, longer durability or a higher degree of safety," in which case the Fund will choose the "best overall value."[214] The choice of the enrollee's family or health professional is apparently irrelevant.

Paragraph (i) permits "cost effective repairs" with written justification "and two or more estimates for the repair," as well as "a plan to minimize future loss or damage."[215] There is no discussion as to how often AT equipment can be replaced as needs change or technology improves.[216] Paragraph (j) may severely limit access to AT equipment. It arbitrarily provides that the Fund will not pay "more than the wholesale cost of the equipment plus 50 percent."[217] It is unknown whether this will impair the availability of certain types of equipment to Fund enrollees.

J. Prior Approval Requests for Private Duty Nursing

Section 69-10.10 provides for prior approval for "private duty nursing."[218] Depending on how private duty nursing is defined (and there is no definition of "private duty nursing" in the regulations or statute) this could be the single most critical item covered, or perhaps not covered, by the Fund. For example, it is unclear as to whether private duty nursing refers to only registered nursing care, or if it refers to someone less credentialed, such as a licensed practical nurse, a licensed care aide, or another person providing skilled or "custodial type" care to a neurologically impaired patient. Many of these children will require caregivers with extensive training and specialized skills. These individuals cannot be safely left with someone whom has

213 *Id.* § 69-10.9(g).
214 *Id.* §§ 69-10.7(h), 10.8(i), 10.9(h).
215 *Id.* § 69-10.9(i).
216 *Id.*
217 *Id.* § 69-10.9(j).
218 *Id.* § 69-10.10.

no experience in dealing with a person who is neurologically impaired, much less providing the specialized care such as suctioning or G-tube feedings that is required.

Paragraph (a) provides that a request for private duty nursing care, either at home or in a hospital, "must be accompanied by a physician's written order and treatment plan."[219] If "private duty nursing" is to be provided in a "hospital setting," paragraph (b) provides that the physician's order must also state that the enrollee requires "individual and continuous care beyond that available by the staff of the hospital."[220]

Paragraph (c) refers to "nursing services" and requires a "physician's order . . . stat[ing] either that there is no approved home health [care] agency available to provide the intermittent or part-time nursing services [required] . . . or that the enrollee is in need of individual and continuous care beyond that available from an approved home health agency."[221] This would seem to imply that nursing services less than registered nurses may be covered by the Fund without prior approval, but there is no provision that actually states this, and the answer to that question remains unclear.[222] It is further provided, however, that "[t]he Fund Administrator may request [updated] periodic treatment plans and other medical information as he or she determines the particular circumstances warrant prior to approving additional periods of private duty nursing."[223]

Paragraph (d) provides that under an urgent situation, a physician may order private duty nursing services for up to two nursing days if a prior approval request is submitted.[224] The section further provides that a claim for these services can be submitted to the Fund for payment, but there is no provision stating that they will actually make payment under these circumstances.[225]

Payment for nursing care services at Medicaid rates has the

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[219] *Id.* § 69-10.10(a). It is unclear whether a hospital setting includes a nursing home, another custodial care type facility, or a group home.

[220] *Id.* § 69-10.10(b)

[221] *Id.* § 69-10.10(c). It should be noted that this paragraph refers to "nursing services" as opposed to "private duty nursing." *Id.* This might imply that "nursing services," and the requirement of prior approval, therefore, is broader than "private duty nursing" services.

[222] *See id.*

[223] *Id.*

[224] *Id.* § 69-10.10(d).

[225] *Id.*

potential to severely compromise the care of enrollees because families will have greater difficulty finding nurses to work at these rates. This will directly impact on the quality of care, quality of life, and even longevity of neurologically impaired children, as well as their families who are providing care. It may also have the effect of requiring families to indefinitely provide the necessary around the clock care simply because there will be a shortage of nurses at below market reimbursement levels. Despite the fact that a court may have found that the plaintiff was entitled to full time nursing care the Fund could nonetheless reject such a request when the plaintiff is enrolled in the Fund. Even if such care is approved, the low payment rates may make it difficult to find willing providers.[226] There have already been concerns raised that payment by the Fund at Medicaid rates will have a negative impact on the accessibility to services of critical providers.[227]

The fact that nursing care is paid at Medicaid rates is apparently based on the presumption that family members are going to be able to provide the majority of care for the injured enrollee. This presumption is neither valid nor appropriate. A parent is not obligated to, in effect, serve a "life sentence" caring for a neurologically impaired individual. Under the law of damages in New York, such parents are entitled to have appropriate assistance either in the home or by facility care. If they do elect to provide care themselves, they are entitled to be compensated for it.[228] Depending on the individual's needs, the level of care may require full time private duty nursing, a full-time registered nurse, or other skilled caregivers. Each enrollee's need is going to be different. Certain enrollees in the Fund are going to require suctioning, specialized feeding, or other care intensive needs. Family members are not obligated to bear these burdens alone, and the regulations are completely devoid of clarification as to what is, and is not, covered in this regard.[229] The low reimbursement rate provided by Medicaid creates an

[226] *See id.* § 69-10.10(c).

[227] Bergen, *supra* note 82.

[228] *See* Schultz v. Harrison Radiator Div. General Motors Corp., 683 N.E.2d 307, 311 (1997); Auer v. New York, 733 N.Y.S.2d 784, 787 (App. Div. 3d Dep't 2001); King v. New York, 393 N.Y.S.2d 93, 94 (App. Div. 3d Dep't 1977); 1B N.Y. PATTERN JURY INSTRUCTIONS, *supra* note 105, at § 2:280.

[229] *See* N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.10–.11.

additional problem.[230] Even if the Fund were to approve nursing care for a certain number of hours, there is no guarantee that the family would be able to find nursing staff who would be willing to work in the home at those rates or on all shifts. The same is true with necessary equipment, and certain providers, particularly those who provide more expensive or higher quality equipment, may refuse to provide their goods at Medicaid rates.

Even if the plaintiff is fortunate enough to acquire providers at Medicaid rates, then the issue is whether the quality of care would be sufficient for the plaintiff's needs. It is not unlikely that the care provided under the Fund would be inferior to that which would be available at market rates if the plaintiff were not forced into the Fund. Recent studies and articles confirm the fear that Medicaid rates will compromise access to the care that these vulnerable children (and adults) require.[231] When care is restricted and inadequate there is legitimate concern that these children may suffer unnecessarily, and perhaps die prematurely.[232]

A 2011 study published in the New England Journal of Medicine established that Medicaid patients (the equivalent of Fund enrollees, since reimbursement for most services are at Medicaid rates) experienced significant delays in getting appointments with medical subspecialists as compared to private pay or private insurance company patients.[233] The delay in getting appointments was about twice as long—an average of forty-two days under Medicaid—compared to twenty days with private insurance.[234]

It is hardly surprising therefore, that recent investigative reporting discovered that developmentally disabled individuals

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[230] Charlene Harrington et al., *Nursing Staff Levels and Medicaid Reimbursement Rates in Nursing Facilities*, 42 HEALTH SERVICES RES. 1105, 1106–07 (2007).

[231] *See* Joanna Bisgaier & Karin V. Rhodes, *Auditing Access to Specialty Care for Children with Public Insurance*, 364 NEW ENG. J. MED. 2324, 2325, 2328 (2011) (describing a study which measures the impact of Medicaid coverage on the availability of medical specialty care).

[232] *See* Kessler, *Critical Analysis*, *supra* note 43; Danny Hakim & Russ Buettner, *In State Care, 1,200 Deaths and Few Answers*, N.Y. TIMES, Nov. 5, 2011, at A1, *available at* http://www.nytimes.com/2011/11/06/nyregion/at-state-homes-simple-tasks-and-fatal-results.html (describing a recent case of an individual drowning, because of an allegedly low staffing level due to inadequate funding).

[233] Bisgaier & Rhodes, *supra* note 231, at 2328.

[234] *Id.*

whose care was either provided or managed by the State of New York were dying prematurely at an alarming rate.[235] A November, 2011 *New York Times* article describes a number of unexplained deaths and other injuries to disabled individuals in state facilities, most of which apparently related to poor care, such as choking, drowning.[236] The *Times* reported "the average age of those who died [from] unknown causes was 40, while the average age of residents dying of natural causes was 54."[237] The State Commission on Quality of Care and Advocacy for Persons with Disabilities found that there had been "concerns about the quality of care in nearly half" of the unexplained deaths.[238]

A 2011 editorial in the Albany Times Union noted that the state of New York was spending on average $144,000 per year per developmentally disabled person under their care.[239] Despite this, *the "unexplained" death rate for individuals cared for by the State of New York was more than four times higher than the rate in Massachusetts and Connecticut.*[240] These findings, therefore, may well be a preview of will happen when the Fund, rather than families, is making health care decisions for neurologically impaired patients.

K. Prior Approval Requests for Enteral Nutritional Formula

Section 69-10.11 requires prior approval for supplemental nutritional formula.[241]

Paragraph (a) specifies that no prior approval is necessary if the Fund has documentation that the child is fed by NG tube, G-tube or J-tube.[242]

Paragraph (b) specifies that requests for additional nutritional formula to be provided orally as a supplement must be ordered by a physician, physician's assistant, or nurse practitioner, and the order must specify "a diagnosed medical condition or pathological process causing malnutrition" *and* "clinical findings

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235 Hakim & Buettner, *supra* note 232.

236 *Id.*

237 *Id.*

238 *Id.*

239 TU Editorial Board, *A Deadly System for the Disabled*, TIMES UNION (Nov. 9, 2011, 6:01 AM), http://blog.timesunion.com/opinion/a-deadly-system-for-the-disabled/15958/.

240 *Id.*

241 N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.11(2012).

242 *Id.* § 69-10.11(a).

supporting malnutrition," a physiologic disorder resulting from surgery, or laboratory confirmation of low protein.[243] Such clinical findings would include involuntary weight loss, a failure to gain weight or height in six months, or the loss of lean body mass.[244]

The regulations do not appear to consider the possibility that a patient may be fed by tube, but still be able, and indeed medically required, to take supplemental enteral formula or other nutrition by mouth.[245]

L. Prior Approval Requests for Transportation for Medical Care and Services

Section 69-10.12 requires prior approval for transportation to receive medical care and other services.[246] *It does not provide for the Fund to pay for specialized transportation services that would be required by a disabled enrollee for recreational or other nonmedical treatment.*[247] Therefore, a disabled individual who cannot afford a vehicle or cannot meet the requirements to obtain vehicle modifications as set forth in Section 69-10.8, but nevertheless needs specialized transportation for activities of daily living, is not entitled to such transportation under the Fund.[248] They will have no means to access the community.

Even transportation for "non-emergency ambulance . . . or . . . ambulette" is subject to prior approval by the Fund Administrator and must be supported by an order from a physician, nurse practitioner, physician's assistant, or a facility servicing the enrollee.[249] Paragraph (b) specifies that only authorized commercial providers will be paid.[250]

Paragraph (c) lists six criteria used in determining whether approval will be granted: "(1) whether . . . the enrollee's condition necessitates a mode of transportation other than that ordinarily used"[251] and if such mode of transportation is the only one that can be safely used; (2) whether multiple treatments are required

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243 *Id.* § 69-10.11(b).
244 *Id.* § 69-10.11(b)(2).
245 *See id.* § 69-10.11.
246 *Id.* § 69-10.12.
247 *See id.*
248 *Id.* § 69-10.12(c); *see id.* § 69-10.8.
249 *Id.* § 69-10.12(a).
250 *Id.* § 69-10.12(b).
251 As noted, because of the restrictions on vans and/or other transportation the enrollee may well not have access to appropriate transportation for regular use to access the community at all.

"over a short period of time that would cause an undue financial hardship;"[252] (3) if "the geographic location of the enrollee and the provider of medical care and/or services are such that the usual mode of transportation would be inappropriate;" (4) "whether the distance to be traveled for medical care and/or services would require a large transportation expense that would result in an undue financial hardship for the enrollee;" (5) whether there is a need to continue medical care or obtain services with a specific provider outside the enrollee's usual geographic location; and (6) the enrollee's unique circumstances.[253]

If the plaintiff cannot acquire a modified van either on their own or through the Fund, his options for transportation are very limited. The only transportation provided by the Fund is that which is required to transport the plaintiff to receive medical care.[254] Therefore, the Fund will not provide for transportation to recreational or other activities that would improve the quality of life of the plaintiff and integrate her into the community. The Fund simply would not provide for trips to the library, a ball game, the mall, or to give an urban enrollee an occasional trip to the country to get some fresh air.

Even if a physician deems such treatment requiring transportation to be necessary, prior approval for such transportation might still be denied pursuant to the criteria that the Fund must consider in determining whether an application should be approved.[255] These criteria effectively eliminate the ability for the enrollee to choose when certain medical care is necessary, who is going to provide that care, and where that care is going to be provided. This is because the Fund simply may not provide for transportation to a certain location or geographic area for care if it is felt that such care could be provided more proximately to the enrollee.[256] Apparently no consideration is given to the quality of care that may be provided elsewhere. Under the Fund's criteria one neurologist, for example, is as good as the next. The Fund has the power to prevent an enrollee from obtaining even necessary medical services outside of their home

[252] As discussed below, apparently ordinary financial hardship, or even simply not being able to afford transportation, is not enough to warrant payment.

[253] *Id.* § 69-10.12(c).

[254] *Id.* § 69-10.12.

[255] *Id.* § 69-10.12(c).

[256] *Id.* § 69-10.12(c)(5).

area because it is likely that the enrollee will not be able to secure a van on her own and has to rely on the Fund for all transportation. For example, someone who lives in rural upstate New York may be precluded from obtaining transportation to obtain medical services in New York City, Boston, or California. It would appear that fundamental decisions about where care is to be provided should not be within the control of the Fund. No other malpractice victim has such restrictions imposed on him. It would appear only fair that the injured plaintiff should be entitled to the care that a jury determined is necessary to make her whole, and not merely the care that the Fund decides they can spare.

Additionally, the regulations are not concerned whether transportation to and from medical care will be a "financial hardship" on the enrollee's caretakers, but will only approve transportation if the Fund decrees that it amounts to an "*undue* financial hardship."[257] It is unclear how the Fund would consider what constitutes an "undue financial hardship" as opposed to just a regular "financial hardship," or if the Fund will consider any other financial means that the plaintiff might have at her disposal, potentially creating an inequity between enrollees with different levels of income.

M. Prior Approval Requests for Other Qualified Health Expense Payments

Section 69-10.13 provides for prior approval requests for qualified health care expenses that are not otherwise specified.[258]

This section specifies "that requests [for] payment or reimbursement for any out of the ordinary qualifying health care cost shall provide the documentation required in section 69-10.6(c) . . . and any other relevant information the Fund Administrator deems necessary."[259] This gives the Fund Administrator the right to insist on prior approval for essentially all "qualified" health care expenses. It is therefore completely contrary to the spirit and intent of the statute, which provides that no qualified health care costs shall require such prior authorization except as provided by the Commissioner by

[257] *Id.* § 69-10.12(c)(2),(4).
[258] *Id.* § 69-10.13.
[259] *Id.*

regulation.[260] The net effect of these prior approval sections, and in particular this section, is that it completely reverses the process, and essentially makes everything subject to prior approval by the Fund.

N. Expedited Prior Approval Process

Section 69-10.14(a) provides for an "expedited prior approval process" within forty-eight hours where a physician certifies and documents that there is an "urgent need" for such services and approval.[261] Paragraph (b) permits such services to be provided on an "emergency basis" pending the expedited prior approval process if the application for approval is submitted without delay.[262]

The problem here is that there is no assurance, even if services are provided on an emergency basis or for expedited prior approval, that such request will ultimately be approved by the Fund.[263] This will tend to discourage providers from providing even "emergency" services that are within the category of prior approval because of the possibility of eventual rejection. Moreover, there is no provision for payment even to a provider who is acting in a good faith belief that there was an urgent or emergency need for services, if the Fund Administrator ultimately disagrees that the service was required.[264]

O. Claim and Prior Authorization Review Process

Section 69-10.15 describes the process for obtaining administrative review of a denial of services applied for under the Fund, whether or not prior approval was required.[265] Pursuant to Paragraph (a), the enrollee must complete a claim denial review form within thirty days of the denial of the requested service. It may be submitted electronically, by mail, or hand delivered.[266]

Paragraph (b) requires the form to specify the basis for an

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260 N.Y. PUB. HEALTH LAW § 2999-j(2) (McKinney Supp. 2012); N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.13.

261 N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.14(a).

262 *Id.* § 69-10.14(b).

263 *Id.* § 69-10.14.

264 *Id.*

265 *Id.* § 69-10.15.

266 *Id.* § 69-10.15(a).

assertion that the request for services was improperly denied, and permits the enrollee to request a review by phone or in person.[267]

Paragraph (c) requires that "[a]ll written evidence, including the names of witnesses a party intends to present at the hearing, must be provided to the other party at least 5 business days prior to the hearing."[268]

Paragraph (d) allows a person who has been denied prior approval to request "an informal conference in addition to a formal review."[269] In this instance, the Fund Administrator will designate someone from the Fund to informally discuss the reasons for the denial, at least one week before the formal hearing.[270] The regulation does not specifically give the "informal" Fund designee the authority to reverse the denial.[271] By scheduling the "informal conference" as little as a week before the formal hearing, it essentially precludes the plaintiff from avoiding the expense to prepare for the formal hearing. Given the apparent lack of authority to alter the denial, it appears that this process exists solely to try to convince the plaintiff that the denial was justified, and therefore discourage pursuit of the formal hearing.

Paragraph (e) provides for the assignment of a hearing officer designated by the Commissioner and providing notice of the hearing to the requesting party.[272]

Paragraph (f) describes the requirements of the hearing notice which must include (1) "the date, time and place of the hearing . . . within a reasonable distance from the requestor;" (2) a statement of the issues at the hearing; (3) " the manner in which the hearing will be conducted;" and (4) a statement informing the enrollee of her right to be represented by counsel.[273] If the plaintiff resides in another state or country, this paragraph would suggest that the hearing would have to be out of the state or country, or any place in the world—though it is difficult to believe that the Fund Administrator would actually

[267] *Id.* § 69-10.15(b).
[268] *Id.* § 69-10.15(c).
[269] *Id.* § 69-10.15(d).
[270] *Id.*
[271] *Id.*
[272] *Id.* § 69-10.15(e).
[273] *Id.* § 69-10.15(f).

comply with this requirement at a distant location.[274]

Paragraph (g) permits all papers and notices to be served by regular mail, which is deemed complete three days after mailing.[275] Actual receipt is not required.[276] No thought is given to the possibility that a party may live across the country or even outside the United States, where delivery within three days may be problematic.

Paragraph (h) requires the Commissioner of Health to assign a Hearing Officer.[277] Presumably this is an employee of the Health Department, though the regulations are silent on this issue.[278] The Hearing Officer must not have a "personal bias," though this term is undefined.[279] Any party (presumably the Fund, the enrollee, and perhaps a provider denied payment) may request that the Hearing Officer be disqualified "for personal bias or for other good cause" established by affidavit stating the basis for disqualification.[280] Apparently it is the Hearing Officer who will decide whether he or she should self-disqualify.[281] The Hearing Officer may also, on her own motion, disqualify herself "for bias."[282]

Paragraph (i) provides that the hearing is to be conducted "in a fair and impartial manner."[283] It also enumerates the powers of the Hearing Officer, granting her the authority to (1) "rule upon requests by all parties to the hearing, including requests for adjournments"[284] (2) administer oaths and issue subpoenas to require the attendance of witnesses and the production of documents;[285] (3) "admit or exclude evidence," though no

274 This is not just hypothetical. The author was actually recently consulted by an attorney in Australia who represents an Australian citizen injured at birth in New York City, but who currently resides in Australia. Does anyone seriously think that the Fund would schedule a hearing in Australia?

275 *Id.* § 69-10.15(g).

276 *Id.*

277 *Id.* § 69-10.15(h).

278 *See id.* § 69-10.15(h).

279 *See id.*

280 *Id.* § 69-10.15(h)(1).

281 *Id.* § 69-10.15(h)(4).

282 *Id.* § 69-10.15(h)(2).

283 *Id.* § 69-10.15(i).

284 *Id.* § 69-10.15(i)(1).

285 *Id.* § 69-10.15(i)(2). It is unclear where this subpoena power comes from, or how one enforces a subpoena for an out of state or foreign witnesses or records. *See* N.Y. PUB. HEALTH LAW § 2999-j (McKinney Supp. 2012) (making no mention of any subpoena power).

standards are provided;[286] (4) "limit repetitious examination or cross examination . . . or . . . testimony;"[287] (5) "hear arguments on facts and law," though again no standards as to how this is applied are presented;[288] (6) "order . . . opening statements summarizing why the . . . Fund Administrator's [decision] was [correct] or was not correct;"[289] (7) "order the parties to appear at a pre-hearing conference . . . to simplify the issues[and] expedite the hearing;"[290] (8) "ensure that a written or electronic verbatim record of the proceedings is made and made available to the parties;"[291] (9) "perform [any] other acts . . . necessary for the maintenance of order and efficien[cy]" throughout the hearing "unless otherwise prohibited by law or regulation;"[292] and (10) adjourn the hearing at the request of a party for good cause, or at the hearing officer's own motion if he or she determines that proceeding "would be prejudicial to a party's due process rights."[293]

Paragraph (j) describes the manner in which the hearing shall be conducted which "shall provide . . . a fair and prompt resolution of [the] dispute."[294] The parties have the right to be "represented by legal counsel or other individuals with specialized training relevant to the hearing and may be accompanied by a person of his or her choice."[295] "The hearing shall be closed to the public unless the enrollee [or her representative] requests an open hearing."[296] "The parties . . . shall have an opportunity to present evidence and to question all witnesses at the hearing" and every witness shall be under

286 N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.15(i)(3). A later paragraph does state that "[t]he formal rules of evidence shall not apply," *id.* § 69-10.15(j)(5), There is no provision for out of state witnesses or "trial" depositions from experts who cannot attend a hearing, *see id.* §69-10.15 (noting that the regulations do not provide for out of state witnesses or depositions from experts who may be absent from a hearing).

287 *Id.* § 69-10.15(i)(4).

288 *Id.* § 69-10.15(i)(5).

289 *Id.* § 69-10.15(i)(6).

290 *Id.* § 69-10.15(i)(7). This also could increase legal fees to the enrollee.

291 *Id.* § 69-10.15(i)(8). There is no specific requirement that the plaintiff is entitled to this without cost, thereby further increasing the cost to the plaintiff to challenge a denial of services. *Id.* § 69-10.15.

292 *Id.* § 69-10.15(i)(9).

293 *Id.* § 69-10.15(i)(10).

294 *Id.* § 69-10.15(j).

295 *Id.* § 69-10.15(j)(1).

296 *Id.* § 69-10.15(j)(2).

oath.[297]

Subparagraph (5) requires the Hearing Officer to "consider all relevant evidence" including "records, documents, and memoranda submitted into evidence," though "[t]he formal rules of evidence shall not apply."[298] There is no guidance as to what is or is not admissible evidence.[299] In the event that the parties stipulate to settle the dispute prior to the decision, "a hearing officer will issue a consent order" that will "have the same force and effect as an order issued by the Commissioner."[300]

Paragraph (k) requires the hearing officer to "render a written *recommendation* to the Commissioner within 30 days of the hearing."[301] The hearing officer's recommendation includes "the relevant facts, the applicable law[s], regulations, and official policies . . . upon which the recommendation is based."[302]

Under Paragraph (l), "[t]he Commissioner or his or her designee shall review the hearing record and the hearing officer's recommendation and issue a decision that contains findings of fact, conclusions of law and the reason(s) for the determination and, when appropriate, directs the Fund Administrator to take specific action."[303] The Commissioner's decision shall be issued no more than thirty days from the Hearing Officer's recommendation.[304] *Thus, the Commissioner is not bound by the Hearing Officer's "recommendation" even if it is favorable to the enrollee.*

Paragraph (m) requires mailing of a decision to all parties to the hearing and the Fund Administrator, and provides that the Commissioner's decision shall be final subject to the enrollee's right to seek judicial review.[305]

This appeals process is burdensome because the enrollee will need to pay for attorneys, experts, and possibly the enrollee's care while the appeal is pending. The regulations create even more impediments to an enrollee successfully reversing a denial of services.

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297 *Id.* § 69-10.15(j)(3)–(4).
298 *Id.* § 69-10.15(j)(5).
299 *Id.* § 69-10.15(j).
300 *Id.* § 69-10.15(j)(6).
301 *Id.* § 69-10.15(k) (emphasis added).
302 *Id.* It is unclear what might constitute an "official policy." *Id.*
303 *Id.* § 69-10.15(l).
304 *Id.*
305 *Id.* § 69-10.15(m).

First, there does not appear to be any requirement that the Fund initially specify the basis for the denial. As a result the enrollee must guess the reason and blindly attempt to respond to it.[306] Moreover, although the enrollee is required to disclose to the Fund all of her written evidence and the names of her witnesses, there is no reciprocal provision requiring the Fund to specify any witnesses or written evidence so as to enable the enrollee to prepare her argument.[307]

Second, the family will likely have to incur significant legal expense, including expenses for expert witnesses to present an appeal, despite the fact that such witnesses likely had already either testified or submitted reports justifying the requested services at trial, and may have had their position accepted in a court of law. Experts at trial, who may have been secured at great expense and from a great distance may have to retestify, possibly on short notice, especially if the services denied are time sensitive. The enrollee may not be able to afford either the legal expense or appropriate expert testimony. This will not only limit chances of a successful appeal, but may deter the enrollee from even initiating a review.

Third, there is no provision for the reimbursement of attorney's fees or expert expenses, even if the appellant is successful in overturning the Fund denial.[308] Nor is there a provision for continued services pending the review decision, which can take up to sixty days (thirty days for the hearing officer's recommendation to the Fund Administrator and another thirty days for the Fund Administrator's decision).[309] In the meantime, even if ultimately successful, the enrollee must do without the necessary services and incur the expense of the review process, merely to get that care that she has already won in court.

Finally, the Fund will presumably be having multiple hearings involving what may be a limited number of Hearing Officers. This will enable the Fund, in contrast to the enrollee, to establish

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306 *Id.* § 69-10.6 (providing process for approval of requests); *See id.* § 69-10.15 (providing process for denial review but not requiring the Fund to provide the basis for the denial).

307 *See id.* § 69-10.15(c) (allowing for witnesses but not requiring Fund to specify witnesses).

308 *See id.* § 69-10.15 (allowing for representation by attorney during denial proceedings but not providing for reimbursement of fees incurred).

309 *See id.* § 69-10.15(k)–(l) (providing for a review period of up to sixty days but no continued services in the interim).

a "track record" of favorable Hearing Officers who are inclined to control costs. The Fund can keep track of these Examiners and potentially misuse their knowledge of a hearing officer's proclivities to seek disqualification. Since the regulations make no reference to payment of the hearing officer, it can be presumed that they will be state employees, and thus possibly not entirely impartial.

The net effect of these provisions, when combined with the fact that services may not be provided while the review process is pending, may well mean that the enrollee could go without services—even if they are successful in overturning the denial—for an extended period of time.[310] If the denial is maintained and the plaintiff is required to go back to court, the delay will be even longer, even if they are eventually successful. The significant costs and potentially devastating consequences to the plaintiff in the meantime are apparently not considered by the regulations.

Should the enrollee have to go back to court in an attempt at an appeal, she would be limited to an Article 78 proceeding.[311] In this setting the plaintiff will have a higher burden of proving the need for services than she did in establishing her need "'for the care at trial in the first instance. At the malpractice trial all that was required was establishing the need for care by a preponderance of the evidence.[312] By contrast, in order to reverse a determination by the Fund denying care, she will have to show that the determination made by the Fund Administrator (1) "was made in violation of lawful procedure;" (2) "was affected by an error of law;" (3) "was arbitrary or capricious;" or (4) lacked "substantial evidence."[313]

It also remains to be seen what, if any, standards there will be for reapplying for the same, or similar, benefits after a denial. Would *res judicata* apply to the Commissioner's denial if the enrollee simply reapplied for a denied benefit at a later date? What if any change in circumstances need to be shown to reapply?[314] The regulations do not specify if any time limits are

310 *See id.* (describing time period for review without reference to continued services during that time regardless of success of claim).

311 *See* N.Y. C.P.L.R. § 7801 (McKinney 2008) (describing scope of Article 78 proceeding).

312 1A N.Y. PATTERN JURY INSTRUCTIONS, *supra* note 105, at §1:23.

313 C.P.L.R. § 7803.

314 N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.15 (providing procedure for a hearing for the denial of a claim but failing to provide standards for reapplying

applicable to prohibit reapplication for the same benefits following a denial.[315]

P. Right to Expedited Review of Denials of Request for Prior Approval

Section 69 10.16 provides for expedited review of prior approval denials under certain circumstances.[316] If a physician provides a written statement that the enrollee has an urgent need for medical services or other items, and the reason why such service or item is needed on an expedited basis, a review of the request must be conducted within ten business days of the request for expedited review and supporting documentation.[317] The Hearing Officer must make a recommendation to the Commissioner within five business days of the hearing.[318] The Commissioner is then obligated to make his or her decision within five business days of the Hearing Officer's written recommendation.[319]

Subparagraph (d) provides that pending an expedited review determination, a service or item may—but is not required—to be provided.[320] Therefore, even under the "expedited review process," the enrollee might have to go twenty days without urgently needed services even if successful.[321]

Q. Actuarial Calculations for the Fund

Section 69 10.18 relates to actuarial calculations for the Fund.[322] Paragraph (a) requires "the Superintendent [to] conduct an actuarial calculation of the estimated liabilities of the Fund for the year following [the] annual deposit [to fund it]."[323] Significantly, as noted below, there is no calculation as to

benefits after a denial, a standard of review for denial, or any requirement to disclose change in circumstances).

315 *See id.* § 69-10.5, .15.

316 N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.16 (2012).

317 *Id.* § 69-10.16(a).

318 *Id.* § 69-10.16(b).

319 *Id.* § 69-10.16(c).

320 *Id.* § 69-10.16(d).

321 *Id.* § 69-10.16 (adding together the ten business days allowed for the review of the request, the five business days the Hearing Officer has to make a recommendation, and five business days to get the Commissioner's decision, the child could potentially have to wait 20 business days for critical services).

322 *Id.* § 69-10.18.

323 *Id.* § 69-10.18(a).

whether the Fund is actuarially sound over the lifetimes of the enrollees.[324]

Actuarial calculations of estimated liability must be conducted quarterly thereafter, assessing the estimated liabilities, but again only for the ensuing year.[325] The actuarial analysis must include (1) "the number of qualifying plaintiffs admitted in the Fund, and estimates of the number of qualified plaintiffs not yet admitted;"[326] (2) mortality experiences of the plaintiffs in the Fund;[327] (3) "the amounts of benefits paid by the Fund;"[328] (4) "patterns of utilization;"[329] (5) inflationary patterns;[330] (6) expenses of the Fund administration;[331] (7) "the impact available health insurance has on the benefits paid by the Fund;"[332] and (8) "investment earnings on the assets held by the Fund."[333]

There is no discussion as to who will conduct the actuarial analysis; whether it will be done internally by the Department of Insurance or whether it can be contracted out, and if so, whether it is paid for as a cost of administration of the Fund. There is no description as to whether this analysis will be made public and whether it can be challenged.[334] The latter is important because the actuarial calculations will determine when the Fund is closed to new enrollees. If the estimates are unrealistic, it could adversely affect the settlement value of a plaintiff's case depending on whether it is likely to be within or outside the Fund.[335]

R. Suspension of the Fund

Section 69 10.19, as provided by statute, reiterates that when the Fund's current liabilities equal or exceed 80 percent of the

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[324] *Id.* § 69-10.18.

[325] *Id.* § 69-10.18(a).

[326] *Id.* § 69-10.18(b)(1).

[327] *See id.* § 69-10.18(b)(2). The mortality experience will be somewhat, if not largely, dependent on the estimate of services provided to the admitted plaintiffs. The less services that are provided, the higher the mortality rate will be.

[328] *Id.* § 69-10.18(b)(3).

[329] *Id.* § 69-10.18(b)(4).

[330] *Id.* § 69-10.18(b)(5).

[331] *Id.* § 69-10.18(b)(6).

[332] *Id.* § 69-10.18(b)(7).

[333] *Id.* 10 § 69-10.18(b)(8).

[334] *See id.* § 69-10.18 (failing to mention whether the analysis will be made public or if it may be challenged).

[335] N.Y. PUB. HEALTH LAW § 2999(i)(6) (McKinney Supp. 2012).

Fund's assets as determined by the actuarial analysis described above, the Fund shall suspend enrollment and no new enrollees will be accepted.[336] This issue is critical since it would appear to create a denial of equal protection. Some plaintiffs will be limited to the Fund, and others with the exact same injury and damage—even theoretically one of two injured twins—will be able to collect their full damages from the defendant.[337] This will be determined solely by the financial status of the Fund at a given time.[338]

Paragraph (b) provides that if the Fund's current liabilities are no longer equal to or in excess of 80 percent of the Fund's assets, enrollments will again be accepted.[339] Paragraph (c) provides that the Fund Administrator is required to provide proper notice of suspension or reinstatement of enrollment on the Fund's website.[340] Paragraph (d) provides that "[o]nce enrolled, a qualified plaintiff will remain in the Fund for his or her lifetime, and will not be impacted by a suspension in enrollment."[341] This language also raises an interesting question of whether an applicant can be placed into the Fund while a defendant appeals liability. There is no provision to deny enrollment based on an appeal, and this language states that "[o]nce enrolled, a qualified plaintiff will remain in the Fund for his . . . lifetime."[342] Since there is no lifetime reserve for any enrollee, and since neither the actuarial soundness of the Fund over a lifetime, nor the degree of funding by the state for ensuing years, much less decades, can be predicted or assured, it is difficult to see how this promise can be made or backed up.

Although the language in this section is apparently directed to the possibility of Fund suspension, it may be broad enough to cover a reversal of the defendant's liability on appeal.[343] It is possible therefore, that without a stay on appeal, a child could be

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[336] *Id.* § 2999(i)(6); N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.19(a).

[337] *See* discussion *infra* Part V.B.

[338] PUB. HEALTH § 2999(i)(6); N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.19(a); *see* discussion *infra* Part V.B.

[339] N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.19(b).

[340] *Id.* § 69-10.19(c).

[341] *Id.* § 69-10.19(d).

[342] *Id. See also id.* § 69-10.2(b) (requiring applicants to submit only a "certified copy of the court-approved settlement or judgment" and not requiring applicants to provide appellate documentation if they are appealing).

[343] *See id.* § 69-10.19(d) (maintaining that qualified plaintiffs will remain in the Fund for their lifetimes regardless of any suspensions in enrollment).

enrolled in the Fund pending appeal and, under this provision, cannot be removed even if liability is reversed.[344]

This provision, therefore, arbitrarily creates four subclasses of malpractice victims with the exact same injury, damages, and cost of care. The first class constitutes infants who suffer from a neurologic impairment as a result of malpractice after or not involving birth. They will receive their full measure of damages and can collect them from the defendant. The second category consists of birth injured children whose judgments come before 80 percent of the Fund is exhausted. The care for these victims, as long as there is continued state funding, will require Fund approval and will be paid exclusively by the Fund at Medicaid rates, instead of by the defendant or its malpractice carrier at market costs.[345] The third category will be those birth injured children whose judgment comes after 80 percent of the Fund is exhausted. They will be paid their full damages by the defendant (and/or insurance carrier) as determined by the court, just as if the Fund did not exist.[346] The fourth, hybrid category of the second and third classes, consists of those who start out in the Fund, but may be forced to remain in the Fund even if the Fund appropriation is exhausted and there is no money left to pay for their care. These children will begin by having part of their damages paid at Medicaid rates and requiring Administrative approval, but were the Fund to run out of money, the rest would presumably be paid at full rates by the defendant, but perhaps not. The question of what happens if the Fund runs out of money for individuals already in it, remains unanswered, the promise by the Fund regulations to continue paying notwithstanding.[347]

S. Rates of Payment

Section 69 10.20 provides for the rates of payment to providers

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[344] *See id.* (allowing qualified plaintiffs to remain in the Fund for their lifetimes).

[345] N.Y. PUB. HEALTH LAW § 2999-j(4) (McKinney Supp. 2012); N.Y. COMP. CODES R. & REGS. tit. 10, § 10.20(b).

[346] PUB. HEALTH § 2999-i(6).

[347] *Id.* § 2999-i(6). This creates yet more administrative headaches. It is not clear whether a defendant can ever be released or a judgment satisfied even if a child starts out in the Fund. Since there can never be any assurance that there will be a sufficient appropriation to pay future care costs, either the defendant remains responsible to pay the judgment or the plaintiff has to go without essential care services.

of services.[348] This is a critical section because, as discussed previously, the rate of payment for services will have a direct impact on the availability and access to care by enrollees.[349] This will necessarily adversely impact the quality of life and even the longevity of the plaintiff.

Paragraph (a) provides that physician's services are paid at the "usual and customary charges for [such] services" as specified by "FAIR Health, Inc."[350] Even if it is assumed that such payments are "reasonable" and generally accepted by physicians, there is certainly no assurance that any particular physician or specialist will accept this amount. This has the significant potential, therefore, to reduce access to care and health care choices by the plaintiff.

More importantly, Paragraph (b) provides that for "services, supplies, equipment and medications"—a category that encompasses almost everything else—payment for such items will be at the Medicaid rate.[351] Paragraph (c) provides that services for which there is not a Medicaid rate will be paid in the manner described by the prior approval process, that is, the three competitive bids.[352]

T. Payment for Services Between April 1, 2011 and October 1, 2011

Section 69 10.21 provides for payment for expenses incurred between (a) the six month period of time between when the Fund took effect on April 1, 2011 and when the Fund started accepting enrollees on October 1, 2011, and (b) the time between the judgment or settlement and actual enrollment in the Fund.[353]

Paragraph (a) states that plaintiffs who were eligible to enroll after April 1, 2011 "must rely upon private health insurance or Medicaid to cover medical expenses" for the period prior to October 1, 2011. [354] Paragraph (b) provides that after October 1, 2011 (when the Fund actually started taking applications) the

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348 N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.20.

349 Moore & Gaier, *supra* note 6.

350 N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.20(a).

351 *Id.* § 69-10.20(b).

352 *Id.* § 69-10.20(c).

353 *Id.* § 69-10.21.

354 *Id.* § 69-10.21(a). This means that they have been deprived of payment for services from the defendant *and also deprived of payment for these services by the Fund as well.*

Fund will reimburse health care costs incurred between the time of approval of a settlement or judgment and the date the plaintiff is enrolled in the Fund.[355]

U. Residence of Qualified Plaintiffs

Section 69 10.22 deals with the residence of qualified plaintiffs.[356] Under Paragraph (a), enrollees are "required" to advise the Fund administrator of any address change.[357] It is unclear where the authority to require this information is found. Nor is any concern expressed about the loss of privacy associated with this obligation.[358]

Paragraph (b) specifies that eligibility or continued enrollment "is not dependent on the current or past residency of a qualified plaintiff."[359] Although this statement may be technically true, as a practical matter, the regulations present numerous problems related to the freedom to travel.[360]

The Fund does not address many issues that would arise with respect to where the plaintiff can live. It is unclear how the Fund would handle situations where the plaintiff has more than one residence, such as where his parents are divorced. In that instance, the plaintiff might not be eligible for any modification assistance from the Fund, for example, because it is possible that between the two households the plaintiff might not have a "primary" residence.[361] The Fund also creates the potential to disturb whether the plaintiff can even stay at the home of certain family members if it refuses to allow for the modification of more than one residence. These limitations would not arise if the plaintiff received his damages from the tortfeasor and was

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[355] *Id.* § 69-10.21(b). This of course assumes that the child's family had access to such care during that period.

[356] *Id.* § 69-10.22.

[357] *Id.* § 69-10.22(a).

[358] The basis for this requirement, as well as the obligation to continue to provide medical authorizations would presumably be justified on the grounds that they are necessary to maintain eligibility for a government benefit, such as would be the case with Medicaid. The critical distinction is that the child is *forced* into the Fund, and is there only because the State took away his right to obtain payment for judicially determined damages from the defendant, and thereby the concurrent right to avoid these invasions of privacy.

[359] N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.22(b).

[360] *See* discussion *infra* Parts V.B., V.D.2.

[361] N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.7(a).

thereby able to tailor her care to her own unique situation.[362]

Additional issues arise when a plaintiff's family wishes to relocate. There are currently no regulations regarding payments for expenses that result from relocation. The Fund then may very well refuse to pay for environmental modifications for a new home, especially if the home they are leaving is equipped with the necessary modifications.

Residence issues are also created with respect to payment of services. If the child is not a resident of New York, or moves out of New York State, it is unclear what the reimbursement rate would be, especially if the other state's Medicaid reimbursement rates are higher than those in New York.[363] It would appear that an enrollee would not be allowed to use a higher Medicaid reimbursement rate from another state.[364] As a result, a child receiving New York rates in another state risks not having access to services. In fact, if a child who is a resident of another state is born in New York, and personal jurisdiction cannot be asserted in her home state, the child's only recourse might be to accept payment from the Fund, at New York Medicaid rates, even though her only connection to New York was her birth. The child's residence should not affect the damages recoverable. Finally, it is also conceivable that the child might live outside the U.S., and outside the reach of Medicaid providers. Forced enrollment in the Fund might preclude them from receiving care overseas.

IV. PRACTICAL DIFFICULTIES OF THE FUND

The Fund creates several practical difficulties for both the state and the enrollees who will be covered by the Fund. The most critical issue is the manner by which the Fund receives its

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[362] *Id.* § 69-10.21(b).

[363] *See* Moore & McMullen, *supra* note 26 § 17:2.4 (noting that it is unclear whether New York rates can be used while residing in Florida).

[364] Consider two twins, both injured by New York obstetric malpractice, at the same time, with identical injuries. One twin lives in a different state. This might result in the twins receiving different amounts from the Fund. *See* Moore & McMullen, *supra* note 26 §17:2.4 (questioning whether under § 69-10.22 a person who lives out of state can use New York rates). Depending on the timing of their actions, the order of their births, and the approval process for acceptance in the Fund it is theoretically possible that even if they lived in the same household, one of the twins may be covered under the Fund, and one not. *See* N.Y. PUB. HEALTH LAW § 2999-i(6) (McKinney Supp. 2012); *see also* N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.19(a).

assets, and whether it will be able to survive at over the long term. As noted previously, there are also significant issues with regard to patient's rights, such as medical privacy and access to care.

A. Funding Insufficiency

How the Fund will manage its assets, and more important whether there will be sufficient funding to fulfill its obligations, presents a major potential problem. The Fund is limited to a first year appropriation of $30 million dollars.[365] The level of future funding is based on a 1.6 percent tax on obstetrical services in New York. The amount raised in the future is unlikely to keep pace with the number of enrollees added to the Fund each year. The number of births in New York will remain relatively constant.[366] Therefore, the number of new enrollees will continue to grow, essentially doubling (or more) in the second year and increasing by a similar number each year for decades until the enrollees start to decease. As the Fund continues to get more and more enrollees, there is no way to assure sufficient funding to keep the promise that their services will be paid, and once the Fund fills up there will be no way to accept new enrollees without significantly more money. At some point the financial burden on the state may become unsustainable. In addition, new enrollees and the expenses for each enrollee are not going to remain consistent from year to year, and how the Fund is going to deal with this dilemma is unclear. Finally, the Fund is dependent not only on appropriations at the state level, but it will also likely be very sensitive to any changes in the Medicaid system.[367]

The cost of future care will be paid from the Fund.[368] It appears that the sum of $30 million that was appropriated to the Fund in the first year includes the cost of administering the Fund, and

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[365] PUB. HEALTH § 2807-d-1; Stashenko, *supra* note 28.

[366] *Table 5: Live Birth Summary by Mother's Age 2009*, N.Y. DEP'T HEALTH, http://www.health.ny.gov/statistics/vital_statistics/2009/table05.htm (last visited Feb. 29, 2012); *Table 5: Live Birth Summary by Mother's Age 2008*, N.Y. DEP'T HEALTH, http://www.health.ny.gov/statistics/vital_statistics/2008/table05.htm (last visited Feb. 29, 2012); *Table 5a: Live Birth Summary by Mother's Age 2007*, N.Y. DEP'T HEALTH, http://www.health.ny.gov/statistics/vital_statistics/2007/table05a.htm (last visited Feb. 29, 2012).

[367] *See* PUB. HEALTH § 2999-j(4); N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.20(b).

[368] PUB. HEALTH § 2999-j(6)–(7).

this cost can be contracted out privately.[369] Even the initial appropriation may be inadequate, because as described above (1) every year the number of enrollees in the Fund will increase until they start to expire in significant numbers over ensuing decades; (2) the cost to provide care for these enrollees will increase every year due to inflation;[370] (3) it cannot be known how many plaintiffs will be eligible for the Fund in any given year;[371] (4) the cost to provide care for each applicant will vary —perhaps significantly; (5) the annual cost of the Fund will be difficult to predict due to necessary up-front expenditures related to patient care such as home or vehicle modifications; and (6) the cost to administer the Fund must be covered by the Fund itself.[372]

In fact, the fiscal stability of the Fund depends on the hope that the Fund will never reach its 80 percent limit. For example, consider the scenario where the Fund starts out the year with the initial $30 million appropriation.[373] Assuming that there is a 15 percent cost of administering the Fund ($4.5 million) no new applicants can be taken into the Fund after $20,400,000 (80 percent of the balance) is spent.[374] Even if it were assumed that approximate net cost of care is only $100,000 per case per year, this is only a maximum of 204 potential plaintiffs covered.[375] Interestingly, it is estimated that the Fund could be responsible for up to 200 new applicants per year.[376] However, whatever magic number of enrollees exhausts the Fund in any given year, if the 80 percent limit is reached the Legislature would have to increase funding beyond the first year's $30 million appropriation in subsequent years merely to provide for the enrollees already in the program.[377] This is because each year the number of plaintiffs whom the Fund will be capable of covering will decrease because

369 *See id.* §§ 2807-d-1, 2999-i(2)(c); Stashenko, *supra* note 28.

370 Johnson, *supra* note 44.

371 *See* Stashenko, *supra* note 28 (noting that the care provided to an enrollee will be decided on a case by case basis and that the size of the Fund in later years will vary according to its needs).

372 PUB. HEALTH § 2999-i(3).

373 *Id.* § 2807-d-1(2).

374 *Id.* § 2999-i(6).

375 VIRGINIA BIRTH-RELATED NEUROLOGICAL INJURY COMPENSATION PROGRAM, COMPREHENSIVE ANNUAL FINANCIAL REPORT 26 (2010) (showing that the average expense per claimant is roughly 100,000 dollars). Many of these children can require care that can cost several times $100,000 per year, even excluding high front end first year costs.

376 Knipel, *supra* note 7; Stashenko, *supra* note 28.

377 PUB. HEALTH § 2999-i(6).

of inflation.[378] Depending on how many of the enrollees die in any given year, only a very small number of additional plaintiffs will ever again be covered by the Fund without an additional influx of cash. Assuming that the first year $30 million appropriation is sufficient to pay for all of the eligible enrollees in that year, in order to take in any new plaintiffs, the Legislature would likely have to appropriate more than $60 million in the following year (because of inflation), and likely more than $90 million in the year after that, increasing every year until the Fund becomes unsustainable. If such multiplying appropriations do not occur, despite even the best of intentions, there can be no assurance that future Legislatures will increase Fund appropriations sufficiently. The Fund will have to cease taking new plaintiffs forever, thus creating even more different subcategories of infants that have suffered a birth related neurological injury as a result of malpractice. Any birth injury plaintiff who is unlucky enough to be in the first cases tried or settled will be in a wholly different class of recovery from everyone else with the exact same injury and damages, and for whom the Fund will lack the assets to cover them.

The way the Fund is structured and financed, it is by no means certain that payments of future care costs will be available over an enrollee's entire lifetime. Indeed it is highly likely that they will not.[379] There was no requirement that an actuarial computation determine that the Fund would be actuarially sound in the first place (beyond the ensuing year).[380] Were there no concern about the ongoing solvency of the Fund, it would not have been necessary to include the "failsafe" of stopping enrollment when the Fund is 80 percent exhausted. Nor is there a requirement of an actuarially sound lifetime reserve for each enrollee. Rather, the Fund makes payments on a "pay as you go" basis in the same manner as does Social Security.[381] If the Fund runs out of money, or the Legislature decides to eliminate or

[378] *See* Johnson, *supra* note 44 (discussing the effects of inflation on medical costs).

[379] *See* PUB. HEALTH § 2999-i(5), (6)(a) (detailing how additional funds will need to be deposited into the Fund, and the contingency of Fund liabilities becoming larger than the amount of monies within the Fund).

[380] *See id.* § 2999-i; N.Y. COMP. CODES R. REGS. tit. 10 § 69-10.18(a) (2012) (setting out how to determine the amount paid into the fund, without mandating the process would be actuarially sound).

[381] Stashenko, *supra* note 28.

reduce funding in the future, the plaintiff may be without a remedy. It is unclear whether an enrollee will be able to go back to the original defendant or their insurer in order to get the resources necessary to obtain care. If the defendant has since gone bankrupt, or the insurance aggregate that would have been available to an initially covered plaintiff has been used, then the plaintiff may well be totally out of luck when it comes to funding future care.

B. Potential Backlogs of Enrollees and Up-Front Costs

It is also possible that the Fund will become bombarded with applicants in future years, particularly over the next several years. It was initially estimated that there are approximately 200 cases per year of obstetrical malpractice involving hypoxic injury to which the Fund would be applicable.[382] If this is accurate, then because (1) the Fund purports to apply to pending cases as well as new cases, and (2) it may take 3–4 years or more for these pending cases to be resolved, there may be as many as 800 or more pending cases with approximately 200 more coming on line each year.[383] This backlog alone, therefore, will mean that without a quadrupling of the budget allocation over the next three years–and continuing significant increases in future years–less than one out of four eligible qualified plaintiffs may be "covered" by the Fund.[384]

This computation assumes that the Fund can only expect 200 applicants per year. There is reason to believe that the Fund may be subject to many more potential enrollees. Since the Fund is now willing to accept future care costs—which in most instances is the largest component of damages—the defendant has a decreased incentive to take the risk of an adverse outcome, and may be more inclined to settle with the plaintiff and stick him in the Fund.[385] As a result, plaintiffs who have more questionable claims of liability or causation may be more likely to get a settlement from the defendant for a nominal amount of pain and suffering because the defendant knows that it will not be

[382] Knipel, *supra* note 7; Stashenko, *supra* note 28.

[383] N.Y. COMP. CODES R. REGS. tit. 10 § 69-10.2(a)(3).

[384] *See* Stashenko, *supra* note 28.

[385] *See* Knipel, *supra* note 7 ("For a severely impaired infant, lifetime benefits could easily be worth millions of dollars . . . [while the] settling defendant does not have to pay the cost for plaintiff's inclusion in the Fund, and its annual premium to finance the Fund, if any, remains unaffected.").

responsible for future care costs.[386] There is also an issue with respect to the possibility that autism, or unrelated post delivery/resuscitation malpractice occurring prior to discharge but after delivery, may be covered by the Fund.[387]

Regardless of how small the recovery for future care costs or the amount allocated to future care in a settlement, full lifetime benefits are required to be paid by the Fund.[388] Instead of diminishing the number of lawsuits, the Fund may actually increase them, and thereby contribute to its own demise as unsustainable.

It is unclear how the Fund would address actuarial reserves and pay for front end loaded upfront costs like future home renovations, or a handicapped accessible van that may be required to keep a child (and eventually an adult) at home. If these upfront costs are included, the number of enrollees who can be covered in the first year will drop significantly. Usually these big ticket items, such as handicapped accessible vehicles, or home renovations are accounted for in a life care plan on an annualized basis.[389] But if they are all required–as will likely be the case–in the first year of the Fund, the first year cost to the Fund will be much higher than the average annual cost for typical care–thus further reducing the number of new plaintiffs that the Fund can accept, both in the first year and in each subsequent year, without a significant increase in funding.

C. Dependence on Medicaid

Nor is there any assurance that Medicaid will continue to provide necessary services or funding, much less at rates that will provide the care that the court has determined are appropriate. There are currently serious proposals before Congress to transform Medicaid payments to make "block" grants to states, and the states may or may not use these grants to pay

386 *See id.* (demonstrating for questionable claims it is better to settle because plaintiff will receive millions of dollars in care over their lifetime and the defendant is less likely to resist because they do not pay any of the costs).

387 *Id. See supra* note 65; *infra* note 468.

388 *See* Knipel, *supra* note 7. Ironically, the amount of future care costs that the Fund is obligated to pay is entirely unrelated to the amount of the verdict for future care costs or settlement. Theoretically the defendant can agree to settle a birth injury claim for one dollar and bind the Fund to millions of dollars in future care costs.

389 Joel N. Morse & Jeffrey M. Siedenberg, *Transportation Expenses in Life Care Plans: An Incremental Approach*, 10 J. LEGAL ECON. 61 (2000).

Medicaid benefits as presently constituted.[390] The fact that the Fund relies on the Medicaid payment rates set at the federal level means that the Fund, and all of its enrollees, are directly affected by any changes to these rates.[391] Any changes to Medicaid rates could have a dramatic and unpredictable impact on the availability of essential care services.

D. Medical Records and Documentation

As discussed earlier, a defendant may enroll the plaintiff in the Fund and thereby escape liability to pay the cost of future care necessitated by their negligence.[392] This forced enrollment in the Fund infringes on the plaintiff's medical privacy interest, and imposes a continuing significant burden to provide extensive medical information to the Fund over her entire lifetime.[393]

The regulations require that an application include (1) "a [signed] medical release form, which shall be in compliance with applicable laws and regulations pertaining to patient confidentiality;" (2) "documentation regarding the specific nature and degree of the applicant's birth-related neurological injury or injuries, including diagnoses and impact on the applicant's activities of daily living and instrumental activities of daily living;" and (3) a life care plan.[394]

The Fund's impact on the privacy interests of the plaintiff, including any HIPPA implications, could be the topic of another paper. The most obvious question presented by the regulations is what happens when a defendant files an application to enroll the plaintiff but the plaintiff refuses to sign a medical release form. It would appear that, because acceptance into the Fund is required by the statute in order to receive any payment at all for future medical expenses, the plaintiff is required to waive his medical confidentiality to the Fund Administrator, forever.[395] In

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[390] Mary Agnes Carey & Marilyn Werber Serafini, *How Medicaid Block Grants Would Work*, KAISER HEALTH NEWS (Mar. 6, 2011), http://www.kaiserhealthnews.org/Stories/2011/March/07/block-grants-medicaid-faq.aspx (last visited Feb. 25, 2012).

[391] N.Y. PUB. HEALTH LAW § 2999-j(4) (McKinney Supp. 2012); N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.20 (2012).

[392] PUB. HEALTH § 2999-j(7); N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.2(a).

[393] *See* discussion *infra* Part V.D.4. As noted previously this may also violate HIPPA. Health Insurance Portability and Accountability Act of 1996, Pub. L. 104–191, 110 Stat. 1936 (1996).

[394] N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.2(b).

[395] PUB. HEALTH § 2999-j(7).

addition, the Fund claims that it is authorized to share this information with third parties for a variety of reasons. For example, the Fund can use the medical release to determine eligibility of the plaintiff for other governmental benefit programs (presumably to see if the Fund can reduce its own liabilities); to review the quality of care provided; to coordinate with health insurance companies; to "gather statistics and data for use in shaping public policy;" and to "determine the financial status" of the Fund.[396] Once a neurologically impaired child injured at birth is enrolled in the Fund, she will be required to "consent" to the lifetime release of her medical records, and such records will end up in any number of places beyond her control.

In addition, the documentation that an enrollee is required to submit in order to qualify under the Fund is extremely burdensome for the plaintiff to produce.[397] There is significant time, effort and cost associated with creating and updating these materials.[398] Although it is true that under most circumstances such documentation would have been created for the litigation, that is not necessarily so. Once it is recognized that a child may end up in the Fund there is less reason for plaintiff's counsel to incur the expense and effort necessary to produce these materials.[399] In a settlement situation, a higher percentage of damages allocated to future care costs would actually work against the plaintiff because it would reduce any proportion of cash that is collectable.[400] Therefore, the Fund required "life care plan" type documents will not necessarily be available to the plaintiff, who must bear the burden and cost of providing them to the Fund.

E. Plaintiff's Actual Recovery: Medicaid Liens and Attorney's Fees

Since costs awarded for future care will not be recoverable under the Fund, the plaintiff's actual cash recovery for any injury

396 NEW YORK STATE MEDICAL INDEMNITY FUND, NOTICE OF PRIVACY PRACTICES 1–2 (2012), *available at* http://www.dfs.ny.gov/insurance/mif/mif_privacy.pdf.

397 N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.2.

398 *See* JOY PRITTS, HEALTH POLICY INST. GEORGETOWN UNIV., YOUR MEDICAL RECORD RIGHTS IN NEW YORK: A GUIDE TO CONSUMER RIGHTS UNDER HIPAA, 10–12 (2005) (stating that a request for a copy of medical records could take up to 30 days and can require a fee for every copy).

399 PUB. HEALTH § 2999-j(6).

400 *Id.* § 2999-j(6)(a).

caused by medical malpractice will be limited and reduced. In fact, plaintiff's cash recovery will be reduced even further by any Medicaid liens for reimbursement of past medical expenses paid.[401] Finally, even though the plaintiff is in the Fund, her attorney still needs to get paid, and the flawed methodology for determining the attorney's fee actually creates a potential conflict of interest between the attorney and the plaintiff client.[402] Between the Fund, Medicaid liens, and attorney's fees, it is unclear whether there will be sufficient cash left for the plaintiff to make a significant impact on quality of life.

1. Medicaid Liens

In many, if not most, instances the neurologically impaired child will have been receiving Medicaid assistance up until the judgment or settlement. Medicaid is entitled to place a lien on any recovery collected by the plaintiff for the past medical expenses it paid.[403] The state, however, may not encumber any recovery beyond that expended for medical care.[404] Therefore, if there is a settlement reached between a plaintiff and a defendant for less than the amount that the entire case is worth as determined by the court or agreed to by stipulation, the state is only entitled to recover the portion of the settlement that represents compensation for past medical expenses.[405] In the case where a settlement does not provide an allocation for past medical expenses, the state can recover no more than the proportion between the amount of the claim was worth and the amount of the entire settlement.[406] This principle has come to be known as "equitable allocation."[407]

Before *Arkansas Dept. of Health and Human Services v. Ahlborn*,[408] New York law had been that Medicaid had a lien on the plaintiff's entire recovery regardless of how the recovery was apportioned.[409] Although it appears *Ahlborn* has overruled this

401 N.Y. SOC. SERV. LAW § 104-b(1) (McKinney 2003).
402 PUB. HEALTH § 2999-j(14).
403 SOC. SERV. § 104-b(1).
404 *Id.*
405 Ark. Dep't of Health and Human Servs. v. Ahlborn, 547 U.S. 268, 284–85 (2006).
406 *Id.* at 274–75, 292.
407 Morales v. N.Y.C. Health & Hosp. Assoc., 935 N.Y.S.2d 850, 851–52 (Sup. Ct. N.Y. Cnty. 2011).
408 547 U.S. 268 (2006).
409 Calvanese v. Calvanese, 710 N.E.2d 1079, 1080 (N.Y. 1999).

principle, it is unclear to what extent New York will accept or attempt to limit its holding. Some cases have embraced *Ahlborn* and have required allocation hearings to determine how much of their lien Medicaid can collect.[410] At least one case however, *Morales v. New York City Health and Hospital Assoc.*,[411] appears to limit the holding of *Ahlborn*, asserting that equitable allocation only applies when there is a "legal . . . impediment" to the plaintiff's full recovery.[412]

Although *Morales* has speculated that the Medical Indemnity Fund would qualify as such a legal impediment where equitable allocation would be appropriate, New York law, at least according to *Morales*, may not be as settled as previously thought, even before adding the additional ingredient of the Fund.[413] Regardless of whether equitable allocation is embraced, the injured plaintiff still has to satisfy a Medicaid lien with a cash recovery now further reduced by the application of the Fund and the restriction on recovery for future care costs. If equitable allocation is used in a settlement involving a qualified plaintiff, it becomes very important to determine the portion of the settlement allocated to "future care costs," which is picked up by the Fund and is not recoverable by the plaintiff, that should be counted toward the total value of the claim.[414] If equitable allocation is applied and excludes future care costs in calculating the full value of the case, then Medicaid may be able to collect a large portion of the cash available to the plaintiff.[415] This is because the cost of any past medical care received by the qualified plaintiff would represent a much greater proportion of the total value of the case, as compared to if future care costs were included into the calculation. For example, in a $50,000 settlement on what is agreed to be a $100,000 claim that excludes future care costs in the calculation would allow Medicaid to take half of their lien.[416] If the full value of the claim

410 *See, e.g.*, Homan v. Cnty. of Cattaraugus Dept. of Soc. Serv., No. 76064, 2009 WL 2751070, at 1–2 (Sup. Ct. Cattaraugus Cnty. Aug. 27 2009); Lugo v. Beth Israel Med. Ctr., 819 N.Y.S.2d 892, 895–97 (Sup. Ct. N.Y. Cnty. 2006).

411 935 N.Y.S.2d 850 (Sup. Ct. N.Y. Cnty. 2011).

412 *Id.* at 852.

413 *See id.*

414 *See* N.Y. PUB. HEALTH LAW § 2999-j(6)(a) (McKinney 2012) (stating that future medical payments shall be made in accordance with the fund/title).

415 *See Morales*, 935 N.Y.S.2d at 851 (noting that the state can only recover a Medicaid lien representing past medical expenses).

416 *See Ahlborn*, 547 U.S. at 269–70 (explaining that the state can only take a

includes future care costs, raising the value to $1 million, then a $50,000 settlement would only allow for Medicaid to collect one-twentieth of the settlement under *Ahlborn*. Either way, Medicaid will be able to take a significant portion of the limited cash available to the plaintiff.

2. Attorney's Fees

The manner in which the plaintiff's attorney gets paid in a Fund eligible case has the potential to place the attorney's interests at odds with that of his client.[417] In the case of a settlement, the Fund legislation requires that the settlement designate the percentage of the settlement that is to be attributed to future medical care.[418] Since the qualified plaintiff will not be able to actually recover any cash amount for future care, it is in the qualified plaintiff's interest to get the highest percentage of the settlement allocated to pain and suffering, rather than to future care costs.[419] When the Fund would apply to a particular settlement however, the attorney's fee for the qualified plaintiff's counsel is calculated by the full amount of the settlement, including the allocation to unrecoverable future care costs, and regardless of how the settlement is allocated.[420] The defendant pays the plaintiff's attorney for the portion of the fee attributable to future care costs while the proportion of the fee attributable to pain and suffering would come out of the plaintiff's recovery.[421] In the end however, the attorney's fee is still computed as if the Fund did not exist, even though his client can only actually recover the cash amount that is not apportioned to future care.[422] Thus, under these circumstances, the attorney's fee being computed is based on the total, even though the plaintiff will not get cash but instead a promise of future care benefits from the Fund. For fee purposes it does not matter how the allocation for future care costs is made, since it will

proportion of the settlement that represents medical expenses, where in this case the settlement was for one-sixth of damages so the state could only collect on one-sixth).

417 Robert Vilensky, *Settlement and Compromise Orders Under New Medical Indemnity Fund*, N.Y L.J., Oct. 26, 2011.

418 PUB. HEALTH § 2999-j(6)(a).

419 Vilensky, *supra* note 417.

420 PUB. HEALTH § 2999-j(14).

421 *Id.*

422 *Id.*

theoretically result in the same fee. This could result in the anomalous situation where the plaintiff's attorney receives more cash than does the plaintiff.

Another potential source of conflict results from the plaintiff's attorney's reduced incentive to dispute (and decrease) the proportion of the settlement designated for future medical care.[423] In fact, the plaintiff's attorney might tempted to demand a higher total settlement amount from defendant, but simultaneously agree that a higher percentage of that number be designated for future care costs.[424] This would tend to increase the plaintiff's attorneys fee, but does nothing to enhance the cash recovery of his client, and could actually decrease it.[425]

V. QUESTIONS OF CONSTITUTIONALITY

The foregoing discussion highlights the many difficult issues that are raised by the Fund, how it will be administered under the regulations, and how it will likely adversely impact the covered neurologically impaired children and their families. There is a much more fundamental threshold question, however, that is presented by this unprecedented drastic change in what has been hundreds of years of jurisprudence concerning damages in tort cases. Is the Fund legislation and its scheme even constitutional? The Fund, how it is to be operated, funded, and administered, and its disparate treatment of identically situated individuals raises a number of serious federal and state constitutional issues that will be considered in this section.[426] In

[423] *See* Vilensky, *supra* note 417 (explaining how negotiations with defendants could lead to a situation in which ultimately "the defendant pays less, the lawyer gets paid more and the client receives less up front money").

[424] *Id.* Of course since the defendant would have to pay the plaintiff's attorney's fee based on the amount allocated to future care cost, the defendant would have an incentive not to accommodate this request.

[425] *Id.*

[426] Many of the constitutional issues discussed in this article were raised in *Swanson v. N. Westchester Hosp. Ctr.* Plaintiffs' Affirmation in Sur-Reply at 2 Swanson v. N. Westchester Hosp. Ctr., No. 16743/2007 (N.Y. Sup. Ct. Westchester Cnty. Sept. 2, 2011). The authors are indebted to Christopher Meagher, Esq., for providing access to the motion papers in *Swanson*, as well as to Robert Peck, Esq., of the Center for Constitutional Litigation, and Anthony Maragno Esq., for their work on these constitutional issues. Some their efforts have been incorporated in this article, which, together with previous extensive constitutional analysis by the authors, forms the basis for much of the constitutional discussion presented here. *Swanson* was settled before the constitutional issues raised were decided.

summary, the Fund raises constitutional concerns regarding (1) separation of powers; (2) equal protection; (3) Article VII, Section 8 of the New York State Constitution; (4) due process; (5) the right to a jury trial; (6) the right of privacy; and (7) Article VII, Section 6 of the New York State Constitution.

A. Separation of Powers

A strong argument can be made that the Fund legislation is unconstitutional because it significantly infringes on judicial authority and function, and therefore violates the doctrine of separation of powers. It is important to observe precisely what the Fund statutory scheme does and what it does not do. This is not a situation where the legislature has limited the damages that can be determined by a jury or the court after liability is established in favor of the plaintiff. Rather, once there is a judicial finding of fact,[427] the legislative and executive branches of government are purporting to prevent the court from entering and enforcing a judgment based on the law and the facts of the case.[428] This is all without any assurance that the injured child will be accepted for coverage under the Fund, or that his full care needs as determined by the court will ever be paid by it.[429]

Article VI of the New York Constitution vests judicial authority exclusively in the courts of New York, and "mandates that the legislative and executive branches refrain from hindering the independence and proper functioning of the judicial branch."[430] As such, "[t]here are some matters which are not subject to legislative control because they deal with the inherent nature of the judicial function."[431] The court "has all powers reasonably required to enable a court to perform efficiently its judicial functions, to protect its dignity,

[427] As discussed below, the Fund may also violate the plaintiff's right to a jury trial. *See infra* Part V.E.

[428] N.Y. PUB. HEALTH LAW § 2999-j(6)(b), (13) (McKinney Supp. 2012).

[429] *Id.* N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.2 (2012). As discussed above, this can happen for one of three reasons: first, between the time that the judgment is entered and the plaintiff is considered for enrollment into the Fund —a period that could be several years with appeals and post-verdict proceedings—the Fund may have become 80 percent exhausted and not be accepting new enrollees; second, the Fund could accept the plaintiff and then run out of money; and third, the Fund may subsequently be dissolved.

[430] Maron v. Silver, 871 N.Y.S.2d 404, 414 (App. Div. 3d Dep't 2008), *aff'd*, 925 N.E.2d 899 (2010).

[431] A.G. Ship Maint. Corp. v. Lezak, 503 N.E.2d 681, 683 (N.Y. 1986).

independence and integrity, and to make its lawful actions effective."[432] Since the cases to which the Fund is applicable necessarily concerns infants and persons under disability, the statutory framework also significantly interferes with the courts' authority to act "in the best interests of the infant."[433]

The separation of powers doctrine is strictly construed, when, as here, there is an attempt to transfer judicial functions to the Executive—in this case the Fund Administrator.[434]

Critically, one of these "inherent" powers "is the power of a court to grant relief from its own judgments and processes."[435] As specifically related to the Fund legislation, the legislature is not permitted to affect the final judgment of a court, as it has "passed beyond the legislative power."[436] Yet, that is precisely what the Fund legislation purports to do by its very terms. It directs a court, contrary to the interests of an infant or impaired plaintiff, to enter a judgment that simultaneously is at variance with judicially determined facts and impairs the infant's ability to recover what he is due.

The legislature cannot

> assume the functions of the judiciary to determine controversies among citizens, or even to expound its own laws so as to control the decisions of the courts in respect to past transactions. . . . To declare what the law shall be, is a legislative power; to declare what it is or has been, is [a] judicial [power].[437]

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[432] People v. Little, 392 N.Y.S.2d 831, 834–835 (Yates Cnty. Ct. 1977), *aff'd*, 400 N.Y.S.2d 615 (App. Div. 4th Dep't 1977).

[433] *See* N.Y. C.P.L.R. § 1207 (McKinney 1972 & Supp. 2012); Sutherland v. City of N.Y., 483 N.Y.S.2d 307, 308 (App. Div. 1st Dep't 1985), *aff'd*, 488 N.E.2d 837 (N.Y. 1985);.

[434] *See* Ward Baking Co. v. W. Union Tel. Co., 200 N.Y.S. 865, 866, 873–74 (App. Div. 3d Dep't 1923) (holding that a statute granting the Attorney General the judicial power to subpoena should be construed narrowly so that only a judicial officer may impose punishment on "a witness for failure to obey an order or answer a question"); People *ex rel.* Sanford v. Thayer, 199 N.Y.S. 899, 900 (Sup. Ct. Ulster Cnty. 1923) (doubting the validity of a statute that empowers a state commission to make a determination of mental defect, which is a judicial question).

[435] Jones v. Allen, 712 N.Y.S.2d 306, 309–10 (App. Term. 2d Dep't 2000).

[436] *See* Gilman v. Tucker, 28 N.E. 1040, 1044 (N.Y. 1891) ("After adjudication the fruits of the judgment become rights of property. These rights became vested by the action of the court, and were thereby placed beyond the reach of the legislative power to affect."); People v. Keenan, 97 N.Y.S. 77, 79–81 (App. Div. 1st Dep't 1905), *aff'd*, 78 N.E. 1108 (N.Y. 1906) (holding that the legislature exceeds its power if it attempts to modify or vacate a judgment).

[437] McDonald v. Keeler, 2 N.E. 615, 623 (N.Y. 1885) (citation omitted). The Fund legislation purports to apply retroactively. *See* N.Y. PUB. HEALTH LAW

Certainly, at least with respect to the purported retroactive application of the Fund to causes of action and cases pending on April 1, 2011, and even to cases where a verdict was rendered but no judgment yet entered, it would seem that the judicial power is being invaded, contrary to the doctrine of the separation of powers.[438] Nor would there seem to be much distinction between those situations, and future cases in which the jury and the court has made a finding of liability and determined damages owed by a defendant as required by the CPLR In each instance the Legislature and the Executive can be considered to be improperly undercutting the judicial function.

Although the legislature is allowed to create procedural rules for the court, it is not allowed to interfere with the court's duties that "deal with the inherent nature of the judicial function."[439] Although the legislature may create "judicial procedures designed to relieve the court of specific categories of cases," it may not "regulate the details of the manner of performance of the court's constitutionally mandated duties."[440] Therefore, "[t]he Legislature is not vested with the power to arbitrarily provide that any procedure it may choose to declare such shall be regarded as due process of law."[441] In other words, the legislature cannot substitute the judgment of the court in a particular case by "compelling the court to perform a ministerial act."[442]

The Fund may therefore be violating the inherent authority of the judiciary by preventing a court from entering a judgment based on the findings made by the trier of fact. Actually, by prohibiting a judgment from being entered on future medical care costs, the statute purports to require that a court *not* enter a judgment specific to the facts found.[443] In what may be an even

§ 2999-j(6) (McKinney Supp. 2012); N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.2(a)(3) (2012); *infra* part V.D.5.

[438] In *Swanson*, the verdict was before April 1, 2011, but judgment had not been entered by that date. Plaintiffs' Affirmation in Sur-Reply, *supra* note 426, at 26–28; *infra* part V.D.5.

[439] A.G. Ship Maint. Corp. v. Lezak, 503 N.E.2d 681, 683 (N.Y. 1986).

[440] Comm'r of Soc. Servs. v. Roberto G., 423 N.Y.S.2d 155, 162 (App. Div. 1st Dep't 1979).

[441] Colon v. Lisk, 47 N.E. 302, 304 (N.Y. 1897).

[442] Riglander v. Star Co., 90 N.Y.S. 772, 775 (App. Div. 1st Dep't 1904).

[443] *Id.* The Fund legislation specifically directs that

Except as provided for by this title, with respect to a qualified plaintiff, no payment shall be required to be made by any defendant or such defendant's insurer for qualifying health care costs and no judgment shall be made or entered requiring that any such payment be made by any defendant or such

greater affront to judicial function and independence, the Fund legislation requires that once a "*prima facie*" showing is made that the infant plaintiff will be eligible for acceptance into the Fund, the court must modify *its* judgment to "reflect that, in lieu of that portion of the award that provides for payment of [future medical] expenses, and upon a determination by the fund administrator[,] that the plaintiff is a qualified plaintiff, the future medical expenses of the plaintiff shall be paid out of the fund."[444] It should be observed that there is no assurance that plaintiff will actually receive his judicially determined future care costs or even the care that the jury determined was necessary.

Moreover, once that judgment language is so modified, the court loses authority to enforce its own judgment and to assure that payment for services is ever made by the Fund.[445] This now becomes an executive function of the Fund Administrator, notwithstanding a judicial finding and the plaintiff's right to a judgment.[446] In fact, if the language is missing from such a judgment where the plaintiff has applied for inclusion into the Fund, the Fund Administrator is *required* to send the judgment or settlement back to the judge to add the necessary language to the judgment.[447] By requiring judges to include specific language in the judgment that the payment of future care costs be made by the Fund, at the direction of the executive branch (the Fund Administrator), and contrary to the jury and the court's finding, the Fund legislation may be viewed as breaching the doctrine of separation of powers.[448]

The Fund statute does not appear to be merely one of procedure. Rather, it directly impairs the substantive rights of the plaintiff. Without the "Fund language" in the judgment, the

defendant's insurer for such health care costs.
N.Y. PUB. HEALTH LAW § 2999-j(13) (McKinney Supp. 2012).

444 PUB. HEALTH § 2999-j(6)(b).

445 *See id.* § 2999-j(15) (stating that the superintendent of financial service and the commissioner will enforce the payment of claims and thereby vesting the power to enforce judgments requiring the Fund to pay in the hands of the executive branch).

446 *See id.* §§ 2999-i(2), 2999-j(5)–(6) (directing the court to modify its verdict in accordance with the Fund legislation and vesting the power to enforce payments out of the Fund in the hands of the commissioner and of the superintendent of financial services).

447 N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.2(d) (2012).

448 *See id.*

plaintiff is entitled to a judgment that would be enforceable against the defendant. With the language, she is beholden to the Fund to provide for the care to which she would otherwise have been entitled from the defendant under the verdict and judgment. Nor can the Fund be compared to the no fault or workers compensation statutes with respect to its interplay with judicial functioning. Those schemes substitute a remedy and eliminate a particular cause of action from the judicial process entirely, removing the obligation that the plaintiff had to prove liability.[449] Those statutes properly "relieve the court of specific categories of cases" without interfering with judicial authority.[450] In contrast, the Fund specifically invokes the courts and relies on their resources and discretion in determining liability and damages, including future care costs that results from the negligence of a defendant, and then proceeds to ignore the judgment with regard to this critical component of damages.[451]

In another possible breach of the separation of powers doctrine, the judgment that results from a verdict determining future care costs will not have the effect of *res judicata*.[452] Instead of binding the Fund Administrator to enforce the jury's finding of the nature and types of care required, the level of care, and how much will be paid for it, these questions will ultimately be decided anew by an administrative agency in the Executive Branch.[453] The Fund Administrator does not take into consideration the findings made by the court regarding future care costs.[454] In the event that the Administrator denies payment for an item that the court had previously determined was appropriately an item of damage or essential care, the plaintiff would be required to go through an administrative appeal, and if unsuccessful, back to court with an Article 78 proceeding.[455] This

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449 N.Y. WORKERS' COMP. LAW § 10 (McKinney Supp. 2012); N.Y. INS. LAW § 5104 (McKinney 2011).

450 Comm'r of Soc. Serv. v. Roberto G., 423 N.Y.S.2d 155, 162 (App. Div. 1st Dep't 1979).

451 PUB. HEALTH § 2999-j(6); N.Y. C.P.L.R. § 5031(d) (McKinney 2007).

452 *Id.* § 2999-j(6).

453 *See id.*

454 *See id.* § 2999-j; N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.5–.6 (2012) (explaining the pre-approval process for payment for services rendered, and the possible denial of payment for certain services by the Fund).

455 *See* C.P.L.R. § 7801. Under an Article 78 Proceeding, the burden shifts to the plaintiff to show that the denial of services was without rational basis instead of the Fund Administrator bearing the burden to show that he was complying with the court's previous finding. *See id.* § 7803 (showing that the

would be despite the fact that such denial of services may have involved an item of damage that the plaintiff had already successfully litigated.

Finally, the right to "judicial review" of a Fund denial of services underscores the separation of powers issue, as well as the denial of the right to a jury trial, the lack of fundamental fairness, and the lack of finality of a judicial determination. Consider this scenario: the plaintiff gets a judgment that enumerates or effectively incorporates various components and costs of future care. The Fund Administrator is then free to ignore this finding and make his or her own determination of the services to be provided and can deny approval of services even if they were inherent or specifically found necessary by the court.[456] The plaintiff then must go through an internal administrative appeal and the hearing officer can only recommend—not determine, but only recommend—reversal of the denied services.[457] The Fund Administrator then gets another opportunity to adopt or ignore the hearing officer's finding and maintain the denial of the services that the plaintiff already succeeded in persuading the court was necessary in the first instance.[458] The plaintiff must then seek judicial review, and in order to succeed, now instead of a preponderance of evidence standard, she must show that there was no rational basis for the Commissioner's decision—merely to get back what she already won in court at the trial.[459] The burden of proof has completely shifted to the plaintiff and the standard to succeed has been raised much higher than it was before. The Fund gets four bites at the apple. First by ignoring the jury's finding and starting afresh to deny services. Second, by the hearing officer's recommendation that that the denial of services be maintained.[460] Third, the Commissioner is entitled to ignore a recommendation of a hearing examiner that the requested services be approved, and thus the Commissioner can maintain

plaintiff must raise the question that the Fund was in abuse of discretion or made a completely arbitrary finding).

[456] *See* N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.6.

[457] *Id.* § 69-10.15(k).

[458] *Id.* § 69-10.15(l).

[459] C.P.L.R. § 7803(3)–(4); 1A N.Y. PATTERN JURY INSTRUCTIONS, *supra* note 105, at § 1:23.

[460] N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.15(k).

the denial.[461] Finally, in order to reverse the Commissioner's denial the plaintiff must go to court and demonstrate that the Commissioner's decision denying benefits was "arbitrary and capricious" or without rational basis. This puts the plaintiff to an enormous burden of proof, and even if the Article 78 proceeding is successful, she has undergone significant delay and expense.[462]

Finally, the Fund eliminates a court's power to modify a verdict "if it deviates materially from what would be reasonable compensation" as to future medical costs. In doing so it upsets the power of the Appellate Division to review such verdicts where "it is contended that the award is excessive or inadequate and that a new trial should have been granted."[463]

By requiring a court, therefore, to enter a judgment at variance with the facts of a case–and the law of damages—as the jury found and applied them, a strong argument could be made that the Fund unconstitutionally interferes with judicial sovereign authority and thus violates the doctrine of separation of powers.

B. Equal Protection

The Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution, and the Equal Protection Clause of the New York State Constitution (Article I, section 11) similarly provide that no one is to be denied "the equal protection of the laws."[464] Although the state may make reasonable classifications between people, the classifications must bear some rational basis to the disparate treatment.[465] It cannot treat identically situated people differently without violating the state and federal equal protection clauses.[466]

Children who have suffered a neurologic impairment as a result of negligent care at the time of birth are treated vastly differently than others who have been injured by another mechanism or were injured only a few days after birth. Thus—even after getting a verdict and establishing their legal entitlement to a recovery—birth injured children must not only

[461] *Id.* § 69-10.15(l).
[462] C.P.L.R. § 7803(3)–(4).
[463] C.P.L.R. § 5501(c); Seidner v. Unger, 667 N.Y.S.2d 384 (App. Div. 2d Dep't 1997).
[464] U.S. CONST. amend. XIV, § 1; N.Y. CONST. art. I, § 11.
[465] Neale v. Hayduk, 316 N.E.2d 861, 862 (N.Y. 1974).
[466] U.S. CONST. amend. XIV, § 1; N.Y. CONST. art. I, § 11.

suffer a reduced recovery but surrender a panoply of rights.[467] Their rights are irrationally reduced, and in some cases eliminated as compared to (a) persons injured by nonmalpractice tortfeasors; (b) children injured by nonbirth injury malpractice tortfeasors; and (c) *even as between obstetric malpractice victims* with identical injuries and damages, an arbitrarily determined group of those who by poor timing are enrolled while the Fund is not suspended because it has not run out of funds.[468] Those excluded from the Fund because enrollment has been suspended when 80 percent of the Fund has been exhausted will get their full measure of damages and get to make their own health care decisions, while those forced into the Fund before it runs out of money, will not.[469] Likewise, the Fund discriminates amongst defendants and their insurers who—after the Fund is exhausted—will have to pay directly.[470] When a judgment is rendered or a settlement reached, it is a lottery as to whether the plaintiff will be limited to the Fund or if the defendant must pay the full amount of damages for future care.[471]

When addressing a claim that there is a violation of the Equal Protection Clause under both the federal and state constitutions,

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[467] *See infra* Part V.D.2–4 (discussing for example, children forced into the Fund suffer a loss of medical privacy, restriction to travel, and the right to make fundamental health care decisions).

[468] N.Y. PUB. HEALTH LAW §§ 2999-g–2999-j (McKinney Supp. 2012). Consider these possibilities. Each of two twins is diagnosed with a medical condition unrelated to delivery and resuscitation. One is deemed well enough to be discharged from the hospital and the other remains. Within a few days, both require identical treatment to remedy the situation. The one remaining in the hospital would arguably be covered under the Fund whereas the one that is discharged and returns from care would not, even with the identical malpractice and the same outcome and injury. What if one twin is transferred to another hospital for specialized care, creating a new admission? Is she covered by the Fund? What if the malpractice is in negligently discharging the child from delivery admission? Would this child be covered by the Fund? These scenarios may expand the Fund's obligations well beyond that which was anticipated.

[469] *Id.* § 2999-i(6)(b).

[470] *Id.*

[471] The same is true even after a child is accepted into the Fund. It is unclear what would happen if the Fund is exhausted or terminates. Although the regulations speak in terms of continuing benefits, there is no assurance that such will take place. Under those circumstances the plaintiff may be entitled to full compensation, and the defendant may be obligated to pay it. These represent yet another arbitrary and unpredictable class of identical plaintiffs and defendants against whom the Fund statute irrationally discriminates.

the applicable standard of review must first be determined.[472] As discussed below, the plaintiff's fundamental freedom to travel and her right to a trial by jury may be compromised by the way the Fund operates.[473] The right to travel is implicated because the Fund's reimbursement scheme limits payment for most services at New York Medicaid rates, and requires providers to accept Fund payments. These restrictions severely limit the rights of these children to seek care, or reside outside of New York State. The right to a jury trial is implicated because it is explicitly granted by the New York State Constitution.[474]

The strict standard of review applies to any fundamental right explicitly or implicitly protected by the Constitution.[475] Under an equal protection analysis the "freedom to travel" is a fundamental right and subjects the Fund's statutory mechanism to "strict scrutiny."[476] "In order to withstand strict scrutiny, the law must advance a compelling state interest by the least restrictive means available."[477] "[L]egislation which deprive[s], infringe[s], or interfere[s]" with a fundamental right, requires "strict scrutiny" even if such right is not completely abridged.[478]

Since New York State cannot require out of state providers to accept payments from the Fund or at New York Medicaid rates, the care available to children who live outside New York but remain in the Fund, will likely be limited. Even though both the statute and regulations assert that the residence of the plaintiff will not impact his "right" to receive benefits, in fact, the operation of the Fund severely impairs this right to any enrollee seeking care outside the state for the simple reason that their providers cannot be required by New York to accept Fund payments, much less at New York Medicaid rates.[479]

Even if the state has a compelling interest "to reduce premium

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[472] Alevy v. Downstate Med. Ctr., 348 N.E.2d 537, 542 (N.Y. 1976).

[473] *See* discussion *infra* Part V.D.2.

[474] *See* N.Y. CONST. art. I, § 2.

[475] San Antonio Indep. Sch. Dist. v. Rodriguez, 411 U.S. 1, 17 (1973); People v. Fox, 669 N.Y.S.2d 470, 474 (Nassau Cnty. Ct. 1997).

[476] United States v. Guest, 383 U.S. 745, 757 (1966); *Alevy*, 348 N.E.2d at 543.

[477] Bernal v. Fainter, 467 U.S. 216, 219 (1984); Aliessa v. Novello, 754 N.E.2d 1085, 1094 (N.Y. 2001); *Alevy*, 348 N.E.2d at 543.

[478] *San Antonio Indep. Sch. Dist.*, 411 U.S. at 37–38 (internal quotations omitted).

[479] N.Y. PUB. HEALTH LAW § 2999-j(11) (McKinney Supp. 2012); N.Y. COMP. CODES R. REGS. tit. 10 § 69-10.22 (2012).

costs for medical malpractice insurance coverage," it may not do so by arbitrarily discriminating between identically situated groups of individuals harmed by malpractice.[480] Pervasive social issues such as protecting children from harm and ensuring the public health are considered compelling interests.[481] Reducing malpractice insurance premiums or Medicaid costs, however desirable, would not appear to constitute a "compelling" interest sufficient to justify a denial of equal protection.

If the right to travel and the right to a jury trial are not considered, then a rational basis analysis will need to be applied because it is possible that handicapped children may not constitute a "suspect class."[482] However even if a court were to utilize a "rational basis" analysis it would appear that the Fund violates the Equal Protection Clauses of the New York and federal constitutions. The Fund treats obstetric malpractice victims differently from persons injured by every other type of medical provider, and does so without any rational relationship to a legitimate governmental purpose.[483] A statute fails rational basis when it "is so unrelated to the achievement of any combination of legitimate purposes that we can only conclude that the [statute] was irrational."[484] As discussed in more detail below, the use of public coffers to lower the cost of medical malpractice premiums is not likely to be a legitimate governmental purpose in the first place. The avowed goal of reducing malpractice insurance premiums certainly cannot be applicable to cases already litigated, or claims for which premiums have already been paid, as is the case with the purported retroactive application of the Fund statute. Retroactive application can only constitute a windfall to

480 PUB. HEALTH § 2999-g.

481 *See* New York *ex rel.* Wayburn v. Schupf, 350 N.E.2d 906, 908 (N.Y. 1976); *In re.* Lauren L., 912 N.Y.S.2d 732, 735 (App. Div. 3d Dep't 2010); Schulman v. N.Y.C. Health & Hosp. Corp., 355 N.Y.S.2d 781, 784–85 (App. Div. 3d Dep't 1974); City of New York v. New St. Mark's Baths, 497 N.Y.S.2d 979, 982 (Sup. Ct. N.Y. Cnty. 1986).

482 Matter of Levy, 345 N.E.2d 556, 558 (N.Y. 1976); *In re* Bd. of Educ. of Northport-East Northport Union Free Sch. Dist. v. Ambach, 458 N.Y.S.2d 680, 688 (App. Div. 3d Dep't 1982).

483 As noted elsewhere, even some birth trauma malpractice plaintiffs will be fully compensated once 80 percent of the Fund is exhausted, and some will be perpetually stuck in the Fund–purely by virtue of the time within the fiscal year that their case is finally resolved. PUB. HEALTH § 2999-i(6)(b).

484 Kimel v. Fla. Bd. of Regents, 528 U.S. 62, 83–84 (2000); Affronti v. Crosson, 746 N.E.2d 1049, 1052 (N.Y 2001).

malpractice insurance carriers, who having been paid the premium commensurate with the risk assumed, are no longer obligated to pay the damages for which the premiums were charged. Even if the Fund does indeed lower malpractice costs for future care, it does so by rationing the care that the court determined was required. Thus the burden of reducing malpractice premiums is borne solely by the injured children who have proven that they were harmed by malpractice at birth. There is good reason, therefore, to believe that the Fund will fail the rational basis test as well.

C. Article VII, Section 8

In order to understand how the Fund legislation runs afoul of Article VII, Section 8 of the New York State Constitution, it is critical to recall exactly what the Medical Indemnity Fund legislation does. After the plaintiff succeeds in getting a final judicial determination that a health care provider negligently caused a neurologic impairment that requires future care costs, the defendant is entirely relieved from what would otherwise be his obligation to pay for these costs.[485] *Such obligation is transferred to the state, which pays off what would be the obligation of the defendant judgment debtor*. The state is therefore assuming the private debt obligation of the defendant and paying for the plaintiff's future care costs with state funds appropriated by the Legislature.[486] Although it may be hoped that the obstetric services tax will raise enough money to support Fund obligations there is no way to predict, much less assure, that such tax will match the Fund payments required.[487] Nor does it change the fact that this is a tax, and that state funds will always be required to relieve the private defendant of what otherwise would be a judgment debt. Even though the "quality contribution" will be placed in the Health Care Reform Act Resources Fund (HCRA), any money received by the HCRA Fund is still subject to control by the legislature through appropriation.[488] If the tax does not raise enough money to

485 PUB. HEALTH § 2999-j(6).

486 *Id.* §§ 2807-d-1, 2999-i(5); Moore & McMullen, *supra* note 26, at § 17:2.4.

487 Moore & McMullen, *supra* note 26, at § 17:2.4.

488 N.Y. STATE FIN. LAW § 92-dd (McKinney); PUB. HEALTH § 2807-d-1(3); OFFICE OF THE N.Y.S. COMPTROLLER, FUND CLASSIFICATION MANUAL 16, 47 (2011); Stashenko, *supra* note 28.

support the Fund there are one of two consequences: either the Legislature will have to appropriate sufficient additional general revenues to support the Fund, or the Fund will cease to take in new enrollees and/or default on making payments to current enrollees. On the other hand, in the unlikely event that the tax on obstetric services raises more money than the Fund currently needs, the state gets to keep the money to use for general state purposes.[489] It is indisputable, therefore, that state tax dollars are being used to pay off a portion of a private judgment in favor of a private individual against another private individual or corporation.

This has significant state constitutional ramifications. Article VII, Section 8 of the New York State Constitution provides that "[t]he money of the state shall not be given or loaned to or in aid of any private corporation or association, or private undertaking."[490] It would seem however, that this is precisely what the Fund legislation does. The Fund does not provide for the general payment to obstetric malpractice victims, or subsidize obstetric or hospital malpractice premiums, but rather pays off a portion of a specific judgment (at a reduced rate) to a private plaintiff, on behalf of a private defendant, thereby relieving him of a payment obligation.[491] No matter how laudable the asserted purpose to lower malpractice premiums or reduce Medicaid payments, it would appear that the Fund legislation is a clear violation of Article VII, Section 8.[492]

Article VII, Section 8 of the New York Constitution was enacted to "curb raids on the public purse for the benefit of

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[489] *See* PUB. HEALTH § 2807-d-1(2); COMPTROLLER, *supra* note 488, at 16, 47 (outlining how moneys are placed within New York's general fund and what the sources of income are under the Health Care Reform Act). It is not as though this has never happened before. In fact, the state has a history of taking monies from programs designed to help control medical malpractice premiums. *See Med. Malpractice Ins. Ass'n*, N.Y. LIQUIDATION BUREAU, http://www.nylb.org/mmia.htm (last modified Aug. 4, 2009); CONSUMER FED'N OF AM.,TESTIMONY OF J. ROBERT HUNTER, DIRECTOR OF INSURANCE BEFORE THE N.Y. DEP'T OF HEALTH MEDICAID REDESIGN TEAM: MEDICAL MALPRACTICE REFORM WORKING GROUP 3 (Oct. 27, 2011) [hereinafter HUNTER TESTIMONY], *available at* http://www.consumerfed.org/pdfs/Testimony%20NY%20MM.pdf.

[490] N.Y. CONST. art. VII, § 8 (McKinney).

[491] PUB. HEALTH § 2999-j(6), (13).

[492] To the extent that the Fund applies to pending cases, it cannot lower premiums, since they have already have been paid. This windfall to malpractice insurance companies—who have collected premiums for claims that they will never have to pay— may also be considered a "gift" of state funds to a private corporation in violation of Article VII, Section 8.

favored individuals or enterprises."[493] In *Wein v. State*,[494] the Court of Appeals considered the constitutionality of the state legislature's appropriation of funds to a municipality, and chronicled the history of this provision and its importance.[495] In *Wein*, the court noted that prior to the enactment of the predecessor to what is now Article VII, Section 8, the state had subsidized private railroad and canal companies and had not been repaid.[496] As a result, what is now Article VII, Section 8 was adopted.[497]

Wein was a "taxpayer's action" in which the plaintiff challenged the appropriation of state funds to the City of New York, which was at the time in a financial crisis.[498] The Court of Appeals held that the use of state funds for this purpose was proper, *but only because the City of New York is a public corporation*.[499] That is clearly not the case here where—no matter how "laudable" the claimed "public purpose" of this legislation—state funds are being used to make payments to a private individual, by paying a portion of a judgment of a private defendant for the benefit of a private defendant and/or private malpractice insurer.

The plain language of Article VII, Section 8, which was adopted in 1938, provides that none of the state's "money" shall be given to "any private corporation or association, or private undertaking."[500] The Court of Appeals has described the clear and unmistakable mandate of this provision:

> Subsidization by gifts of public funds to private undertakings, or by pledging public credit on their behalf, [is] banned, irrespective of how beneficent or desirable to the public the subsidized activity might seem to be. And this remains so even when the subsidized private organization performs functions beneficial to the public.[501]

In short, appropriating funds for the benefit of "a non-governmental entity"—exactly what is being done here by using

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493 Teachers Assoc., Cent. High Sch. Dist. No. 3 v. Board of Ed., Cent. High Sch. Dist. No. 3, 312 N.Y.S.2d 252, 254 (App. Div. 2d Dep't 1970).

494 347 N.E.2d 586 (N.Y. 1976).

495 *Id.* at 588.

496 *Id.* at 588–89.

497 *Id.*

498 *Id.* at 586.

499 *Id.* at 586–87.

500 N.Y. CONST. art. VII, § 8(1).

501 Schultz v. New York, 654 N.E.2d 1226, 1230 (N.Y. 1995) (citations omitted).

state funds to "pay" a portion of a private judgment—is forbidden, regardless of the intent or purpose of the appropriation.

In *Schultz v. New York*,[502] a "citizen taxpayer" commenced an action against Governor Mario Cuomo and the Governor's campaign committee, known as The Friends of Mario M. Cuomo Committee, Inc., for using state funds to publish a newsletter entitled "The Voice of the New, New York."[503] The plaintiff claimed that this document, which portrayed a one-sided viewpoint of welfare reform—a hot political issue at the time—was published only "to serve the individual and private purposes of Governor Cuomo."[504] The court held "that the document transgresses the constitutional boundary."[505] The court explained that under the constitution it is "unassailable that the use of public funds out of a state agency's appropriation" could not be used for what was clearly Governor Cuomo's private political purpose.[506] The court also distinguished the facts of this case from a situation where public funds were appropriated for a proper purpose, such as by "conveying information" or to "educate the public."[507] Significantly, however, the court also stated that Article VII, Section 8(1) applies "even when the subsidized private organization performs functions beneficial to the public."[508]

In *People v. Grasso*,[509] the Attorney General sought to prosecute a cause of action under the not-for-profit corporation law against Richard Grasso, the former Chairman of the New York Stock Exchange, for allegedly receiving "excessive compensation" during his tenure.[510] The First Department held that the cause of action must be dismissed because the New York Stock Exchange was at the time of the lawsuit a private corporation.[511] Thus, "the sole relief sought is the recovery of money that belongs to the for-profit entity and would inure to its

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502 654 N.E.2d 1226 (N.Y. 1995).
503 *Id.* at 1228.
504 *Id.* at 1230 (citing Complaint at 55 Schultz v. New York, 654 N.E.2d 1226 (N.Y. 1995) No. 6843-92).
505 *Id.* at 1231.
506 *Id.* at 1230.
507 *Id.* at 1230–31.
508 *Id.* at 1230.
509 861 N.Y.S.2d 627 (App. Div. 1st Dep't 2008).
510 *Id.* at 631, 656.
511 *See id.* at 639–41.

benefit and the private parties."[512] This use of public funds violated Article VII, Section 8 of the state constitution.[513] More specifically, in its decision the First Department stated:

> Here, the Attorney General is using public funds out of appropriations to his office to prosecute causes of action on behalf of an entity that is no longer a not-for-profit corporation and seeks only a money judgment that would benefit the owners of the for-profit entity into which the not-for-profit has been converted (even if the judgment nominally would be paid to the not-for-profit corporation). The Attorney General's continued prosecution of these causes of action . . . vindicates no public purpose.[514]

That is precisely what is happening under the Fund. A judgment by a private individual against a private physician is being "paid" at a discount with state tax funds.

Recently in *Bordeleau v. New York*,[515] the Court of Appeals revisited the restrictions set forth in Article VII, Section 8. *Bordeleau* was a taxpayer action in which the court examined whether state appropriations granted to the State Department of Agriculture and Markets (DAM) to advertise and promote New York agricultural products violated Article VII, Section 8.[516] This funding was procured for the benefit of non-profit apple and winery associations.[517]

After explaining the long history behind Article VII, Section 8, the Court of Appeals in a five to two vote upheld the state's appropriations to these public benefit associations as constitutionally valid.[518] The court determined that the plaintiff taxpayer had failed to meet its burden to establish that the appropriations were unconstitutional.[519] It held that the state may under limited circumstances directly give funding to private parties, *but only if there is "a predominant public purpose and any private benefit is merely incidental."*[520] Judge Pigott and Judge Smith both vigorously dissented from the majority,

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[512] *Id.* at 631.

[513] *Id.* at 639–41.

[514] *Id.* at 641.

[515] 960 N.E.2d 917 (2011).

[516] *Id.* at 918–19. In *Bordeleau*, the court also examined how Article VII Section 8 applied to public benefit corporations. The court determined that public benefit corporations, as independent entitles separate from the state, are not subject to Article VII § 8. *Id.* at 921–23.

[517] *Id.* at 918–19.

[518] *Id.* at 919–24.

[519] *Id.* at 919–20, 922–24.

[520] *Id.* at 923 (emphasis added).

proclaiming that the "predominant public purpose" test made it "hard to see what is left of the constitutional prohibition."[521]

It would appear that the decision and reasoning in *Bordeleau* can be readily distinguished from an Article VII, Section 8 challenge to the Fund. Although the Fund legislation asserts that the "purpose of the fund is to provide a funding source for future health care costs associated with birth related neurological injuries, in order to reduce premium costs for medical malpractice insurance coverage," as we have seen, that is not how the Fund operates.[522] Perhaps a state subsidy to physicians or hospitals to reduce their malpractice premium payments might withstand scrutiny, but clearly that is not what is occurring here. A judgment against a particular tortfeasor is being paid in part by the state. The public is not receiving the primary benefit—a private tortfeasor and/or a private insurer is getting the entire benefit by having its judgment debt paid by the state. Unlike in *Bordeleau*, neither of these purely private parties to a particular lawsuit represents an entire industry—only private entities within that industry that the state has singled out in a particular individual case. In addition, such judgments will be paid only until the Fund is 80 percent exhausted.[523] Thus some defendants' judgments will be paid, and some will not. This is hardly a manifestation of a public use of funds for a public purpose. Instead, the Fund exclusively benefits a small group of private defendants under very isolated and limited circumstances. *Bordeleau*, *Schultz*, and *Grasso* all support this notion.

In *Bordeleau*, the free advertising provided by the DAM was for the benefit of an entire industry, as opposed to any individual producer.[524] The court explained that the legislature could fairly consider the well-being of the apple and winery industries as in

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[521] *Id.* at 924–27 (Pigott, J., dissenting).

[522] N.Y. PUB. HEALTH LAW § 2999-g (McKinney Supp. 2012). The Fund does not even advance its stated purpose. First, the Fund does not apply to lower "malpractice premiums" in general, but rather applies only to malpractice premiums for a small subclass of plaintiffs and defendants—obstetricians and hospitals where babies are delivered. *Id.* § 2999-j(6). Second, application of the law to current cases cannot reduce malpractice premiums because premiums for pending cases have already been paid. N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.2(a)(3) (2012). This creates a windfall for private insurers in existing cases, but not to the defendants who paid the premiums.

[523] PUB. HEALTH § 2999-i(6).

[524] *Bordeleau*, 18 N.E.2d at 923.

the public interest, and that funding for advertising in promoting the industry furthered this public purpose.[525] *Bordeleau* did not really have the element of a definite, tangible, nonincidental benefit to a specific private party that is clearly present in this setting.[526] The funding provided was directed at interest groups that represented the industry as a whole.[527] The analogue under *Bordeleau*, as may be applied to the Fund, would be if the state decided to use its Funds to reimburse a private apple grower for advertising the unique aspects of the apples on his or her farm. It is difficult to believe that such a program would have prevailed in *Bordeleau*. Yet that is what the state is doing here: using its funds to pay off a portion of a unique judgment in favor of a birth injured child with unique care needs for the specific and sole benefit of an individual tortfeasor who caused that harm.

Both *Schultz* and *Grasso* contained an element of an individualized benefit, and it is clear from those cases that the appropriation in *Bordeleau* surely would not have survived had it been provided to one individual apple farmer rather than to the entire industry. *Schultz* involved a governor who used public monies for a newsletter that, in the opinion of the court, was primarily of value as partisan propaganda.[528] The governor and his party were seen to have benefitted from the public allocation, in that they received favorable press from public monies not available to political competitors.[529] *Grasso* involved an attorney general who, in seeking a money judgment that would only be recoverable by a for-profit entity, violated Article VII, Section 8 because the tangible benefit from any positive result would have been realized by the private entity.[530] The prosecution undertaken by the Attorney General essentially picked out one particular, individual private entity, and provided them the benefit of public labors with regard to one specific individual occurrence.[531] This is exactly what is occurring under the Fund.

The Fund picks out specific private entities who would benefit from the public coffers to the exclusion of others in the industry, and requires that a private entity actually owe a specific

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525 *Id.* at 919, 922–23.
526 *Id.* at 923.
527 *Id.* at 919, 922–23.
528 Schultz v. New York, 654 N.E.2d 1226, 1231 (N.Y. 1995).
529 *Id.* at 1230–32.
530 People v. Grasso, 861 N.Y.S.2d 627, 641 (App. Div. 1st Dep't 2008).
531 *Id.*

obligation resulting from an individual occurrence in order to realize any tangible benefit.[532] The way the Fund is set up to operate, the only tangible benefit accrues to individual private entities who have actually been found to have committed medical malpractice that resulted in a birth related neurological injury, and have been subjected to a judgment for future care damages.[533] This places the Fund far closer to the facts in *Schultz* and *Grasso* rather than it does *Bordeleau*, and even in *Bordeleau* there were two dissenters.

Unlike *Bordeleau*, which subsidized advertising for an entire industry, the Fund does not subsidize physicians or hospitals in general.[534] Only those providing obstetrical services, and even then, ironically, only the ones who have been found to have negligently caused a birth related neurologic injury in a specific case.[535] It is difficult to imagine anyone that would have less of a "public" purpose to be served—a specifically identified private health care provider who has been judicially determined to be negligent and caused significant permanent harm to a particular infant. Another Fund analogue to *Bordeleau* would be that if instead of using taxpayer funds to promote apple crop marketing, state money was used to pay a specific judgment in favor of a plaintiff injured by E-coli from the negligence of a single grower. It would seem that under this scenario, *Bordeleau* would not have been decided the same way

Finally, the fact that the Fund receives a portion of its allocated monies from a tax on hospital revenues from in-patient obstetrical services does not alter the foregoing discussion.[536] Even though there will be a tax in place that will, in theory, provide assets for the Fund, the money the Fund will actually receive is still subject to an appropriation by the legislature.[537] Monies collected from hospital obstetrical income will be deposited into the Health Care Reform Act Resources Fund (HCRA Fund), and the legislature will appropriate money from the HCRA Fund into the Fund.[538] In the past, the legislature has

[532] N.Y. PUB. HEALTH LAW § 2999-j(6)-(7) (McKinney Supp. 2012).
[533] *Id.*
[534] *See id.* § 2999-j(6)-(7).
[535] *Id.*
[536] *Id.* § 2807-d-1(1).
[537] *Id.* § 2807-d-1(3); COMPTROLLER, *supra* note 488, at 16, 47.
[538] N.Y. STATE FIN. LAW § 92-dd(b), (c), (e) (McKinney Supp. 2012); PUB. HEALTH § 2807-d-1(3); COMPTROLLER, *supra* note 488, at 16, 47; Stashenko,

collected money in the name of reducing medical malpractice premiums, only to raid the fund and use it for general state purposes. In 1975, the legislature created the Medical Malpractice Insurance Association (MMIA) to increase the availability of malpractice insurance.[539] The MMIA had to shut down in 2000, partially because the legislature kept raiding the MMIA to use its funds for general state purposes.[540] Between 1992 and 1997, the state took $691 million from the MMIA, and none of this sum was repaid.[541] There is no reason to think that the monies received from hospitals for the Fund would not be subject to the same risks.

Using state funds to pay portion of a private judgment, therefore, would appear to violate Article VII, Section 8 of the New York State Constitution.

D. Due Process

The Fifth and Fourteenth Amendments to the U.S. Constitution prohibit the taking of liberty and property without "due process" and just compensation.[542] Similarly, Article I, Section 6 of New York State Constitution provides that "no person shall be deprived of life, liberty or property without due process of law."[543] Article I, Section 7 of the New York State Constitution prohibits the taking of property for a public purpose without just compensation.[544] The Fund legislation, and the manner in which the Fund is set up to operate, presents a number of potential due process issues.[545]

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supra note 28.

539 N.Y. LIQUIDATION BUREAU, *supra* note 489.

540 *See id.* ("MMIA ceased writing policies effective June 30, 2000."); HUNTER TESTIMONY, *supra* note 489, at 3 (explaining that the state did not refund large sums taken from MMIA reserves in the 1990's).

541 HUNTER TESTIMONY, *supra* note 489, at 3.

542 U.S. CONST. amends. XIV, § 1, V.

543 N.Y. CONST. art. I, § 6.

544 *Id.* art. I, § 7(a). Ironically, if, in order to avoid the application of Article VII, Section 8 of the New York Constitution, the state were to claim that the restrictions on the recoveries of obstetric malpractice victims were for a "public" instead of a "private" purpose, they would run afoul of the just compensation requirements by impairing the plaintiff's right to recovery.

545 It is important to consider both the federal and state constitutions. Even though the language of each is virtually identical, New York's constitutional protections cannot be less than those provided by the U.S. Constitution—but state provisions may be interpreted by the state courts as providing greater protection. *See* State v. Cline, 617 N.W.2d 277, 285 (Iowa 2000), *abrogated on*

First, the Fund legislation may be depriving the plaintiff of a vested property interest in a fully litigated verdict, judgment, or settlement without just compensation. Second, by requiring her providers to accept payment from the Fund at New York Medicaid rates, the state may be impairing the plaintiff's fundamental right to freely travel and reside in venues where payment by the Fund would not be accepted, and cannot be compelled. Third, since the Fund claims the right to make health care services determinations that could limit the care chosen by the plaintiff, she might be deprived of her fundamental right to make health care decisions in order to obtain the best possible care that is specialized to her needs, and which a jury may have already determined is required. Fourth, given that the plaintiff has been involuntarily forced into the Fund, the Fund might violate the plaintiff's fundamental right to medical and personal privacy by requiring her—as a condition to receiving the care determined by a court—to give *lifetime* access to her medical, educational, insurance, and other personal information.[546] Finally, by purporting to retroactively apply the Fund to causes of action that have accrued, to actions already pending at the time that the Fund legislation was enacted, and even to cases in which a verdict has been rendered in favor of the plaintiff but not yet converted into a judgment, the Fund might violate the federal and/or state Due Process Clauses.

The purpose of the Due Process Clause is not "only to ensure abstract fair play to the individual," but also "to protect his use and possession of property from arbitrary encroachment—to minimize substantively unfair or mistaken deprivations of property, a danger that is especially great when the state seizes goods simply upon the application of and for the benefit of a private party." [547] "[T]he guaranty of due process . . . demands

other grounds by State v. Turner, 630 N.W.2d 601 (Iowa 2001) (explaining that while a state court may not interpret its "Constitution to provide *less* protection than that provided by the U.S. Constitution, the state court is free to interpret [its] constitution as providing *greater* protection for [its] citizens' constitutional rights").

[546] Griswold v. Conn., 381 U.S. 479, 485 (1965) (acknowledging "zone[s] of privacy created by several fundamental constitutional guarantees"). Does this requirement also violate HIPPA? Health Insurance Portability and Accountability Act of 1996, Pub. L. 104–191, 110 Stat. 1936 (1996).

[547] Fuentes v. Shevin, 407 U.S. 67, 80–81 (1972); Mark N. v. Runaway Homeless Youth Shelter, 733 N.Y.S.2d 566, 569 (N.Y. Fam. Ct. Chautauqua Cnty. 2001).

only that the law shall not be unreasonable, arbitrary, or capricious, and that the means selected shall have a real and substantial relation to the object sought to be attained."[548] A law that discriminates arbitrarily, without a "reasonable and just relation" to a "real and substantial distinction," violates due process.[549] The discrimination against some—but not necessarily all—infants who have proven that they have been harmed by malpractice at birth as compared to other tort victims, may therefore violate the Due Process Clauses as well as deny equal protection. This is particularly so when the manner in which the Fund is applied and the rights taken from these children are considered.

In addition, "[t]he fundamental requirement of due process is the opportunity to be heard 'at a meaningful time and in a meaningful manner.'"[550] The "very essence of civil liberty certainly consists in the right of every individual to claim the protection of the laws, whenever he receives an injury. One of the first duties of government is to afford that protection."[551] Specifically, the legislature cannot, "without violence to the constitutional guaranty of 'due process of law,' suddenly set aside all common law rules respecting liability . . . without providing a reasonably just substitute."[552] An infant who is forced into the Fund has been deprived of these rights because she is obligated to pursue an administrative remedy after she has already proven her entitlement to a remedy at common law.[553] The Fund is not a reasonably just substitute for her remedy because, in addition to the reasons discussed above, by taking away her money judgment she may be deprived from receiving the care that she feels is most appropriate for her unique needs.[554] Instead, the Fund replaces this money judgment for future medical care,

[548] Nebbia v. N.Y., 291 U.S. 502, 510–11 (1934); Spielvogel v. Ford, 136 N.E.2d 856, 857–858 (N.Y. 1956); Defiance Milk Prod. Co. v. Du Mond, 132 N.E.2d 829, 830 (N.Y. 1956).

[549] Hotel Ass'n. of N.Y. v. Weaver, 144 N.E.2d 14, 19 (N.Y. 1957) (quoting S. Ry. Co. v. Greene, 216 U.S. 400, 417 (1910)); Cluett, Peabody & Co., Inc. v. J.W. Mays, Inc., 170 N.Y.S.2d 255, 261 (App. Div. 2d Dep't 1958) (citing *Nebbia*, 291 U.S. at 510–11), *aff'd*, 161 N.E.2d 223 (N.Y. 1959).

[550] Mathews v. Eldridge, 424 U.S. 319, 333 (1976) (quoting Armstrong v. Manzo, 380 U.S. 545, 552 (1965)).

[551] Marbury v. Madison, 5 U.S. 137, 163 (1803).

[552] New York Central R.R. Co. v. White, 243 U.S. 188, 201 (1917).

[553] N.Y. PUB. HEALTH LAW § 2999-j(7) (McKinney Supp. 2012).

[554] *See id.*

which she has already proven to a jury, with care that the Fund deems necessary for her, and which may be inadequate or underfunded.[555]

1. Vested Right to Money Judgment

The Due Process Clauses prohibit a "taking" or deprivation of property without just compensation.[556] In this setting, after the plaintiff receives a verdict, the cause of action has been proven and damages determined: "The plaintiff's right to be made whole becomes fixed when the verdict holding the defendant liable is rendered."[557] All that is necessary to convert that verdict into a judgment for money damages is the essentially ministerial act of converting that verdict into a judgment. Indeed, the Legislature and the courts specifically recognize that the plaintiff's property rights to the amount of the verdict are established at that time by providing for interest on that amount between the time of the verdict, and the entry of judgment.[558]

It is clear that a money judgment creates a vested property interest that is constitutionally protected by the Due Process Clause. By forcing an infant plaintiff to take part in the Fund upon an application by the defendant, and thereby eliminating her ability to recover a significant part of the amount of damages determined by the court, the state may be depriving an infant plaintiff of her vested property interest in any judgment or settlement to which she had been entitled.[559] This is in contrast to "tort reform" in other states, which limits the plaintiff's recovery of damages, or schemes such as Workers' Compensation, where the plaintiff trades off his tort recovery for a certainty of payment.[560] Here, the property right has already been determined by a court—and then taken away without any compensation for the loss, that is, the difference between the judgment (and the rights and flexibility that inure with it) and the promise of payment solely for those services that the Fund determines are appropriate.

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555 *Id.*

556 U.S. CONST. amends. V, XIV, § 1; N.Y. CONST. art. I, § 7.

557 Love v. State, 583 N.E.2d 1296, 1298 (N.Y. 1991).

558 N.Y. C.P.L.R. § 5002 (McKinney 2007).

559 PUB. HEALTH § 2999-j(6)–(7); Andree *ex rel.* Andree v. Nassau Cnty., 311 F.Supp. 2d 325, 335 (E.D.N.Y. 2004).

560 *See* FLA. STAT. ANN. § 766.118 (West 2012) (legislation limiting damages available to patient); N.Y. WORKERS' COMP. LAW § 10 (McKinney 2012).

Not only has a taking occurred, but such taking is being utilized for a private purpose—relieving a private defendant from paying a judgment obligation. A taking cannot occur against a private individual for an "incidental or colorable benefit to the public."[561] It is simply a transfer of funds from plaintiffs who have established their right to them, to private judgment debtors—doctors, nurses, hospitals and malpractice insurers—who are relieved from paying such damages.

It would appear, therefore, that the Fund may violate the Due Process Clause prohibition against taking property without either just compensation or a public purpose.[562]

2. Freedom to Travel

As discussed in the analysis of the denial of equal protection, the freedom to travel is a fundamental constitutional right.[563] "The right to travel is a part of the 'liberty' of which the citizen cannot be deprived without the due process of law under the Fifth Amendment."[564] The Fund legislation may violate both the due process and equal protection clauses, because an enrollee may be deprived of her right to travel independently from any discrimination on the part of the state. It would appear that the manner in which the Fund operates would impair the ability of a child and her family either to reside outside of New York State or obtain care outside of the state.[565]

The Fund requires that "[a]ll health care providers shall accept

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561 N.Y.C. Hous. Auth. v. Muller, 1 N.E.2d 153, 156 (N.Y. 1936).

562 Nor do the projected numbers even add up. Although some project that the Fund will reduce malpractice costs by $320 million, assuming 200 infant enrollees per year, the Fund would have to save about $1.6 million per infant, *every year*, in order to make that number. Since the annual cost of care for each child is far less that amount, it is hard to imagine how this computation was made. The more tangible benefit of the Fund actually goes to private hospitals and insurance companies, where the burden of providing future care for infant victims of malpractice falls to the state. More specifically, the system as set up actually benefits hospitals that are more prone to malpractice. With the state picking up the tab, there is no incentive for these hospitals with high rates of malpractice to improve the quality of their care. Even if a public benefit is assumed, it is hard to imagine such a benefit to the public being more than incidental to the benefit enjoyed by obstetricians, hospitals and insurance companies. Knipel, *supra* note 7, at 2–3.

563 U.S. v. Guest, 383 U.S. 745, 757 (1966); Alevy v. Downstate Med. Cntr., 348 N.E.2d 537, 543 (N.Y. 1976); *see* discussion *supra* Part V.B.

564 Kent v. Dulles, 357 U.S. 116, 125 (1958).

565 PUB. HEALTH § 2999-j(11).

from qualified plaintiff's [sic] or persons authorized to act on behalf of such plaintiff's assignments of the right to receive payments from the fund for qualifying health care costs."[566] This completely ignores the very real possibility that a health care provider outside of New York may not agree to treat an enrollee because the provider does not want to deal with the bureaucracy of the Fund, or does not want to accept New York Medicaid rates.[567] It would appear that a New York State law cannot require health care providers outside of the state to accept payment from the Fund. This will inherently impair the right of a Fund enrollee to either reside outside of New York or seek care in another jurisdiction.[568] As discussed above, an enrollee can physically travel or reside outside of New York, but not without severe restrictions to their access to medical care, because out-of-state health care providers will not necessarily accept the New York reimbursement rate, or the Fund's bureaucracy.[569] In *Swanson* referred to in this article, for example, the infant plaintiff's treating physicians were in Connecticut.[570]

By taking health care decisions away from the plaintiff and by potentially limiting her treatment and care to New York, not only does this provision limit the ability of in state residents to leave New York, but the Fund could also fail to provide an out of state resident with the necessary care to which they would be entitled. For example, if an out of state resident gave birth while passing through New York, she could be subject to the Fund if she cannot obtain jurisdiction over the defendant in her home state.[571] The freedom to travel "require[s] that all citizens be free to travel throughout the length and breadth of our land uninhibited by statutes, rules, or regulations which unreasonably burden or

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[566] *Id.* § 2999-j(11).

[567] *Id.*

[568] *Id.* (requiring out of state health care providers to accept payment from the Fund, which, practically speaking, may prevent a plaintiff from leaving the state of New York since out of state providers have no legal obligation to accept payment from the Fund).

[569] *Id. See* N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.22 (2012); Given the Fund regulation's restrictions on access to transportation and the limitations on providing a handicapped accessible vehicle, even the physical or financial ability to travel to get care is open to question. *See* N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.8, .12.

[570] Plaintiffs' Affirmation in Sur-Reply, *supra* note 426, at 14.

[571] The Medical Indemnity Fund does not deny coverage to out of state residents so long as their injuries are sustained while in New York. *See* N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.22.

restrict this movement."[572] As discussed above, the right to travel is a fundamental right, and any interference with such a right is subject to strict scrutiny, requiring a compelling government interest that is narrowly tailored.[573] States cannot infringe upon the freedom to travel by denying a traveler's "basic necessities of life."[574] Medical care, including nonemergency medical care, is in fact quite properly considered to be a basic necessity of life.[575] Under this standard of review, the Fund would appear to have difficulty passing constitutional muster.

When a plaintiff receives a judgment for future care damages, she is entitled to take those damages and use them to obtain care anywhere she may choose.[576] This portability is important because it allows her to travel wherever is necessary to receive the best care available. Under prior law, if the child were to have to move out of New York for any reason, or if they were actually a resident of another state, she would be able to use the recovery to receive the care that a jury found to be appropriate.[577] Under the Fund, however, the infant plaintiff is not entitled to recover such damages or to spend them as she chooses. In order for the infant plaintiff to receive care, the Fund requires that the health care provider accept the assignment of payment from the Fund, and all of the Fund's bureaucratic requirements that go along with it.[578] This provision is to ensure that all providers accept payment from the Fund, most of which is at Medicaid rates.[579] As discussed previously, an out-of-state provider cannot be forced to accept payment from New York, and if an out-of-state provider does not want to have to deal with the Fund, the infant plaintiff who seeks treatment from such provider is just out of luck.

Therefore, the result is that the infant plaintiff is forced to accept care that is effectively limited to New York—even if the Fund approves all of the requested services. Instead of getting paid in cash, the state essentially forces the plaintiff to accept what is the equivalent of a gift certificate that would force her to

572 Shapiro v. Thompson, 394 U.S. 618, 629 (1969).

573 Memorial Hosp. v. Maricopa Cnty., 415 U.S. 250, 262, 269 (1974); *Shapiro*, 394 U.S at 634.

574 *Memorial Hosp.*, 415 U.S. at 269.

575 *Id.*

576 *See* N.Y. C.P.L.R. §§ 5031, 5041 (McKinney Supp. 2012).

577 *See id.*

578 N.Y. PUB. HEALTH LAW § 2999-j(11) (McKinney Supp. 2012).

579 *See id.*

keep coming back again and again to the same store, whether or not the service was adequate, and even if she moves thousands of miles away from it. For a neurologically impaired child who lives or decides to move out of state or seek care there, the Fund cannot guarantee that out of state providers would accept payment from the Fund and such care may therefore become unavailable. If a neurologically impaired child or his family should choose to live outside New York, or seek care outside the state, the Fund may provide little, if any care benefit to him, thus effectively forfeiting the future care component of his recovery. This is the inevitable result of eliminating the plaintiff's right to recover damages for future care and replacing it with the Fund's managed care system, in which care can only be "guaranteed" in New York—and even then only by providers who will agree to accept Medicaid reimbursement rates and the Fund's other restrictions. Instead of being able to collect and manage funds for future care, she is obligated to receive a lifetime of whatever care the Fund chooses to give her. Since the Fund cannot promise her that it will provide her own unique "basic necessities of life," or even medical care that she may require to survive, if she were to leave the state—the Fund would appear to violate or at least significantly infringe the constitutional right to freedom of travel.[580]

3. Right to Make Health Care Decisions

In addition to impairing the right to live outside the state of New York, the Fund may also create due process issues by restricting the ability of infant plaintiff and her parents to make private health care decisions. Such decisions are fundamental constitutional rights that go to the very core of liberty and even life itself. A judgment granted to an infant plaintiff in a malpractice case for future care costs is valuable to the plaintiff as a means for her to obtain the specialized care that she needs, and to maximize her quality and length of life in a manner that is best suited for her. As described above, in order to invoke strict scrutiny, it is only necessary that the state creates "legislation which deprive[s], infringe[s], or interfere[s]" with such a right.[581] The U.S. Supreme Court has recognized that "it cannot now be

[580] *Memorial Hosp.*, 415 U.S. at 269.

[581] Washington v. Glucksberg, 521 U.S. 702, 720 (1997); San Antonio Indep. Sch. Dist. v. Rodriguez, 411 U.S. 1, 37–38 (1973).

doubted that the Due Process Clause of the Fourteenth Amendment protects the fundamental right of parents to make decisions concerning the care, custody, and control of their children."[582] By taking away the right to be paid the damages required for future care, and the inherent freedom to make health care choices that comes with it, the Fund legislation is effectively denying the family the right to choose their care, and even more disturbingly, the care that was deemed appropriate by a jury. This raises serious due process concerns.

The Fund is distinguished from a benefit program where a person voluntarily applies for and accepts benefits, and thereby subjects themselves to the conditions and limitations of that program. Rather, the Fund is a mandatory, involuntary substitution where the Fund makes future care decisions instead of the family using the funds owed to it as a result of a jury finding that such care was required.[583] The "care" and "benefits" provided by the Fund should not be seen in the same light as Medicaid, which sets the floor for the most basic care needs. The Fund is replacing a plaintiff's right to the care that a court has determined she was entitled.[584] The Fund and its limitations and restrictions on care is the complete antithesis of the fundamental right to make health care decisions and thereby, would appear to violate the plaintiff's due process rights in this regard as well.

The Fund has an inherent conflict of interest arising from its need to keep care costs down in order to remain solvent. As a result, the most expensive and essential components of an infant plaintiff's care all require prior approval by the Fund.[585] The application process for approval is tedious, requiring multiple bids and evaluations regarding efficiency.[586] If the Fund denies the request, and the infant plaintiff fails to meet the increased standard in order to reverse the denial in court, she will be denied even those services that the jury determined were appropriate.[587]

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582 Troxel v. Granville, 530 U.S. 57, 66 (2000).

583 PUB. HEALTH § 2999-j(6).

584 *Id.* at § 2999-j (2), (3), (6).

585 N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.6(a) (2012).

586 *Id.* §§ 69-10.2, .7(g)–(h).

587 N.Y. C.P.L.R. § 7803 (McKinney 2008); PUB. HEALTH § 2999-j(6)–(7); Knipel, *supra* note 7. Whatever is "saved" by rationing care under the Fund is coming directly out of the care being provided to innocent children who were the victims of malpractice. If in fact it were true that the child would be getting the same care as without the Fund, there would be no savings at all. There

Where the Fund does not exclude care altogether, it limits the availability of care by only allowing payment at Medicaid rates for goods and services.[588] For example, even if the Fund accepts a prior approval request for private duty nursing, it is debatable whether the enrollee will be able to find caretakers willing to work at Medicaid rates. In addition, several provider organizations have already come out against the Fund, claiming that payment at Medicaid rates not only limits their ability to make care accessible, but also prevents them from providing an adequate quality of care.[589] There is already evidence that care provided at Medicaid rates has a negative impact on patient care, and can even reduce the life expectancy.[590] In the absence of the Fund the plaintiff had the right to choose her care and, if necessary, to pay higher rates to acquire needed care. Instead, the Fund denies her this right and even requires her to ask permission to acquire the kinds of care that are necessary for the patient, simply because they are expensive.[591] This raises serious due process issues as well.

4. Right to Privacy

Another fundamental constitutional liberty right that is protected by the Due Process Clauses is the right to personal privacy.[592] Unfortunately, the manner in which the Fund operates vitiates these rights, as well. As a condition of receiving benefits under the Fund, the plaintiff is required to provide a medical authorization waiving medical confidentially to the Fund Administrator *for the rest of her life*.[593] Since the Fund is entitled to require payment from School Districts and or private health insurance carriers before the Fund pays, it would also appear that they will assert the right for authorizations waiving the child's confidentiality from these sources as well.[594]

certainly can be no claim that the Fund will be more efficient in managing care, which requires permanent administrative costs. *See* PUB. HEALTH § 2999-i(3) ("The expense of administering the fund . . . shall be paid from the fund.").

588 N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.20.

589 Bergen et al., *supra* note 82.

590 Bisgaier & Rhodes, *supra* note 231, at 2324; Harrington et al., *supra* note 230, at 1105; Hakim & Buettner, *supra* note 232.

591 N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.6.

592 Griswold v Conn., 381 U.S. 479, 484–86 (1965).

593 N.Y. COMP. CODES R. REGS. tit. 10 § 69-10.2(b); NOTICE OF PRIVACY PRACTICES, *supra* note 396; *see* discussion *supra* Part IV.B.

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This would seem to be a fundamental infringement on individual privacy, extending over a lifetime. As discussed above, the Fund is critically different than someone applying for governmental benefits, and who is obligated to agree to various conditions in order to receive such benefits. Nor is this equivalent to requiring a personal injury plaintiff to waive medical confidentiality. In the latter instance, the plaintiff initiated the action, and the defendant is entitled to the plaintiff's medical information to confirm the validity of his injury.[595] Even then, such medical authorization expires after the lawsuit is determined.[596] In contrast, under the Fund the authorization and loss of medical confidentiality does not even start until after the validity of the medical condition and entitlement to future care damages has been established to the satisfaction of a court. In order to get care under the Fund, the loss of medical privacy extends *forever*.[597]

Thus, in addition to involuntarily depriving the plaintiff of the judgment amount that would enable her to make her own health care decisions, the state is also compelling her to waive all medical confidentiality for the rest of her life.[598] The Fund has apparently recognized that it cannot effectively ration care without this information.[599] The innocent neurologically impaired malpractice victim, therefore, is not only subjected to losing her right and ability to make health care decisions, but will be subjected to rationed care, and as a condition to getting even that, will be obligated to waive medical confidentiality as long as she lives. This infringement on privacy should be sufficient by

INDEMNITY FUND APPLICATION 1–2, *available at* http://www.dfs.ny.gov/insurance/mif/mif_application.pdf.

595 Koump v. Smith, 250 N.E.2d 857, 861 (1969).

596 *See id.*

597 *See* N.Y. COMP. CODES R. & REGS. tit. 10 § 69-10.2(b)(1), (2) (noting that the release of confidential health information to the Fund is provided when patients are eligible to apply for enrollment, which usually is not until the court-approved judgment can be submitted with the application). As noted previously this requirement may also violate HIPPA. Health Insurance Portability and Accountability Act of 1996, Pub. L. 104–191, 110 Stat. 1936 (1996).

598 N.Y. PUB. HEALTH LAW § 2999-j(1), -j(4), -j(8)(a), -j(12) (McKinney Supp. 2012) (showing that the plaintiff is deprived of the judgment amount because an administrator of the Fund is the one who determines what qualifying health care costs will be paid by the Fund, and which costs require payment from other sources, like private health insurance); *see* discussion *supra* Part IV.B.

599 *See* NOTICE OF PRIVACY PRACTICES, *supra* note 396.

itself to raise serious due process concerns.

5. Retroactive Application

As discussed above, the Fund legislation unprecedentedly purports to apply to all cases in which a judgment was not entered prior to April 1, 2011.[600] This would purport to deprive a plaintiff of the right to obtain full recovery of damages for future care costs in cases (a) where the cause of action has accrued but the plaintiff has not yet sued; (b) where the case has been commenced but not reached a trial verdict, and (c) even where there was a verdict prior to April 1, 2011 but no judgment had been entered.[601] The claim could also be made that the Fund applies to settlements agreed to by the parties prior to April 1, 2011, but which had not been approved by the court by that date.[602] To the extent that this legislation may be applied to pending cases that have not yet ripened into judgments, there is a concern that retroactive application may be an unconstitutional taking–and at least violate New York laws of statutory construction.

Section 53 of NY Statutes (McKinney's Vol. 1) provides: "A statute generally will not be applied retroactively where it would deprive one of a substantial right, or affect antecedent rights."[603] The Comment to this section notes:

> As a general rule, a statute will not be applied retroactively where it would, in effect, deprive one of a substantial right, or affect, or interfere with, antecedent rights, or impose an unexpected liability, at least in the absence of an unequivocal expression in the statute that the Legislature intended that the statute should have such effect. So, a preexisting right or liability, whether or not it is

600 2011 N.Y. Sess. Laws ch. 59 § 52 (McKinney); N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.2(a)(3). When there had been prior legislation to limit the recoveries of plaintiffs in malpractice cases they were applied prospectively to actions that had not yet been commenced. *See*, *e.g.*, 2003 N.Y. Sess. Laws ch. 86 §§ 1–2 (McKinney).

601 PUB. HEALTH § 2999-j(7); N.Y. COMP. CODES R. & REGS. tit. 10, § 69-10.2(a) (noting the requirement that a person may only apply for enrollment in the Fund if he or she has a judgment for a claim or action issued on or after April 1, 2011).

602 *See* N.Y. PUB. HEALTH LAW § 2999-j(7); N.Y. COMP. CODES R. & REGS. tit. 10 § 69-10.2(a)(3). Indeed in the *Swanson* case referred to, the verdict was reached many months before April 1, 2011, but post trial motions delayed entry of a judgment until the effective date of the Fund legislation. Plaintiffs' Affirmation in Sur-Reply, *supra* note 426, at 26–28.

603 N.Y. STATUTES § 53 (McKinney 1971).

> constitutionally protected from change, will not be affected by legislation, unless legislative intent to the contrary is obvious. The doubts, if any, will be resolved in favor of holding the subsequent statute to be prospective only. Nonprocedural statutes will not be interpreted as retroactive unless the Legislature clearly intends such interpretation, and where the effect of a statute is to create a right of action which did not previously exist, it is presumed that the statute was intended to have only prospective application.[604]

In *Knapp v. Consolidated Rail Corp.*,[605] a case addressing the possible retroactive application of changes to the Workers' Compensation Law in New York, the court ruled on the issue of whether a cause of action for contribution was a vested right, and the principle of applying statutory changes to causes of action prospectively only.[606] The court stated: "[W]hile the *quantum* of [a cause of action for] contribution may be inchoate, the right to seek contribution itself is vested."[607] Any attempt to eliminate this vested right retroactively "would constitute an unconstitutional taking."[608]

Under the reasoning of *Knapp*, the Fund may not retroactively apply to cases that had been initiated before April 1, 2011, and perhaps even causes of action that had accrued but had not yet been granted a judgment. Just as *Dole v. Dow Chemical Co.*[609] granted a vested right to seek contribution, the right to seek recovery of future care costs is established by statute.[610] The Fund disrupts this vested right by eliminating the ability to recover future care damages. Juries are still required to make determinations regarding future care costs, but the Fund removes the right of the plaintiff to recover that determined sum.[611] When the plaintiff is required to prove his future care damages and obtains a verdict establishing his entitlement to them, and then is deprived of the right to such recovery, it is hard to imagine a more compelling example of the unlawful impairment of a vested right. The right to seek prove future

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604 *Id.* § 53 cmt.

605 Knapp v. Consol. Rail Corp., 655 N.Y.S.2d 732, 733 (Sup. Ct. Albany Cnty. 1997).

606 *Id.* at 735, 736.

607 *Id.* at 734.

608 *Id.* at 735.

609 282 N.E.2d 288 (N.Y. 1972).

610 N.Y. C.P.L.R. §§ 4111(d), 5031(d) (McKinney 2007).

611 N.Y. PUB. HEALTH LAW § 2999-i(6)(a) (McKinney Supp. 2012); C.P.L.R. § 4111(d).

damages is rendered worthless without the right to recover them from the defendant. [612] Thus, it may well be that the purported retroactive application violates the Due Process Clause by creating an unconstitutional taking.

E. Denial of Jury Trial

Both the New York State Constitution and the CPLR guarantee the right of a trial by jury.[613] Clearly that provision of the New York constitution is applicable to a claim for medical negligence and therefore, the plaintiff in such an action is constitutionally entitled to a determination of liability and damages by *a jury*–and not by the Fund Administrator.[614]

By its terms, the Fund cannot even apply unless a suit has been filed, and all of the litigation steps through and including appeal are followed.[615] "The assessment of damages in a personal injury action is primarily a factual determination to be made by the jury, and is accorded great deference . . . ."[616] The Fund statute only applies after a verdict determining future care cost damages is decided and judgment is rendered, and still requires that the plaintiff prove to the jury the basic elements of liability, as well as future damages, including care costs.[617]

It would appear that the plaintiff's right to a jury trial may be violated by the Fund legislation because after liability, causation, and damages for future care costs are determined by the jury, such future care cost determinations are not considered, and in fact they are completely ignored by the Fund. As discussed previously, the plaintiff is then required to apply for—and may be denied—the very care that the jury determined was required.[618] Thus, the Fund replaces the jury's determination of

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[612] In addition, it is difficult to discern how retroactive application can reduce malpractice premiums that had already been paid for the claims in existence. Retroactive application simply constitutes a windfall to liability insurers who collected premiums for risks that they will never have to pay if retroactivity is upheld.

[613] N.Y. CONST. art. I, § 2; C.P.L.R. §§ 4101, 4104, 4113.

[614] *See* Treyball v. Clark, 483 N.E.2d 1136, 1137 (N.Y. 1985) (stating that for a medical malpractice claim, a plaintiff has a constitutional right to a meaningful jury trial).

[615] *See* PUB. HEALTH § 2999-j(6).

[616] Lolik v. Big V Supermarkets, Inc., 698 N.Y.S.2d 762, 763 (Sup. Ct. N.Y. Cnty. 1999).

[617] PUB. HEALTH §§ 2999-i(6), 2999-j(6).

[618] N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.6–13 (2012).

damages, and instead promises future care that may or may not require prior approval from the Fund and that the Fund may lack the resources to provide. If the Fund denies the care requested by the enrolled plaintiff, there is no reason to think that the enrolled plaintiff will ever receive the actual future care services as determined by the jury. To that extent, the Fund Administrator acts as a "super jury." Instead of the negligent defendant paying for the plaintiff's future medical care as assessed by a jury, the plaintiff's health insurance will pay for many aspects of her care.[619] As for the expensive needs of the plaintiff that are not likely to be covered by her insurance, she will require prior approval from the Fund to get payment.[620] All of this potentially violates the plaintiff's right to a jury trial and the right to enforce the right to collect damages as determined by the jury—whose verdict with respect to future care has become entirely irrelevant by the Fund.

F. Article VII, Section 6

The Fund legislation was inserted as part of the bill approving the New York State budget. Article VII, Section 6 of the New York State Constitution prohibits substantive legislation to be part of the budget: "No provision shall be embraced in any appropriation bill submitted by the governor or in such supplemental appropriation bill unless it relates specifically to some particular appropriation in the bill, and any such provision shall be limited in its operation to such appropriation."[621] When proposing Article VII legislation, "a Governor should not put into such a bill essentially nonfiscal or nonbudgetary legislation."[622] The Legislation creating the Fund—and more importantly it as relates to this constitutional restriction—which takes away the substantive rights to a birth trauma malpractice victim to obtain his full measure of damages, the ability to make health care choices, the freedom to travel, etcetera—was passed as part of the 2011 New York State Budget.[623] It is clear that the Fund legislation does not deal solely with fiscal matters, but rather, for the most part, with substantive and procedural rights of the

619 PUB. HEALTH § 2999-j(3).
620 N.Y. COMP. CODES R. REGS. tit. 10, § 69-10.6–13.
621 N.Y. CONST. art. VII, § 6.
622 Pataki v. Silver, 824 N.E.2d 898, 909 (N.Y. 2004).
623 2011 N.Y. Sess. Laws ch. 59 (McKinney); *see supra* Part V.D.2–4.

plaintiff in a civil action, which are clearly not necessary for the appropriations to the Fund.[624] It would appear, therefore, that this legislation violates the restriction set forth in Article VII, Section 6 of the New York State Constitution prohibiting substantive law matters from being enacted through a budget bill.

VI. CONCLUSION

As detailed in this article, the Fund legislation raises a number of serious questions with respect to its constitutionality. In addition there are a number of practical difficulties in the administration of the Fund that have either not been considered by the Fund regulations, or were considered and ignored. By infringing on the ability of judges to enforce their judgments after a full trial, and allowing an executive agency to override the findings of a jury and the court, the Fund may violate the doctrine of separation of powers. Also, by using public funds to pay a portion of a judgment against a private defendant, the Fund legislation may run afoul of Article VII, Section 8. The operation of the Fund also raises multiple due process and equal protection issues where the rights of some—but not all—children who suffered a birth related neurological injury are being singled out and required to take part in a managed care system in which no other malpractice plaintiff is required to participate. Finally, the funding mechanism as well as the obligations that have been promised, raises serious questions about the long term financial viability of the Fund, and whether the Fund can actually care for its enrollees over the long term.

It is also likely that the care that these children receive will be rationed and reduced—creating long-term health and quality of life issues. Although the Fund was theoretically created to control medical malpractice costs, to the extent that it can accomplish this goal it can only do so by limiting the care available to these children, with potential adverse consequences to their quality of life and longevity. The Fund ultimately places its enrollees in a situation that is not much better than Medicaid, paying for services at Medicaid rates, and requiring prior approval for most critical services. Even though the statute seems to imply that prior approval requests are supposed to be

[624] Moore & Gaier, *supra* note 6, at 2–3.

the exception rather than the rule, the reality is that the most expensive and necessary care that would be required, such as environmental modifications, a van for transportation, private duty nursing, and enteral nutrition, would each require an extensive approval process and could end up being limited or denied. It would seem at a minimum, that an innocent child who has been harmed by the wrongful acts of another—even if the tortfeasor is a health care professional—should be at least be entitled to get the care that was necessitated by such negligence and not have her care rationed by the state. Yet the Fund has taken away that right, and it would appear inevitable that there will be a constitutional challenge to the Fund legislation that could well lead to it being invalidated.

Therefore, either because of a successful constitutional challenge, or the likely need for significantly increased funding, it is difficult to see how this Fund will remain in place over the next decade. In the meantime, unfortunately a significant number of innocent children and their families will be adversely impacted by this experiment.

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SB 879 – Maryland Infant Lifetime Care Trust

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A New, Evidence-based Estimate of Patient Harms Associated with Hospital Care

John T. James, PhD

Objectives: Based on 1984 data developed from reviews of medical records of patients treated in New York hospitals, the Institute of Medicine estimated that up to 98,000 Americans die each year from medical errors. The basis of this estimate is nearly 3 decades old; herein, an updated estimate is developed from modern studies published from 2008 to 2011.

Methods: A literature review identified 4 limited studies that used primarily the Global Trigger Tool to flag specific evidence in medical records, such as medication stop orders or abnormal laboratory results, which point to an adverse event that may have harmed a patient. Ultimately, a physician must concur on the findings of an adverse event and then classify the severity of patient harm.

Results: Using a weighted average of the 4 studies, a lower limit of 210,000 deaths per year was associated with preventable harm in hospitals. Given limitations in the search capability of the Global Trigger Tool and the incompleteness of medical records on which the Tool depends, the true number of premature deaths associated with preventable harm to patients was estimated at more than 400,000 per year. Serious harm seems to be 10- to 20-fold more common than lethal harm.

Conclusions: The epidemic of patient harm in hospitals must be taken more seriously if it is to be curtailed. Fully engaging patients and their advocates during hospital care, systematically seeking the patients' voice in identifying harms, transparent accountability for harm, and intentional correction of root causes of harm will be necessary to accomplish this goal.

Key Words: patient harm, preventable adverse events, transparency, patient-centered care, Global Trigger Tool, medical errors

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"All men make mistakes, but a good man yields when he knows his course is wrong, and repairs the evil. The only crime is pride."— Sophocles, Antigone"

Medical care in the United States is technically complex at the individual provider level, at the system level, and at the national level. The amount of new knowledge generated each year by clinical research that applies directly to patient care can easily overwhelm the individual physician trying to optimize the care of his patients.[1] Furthermore, the lack of a well-integrated and comprehensive continuing education system in the health professions is a major contributing factor to knowledge and performance deficiencies at the individual and system level.[2] Guidelines for physicians to optimize patient care are quickly out of date and can be biased by those who write the guidelines.[3–5] At the system level, hospitals struggle with staffing issues, making suitable technology available for patient care, and executing effective handoffs between shifts and also between inpatient and outpatient care.[6] Increased production demands in cost-driven institutions may increase the risk of preventable adverse events (PAEs). The United States trails behind other developed nations in implementing electronic medical records for its citizens.[7] Hence, the information a physician needs to optimize care of a patient is often unavailable.

At the national level, our country is distinguished for its patchwork of medical care subsystems that can require patients to bounce around in a complex maze of providers as they seek effective and affordable care. Because of increased production demands, providers may be expected to give care in suboptimal working conditions, with decreased staff, and a shortage of physicians, which leads to fatigue and burnout. It should be no surprise that PAEs that harm patients are frighteningly common in this highly technical, rapidly changing, and poorly integrated industry. The picture is further complicated by a lack of transparency and limited accountability for errors that harm patients.[8,9]

There are at least 3 time-based categories of PAEs recognized in patients that are or have been hospitalized. The broadest definition encompasses all unexpected and harmful experience that a patient encounters as a result of being in the care of a medical professional or system because high quality, evidence-based medical care was not delivered during hospitalization. The harmful outcomes may be realized immediately, delayed for days or months, or even delayed many years. An example of immediate harm is excess bleeding because of an overdose of an anticoagulant drug such as that which occurred to the twins born to Dennis Quaid and his wife.[10] An example of harm that is not apparent for weeks or months is infection with Hepatitis C virus as a result of contaminated chemotherapy equipment.[11] Harm that occurs years later is exemplified by a nearly lethal pneumococcal infection in a patient that had had a splenectomy many years ago, yet was never vaccinated against this infection risk as guidelines and prompts require.[12]

METHODS

The approach to the problem of identifying and enumerating PAEs was 4-fold: (1) distinguish types of PAEs that may occur in hospitals, (2) characterize preventability in the context of the Global Trigger Tool (GTT), (3) search contemporary medical literature for the prevalence and severity of PAEs that have been enumerated by credible investigators based on medical

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records assessed by the GTT, and (4) compare the studies found by the literature search.

Types of PAEs

The cause of PAEs in hospitals may be separated into these categories:

- Errors of commission,
- Errors of omission,
- Errors of communication,
- Errors of context, and
- Diagnostic errors

These distinctions are important because investigators searching for preventable harm must be aware of what they can find and what they cannot find. The easiest error to detect in medical records is an error of commission. This occurs when a mistaken action harms a patient either because it was the wrong action or it was the right action but performed improperly. For example, the patient may need his gall bladder removed, but during the surgery, the intestine is nicked, and the patient develops a serious infection, such as was alleged to be the cause leading to the death of Representative John Murtha. Errors of omission can be detected in medical records when an obvious action was necessary to heal the patient, yet it was not performed at all. For example, a patient may need a β-blocker, but because it was not prescribed, the patient died prematurely.[13] Errors of omission because of failure to follow evidence-based guidelines are much more difficult to detect, partly because there are many complex guidelines and also because adverse consequences of failure to follow guidelines may be delayed until after discharge.[14,15]

Errors of communication can occur between 2 or more providers or between providers and patient. One example of a lethal error of communication between provider and patient occurred when cardiologists failed to warn their 19-year-old patient not to run. The patient had experienced syncope while running, and 5 days of inpatient, diagnostic testing were inconclusive; however, his cardiologists knew he was not ready to return to running but failed to warn him against this risk. Having not been warned against running, he resumed running and died 3 weeks later while running.[15]

Contextual errors occur when a physician fails to take into account unique constraints in a patient's life that could bear on successful, postdischarge treatment. For example, the patient may lack the cognitive ability to comply with a medical treatment plan or may not have reasonable access to follow-up care.[16] Diagnostic errors resulting in delayed treatment, the wrong treatment, or no effective treatment may also be considered separately, although a small subset of these might be included as errors of commission or omission. For example, a diagnostic error may lead to harm from errors of commission by overtreatment or mistreatment of the patient until the mistake is discovered. The apparent eagerness of the U.S. health-care industry to over diagnose patients often leads to harmful consequences for patients.[17]

Preventability and the Global Trigger Tool

The prevailing view is that "preventability" of an adverse event links to the commission of an identifiable error that caused an adverse event. Adverse events that cannot be traced to a likely error should not be called "preventable." The portion of adverse events that are deemed preventable tends to be about 50% to 60%; however, recently, experts have postulated that virtually all adverse events they identified with the "GTT are preventable."[18] The GTT depends on systematic review of medical records by persons trained to find specific clues or triggers suggesting that an adverse event has taken place. For example, triggers might include orders to stop a medication, an abnormal lab result, or prescription of an antidote medication such as naloxone. As a final step, the examination of the record must be validated by 1 or more physicians. As will be shown shortly, the methods used to find adverse events in hospital medical records target primarily errors of commission and are much less likely to find harm from errors of omission, communication, context, or missed diagnosis.[19] There are some overlaps in these categories and cascades of harmful events can ensue from a single root cause. A "perfect storm" of unrecognized but correctable medical errors can result in serious harm or death.[15,20]

Literature Search

Our literature search included the following three terms: medical error, global trigger tool, and hospital. We searched Pub Med and "reports and publications" from the government Web site *http://oig.hhs.gov*. Those searches turned up 20 articles published between 2006 and 2012, of which, 4 were found to be suitable for the present analysis. The unsuitable studies included studies of populations outside the United States, studies confined to narrow hospital populations (e.g., intensive care unit), studies of ambulatory patients, studies involving only methodological comparisons, adverse-event issue papers, failures of incident reporting systems, and studies that did not classify the severity of the harm associated with adverse events.

Characterization of the Core Studies

The 4 key studies were reviewed for similarity and difference in methods used to find adverse events. It was found that each one employed similar methods to flag, confirm, and then classify adverse events according to level of harm. All studies used a 2-tier approach that consisted of screening of medical records by nonphysicians, usually nurses or pharmacists, to flag suspect events. In the second tier, physicians examined the suspect events to determine if a genuine adverse event had occurred and, if so, the level of seriousness of the event. In all studies, the GTT from the Institute for Healthcare Improvement was the primary screening tool;[21] however, there were variations in the supplementary tools used to detect potential adverse events.

A 2008 pilot study by the Office of Inspector General (OIG) of the Department of Health and Human Services used 5 methods in its search for adverse events—nurse reviews using the GTT, conditions that were not present on admission (POA), beneficiary interviews, hospital incidence reports, and patient safety indicators.[22] The pilot study revealed that the GTT captured the highest percentage (78%) of the events ultimately deemed to be adverse events in the second tier review by physicians. The use of POA indicator codes was second best at 61%. Together, these methods were found to identify 94% of the flags that led physicians to declare that an adverse event had taken place. A more comprehensive OIG study in 2010 employed these 2 screening methods and a third based on whether the patient had been readmitted to the hospital with 30 days of discharge from the last discharge during the October 2008 index period.[23]

A study by Classen and colleagues also employed the GTT along with Agency for Healthcare Research and Quality Patient Safety Indicators (PSIs) and hospital reports of adverse events. Of the 167 flagged events that ultimately were deemed true adverse events by physician review, the GTT detected 90% in the severity levels F through I (Table 1).[18] The longitudinal

TABLE 1. Adverse Events Classified as Serious

Level of Harm	Description
F	Required prolonged hospital stay
G	Permanent harm
H	Life sustaining intervention required
I	Contributing to death of patient

Adapted from the National Coordinating Council for Medication Errors Reporting and Prevention.

study by Landrigan and colleagues relied on the GTT and POA indicators to flag possible adverse events. Like the other studies, the ultimate determination of a genuine adverse event and the severity of the event were judged by physicians during the second-tier analysis.[24] Although there are slight variations in the approach used to discover flags in the records examined by the 4 studies, the GTT was the core method placed in the hands of trained and experienced nurses. All studies used a second tier requiring physicians to determine whether a flag signaled a genuine adverse event and, if so, then assign a severity level to that event. All studies used the National Coordinating Council for Medication Reporting and Prevention scale (Table 1).

RESULTS

Recent data from the 4 key studies provide a more comprehensive, evidence-based estimate of the number of lethal and serious medical errors than the one provided by the Institute of Medicine (IOM).[25] These data are compiled in Table 2, and the studies are described below.

A pilot study by the OIG was published in 2008 in an effort to explore the effectiveness of search methods for adverse events.[21] As noted in the methods section, this study relied on 5 search methods for flagging potential adverse events in medical records but did not specify whether such events were preventable. The 278 medical records reviewed by screeners and physicians were not randomly selected to be representative of Medicare hospitalizations; instead, they originated from hospitals in 2 unspecified counties. Of the 51 serious adverse events identified, only 3 were on the National Quality Forum's list of serious reportable events and only 11 were on Medicare's Hospital Acquired Condition (HAC) list. In 2010, the OIG estimated adverse events in hospitalized Medicare patients.[23]

Investigators looked at the medical records of 780 randomly selected patients chosen to represent the 1 million Medicare patients "discharged" from hospitals in the month of October 2008. The total number of hospital stays for the 780 patients during this period was 838 because some of the beneficiaries were hospitalized and discharged more than once during the 1-month index period. Using primarily the GTT developed by the Institute for Healthcare Improvement to find adverse events, investigators found 128 serious adverse events (level of harm F, G, H, or I) that caused harm to patients, and an adverse event contributed to the deaths of 12 of those patients. Seven of these deaths were medication related, 2 were from blood stream infections, 2 were from aspiration, and the 12th one was linked to ventilator-associated pneumonia. Only 2 of these events were on the National Quality Forum list, and none were on the Medicare HAC list. The authors of this report estimated that "events" contributed to the deaths of 1.5 % (12/780) of the 1 million Medicare patients hospitalized in October 2008. That amounts to 15,000 per month or 180,000 per year.

TABLE 2. Recent Studies of Preventable Adverse Events

Reference	Source of Medical Record Data	Time Covered by Records	No. records Reviewed	Search Tool or Method	Serious Adverse Events (Class F to I) Found (%)	% Deemed Preventable	Lethal Adverse Events (%)	Major Causes of Lethal Events
OIG (2008)	Medicare beneficiaries in 2 counties	1 wk in August 2008	278	Global trigger tool	43 (15%)	n/s	3 (1.1%)	n/s
OIG (2010)	Representative Medicare patients	October 2008	838	Global trigger tool	128 (15%)	44%	12 (1.4%)	7-medication, 2-sepsis, 2-aspiration, 1-other*
Classen et al. (2011)	3 tertiary-care hospitals	October 2004	795	Global trigger tool	167 (21%)	~100%	9 (1.1%)	4-procedure, 2-pulmonary, 1-infection, 2-not specified
Landrigan, et al. (2010)	10 hospitals in North Carolina	Jan 2002 through Dec 2007	2341	Global trigger tool	332 (14%)	63%	14 (0.6%)	7- HAI, 3-Renal/endocr. 4-other systems†

* Ventilator-associated pneumonia.

† Cardiac arrest, pulmonary embolism, hematologic event, neurological event.

Note that the percentage of deaths per hospitalization was slightly lower at 1.4% (12/838). The authors did not explicitly state the percentage of the lethal adverse events that were preventable, but given their description of the events, it seems that most were preventable. Overall, physician reviewers estimated that 44% of serious medical events were preventable.

In a somewhat similar study published in March 2011 in the journal *Health Affairs*, investigators examined the medical records of 795 patients treated in 1 of 3 tertiary hospitals in the month of October 2004.[18] These hospitals had been recognized for their efforts to improve patient safety. The investigators also used the GTT to discover adverse events. They found 167 adverse events in the categories F through I, and 9 of the adverse events contributed to the deaths of patients (category I). Thus, an adverse event contributed to death in 1.1% of these patients. The causes were as follows: procedure related (not infection)—4, nosocomial infection—1, pulmonary/venous thromboembolism—2, and unspecified other—2. Interestingly, none of the deaths were explicitly associated with medication errors, which were the primary causes of death in the Medicare patients studied by the OIG.[23] Medication-related errors caused 35% of the category-F harms in the *Health Affairs* study.[18] The average age of the patients whose records were examined was 59 years. The 10 authors of the original study did not formally assess the preventability of errors, declaring instead that it is their belief that all adverse events are preventable.

In a fourth recent study targeting changes in patient safety in 10 hospitals in North Carolina, there was a lower incidence of deaths associated with adverse events.[24] Hospitals in North Carolina were chosen because hospitals in that state had shown a "high level of engagement in efforts to improve patient safety." In that state, 96% of the hospitals had enrolled in a national campaign to improve patient safety, whereas the average in other states was only 78%. A priori, a lower rate of preventable adverse events than the national average could be expected. The investigators studied the change in incidence of adverse events using the GTT on 10 randomly selected medical records per quarter from the first quarter of 2002 to the last quarter of 2007. The tool was applied by internal and external reviewers; however, the internal reviewers had better kappa scores (a measure of agreement) when compared with experienced external reviewers, so the results of internal reviews, which were the only ones given in detail in the original paper, will be used here. Based on 2341 admissions and the finding of 14 cases where adverse events contributed to death, the percentage of lethal adverse events was 0.60%. The primary causes of death were hospital-acquired infections (HAIs) (7) and acute renal failure (2). Other causes are shown in Table 2. This study involved many more medical records than the OIG or *Health Affairs* study, but the hospitals and patients were not selected to be representative of hospitals around the country. The hospitals were selected because the investigators felt that North Carolina had made a concerted effort to improve patient safety over the study period. It is not surprising that the percentage of serious or lethal adverse events was lower than in the other studies summarized in Table 2.

All 4 studies (Table 2) have similar, 2-tier search methods to identify serious adverse events. The GTT, supplemented by other less comprehensive methods, was applied to medical records by experienced nonphysicians to identify possible adverse events, and then, physician reviewers determined which flags were associated with an adverse event. However, the study populations were quite different. One would expect the OIG studies of Medicare patients, who tend to have more comorbidity than the average hospitalized patient, to show the highest incidence of lethal PAEs. One would expect the incidence of lethal adverse events in tertiary hospitals to be above the national average for all hospitalizations because more complex illnesses are treated there with longer hospital stays. One would expect, as the original authors did, that the incidence data from North Carolina would be below the national average for lethal adverse events because of concerted efforts in that state to improve patient safety in hospitals compared with the average of other states in the United States.

It is our opinion that none of the 4 studies alone can provide a defensible estimate for hospitals across the United States; however, by combining the studies, an evidence-based estimate of the number of lethal PAEs across the country can be developed. The most favorable way to combine the 4 studies to find the lowest reasonable estimate is to weigh the studies according to how many medical records from a single hospital stay were reviewed by each team of investigators. This means that the study of patients hospitalized in North Carolina was heavily weighted compared with the other studies. Thus, there were a total of 4252 records reviewed (compiled from Table 2). Among the records reviewed, there were 38 total deaths associated with adverse events. The ratio projects to a death rate from adverse events of 0.89%. This is well below the percentages from Medicare and tertiary-care studies (1.1%–1.4%) and well above the data from the North Carolina study (0.60%). There were an estimated 34.4 million hospital discharges in 2007,[26] and the average percentage of preventable adverse events among all adverse events in the 3 studies where this was reported or postulated was 69% (averaged from Table 2). Thus, the best estimate from combining these 4 studies is $34{,}400{,}000 \times 0.69 \times 0.0089 = 210{,}000$ preventable adverse events per year that contribute to the death of hospitalized patients—based primarily on evidence in hospital medical records found by the GTT method.

DISCUSSION

There has been no lack of contention about the prevalence of PAEs, which herein will be considered synonymous with medical errors that cause harm to patients; this does not include near misses that do not harm patients.[27,28] The first estimate of medical errors that received widespread attention was declared by the IOM in its now- famous book called "To Err is Human."[25] The IOM provided 2 estimates of the number of deaths from medical errors, but careful inspection of the origin of these estimates show that they were based on data that are now quite old. The earliest estimate originated from the Harvard Medical Practice Study in which 30,000 randomly selected discharge records from 1984 in 51 New York hospitals were examined.[29] The investigators found that serious adverse events occurred in 3.7% of the hospitalizations. Of the adverse events, 58% were attributable to error (i.e., they were preventable). Of this fraction, 13.6% resulted in death. Extrapolated to 33.6 million hospitalizations nationwide in 1997, simple arithmetic yielded the following: $33{,}600{,}000 \times 0.037 \times 0.136 \times 0.58 = 98{,}000$ deaths per year. Another study of 15,000 medical records from Colorado and Utah in 1992 found lower rates of adverse events and death, from which the IOM estimated 44,000 deaths nationwide per year.[25] Although physician reviews reveal adverse events due to "negligence," which was about 28% to 29% in both studies, a later publication from the IOM suggested that the 44,000 to 98,000 deaths did not include errors of omission.[30] Because the New York study included a larger sample, the deaths-per-year figure of 98,000 attributed to the IOM is the estimate most often quoted. In fact, the IOM declared that the "number of deaths [per year] due to medical error may be as high as 98,000."

Why is the present estimate of the number of lethal PAEs so much higher than the highest estimate (98,000) from the IOM? It is likely that the bar for identification of a PAE in the New York/IOM study was much higher than in the 4 modern studies and that the GTT is better able to identify adverse events than general reviews by physicians, which was the method used in the older studies cited by the IOM.[19] It is also possible that the frequency of preventable and lethal patient harms has increased from 1984 to 2002–2008 because of the increased complexity of medical practice and technology, the increased incidence of antibiotic-resistant bacteria, overuse/misuse of medications, an aging population, and the movement of the medical industry toward higher productivity and expensive technology, which encourages rapid patient flow and overuse of risky, invasive, revenue-generating procedures.[31–33]

Several observations about the 4 varied studies described in the "Results" section are in order. Although they used varied selection criteria for the patient populations and hospitals, the results in terms of the portion of adverse events found and the portion of death-associated events are not remarkably varied. The percentage of serious adverse events (class F to I) ranged from 14% to 21%, and the percentage of death-associated adverse events (class I) varied from 0.60% to 1.4%. The result found in records from North Carolina hospitals (0.60%) is likely to be below the national average because patient safety efforts in that state have been more intense when compared with other states. The results from the other studies would be expected to be above the national average because of the age of the patients and seriousness of the illnesses. This dispersion of percentages makes sense and gives one confidence that the estimate of the average number of preventable, lethal adverse events based on hospital medical records screened by the GTT approach is representative of the nation as a whole. The portion of serious adverse events that were not lethal (class F, G, and H) were roughly 10- to 20-fold larger than the portion of lethal PAEs. This leads to a rough estimate of 2 to 4 million serious, PAEs per year that would be discoverable in medical records using the GTT approach.

There are important limitations to the 4 modern studies that must be considered. Premature deaths as a result of medical errors may occur many years after the hospital stay because the patient's care was not optimal or did not follow guidelines.[12] Furthermore, lethal PAEs can been missed by the GTT and by physician reviews. The GTT does not detect diagnostic errors or errors of omission, especially those involving failure to follow guidelines.[19] Lethal diagnostic errors have been estimated to affect 40,000 to 80,000 people per year including outpatients.[34] Physicians have been indefensibly slow to adopt guidelines that would potentially prevent premature deaths or harm.[35] One egregious example is the estimated 100,000 heart failure patients that died prematurely each year in the late 1990s because they did not receive beta-blockers.[13] The efficacy of beta-blockers was established by a study published in the *JAMA* in 1982.[36]

The 4 modern studies also rely heavily on information in medical records. One study of medical records showed that quality scores of 607 randomly selected medical records on cardiac patients treated in 219 hospitals from January 2004 to June 2005 averaged 12.5/20 points, which suggests rather poor medical record keeping.[37] The quality scores were determined based on the medical records including cardiac history, performance and cognition levels, current medications and medication allergies, differential diagnosis, and planned use of evidence-based medicine. Hospitals with low-scoring records (0–10 points) had a 40% higher in-hospital death rate than those that scored high (15–20 points). Furthermore, the larger OIG study noted that "To the extent that the study did not identify an event, it was likely because the three screening methods failed to flag the case for physicians review or because documentation in the medical records was incomplete."[23]

A few years after the seminal publication by the IOM, another IOM panel recognized the limitations of using medical records provided by medical institutions as the basis for identifying medical errors. When an adverse event is alleged and an evaluation is undertaken, the "sentinel effect can significantly alter the data that are recorded."[30] There are anecdotal accounts of data altering or omission of critical data when mistakes are alleged; however, to our knowledge, scientific studies of this phenomenon have been lacking until recently.

In a study that broke past the wall of silence about discovery of medical errors that were missing from medical records, Weissman and colleagues found that 6 to 12 months after their discharge, patients could recall 3 times as many serious, preventable adverse events as were reflected in their medical records.[14] This study involved review of 998 medical records of patients hospitalized in Massachusetts for medical or surgical treatment from April to October 2003. Record reviews by specially trained nurses and doctors identified 11 serious PAEs from the records. The method was one adapted from the Harvard Medical Practice Study, which is the method used by the core result in the report from the IOM asserting up to 98,000 deaths per year occur from medical errors.[25] However, interviews with patients identified 21 additional serious PAEs that were not documented in the medical records. Of the 21 undiscovered, serious PAEs, 12 occurred predischarge and 9 occurred postdischarge. The predischarge serious PAEs included the following: adverse drug events (3), nerve or vessel injury or wrong operation (4), deep venous thrombosis (2), hospital acquired infection (2), and postoperative respiratory distress (1). The serious PAEs postdischarge included the following: wound infection (6), deep venous thrombosis (1), operative wound dehiscence (1), and operative organ injury (1). Even in this study, the investigators found only those errors that patients were aware had happened. There certainly may be more serious errors that went undocumented and were unknown to patients. Weismann's finding that evidence of many serious adverse events is not apparent in medical records is reinforced by some older studies. For example, it has been pointed out that some medical errors are not known by clinicians and only come to light during autopsies, which have found misdiagnoses in 20% to 40% of cases.[38] "Aggressive" searches for adverse drug events and prompted self-reports from clinicians have shown a much higher rate of adverse drug events than are evident in the medical records.[39] A comparison of direct observation for medication errors with review of documentation in medical records in 36 hospitals and skilled-nursing facilities found that far more errors were found by direct observation than by inspection of medical records.[40]

A recent national survey showed that physicians often refuse to report a serious adverse event to anyone in authority.[41] In the case of cardiologists, the highest nonreporting group of the specialties studied, nearly two-thirds of the respondents admitted that they had recently refused to report at least one serious medical error, of which they had first-hand knowledge, to anyone in authority. It is reasonable to suspect that clear evidence of such unreported medical errors often did not find their way into the medical records of the patients who were harmed.

The bottom line on total, lethal PAEs as a result of care in hospitals cannot be estimated in a statistically rigorous way.

Based on our extrapolation from the 4 modern studies, there are at least 210,000 lethal PAEs detectable by the GTT approach to record reviews. To deal with other factors that should be applied to this estimate, the "weight of evidence" approach must be engaged. In addition to the core estimate of 210,000, one must consider evidence of the following:

- life-shortening errors of omission due to failure to follow medical guidelines that the GTT approach misses,[19]
- a factor for evidence of errors of commission that are not documented in medical records,[37,39]
- failure to make life-saving diagnoses.[38]

In light of the evidence above, and especially that of the Weisman study,[14] and although it is probably an underestimate, a minimum estimate of a 2-fold increase in the medical record–based estimate is reasonable to compensate for the known absence of evidence in medical records of errors of commission and the inability of the GTT to detect errors of omission even when the evidence that guidelines were not followed may be present in the medical record. Note that the Weisman study suggests a factor of 3 (32/11) for undocumented evidence of serious PAEs caused during hospitalization, but here, we settle for a factor of 2.[14] To this, one should add the undetected diagnostic errors. If we begin with the minimum estimate of 40,000 and assume that only half of these occur in hospitals, then the math looks like this: $(210{,}000 \times 2) + 20{,}000 \sim 440{,}000$ PAEs that contribute to the death of patients each year from care in hospitals. This is roughly one-sixth of all deaths that occur in the United States each year. The problem of PAEs must emerge from behind the "Wall of Silence" and be addressed for the sake of prolonging the lives of Americans.

Needed changes involve not only doctors and hospitals but increased participation by patients in their health-care decisions. Perhaps it is time for a national patient bill of rights for hospitalized patients that would empower them to be thoroughly integrated into their care so that they can take the lead in reducing their risk of serious harm and death.[15] All evidence points to the need for much more patient involvement in identifying harmful events and participating in rigorous follow-up investigations to identify root causes.[42] Even for those harms identified in the medical records of Medicare patients, only 14% become part of the hospital's incident reporting system.[9] Physician observers of our hospitals have made Congress painfully aware that the hospital peer-review system has widespread failures that permit negligent care by physicians.[43] Hospitals are simply not going to heal without attentive, systematic listening to those harmed patients or their survivors.

CONCLUSIONS

There was much debate after the IOM report about the accuracy of its estimates. In a sense, it does not matter whether the deaths of 100,000, 200,000 or 400,000 Americans each year are associated with PAEs in hospitals. Any of the estimates demands assertive action on the part of providers, legislators, and people who will one day become patients. Yet, the action and progress on patient safety is frustratingly slow; however, one must hope that the present, evidence-based estimate of 400,000+ deaths per year will foster an outcry for overdue changes and increased vigilance in medical care to address the problem of harm to patients who come to a hospital seeking only to be healed.

REFERENCES

1. Zilberberg MD. The clinical research enterprise—time to change course? JAMA. 2011;305:604–605.
2. IOM (Institute of Medicine). *Redesigning Continuing Education in the Health Professions*. Washington, DC: The National Academies Press; 2010.
3. Sniderman AD, Furberg CD. Why guideline-making requires reform. *JAMA*. 2009;301:429–431.
4. Ferket BS, Colkesen EB, Visser JJ, et al. Systematic review of guidelines on cardiovascular risk assessment. *Arch Intern Med*. 2010;170:27–40.
5. Mendelson TB, Meltzer M, Campbell EG, et al. Conflicts of interest in cardiovascular clinical practice guidelines. *Arch Intern Med*. 2011;171:577–585.
6. Gittell JH. *High Performance Healthcare—Using the Power of Relationships to Achieve Quality, Efficiency and Resilience*. New York, NY: McGraw Hill; 2009
7. American College of Physicians. Achieving a high performance health care system with universal access: What the United States can learn from other countries. *Ann InternMed*. 2008;148:55–75.
8. Reid, RO, Friedberg MW, Adams JL, et al. Associations between physician characteristics and quality of care. *Arch Intern Med*. 2010;170:1442–1449.
9. Levinson DR. *Hospital Incident Reporting Systems Do Not Capture Most Patient Harm. DHHS, OIG*. 2012, OEI-06-09-00091.
10. California Injury Lawyers Blog. Available at: http://www.californiainjurylawyersblog.com/2009/06/california-medical-malpractice-dennis-quaids-twins-to-receive-500000-for-heparin-overdose.html. Accessed July 12, 2012.
11. McKnight EV, Bennington TT. *A Never Event—Exposing the Largest Outbreak of Hepatitis C in American Healthcare History*. Fremont, NE: History Examined, LLC; 2010
12. Ghandi TK, Zuccotti G, Lee TH. Incomplete care—On the trail of flaws in the system. *N Engl J Med*. 2011:365:486–488.
13. Gheorghaide M, Gattis WA, O'Conner CM. Treatment gaps in the pharmacologic management of heart failure. *Rev Cadiovasc Med*. 2002;3:S11–S19.
14. Weismann JS, Schneider EC, Weingart SN, et al. Comparing patient-reported hospital adverse events with medical records reviews: Do patients know something that hospitals do not? *Ann Intern Med*. 2008;149:100–108.
15. James JT. *A Sea of Broken Hearts—Patient Rights in a Dangerous, Profit-Driven Health Care System*. Bloomington, IN: AuthorHouse; 2007.
16. Weiner SJ, Schwartz A, Weaver F, et al. Contextual errors and failures in individualizing patient care. *Ann Intern Med*. 2010;153:69–75.
17. Welch HG, Schwartz LM, Woloshin S. *Over-diagnosed—Making People Sick in the Pursuit of Health*. Boston, MA: Beacon Press; 2011.
18. Classen, DC, Resar R, Griffin F, et al. "Global trigger tool" shows that adverse events in hospitals may be ten times greater than previously measured. *Health Aff*. 2011;30:581–589.
19. Parry G, Cline A, Goldmann D. Deciphering harm measurement. *JAMA*. 2012;307:2155–2156.
20. Walter D. *Collateral Damage—A Patient, a New Procedure, and the Learning Curve*. Charleston, SC: CreateSpace; 2010.
21. Institute for Healthcare Improvement. IHI Global Trigger Tool Guide. Cambridge MA, 2008. Available at: http://www.ihi.org/knowledge/Pages/Tools/IHIGlobalTriggerToolforMeasuringAEs.aspx. Accessed July 12, 2012.
22. Department of Health and Human Services, Office of the Inspector General. *Adverse Events in Hospitals: Case Study of Incidence among Medicare Beneficiaries in Two Selected Counties*. Washington, DC; 2008, Available at: *http://oig.hhs.gov/oei/reports/OEI-06-08-00220.pdf*.
23. Department of Health and Human Services, Office of the Inspector General. *Adverse Events in Hospitals: National Incidence among*

Medicare Beneficiaries. Washington, DC; 2010, Available at: http://oig.hhs.gov/oei/reports/OEI-06-09-00090.pdf.

24. Landrigan, CP, Parry GJ, Bones CB, et al. Temporal trends in rates of patient harm resulting from medical care. *N Engl J Med*. 2010;363:2124–2134.
25. IOM (Institute of Medicine). *To Err is Human—Building a Safer Health System*. Washington, DC: The National Academies Press; 2000.
26. Hall MJ, DeFrances CJ, Williams SN, et al. *National Health Statistics Report. CDC Report Number 29*; 2010. Available at: http://www.cdc.gov/nchs/data/nhsr/nhsr029.pdf.
27. Hayward RA, Hofer TP. Estimating hospital deaths due to medical errors. *JAMA*. 2001;286:415–420.
28. Goodman JC, Villarreal P, Jones B. The social cost of adverse medical events, and what we can do about it. *Health Aff*. 2011;30:590–595.
29. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospital patients: results of the Harvard Medical Practice Study. *N Engl J Med*. 1991;324:370–376.
30. IOM (Institute of Medicine). *Patient Safety–Achieving a New Standard of Care*. Washington, DC: The National Academies Press; 2004.
31. Moody J, Cosgrove SE, Olmsted R, et al. Antimicrobial stewardship: a collaborative partnership between infection preventionists and healthcare epidemiologists. *Infect Control Hosp Epidemiol*. 2012;33:328–330.
32. Schneider EL, Campese VM. Adverse drug responses, an increasing threat to the well- being of older patients. *Arch Intern Med*. 2010;170:1148–1149.
33. Stergiopoulos K, Brown DL. Initial coronary stent implantation with medical therapy vs medical therapy alone for stable coronary artery disease. *Arch Intern Med*. 2012;172:312–319.
34. Newman-Toker DE, Pronovost PJ. Diagnostic errors—the next frontier for patient safety. *JAMA*. 2009;301:1060–1062.
35. Kotchen TA. Why the slow diffusion of treatment guidelines into clinical practice? *Arch Intern Med*. 2007;167:2394–2395.
36. A randomized trial of propranolol in patients with acute myocardial infarction. I. Mortality results. *JAMA*. 1982;247:1707–14. Available at: http://www.ncbi.nlm.nih.gov/pubmed/7038157.
37. Dunlay SM, Alexander KP, Melloni C, et al. Medical records and quality of care in acute coronary syndromes. *Arch Intern Med*. 2008; 168:1692–1698.
38. Leape L. Institute of Medicine medical error figures are not exaggerated. *JAMA*. 2000;284:95–97.
39. Weingart SN, Wilson RM, Gibberd RW, et al. Epidemiology of medical error. *BMJ*. 2000:320:774–777.
40. Flynn EA, Barker KN, Pepper GA, et al. Comparison of methods for detecting medication errors in 36 hospitals and skilled-nursing facilities. *Am J Health-System Pharm*. 2002;59:436–446.
41. Campbell EG, Regan S, Gruen RL, et al. Professionalism in medicine: results of a national survey of physicians. *Ann Intern Med*. 2007; 147:795–802.
42. Junya Z, Struver S, Epstein A, et al. Can we rely on patients' reports of adverse events? *Med Care*. 2011;49:948–955.
43. Rogan GN, Sebat F, Grady I. How Peer Review Failed at Redding Medical Center, Why It Is Failing Across the Country and What Can be Done About It. Congressional Report, June 1, 2008. Available at: http://www.allianceforpatientsafety.org/redding-failure.pdf. Accessed July 12, 2012.

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ANALYSIS

Medical error—the third leading cause of death in the US

Medical error is not included on death certificates or in rankings of cause of death. **Martin Makary** and **Michael Daniel** assess its contribution to mortality and call for better reporting

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The annual list of the most common causes of death in the United States, compiled by the Centers for Disease Control and Prevention (CDC), informs public awareness and national research priorities each year. The list is created using death certificates filled out by physicians, funeral directors, medical examiners, and coroners. However, a major limitation of the death certificate is that it relies on assigning an International Classification of Disease (ICD) code to the cause of death.[1] As a result, causes of death not associated with an ICD code, such as human and system factors, are not captured. The science of safety has matured to describe how communication breakdowns, diagnostic errors, poor judgment, and inadequate skill can directly result in patient harm and death. We analyzed the scientific literature on medical error to identify its contribution to US deaths in relation to causes listed by the CDC.[2]

Death from medical care itself

Medical error has been defined as an unintended act (either of omission or commission) or one that does not achieve its intended outcome,[3] the failure of a planned action to be completed as intended (an error of execution), the use of a wrong plan to achieve an aim (an error of planning),[4] or a deviation from the process of care that may or may not cause harm to the patient.[5] Patient harm from medical error can occur at the individual or system level. The taxonomy of errors is expanding to better categorize preventable factors and events.[6] We focus on preventable lethal events to highlight the scale of potential for improvement.

The role of error can be complex. While many errors are non-consequential, an error can end the life of someone with a long life expectancy or accelerate an imminent death. The case in the box shows how error can contribute to death. Moving away from a requirement that only reasons for death with an ICD code can be used on death certificates could better inform healthcare research and awareness priorities.

How big is the problem?

The most commonly cited estimate of annual deaths from medical error in the US—a 1999 Institute of Medicine (IOM) report[7]—is limited and outdated. The report describes an incidence of 44 000-98 000 deaths annually.[7] This conclusion was not based on primary research conducted by the institute but on the 1984 Harvard Medical Practice Study and the 1992 Utah and Colorado Study.[8 9] But as early as 1993, Leape, a chief investigator in the 1984 Harvard study, published an article arguing that the study's estimate was too low, contending that 78% rather than 51% of the 180 000 iatrogenic deaths were preventable (some argue that all iatrogenic deaths are preventable).[10] This higher incidence (about 140 400 deaths due to error) has been supported by subsequent studies which suggest that the 1999 IOM report underestimates the magnitude of the problem. A 2004 report of inpatient deaths associated with the Agency for Healthcare Quality and Research Patient Safety Indicators in the Medicare population estimated that 575 000 deaths were caused by medical error between 2000 and 2002, which is about 195 000 deaths a year (table 1 ⇓).[11] Similarly, the US Department of Health and Human Services Office of the Inspector General examining the health records of hospital inpatients in 2008, reported 180 000 deaths due to medical error a year among Medicare beneficiaries alone.[12] Using similar methods, Classen et al described a rate of 1.13%.[13] If this rate is applied to all registered US hospital admissions in 2013[15] it translates to over 400 000 deaths a year, more than four times the IOM estimate.

Similarly, Landrigan et al reported that 0.6% of hospital admissions in a group of North Carolina hospitals over six years (2002-07) resulted in lethal adverse events and conservatively estimated that 63% were due to medical errors.[14] Extrapolated nationally, this would translate into 134 581 inpatient deaths a year from poor inpatient care. Of note, none of the studies captured deaths outside inpatient care—those resulting from errors in care at home or in nursing homes and in outpatient care such as ambulatory surgery centers.

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Case history: role of medical error in patient death

A young woman recovered well after a successful transplant operation. However, she was readmitted for non-specific complaints that were evaluated with extensive tests, some of which were unnecessary, including a pericardiocentesis. She was discharged but came back to the hospital days later with intra-abdominal hemorrhage and cardiopulmonary arrest. An autopsy revealed that the needle inserted during the pericardiocentesis grazed the liver causing a pseudoaneurysm that resulted in subsequent rupture and death. The death certificate listed the cause of death as cardiovascular.

A literature review by James estimated preventable adverse events using a weighted analysis and described an incidence range of 210 000-400 000 deaths a year associated with medical errors among hospital patients.[16] We calculated a mean rate of death from medical error of 251 454 a year using the studies reported since the 1999 IOM report and extrapolating to the total number of US hospital admissions in 2013. We believe this understates the true incidence of death due to medical error because the studies cited rely on errors extractable in documented health records and include only inpatient deaths. Although the assumptions made in extrapolating study data to the broader US population may limit the accuracy of our figure, the absence of national data highlights the need for systematic measurement of the problem. Comparing our estimate to CDC rankings suggests that medical error is the third most common cause of death in the US (fig 1⇓).[2]

Better data

Human error is inevitable. Although we cannot eliminate human error, we can better measure the problem to design safer systems mitigating its frequency, visibility, and consequences. Strategies to reduce death from medical care should include three steps: making errors more visible when they occur so their effects can be intercepted; having remedies at hand to rescue patients [17]; and making errors less frequent by following principles that take human limitations into account (fig 2⇓). This multitier approach necessitates guidance from reliable data.

Currently, deaths caused by errors are unmeasured and discussions about prevention occur in limited and confidential forums, such as a hospital's internal root cause analysis committee or a department's morbidity and mortality conference. These forums review only a fraction of detected adverse events and the lessons learnt are not disseminated beyond the institution or department.

There are several possible strategies to estimate accurate national statistics for death due to medical error. Instead of simply requiring cause of death, death certificates could contain an extra field asking whether a preventable complication stemming from the patient's medical care contributed to the death. An early experience asking physicians to comment on the potential preventability of inpatient deaths immediately after they occurred resulted in an 89% response rate.[18] Another strategy would be for hospitals to carry out a rapid and efficient independent investigation into deaths to determine the potential contribution of error. A root cause analysis approach would enable local learning while using medicolegal protections to maintain anonymity. Standardized data collection and reporting processes are needed to build up an accurate national picture of the problem. Measuring the consequences of medical care on patient outcomes is an important prerequisite to creating a culture of learning from our mistakes, thereby advancing the science of safety and moving us closer towards the Institute of Medicine's goal of creating learning health systems.[19]

Health priorities

We have estimated that medical error is the third biggest cause of death in the US and therefore requires greater attention. Medical error leading to patient death is under-recognized in many other countries, including the UK and Canada.[20 21] According to WHO, 117 countries code their mortality statistics using the ICD system as the primary indicator of health status.[22] The ICD-10 coding system has limited ability to capture most types of medical error. At best, there are only a few codes where the role of error can be inferred, such as the code for anticoagulation causing adverse effects and the code for overdose events. When a medical error results in death, both the physiological cause of the death and the related problem with delivery of care should be captured.

To achieve more reliable healthcare systems, the science of improving safety should benefit from sharing data nationally and internationally, in the same way as clinicians share research and innovation about coronary artery disease, melanoma, and influenza. Sound scientific methods, beginning with an assessment of the problem, are critical to approaching any health threat to patients. The problem of medical error should not be exempt from this scientific approach. More appropriate recognition of the role of medical error in patient death could heighten awareness and guide both collaborations and capital investments in research and prevention.

Contributors and sources: MM is the developer of the operating room checklist, the precursor to the WHO surgery checklist. He is a surgical oncologist at Johns Hopkins and author of *Unaccountable*, a book about transparency in healthcare. MD is the Rodda patient safety research fellow at Johns Hopkins and is focused on health services research. This article arose from discussions about the paucity of funding available to support quality and safety research relative to other causes of death.

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1 Moriyama IM, Loy RM, Robb-Smith AHT, et al. *History of the statistical classification of diseases and causes of death*. National Center for Health Statistics, 2011.
2 Deaths: final data for 2013. National vital statistics report. http://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm.
3 Leape LL. Error in medicine. *JAMA* 1994;272:1851-7. doi:10.1001/jama.1994.03520230061039 pmid:7503827.
4 Reason J. *Human error*. Cambridge University Press, 1990. doi:10.1017/CBO9781139062367.
5 Reason JT. Understanding adverse events: the human factor. In: Vincent C, ed. *Clinical risk management: enhancing patient safety*. BMJ, 2001:9-30.
6 Grober ED, Bohnen JM. Defining medical error. *Can J Surg* 2005;48:39-44.pmid:15757035.
7 Kohn LT, Corrigan JM, Donaldson MS. *To err is human: building a safer health system*. National Academies Press, 1999.
8 Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med* 1991;324:370-6. doi:10.1056/NEJM199102073240604 pmid:1987460.
9 Thomas EJ, Studdert DM, Newhouse JP, et al. Costs of medical injuries in Utah and Colorado. *Inquiry* 1999;36:255-64.pmid:10570659.
10 Leape LL, Lawthers AG, Brennan TA, Johnson WG. Preventing medical injury. *Qual Rev Bull* 1993;19:144-9.pmid:8332330.
11 HealthGrades quality study: patient safety in American hospitals. 2004. http://www.providersedge.com/ehdocs/ehr_articles/Patient_Safety_in_American_Hospitals-2004.pdf.
12 Department of Health and Human Services. Adverse events in hospitals: national incidence among Medicare beneficiaries. 2010. http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf.
13 Classen D, Resar R, Griffin F, et al. Global "trigger tool" shows that adverse events in hospitals may be ten times greater than previously measured. *Health Aff* 2011;30:581-9doi:10.1377/hlthaff.2011.0190.

Summary points

Death certificates in the US, used to compile national statistics, have no facility for acknowledging medical error

If medical error was a disease, it would rank as the third leading cause of death in the US

The system for measuring national vital statistics should be revised to facilitate better understanding of deaths due to medical care

14 Landrigan CP, Parry GJ, Bones CB, Hackbarth AD, Goldmann DA, Sharek PJ. Temporal trends in rates of patient harm resulting from medical care. *N Engl J Med* 2010;363:2124-34. doi:10.1056/NEJMsa1004404 pmid:21105794.

15 American Hospital Association. Fast facts on US hospitals. 2015.http://www.aha.org/research/rc/stat-studies/fast-facts.shtml.

16 James JTA. A new, evidence-based estimate of patient harms associated with hospital care. *J Patient Saf* 2013;9:122-8. doi:10.1097/PTS.0b013e3182948a69 pmid:23860193.

17 Ghaferi AA, Birkmeyer JD, Dimick JB. Complications, failure to rescue, and mortality with major inpatient surgery in Medicare patients. *Ann Surg* 2009;250:1029-34. doi:10.1097/SLA.0b013e3181bef697 pmid:19953723.

18 Provenzano A, Rohan S, Trevejo E, Burdick E, Lipsitz S, Kachalia A. Evaluating inpatient mortality: a new electronic review process that gathers information from front-line providers. *BMJ Qual Saf* 2015;24:31-7. doi:10.1136/bmjqs-2014-003120 pmid:25332203.

19 Institute of Medicine of the National Academies. *Continuous improvement and innovation in health and health care. Round table on value and science-driven health care.* National Academies Press, 2011.

20 Office for National Statistics' Death Certification Advisory Group. Guidance for doctors completing medical certificates of cause of death in England and Wales. 2010.

21 Statistics Canada. Canadian vital statistics, death database and population estimates. http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/hlth36a-eng.htm.

22 World Health Organization. International classification of diseases.http://www.who.int/classifications/icd/en/.

Table

Table 1| **Studies on US death rates from medical error since the 1999 IOM report and point estimate from pooled results**

Study	Dates covered	Source of information	Patient admissions	Adverse event rate (%)	Lethal adverse event rate (%)	% of events deemed preventable	No of deaths due to preventable adverse event	% of admissions with a preventable lethal adverse event	Extrapolation to 2013 US admissions†
Health Grades[11]	2000-02	Medicare patients	37 000 000	3.1	0.7*	NR	389 576	0.71	251 454
Office of Inspector General[12]	2008	Medicare patients	838	13.5	1.4	44	12	0.62	219 579
Classen et al[13]	2004	3 tertiary care hospitals	795	33.2	1.1	100	9	1.13	400 201
Landrigan et al[14]	2002-07	10 hospitals in North Carolina	2341	18.1	0.6	63	14	0.38	134 581
Point estimate from all data	2000-08	—	—	—	—	—	—	0.71	251 454‡

NR=Not reported.

*All were considered preventable.

†Total number of US hospital admissions in 2013 was 35 416 020.[10]

‡Total number of people who died from a preventable lethal adverse event calculated as a point estimate of the death rate among hospitalized patients reported in the literature extrapolated to the reported number of patients hospitalized in 2013.

Figures

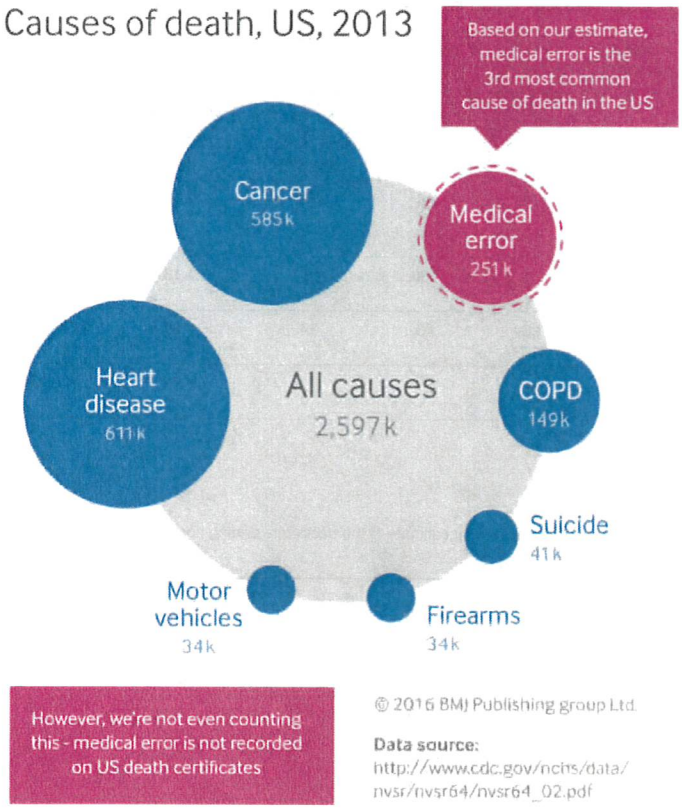

Fig 1 Most common causes of death in the United States, 2013[2]

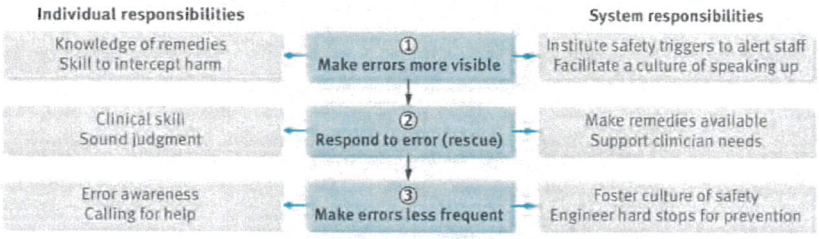

Fig 2 Model for reducing patient harm from individual and system errors in healthcare

Prevalence, severity, and nature of preventable patient harm across medical care settings: systematic review and meta-analysis

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ABSTRACT

OBJECTIVE

To systematically quantify the prevalence, severity, and nature of preventable patient harm across a range of medical settings globally.

DESIGN

Systematic review and meta-analysis.

DATA SOURCES

Medline, PubMed, PsycINFO, Cinahl and Embase, WHOLIS, Google Scholar, and SIGLE from January 2000 to January 2019. The reference lists of eligible studies and other relevant systematic reviews were also searched.

REVIEW METHODS

Observational studies reporting preventable patient harm in medical care. The core outcomes were the prevalence, severity, and types of preventable patient harm reported as percentages and their 95% confidence intervals. Data extraction and critical appraisal were undertaken by two reviewers working independently. Random effects meta-analysis was employed followed by univariable and multivariable meta regression. Heterogeneity was quantified by using the I^2 statistic, and publication bias was evaluated.

RESULTS

Of the 7313 records identified, 70 studies involving 337 025 patients were included in the meta-analysis. The pooled prevalence for preventable patient harm was 6% (95% confidence interval 5% to 7%). A pooled proportion of 12% (9% to 15%) of preventable patient harm was severe or led to death. Incidents related to drugs (25%, 95% confidence interval 16% to 34%) and other treatments (24%, 21% to 30%) accounted for the largest proportion of preventable patient harm. Compared with general hospitals (where most evidence originated), preventable patient harm was more prevalent in advanced specialties (intensive care or surgery; regression coefficient b=0.07, 95% confidence interval 0.04 to 0.10).

CONCLUSIONS

Around one in 20 patients are exposed to preventable harm in medical care. Although a focus on preventable patient harm has been encouraged by the international patient safety policy agenda, there are limited quality improvement practices specifically targeting incidents of preventable patient harm rather than overall patient harm (preventable and non-preventable). Developing and implementing evidence-based mitigation strategies specifically targeting preventable patient harm could lead to major service quality improvements in medical care which could also be more cost effective.

WHAT IS ALREADY KNOWN ON THIS TOPIC

A better understanding of the nature of preventable patient harm has the potential to impact on international healthcare policy and practice

The prevalence of overall patient harm has been established by systematic reviews but the prevalence of preventable patient harm has received less attention

WHAT THIS STUDY ADDS

A meta-analysis that quantifies the prevalence, nature, and severity of preventable patient harm in a range of medical care settings

At least one in 20 patients are affected by preventable patient harm in medical care settings

Approximately 12% of preventable patient harm causes permanent disability or patient death and is mostly related to drug incidents, therapeutic management, and invasive clinical procedures

Introduction

Patient harm during healthcare is a leading cause of morbidity and mortality internationally.[1 2] The World Health Organization defines patient harm as "an incident that results in harm to a patient such as impairment of structure or function of the body and/or any deleterious effect arising there from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury, and may be physical, social or psychological (eg, disease, injury, suffering, disability and death)."[3] The health burden and patient experiencing healthcare-related patient harm has been reported to be comparable to chronic diseases such as multiple sclerosis and cervical cancer in developed countries, and tuberculosis and malaria in developing countries.[4 5] Harmful patient incidents are also a major financial burden for healthcare systems across the globe. It is estimated that 10-15% of healthcare expenditure is consumed by the direct sequelae of healthcare-related patient harm.[6 7]

Early detection and prevention of patient harm in healthcare is an international policy priority.[8] In principle, zero harm would be the ideal goal. However, this goal is not feasible because some harms cannot be avoided in clinical practice. For example, some adverse drug reactions which occur in the absence of any error in the prescription process and without the possibility

of detection are less likely to be preventable. In recent years, the recognition that a proportion of patient harm is not preventable has increased attention to the notion of preventable patient harm.[9] Most studies classify patient harm as preventable if it occurs as a result of an identifiable modifiable cause, and its future recurrence can be avoided by reasonable adaptation to a process, or adherence to guidelines, although universal consensus has not been established.[10] Key sources of preventable patient harm could include the actions of healthcare professionals (errors of omission or commission), healthcare system failures, or involve a combination of errors made by individuals, system failures, and patient characteristics.[11-14] Strengthening the focus on preventable patient harm has the potential to lead to greater tangible clinical benefits and improved translation of patient safety research findings into clinical practice. Patient safety improvement strategies underpinned by better understanding of the nature of preventable patient harm have greater prospects of efficiency (because they are more specific) and implementation (because clinicians can readily recognise their value).[10]

There are several systematic reviews on overall patient harm across different medical settings, but none of these have focused on preventable patient harm.[1 15-17] We undertook a systematic review and meta-analysis to estimate the prevalence of preventable patient harm across medical settings including hospitals, various specialties, and in primary care. We also examined the severity and most commonly occurring types of preventable patient harm.

Methods

This systematic review was conducted and reported in accordance with the Reporting Checklist for Meta-analyses of Observational Studies (MOOSE).[18] The completed MOOSE checklist is available in eTable 1.

Eligibility criteria

We included quantitative observational studies such as cohort (prospective or retrospective) and cross sectional studies in any geographical area in any medical care setting (primary, secondary, and tertiary care) published from January 2000 onwards. We selected this start date because it coincides with when the published patient safety research began to increase in volume after the publication of the landmark report *To Err is Human: Building a Safer Health System* in 1999.[1 5 19]

The primary outcome was the prevalence of preventable patient harm. Patient harm (which is synonymous with adverse events in healthcare) is defined as unanticipated, unforeseen accidents (eg, patient injuries, care complications, or death) which are a direct result of the care dispensed rather than the patient's underlying disease. Patient harm is preventable firstly, when occurring as a result of an identifiable and modifiable cause and secondly, when the prevention of future recurrence of the patient harm is possible with reasonable adaptation to a process and adherence to guidelines.[10]

The secondary outcomes were the severity and types of preventable patient harm. In accordance to the reporting format of the eligible studies, severity of preventable patient harm was classified into mild, moderate, and severe. Key types of preventable harm were drug-related, diagnostic, medical procedure-related, and healthcare-acquired infections (definitions are presented in eTable 1).

We excluded the following: studies reporting data on harm but not on preventable patient harm; studies with an exclusive focus on a specific type of harm only (only drug-related harm) or a specific severity level of harm only (incidents which only resulted in readmissions or extended length of stay) because such estimates would differ from estimates based on any type or any severity level of preventable patient harm; and studies focused on specific patient populations (eg, patients with a particular disease) because such estimates could differ from estimates in the general population.

Searches

We searched five electronic bibliographic databases from January 2000 to 27 January 2019: Medline, Cinahl, Embase, Pubmed, and PsycINFO. We supplemented these searches by screening grey literature sources including three databases (WHOLIS, Google Scholar, SIGLE), relevant reports, and conference abstracts. We also screened existing systematic reviews and checked the reference lists of eligible studies. The search strategy is available in eTable 3.

Study selection and extraction

We exported the results of the searches to Endnote X8 and removed duplicates. We completed screening in two stages. Initially, the titles and abstracts of the studies were screened for eligibility. Afterwards, the full texts of studies initially assessed as relevant for the review were retrieved and checked against our inclusion or exclusion criteria. We devised a data extraction spreadsheet, after being piloted, to extract descriptive data on key study characteristics (eg, number and age of participants, research design, data collection, assessment of preventability) and quantitative outcomes (prevalence, types, and severity of preventable patient harm). Two independent researchers (KK and MP) performed the screening and data extraction with disagreements resolved by discussion within the wider team (AA, DA, RH, RK). The inter-rater reliability was excellent (kappa=0.88 and 0.90).

Risk of bias assessment

We evaluated the risk of bias in the studies by using an adapted form of the Newcastle Ottawa scale for cross sectional and cohort studies.[20] This assessed the representativeness of the sample, sample size, response rate, ascertainment of the exposure, control of confounding variables, assessment of preventability, and appropriate statistical analysis, which provided a score ranging from 0 (lowest grade) to 9 (highest grade). A higher grade indicated a lower risk of bias.

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For our analyses, studies scoring 7 or above were considered as low risk, whereas studies scoring below 7 were considered as high risk.

Analyses

Our primary outcome was the prevalence of preventable patient harm expressed as the proportion of patients with at least one preventable patient harmful incident and stratified according to different medical services. We also calculated and reported the median prevalence of preventable patient harm and interquartile ranges across all medical care settings. Our secondary outcomes were the severity and types of preventable patient harm expressed as proportions of the total number of preventable patient harmful incidents. We pooled all data in Stata 15 by using the metaprop command.[21] To improve the meaning and interpretation of our findings in relation to the prevalence, severity, and common types of preventable patient harm, we also present data on the prevalence, severity, and common types of overall harm (preventable and non-preventable) by using the same pool of studies in all analyses.

We conducted univariable and multivariable meta regression to test the influence of study level moderators on the prevalence of preventable patient harm using the metareg command.[22] Consistent with the recommendations of Thompson and Higgins,[23] eight prespecified study level moderators were hypothesised to have an effect on the prevalence of preventable patient harm (medical setting, population, research design, assessment method of harm, assessment of preventability, sample size, risk of bias, WHO region). Moderators were selected and coded following consensus procedures and each moderator value was based on a minimum of eight studies.[23] Covariates meeting our significance criterion ($P<0.10$) were entered into a multivariable meta regression model. The $P<0.10$ threshold was conservative, to avoid prematurely discounting potentially important explanatory variables. Because proportions were often expected to be small, we used Freeman-Tukey Double Arcsine transformation to stabilise the variances and then performed a random effects meta-analysis implementing the DerSimonian-Laird method.[24 25]

Random effects models were used in all analyses because they are more conservative and have better properties in the presence of heterogeneity.[26 27] Heterogeneity was quantified by using the I^2 statistic. Conventionally, I^2 values of 25%, 50%, and 75% indicate low, moderate, and high heterogeneity, respectively.[28] We inspected the symmetry of the funnel plots and used Egger's test to examine for publication bias.[29] Funnel plots were constructed using the metafunnel command,[30] and the Egger test was computed using the metabias command.[31]

Patient and public involvement

Two patient partners, who were members of our research advisory panel, were involved in the development of our research questions and in selecting the outcome measures of this study. The two patients also provided critical feedback to the protocol of the systematic review and advised on the interpretation and dissemination of results.

Results

The searches yielded 7313 citations. After we removed duplicates and reviewed the titles and abstracts, 6522 articles were excluded. Of the remaining 307 studies, 241 were excluded after reviewing the full article. A total of 66 studies reporting 70 independent samples were included in the review.[17 32-98] Figure 1 shows the study flow for the selection process.

Descriptive characteristics

This review is based on a pooled sample of 337 025 patients, 28 150 of who experienced harmful incidents and 15 419 experienced preventable harmful incidents. A total of 47 148 harmful incidents were identified in the pooled sample, 25 977 (55%) of which were preventable. The sample sizes ranged widely across studies (median 1440 patients, range 128-96 047). Thirty three studies (47%) were conducted in the US, 27 (39%) in Europe, and 10 (14%) elsewhere. The most common study design was retrospective or cross-sectional (n=50; 71%) followed by prospective (20; 29%). Fifty three studies (76%) reviewed the medical charts of patients to detect harm, whereas 17 studies (24%) monitored patients over time or were based on self reports (eg, interviews with patients). All included studies assess the preventability of patient harm by using consensus procedures between two or more trained reviewers (physicians or teams of physicians and nurses). Fifty studies (71%) used a standardised Likert scale to facilitate the consensus decisions for the preventability of patient harm among the reviewers (harmful incidents assigned a score of four out of six and over were considered preventable).[99] The remaining 20 studies (29%) used implicit agreed criteria to reach consensus regarding the preventability of patient harm among the reviewers. Most studies were conducted in general hospitals involving patients from a range of specialties (45 studies; 64%). Twelve studies (17%) were conducted in advanced care specialties (intensive care 6 studies; surgery 6 studies), six studies (8%) in emergency department, four in obstetrics (6%), and three in primary care (4%). Except for six studies (9%), which were based on children and adolescents, and five studies on older adults (7%), the remaining 59 studies (84%) were mainly based on adults. Further details of the descriptive characteristics of the included studies are available in eTable 2.

All 70 studies reported data on the prevalence of preventable patient harm and overall patient harm. One third of the studies (20 studies, 29%) reported data on the severity of preventable patient harm. Forty three studies (60%) reported proportions of at least two of the following six types of preventable patient harm: drug management, non-drug therapeutic management, diagnosis, invasive medical procedures,

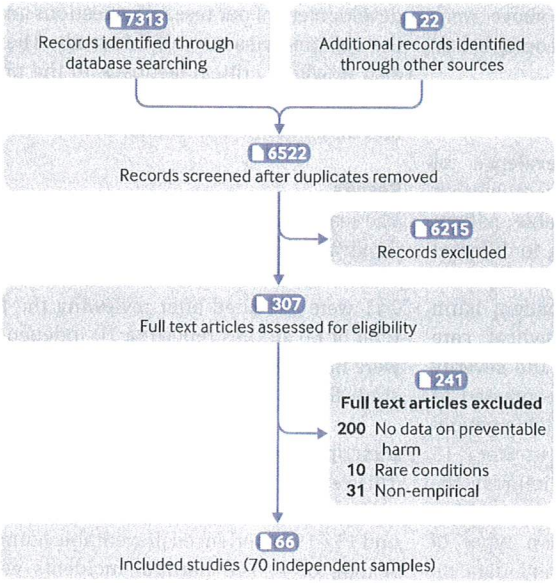

Fig 1 | Flowchart of the inclusion of studies in the review

surgical procedures, and infections acquired during healthcare.

Risk of bias results

The Newcastle Ottawa scores for the studies ranged from three to nine (maximum 9, a higher score indicating a lower risk of bias). Twenty nine studies (41%) scored eight or above and were considered to be at low risk of bias (see full assessment in eTable 3).

Meta-analysis of the prevalence of preventable patient harm stratified by medical settings

Table 1 shows that the pooled prevalence of preventable patient harm was 6% (95% confidence interval 5% to 7%, I^2=99%) and the median prevalence was 5% (interquartile range 3-9%). In comparison, the pooled prevalence of overall harm (preventable and non-preventable) was 12% (95% confidence interval 9% to 14%, I^2=99%; table 1) and the median was 10% (interquartile range 7-15%). The highest pooled prevalence estimate of preventable patient harm was reported in intensive care (18%, 95% confidence interval 12% to 26%, I^2=96%) and surgery (10%, 7% to 13%, I^2=97%) and the lowest in obstetrics (2%, 0% to 4%, I^2=95%). Figure 2 presents the forest plot of the prevalence of preventable patient harm across medical care settings.

Meta-analysis of the severity and types of preventable patient harm

Table 1 shows the pooled proportions of the severity and types of preventable patient harm. The pooled proportion of mild harm was 49% (95% confidence interval 43% to 56%, I^2=97%), moderate harm was 36% (31% to 42%, I^2=96%), and severe harm was 12% (9% to 15%, I^2=94%).

Drug management incidents (25%, 95% confidence interval 16% to 34%, I^2=98%), and other therapeutic management incidents (24%, 21% to 30%, I^2=98%), accounted for the highest proportion of preventable patient harm followed by incidents related to surgical procedures (23%, 9% to 38%, I^2=98%), healthcare infections (16%, 11% to 22%, I^2=98%), and diagnosis (16%, 11% to 21%, I^2=98%).

Meta-regressions exploring the variance in the prevalence of preventable patient harm

Table 2 shows the results of the univariable and multivariable analyses. The univariable analyses showed that the prevalence of preventable patient harm was higher across studies based in advanced

Table 1 | Proportions of types of preventable patient harm and overall patient harm

		Preventable harm			Overall harm		
Outcome	No	% (95% CI)	I^2	Median (IQR)	% (95% CI)	I^2	Median (IQR)
Prevalence							
Overall	70	6 (5 to 7)	99	5 (3-9)	12 (9 to 14)	99	10 (7-15)
Emergency department	6	3 (2 to 4)	78	3 (3-4)	5 (3 to 6)	84	5 (4-6)
Hospitals	45	5 (4 to 6)	99	5 (3-7)	10 (9 to 12)	99	10 (7-12)
Intensive care	6	18 (12 to 26)	96	14 (10-28)	34 (19 to 50)	99	29 (20-59)
Obstetrics	4	2 (0 to 4)	95	NA	4 (2 to 6)	92	NA
Primary care	3	3 (0 to 9)	0	NA	7 (3 to 10)	0	NA
Surgery	6	10 (7 to 13)	97	9 (9-10)	20 (14 to 27)	99	22 (15-30)
Severity of patient harm							
Mild	20	49 (43 to 56)	97	45 (40-55)	50 (41 to 59)	98	49 (43-58)
Moderate	20	36 (31 to 42)	96	38 (30-50)	36 (28 to 44)	98	36 (27-47)
Severe	20	12 (9 to 15)	94	10 (8-19)	12 (8 to 15)	95	13 (6-17)
Types of patient harm							
Drugs	25	25 (16 to 34)	98	20 (9-35)	26 (19 to 34)	99	21 (17-30)
Other therapeutic	17	24 (21 to 30)	98	22 (16-30)	20 (9 to 31)	98	21 (12-32)
Procedure	20	23 (13 to 33)	98	18 (6-28)	24 (17 to 31)	98	19 (14-32)
Surgical procedure	18	23 (9 to 38)	98	21 (8-36)	31 (20 to 42)	98	27 (16-41)
Diagnosis	20	16 (11 to 21)	98	12 (5-22)	9 (6 to 12)	98	10 (6-11)
Healthcare infections	14	16 (11 to 22)	98	NA	21 (15 to 28)	98	NA

The proportions for types of preventable or overall harm do not add to 100% because each figure in the table is the pooled proportion which has been calculated by combining (after assigning appropriate weights) proportions extracted from several independent studies using meta-analysis. Moreover, not all studies reported all types of preventable or overall harm and therefore it is not appropriate to assume they add up to 100%.
NA=not applicable.

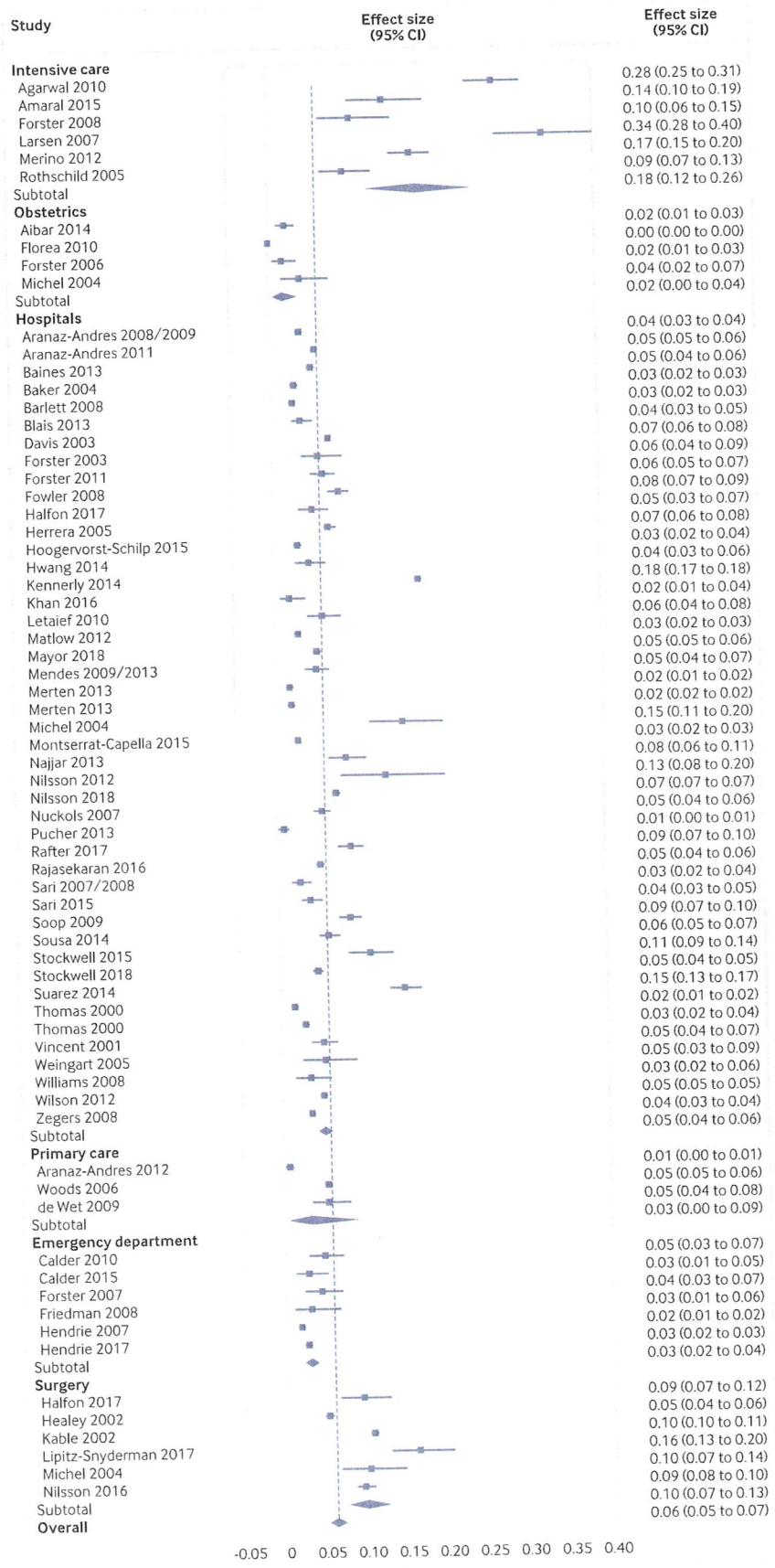

Fig 2 | Forest plot of the pooled prevalence of preventable patient harm across medical care settings

specialties such as surgery and intensive care (b=0.08, 95% confidence interval 0.05 to 0.11), in studies with relatively small sample sizes (b=0.03, 0.01 to 0.06), and in studies on children and older adults (b=0.03, −0.01 to 0.05). These three variables (medical care setting, population group, and sample size) were therefore eligible for inclusion in the multivariable regression analysis. All the other variables (research design, assessment method of harm, assessment of preventability, risk of bias, and WHO region) were ineligible for inclusion in multivariable analyses because none of them influenced the prevalence of preventable patient harm in unvariable analyses (P>0.10).

The overall multivariable model was statistically significant (χ^2 (4)=33.98, P<0.001) and reduced the I^2 statistic from 79% to 31%. Only the medical care setting (b=0.07, 95% confidence interval 0.04 to 0.10) remained a significant predictor of the prevalence of preventable patient harm in multivariable analyses suggesting that the prevalence of preventable patient harm is higher in advanced medical specialties (surgery and primary care) compared with studies in general hospitals. The population group and sample size were not significantly associated with the prevalence of preventable patient harm after controlling for the medical care setting in the multivariable analyses.

Small study bias

Figure 3 shows some evidence of publication bias as indicated by visual inspections of the funnel plots and by the Egger test for small study effects for the primary outcome (bias coefficient for the main analysis 1.20, 95% confidence interval 0.24 to 2.15, P=0.02).

Discussion

Understanding and mitigating preventable patient harm is a major public health challenge across the globe. We conducted a systematic review and meta-analysis to understand the prevalence, severity, and common types of preventable patient harm across medical care settings. We pooled data from 70 studies and we found that preventable patient harm occurs in 6% of patients across medical care settings. Considering that a pooled prevalence of 12% for overall harm was found, we conclude that half of patient harm is preventable. The proportion of severe preventable patient harm causing prolonged, permanent disability or death was 12%. The most common types of preventable patient harm were related to drugs, other therapeutic management, and invasive medical and surgical procedures. The most extensive evidence on preventable patient harm comes from hospitals (45 studies) but less evidence is available for specific medical specialties. Preventable patient harm was more prevalent in patients treated in surgical and intensive care units compared with patients treated within across general hospitals. None of the other method variations which we examined across the studies influenced the pooled prevalence of preventable patient harm (population group, research design, assessment method of harm, assessment of preventability, sample size, risk of bias, or WHO region).

Table 2 | Univariable and multivariable predictors of the prevalence of preventable patient harm (n=70)

		Univariable			Multivariable		
Variable	No	Regression coefficient (95% CI)	SE	P value	Regression coefficient (95% CI)	SE	P value
WHO region:							
US	33	1	—	—	—	—	—
Europe	27	−0.01 (−0.03 to 0.01)	0.01	0.59	NA	NA	NA
Asia or other	10	−0.01 (−0.02 to 0.04)	0.02	0.54	NA	NA	NA
Medical setting:							
General hospitals and obstetrics	49	1	—	—	1	—	—
Primary care and emergency department	9	−0.02 (−0.05 to 0.01)	0.02	0.18	−0.03 (−0.06 to 0.01)	0.02	0.12
Advanced hospital specialties	12	0.08 (0.05 to 0.11)	0.02	<0.001	0.07 (0.04 to 0.10)	0.01	<0.001
Research design:							
Retrospective or cross sectional	50	1	—	—	—	—	—
Prospective	20	0.01 (−0.01 to 0.04)	0.01	0.31	NA	NA	NA
Sample size:							
Large (n>1000)	43	1	—	—	1	—	—
Small (n<1000)	27	0.03 (0.01 to 0.06)	0.01	0.02	0.02 (−0.01 to 0.04)	0.01	0.12
Population:							
Adults	59	1	—	—	—	—	—
Children or older adults	11	0.03 (−0.01 to 0.05)	0.02	0.09	0.02 (−0.01 to 0.05)	0.01	0.09
Assessment method:							
Medical record review	53	1	—	—	—	—	—
Surveys with patients and health providers	17	−0.01 (−0.04 to 0.02)	0.01	0.58	NA	NA	NA
Preventability by consensus among reviewers using:							
Standardised Likert scale	43	1	—	—	1	—	—
Implicit criteria	27	0.01 (−0.01 to 0.04)	0.01	0.36	NA	NA	NA
Risk of bias:							
High (<7 score)	41	1	—	—	—	—	—
Low (>7 score)	29	−0.01 (−0.03 to 0.02)	0.01	0.89	NA	NA	NA

SE=standard error; NA=not applicable.

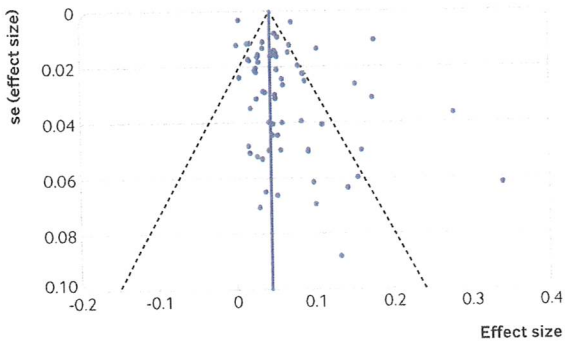

Fig 3 | Funnel plot of studies included in analysis with pseudo 95% confidence intervals (se=standard error)

Strengths and limitations of the study

Despite the unique focus on preventable patient harm and several method strengths, this review has also limitations. Firstly, the prevalence of preventable patient harm varied considerably across studies and this variation was only partly explained in meta regression analyses. Other relevant factors likely accounted for the unexplained heterogeneity. For example, variations in the timeframe used to detect harm might be important when interpreting the differences in the prevalence estimates,[1] alongside variations in the implementation of quality assurance programmes and the quality of the documentation used for detecting preventable patient harm. For example, quality assurance programmes have possibly been implemented in parallel with some of the reviewed studies which might account for some proportion of the heterogeneity that we observed in this meta-analysis.

Secondly, a critical eligibility criterion to ensure feasibility of this review was that data on preventable patient harm were available in the published reports of the studies. Studies which did not report data on preventable patient harm were excluded from the analyses. However, most studies focused primarily on overall patient harm, reported preventable patient harm as a secondary outcome, and only one third of the studies provided an analysis of severity and types of preventable patient harm.[100]

Thirdly, preventability rankings are likely to evolve over time especially after new technological advancements in healthcare. Consequently, some patient harms which are now considered non-preventable might be preventable in the future.[10] However, the studies we reviewed consistently found that about 50% of patient harm was preventable and we did not observe any different patterns over the past 19 years.

Fourthly, over half of the reviewed studies employed retrospective case record reviews to investigate the prevalence, nature, and severity of preventable patient harm. Although case record reviews are the most universally used method for assessing patient harm to date, patients and healthcare providers have repeatedly expressed concerns that data contained in case records do not capture the full range of harms that they experience during their healthcare encounters.[101 102] On the other hand, self reporting of patient harms (either by patients or healthcare providers) relies on recall and has its own limitations. Combining methods (such as prospective case record reviews with surveys with patients and healthcare providers)[103] with the parallel engagement of patients as partners in identifying medical errors and mitigating preventable patient harm are promising approaches for enhancing patient safety.[104 105]

Comparison with other studies

Our headline finding is that preventable patient harm is a highly prevalent international healthcare challenge which causes unnecessary patient suffering and can result in several avoidable deaths. As this review is specifically designed to understand patterns of preventable patient harm, comparisons with existing reviews focused on overall harm is problematic.[1 15 106-108] Although we concur that examining the nature of overall harm is important, increasing the emphasis on preventable patient harm (which is the most amenable form of patient harm) is critical in terms of designing efficient patient safety strategies.

There is also evidence that preventable patient harm is not only a public health concern but incurs a considerable opportunity cost. The excess length of hospital stays attributable to medical errors is estimated to be 2.4 million hospital days, which accounts for $9.3 billion (£7.3bn; €8.2bn) excess charges in the US.[7] Similarly, only six selected types of preventable patient harms in English hospitals result in 934 excell bed days per 100 000 population, which is equivalent to over 3500 salaried hospital nurses each year.[109] Thus, investments in developing and evaluating mitigation strategies for preventable patient harm are urgently needed and are strongly supported by our findings.

Policy implications

Our findings provide a useful agenda of priority areas for mitigating preventable patient harm. When exploring the nature of preventable patient harm, drug related and therapeutic incidents comprise the majority. This finding echoes recommendations from international patient safety policy initiatives in the past decade including the recent WHO's third global patient safety challenge "medication without harm."[106 110] Thus, it would be logical to prioritise efforts on developing and testing evidence-based mitigation strategies for these specific types of preventable patient harm. As this study establishes the scale of preventable patient harm in medical care settings, the need to gain better insight about the systemic and cultural circumstances under which preventable patient harm occurs is highlighted as a priority area. Several studies have sought to explain patient harms by reference to their sociotechnical context. For example, Vincent and colleagues proposes that patient harm occur because of contributory factors (which include "active" and "latent" failures) in the healthcare system.[111] These failures correspond to

characteristics of the system such as the tasks that are undertaken, the people, technology, and tools that are involved, and the organisational values and structures in which the system operates.[112] The studies included in our review, however, did not provide much insight into the way in which such factors might have contributed to the instances of preventable harm identified. Retrospective examination of patient harm often does not capture the myriad ways in which contributory factors could combine to produce—or avert—a preventable incident of patient harm.[113] Mixed method approaches, which connect the occurrence of patient harm to the presence of specific contributory factors and engage patients as partners in establishing these connections, have excellent prospects to achieve an in depth understanding of possible pathways to patient harm.[114-118]

A thorough understanding of the nature of preventable patient harm and its determinants could offer useful, evidence-based directions for designing efficient mitigation strategies. A combination of individual-level measures (eg, educational interventions for practitioners), system-level measures (eg, human-centred design of healthcare tasks and work environments), and organisational-level measures (eg, introducing quality monitoring and improvement processes) are likely to be a promising strategy for mitigating preventable patient harm,[119 120] but scalable evaluations of these interventions are needed to support wider implementation. Furthermore, the interventions depend on the presence of an organisational context that supports their implementation.[121 122]

Another important finding is that preventable patient harm appears to be a serious concern in advanced medical specialties including intensive care and surgical units. Patients treated in these specialties were more likely to experience preventable patient harm compared with patients treated in general hospitals. Surgical harm is a sizeable part of the overall in-hospital harm,[15 123] but our estimates are higher than anticipated. The underlying causes of these figures warrant further investigation because current safety standards could "be failing to rescue" many high risk patients treated in advanced specialties.[124] Moreover, clinicians in these specialties are often exposed to work pressures and are expected to deliver life-changing decisions quickly which might negatively impact on their personal wellbeing, a well known risk factor for preventable medical incidents.[125] On the other hand, surgery and intensive care units deal with high risk patients to whom complex medical procedures are implemented. Patient harm therefore might be more detectable in these settings because of its immediate, serious, or cumulative impact on patients' health or because better surveillance systems for detecting patient harm are implemented in these settings. Additionally, it is not always clear from the study designs that some proportion of the preventable patient harm has not occurred in the transition between general hospital care and advanced specialty care.[108]

Another major contribution of our synthesis is that it highlights key gaps in the literature on preventable patient harm. Only two studies were based in primary care, where over 80% of healthcare service is delivered internationally,[8 126] and no evidence was identified in psychiatry. Certain types of preventable harms which tend to occur in primary care and psychiatry might remain undetected or untargeted by quality and safety improvement programmes. For example, we found that diagnostic harm is a common preventable type of harm but our understanding of its nature needs to be improved. A likely explanation is that diagnostic harm is directly or indirectly linked with the provision of services in primary care where research on preventable patient harm is sparse.[127 128] Obtaining more precise estimates of the types and sources of preventable diagnostic harm occurring in primary care or in transitions from primary care to hospital care could lay the foundation for implementing efficient interventions for diagnostic harm. Systemic interventions, enhanced patient involvement in decision making for diagnoses, use of electronic tools, and emotion-cognitive interventions for boosting practitioners' confidence or certainty in making diagnoses are potentially fruitful intervention areas for reducing diagnostic harm but have not been systematically evaluated or implemented in practice.[104 127-130]

Less than a handful of studies focused on children and older adults, groups increasingly viewed as vulnerable to low quality or unsafe care. Furthermore, only a fraction of the included studies were conducted in developing countries, as many studies from developing countries failed to provide data on preventability of harm which rendered them ineligible. Thus, despite the evidence showing that the prevalence of overall harm is higher in developing countries compared with developed countries, we did not find such difference for preventable patient harm.

Commissioning research to understand the prevalence, nature, and impact of preventable patient harm in primary care and psychiatry, among vulnerable patient groups (eg, young children, older adults, or marginalised groups of the society such prison healthcare) and in developing countries has the potential to advance policy guidance and practice for mitigating preventable patient harm.

Conclusion

Our findings affirm that preventable patient harm is a serious problem across medical care settings. Priority areas are the mitigation of major sources of preventable patient harm (such as drug incidents) and greater focus on advanced medical specialties. It is equally imperative to build evidence across specialties such as primary care and psychiatry, vulnerable patient groups, and developing countries. Improving the assessment and reporting standards of preventability in future studies is critical for reducing patient harm in medical care settings.

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extraction. MP, KK, and DMA wrote the paper. All authors interpreted the findings and contributed to critical revision of the manuscript. All authors had full access to the data in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis. MP is the guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted.

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1 de Vries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. *Qual Saf Health Care* 2008;17:216-23. doi:10.1136/qshc.2007.023622
2 Jha AK, Larizgoitia I, Audera-Lopez C, Prasopa-Plaizier N, Waters H, Bates DW. The global burden of unsafe medical care: analytic modelling of observational studies. *BMJ Qual Saf* 2013;22:809-15. doi:10.1136/bmjqs-2012-001748
3 The Conceptual Framework for the International Classification for Patient Safety. *World Alliance for Patient Safety Taxonomy*. World Health Organisation, 2009.
4 Makary MA, Daniel M. Medical error-the third leading cause of death in the US. *BMJ* 2016;353:i2139. doi:10.1136/bmj.i2139
5 Stelfox HT, Palmisani S, Scurlock C, Orav EJ, Bates DW. The "To Err is Human" report and the patient safety literature. *Qual Saf Health Care* 2006;15:174-8. doi:10.1136/qshc.2006.017947
6 Slawomirski L, Auraaen A, Klazinga N. *The economics of patient safety*. Organisation for Economic Co-operation and Development, 2017.
7 Zhan C, Miller MR. Excess length of stay, charges, and mortality attributable to medical injuries during hospitalization. *JAMA* 2003;290:1868-74. doi:10.1001/jama.290.14.1868
8 Sheikh A, Panesar SS, Larizgoitia I, Bates DW, Donaldson LJ. Safer primary care for all: a global imperative. *Lancet Glob Health* 2013;1:e182-3. doi:10.1016/S2214-109X(13)70030-5
9 Pronovost PJ, Colantuoni E. Measuring preventable harm: helping science keep pace with policy. *JAMA* 2009;301:1273-5. doi:10.1001/jama.2009.388
10 Nabhan M, Elraiyah T, Brown DR, et al. What is preventable harm in healthcare? A systematic review of definitions. *BMC Health Serv Res* 2012;12:128. doi:10.1186/1472-6963-12-128
11 Chang A, Schyve PM, Croteau RJ, O'Leary DS, Loeb JM. The JCAHO patient safety event taxonomy: a standardized terminology and classification schema for near misses and adverse events. *Int J Qual Health Care* 2005;17:95-105. doi:10.1093/intqhc/mzi021
12 Elder NC, Dovey SM. Classification of medical errors and preventable adverse events in primary care: a synthesis of the literature. *J Fam Pract* 2002;51:927-32.
13 Loeb JM, Chang A. *Patient safety: Reduction of adverse events through common understanding and common reporting tools. Towards an international patient safety taxonomy*. World Health Organization, 2003.
14 Brennan TA, Leape LL, Laird NM, et al. Harvard Medical Practice Study I. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. 1991. *Qual Saf Health Care* 2004;13:145-51, discussion 151-2. doi:10.1136/qshc.2002.003822
15 Anderson O, Davis R, Hanna GB, Vincent CA. Surgical adverse events: a systematic review. *Am J Surg* 2013;206:253-62. doi:10.1016/j.amjsurg.2012.11.009
16 Long SJ, Brown KF, Ames D, Vincent C. What is known about adverse events in older medical hospital inpatients? A systematic review of the literature. *Int J Qual Health Care* 2013;25:542-54. doi:10.1093/intqhc/mzt056
17 Nilsson L, Pihl A, Tågsjö M, Ericsson E. Adverse events are common on the intensive care unit: results from a structured record review. *Acta Anaesthesiol Scand* 2012;56:959-65. doi:10.1111/j.1399-6576.2012.02711.x
18 Stroup DF, Berlin JA, Morton SC, et al. Meta-analysis of observational studies in epidemiology: a proposal for reporting. Meta-analysis Of Observational Studies in Epidemiology (MOOSE) group. *JAMA* 2000;283:2008-12. doi:10.1001/jama.283.15.2008
19 Lilford R, Stirling S, Maillard N. Citation classics in patient safety research: an invitation to contribute to an online bibliography. *Qual Saf Health Care* 2006;15:311-3. doi:10.1136/qshc.2005.017178
20 Luchini C, Stubbs B, Solmi M, et al. Assessing the quality of studies in meta-analyses: Advantages and limitations of the Newcastle Ottawa Scale. *World J Metaanal* 2017;5:80-4. doi:10.13105/wjma.v5.i4.80
21 Kontopantelis E, Reeves D. metaan: Random-effects meta-analysis. *Stata J* 2010;10:395-407. doi:10.1177/1536867X1001000307
22 Harbord RM, Higgins JPT. Meta-regression in Stata. *Stata J* 2008;8:493-519. doi:10.1177/1536867X0800800403
23 Thompson SG, Higgins JPT. How should meta-regression analyses be undertaken and interpreted?*Stat Med* 2002;21:1559-73. doi:10.1002/sim.1187
24 Freeman MF, Tukey JW. Transformations Related to the Angular and the Square Root. *Ann Math Stat* 1950;21:607-11. doi:10.1214/aoms/1177729756
25 DerSimonian R, Laird N. Meta-analysis in clinical trials. *Control Clin Trials* 1986;7:177-88. doi:10.1016/0197-2456(86)90046-2
26 Brockwell SE, Gordon IR. A comparison of statistical methods for meta-analysis. *Stat Med* 2001;20:825-40. doi:10.1002/sim.650
27 Kontopantelis E, Reeves D. Performance of statistical methods for meta-analysis when true study effects are non--normally distributed: a comparison between DerSimonian-Laird and restricted maximum likelihood. *Stat Methods Med Res* 2012;21:657-9. doi:10.1177/0962280211413451
28 Higgins JP, Thompson SG, Deeks JJ, Altman DG. Measuring inconsistency in meta-analyses. *BMJ* 2003;327:557-60. doi:10.1136/bmj.327.7414.557
29 Egger M, Davey Smith G, Schneider M, Minder C. Bias in meta-analysis detected by a simple, graphical test. *BMJ* 1997;315:629-34. doi:10.1136/bmj.315.7109.629
30 Sterne JAC, Harbord RM. Funnel plots in meta-analysis. *Stata J* 2004;4:127-41. doi:10.1177/1536867X0400400204
31 Harbord RM, Harris RJ, Sterne JAC. Updated tests for small-study effects in meta-analyses. *Stata J* 2009;9:197-210. doi:10.1177/1536867X0900900202
32 Agarwal S, Classen D, Larsen G, et al. Prevalence of adverse events in pediatric intensive care units in the United States. *Pediatr Crit Care Med* 2010;11:568-78. doi:10.1097/PCC.0b013e3181d8e405
33 Aibar L, Rabanaque MJ, Aibar C, Aranaz JM, Mozas J. Patient safety and adverse events related with obstetric care. *Arch Gynecol Obstet* 2015;291:825-30. doi:10.1007/s00404-014-3474-3
34 Amaral ACKB, McDonald A, Coburn NG, et al. Expanding the scope of Critical Care Rapid Response Teams: a feasible approach to identify adverse events. A prospective observational cohort. *BMJ Qual Saf* 2015;24:764-8. doi:10.1136/bmjqs-2014-003833
35 Aranaz-Andrés JM, Aibar-Remón C, Vitaller-Murillo J, Ruiz-López P, Limón-Ramírez R, Terol-García E, ENEAS work group. Incidence of adverse events related to health care in Spain: results of the Spanish National Study of Adverse Events. *J Epidemiol Community Health* 2008;62:1022-9. doi:10.1136/jech.2007.065227
36 Aranaz-Andrés JM, Aibar C, Limón R, et al. A study of the prevalence of adverse events in primary healthcare in Spain. *Eur J Public Health* 2012;22:921-5. doi:10.1093/eurpub/ckr168
37 Aranaz-Andrés JM, Aibar-Remón C, Limón-Ramírez R, et al, IBEAS team. Prevalence of adverse events in the hospitals of five Latin American countries: results of the 'Iberoamerican Study of Adverse Events' (IBEAS). *BMJ Qual Saf* 2011;20:1043-51. doi:10.1136/bmjqs.2011.051284
38 Aranaz-Andrés JM, Aibar-Remón C, Vitaller-Burillo J, et al. ENEAS work group. Impact and preventability of adverse events in Spanish public hospitals: results of the Spanish National Study of Adverse Events (ENEAS). *Int J Qual Health Care* 2009;21:408-14. doi:10.1093/intqhc/mzp047

39 Baines RJ, Langelaan M, de Bruijne MC, et al. Changes in adverse event rates in hospitals over time: a longitudinal retrospective patient record review study. *BMJ Qual Saf* 2013;22:290-8. doi:10.1136/bmjqs-2012-001126
40 Baker GR, Norton PG, Flintoft V, et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. *CMAJ* 2004;170:1678-86. doi:10.1503/cmaj.1040498
41 Bartlett G, Blais R, Tamblyn R, Clermont RJ, MacGibbon B. Impact of patient communication problems on the risk of preventable adverse events in acute care settings. *CMAJ* 2008;178:1555-62. doi:10.1503/cmaj.070690
42 Blais R, Sears NA, Doran D, et al. Assessing adverse events among home care clients in three Canadian provinces using chart review. *BMJ Qual Saf* 2013;22:989-97. doi:10.1136/bmjqs-2013-002039
43 Calder L, Pozgay A, Riff S, et al. Adverse events in patients with return emergency department visits. *BMJ Qual Saf* 2015;24:142-8. doi:10.1136/bmjqs-2014-003194
44 Calder LA, Forster A, Nelson M, et al. Adverse events among patients registered in high-acuity areas of the emergency department: a prospective cohort study. *CJEM* 2010;12:421-30. doi:10.1017/S1481803500012574
45 Davis P, Lay-Yee R, Briant R, Scott A. Preventable in-hospital medical injury under the "no fault" system in New Zealand. *Qual Saf Health Care* 2003;12:251-6. doi:10.1136/qhc.12.4.251
46 de Wet C, Bowie P. The preliminary development and testing of a global trigger tool to detect error and patient harm in primary-care records. *Postgrad Med J* 2009;85:176-80. doi:10.1136/pgmj.2008.075788
47 Florea A, Caughey SS, Westland J, et al. The Ottawa hospital quality incident notification system for capturing adverse events in obstetrics. *J Obstet Gynaecol Can* 2010;32:657-62. doi:10.1016/S1701-2163(16)34569-8
48 Forster AJ, Fung I, Caughey S, et al. Adverse events detected by clinical surveillance on an obstetric service. *Obstet Gynecol* 2006;108:1073-83. doi:10.1097/01.AOG.0000242565.28432.7c
49 Forster AJ, Kyeremanteng K, Hooper J, Shojania KG, van Walraven C. The impact of adverse events in the intensive care unit on hospital mortality and length of stay. *BMC Health Serv Res* 2008;8:259. doi:10.1186/1472-6963-8-259
50 Forster AJ, Murff HJ, Peterson JF, Gandhi TK, Bates DW. The incidence and severity of adverse events affecting patients after discharge from the hospital. *Ann Intern Med* 2003;138:161-7. doi:10.7326/0003-4819-138-3-200302040-00007
51 Forster AJ, Rose NGW, van Walraven C, Stiell I. Adverse events following an emergency department visit. *Qual Saf Health Care* 2007;16:17-22. doi:10.1136/qshc.2005.017384
52 Forster AJ, Worthington JR, Hawken S, et al. Using prospective clinical surveillance to identify adverse events in hospital. *BMJ Qual Saf* 2011;20:756-63. doi:10.1136/bmjqs.2010.048694
53 Fowler FJJr, Epstein A, Weingart SN, et al. Adverse events during hospitalization: results of a patient survey. *Jt Comm J Qual Patient Saf* 2008;34:583-90. doi:10.1016/S1553-7250(08)34073-2
54 Friedman SM, Provan D, Moore S, Hanneman K. Errors, near misses and adverse events in the emergency department: what can patients tell us?*CJEM* 2008;10:421-7. doi:10.1017/S1481803500010484
55 Halfon P, Staines A, Burnand B. Adverse events related to hospital care: a retrospective medical records review in a Swiss hospital. *Int J Qual Health Care* 2017;29:527-33. doi:10.1093/intqhc/mzx061
56 Healey MA, Shackford SR, Osler TM, Rogers FB, Burns E. Complications in surgical patients. *Arch Surg* 2002;137:611-7, discussion 617-8. doi:10.1001/archsurg.137.5.611
57 Hendrie J, Sammartino L, Silvapulle MJ, Braitberg G. Experience in adverse events detection in an emergency department: incidence and outcome of events. *Emerg Med Australas* 2007;19:16-24. doi:10.1111/j.1742-6723.2006.00896.x
58 Hendrie J, Yeoh M, Richardson J, et al. Case-control study to investigate variables associated with incidents and adverse events in the emergency department. *Emerg Med Australas* 2017;29:149-57 doi:10.1111/1742-6723.12736
59 Herrera-Kiengelher L, Chi-Lem G, Báez-Saldaña R, et al. Frequency and correlates of adverse events in a respiratory diseases hospital in Mexico city. *Chest* 2005;128:3900-5. doi:10.1378/chest.128.6.3900
60 Hoogervorst-Schilp J, Langelaan M, Spreeuwenberg P, de Bruijne MC, Wagner C. Excess length of stay and economic consequences of adverse events in Dutch hospital patients. *BMC Health Serv Res* 2015;15:531. doi:10.1186/s12913-015-1205-5
61 Hwang J-I, Chin HJ, Chang Y-S. Characteristics associated with the occurrence of adverse events: a retrospective medical record review using the Global Trigger Tool in a fully digitalized tertiary teaching hospital in Korea. *J Eval Clin Pract* 2014;20:27-35. doi:10.1111/jep.12075
62 Kable AK, Gibberd RW, Spigelman AD. Adverse events in surgical patients in Australia. *Int J Qual Health Care* 2002;14:269-76. doi:10.1093/intqhc/14.4.269
63 Kennerly DA, Kudyakov R, da Graca B, et al. Characterization of adverse events detected in a large health care delivery system using an enhanced global trigger tool over a five-year interval. *Health Serv Res* 2014;49:1407-25. doi:10.1111/1475-6773.12163
64 Khan A, Furtak SL, Melvin P, Rogers JE, Schuster MA, Landrigan CP. Parent-Reported Errors and Adverse Events in Hospitalized Children. *JAMA Pediatr* 2016;170:e154608. doi:10.1001/jamapediatrics.2015.4608
65 Larsen GY, Donaldson AE, Parker HB, Grant MJ. Preventable harm occurring to critically ill children. *Pediatr Crit Care Med* 2007;8:331-6. doi:10.1097/01.PCC.0000263042.73539.99
66 Lehmann LS, Puopolo AL, Shaykevich S, Brennan TA. Iatrogenic events resulting in intensive care admission: frequency, cause, and disclosure to patients and institutions. *Am J Med* 2005;118:409-13. doi:10.1016/j.amjmed.2005.01.012
67 Lipitz-Snyderman A, Pfister D, Classen D, et al. Preventable and mitigable adverse events in cancer care: Measuring risk and harm across the continuum. *Cancer* 2017;123:4728-36. doi.10.1002/cncr.30916
68 Matlow AG, Baker GR, Flintoft V, et al. Adverse events among children in Canadian hospitals: the Canadian Paediatric Adverse Events Study. *CMAJ* 2012;184:E709-18. doi:10.1503/cmaj.112153
69 Mayor S, Baines E, Vincent C, et al. *Health Services and Delivery Research. Measuring harm and informing quality improvement in the Welsh NHS: the longitudinal Welsh national adverse events study.* NIHR Journals Library, 2017.
70 Mendes W, Martins M, Rozenfeld S, Travassos C. The assessment of adverse events in hospitals in Brazil. *Int J Qual Health Care* 2009;21:279-84. doi:10.1093/intqhc/mzp022
71 Mendes W, Pavão ALB, Martins M, Moura MdeL, Travassos C. The feature of preventable adverse events in hospitals in the State of Rio de Janeiro, Brazil. *Rev Assoc Med Bras (1992)* 2013;59:421-8 doi:10.1016/j.ramb.2013.03.002
72 Merino P, Álvarez J, Cruz Martín M, Alonso Á, Gutiérrez I, SYREC Study Investigators. Adverse events in Spanish intensive care units: the SYREC study. *Int J Qual Health Care* 2012;24:105-13. doi:10.1093/intqhc/mzr083
73 Merten H, Zegers M, de Bruijne MC, Wagner C. Scale, nature, preventability and causes of adverse events in hospitalised older patients. *Age Ageing* 2013;42:87-93. doi:10.1093/ageing/afs153
74 Michel P, Quenon JL, de Sarasqueta AM, Scemama O. Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals. *BMJ* 2004;328:199. doi:10.1136/bmj.328.7433.199
75 Montserrat-Capella D, Suárez M, Ortiz L, Mira JJ, Duarte HG, Reveiz L, AMBEAS Group. Frequency of ambulatory care adverse events in Latin American countries: the AMBEAS/PAHO cohort study. *Int J Qual Health Care* 2015;27:52-9. doi:10.1093/intqhc/mzu100
76 Najjar S, Hamdan M, Euwema MC, et al. The Global Trigger Tool shows that one out of seven patients suffers harm in Palestinian hospitals: challenges for launching a strategic safety plan. *Int J Qual Health Care* 2013;25:640-7. doi:10.1093/intqhc/mzt066
77 Nilsson L, Borgstedt-Risberg M, Soop M, et al. Incidence of adverse events in Sweden during 2013-2016: a cohort study describing the implementation of a national trigger tool. *BMJ Open* 2018;8:e020833. doi:10.1136/bmjopen-2017-020833
78 Nilsson L, Risberg MB, Montgomery A, Sjodahl R, Schildmeijer K, Rutberg H. Preventable Adverse Events in Surgical Care in Sweden: A Nationwide Review of Patient Notes *Medicine (Baltimore)* 2016;95:e3047. doi:10.1097/MD.0000000000003047
79 Nuckols TK, Bell DS, Liu H, Paddock SM, Hilborne LH. Rates and types of events reported to established incident reporting systems in two US hospitals. *Qual Saf Health Care* 2007;16:164-8. doi:10.1136/qshc.2006.019901
80 Pucher PH, Aggarwal R, Twaij A, Batrick N, Jenkins M, Darzi A. Identifying and addressing preventable process errors in trauma care. *World J Surg* 2013;37:752-8. doi:10.1007/s00268-013-1917-9
81 Rafter N, Hickey A, Conroy RM, et al. The Irish National Adverse Events Study (INAES): the frequency and nature of adverse events in Irish hospitals-a retrospective record review study. *BMJ Qual Saf* 2017;26:111-9. doi:10.1136/bmjqs-2015-004828
82 Rajasekaran S, Ravi S, Aiyer SN. Incidence and preventability of adverse events in an orthopaedic unit: a prospective analysis of four thousand, nine hundred and six admissions. *Int Orthop* 2016;40:2233-8. doi:10.1007/s00264-016-3282-4
83 Rothschild JM, Landrigan CP, Cronin JW, et al. The Critical Care Safety Study: The incidence and nature of adverse events and serious medical errors in intensive care. *Crit Care Med* 2005;33:1694-700. doi:10.1097/01.CCM.0000171609.91035.BD
84 Sari AA, Doshmangir L, Torabi F, et al. The incidence, nature and consequences of adverse events in Iranian hospitals. *Arch Iran Med* 2015;18:811-15. doi:0151812/AIM.004
85 Sari ABA, Cracknell A, Sheldon TA. Incidence, preventability and consequences of adverse events in older people: results of a

retrospective case-note review. *Age Ageing* 2008;37:265-9. doi:10.1093/ageing/afn043
86 Sari AB-A, Sheldon TA, Cracknell A, et al. Extent, nature and consequences of adverse events: results of a retrospective casenote review in a large NHS hospital. *Qual Saf Health Care* 2007;16:434-9. doi:10.1136/qshc.2006.021154
87 Soop M, Fryksmark U, Köster M, Haglund B. The incidence of adverse events in Swedish hospitals: a retrospective medical record review study. *Int J Qual Health Care* 2009;21:285-91. doi:10.1093/intqhc/mzp025
88 Sousa P, Uva AS, Serranheira F, Nunes C, Leite ES. Estimating the incidence of adverse events in Portuguese hospitals: a contribution to improving quality and patient safety. *BMC Health Serv Res* 2014;14:311. doi:10.1186/1472-6963-14-311
89 Stockwell DC, Bisarya H, Classen DC, et al. A trigger tool to detect harm in pediatric inpatient settings. *Pediatrics* 2015;135:1036-42. doi:10.1542/peds.2014-2152
90 Stockwell DC, Landrigan CP, Toomey SL, et al. GAPPS Study Group. Adverse Events in Hospitalized Pediatric Patients. *Pediatrics* 2018;142:e20173360. doi:10.1542/peds.2017-3360
91 Suarez C, Menendez MD, Alonso J, Castaño N, Alonso M, Vazquez F. Detection of adverse events in an acute geriatric hospital over a 6-year period using the Global Trigger Tool. *J Am Geriatr Soc* 2014;62:896-900. doi:10.1111/jgs.12774
92 Thomas EJ, Brennan TA. Incidence and types of preventable adverse events in elderly patients: population based review of medical records. *BMJ* 2000;320:741-4. doi:10.1136/bmj.320.7237.741
93 Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ* 2001;322:517-9. doi:10.1136/bmj.322.7285.517
94 Weingart SN, Pagovich O, Sands DZ, et al. What can hospitalized patients tell us about adverse events? Learning from patient-reported incidents. *J Gen Intern Med* 2005;20:830-6. doi:10.1111/j.1525-1497.2005.0180.x
95 Williams DJ, Olsen S, Crichton W, et al. Detection of adverse events in a Scottish hospital using a consensus-based methodology. *Scott Med J* 2008;53:26-30. doi:10.1258/RSMSMJ.53.4.26
96 Wilson RM, Michel P, Olsen S, et al, WHO Patient Safety EMRO/AFRO Working Group. Patient safety in developing countries: retrospective estimation of scale and nature of harm to patients in hospital. *BMJ* 2012;344:e832. doi:10.1136/bmj.e832
97 Woods D, Thomas E, Holl J, Altman S, Brennan T. Adverse events and preventable adverse events in children. *Pediatrics* 2005;115:155-60. doi:10.1542/peds.2004-0410
98 Zegers M, de Bruijne MC, Wagner C, et al. Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study. *Qual Saf Health Care* 2009;18:297-302. doi:10.1136/qshc.2007.025924
99 Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *N Engl J Med* 1991;324:370-6. doi:10.1056/NEJM199102073240604
100 Garrouste-Orgeas M, Philippart F, Bruel C, Max A, Lau N, Misset B. Overview of medical errors and adverse events. *Ann Intensive Care* 2012;2:2. doi:10.1186/2110-5820-2-2
101 Schwappach DLB. Review: engaging patients as vigilant partners in safety: a systematic review. *Med Care Res Rev* 2010;67:119-48. doi:10.1177/1077558709342254
102 Ricci-Cabello I, Avery AJ, Reeves D, Kadam UT, Valderas JM. Measuring Patient Safety in Primary Care: The Development and Validation of the "Patient Reported Experiences and Outcomes of Safety in Primary Care" (PREOS-PC). *Ann Fam Med* 2016;14:253-61. doi:10.1370/afm.1935
103 Bjertnaes O, Deilkås ET, Skudal KE, Iversen HH, Bjerkan AM. The association between patient-reported incidents in hospitals and estimated rates of patient harm. *Int J Qual Health Care* 2015;27:26-30. doi:10.1093/intqhc/mzu087
104 McDonald KM, Bryce CL, Graber ML. The patient is in: patient involvement strategies for diagnostic error mitigation. *BMJ Qual Saf* 2013;22(Suppl 2):ii33-9. doi:10.1136/bmjqs-2012-001623
105 Khan A, Spector ND, Baird JD, et al. Patient safety after implementation of a coproduced family centered communication programme: multicenter before and after intervention study. *BMJ* 2018;363:k4764. doi:10.1136/bmj.k4764
106 Laatikainen O, Miettunen J, Sneck S, Lehtiniemi H, Tenhunen O, Turpeinen M. The prevalence of medication-related adverse events in inpatients-a systematic review and meta-analysis. *Eur J Clin Pharmacol* 2017;73:1539-49. doi:10.1007/s00228-017-2330-3
107 Stang AS, Wingert AS, Hartling L, Plint AC. Adverse events related to emergency department care: a systematic review. *PLoS One* 2013;8:e74214. doi:10.1371/journal.pone.0074214
108 Vlayen A, Verelst S, Bekkering GE, Schrooten W, Hellings J, Claes N. Incidence and preventability of adverse events requiring intensive care admission: a systematic review. *J Eval Clin Pract* 2012;18:485-97. doi:10.1111/j.1365-2753.2010.01612.x
109 Hauck KD, Wang S, Vincent C, Smith PC. Healthy Life-Years Lost and Excess Bed-Days Due to 6 Patient Safety Incidents: Empirical Evidence From English Hospitals. *Med Care* 2017;55:125-30. doi:10.1097/MLR.0000000000000631
110 Donaldson LJ, Kelley ET, Dhingra-Kumar N, Kieny MP, Sheikh A. Medication Without Harm: WHO's Third Global Patient Safety Challenge. *Lancet* 2017;389:1680-1. doi:10.1016/S0140-6736(17)31047-4
111 Vincent C, Taylor-Adams S, Stanhope N. Framework for analysing risk and safety in clinical medicine. *BMJ* 1998;316:1154-7. doi:10.1136/bmj.316.7138.1154
112 Hignett S, Lang A, Pickup L, et al. More holes than cheese. What prevents the delivery of effective, high quality and safe health care in England?*Ergonomics* 2018;61:5-14. doi:10.1080/00140139.2016.1245446
113 Reason J. The contribution of latent human failures to the breakdown of complex systems. *Philos Trans R Soc Lond B Biol Sci* 1990;327:475-84. doi:10.1098/rstb.1990.0090
114 Howard R, Avery A, Bissell P. Causes of preventable drug-related hospital admissions: a qualitative study. *Qual Saf Health Care* 2008;17:109-16. doi:10.1136/qshc.2007.022681
115 Neale G, Woloshynowych M, Vincent C. Exploring the causes of adverse events in NHS hospital practice. *J R Soc Med* 2001;94:322-30. doi:10.1177/014107680109400702
116 Jylhä V, Saranto K, Bates DW. Preventable adverse drug events and their causes and contributing factors: the analysis of register data. *Int J Qual Health Care* 2011;23:187-97. doi:10.1093/intqhc/mzq085
117 Sujan MA, Ingram C, McConkey T, Cross S, Cooke MW. Hassle in the dispensary: pilot study of a proactive risk monitoring tool for organisational learning based on narratives and staff perceptions. *BMJ Qual Saf* 2011;20:549-56. doi:10.1136/bmjqs.2010.048348
118 Phipps DL, Walshe K, Parker D, Noyce PR, Ashcroft DM. Job characteristics, well-being and risky behaviour amongst pharmacists. *Psychol Health Med* 2016;21:932-44. doi:10.1080/13548506.2016.1139142
119 Huiskes VI, Burger DM, van den Ende CH, van den Bemt BJ. Effectiveness of medication review: a systematic review and meta-analysis of randomized controlled trials. *BMC Fam Pract* 2017;18:5. doi:10.1186/s12875-016-0577-x
120 Khalil H, Bell B, Chambers H, et al. Professional, structural and organisational interventions in primary care for reducing medication errors. *Cochrane Db Syst Rev* 2017;10:CD003942. doi:10.1002/14651858.CD003942.pub3
121 Dixon-Woods M, McNicol S, Martin G. Ten challenges in improving quality in healthcare: lessons from the Health Foundation's programme evaluations and relevant literature. *BMJ Qual Saf* 2012;21:876-84. doi:10.1136/bmjqs-2011-000760
122 Phipps DL, Jones CEL, Parker D, Ashcroft DM. Organizational conditions for engagement in quality and safety improvement: a longitudinal qualitative study of community pharmacies. *BMC Health Serv Res* 2018;18:783. doi:10.1186/s12913-018-3607-7
123 Ahmed AH, Giri J, Kashyap R, et al. Outcome of adverse events and medical errors in the intensive care unit: a systematic review and meta-analysis. *Am J Med Qual* 2015;30:23-30. doi:10.1177/1062860613514770
124 Ghaferi AA, Birkmeyer JD, Dimick JB. Variation in hospital mortality associated with inpatient surgery. *N Engl J Med* 2009;361:1368-75. doi:10.1056/NEJMsa0903048
125 Shanafelt TD, Balch CM, Bechamps G, et al. Burnout and medical errors among American surgeons. *Ann Surg* 2010;251:995-1000. doi:10.1097/SLA.0b013e3181bfdab3
126 Panesar SS, deSilva D, Carson-Stevens A, et al. How safe is primary care? A systematic review. *BMJ Qual Saf* 2016;25:544-53. doi:10.1136/bmjqs-2015-004178
127 Zwaan L, Schiff GD, Singh H. Advancing the research agenda for diagnostic error reduction. *BMJ Qual Saf* 2013;22(Suppl 2):ii52-7. doi:10.1136/bmjqs-2012-001624
128 Riches N, Panagioti M, Alam R, et al. The Effectiveness of Electronic Differential Diagnoses (DDX) Generators: A Systematic Review and Meta-Analysis. *PLoS One* 2016;11:e0148991. doi:10.1371/journal.pone.0148991
129 Singh H, Graber ML, Kissam SM, et al. System-related interventions to reduce diagnostic errors: a narrative review. *BMJ Qual Saf* 2012;21:160-70. doi:10.1136/bmjqs-2011-000150
130 McDonald KM, Matesic B, Contopoulos-Ioannidis DG, et al. Patient safety strategies targeted at diagnostic errors: a systematic review. *Ann Intern Med* 2013;158:381-9. doi:10.7326/0003-4819-158-5-201303051-00004

Supplementary materials: Searches and eTable 1-4

MARYLAND
Department of Health
Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

December 12, 2018

The Honorable Larry Hogan
Governor
State of Maryland
Annapolis, MD 21401-1991

The Honorable Thomas V. Mike Miller, Jr.
President of the Senate
H-107 State House
Annapolis, MD 21401-1991

The Honorable Michael E. Busch
Speaker of the House
H-101 State House
Annapolis, MD 21401-1991

RE: Health-General Article, §13-1207, Annotated Code of Maryland - 2018 Annual Report Maryland Maternal Mortality Review

Dear Governor Hogan, President Miller, and Speaker Busch:

Pursuant to Health-General Article, §13-1207 and Senate Bill 459, Chapter 74 of the Acts of 2000, the Department of Health submits this legislative report on the findings, recommendations, and program actions of the Maternal Mortality Review Program.

If you have questions concerning this report, please contact Webster Ye, Deputy Chief of Staff, Office of the Secretary, at (410) 767-6480.

Sincerely,

Robert R. Neall
Secretary

MARYLAND
Department of Health

MARYLAND MATERNAL MORTALITY REVIEW 2018 ANNUAL REPORT

Health – General Article § 13-1207

Larry Hogan
Governor

Boyd Rutherford
Lt. Governor

Robert R. Neall
Secretary of Health

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ACKNOWLEDGEMENTS

This review of maternal deaths in Maryland would not be possible without the data, expertise, and collaboration of the Maryland Department of Health's Vital Statistics Administration and the Office of the Chief Medical Examiner. The Maternal Mortality Review Program would like to also offer special thanks to the volunteer members of its Maternal Mortality Review Committee for the hours spent in discussion and the serious attention given to this important public health project. The Program is also grateful for the diligent work of the case abstractors in their careful and thorough abstraction of case materials. The Program also thanks MedChi, the Maryland State Medical Society for their collaboration in the administrative support of the Committee. Special thanks to all those who participated in this year's Committee meetings and case reviews:

Committee Member	**Hospital / Affiliation**
Cristina Aquia, RN	University of Maryland St. Joseph Medical Center
Pablo Argeles, MD	University of Maryland Baltimore Washington Medical Center
Pedro Arrabal, MD	Sinai Hospital
Robert Atlas, MD	Mercy Medical Center
Carol Ator, RN	University of Maryland St. Joseph Medical Center
Shobana Bharadwaj, MD	University of Maryland Medical System
Ann Burke, MD	Holy Cross Hospital
Diana Cheng, MD	MMR Abstractor
Andreea Creanga, MD, PhD	Johns Hopkins Bloomberg School of Public Health
Deborah Doerfer, CNM	Johns Hopkins Hospital
Jill Edwardson, MD	Johns Hopkins Bayview Medical Center, MMR Abstractor
Jen Fahey, CNM	University of Maryland Medical System
Stacy Fisher, MD	University of Maryland Medical System
Lorraine Goldstein, CNM	MMR Abstractor
Katherine Goetzinger, MD	University of Maryland Medical System
Elizabeth Greely, MD	Anne Arundel Medical Center
Asrar Green, RN	Medstar Southern Maryland Hospital
Clark Johnson, MD	Johns Hopkins Hospital, MMR Committee Chair
Jan Kriebs, CNM	MMR Abstractor
Lorraine Milio, MD	Johns Hopkins Bayview Medical Center, Center for Addiction and Pregnancy, MMR Abstractor
Judith Rossiter, MD	University of Maryland St. Joseph Medical Center
S. Lee Woods, MD, PhD	Maryland Department of Health, MMR Program Director

Staff to the Committee:

Shayna Banfield
Clara Richards

BACKGROUND

The Maryland Maternal Mortality Review Program (the Program) was established in statute in 2000. Md. Ann. Code Health-General Art., §13-1203—1207, establishes the Program in the Maryland Department of Health (the Department) and describes its scope. The purpose of the Program is to: (1) identify maternal death cases; (2) review medical records and other relevant data; (3) determine preventability of death; (4) develop recommendations for the prevention of maternal deaths; and (5) disseminate findings and recommendations to policymakers, health care providers, health care facilities, and the general public.

The Maternal Mortality Review Committee (the MMR Committee), which was established by the Program and is made up of volunteer heath care and public health professionals, conducts maternal mortality case reviews. The Department collaborates with MedChi, the Maryland State Medical Society, to provide administrative support in the maternal mortality review process by obtaining medical records, abstracting cases, and hosting meetings of the Department's MMR Committee. The MMR Committee provides an in-depth review of maternal deaths to determine pregnancy-relatedness and preventability. The MMR Committee then develops recommendations for the prevention of maternal deaths, and disseminates their findings and recommendations.

Key Definitions

- A **maternal death** is defined by the World Health Organization's (WHO's) International Classification of Diseases Ninth and Tenth Revisions (ICD-9 and ICD-10) as "the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by pregnancy or its management but not from accidental or incidental causes."
- The **maternal mortality ratio or rate (MMR)** is the number of maternal deaths per 100,000 live births in the same time period.
- A **pregnancy-associated death** is defined by the Centers for Disease Control and Prevention (CDC) as "the death of a woman while pregnant or within one year or 365 days of pregnancy conclusion, irrespective of the duration and site of the pregnancy, regardless of the cause of death."
- The **pregnancy-associated mortality rate** is the number of pregnancy-associated deaths per 100,000 live births in the same time period.
- A **pregnancy-related death** is defined by the CDC as "the death of a woman while pregnant or within one year of conclusion of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by her pregnancy or its management, but not from accidental or incidental causes."
- The **pregnancy-related mortality rate** is the number of pregnancy-related deaths per 100,000 live births in the same time period.

The three terms "maternal death," "pregnancy-associated death," and "pregnancy-related death," create a challenge when comparing data from different sources and reports for different jurisdictional entities. The WHO monitors maternal deaths worldwide as a key indicator of population health, and of social and economic development. Maternal deaths are identified solely from information on the death certificate or similar registration of the occurrence and cause of death. Maternal deaths are limited in both the time period and causes considered.

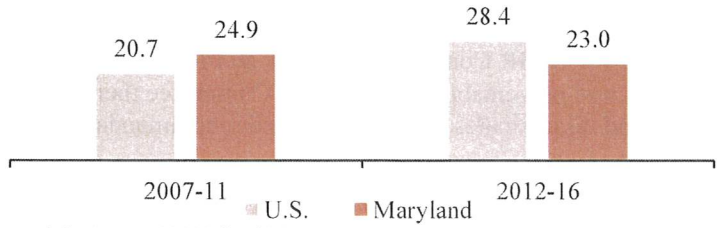
In more developed countries with improved medical care, many deaths related to pregnancy occur beyond 42 days after the end of pregnancy. In 1986, the CDC and the American College of Obstetricians and Gynecologists (ACOG) collaborated to recommend the use of expanded definitions to more accurately identify deaths among women where pregnancy was a contributing factor. This collaboration led to the definitions for pregnancy-associated and pregnancy-related deaths. Enhanced surveillance methods are necessary to determine pregnancy-associated and pregnancy-related deaths and will be discussed below.

Rising Rates of Maternal Deaths

Nationally, maternal deaths as defined above have declined dramatically since the 1930s when the MMR was 670 maternal deaths per 100,000 live births. The U.S. MMR was at its lowest level in 1987 at 6.6 maternal deaths per

100,000 live births. However, the MMR has risen since that time, and was 31.2 maternal deaths per 100,000 live births in 2016, the latest year for which national data are available. To compare Maryland's MMR with the national rate, a five-year average is used. This stabilizes the Maryland rate because maternal deaths are relatively infrequent events that may vary considerably year to year, particularly in a small state like Maryland. The Maryland MMR had consistently been higher than the national average. However, for the period from 2011 to 2015, the Maryland MMR was slightly lower than the national rate for the first time, and the most recent data (Figure 1) show that the Maryland MMR is now 19% less than the national rate. Between the two 5-year periods shown, the U.S. MMR increased by 37.2 percent and the Maryland rate decreased by 7.6 percent. Both, however, remain above the Healthy People 2020 Objective MICH-5 target of 11.4 maternal deaths per 100,000 live births.

Figure 1. Maternal Mortality Rates*, U.S. and Maryland 2007-11 and 2012-16



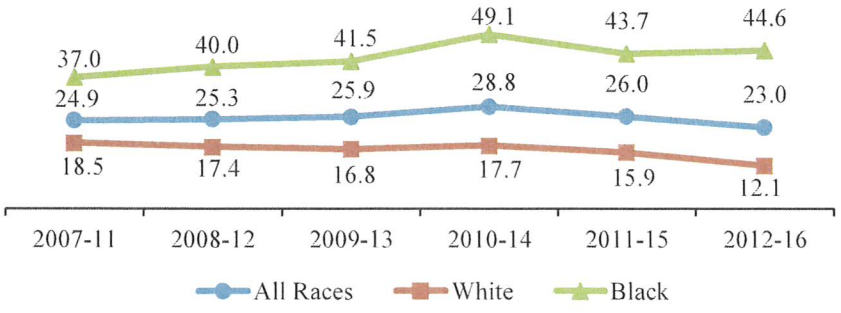
* Rate of maternal deaths per 100,000 live births
Data Source: CDC, NVSS; Maryland Department of Health (MDH), Vital Statistics Administration (VSA)

The reason for the increase in MMR since the 1980s is unclear. Many studies have shown an increase in chronic health conditions among pregnant women in the United States, including obesity, hypertension, diabetes, and heart disease.[1, 2, 3] These conditions likely put pregnant women at higher risk of adverse outcomes.

Racial Disparity

In the U.S., Black women have an MMR 2.4 times greater than White women, a disparity that has persisted since the 1940s. In Maryland, there is also a large disparity between the rates among Black and White women. Figure 2 shows the MMR by race in Maryland for six overlapping 5-year periods over the past decade. Compared to 2007-2011, the 2012-2016 White MMR in Maryland decreased 34.6 percent and the Black MMR increased 20.5 percent, increasing the racial difference. The 2012-2016 Black MMR is 3.7 times the White MMR. Given this racial disparity, it appears that the recent decrease in the Maryland MMR is a result of the decrease in the White MMR.

Figure 2. Five Year Rolling Average Maternal Mortality Rate* by Race, Maryland, 2007-2016



*Rate of maternal deaths per 100,000 live births. Data Source: MDH, VSA

[1] Kuklina EV, Ayala C, Callaghan WM. Hypertensive disorders and severe obstetric morbidity in the United States: 1998–2006.Obstet Gynecol. 2009;113(6):1299–1306.

[2] Albrecht SS, Kuklina EV, Bansil P et al. Diabetes trends among delivery hospitalizations in the United States, 1994–2004.Diabetes Care. 2010;33(4):768–773.

[3] Kuklina EV, Callaghan WM. Chronic heart disease and severe obstetric morbidity among hospitalizations for pregnancy in the USA: 1995–2006. Br J Obstet Gynaecol. 2011;118(3):345–352.

METHODOLOGY

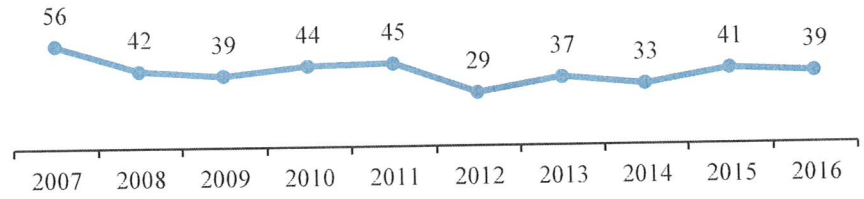
Case Identification

Cases for review are limited to women who were residents of Maryland at the time of their death. Maryland residents who died in other states are not included in the MMR case reviews. Maternal deaths are determined by cause of death and pregnancy information on the death certificates alone. The Maryland death certificate was revised in January 2001 to include questions about pregnancy status, pregnancy outcome, and date of delivery for the 12 months preceding death. This pregnancy checkbox has significantly increased identification of maternal deaths beyond those recognized by cause of death alone.[4, 5]

Pregnancy-associated deaths are identified in one of three ways in Maryland. Individual death certificates are the first method of identifying pregnancy-associated deaths through the use of checkbox questions, or because the cause of death is clearly related to pregnancy (e.g., ruptured ectopic pregnancy, postpartum hemorrhage). The second method of determining pregnancy-associated deaths comes from linking death certificates for women aged 10-50 years with birth certificates and fetal death certificates from the 365 days preceding death to identify additional cases that were not found through examination of death certificates alone. Thirdly, cases reported to the Office of the Chief Medical Examiner are reviewed to identify evidence of pregnancy in deceased women.

All deaths occurring during pregnancy or within 365 days of pregnancy conclusion are designated as pregnancy-associated and investigated further. Using the three methods above, 39 pregnancy-associated deaths were identified in 2016. These cases are reviewed in detail in this report. Figure 3 shows the numbers of pregnancy-associated deaths in Maryland from 2007 to 2016. An average of 41 pregnancy-associated deaths occurred per year during this period.

Figure 3. Number of Pregnancy-Associated Deaths*, Maryland, 2007 - 2016



*Deaths of women from any cause while pregnant or within 365 days of pregnancy. Data Source: MDH, VSA

Case Review

Pregnancy-associated deaths undergo several stages of review. Once cases are identified, medical records are obtained from the hospitals of death and delivery, when applicable. Physician and nurse-midwife abstractors review death certificates, hospital records, Medical Examiner records, and other available materials for all cases and prepare case summaries that go to the MMR Committee for review. All 2016 pregnancy-associated deaths from all causes (medical, injury, substance use, homicide, and suicide) were reviewed for cause of death, pregnancy-relatedness, and preventability.

Pregnancy-relatedness and potential preventability of the deaths are determined through Committee discussion. The MMR Committee includes obstetric, maternal fetal medicine, nurse-midwifery, nursing and social work specialties, as well as public health professionals, including representatives from the Department's Maternal and Child Health Bureau. The Committee discussions incorporate the CDC framework for case review outlined in "Strategies to

[4] Horon IL. Underreporting of maternal deaths on death certificates and the magnitude of the problem of maternal mortality. Am J Public Health. 2005; 95:478-82.
[5] Horon IL, Cheng D. Effectiveness of pregnancy check boxes on death certificates in identifying pregnancy-associated mortality. Pub Health Reports. 2011; 126:195-200.

Reduce Pregnancy-Related Deaths: From Identification and Review to Action."[6] This approach takes into account medical and non-medical factors contributing to maternal death, and examines quality and content of medical care. Cases discussed by the Committee are de-identified and all members sign confidentiality agreements.

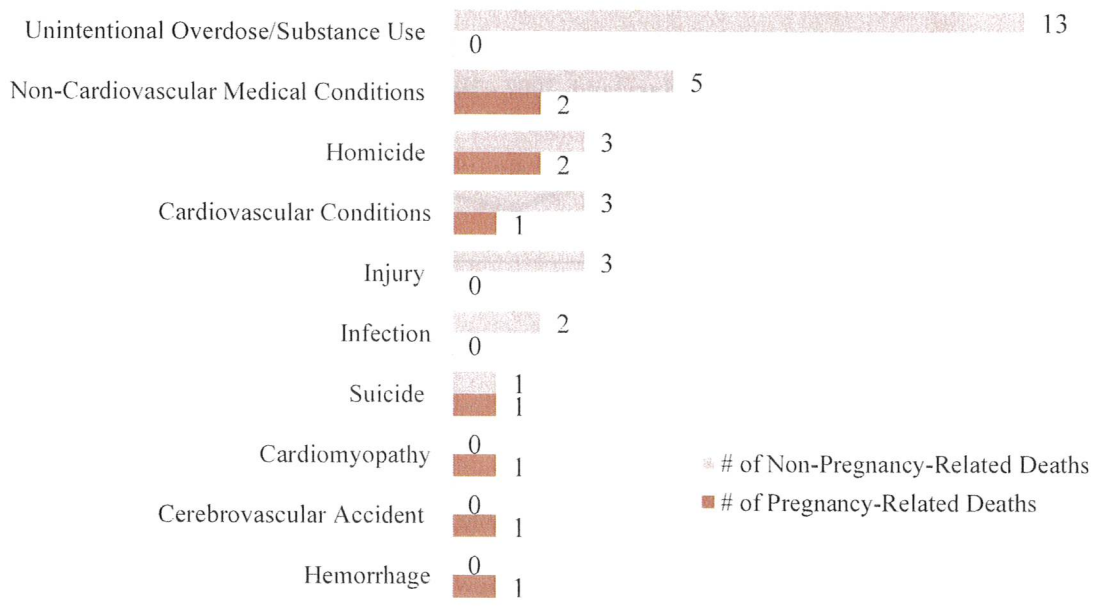
2016 CASE FINDINGS

A total of 39 pregnancy-associated deaths were identified in 2016 for a pregnancy-associated mortality rate of 53.4 deaths per 100,000 live births. For further analysis, these deaths were divided into pregnancy-related and non-pregnancy-related deaths, which represent two non-overlapping groups. Of the 39 pregnancy-associated deaths, nine were determined to be pregnancy-related, for a pregnancy-related mortality rate of 12.3 deaths per 100,000 live births. The remaining 30 deaths were determined to be non-pregnancy-related.

Cases by Cause of Death Category

Figure 4 shows pregnancy-related and non-pregnancy-related deaths by category of cause of death. The leading cause of non-pregnancy-related death was substance use with unintentional overdose, accounting for 13 deaths (43 percent of non-pregnancy-related deaths and 33 percent of all pregnancy-associated deaths in 2016). This is the highest number of overdose deaths reported in one year. Other leading causes of non-pregnancy-related death were non-cardiovascular medical conditions (predominantly cancer), followed by homicide, cardiovascular conditions, and injury (predominantly motor vehicle accidents).

Figure 4. Number of Pregnancy-Related* and Non-Pregnancy-Related Deaths by Category of Cause of Death, Maryland, 2016 (Total Deaths = 39)**



*Deaths of women while pregnant or within 365 days of pregnancy from a cause related to or aggravated by pregnancy or its management.
** Deaths of women while pregnant or within 365 days of pregnancy from any cause not related to or aggravated by pregnancy or its management.
Data Source: MDH, VSA, and Maryland Maternal Mortality Review Program

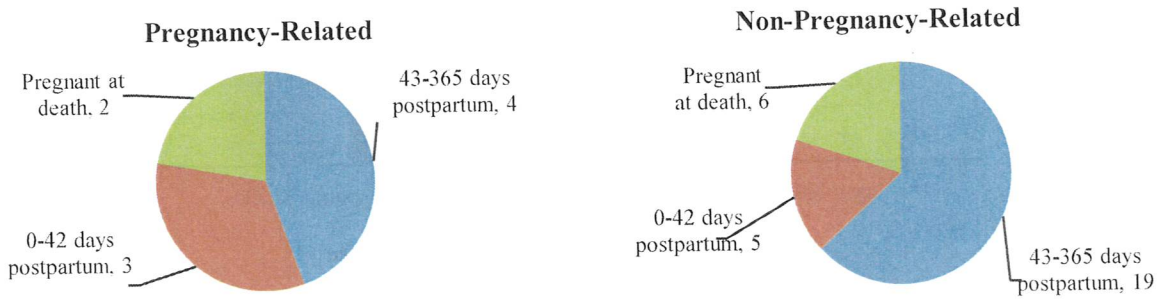
Among the nine pregnancy-related deaths in 2016, the leading causes of death were non-cardiovascular medical conditions and homicide, each accounting for two deaths. The remaining pregnancy-related deaths were single cases of cardiovascular conditions, suicide, cardiomyopathy, cerebrovascular accident, and hemorrhage.

[6] Berg C, Danel I, Atrash H, Zane S, Bartlett L (Editors). Strategies to reduce pregnancy-related deaths: from identification and review to action. Atlanta: Centers for Disease Control and Prevention; 2001 <https://stacks.cdc.gov/view/cdc/6537>.

Cases by Timing of Death in Relation to Pregnancy

Among the nine pregnancy-related deaths in 2016, four (44 percent) occurred between 43-365 days postpartum, three (33 percent) occurred within 42 days postpartum, and in two cases (22 percent) the woman was pregnant at the time of death (Figure 5). Of the 30 non-pregnancy-related deaths, 19 deaths (63 percent) occurred between 43-365 days postpartum, five (17 percent) occurred within 42 days postpartum, and six deaths (20 percent) occurred during pregnancy. Deaths in the early postpartum period, before the traditional six-week postpartum visit, were almost twice as frequent among pregnancy-related deaths compared to non-pregnancy-related deaths.

Figure 5. Number of Pregnancy-Related* and Non-Pregnancy-Related Deaths by Timing of Death, Maryland, 2016**

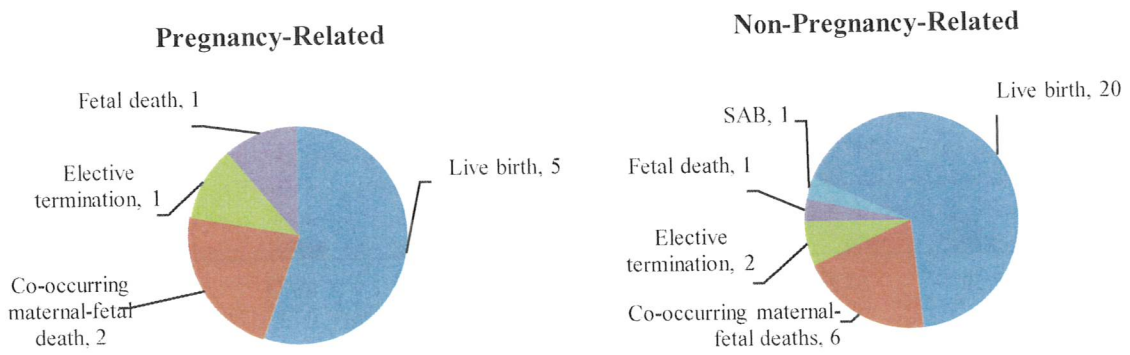


*Deaths of women while pregnant or within 365 days of pregnancy from a cause related to or aggravated by pregnancy or its management
** Deaths of women while pregnant or within 365 days of pregnancy from any cause not related to or aggravated by pregnancy or its management.
Data Source: Maryland Maternal Mortality Review Program

Cases by Outcome of Pregnancy

Among the nine pregnancy-related deaths in 2016, five cases (56 percent) had a live birth, two (22 percent) involved co-occurring maternal and fetal deaths, one had an elective termination, and one involved a fetal death prior to the mother's death (Figure 6). Among the 30 non-pregnancy-related deaths, 20 cases (67 percent) had a live birth, six (20 percent) involved co-occurring maternal and fetal deaths, two (7 percent) had elective terminations, one involved a fetal death and one involved a spontaneous abortion.

Figure 6. Number of Pregnancy-Related* and Non-Pregnancy-Related Deaths by Pregnancy Outcome, Maryland, 2016**

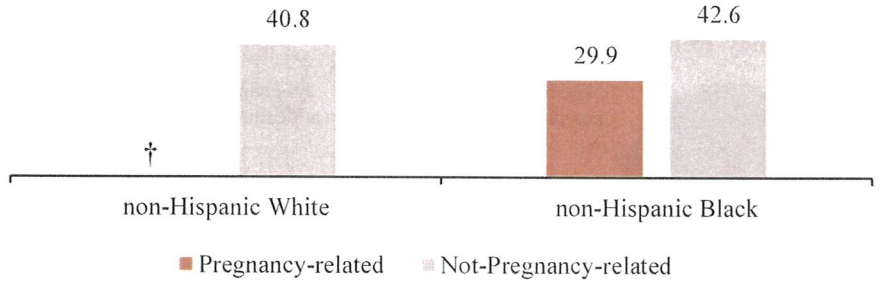


*Deaths of women while pregnant or within 365 days of pregnancy from a cause related to or aggravated by pregnancy or its management
** Deaths of women while pregnant or within 365 days of pregnancy from any cause not related to or aggravated by pregnancy or its management.
SAB: spontaneous abortion. Data Source: Maryland Maternal Mortality Review Program

Cases by Maternal Race and Ethnicity

Of the 9 pregnancy-related deaths occurring in 2016, one case involved a non-Hispanic White woman and one an Asian woman. The remaining seven pregnancy-related deaths (78 percent) were among non-Hispanic Black women. Among non-pregnancy-related deaths, 13 (43 percent) occurred among non-Hispanic White women, 10 (33 percent) among non-Hispanic Black women, six (20 percent) among Hispanic women, and one case involved a woman with race listed as other. Pregnancy-related and non-pregnancy-related mortality rates among non-Hispanic Black and non-Hispanic White women in 2016 are shown in Figure 7. A rate is not displayed if there are fewer than five deaths within a group.

Figure 7. Pregnancy-Related and Non-Pregnancy-Related Mortality Rates* by Selected Race/Ethnicities, Maryland, 2016



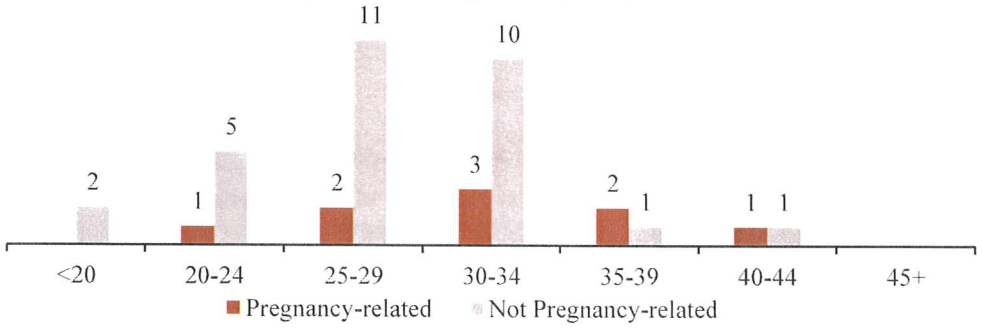
* Number of deaths per 100,000 live births. † Rate suppressed due to fewer than 5 deaths.
Data Source: Maryland Maternal Mortality Review Program

The rate of non-pregnancy-related deaths is similar between non-Hispanic White and non-Hispanic Black women. Although a rate cannot be calculated for pregnancy-related deaths among non-Hispanic White women since there was only one case, it is clear that the preponderance of pregnancy-related deaths are occurring among non-Hispanic Black women.

Cases by Maternal Age

The distribution of pregnancy-related and non-pregnancy-related deaths by maternal age group is shown in Figure 8. Rates of death by age group are not calculated because the numbers of deaths in most groups are very small. Rates involving fewer than five events are unstable and would not be reported.

Figure 8. Number of Pregnancy-Related and Non-Pregnancy-Related Deaths by Maternal Age, Maryland, 2016

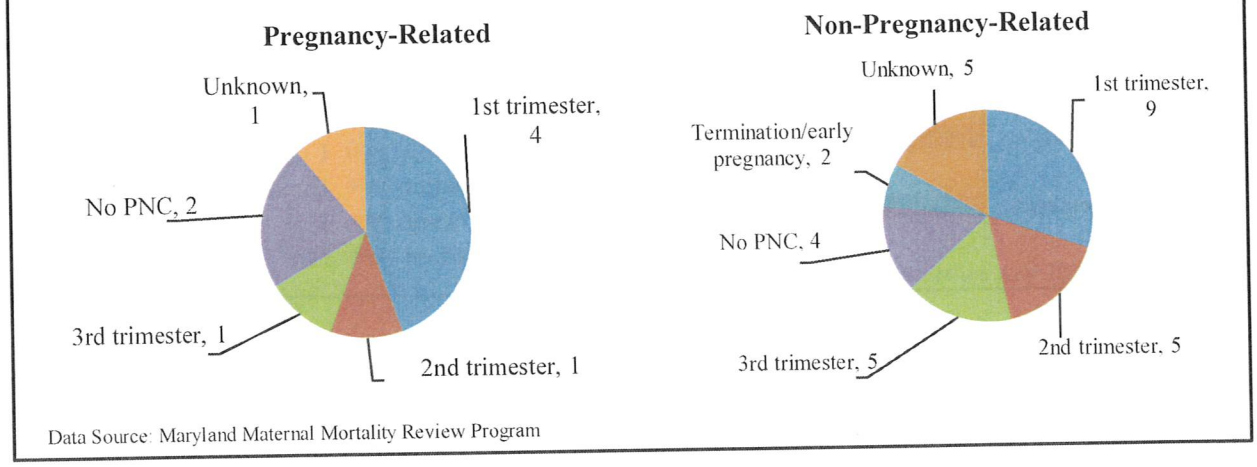


Data Source: MDH, VSA, and Maryland Maternal Mortality Review Program

Cases by Timing of Prenatal Care Initiation

Pregnancy-related and non-pregnancy-related deaths by the trimester when prenatal care was initiated are shown in Figure 9. Of the nine pregnancy-related deaths, five (56 percent) were among women who initiated care in the first or second trimester of pregnancy. Among the 30 non-pregnancy-related deaths, 14 (47 percent) of the women began prenatal care in the first or second trimester. In one pregnancy-related and five non-pregnancy-related cases, timing of prenatal care initiation was unknown.

Figure 9. Number of Pregnancy-Related and Non-Pregnancy-Related Deaths by Prenatal Care Initiation, Maryland, 2016



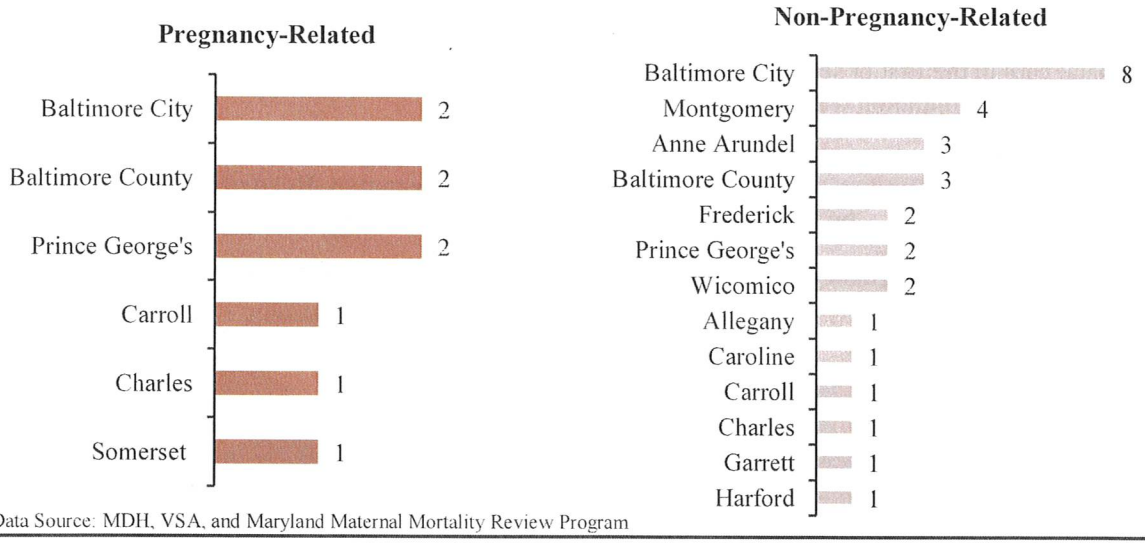
Data Source: Maryland Maternal Mortality Review Program

Cases by Jurisdiction of Residence and Occurrence

Figure 10 shows pregnancy-related and non-pregnancy-related deaths by jurisdiction of residence. Six (67 percent) of the nine pregnancy-related deaths were among residents of Baltimore City, Baltimore County and Prince George's County. There were single death cases among residents of Carroll, Charles, and Somerset Counties. Of the 30 non-pregnancy-related deaths, eight (27 percent) occurred among residents of Baltimore City and an additional ten cases (33 percent) among residents of Montgomery, Anne Arundel, and Baltimore Counties. Residents of nine other counties accounted for the remaining deaths.

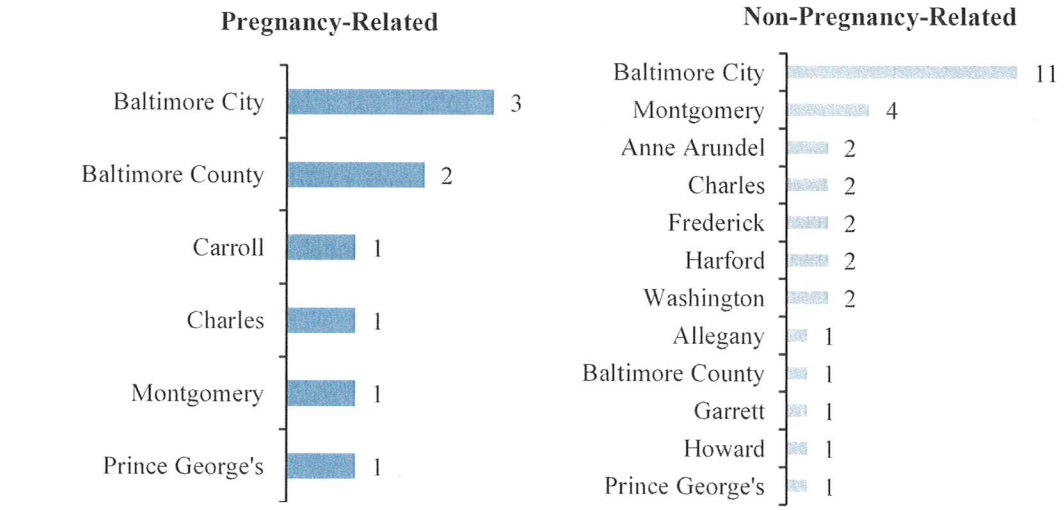
Figure 11 shows pregnancy-related and non-pregnancy-related deaths by jurisdiction in which the death occurred. Three (33 percent) of the nine pregnancy-related deaths occurred in Baltimore City and two (22 percent) in Baltimore County. Single deaths occurred in Carroll, Charles, Montgomery, and Prince George's Counties. Eleven (37 percent) of the non-pregnancy-related deaths occurred in Baltimore City and four (13 percent) in Montgomery County. The remaining deaths occurred in ten other counties.

Figure 10. Number of Pregnancy-Related and Non-Pregnancy-Related Deaths by Jurisdiction of Residence, Maryland, 2016



Data Source: MDH, VSA, and Maryland Maternal Mortality Review Program

Figure 11. Number of Pregnancy-Related and Non-Pregnancy-Related Deaths by Jurisdiction of Occurrence, Maryland, 2016



Data Source: MDH, VSA, and Maryland Maternal Mortality Review Program

Preventability of Deaths

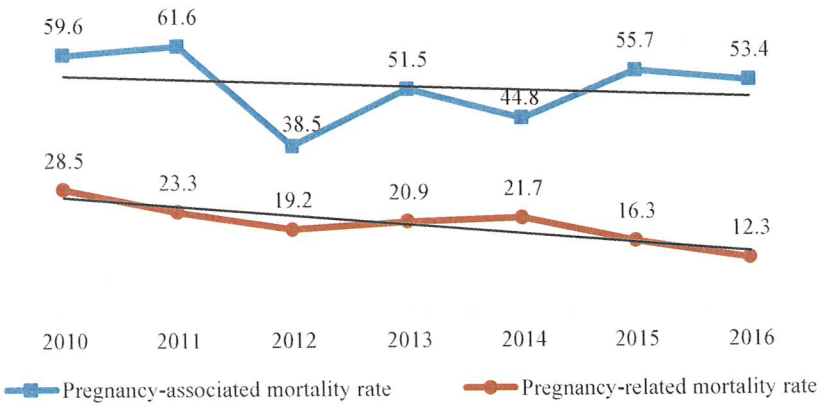
A death was considered preventable if the death "may have been averted by one or more changes in the health care system related to clinical care, facility infrastructure, public health infrastructure and/or patient factors."[7] Whether the death was clearly preventable or only potentially preventable by some intervention is a decision made by the MMR Committee. Of the 9 pregnancy-related deaths, eight (89 percent) were judged to be preventable or potentially preventable. One case was considered an unpreventable death. Among the 30 non-pregnancy-related deaths, 21 (70 percent) were judged to be preventable or potentially preventable. In three cases, preventability could not be determined, and six deaths were considered unpreventable. All of the unintentional overdose deaths were considered potentially preventable, as were the two suicide and five homicide deaths. Two of the three injury deaths were also considered potentially preventable. The seven deaths considered unpreventable involved medical causes of death (including cardiovascular conditions and cancer) and one motor vehicle accident death.

TRENDS IN PREGNANCY-ASSOCIATED AND PREGNANCY-RELATED DEATHS

Figure 2 above showed the trend and racial disparity in the Maryland maternal mortality rate (MMR). As noted, the MMR has dropped over the past ten years and is now below the national average, but the racial disparity has widened. The MMR, however, is limited in both causes of death considered and the timeframe in relation to pregnancy. The MMR includes only deaths from pregnancy-related causes that can be identified by the death certificate alone and that occurred during pregnancy or within 42 days of pregnancy conclusion. The decrease in the Maryland MMR suggests that fewer early pregnancy-related deaths are occurring, and this decrease has occurred primarily among White maternal deaths.

The cases reviewed by the Maryland Maternal Mortality Review Committee are more comprehensive and include all pregnancy-associated deaths, which include deaths from any cause that occur during pregnancy or up to 365 days after the conclusion of pregnancy. All pregnancy-associated deaths are reviewed for pregnancy-relatedness, creating a subgroup of pregnancy-related deaths. The trends in pregnancy-associated and pregnancy-related mortality rates from 2010 to 2016 are shown in Figure 12. The pregnancy-associated mortality rate shows considerable variability over the seven-year period and has dropped by 10.4 percent over that time. The pregnancy-related mortality rate, however, shows a steady decrease of 56.8 percent over the seven-year period.

Figure 12. Pregnancy-Associated and Pregnancy-Related Mortality Rates*, Maryland, 2010-2016



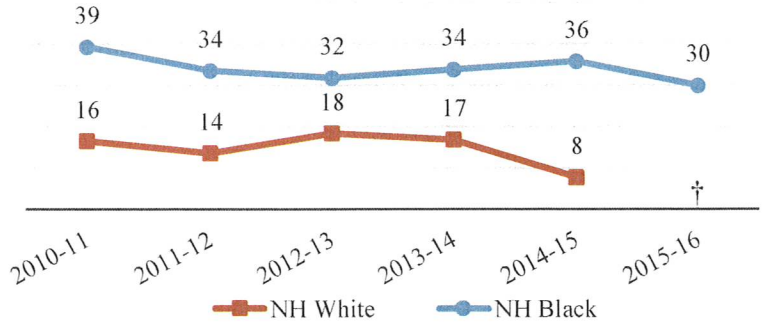
* Number of pregnancy-associated and pregnancy-related deaths per 100,000 live births.
Data Source: MDH, VSA, and Maryland Maternal Mortality Review Program

[7] Berg CJ, Harper MA, Atkinson SM, et al. Preventability of Pregnancy-Related Deaths - Results of a State-Wide Review. Obstet and Gynecol. 2005; 106:1228-1234.

Causes of pregnancy-related deaths are largely medical conditions directly related to pregnancy (such as postpartum hemorrhage, amniotic fluid embolus, or pre-eclampsia) or those exacerbated by pregnancy (such as pre-existing cardiovascular disease). There are some cases of homicide and suicide that are also determined to be pregnancy-related. The number of cases in Maryland from any individual cause is so small that determining trends for specific causes of pregnancy-related death is not possible. It does appear, however, that the number of deaths from hemorrhage and amniotic fluid embolus are decreasing.

Pregnancy-related mortality rates were calculated for non-Hispanic White and non-Hispanic Black women to see if the same trends were evident as seen for the MMR in Figure 2. Rates are shown as rolling two-year averages because of small numbers of cases when looking at deaths by race by individual year. Over the seven-year period, the non-Hispanic Black pregnancy-related mortality rate was consistently higher than the non-Hispanic White rate. Comparing rates from 2010-2011 and 2015-2016, there was a 23 percent decrease in the non-Hispanic Black rate. The non-Hispanic White rate decreased by at least 50 percent during this time period, but a rate for 2015 to 2016 could not be calculated because there were fewer than five deaths in this group during those two years.

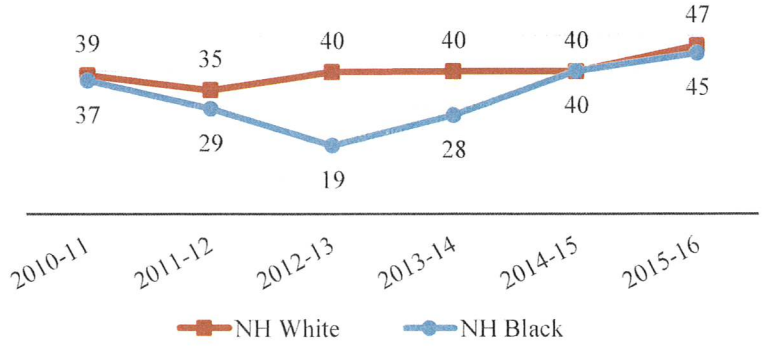
Figure 13. Pregnancy-Related Mortality Rates*



*Number of pregnancy-related deaths per 100,000 live births. † Rate suppressed due to fewer than 5 deaths. Data Source: Maryland Maternal Mortality Review Program

Non-pregnancy-related mortality rates by race were also calculated (Figure 14). Deaths from unintentional overdose have contributed increasingly to these deaths in the past several years. Overdose deaths have been predominantly among non-Hispanic White women, but the number of such deaths among other racial and ethnic groups has increased, which may be contributing to the increase in the non-pregnancy-related mortality rate among Black non-Hispanic women seen in Figure 14. Unintentional overdose deaths are reviewed in detail in the following section.

Figure 14. Non-Pregnancy-Related Mortality Rates* by Race/Ethnicity, Maryland, 2010-2016



*Number of non-pregnancy-related deaths per 100,000 live births.
Data Source: Maryland Maternal Mortality Review Program

FOCUS ON SUBSTANCE USE DISORDER AND OVERDOSE DEATHS

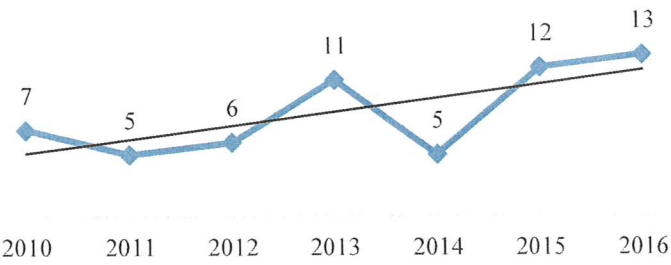
In 2016, for the fourth consecutive year, unintentional drug overdose was the leading cause of pregnancy-associated death in Maryland. Thirteen of the 39 total deaths (33 percent) resulted from substance use and unintentional overdose. All of the overdose deaths were considered to be non-pregnancy-related. The 13 overdose deaths accounted for 43 percent of the 30 non-pregnancy-related deaths. All of these deaths involved opioids. In 12 of the 13 cases (92 percent), two or more drugs were found by postmortem toxicology testing. Nine of the 12 multi-drug cases (75 percent) involved two or more different opioids. Ten of the overdose deaths (77 percent) involved the potent opioid fentanyl or one of its analogs. Alcohol was detected in three cases, cocaine in three cases, and marijuana in two cases.

The average age at death was 27.5 years (range 19 to 34 years). Six overdose deaths (46 percent) were among non-Hispanic White women, four (31 percent) among non-Hispanic Black women, two among Native American women, and one involved a Hispanic woman. Nine of the 13 women (69 percent) had delivered live born infants and the average timing of death was 193 days postpartum. Two women were pregnant at the time of death, one had a spontaneous abortion, and one had an elective termination. None of the overdose deaths occurred in the traditional postpartum period up to 42 days after the conclusion of pregnancy. All 13 of the overdose victims had a known history of substance use. In nine (69 percent) of the 13 cases, there was a history of one or more mental health diagnosis, with depression documented in eight cases, anxiety in four, and bipolar disorder in four.

Multiyear Review of Overdose Deaths

To better understand factors involved in overdose deaths, a review of all pregnancy-associated deaths in Maryland from 2010 to 2016 was undertaken. Over this seven-year period, substance use and unintentional overdose was the leading cause of death, accounting for 59 (22 percent) of 267 pregnancy-associated deaths. Figure 15 shows the number of unintentional overdose deaths by year, with the highest number of cases occurring in 2016.

Figure 15. Number of Pregnancy-Associated* Deaths From Unintentional Overdose, Maryland, 2010-2016



* Number of deaths of women from any cause while pregnant or within 365 days of pregnancy.
Data Source: MDH, VSA, and Maryland Maternal Mortality Review Program

Of the 59 overdose deaths, 57 (97 percent) involved opioids (one of the remaining two cases involved alcohol, and the other involved alcohol plus the amphetamine methylone). Table 1 shows the specific opioid(s) identified by toxicology testing at the time of death in these cases. The most frequently detected opioid was morphine, a metabolite of heroin, followed by methadone and fentanyl (including fentanyl analogs). Fentanyl was not detected in any overdose death prior to 2014. One case from 2014, three cases from 2015, and ten cases from 2016 involved fentanyl or a fentanyl analog. In 54 (92 percent) of the 59 overdose deaths, two or more drugs were detected by postmortem testing. In 20 (37 percent) of the multiple drug cases, two to four different opioids were identified. Benzodiazepines were detected in 14 (24 percent) and alcohol in 14 (24 percent) of the 59 overdose death cases. The risk of fatal overdose is substantially increased when opioids are combined with other central nervous system depressants such as benzodiazepines or alcohol.

Table 1. Opioid Identified Postmortem, Pregnancy-Associated Unintentional Overdose Deaths, Maryland, 2010-2016	
Opioid	**Number of cases (n=57)**
Morphine (heroin)	23
Methadone	15
Fentanyl / fentanyl analogs	14
Oxycodone	10
Unspecified opioid	6
Tramadol	4
Codeine	3
Oxymorphone	2
Buprenorphine	1
Hydrocodone	1
Hydromorphone	1
Meperidine	1

Data Source: Maryland Maternal Mortality Review Program
NOTE: The values in the table do not add up to the sample size of 57 because multiple drugs can be detected in a single case.

Among the 59 unintentional overdose deaths occurring from 2010 to 2016, the average age at death was 29 years. Forty-four (75 percent) of these deaths were among non-Hispanic White women and 12 (20 percent) among non-Hispanic Black women, with two cases (three percent) among non-Hispanic Native American women and one case (two percent) in a Hispanic woman. Prior to 2016, non-Hispanic White and non-Hispanic Black were the only racial or ethnic groups represented among the overdose deaths. Among overdose deaths from 2010 to 2015, 83 percent were among non-Hispanic White women and 17 percent among non-Hispanic Black women. In 2016, the distribution of unintentional overdose deaths was 46 percent non-Hispanic White, 31 percent non-Hispanic Black, 22 percent Native American, and 11 percent Hispanic, suggesting that the problem of substance use and risk of overdose is increasing among non-Hispanic Black women and women of other racial and ethnic groups.

Nine women (15 percent) among the 59 deaths were pregnant at the time of death and seven (12 percent) had had an elective termination, spontaneous abortion or fetal demise prior to death. The remaining 43 women (73 percent) delivered live born infants. Only four deaths (7 percent) occurred at 42 days or less postpartum; the remaining 46 (78 percent) occurred between 43 and 365 days postpartum. The average timing of death was 194 days postpartum. In 48 cases (81 percent), one or more mental health diagnosis was documented. Depression was diagnosed in 37 cases (63 percent), anxiety in 34 cases (58 percent), and bipolar disorder in 20 (34 percent). Fifty-five (93 percent) of the women who died of overdose had a known history of substance use and twenty-five (42 percent) had documentation of some substance use treatment.

In Table 2, the 59 overdose deaths are compared with the 208 non-overdose deaths that occurred between 2010 and 2016. Average age at death was comparable in both groups. However, the racial distribution is strikingly different, with a preponderance of non-Hispanic White women among the overdose deaths and overrepresentation of non-Hispanic Black women among the non-overdose deaths. A similar percentage of women were pregnant at the time of death in both groups, but deaths after the conclusion of pregnancy occurred on average much later among the overdose group. Pregnancy outcome was similar in both groups, with 73 percent of pregnancies among the overdose group and 68 percent among the non-overdose group resulting in a live birth. Timing of prenatal care initiation was similar, with more than half of women in both groups starting prenatal care in the first or second trimester.

Table 2: Incident Characteristics of Pregnancy-Associated Deaths, Maryland, 2010-2016 Data presented as mean ± standard deviation, or number (%)		
Characteristic	**Overdose Deaths (n=59)**	**Non-overdose Deaths (n=208)**
Demographics		
Average age at death (years)	29 ±5	31 ±7
White non-Hispanic	44 (75)	75 (36)
Black non-Hispanic	12 (20)	102 (49)
Native American non-Hispanic	2 (3)	14 (7)
Hispanic	1 (2)	17 (8)
Timing of death		
Pregnant at death	9 (15)	39 (19)
0-42 days postpartum	4 (7)	84 (41)
43-365 days postpartum	46 (78)	84 (40)
Average days postpartum	194 ±89	107 ±116
Pregnancy outcome		
Live born infant	43 (73)	141 (68)
Co-occurring maternal-fetal deaths	9 (15)	38 (18)
Spontaneous abortion / fetal death	6 (10)	18 (9)
Prenatal care initiation		
1st trimester	19 (32)	86 (41)
2nd trimester	14 (24)	23 (11)
3rd trimester	5 (9)	7 (3)
No prenatal care	6 (10)	18 (9)
Termination or death in early pregnancy	4 (7)	7 (3)
Unknown	11 (19)	67 (32)
Behavioral health / social factors		
Known history of substance use	55 (93)	42 (20)
Any history of substance use treatment (among those with known history of substance use)	25 (46)	17 (41)
Smoking	47 (80)	52 (25)
Mental health diagnosis(es)	48 (81)	44 (21)
Intimate partner violence	5 (9)	18 (9)
Preventability		
Death preventable / potentially preventable	57 (97)	115 (55)

Data Source: Maryland Maternal Mortality Review

There were large differences, however, between the two groups related to several behavioral health factors. Women who died of overdose were more than four-times as likely as women who died of other causes to have a known history of substance use (93 percent vs. 20 percent), although a similar proportion of each group with a history of

substance use had received any substance use treatment. Women who died of overdose were more than three-times as likely to smoke (80 percent vs. 25 percent) and almost four-times as likely to have one or more mental health diagnosis (81 percent vs. 21 percent). Also, 57 of 59 overdose deaths (97 percent) were considered preventable or potentially preventable, compared with 55 percent of the non-overdose deaths.

2018 MATERNAL MORTALITY REVIEW RECOMMENDATIONS

Substance use with unintentional overdose remains the leading cause of pregnancy-associated death for the fourth consecutive year in Maryland. The number and proportion of overdose deaths among deaths during pregnancy and the first year postpartum continue to increase, with overdose accounting for 33 percent of all pregnancy-associated deaths in 2016. The Committee, therefore, puts forward the following recommendations related to substance use disorder and unintentional overdose.

MMR Recommendations - Overdose Deaths	Action Items
• Promote universal screening at least once during pregnancy, at delivery, and postpartum for substance use, mental health, and intimate partner violence conditions. • Document screening tools used, referrals given, and treatment plans in perinatal records. • Reduce unintended pregnancy and encourage reproductive life planning. • Improve communication and collaboration between providers of prenatal care and other providers (mental health, substance use, primary care, oral health, etc.). • Promote interdisciplinary case management among substance use, mental health, and obstetric providers. • Improve safe opioid prescribing practices. • Encourage Prescription Drug Monitoring Program (PDMP) utilization by providers. • Encourage naloxone co-prescribing and 3rd party prescribing (prescribing for family or friends of individuals at risk of overdose). • Inform substance use treatment providers about perinatal health.	• Create and disseminate a resource list of valid screening tools for substance use, mental health, and intimate partner violence. • Create and disseminate a resource list of referral service options by Maryland jurisdiction. • Strive for a single point of contact for behavioral health services to facilitate provider access and care coordination among providers. • Promote integration of reproductive life planning and preconception counseling into health care visits by all disciplines. • Encourage use of Long Acting Reversible Contraception (LARC) for women who indicate they do not desire to become pregnant. • Promote the importance of establishing linkages and relationships to ongoing care during the perinatal and postpartum period. • Facilitate obtaining medical records from behavioral health service providers so that the obstetric chart has complete information of the patient's behavioral health care. • Provide obstetric support to behavioral health providers in the care of the pregnant patient. • Raise provider awareness about substance use during pregnancy and promote current resources and trainings. • Educate providers on the use and importance of the PDMP. • Train providers, patients, and families on naloxone use and response to opioid overdose. • Inform patients and families about the Maryland Good Samaritan law pertaining to response to an overdose emergency. • Develop consultation resources on perinatal and reproductive health issues for mental health and substance use treatment providers.

In addition, the Committee supports the Department's Perinatal Neonatal Quality Collaborative in partnership with the Maryland Patient Safety Center in its upcoming initiative related to substance use. The Collaborative is an effort among all Maryland delivery hospitals to address quality improvement in obstetric and neonatal care. In early 2019, the Collaborative will begin a quality improvement project to address care of the pregnant woman with substance use disorder.

The Committee also supports the Maryland SBIRT (Screening, Brief Intervention, and Referral to Treatment) Project in the Department's Behavioral Health Administration. SBIRT is an evidence-based approach to providing early intervention and treatment to patients with problem alcohol or drug use. Maryland SBIRT trains health care providers throughout Maryland in how to initiate conversations with patients about alcohol and drug use, and provide further assessment or referral when needed. Upcoming Maryland SBIRT efforts include SBIRT training for obstetric providers.

The Committee would also like to promote the resources made available by MedChi's Opioid Task Force. These provider resources include opioid-related educational materials and activities, information on opioid alternatives and opioid prescribing guidelines, substance use screening tools, and information and training on the Prescription Drug Monitoring Program (PDMP). MedChi has also made available an iPrescribe app which allows providers to easily access PDMP data from mobile devices.

The Committee is also continuing to develop *Provider Alerts* to disseminate information about maternal deaths in Maryland. One *Alert* will address overdose deaths to increase provider awareness of the contribution of substance use and unintentional overdose to maternal mortality in Maryland. Another will address recent guidance from ACOG and the Alliance for Innovation on Maternal Health to modernize paradigms of postpartum care, extending the postpartum period to improve maternal outcomes.

MATERNAL MORTALITY REVIEW STAKEHOLDER GROUP

House Bill 1518, enacted by the 2018 Maryland General Assembly, requires the Department to establish a Maternal Mortality Stakeholder Group to meet at least twice a year, to review the findings and recommendations in the annual Maternal Mortality Review Report. This group will include representatives of the Maryland Office of Minority Health and Health Disparities; the Maryland Patient Safety Center; the Maryland Healthy Start Program; women's health advocacy organizations; community organizations engaged in maternal health and family support issues; families that have experienced a maternal death; local health departments; and health care providers that provide maternal health services.

The Stakeholder Group is charged with examining issues resulting in disparities in maternal deaths, reviewing the status of implementation of previous recommendations, and identifying new recommendations with a focus on initiatives to address disparities in maternal deaths. House Bill 1518 requires that the Stakeholder Group meet once within 90 days of the publication this report and once 6 months after this report's annual publication. Members are currently being recruited for the Stakeholder Group, which will be convened for the first time in early 2019. The group will review the current report, and responses and recommendations from the stakeholders will be included in the 2019 Maternal Mortality Review Report.

SUMMARY

Maryland's MMR in the most recent five-year average data is 19 percent below the national rate for the first time. While the U.S. MMR continued to increase, the Maryland rate decreased by almost eight percent. Both rates, however, remain above the Healthy People 2020 goal of 11.4 deaths per 100,000 live births. While the MMR is limited in causes of death and timeframe of occurrence considered, this improvement is encouraging. However, significant racial disparities in maternal death persist.

Thirty-nine pregnancy-associated deaths were identified in 2016. Nine (23 percent) of these cases were determined

to be pregnancy-related, with the cause of death related to or aggravated by the pregnancy or its management. The remaining 30 cases were non-pregnancy-related deaths. The leading cause of non-pregnancy-related death for the fourth consecutive year was substance use and unintentional overdose. Non-cardiovascular medical conditions and homicide were the leading causes of pregnancy-related death. A majority of these deaths (70 percent of non-pregnancy-related deaths and 89 percent of pregnancy-related deaths) were considered preventable or potentially preventable.

In this report, the MMR Committee focused its recommendations on unintentional overdose deaths and improving its dissemination of maternal mortality review findings and recommendations to the provider community. The MMR Committee will continue to promote communication and collaboration among all providers caring for pregnant and postpartum women in an effort to reduce pregnancy-associated deaths in Maryland.

Hospitals know how to protect mothers. They just aren't doing it.

Alison Young, USA TODAY
Updated 6:58 p.m. EST Mar. 6, 2019

Every year, thousands of women suffer life-altering injuries or die during childbirth because hospitals and medical workers skip safety practices known to head off disaster, a USA TODAY investigation has found.

Doctors and nurses should be weighing bloody pads to track blood loss so they recognize the danger sooner. They should be giving medication within an hour of spotting dangerously high blood pressure to fend off strokes.

These are not complicated procedures requiring expensive technology. They are among basic tasks that experts have recommended for years because they can save mothers' lives.

Yet hospitals, doctors and nurses across the country continue to ignore them, USA TODAY found.

As a result, women are left to bleed until their organs shut down. Their high blood pressure goes untreated until they suffer strokes. They die of preventable blood clots and untreated infections. Survivors can be left paralyzed or unable to have more children. The vast majority of women in America give birth without incident. But each year, more than 50,000 are severely injured. About 700 mothers die. The best estimates say that half of these deaths could be prevented and half the injuries reduced or eliminated with better care.

Instead, the U.S. continues to watch other countries improve as it falls behind. Today, this is the most dangerous place in the developed world to give birth.

Maternal deaths on rise because hospitals and doctors ignore safety measures.

Identifying every hospital that doesn't provide recommended care is next to impossible. There is no national tracking system for childbirth complications. Mothers tell harrowing tales of survival, but they often have no idea whether their doctors and nurses did something wrong.

USA TODAY obtained more than a half-million pages of internal hospital quality records and examined the cases of more than 150 women whose deliveries went terribly wrong. Reporters contacted 75 birthing hospitals to track whether they follow recommended procedures.

Together, these documents and interviews reveal a stunning lack of attention to safety recommendations and widespread failure to protect new mothers.

At dozens of hospitals in New York, Pennsylvania and the Carolinas – where USA TODAY obtained records through federally funded quality programs – fewer than half of maternity patients were promptly treated for dangerous blood pressure that put them at risk of stroke. At some of those hospitals, less than 15 percent of mothers in peril got recommended treatments, the records show.

Many hospitals across the country conceded in interviews with USA TODAY that they were not taking safety steps such as quantifying women's blood loss or tracking whether moms with dangerously high blood pressure got proper medication in time.
The lack of attention happens at hospitals big and small, from tiny community delivery units to major birthing centers that tout state-of-the art technology and training. It also happens in doctors' offices when they miss or fail to act on signs of serious complications during pregnancy and after delivery.

In Ohio, Ali Lowry bled internally after giving birth in 2013, but medical staff didn't recognize and act on the warning signs for hours, according to records in a lawsuit that she has since settled. By the time she was airlifted to another hospital for lifesaving surgery, her delivery hospital had nearly run out of blood and Ali's heart had stopped.
In Texas, Beatriz Garcia nearly bled to death when doctors and nurses were slow to help her after not quantifying her blood loss, she alleged in federal and state lawsuits. Garcia's heart stopped. She needed a hysterectomy. She's now awaiting a kidney transplant.
And in South Carolina, one of the state's top hospitals sent YoLanda Mention home with her newborn despite her dangerously high blood pressure. When she returned to the emergency room with even higher blood pressure and an excruciating headache, the staff made her sit for hours in the waiting room, according to a lawsuit led by her husband. She had a stroke while waiting, and later died.

Today, YoLanda's husband, Marco, is raising their three daughters alone in rural Nesmith. He balances work as a school bus driver with all the demands of raising kids on his own – cooking the meals, cleaning and getting three girls to schools and day care.
He spends his evenings leading his church choir and reminding his girls about a mother who the youngest knows as a picture in a curio cabinet.

"The girls, they ask when she's coming home and I don't know what to tell them," Mention said, wiping tears. "It seems like a nightmare and I just need to wake up."
It doesn't have to be this way.

Countries around the world have reduced maternal deaths and injuries by aggressively monitoring care and learning from mistakes. The result has been two decades of steady or reduced maternal harms in the rest of the developed world – as U.S. rates climbed.

Divergent paths

From 1990 to 2015, the number of maternal deaths per 100,000 births in most developed nations has been flat or dropping. In the U.S., the rate has risen sharply.

One exception in the U.S.: California, where safety experts and hospitals worked together to implement practices that are now endorsed by leading medical societies as the gold standard of care. Statewide, California's maternal death rate has fallen by half, while deaths rose across most of the country.

Despite widespread recognition that the California safety measures save lives, hospitals elsewhere have been slow to use them.

"Our medicine is run by cowboys today, where everyone is riding the range doing whatever they're wanting to do," said Dr. Steven Clark, a leading childbirth safety expert and a professor at Baylor College of Medicine. While there are hospitals that follow best safety practices, change is happening slowly, he said. "It's a failure at all levels, at national organization levels and at the local hospital leadership levels as well."

In part, that's because regulators and oversight groups that could require hospitals to do more have not, USA TODAY found.
SOURCE The Global Burden of Disease 2015 Maternal Mortality study as published in The Lancet medical journal.

The lack of action by the Centers for Medicare and Medicaid Services to protect mothers stands in sharp contrast to its more aggressive approach to trying to improve care for elderly Medicare patients.

As a condition of getting Medicare payments, the federal agency requires hospitals to disclose information such as complication rates for hip and knee surgeries and whether heart attack patients got prompt care. All of that information is posted online.
That same agency helps pay for about half of the nation's nearly 4 million births each year via Medicaid, and it could set similar rules about childbirth complications.

So far, it has not.

The Joint Commission, a private accreditation group that sets safety standards for thousands of hospitals, makes hospitals track cesarean section rates.
But the commission has no requirements that hospitals report how o□en their health care providers fail to follow national guidelines for protecting moms against leading childbirth dangers. Officials said the group is still studying the safety practices, some of which have been known for at least eight years.

"For us to make it a requirement for every organization to follow something, there has to be clear national consensus that this is the standard of care," said Dr. David Baker,

executive vice president of the commission's Division of Health Care Quality Evaluation. Baker said the safety practices to protect moms from hemorrhages are "promising." But he said there are questions about whether the protocols calling for fast treatment of dangerous blood pressure are appropriate for the commission to require at the hospital level. "I suspect within the next two months, there will be a decision on whether to go forward," he said.

The American Hospital Association, the influential trade association representing nearly 5,000 hospitals and health networks, has in recent years held closed-door training sessions aimed at getting maternity hospitals to improve care.
In a series of webinars, AHA first warned anyone not invited to disconnect.
Then, trainers for the association went on to bluntly discuss how wide-ranging care failures at birthing hospitals are causing needless deaths and injuries.

"What we know about those deaths is that most of them were absolutely preventable," a trainer for the association told maternity staffs during a 2015 webinar. "They were from causes that we could have done something about. We could have prevented it if we had recognized the emergency early on."

During another closed session in 2016, a hospital association trainer said studies show that as many as 93 percent of women who bled to death during childbirth could have been saved if hospital staff had been aware of how much blood the woman lost.
The trainer said 60 percent of studied deaths from preeclampsia, a severe blood pressure disorder in pregnancy, also were preventable "because we failed to control the blood pressure or to recognize other emergencies that were happening."

"We're not talking about a Third World country, we're talking about us, here," the trainer said. "This shouldn't be happening here."

The hospital association declined to grant an interview and wouldn't answer questions about the toll of preventable harms at its member hospitals or how many of those hospitals follow best practices. In a statement, the group said U.S. hospitals are "committed to continuously working to keep all patients safe."

There is a growing recognition by hospitals that they need to adopt standardized care practices to save mothers' lives. In the past year, the number of maternity hospitals participating in a voluntary childbirth safety improvement program endorsed by leading medical societies has more than doubled.

The 985 hospitals currently enrolled in the AIM Program to reduce harms to mothers represent about 40 percent of the nation's birthing hospitals and they are in various stages of implementing care reforms, organizers say.

For more than a decade, the experts who guide medical practices in the U.S. have been

pushing doctors and hospitals to change how they treat pregnant women.
At least as far back as 2010, researchers in California began promoting "tool kits" of childbirth safety practices to reduce deaths and injuries.

Routine failures

These kits, built upon years of published research, were made up of policies, procedures and checklists that, pursued together, appeared to save mothers' lives.
Around the same time, the American College of Obstetricians and Gynecologists was lending its influence to address one of the leading childbirth killers: high blood pressure. In a 2011 bulletin to providers, the group warned that blood pressure above certain levels "if not treated expeditiously can result in maternal death." The group gave hospitals and doctors step-by-step instructions, even specifying which IV drugs to give.

Three years later, a coalition of the nation's leading medical societies created the AIM Program. The program formalized safety practices that have been shown to reduce maternal injuries into a series of "safety bundles" that detail treatment policies, safety equipment, training programs and internal reviews every maternity hospital should have. The AIM Program's "safety bundles" have been sponsored by a coalition of leading medical societies whose members include ACOG, the American College of Nurse-Midwives, the American Academy of Family Physicians and groups representing obstetric nurses and anesthesiologists.

For example, the AIM recommendations set time deadlines for taking blood pressure readings and administering medications to pregnant women and new moms experiencing dangerously high blood pressure.

Despite nearly a decade of medical studies, warnings, advice and training, hospitals continue to provide uneven care.

USA TODAY obtained internal hospital data collected from dozens of hospitals in 2015 and 2016 as part of other voluntary quality-improvement programs. Among other things, some of the federally funded programs tracked how often staff gave recommended blood pressure medicine within the called-for, one-hour deadline.
Among about 40 maternity hospitals in New York state, less than half of mothers experiencing dangerously high blood pressure got proper treatment, the records show. In Pennsylvania, the data for about a dozen hospitals show mothers being promptly treated only 49 to 67 percent of the time.

More than 65 percent of mothers didn't get proper treatment at Bon Secours St. Francis Hospital in Charleston, South Carolina.

At Carolinas Medical Center in Charlotte, North Carolina, nearly 40 percent of mothers did not receive timely blood-pressure treatments. The failure rate was 78 percent at Carolinas HealthCare System NorthEast in Concord and nearly 90 percent at Stanly Regional

Medical Center in Albemarle.

At Alamance Regional Medical Center in Burlington, North Carolina, the breakdown was almost universal. Only one of the 48 maternity patients with dangerous blood pressure readings got proper treatment.

Officials at each of these hospitals said their performance has since improved.
Women's Hospital in Greensboro is one of the biggest birthing hospitals in North Carolina, delivering about 6,000 babies a year in a metropolitan area of about 760,000 people. The hospital says on its website "...whether you seek specialized care for a high-risk pregnancy, the latest diagnostic services, or alternative birth options such as a water birth, you can count on us for world-class service that's close to home."

But the federal records obtained by USA TODAY show doctors and nurses there put scores of mothers at risk by reacting slowly to signs of dangerously high blood pressure. Women's Hospital failed to provide timely blood pressure treatment for 189 of 219 mothers, according to its own monthly tallies from October 2015 through June 2016. The treatment failures at Women's Hospital occurred even though medical staff knew their work was being tracked.

"It's unacceptable. That's really what it is," said Eleni Tsigas, who leads the Preeclampsia Foundation. She questions whether voluntary care-improvement programs alone will ever get enough hospitals to make lifesaving changes.

There is no way to know how widespread the failures like those in the Carolinas are at maternity units nationwide. The government doesn't track it and hospitals' internal numbers are usually a closely guarded secret.

Cone Health, which operates Women's Hospital and Alamance Regional Medical Center, excused its poor performance in 2015-2016 by saying it had just started training staff to quickly treat dangerous blood pressure – even though ACOG issued its treatment warning in 2011.

Cone Health defended the delayed training by saying ACOG treatment guidelines aren't mandatory and its own hospitals and doctors needed time to evaluate whether the best practices being touted by the nation's top experts were appropriate.
The numbers suggest they were. Cone Health said its two hospitals that participated in the federal quality program have significantly improved.

At Women's Hospital, 84 percent of mothers with high blood pressure got proper treatment from June 2016 to April 2017, officials said. At Alamance, it was 72 percent. And the number of mothers suffering seizures and strokes – consequences of dangerous, untreated high blood pressure – have dropped.

It was about 4 a.m. when they wheeled Ali Lowry back to Room 25 at Knox Community Hospital after delivering her baby.

'I was really scared'

As a nurse in the hospital's birthing center in Mount Vernon, Ohio, an hour northeast of Columbus, she had helped many other women deliver babies. But this was finally a baby of her own, and she was so excited to finally hold him.

As Lowry, 24, settled in and began breastfeeding her son, her vision went black.

"I was really scared, because I knew that, that I shouldn't have been feeling that way," she recalled of that morning in August 2013.

Lowry's blood pressure had plummeted. Over the next hours, nurses took her blood pressure repeatedly and found it to be low. Around 5:30 a.m., the readings were: 52/26, 57/25, 56/24, 59/27.

Blood pressures at 85/45 or below ought to be a warning sign to hospital staff that a woman is losing life-threatening amounts of blood and action is needed, according to the childbirth safety tool kit California experts made available to hospitals across the country in 2010. For women like Lowry, who deliver by C-section, the bleeding can be internal and hidden from sight.

Yet for hours, no one at the hospital took emergency action to check for internal bleeding, according to records in Lowry's lawsuit against her providers. Not the nurses on duty nor Dr. Ioanna Kanellitsas, who delivered Lowry's baby. Instead, blood continued to pool inside her body and no one knew how bad it was.

It wasn't until 7 a.m. – nearly three hours after she first began passing out – that the court records show Lowry started to get meaningful help to save her life.

A supervising nurse coming on duty saw Lowry's blood pressure history and terrible condition, and mobilized a rapid response team. Lowry was moved to intensive care and started getting blood transfusions.

A doctor coming on duty, David De Lorenzo, found Lowry no longer lucid, her skin turning blue.

Around 10 a.m., Kanellitsas took Lowry into surgery and removed six cups of blood and clots from her abdomen. But she saw no active bleeding.

"We were in the operating room for an hour and a half watching this. So, I was as certain as I could be that we had controlled the bleeding and that she wasn't having further bleeding," Kanellitsas said in a deposition in the family's lawsuit against the doctor and the hospital.

Yet Lowry kept bleeding. Unconscious and on a ventilator, blood soaked her legs and drenched her bed.

When nurses alerted Kanellitsas, the court records indicate the doctor told them it was OK. It looked like normal postpartum bleeding, she testified.

It is unclear whether the doctor and hospital staff had been quantifying Ali's cumulative blood loss since her delivery. At least during Lowry's C-section and later exploratory surgery, her blood loss – beyond what was collected in a suction machine – was being visually estimated, according to deposition testimony of the nurse anesthetist who was in the operating room for both procedures.

Multiple studies have found visual estimates underestimate blood loss, which can delay lifesaving treatments.

"She just kept getting worse and worse," Ali Lowry's husband, Shaun, said.
He had been asking for Ali to be transferred to a major medical center, but it refused to take her because she was too unstable.

By then it was clear that Lowry needed a hysterectomy to save her life – something Knox normally would have been able to handle.

But the hospital was down to its last unit of matching blood, according to court records. "We didn't even have enough blood to give her a hysterectomy," De Lorenzo said in a deposition.

De Lorenzo called Riverside Methodist Hospital in Columbus, which agreed to take Lowry. As paramedics lifted her off the gurney, she went into cardiac arrest. If Lowry had stayed at Knox, De Lorenzo said: "She surely would have died."

At Riverside, doctors found a lacerated artery, but had to remove Ali's uterus to stop the bleeding.

"I was just kind of shocked by everything," Lowry said. "I was definitely devastated by losing my uterus but at the same time I was also so thankful to be alive and that my baby was OK."

The family settled a lawsuit against Kanellitsas and the hospital, who denied the suit's allegations of wrongdoing. The terms are secret.

Knox officials declined to be interviewed. Frederick Sewards, an attorney for the hospital and Kanellitsas, said: "The resolution of that doubtful and disputed claim was subject to a confidentiality agreement, which neither I nor my clients will violate."

Across the country, USA TODAY talked with dozens of women who are among the 50,000 each year who suffer severe injuries after surviving potentially deadly deliveries.

Frustrations of the 50,000

Some praise the care they received. But many women said they felt frustrated, angry and powerless after encountering doctors and nurses they felt didn't listen or weren't prepared for emergencies.

"This was supposed to be the best time of my life and this is the worst and nobody should feel that way about the birth of their child," said Susan Goodhue of Annapolis, Maryland. Her blood pressure spiked and her liver and kidneys started to fail when she gave birth in 2012.

"The staff, by not knowing, and not listening and not taking precautions, almost killed us," she said.

Women talked about excruciating pain and fighting to survive for their children. Some say they never got good explanations for what went wrong and why.

ZaKiya Bell-Rogers of Asheville, North Carolina, said she still doesn't know what caused the blood loss that required her emergency hysterectomy in 2015. "I need to know what happened, but I don't know if mentally I can take it if there was a mistake on their end." Donielle Bell, who lives in the Atlanta suburb of Marietta, also says she never got good answers about why she hemorrhaged in 2016 – and whether it would happen again when she gave birth to her third child this spring.
"I'm facing this fear daily," she told USA TODAY earlier this year. "I'm terrified that I won't walk away from it."

In April, Bell delivered a healthy son, but she lost so much blood this time that she needed an emergency hysterectomy to save her life.

Over and over, these women said they wanted other mothers to know the importance of finding health care providers who listen to their concerns, pay attention to warning signs and are trained to deal with complications.

"Having the right hospital is life and death," said Alana Alvarez of Mililani, Hawaii, who nearly bled to death and needed a hysterectomy and other surgeries to survive a 2015 birth.

"Having the right doctors, having the right care, having the right people that know about your diagnosis, that understand your diagnosis, that know what they're doing, it's life and death," she said.

At University of Utah Hospital in Salt Lake City, maternity officials didn't want to believe

that the way they cared for mothers could be one of the reasons why 12 percent of their patients suffered hemorrhages in 2013 – triple the national rate.

Like many hospitals, they were quick to blame the women as being unusually high risk instead of scrutinizing their own care.

"We initially rationalized this," Dr. Erin Clark, the hospital's director for maternal-fetal medicine, told maternity staff from other hospitals at a 2015 training session.
But the hospital realized it had a problem when it compared its results with other university hospitals. Their peers also cared for high-risk moms, but their patients weren't hemorrhaging as often.

"We stood out in an obvious way and not a good way," she told USA TODAY.
The hospital dug into patients' records. "We diagnosed hemorrhages too late," Clark said. "And we didn't treat them fast enough or aggressively enough."

The hospital reduced its rate by one-third after it began adopting the best practices called for by California experts and the AIM Program, Clark said. That progress has been seen in other groups of hospitals following the safety practices, too.

According to a study published last year in the American Journal of Obstetrics & Gynecology, women giving birth in hospitals participating in a California quality improvement collaborative suffered 21 percent fewer severe harms related to hemorrhage from 2014 through early 2016 than those in previous years. That's fewer women suffering heart attack, kidney failure or blood-clotting disorders, and fewer women being put on ventilators or undergoing hysterectomies.

When hospitals work with well-organized state-wide quality groups – that help them train staff, track data and benchmark against peers – care can improve faster than if they're le to do it on their own, experts said. From May 2016 through June 2017, about 100 Illinois hospitals participating in an AIM Program-affiliated project increased from 42 percent to 79 percent the number of maternity patients getting treatment for dangerous blood pressure within one hour, according to data published earlier this year in the same medical journal.

For decades, hospitals and medical experts have often blamed rising maternal deaths and injuries on women for being unhealthy or overweight, or pointed to risk factors such as poverty or the age of mother.

"Just because you're older and heavier, doesn't mean you should die," said Dr. Elliott Main, medical director of the California Maternal Quality Care Collaborative, which is credited with reducing maternal injuries and deaths in the state. "That just means you should be on guard, you should bring your A game."

Blaming moms for poor health or lacking prenatal care helps mask care failures. "We cannot just blame the women," said Debra Bingham, a former vice president at Association of Women's Health, Obstetric and Neonatal Nurses, who is now at the University of Maryland School of Nursing.

Nurses and doctors believe they provide good care and don't want to harm patients, Bingham said.

"So it's very hard to accept that what I've been doing for years may not have been the best way to do it," she said.

Rachel Yencha, who nearly bled to death after giving birth in 2015, said it would have been helpful to know upfront whether hospitals follow best safety practices.

Yencha, who was young and healthy, chose a small maternity hospital near her suburban Cleveland home. But when complications arose during delivery, she had to be transferred to a bigger hospital that could save her life.

"Even if you have a normal pregnancy, you want them to be prepared for anything," she said.

Because there are no requirements that U.S. maternity hospitals follow best practices, nobody knows how many of them take all of the AIM Program's recommended actions.

"I don't have a good sense for what percentage of the hospitals. It's not huge yet, but it's gaining momentum rapidly," said Dr. Barbara Levy, vice president of health policy at ACOG.

Even if women and their loved ones knew the questions to ask, USA TODAY found that it would be nearly impossible for them to find out the safety records of maternity hospitals or whether they are following best safety practices.

USA TODAY repeatedly contacted 75 hospitals in 13 states to press for specific answers about whether they are following the AIM Program's recommended practices for hemorrhage and hypertension.

Half wouldn't answer the questions.

Those refusing to answer included Northside Hospital in Atlanta, one of the nation's largest birthing hospitals, which annually handles about 16,000 deliveries. "We are going to have to pass on this opportunity. I'm not able to get you what you need," hospital spokesperson Katherine Watson said in an email.

"We respectfully decline to participate," said Giselle Tiley, spokeswoman for Osceola

Regional Medical Center in Kissimmee, Florida.

Even hospitals that brag about their expertise in childbirth emergencies wouldn't answer questions about whether they are taking AIM's recommended safety steps.
"We will pass on this one," Johnny Smith, a spokesman for St. Agnes Hospital in Baltimore, said in an email after a reporter contacted the hospital and its parent health system, Ascension, nearly a dozen times. On its website, the hospital says: "Our innovative approach to obstetric emergencies set us apart."

The 37 maternity hospitals that answered USA TODAY's questions said they are doing many of the AIM Program's best practices to prevent women from bleeding to death. But more than 40 percent acknowledged they were not quantifying blood loss after every birth – despite it being a cornerstone safety practice.

When it came to ensuring women with dangerous blood pressure readings got proper treatment within 60 minutes, the hospitals' answers also indicated lax compliance. Of 31 hospitals that said they follow a 60-minute treatment policy, only nine said they track how often doctors and nurses actually gave treatment in time.

Experts say the slow pace of change is largely because, in this country, doctors and hospitals enjoy wide latitude in how they practice medicine. How they treat patients is often based on what providers were taught – years or decades earlier – in medical or nursing school, plus their individual experiences over time.

When researchers identify safer ways of caring for patients, there are no mandates that providers read or follow these practices. In maternity care – as well as other areas of medicine – it can take a decade or more for best practices to be widely adopted by health care providers.

The result: a system that experts say fails patients and leads to needless deaths and injuries.

In countries with publicly funded national health care systems, such as the U.K, it is easier to insist hospitals and health providers follow standard safety practices, said Dr. James Martin Jr., director of maternal-fetal medicine at the University of Mississippi Medical Center and a past president of ACOG.

Martin and other experts said that's one reason why women giving birth in Great Britain die from childbirth complications at one-third of the rate they do here.
Without a centralized system, reform will require multiple entities to insist on change: hospital administrators, insurance companies and others that pay for childbirth, and malpractice insurers who defend practitioners against lawsuits, Martin said.
"If they say, 'We expect you to do it this way,' that you've got to get on and use this safety bundle ... it can be driven from that point of view," Martin said.

Hospitals need to be accountable and the public should be able to find out each hospital's rates of childbirth complications, said Helen Haskell, president of Mothers Against Medical Error, a nonprofit patient safety group in South Carolina.
"We've put a lot of credence in the idea of voluntary improvement and it's just not enough," Haskell said. "You have to have transparency and you have to have regulation." Until that happens, women will continue to be harmed.

"So many of these are preventable," said Monica Simpson, executive director of SisterSong, an Atlanta group that is part of the Black Mamas Matter Alliance, which is pushing for national policy discussions. "I think the country should be outraged."

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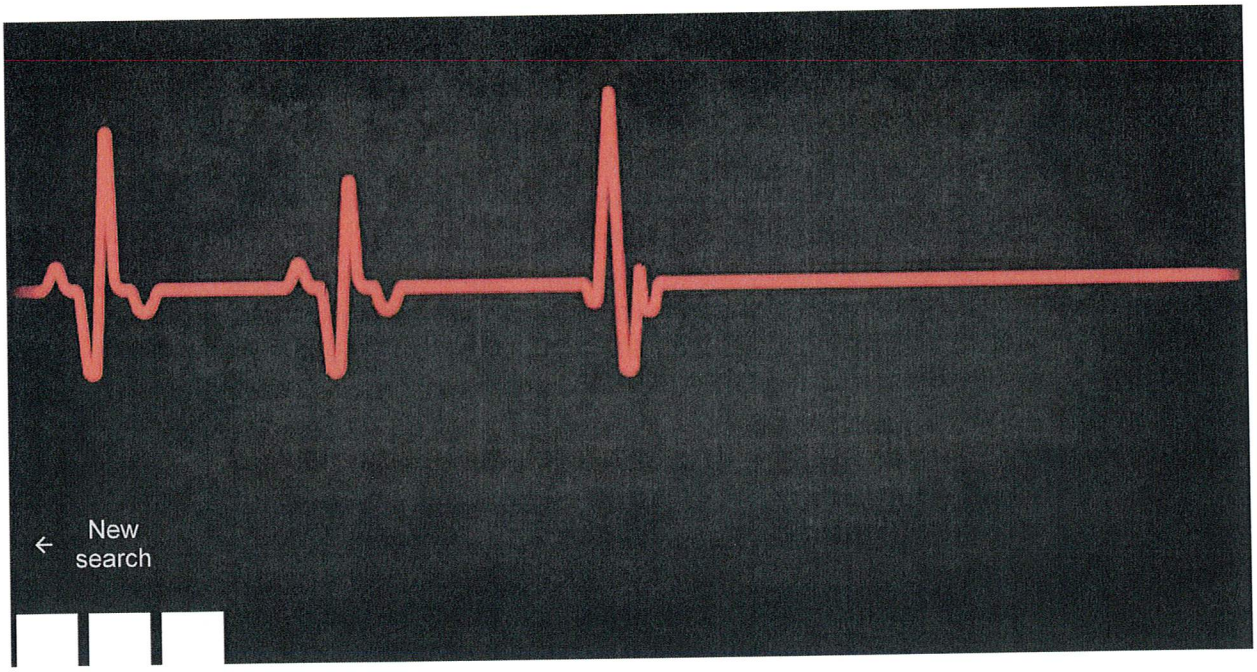
Originally Published 6:05 a.m. EDT July 26, 2018
Updated 6:58 p.m. EST Mar. 6, 2019

A security empire deployed guards with violent pasts across the US. Some went on to rape, assault or kill



Johns Hopkins Bayview Medical Center

4940 Eastern Ave., Baltimore, Md. 21224

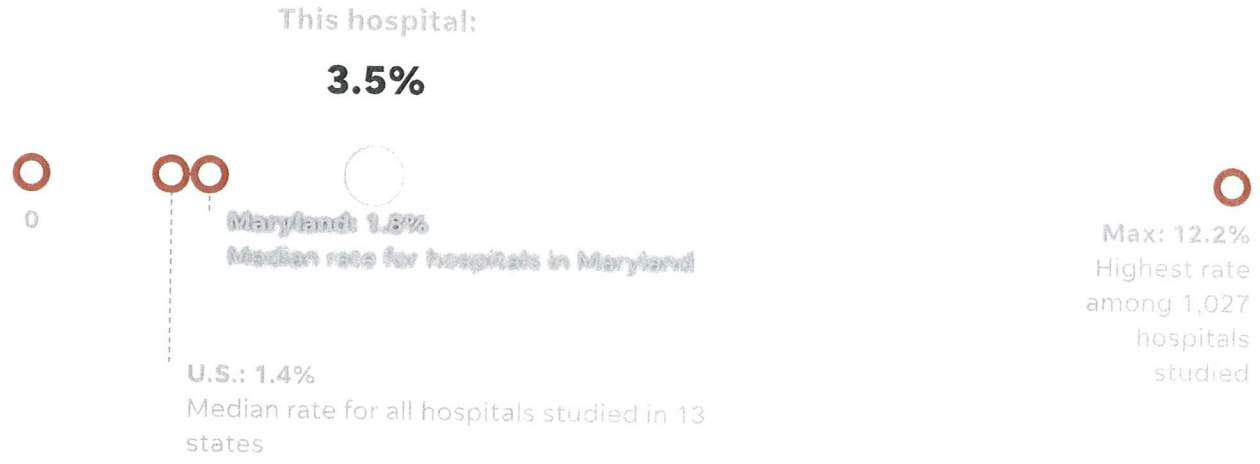
Severe maternal morbidity (SMM) rate

The SMM rate is a composite measure of things that can go wrong at the hospital before, during or after delivery – heart attacks, strokes, blood transfusions, hysterectomies and other perilous emergencies that can permanently harm or even kill a new mother. Because of national concern about disparities in harms experienced by black mothers, USA TODAY also is displaying a separate calculation for these patients.

Learn more

This hospital's severe maternal morbidity rate for births to **all mothers** is greater than the rate for Maryland

5,151 deliveries (2014-17)



This hospital's severe maternal morbidity rate for births to **black mothers** is greater than the rate for Maryland

1,101 of 5,151 deliveries

This hospital's severe maternal morbidity rate for births to **low-income mothers paid for by Medicaid** is greater than the rate for Maryland

1,727 of 5,151 deliveries

This hospital:

STORY

Hospitals blame moms when childbirth goes wrong. Secret data suggest it's not that simple.

Read the story

Other indicators

Cesarean rate

The percentage of deliveries that were the mother's first C-section. This measure excludes deliveries involving mothers who've had a previous C-section. Health safety advocates have long cautioned against unnecessary C-sections.

This hospital:

19.0%

Rate for deliveries in 13 states:

19.9%

Have questions?

What is the severe maternal morbidity (SMM) rate?

The Centers for Disease Control and Prevention created a method for calculating how often women giving birth experience severe complications by using codes in patients' billing records that show what conditions they were diagnosed as having, and what medical procedures they were given.

The resulting "severe maternal morbidity rate" is a composite index of things that can go wrong at the hospital before, during or after delivery – heart attacks, strokes, blood transfusions, hysterectomies and other perilous emergencies that can permanently harm or even kill a new mother.

The CDC developed the rate to study trends at state and national levels, but it's now widely used privately by patient safety organizations, state health departments, insurance companies and hospitals to measure hospitals' progress as they try to reduce preventable injuries and deaths.

How to use this information

Experts stress that a hospital's SMM rate should only be a starting point for asking questions about a hospital's childbirth safety practices and its experience, equipment and resources for responding to emergencies. A high rate alone doesn't mean a hospital provides bad maternity care and a low rate doesn't mean the hospital is the safest place to give birth. A major medical center with a higher SMM rate will have more expertise and resources for treating high-risk deliveries than a community hospital with a lower SMM rate and staff that delivers fewer babies and has less experience and resources when emergencies happen. The SMM rate is just one piece of information consumers should use in evaluating birthing hospitals.

What are the known weaknesses of the SMM rate?

The rate is not a definitive count of how many women suffered serious complications, but instead an indicator or estimate. The rate cannot measure, for instance, how many complications could have been prevented by better medical care or how many patients arrived with existing medical problems that put them at higher risk of a dangerous delivery. For instance, the records do not detail a patient's weight, even though obesity can contribute to complications.

Is the SMM rate published above risk-adjusted?

No. The data USA TODAY obtained does not include all of the information that is needed to adequately risk adjust for the unique factors of childbirth. In fact, there is no consensus among experts of a method for risk-adjusting the SMM rate, in part because of the vast array of contributing factors unique to childbirth.

Can the SMM rate be used to compare hospitals against one another?

Hospitals and many researchers in the field say limitations of the measurement make it difficult to use it to compare one hospital to another. The rates are most commonly used to compare a hospital to larger populations of patients or a group of hospitals. Importantly, they are recommended as a measure that a hospital should compare to its own past rate to monitor its progress in reducing complications.

What deliveries are included?

Throughout most of this database, the numbers utilized are calculations drawn from deliveries in 13 states. References to medians or national figures are aggregates of figures from across the 13 states where USA TODAY was able to get hospital data.

The deliveries in almost all cases are those from 2014-2017. In two states, there were fewer: New York's does not include the fourth quarter of 2017. Vermont's data does not include 2017. Several small Louisiana hospitals did not report hospitalization data for full quarters, but rates calculated for those hospitals from the reported quarters were consistent with rates calculated for those hospitals from previous years' data, going back to 2010.

For episiotomies, figures are a rate derived from vaginal deliveries only, and are available for eight states. The national rate is derived from those eight states. An earlier version of this graphic listed a national rate incorrectly citing all deliveries in 13 states.

Where did this data come from?

USA TODAY calculated SMM rates, following the CDC formula, from de-identified patient discharge records for every hospital in 13 states that had at least 500 births during the four-year period. USA TODAY attempted to obtain these records from all 50 states and the District of Columbia, but most denied the request, or imposed restrictions that amounted to denial or made the data useless for analysis. No patients' names or other identifying information are contained in the records USA

TODAY reviewed. Reporters followed the same strict patient privacy rules imposed on any researchers who use such data.

The records analyzed came from the following agencies: California Office of Statewide Health Planning and Development, Florida Agency for Health Care Administration, Kentucky Cabinet for Health and Family Services, Louisiana Department of Health's Bureau of Health Informatics, Maryland Department of Health and Mental Hygiene, Nevada Division of Health Care Financing and Policy, New Hampshire Bureau of Public Health Statistics and Informatics, New York State Department of Health, Pennsylvania Health Care Cost Containment Council, Rhode Island Center for Health Data and Analysis, Texas Department of State Health Services, Vermont Division of Health Care Administration, Washington State Department of Health and West Virginia Department of Health and Human Resources.

The analytical findings are USA TODAY's and not the work of the agencies that provided data and records.

Why are rates not available for some groups of mothers?

USA TODAY is not publishing rates derived from numbers of patients that are very small, in part to protect patient privacy and comply with state regulations related to the use of the hospital data behind this special report. This impacts rates for black mothers, for instance, at hundreds of hospitals.

What if I see a potential error in this database?

If you spot anything you believe is incorrect in this database, we want to hear from you. We will look into it, using available records, and get back to you. Every effort has been made to ensure hospital names, addresses and statistics reported here are accurate, according to the hospital records submitted to state agencies and obtained by USA TODAY. However, if you believe you see an error, we will review your concern and correct inaccuracies. If you spot a potential error, please let us know at jkelly@usatoday.com.

Back to top

— Ryan Marx, Michael Varano, Christopher Schnaars, Alison Young, John Kelly and Matt Wynn.

Damage Caps and Defensive Medicine, Revisited

Myungho Paik
Hanyang University, College of Policy Science

Bernard Black
Northwestern University, Law School and Kellogg School of Management

David A. Hyman
University of Illinois, School of Law and School of Medicine

Northwestern University Law School
Law and Economics Research Paper No. 13-20

University of Illinois
Program in Law, Behavior and Social Science Research Paper No. LBSS14-21

(Draft November 2016)

Forthcoming, *Journal of Health Economics* (2017)

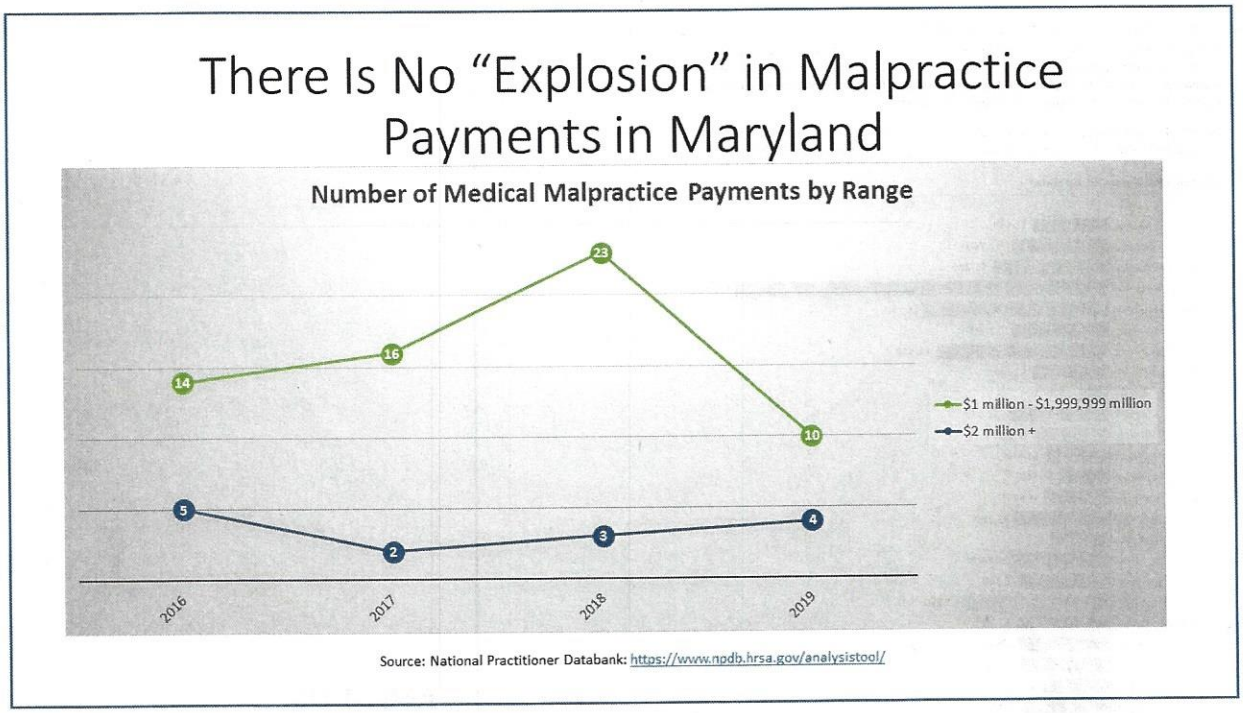
MAJ_MILCT_SB879_OPP - pt1
Uploaded by: Garagiola, Rob
Position: UNF

MARYLAND ASSOCIATION FOR JUSTICE

SB 879 Fact Sheet #1
Why the Maryland Infant Lifetime Care Trust is a Bad Bill

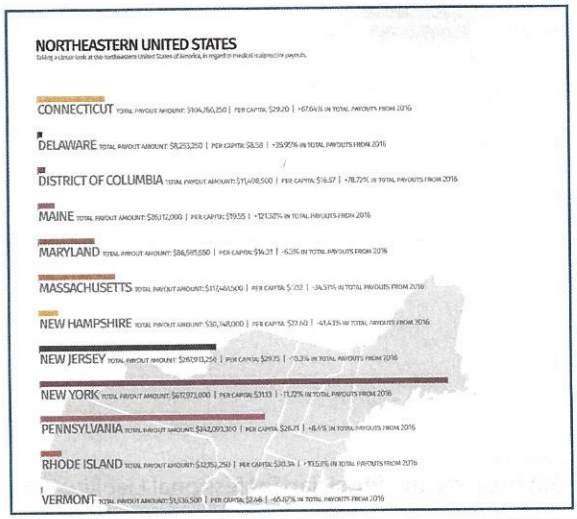
THERE IS NO "EXPLOSION" IN MALPRACTICE PAYMENTS IN MARYLAND

According to the National Practitioner Databank, there has been only one malpractice payment over $10 million in the past 10 years, and only a handful over $2 million. There is no "explosion" in malpractice payments in Maryland.



In fact, the most recent version of a study by Dietrich Healthcare has Maryland seeing payouts drop 6% since 2016.

Source: Dietrich Healthcare 2018 Medical Malpractice Payout Analysis, p 6



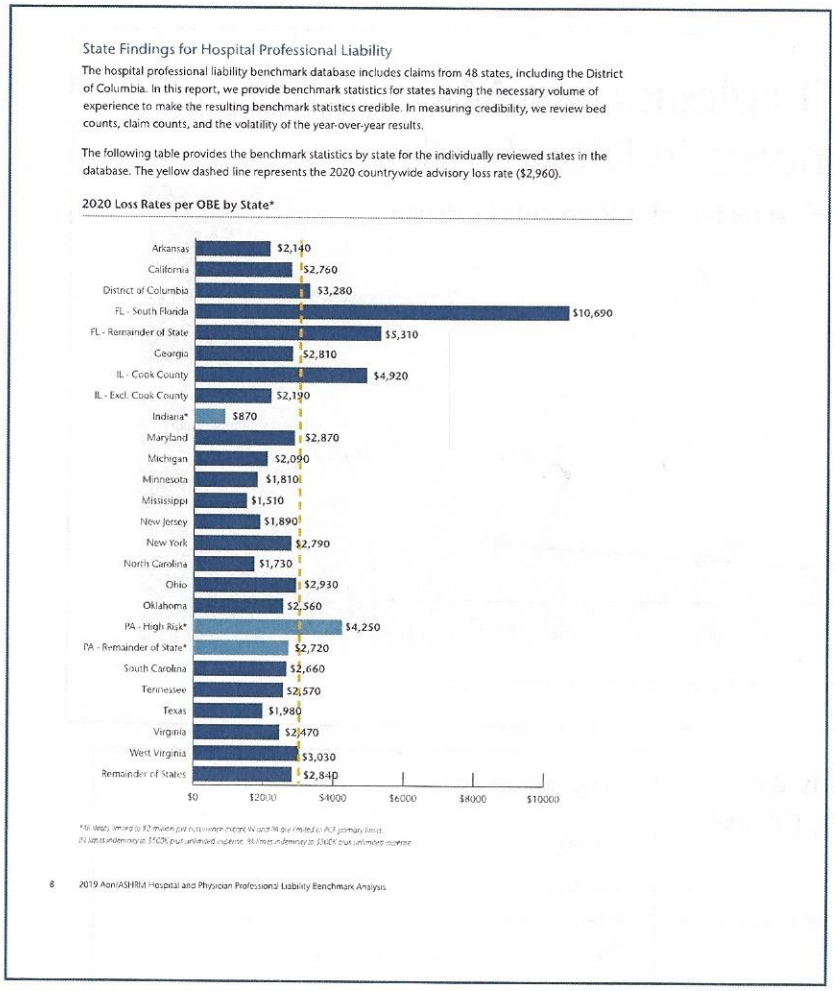
For questions regarding this fact sheet, please contact MAJ's Legislative Chair George S. Tolley, III at gtolley@medicalneg.com or (410) 308-1600

MARYLAND ASSOCIATION FOR JUSTICE

SB 879 Fact Sheet 2020

The most recent Aon/ASHRM Hospital and Physician Professional Liability (2019) shows Maryland below the benchmark rate projected by the reinsurer for medical malpractice claims[1]. The OBE stands for "number of non-zero claims per occupied bed equivalent."

The previous year (2018) it was slightly above average, so it's decreasing.



State Findings for Hospital Professional Liability

The hospital professional liability benchmark database includes claims from 48 states, including the District of Columbia. In this report, we provide benchmark statistics for states having the necessary volume of experience to make the resulting benchmark statistics credible. In measuring credibility, we review bed counts, claim counts, and the volatility of the year-over-year results.

The following table provides the benchmark statistics by state for the individually reviewed states in the database. The yellow dashed line represents the 2020 countrywide advisory loss rate ($2,960).

2020 Loss Rates per OBE by State*

8 2019 Aon/ASHRM Hospital and Physician Professional Liability Benchmark Analysis

ABOUT US

Founded in 1954, Maryland Association for Justice (MAJ) represents over 1,300 trial attorneys throughout the state of Maryland. MAJ advocates for the preservation of the civil justice system, the protection of the rights of Marylanders, and the education and professional development of its members. *Learn more at mdforjustice.com*

MAJ's legislative advocacy is led by MAJ's lobbying team at Compass Government Relation Partners and lobbyist Frank Boston, Esq., in addition to an active volunteer Legislative Committee under the leadership of George S. Tolley, III; MAJ PAC Chair Bruce M. Plaxen; and MAJ President Ellen B. Flynn.

1Aon/ASHRM Hospital and Physician Professional Liability Benchmark Analysis, October 2019, Executive Summary - Abridged Version, p 9

For questions regarding this fact sheet, please contact MAJ's Legislative Chair George S. Tolley, III at gtolley@medicalneg.com or (410) 308-1600

MARYLAND ASSOCIATION FOR JUSTICE

SB 879 Fact Sheet #2

Hopkins has a BIG Problem in Florida

DON'T PUNISH MARYLAND TAXPAYERS FOR FLORIDA'S PROBLEM

A Tampa Bay Times federal investigative report[1] from January 2019 identified extreme deficiencies in care at Johns Hopkins All Children's Hospital in Florida[2]. Hopkins now faces record fines in Florida, $40M from a few families alone. The report below shows an excerpt from a January 2019 Department of Health and Human Services Report that makes it clear that Hopkins ignored complaints and knowingly put patients at risk. Marylanders should NOT take the blame for Hopkin's rising insurance costs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 01/28/2019
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	103300	A. BUILDING _____ B. WING _____	C 01/11/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
JOHNS HOPKINS ALL CHILDREN'S HOSPITAL	501 SIXTH AVENUE SOUTH SAINT PETERSBURG, FL 33701

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 043	Continued From page 1 ensure Emergency Services were provided in compliance with the Medical Staff Bylaws, failed to provide oversight and accountability for the Medical Staff (refer to A49), and failed to provide oversight and monitoring for the Infection Control Program (refer to A747, A749, and A756). Despite the facility's knowledge of complaints that alleged patient deaths due to a lack of oversight and accountability, the facility continued to implement ineffective strategies to ensure safe care. These failures resulted in a finding of ongoing Immediate Jeopardy beginning on 9/20/2018, creating a situation that is likely to result in serious injury, harm, impairment, or death to patients and requires immediate corrective action on the part of the facility.	A 043		
A 049	MEDICAL STAFF - ACCOUNTABILITY CFR(s): 482.12(a)(5) [The governing body must] ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.	A 049		

For questions regarding this fact sheet, please contact MAJ's Legislative Chair George S. Tolley, III at gtolley@medicalneg.com or (410) 308-1600

1 https://projects.tampabay.com/projects/2018/investigations/heartbroken/

2 https://www.tampabay.com/investigations/2019/08/23/johns-hopkins-agrees-to-pay-nearly-40-million-to-two-families-hurt-by-all-childrens-heart-surgeries/

#3

MARYLAND ASSOCIATION FOR JUSTICE

SB 879 Fact Sheet 2020

The most recent Aon/ASHRM Hospital and Physician Professional Liability (2019) shows Maryland below the benchmark rate projected by the reinsurer for medical malpractice claims[1].

State Findings for Hospital Professional Liability

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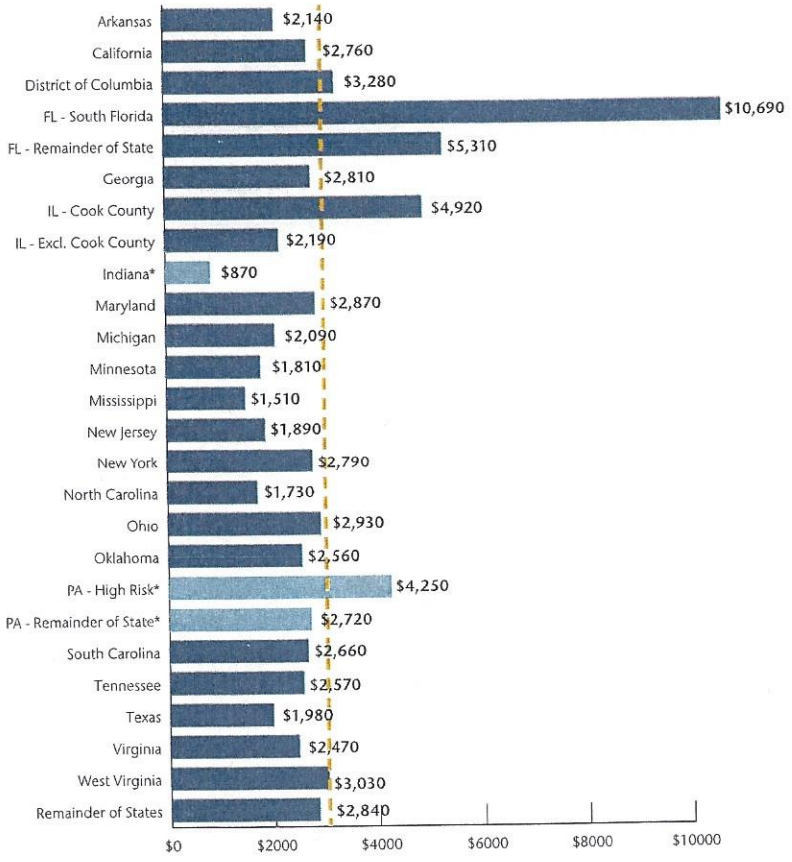
2020 Loss Rates per OBE by State*



*All states limited to $2 million per occurrence except IN and PA are limited to PCF primary limits: IN limits indemnity to $500K plus unlimited expense; PA limits indemnity to $500K plus unlimited expense

6 2019 Aon/ASHRM Hospital and Physician Professional Liability Benchmark Analysis

1Aon/ASHRM Hospital and Physician Professional Liability Benchmark Analysis, October 2019, Executive Summary - Abridged Version, p 9

For questions regarding this fact sheet, please contact MAJ's Legislative Chair George S. Tolley, III at gtolley@medicalneg.com or (410) 308-1600

MARYLAND ASSOCIATION FOR JUSTICE

SB 879 Fact Sheet 2020 #4

The Byrom Verdict is an Outlier

THE STORY OF *BYROM V. JOHNS HOPKINS BAYVIEW MEDICAL CENTER*

On July 1, 2019, a jury in the Circuit Court for Baltimore City returned a unanimous verdict, including about $229,640,000.00 in monetary damages, in a medical negligence case brought by the mother of Zubida Byrom, a minor child, against Johns Hopkins Bayview Medical Center and other defendants.

Zubida suffered catastrophic brain damage during labor and delivery because, for days while her mother was admitted to the hospital, the hospital staff miscalculated Zubida's gestational age and weight and, when the staff realized their mistake, they withheld the truth from Zubida's mother.[1]

The jury's verdict included $25,000,000 in non-economic damages (which is subject to a statutory cap), and $200,000,000 in future economic damages. The future economic damages represents the present cost of medical care that the jury found the minor plaintiff likely will need in the future to treat the injuries caused by the defendants' negligence, for the rest of her life expectancy.

The trial itself came at the end of more than a year of discovery, during which time the plaintiffs and the defendants exchanged documents and other evidence and took testimony from witnesses. In a civil action such as this, the purpose of discovery is so that all of the parties and their lawyers have a clear understanding of all of the evidence that might be offered at trial.

As required by statute, the parties engaged in settlement discussions (called mediation, which is mandatory in medical negligence cases because hospitals claimed that mediation resolves cases more quickly and less expensively).

Settlement discussions continued after the mediation, and the parties continued negotiating even during the trial, until Deb Parraz, Esq., Senior Counsel at Johns Hopkins Health System, informed lawyers for Zubida that Hopkins was no longer interested in negotiations. Ms. Parraz' e-mail, dated June 26, 2019 (five days before the verdict) is reproduced on the other side of this fact sheet.

---

[1]Cynthia Argani, M.D., the Director of Labor and Delivery at Johns Hopkins Bayview Medical Center, testified at trial that the truth about the medical errors in this case was shared in real time with other physicians throughout the Hopkins Health System "could potentially get hospital-wide attention or media attention," but it "wasn't important" for [Zubida's mother to be told the truth, even as she was asked to make decisions about operative delivery based on the same misinformation.

Of course, there is much more to the story than we can fit on one page. **MAJ and the lawyers who represented Zubida at trial are available to meet with any legislators or their staff who want to learn more about the negligent medical care in this case, the evidence and testimony at trial, the settlement negotiations that ended – in the middle of trial – when the Hopkins administration announced that they "need to be willing to take some verdicts," the status of the appeal, or the status of post-verdict settlement negotiations.**

Hopkins and MHA seem to want to make the facts of this case relevant to legislative policy during the 2020 Session. **MAJ believes that legislators should have the right to hear the whole story from both sides.**

For questions regarding this fact sheet, please contact MAJ's Legislative Chair George S. Tolley, III at gtolley@medicalneg.com or (410) 308-1600

Medical Negligence Fact Sheet 2020

From: parrazd@gmail.com
Sent: Wednesday, June 26, 2019 8:14 AM
To: Keith Forman
Subject: Re: Byrom

Keith, it just occurred to me that I never responded to your $14 million demand. I am sorry for the delay. I ran this case all the way up the flagpole at Hopkins and the admin there really believes in the care rendered by our providers in this case. They feel that if we are going to try more cases we need to be willing to take some verdicts. I believe they are tired of paying on non-meritorious cases. I said all that to say that they really would like to see this case through to its trial conclusion. So, I do not have any more money to offer you at this time. I will certainly let you know if that changes.
Best,

Deb

Sent from my iPhone

Of course, Hopkins is a sophisticated consumer of legal services, and the administration at Hopkins had the benefit of legal advice from at least three (3) large law firms full of smart and capable lawyers when it decided that they "really believe[d] in the care rendered by our providers in this case," and that "we need to be willing to take some verdicts."

After trial, Hopkins and its defense team filed post-trial motions, asking the trial judge, the Hon. Audrey J. Carrion, for several things:

1. Arguing that the plaintiff did not prove negligence, Hopkins asked Judge Carrion to overturn the verdict and enter judgment for the defendants. Judge Carrion refused, finding that the evidence was sufficient to prove the defendants' negligence caused the minor plaintiff's injuries.

2. Arguing that the amount of the jury's verdict was not supported by the evidence at trial or otherwise "shocked the conscience" because it was so large, Hopkins asked Judge Carrion to reduce the verdict.

   Judge Carrion reduced the non-economic damages portion of the verdict to the statutory cap, but refused to reduce the future economic damages. This decision reflects a judicial finding that the verdict was supported by the evidence at trial and did not shock Judge Carrion's conscience.

3. Finally, Hopkins asked Judge Carrion to order that the future economic damages could be paid out slowly, over Zubida's lifetime.

Applying a statute enacted more than 30 years ago to deal with cases just like this, Judge Carrion agreed. She also ordered the lawyers for both sides to negotiate an appropriate payment schedule; those negotiations have been continuing ever since (and Hopkins has retained the services of a fourth large law firm to assist in those negotiations).

Hopkins has taken an appeal, which can be expected to take more than a year to resolve (and perhaps even longer). Of course, the parties also may negotiate a settlement at any time.

MAJ will keep interested legislators fully apprised of the ongoing status of the *Byrom* case.

For questions regarding this fact sheet, please contact MAJ's Legislative Chair George S. Tolley, III at gtolley@medicalneg.com or (410) 308-1600

JOHNS HOPKINS
MEDICINE

High-Risk Births in Maryland and the Facts About the Byrom Case

Introduction

In a small number of complex cases, an infant may require long-term medical care as a result of neurological injuries that occur at birth. In a widely publicized 2019 case, a young mother named Erica Byrom sued Johns Hopkins after her baby experienced a neurological injury during her high-risk childbirth. Johns Hopkins is confident in the care and advice provided to the mother and was stunned when the case resulted in one of the largest jury awards in US history.

This case, and others like it, are driving up health care costs in Maryland and making it increasingly difficult for doctors and hospitals to get the insurance they need to be able to treat complex high-risk births in our state. The judgment also highlights the guessing game juries engage in when seeking to determine the costs of future medical care. The jurors in this case awarded nearly five times as much as Ms. Byrom asked for, far more than any reasonable estimate of the child's lifetime medical expenses.

The case has generated many questions, which we answer below, based on publicly available information.

Note: Federal privacy laws limit what may be shared publicly about this or any other case. All of the information below regarding the case is publicly available from trial testimony.

Q: What can you tell us about what happened in this case?

A: In this case, a young mother in medical distress was helicoptered to Johns Hopkins Bayview Medical Center from another hospital in Maryland that was not equipped to handle her care.[1] As described at trial, the mother was 25 weeks pregnant,[2] had no prior prenatal care, and had developed severe preeclampsia – a complication of pregnancy characterized by dangerously high blood pressure – which can be life-threatening for both mother and baby. When she arrived at Johns Hopkins, the mother had reduced amniotic fluid, and the prognosis of the fetus was poor, with a significant chance of death or disability.[3]

Multiple Johns Hopkins physicians strongly and repeatedly advised the mother to deliver the baby via C-section, but she declined each time, citing the potential for pain from the procedure.[4]

1 Trial transcript, Byrom v. Johns Hopkins Bayview, 6/24/19

2 Due to a number of factors, including in part Ms. Byrom's lack of prenatal care, the gestational age when she arrived under emergency circumstances at Johns Hopkins Bayview Medical Center was uncertain and initially believed to be approximately 23 weeks.

3 Trial transcript, Byrom v. Johns Hopkins Bayview, 6/24/19; Trial transcript, Byrom v. Johns Hopkins Bayview, 7/1/19

4 Trial transcript, Byrom v. Johns Hopkins Bayview, 6/21/19; Trial transcript, Byrom v. Johns Hopkins Bayview, 6/20/19; Trial transcript, Byrom v. Johns Hopkins Bayview, 6/24/19

At the mother's insistence and against the advice of the Johns Hopkins team, the baby was delivered by a vaginal birth.[5] Weighing less than 1.5 pounds and with a heart the size of a quarter, she had to be resuscitated and treated and will require continued medical care.[6]

Q: What is the current status of the Byrom case?

A: Ms. Byrom sued Johns Hopkins and was awarded $229 million by the jury, which was nearly five times the $43 million she asked for. The court then reduced the jury award to $205 million (to fall within state limits), but it remains one of the highest jury awards in US history and far exceeds every reasonable estimate of the cost of the child's continued medical care.

Q: Did the young mother have a guardian or advocate available to support her while she made medical decisions?

A: Yes. According to trial transcripts, Ms. Byrom's mother accompanied her at the hospital, was present for multiple discussions with her care team, and was closely involved in her daughter's decision-making throughout the delivery.[7]

Q: Was Ms. Byrom advised to undergo a C-section, rather than attempt a vaginal birth?

A: Yes. As the trial record shows, given the severity of Ms. Byrom's case, and the unusual nature of her refusal to have a C-section, multiple Johns Hopkins physicians strongly and repeatedly advised her to deliver the baby via C-section, which she declined each time, citing the potential for pain from the procedure.[8]

At the insistence of Ms. Byrom, Johns Hopkins proceeded with a vaginal birth.[9] Following delivery, the baby was treated and resuscitated, but her challenges were immediately evident – she weighed less than 1.5 pounds and had a heart the size of a quarter.[10]

Q: What happens next? Where do we go from here?

A: Medical circumstances like this one are tragic and our hearts go out to this child, her family, and those who are caring for her. But these cases also are driving up health care costs in Maryland and making it increasingly difficult for doctors and hospitals to get the insurance they need to be able to treat complex high-risk births in our state.

Johns Hopkins is committed to providing world-class care and advice for Maryland patients facing high-risk medical situations. And if a hospital or doctor makes a mistake, they should be held accountable. But excessive jury awards put our entire Maryland health care and insurance system at risk and could cause even more Maryland hospitals to close maternity wards, discourage obstetricians from practicing in Maryland, and reduce access to obstetrical care in our state.

Legislation currently being considered by the Maryland General Assembly to create an Infant Lifetime Care Trust is a crucial step in the right direction. The bill establishes a trust - funded through hospitals that deliver babies - to cover the cost of care for infants who suffer neurological injury at birth.

5 Trial transcript, Byrom v. Johns Hopkins Bayview, 6/21/19; Trial transcript, Byrom v. Johns Hopkins Bayview, 6/24/19

6 Trial transcript, Byrom v. Johns Hopkins Bayview, 6/19/19; Trial transcript, Byrom v. Johns Hopkins Bayview, 7/1/19

7 Trial transcript, Byrom v. Johns Hopkins Bayview, 6/24/19

8 Trial transcript, Byrom v. Johns Hopkins Bayview, 6/21/19; Trial transcript, Byrom v. Johns Hopkins Bayview, 6/24/19

9 Trial transcript, Byrom v. Johns Hopkins Bayview, 6/21/19; Trial transcript, Byrom v. Johns Hopkins Bayview, 6/24/19

10 Trial transcript, Byrom v. Johns Hopkins Bayview, 6/19/19; Trial transcript, Byrom v. Johns Hopkins Bayview, 7/1/19

The Johns Hopkins Medicine "Fact Sheet" about the *Byrom* case is factually wrong and misleading. Below are corrections to the "Fact Sheet" issued by Johns Hopkins Medicine:

Erica had prenatal care before she arrived at Johns Hopkins.

By the time Erica Byrom was admitted at Johns Hopkins, her adoptive parents had taken her to a pediatrician on August 21, 2014 who confirmed she was pregnant.[1] Erica's pediatrician referred her to an OB/GYN, and her adoptive parents took her to 3 prenatal appointments, on October 6, October 13, and October 20, 2014 before Erica ever went to Johns Hopkins.[2]

The doctors at Johns Hopkins never thought the baby was 23 weeks.

On October 6, 2014 (2 weeks before she arrived at Johns Hopkins), Erica's first prenatal ultrasound showed that her baby, according to her measurements, was approximately 23 weeks and 2 days old, and weighed about 546 grams.[3] On October 13, 2014, Erica's baby was about 24 weeks and 3 days according to the measurements from the second prenatal ultrasound.[4] On October 20, 2014, doctors at Johns Hopkins Bayview wrote in Erica's "History and Physical Chart" that her baby was 25 weeks and 3 days.[5]

The prognosis for Erica's baby was "fair" when she first got to Johns Hopkins.

When Erica arrived at Johns Hopkins on October 20, she signed an informed consent form that had been prepared by one of the residents:

> The indications, benefits and probability of success of the operation(s), treatment(s) or procedure(s) have been explained to me in a manner that I understand. These include:
> Indication: preeclampsia
> Benefit: maternal/fetal well-being
> **Probability of Success: Fair**[6]

At trial, the resident who filled out the informed consent with Erica testified that "probability of success" meant the probability of "...healthy mom and baby."[7]

Erica's medical records from Johns Hopkins Bayview also show that her baby was doing well on October 20, 2014—Erica's baby scored a 10 out of 10 on a biophysical profile, and the fetal heart rate monitoring was reassuring.[8]

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[1] Cambridge Pediatrics Medical Records, Joint Trial Exhibit 1B at pp. 1-4, admitted as evidence on June 18, 2019.
[2] Clinton Women's Prenatal Records, Joint Trial Exhibit 1B, admitted as evidence on June 18, 2019.
[3] Clinton Women's Prenatal Records, Joint Trial Exhibit 1B, at p. 1, admitted as evidence on June 18, 2019.
[4] Clinton Women's Prenatal Records, Joint Trial Exhibit 1B, at p. 9, admitted as evidence on June 18, 2019.
[5] Johns Hopkins Bayview Medical Records, Joint Trial Exhibit 1A at p. 35, admitted as evidence on June 18, 2019.
[6] Joint Trial Exhibit 1A at pp. 3-4, admitted as evidence on June 18, 2019.
[7] Trial testimony of Rebecca Adami, M.D., at pp. 52:21-53:3.
[8] Johns Hopkins Bayview Medical Records, Joint Trial Exhibit 1A at pp. 204-205, admitted as evidence on June 18, 2019.

Erica never "insisted" on a vaginal birth against the advice of the doctors at Johns Hopkins.

When Erica first arrived at Johns Hopkins, she gave the doctors consent to perform a cesarean section if her or her baby's health was at risk.[9] The choice of declining a cesarean section is not mentioned in the medical records until October 21, 2014.[10]

Beginning on October 21, 2014 the doctors at Johns Hopkins told Erica that: (1) her baby would probably not survive childbirth; (2) the NICU would not try to save her baby if she were born alive; (3) her baby had "zero" chance of having a normal brain; and (4) she could terminate the pregnancy.[11]

The doctors at Johns Hopkins also told Erica that if she had a cesarean section, she would never be able to deliver vaginally and had an increased risk of uterine rupture even if she never went into labor.[12]

Erica eventually withdrew her consent for a cesarean section for her baby's health later that day on October 21, 2014.[13]

Johns Hopkins always had Erica's permission to perform a cesarean section if her own health was at risk.

The doctors at Johns Hopkins always had Erica's permission to perform a cesarean section if her health was in danger.[14, 15] At trial, an expert hired by Erica and Zubida testified that it was unsafe for the doctors at Johns Hopkins to even attempt a vaginal delivery because it put Erica's health at risk, since her condition could deteriorate at any moment—**it would have been safer for Erica to do a cesarean section** when it came time to deliver her baby.[16]

Johns Hopkins violated their own patient safety policies when they induced Erica's labor.

In October 2014, Johns Hopkins had patient safety polices that governed induction of labor in patients like Erica.[17] According to Johns Hopkins' policies, an induction of labor begins with 25 micrograms Cytotec—**Johns Hopkins' doctors gave Erica a double dose of Cytotec 4 times.**[18, 19] Also according to

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[9] Johns Hopkins Bayview Medical Records, Joint Trial Exhibit 1A at p. 3, admitted as evidence on June 18, 2019.
[10] Johns Hopkins Bayview Medical Records, Joint Trial Exhibit 1A at p. 211, admitted as evidence on June 18, 2019.
[11] Johns Hopkins Bayview Medical Records, Joint Trial Exhibit 1A at pp. 19, 129-130, 134-135, 211, 212, admitted as evidence on June 18, 2019.
[12] Johns Hopkins Bayview Medical Records, Joint Trial Exhibit 1A at p. 211, admitted as evidence on June 18, 2019.
[13] Johns Hopkins Bayview Medical Records, Joint Trial Exhibit 1A at p. 212, admitted as evidence on June 18, 2019.
[14] Johns Hopkins Bayview Medical Records, Joint Trial Exhibit 1A at p. 3, admitted as evidence on June 18, 2019.
[15] Trial Testimony of Donald Garland, D.O. at pp. 92:3-19.
[16] Trial Testimony of Michael Cardwell, M.D. at p. 89:7-21.
[17] Trial Testimony of Donald Garland, D.O. at pp. 103:8-104:11.
[18] Trial Testimony of Donald Garland, D.O. at pp. 107:1-17.
[19] Johns Hopkins Bayview Medical Records, Joint Trial Exhibit 1A at p. 228, admitted as evidence on June 18, 2019.

Johns Hopkins' policies, the baby is continuously monitored during the induction of labor—Zubida was not monitored for more than 63 hours, including the entire 22 hour induction of labor.[20, 21]

Johns Hopkins does not, and will not, have to pay Zubida Byrom $205 million dollars.

The jury awarded Zubida Byrom $200 million dollars for the cost of her future medical care.[22] After trial, the trial judge granted Johns Hopkins' request to purchase financial instruments called annuities, instead of paying a lump sum.[23, 24] According to the Order, Johns Hopkins Bayview's upfront costs are less than half of the jury's original award of $229 million.[25] Furthermore, at the time of Zubida's death, **unused money will be returned to Johns Hopkins Bayview**.[26]

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[20] Trial Testimony of Donald Garland, D.O. at p. 106:9-14.

[21] Johns Hopkins Bayview Medical Records, Joint Trial Exhibit 1A at pp. 40, 135, admitted as evidence on June 18, 2019.

[22] Verdict Sheet, Circuit Court for Baltimore City, No. 24-C-18-002909.

[23] Defendant's Motion to Annuitize Judgment for Future Economic Damages, Docket No. 173/0, dated July 15, 2019.

[24] Order of Baltimore City Circuit Court, Docket No. 173/4, dated September 25, 2019.

[25] Order of Baltimore City Circuit Court, Docket No. 222/1, dated January 17, 2020.

[26] Order of Baltimore City Circuit Court, Docket No. 222/1, dated January 17, 2020.

Keith Forman

From: Deb Parraz <dparraz1@jhmi.edu>
Sent: Tuesday, June 18, 2019 7:55 PM
To: Keith Forman
Subject: Re: Byrom

Keith, my response is $2.5.

Thanks,
Deb

Sent from my iPhone

On Jun 17, 2019, at 4:57 PM, Keith Forman <kdf@malpracticeteam.com> wrote:

> Hi Deb,
>
> Sorry for the delayed response. I have authority to drop to $15,000,000.00.
>
> Thanks,
> Keith
>
> _____
> Keith D. Forman, Esq.
> Wais, Vogelstein, Forman & Offutt, LLC
> (410) 998-3600
> (410) 591-7967
>
> -------- Original Message --------
> Subject: Re: Byrom
> From: Deb Parraz
> To: Keith Forman
> CC:
>
> Keith, I am responding with an offer of $2 million. I know that is probably not what you want to hear but let's just try to get some momentum going. Thanks.
>
> Sent from my iPhone
>
> On Jun 17, 2019, at 6:16 AM, Keith Forman <kdf@malpracticeteam.com> wrote:
>
> > Deb,
> >
> > Thank you for taking the time to talk yesterday afternoon. I appreciate it.
> >
> > In an effort to get settlement talks back on track I have been given authority to make a new demand of $15,500,000.00.

Thanks,
Keith

Keith D. Forman, Esq.
Wais, Vogelstein, Forman & Offutt, LLC
(410) 998-3600
(410) 591-7967

-------- Original Message --------
Subject: Re: Byrom
From: Deb Parraz
To: Keith Forman
CC:

Thank you for your response. I am not going to bid against myself. If you decide to respond, that's fine. Otherwise, I will consider negotiations closed.

Deb

Sent from my iPhone

> On Jun 14, 2019, at 12:16 PM, Keith Forman <kdf@malpracticeteam.com> wrote:
>
> Deb,
>
> Thank you for your email. I have had an opportunity to discuss same with my client and my partners. Unfortunately, we do not think your latest bracket is reflective of the seriousness and strength of this case, nor is it reflective of what transpired with the motions. As such, we are not in a position to respond.
>
> You can of course call me if you wish to discuss this further.
>
> Thanks,
> Keith
>
> Keith D. Forman, Esquire | Partner
> Wais, Vogelstein, Forman & Offutt, LLC
> 1829 Reisterstown Road | Suite 425
> Baltimore, Maryland 21208
> Office: (410) 998-3600
> Cell: (410) 591-7967
> kdf@malpracticeteam.com
> Admitted in MD, MN & DC
>
> -----Original Message-----
> From: parrazd@gmail.com <parrazd@gmail.com>
> Sent: Friday, June 14, 2019 10:16 AM
> To: Keith Forman <kdf@malpracticeteam.com>
> Subject: Byrom
>
> Keith,
> I know that you have spoken with Mike. I want him to focus on trial so I am going to take over discussing potential for resolution. While we are going full steam ahead for trial and have an appellate team in full gear, I am also willing to explore settlement in a reasonable range to avoid dragging folks through trial. To that end, I am offering a settlement bracket in the range of $1.5

and $2.5. Please let me know your response.
>
> Deb
>
> Sent from my iPhone

Keith Forman

From: parrazd@gmail.com
Sent: Wednesday, June 26, 2019 8:14 AM
To: Keith Forman
Subject: Re: Byrom

Keith, it just occurred to me that I never responded to your $14 million demand. I am sorry for the delay. I ran this case all the way up the flagpole at Hopkins and the admin there really believes in the care rendered by our providers in this case. They feel that if we are going to try more cases we need to be willing to take some verdicts. I believe they are tired of paying on non-meritorious cases. I said all that to say that they really would like to see this case through to its trial conclusion. So, I do not have any more money to offer you at this time. I will certainly let you know if that changes.
Best,

Deb

Sent from my iPhone

> On Jun 14, 2019, at 12:16 PM, Keith Forman <kdf@malpracticeteam.com> wrote:
>
> Deb,
>
> Thank you for your email. I have had an opportunity to discuss same with my client and my partners. Unfortunately, we do not think your latest bracket is reflective of the seriousness and strength of this case, nor is it reflective of what transpired with the motions. As such, we are not in a position to respond.
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> Thanks,
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> 1829 Reisterstown Road | Suite 425
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> Office: (410) 998-3600
> Cell: (410) 591-7967
> kdf@malpracticeteam.com
> Admitted in MD, MN & DC
>
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> From: parrazd@gmail.com <parrazd@gmail.com>
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> To: Keith Forman <kdf@malpracticeteam.com>
> Subject: Byrom
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> Keith,
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explore settlement in a reasonable range to avoid dragging folks through trial. To that end, I am offering a settlement bracket in the range of $1.5 and $2.5. Please let me know your response.
>
> Deb
>
> Sent from my iPhone

Solution: Patient Safety

EXPERT REVIEWS ajog.org

PATIENT SAFETY SERIES

A comprehensive obstetric patient safety program reduces liability claims and payments

Christian M. Pastore, MD; Stephen F. Thung, MD, MSCE; Heather S. Lipkind, MD; Jessica L. Illuzzi, MD; Catalin S. Buhimschi, MD; Cheryl A. Raab, RNC; Joshua A. Copel, MD; Charles J. Lockwood, MD, MHCM; Edmund F. Funai, MD

decreased in the 5-years after program inception. Compared with before program inception, median annual claims dropped from 1.31 to 0.64 ($P = .02$), and median annual payments per 1000 deliveries decreased from $1,141,638 to $63,470 ($P < .01$). Even estimating the monetary awards for the 2 remaining open cases using the median payments for the surrounding 5 years, a reduction in the median monetary amount per case resulting in payment to the claimant was also statistically significant ($632,262 vs $216,815, $P = .046$). In contrast, the Connecticut insurance market experienced a stable number of claims and markedly increased cost per claim during the same period. We conclude that an obstetric safety initiative can improve liability claims exposure and reduce liability payments.

TABLE 2
Comparison of outcomes before and after program inception

Variable	1998–2002	2003–2007	*P* value
Deliveries; n	23,499	23,372	—
Annual deliveries; mean (±SD)	4699 (± 159)	4674 (± 56)	.70[b]
Liability cases			
Total cases; n	30	14	—
Total cases per 1000 deliveries; n	1.28	0.60	—
Annual cases; median (range)	6 (4–7)	3 (1–5)	.02[b]
Annual cases per 1000 deliveries; median (range)	1.31 (0.88–1.45)	0.64 (0.22–1.06)	.02[b]
Closed case analysis			
Total payments	$30,721,033	$2,239,173	—
Annual payments; median (range)	$632,262 (2293–15,421,842)	$61,714 (13,505–1,579,496)	.03[c]
Total payments per 1000 deliveries	$2,158,434	$95,808	—
Annual payments per 1000 deliveries; median (range)	$1,141,638 (264,352–4,536,653)	$63,470 (0–315,342)	< .01[b]
Combined (open + closed) case analysis (estimated)			
Total payments	$30,721,033	$2,878,937	—
Annual payments; median (range)	$632,262 (2293–15,421,842)	$216,815 (13,505–1,579,496)	.046[c]
Total payments per 1000 deliveries	$2,158,434	$123,179	—
Annual payments per 1000 deliveries; median (range)	$1,141,638 (264,352–4,536,653)	$63,925 (13,355–403,284)	.08[b]

[a] Student's t test; [b] Mann-Whitney U test; [c] Median test.

Pastore. Obstetric safety program reduces liability claims and payments. Am J Obstet Gynecol 2008.

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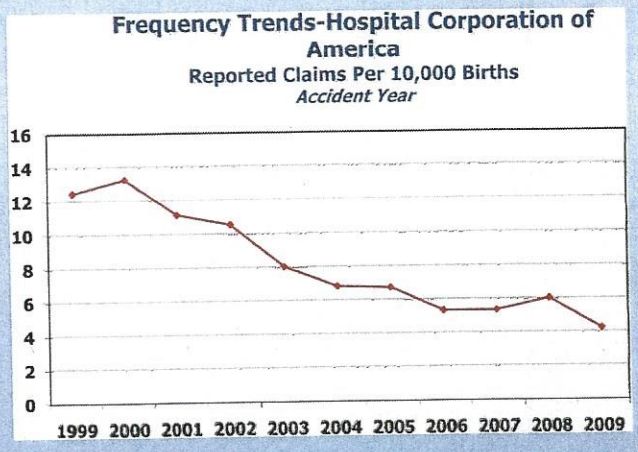
Solution: Patient Safety

REVIEWS www.AJOG.org

PATIENT SAFETY SERIES

Patient safety in obstetrics–the Hospital Corporation of America experience

Steven L. Clark, MD; Janet A. Meyers, RN; Donna K. Frye, RN; Jonathan A. Perlin, MD, PhD



8

PATIENT SAFETY SERIES

A comprehensive obstetric patient safety program reduces liability claims and payments

Christian M. Pettker, MD; Stephen F. Thung, MD, MSCI; Heather S. Lipkind, MD; Jessica L. Illuzzi, MD; Catalin S. Buhimschi, MD; Cheryl A. Raab, RNC; Joshua A. Copel, MD; Charles J. Lockwood, MD, MHCM; Edmund F. Funai, MD

Begun in 2003, the Yale-New Haven Hospital comprehensive obstetric safety program consisted of measures to standardize care, improve teamwork and communication, and optimize oversight and quality review. Prior publications have demonstrated improvements in adverse outcomes and safety culture associated with this program. In this analysis, we aimed to assess the impact of this program on liability claims and payments at a single institution. We reviewed liability claims at a single, tertiary-care, teaching hospital for two 5-year periods (1998-2002 and 2003-2007), before and after implementing the safety program. Connecticut statute of limitations for professional malpractice is 36 months from injury. Claims/events were classified by event-year and payments were adjusted for inflation. We analyzed data for trends as well as differences between periods before and after implementation. Forty-four claims were filed during the 10-year study period. Annual cases per 1000 deliveries decreased significantly over the study period ($P < .01$). Claims (30 vs 14) and payments ($50.7 million vs $2.9 million) decreased in the 5-years after program inception. Compared with before program inception, median annual claims dropped from 1.31 to 0.64 ($P = .02$), and median annual payments per 1000 deliveries decreased from $1,141,638 to $63,470 ($P < .01$). Even estimating the monetary awards for the 2 remaining open cases using the median payments for the surrounding 5 years, a reduction in the median monetary amount per case resulting in payment to the claimant was also statistically significant ($632,262 vs $216,815, $P = .046$). In contrast, the Connecticut insurance market experienced a stable number of claims and markedly increased cost per claim during the same period. We conclude that an obstetric safety initiative can improve liability claims exposure and reduce liability payments.

Key words: medical liability, medical malpractice, obstetric adverse outcomes, patient safety

The health care safety and quality movement has multiple goals, including (1) improvement of quality of care for individual patients, (2) reduction in the incidence of and exposure to adverse events, and (3) control of health care spending through accountable and value-based care. Preventable medical errors and mishaps diminish the ability to achieve all 3 goals, and thus efforts to control their occurrence are taking center-stage in health care improvement discussions.

Patient safety interventions have demonstrated remarkable improvements in quality indicators and reductions in adverse outcomes. However, less is known about how such interventions impact health care costs. Reducing waste and the spending required to respond to adverse outcomes is one way to reduce costs. It is also presumed that improvements in safety culture and the resultant enhanced collaboration and teamwork results in staffing efficiencies, such as less staff turnover and fewer staff vacancies. Finally, quality improvement efforts may alleviate some medicolegally-motivated defensive medicine practices complicating health care.

The contribution of medicolegal concerns to direct and indirect health care costs is a subject of debate. However, with obstetrics in a chronic professional liability insurance crisis, and with liability insurance and defense consuming a considerable amount of financial resources in obstetrics, demonstrating an impact on medicolegal outcomes, in addition to adverse outcomes, is an important goal in this field. Fewer lawsuits may be a surrogate marker of improved outcomes, but are probably a valuable indicator on their own. Decreasing claims also would reduce the overhead costs associated with legal defense and should also reduce overall payments for awards and settlements.

In 2002, Yale-New Haven Hospital (YNHH) partnered with its liability insurance carrier (MCIC Vermont, Inc., New York, NY) to introduce a comprehensive obstetrics safety initiative aimed at improving quality of care and reducing liability costs. We have

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MCIC Vermont, Inc. (New York, NY) provided partial financial support for this project as a quality assurance activity.

The authors report no conflict of interest.

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Reprints not available from the authors.

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previously demonstrated reductions in adverse outcomes and improvements in safety culture/climate associated with this program.[1,2] More than 3 years after the maturity of this program, we now aim to describe the changes in our liability profile, namely the number of and payments for obstetric legal cases.

Materials and methods

We incrementally introduced multiple patient safety interventions from Dec. 2002 to Nov. 2006 at a university-based obstetrics service at YNHH. The details of this program have been previously described.[1] Briefly, the core elements of this project included:

(1) Outside Expert Review: we began in 2002 with a review of our obstetric services by 2 independent consultants. This site visit culminated in recommendations that focused on principles of patient safety, evidence based practice, and consistency with standards of professional and regulatory bodies.

(2) Protocols and Guidelines: protocol and guideline development began in 2004 with the aim to codify and standardize existing practices. Over 40 documents were produced during the study period.

(3) Obstetric Safety Nurse: an obstetric safety nurse was hired in 2004 to facilitate planned interventions and assist in data collection.[3] This nurse was in charge of educational efforts—including team training and electronic fetal heart rate (FHR) monitoring certification—and operations relating to patient safety activities.

(4) Anonymous Event Reporting: we initiated in July 2004 a computerized and anonymous event reporting tool (Peminic Inc, Princeton, NJ) that allows any member of the hospital to report an event or condition leading to harm (or potential harm) to a patient or visitor. Reports were reviewed and investigated.

(5) Obstetric Hospitalists: resident supervision and leadership of the inpatient activities was assumed by our Maternal-Fetal Medicine team to provide 24-hour, 7-day a week in-house coverage, beginning in 2003.

(6) Obstetric Patient Safety Committee: established in 2004 this multidisciplinary committee of physicians, midwives, nurses, and administrators provides quality assurance and improvement oversight. In particular, this group met monthly to review adverse events and address the needs for protocols and policies.

(7) Safety Attitude Questionnaire: to assess employee perception of teamwork and safety, we annually surveyed our teams with this tool, adapted from the aviation field.[4]

(8) Team Training: we implemented crew resource management seminars, based on those of airline and defense industries. These 4-hour classes included videos, lectures, and role-playing with the goal of integrating obstetric staffing silos (physicians, midwives, nurses, administrators, assistants) and teaching effective communication. Completion of the seminar was a condition for employment and/or clinical privileges.

(9) Electronic FHR Certification: teaching for this included dissemination and review of NICHD guidelines, review of tracings, allocation of study guides, and voluntary review sessions, culminating in a standardized, certified examination. All medical staff and employees responsible for FHR monitoring interpretation were obligated to pass this exam at program inception or within 1 year of employment.

Events, claims, and suits related to obstetric cases at YNHH were collected prospectively by the liability carrier (MCIC Vermont, Inc.) for the hospital and all of its employees and providers, and classified according to event year. MCIC Vermont, Inc. covers all care at YNHH, including professional liability insurance for all obstetricians and midwives. For the purposes of this study, only formal claims and suits filed against the hospital or a hospital provider were designated as 'cases.' A case consisted of a claim or suit requesting financial compensation of the patient for alleged harm and resulting in legal involvement and/or response by the liability carrier.[5] This includes cases dropped by the plaintiff or settled with or without payment before the filing of a formal lawsuit. Events noted by the legal or medical liability teams to be at risk for legal action were not included.

Cases were categorized according to high, moderate, or low severity, as described in Table 1, by the liability carrier using the industry standard National Association of Insurance Commissioners Index.[6] Cases were also categorized according to the nature of the case/issue (eg, prenatal diagnosis, fetal monitoring, improper obstetric management, nonobstetric, and other).

Closed cases were defined as those resolved by withdrawal, court judgment, or settlement. Open cases were claims or suits filed in court but still unresolved at the time of performing the analysis. Connecticut state law (CGS § 52-584) requires that a medical malpractice lawsuit must be initiated within 2 years from the date the injury is first sustained or discovered (statute of limitations), or 3 years from the date of the act or omission causing the injury (statute of repose).[7] Thus, a malpractice claim must be initiated within 3 years of the act/omission even if the injury is not discovered until after 3 years have passed. There is no law extending the statute of limitations for injured minors. Thus, obstetric cases up to Dec. 2007 must have been filed before Jan. 2011, ensuring complete accounting for all possible cases in this study. Study completion date of Dec. 2007 was chosen to allow for the statute of repose as well as a subsequent 18-month period to allow any open cases to resolve.

Indemnity payments were identified by our liability carrier and include all compensation to claimants of plaintiffs. Payments do not include costs of investigating or defending the case or other allocated loss adjustment expenses. As events that did not lead to claims or suits were not included, dollars held in reserve for possible future actions were not included. All monetary values are

expressed in dollars and adjusted for inflation to reflect 2007 values, according to the Consumer Price Index.

There were no concurrent changes in malpractice law on caps or noneconomic damages in Connecticut during this study period. A statute requiring a 'certificate of merit' from a qualified health care provider for medical liability cases was passed in 2005 (CGS § 52-184c and 52-190a). There were no institutional changes in mediation or adverse event disclosure policies during the study period.

Analysis was performed tracking the number of liability cases per 1000 deliveries, per year. Cases were normalized per 1000 deliveries to control for any variation in volume across study years or periods. Comparisons were made for 2 5-year periods (before study inception [Jan. 1998-Dec. 2002] and after study inception [Jan. 2003-Dec. 2007]) using Student's t test, the median test, Mann-Whitney U test and χ^2 or Fisher exact test where appropriate. Poisson regression was used to analyze annual trends in numbers of claims per 1000 deliveries. In addition, analysis of differences and trends in annual liability payments was performed on closed as well as open and closed (combined) cases. For combined case payment analysis, we used the overall median liability payment for the 5 surrounding years as the estimate for each open claim, assuming each open case resulted in payment. Cases that did not result in payment were not included in payment analyses. We performed the additional analysis of combined cases because a closed claim analysis may bias results in favor of the second epoch, given that it is likely to have more open claims. When claims remained open we performed worst-case and best-case scenario analyses when estimating the numbers of claims settled without payment. Worst-case scenarios designated open cases as being settled with payment, whereas best-case scenarios designated them as settled without payment. P values $< .05$ were considered statistically significant. Analysis was performed using commercially available software (SPSS version 18.0; SPSS, Inc., Chicago IL).

TABLE 1
Severity classifications with descriptions and examples

Severity	Injury description	Example of injury
High	Death, permanent major	Maternal or neonatal death, cerebral palsy
Moderate	Permanent minor, temporary major, temporary minor	Erb's palsy, bowel perforation, preventable infection
Low	Temporary insignificant, emotional	Retained vaginal sponge, scalp laceration, improper management without physical harm

Pettker. Obstetric safety program reduces liability claims and payments. Am J Obstet Gynecol 2014.

This project was reviewed by the Chair of the Yale University Human Investigations Committee and was deemed a quality assurance activity and thus not required to undergo review by the Committee.

Results

Our unit averaged approximately 4600 deliveries annually, with no statistically significant difference between both epochs (Table 2). We identified 44 cases overall during the entire 10 year study period, with 30 of those associated with events before initiation of our safety initiative and 14 after. Twelve (12) cases resulted in no payment made, with 7 of these in the 5 years before our patient safety project and 5 cases after the initiation of our intervention (Table 3). There were 2 open claims remaining at the time of this report, both being in the second 5-year epoch.

Annual cases per 1000 deliveries decreased significantly over the study period (Poisson regression, $P < .01$; Figure 1). Compared with the rates before initiation of our program, median annual rates of cases per 1000 deliveries were significantly lower after study inception (1.31 before vs 0.64 after, $P = .02$; Table 2 and Figure 1). Distribution of cases by severity and distribution of cases by type, however, did not significantly change after inception of our patient safety program (Table 2). The number of cases resolved without payment did not significantly change, both in the closed case analysis (n = 7 [23%] vs n = 5 [42%]; $P = .27$) and in worst-case and best-case scenarios in the combined case analysis (worst-case: n = 7 [23%] vs n = 5 [35%]; $P = .48$; best-case n = 7 [23%] vs n = 7 [50%]; $P = .19$).

Closed-case analysis revealed that payments were drastically reduced after the patient safety effort, from $50.7 million to $2.2 million (Table 2). Median annual payments, per 1000 deliveries, were significantly lower in the second time period as well ($1,141,638 vs $63,470; $P < .01$); this statistically significant result held true when performing the combined (open and closed) case analysis as well (Table 2). However, annual trends towards reduced payments, both in the closed case and combined case analyses, were not statistically significant. Figure 2 represents a graphic depiction of the yearly trend for the combined case analysis; the closed case analysis does not appear different.

To determine whether the patient safety program had any impact on payments to claimants, we analyzed how payments differed across both time periods. The median monetary amount per case resulting in payment to the claimant was statistically significantly different in the combined case analysis ($632,262 vs $216,815; $P = .046$) and in the closed case analysis ($632,262 vs 81,714; $P = .03$). Furthermore, there was much less variability in payments, as reflected in a narrowing of the interquartile ranges after initiating our safety program (interquartile range before $2,996,068, vs after $270,361 [combined cases] and $267,280 [closed cases]).

Comment

This analysis demonstrates a strong association between introduction of a comprehensive obstetric patient safety

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Comparison of outcomes before and after program inception

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Deliveries; n	23,499	23,372	—
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Total cases; n	30	14	—
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Annual payments per 1000 deliveries; median (range)	$1,141,638 (264,352–4,536,653)	$63,470 (0–335,349)	< .01[b]
Combined (open + closed) case analysis (estimated)			
Total payments	$50,721,033	$2,878,937	—
Annual payments; median (range)	$632,262 (2293–15,421,842)	$216,815 (13,505–1,579,496)	.046[c]
Total payments per 1000 deliveries	$2,158,434	$123,179	—
Annual payments per 1000 deliveries; median (range)	$1,141,638 (264,352–4,536,653)	$63,925 (13,353–403,264)	.08[b]

[a] Student's *t* test; [b] Mann-Whitney U test; [c] Median test.

Pettker. Obstetric safety program reduces liability claims and payments. Am J Obstet Gynecol 2014.

initiative and a dramatic reduction in liability claims and liability payments. We have estimated a 95% reduction in direct liability payments and a savings of $48.5 million over a 5-year period. We also see a consistent pattern of statistically significant trends in reduced payments and in the variability of these payments. Furthermore, during this patient safety intervention there was a 53% reduction in liability claims and lawsuits compared with the 5 years prior. The mean number of annual cases consistently dropped over the 10-year period. We were unable to see differences in the distribution in the quality (severity and types) of the cases, which may be due to small sample sizes, though there were absolute decreases in each category.

There are several limitations to this study. It is important to note that our 2 remaining open claims are in the second study period, and this may bias the results toward showing a difference between the 2 study periods when there is not one in reality (ß-error). Increasing time from injury to case closure (the 'age of the claim') is also typically associated with a larger final payment. However, there is not an association of age of claim and whether any payment at all is made. In Connecticut, approximately 50% of malpractice claims result in payment and there is no association with the age of the claim.[8] As a result, nonpayment for either claim still open in our study would strengthen our results. We believe that our estimate for this report is fair, and that the timely reporting of these results (ie, not waiting until all cases have been finalized, which on average in Connecticut is 5 years after the date of injury) is important for the obstetrics, medicolegal, and patient safety communities.[8]

Our study is also limited by an inability to directly compare with a control group. In our case, we chose the time period before our safety initiative as a comparison. Our institution overall did not experience a statistically significant reduction in claims in nonobstetric fields (eg, surgery, emergency department, medicine, etc), when comparing the same 2 epochs ($P = .16$), suggesting that this was a change specific to our program rather than a generalized institutional phenomenon. Controls outside of our institution would be

difficult to find and/are problematic. First, there is the issue of reporting; institutions are generally very guarded with respect to reporting their liability experiences to outside entities. To put our report into context, however, the Connecticut State Insurance Commissioner has reported that from 2005-2009 the values of claims either awarded or settled actually increased.[8] Moreover, Connecticut juries awarded 2 record judgments of $38.5 million and $58.6 million for obstetrics cases in the time after implementing our program.[9] In terms of claim numbers, closed claim data from the Connecticut State Insurance Commissioner has reported that the total number of medical liability claims in Connecticut closing in 2010 (693) was only negligibly different from those closing in 2006 (714); more discrete data such as those focused on obstetric claims or those sorted by event year are not available.[8] Though not definitive proof, these data suggest that the certificate of merit statute passed in our state had little effect on numbers of claims submitted by plaintiffs. Comparisons to institutions outside of Connecticut are also limited, as other states will have different malpractice environments and few have statutes with such short conditions of repose. However, national rates of claims, as well as the severity of claims, have been reported as increasing, with obstetrics playing a key hospital risk area in this rise.[10,11]

A major strength of this paper lies in its analysis by event year, rather than policy year. Although neither method allows for strict conclusions to be made about causation, analyzing by event year allows us to make stronger temporal associations. Policy year analysis would not necessarily reflect adverse events from a particular time period, as it is a measure of claims filed in a particular year without regard to when they actually occurred. This is further enhanced by Connecticut's short statute of limitations, which makes an analysis 3 years after the final claim year possible. Thus, we are able to analyze a nearly completed dataset of actual claims and payments, rather than an experience based on reserves,[12] sentinel events, or claims during periods with open statutes of limitations.[13,14]

TABLE 3
Liability case characteristics

Cases	1998-2002	2003-2007	*P* value
Total cases	30	14	—
Cases without payment	7 (23%)	5 (42%)[a]	.27
Case severity			
High	16 (53%)	8 (57%)	.97
Moderate	9 (30%)	4 (28%)	
Low	5 (17%)	2 (14%)	
Case type			
Improper management	13 (43%)	7 (50%)	.91
Fetal heart rate monitoring	5 (17%)	2 (14%)	
Failure to diagnose	3 (10%)	2 (14%)	
Other	9 (30%)	3 (21%)	

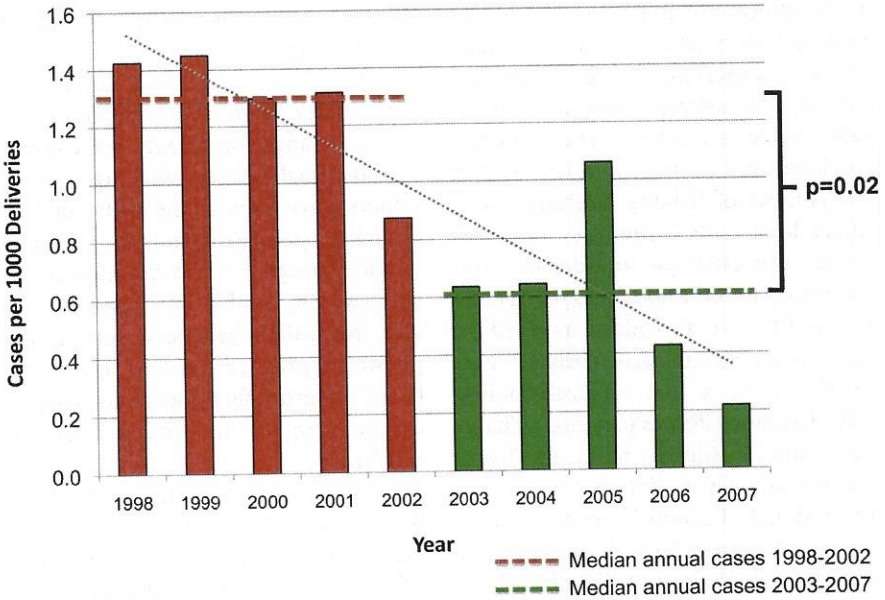
All values reported as: n (%). All comparisons made using Fisher exact test.

[a] Indicates that 2 additional cases remain open.

Pettker. Obstetric safety program reduces liability claims and payments. Am J Obstet Gynecol 2014.

Prior reports have demonstrated this program's impact on reduced adverse outcomes and improved patient safety

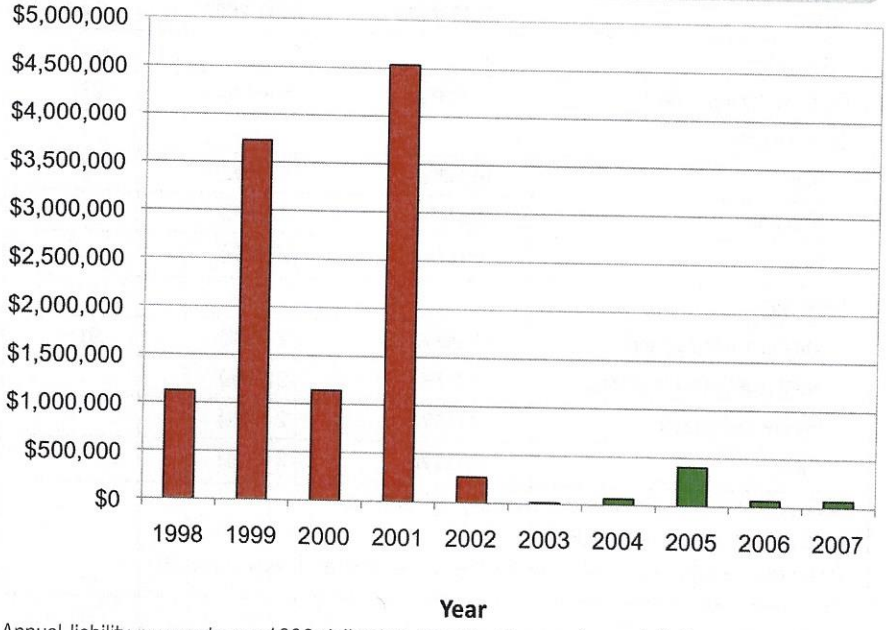
FIGURE 1
Annual cases per 1000 deliveries, classified by event year



Comparison of the two 5-year epochs demonstrates a statistically significant reduction in liability cases ($P = .02$, Mann-Whitney U test). Trend in reduction of annual cases per 1000 deliveries (*shaded line*) is also significant ($P = .01$, Poisson regression).

Pettker. Obstetric safety program reduces liability claims and payments. Am J Obstet Gynecol 2014.

FIGURE 2
Annual liability payments per 1000 deliveries



Annual liability payments per 1000 deliveries, classified by event year (inflation adjusted to 2007 dollars) (open and closed case analysis).

Pettker. Obstetric safety program reduces liability claims and payments. Am J Obstet Gynecol 2014.

culture.[1,2] The results from this analysis document a third benefit of initiating a comprehensive obstetric patient safety effort: possible cost savings. Although the primary motivations driving patient safety efforts are improving quality of care and eliminating harm, these data are also important for demonstrating further downstream impacts patient safety projects can have. The reduction in claims and payments, strictly within the context of liability concerns, saves direct legal costs, minimizes time devoted to investigation and defense, and minimizes the emotional and social costs on health care providers involved in these cases. This is particularly relevant in obstetrics, as the medical liability crisis has hit obstetrics particularly hard. The 2009 American College of Obstetricians and Gynecologists "Survey on Professional Liability" reported that 90.5% of respondents indicated they experienced at least 1 liability claim during their careers, with an average of 2.69 claims per physician.[15]

The significance of these results outside of the narrow medicolegal context should not be underestimated. A reduction in liability claims is likely a hallmark of an environment with improved quality. In fact, coupling these results with our prior report demonstrating reduced adverse outcomes suggest a direct association, as others have reported.[5] Initial resistance to such programs is common, if not ubiquitous, particularly from the viewpoint that system changes seemingly act counter to individual decision-making or skill. Others have proven the value of formalizing standardization in nonacademic settings[14,16]; the findings at our site—which combines a resident service, midwifery practices, community physician practices, and a university-based maternal-fetal medicine group—can have impact in a diverse academic institution.

Furthermore, given the striking reductions in liability payments seen one cannot ignore the economic relevance of this report, particularly in today's health care environment of accountable and value-based care. Savings in legal costs beyond direct payments to plaintiffs are likely. Legal defense costs in Connecticut average from $58,000 to $70,000 per claim, including for claims that result in no payments to claimants.[8] A study involving a random sample of 1452 closed malpractice claims from 5 insurance carriers estimates that the administrative costs of litigating claims increases the cost of these claims by an additional 54% of the compensation paid to plaintiffs.[17] It is difficult to say that projects like this will have an impact on overall health care spending, however. Some experts estimate that legal fees, payments, and insurance premiums contribute to only 0.5% of US health care costs[18]; however, the contribution may be as much as 10% when taking into account broader phenomena related to the liability atmosphere, such as defensive medicine practices.[19] Our study does not address the cost or efficiency of the services that were rendered over the study period. Although we did not specifically encourage any defensive practices during the study period, we did note that our cesarean delivery rate increased over time, in step with national trends.[1] We have no information as to whether this increase affected the risk of adverse outcomes, but we are sure that it did increase costs to patients and their insurers. Furthermore, few of these efforts can be provided at no cost, although the simplicity of many tools (such as checklists) challenges any arguments against them. Whether patient safety projects provide a net cost benefit is difficult to calculate and not known at this time. Initial costs of our program, supported by our liability carrier, are estimated at $210,000, with ongoing yearly costs of $150,000, giving a 5-year estimate of $810,000. Thus, we may estimate a substantial return on investment from the view of our medical liability carrier, on the order of 58:1.

Certainly, our effort is not the only approach to quality and safety with possible impacts on the medical liability climate in obstetrics. For instance enhanced communication skills may improve provider-patient relations after an adverse event or medical error. In fact, formal implementation of a disclosure program that also offers compensation for medical errors has shown a decrease

in claims.[20] Others have demonstrated that most payments for obstetric malpractice cases are a result of substandard care resulting in *preventable* injury, adding that over 50% of litigation costs could be avoided with practices such as 24-hour obstetric coverage, adherence to medication protocols, and improved documentation, particularly in cases of shoulder dystocia.[16] Unfortunately, we are unable to conclude which of the core elements of our patient safety project had the most impact in achieving the results reported here.

Although improving the medical liability climate has generated much discussion, little clinically based work has actually impacted this serious problem. President Obama and the Department of Health and Human Services made patient safety projects an important part of health care reform, explicitly connecting them to improving the medical liability environment.[21] A first step toward this end is for the medical profession to put effective interventions in place that reduce events that result in liability. We believe this report is an important advance toward this end and is particularly important because it impacts the point of care, rather than the political or statutory structures of the medical liability machine. However, whereas we have been able to demonstrate that patient safety efforts can have a significantly positive effect on liability exposure, we do not believe that it can happen without a broad effort to improve the general liability environment. We believe a patient safety program can be even more successful in regions that have embraced meaningful tort reform, when the threat of suit is less likely to be a principle driver of the desire to reduce harm to patients. ■

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REFERENCES

1. Pettker CM, Thung SF, Norwitz ER, et al. Impact of a comprehensive patient safety strategy on obstetric adverse events. Am J Obstet Gynecol 2009;200:492.e1-8.

2. Pettker CM, Thung SF, Raab CA, et al. A comprehensive obstetrics patient safety program improves safety climate and culture. Am J Obstet Gynecol 2011;204:216.e1-6.

3. Will SB, Hennicke KP, Jacobs LS, O'Neill LM, Raab CA. The perinatal patient safety nurse: a new role to promote safe care for mothers and babies. J Obstet Gynecol Neonatal Nurs 2006;35:417-23.

4. Sexton JB, Helmreich RL, Neilands TB, et al. The safety attitudes questionnaire: psychometric properties, benchmarking data, and emerging research. BMC Health Serv Res 2006;6:44.

5. Greenberg MD, Haviland AM, Ashwood JS, Main R. Is better patient safety associated with less malpractice activity? Santa Monica: Rand Institute for Civil Justice; 2010.

6. Taragin MI, Willett LR, Wilczek AP, et al. The influence of standard of care and severity of injury on the resolution of medical malpractice claims. Ann Intern Med 1992;117:780-4.

7. Coppolo G. Medical malpractice-statute of limitations. OLR Research Report, Sept. 22, 2006. Hartford, CT: State of Connecticut General Assembly. Available at: http://www.cga.ct.gov/2006/rpt/2006-R-0583.htm. Accessed May 28, 2014.

8. Sullivan TR. Connecticut medical malpractice annual report. Hartford, CT: State of Connecticut Insurance Department; 2010.

9. Sturdevant M. In medical malpractice case, jury awards record $58.6 million. Hartford Courant. Hartford, 2011. Available at: http://articles.courant.com/2011-05-26/health/hc-medical-malpractice-20110525_1_brain-damage-cesarean-section-obstetrician. Accessed Feb. 29, 2012.

10. AON Risk Solutions and American Society for Healthcare Risk Management. 2010 hospital professional liability and physician liability benchmark analysis, 2010.

11. Hoffman J, Raman S. Malpractice risks in obstetrics. In: Ruoff G, ed. 2010 annual benchmarking report. Cambridge, MA: CRICO; 2011. Available at: http://www.rmf.harvard.edu/sitecore/content/strategies/home/products-and-services/comparative-data/~/media/files/strategies/reports/2010_annual_benchmark.pdf. Accessed Feb. 29, 2012.

12. Iverson RE Jr, Heffner LJ. Obstetric safety improvement and its reflection in reserved claims. Am J Obstet Gynecol 2011;205:398-401.

13. Grunebaum A, Chervenak F, Skupski D. Effect of a comprehensive obstetric patient safety program on compensation payments and sentinel events. Am J Obstet Gynecol 2011;204:97-105.

14. Clark SL, Belfort MA, Byrum SL, Meyers JA, Perlin JB. Improved outcomes, fewer cesarean deliveries, and reduced litigation: results of a new paradigm in patient safety. Am J Obstet Gynecol 2008;199:105.e1-7.

15. American College of Obstetricians and Gynecologists. 2009 ACOG survey on professional liability results. Available at: http://www.acog.org/about_acog/acog_departments/professional_liability/2009_survey results Accessed Feb. 29, 2012.

16. Clark SL, Belfort MA, Dildy GA, Meyers JA. Reducing obstetric litigation through alterations in practice patterns. Obstet Gynecol 2008;112:1279-83.

17. Studdert DM, Mello MM, Gawande AA, et al. Claims, errors, and compensation payments in medical malpractice litigation. N Engl J Med 2006;354:2024-33.

18. Baker T. The medical malpractice myth. Chicago: University of Chicago Press; 2005.

19. PricewaterhouseCoopers LLP. The price of excess: identifying waste in healthcare spending, 2008. Available at: http://www.pwc.com/us/en/healthcare/publications/the-price-of-excess.jhtml. Accessed Feb. 29, 2012.

20. Kachalia A, Kaufman SR, Boothman R, et al. Liability claims and costs before and after implementation of a medical error disclosure program. Ann Intern Med 2010;153:213-21.

21. White House Office of the Press Secretary. Fact sheet: patient safety and medical liability reform demonstration, 2009. Available at http://www.whitehouse.gov/the-press-office/fact-sheet-patient-safety-and-medical-liability-reform-demonstration. Accessed Feb. 29, 2012.

Date: March 5, 2020

Testimony of Michele Stevener, mother of a child with a birth injury
Fairfax, Virginia
Before the Senate Finance Committee

Senate Bill 879
Position: Opposed

Madam Chair Kelley and members of the Senate Finance Committee, my name is Michele Stevener and I am a mother opposed to Senate Bill 879. I very much appreciate the opportunity to share why I am opposed to this bill, as a mother of a daughter with a birth-related brain injury. I have direct experience with a state birth injury fund, the Virginia Birth-Related Neurological Injury Compensation Program, and here is our story.

My daughter, Caroline, was born on Christmas Day in 1998. Both of us almost died that night. I was thrilled to be expecting a daughter and dreamed about so many adventures we would have one day. I had a healthy pregnancy and I delivered her full term, just ten days before my due date. I didn't know at the time that you shouldn't have a child on a holiday. The physician checked on me early in the day, saw that I was fully dilated, then disappeared until just before I delivered – but the damage was already done. The nurse, who had only been in labor and delivery for two months, was not monitoring my daughter nor me close enough. She just didn't know enough about fetal monitoring. When my baby arrived, she was a dark blue color and had no tone. She was virtually dead and had to be intubated. I remember asking why she wasn't crying. They did what they could, but Caroline was left with severe and permanent brain damage. Our lives were forever changed.

The fetal monitoring strip from my daughter's delivery was only provided by the hospital after required by a subpoena. It was clear that my daughter went into distress shortly after 5 pm and remained in distress until her delivery at 5:50. No one did anything to help her. She experienced a lack of oxygen during birth, and would have been born healthy if not for the lack of medical care during a dangerous labor and delivery. The theory is that I had a terminal placental abruption – which explained Caroline's lack of oxygen, my blood in her lungs, and my near fatal hemorrhage. From that day on, I had to focus on keeping my daughter alive.

We weren't aware of the extent of Caroline's brain injury until July 1999. It was a full year from her birth that I actually heard about a birth injury fund in Virginia. I didn't realize that, in the Commonwealth of Virginia, if there is a birth-related neurological injury so severe that the baby meets the statute's eligibility, it must be treated as a bureaucratic inconvenience due to a law passed ten years before Caroline was born. Virginia calls it a no-fault program, and it's supposed to pay for medical care and other expenses for the children who are admitted to the program.

But the fund doesn't work as intended. They made it very difficult for me to get the best care for my daughter.

They reneged on critical benefits that were in place as of my daughter's birth, but denied because of a perceived lack of funding after they forgave assessments for years from the physicians and hospital. The fund only protects hospitals, and by my daughter qualifying to be in the fund, I was not allowed to seek

litigation on Caroline's or my behalf. My separate right of action was also abrogated in favor of this exclusive remedy.

Interpretation of the covered benefits is subject to a conflicted board of directors, represented by the interests who pay into the fund. For example, if I were to take Caroline to an out-of-network physician, I would have to seek approval first or the program would not pay for the difference in in-network costs.

When my daughter needed care that the fund said was outside of its limited coverage, I would have to appeal the decision, and this usually went on for months. But the fund was managed by a board of directors that would only meet once a month, sometimes canceling their meetings for a month, meaning board decisions for Caroline's care threatened our ability to keep her healthy. And, then when I lost to the board of directors, I had to face the Attorney General's office.....alone.

Then, there is the issue that the fund wants to pay for 2019 expenses with 1987 dollars. The Virginia program only covers expenses at the rate that was originally decided when it passed into law in 1987. Therefore, when I needed to pay for insurance for a van to take my daughter to doctor appointments, I had to pay almost half of it out-of-pocket. My complaints fell on deaf ears. And, even though the state requires backup cameras in vehicles such as her van, since it wasn't in the approved expenses list within the fund, my family had to pay for this safety feature.

My daughter's life was complicated, but I never expected that I wouldn't be able to provide her with the best care possible due to a bureaucratic, self-serving fund that was supposed to help children like her. It added injury to a catastrophic injury. The program has one clear goal: protect the hospital's and doctor's money, at the expense of these children.

Senate bill 879 in Maryland would take away the rights of parents just like me and hide hospitals and physicians from being held accountable. I am told by many experts that most, if not all, of these catastrophic injuries are avoidable based on the warning signs during labor or delivery. If hospitals – the very institutions we trust to keep our children healthy – continue to put profit over lives and bills like this one pass, more families will face a heartless system like I did. Hospitals should be focused on fixing their problems, not removing themselves from being at fault and forcing others to pay for the harm inflicted during their oversight in giving quality medical care.

Tragically, my Caroline passed away last October. She aspirated on her formula, went into septic shock and died in my arms a couple of days later. Another expense that is approved with 1980's prices is the funeral costs. We'll have the funeral later, once I can afford the costs myself for a proper send off for my daughter.

Advocating for my daughter involved a fight against the program, its board of directors, the attorney general's office and the medical lobby. While Caroline battled for life, I was battling with people who didn't know a thing about her needs. It pains me to think more families would experience this if this bill in Maryland turns into law.

I recommend that members of the committee oppose the bill. Caroline was among Virginia's youngest and most defenseless victims, and was among Virginia's most disabled citizens. Do not throw out a child's constitutional rights to a jury trial, due process or equal protection, just to mention a few, in favor of such a program. Do not make the same mistake as your neighboring state.

Reducing Malpractice Injuries And Deaths Should Be Highest Priority

By Robert E. Oshel, Ph.D

The real problem with medical malpractice in Maryland is with the amount of malpractice itself, not with too much money being paid out in damages to the most harmed victims. A birth-injury fund or other changes making it more difficult for victims to hold physicians and health care providers accountable won't reduce malpractice. The Maryland legislature should take action to reduce medical malpractice itself, not the amount of compensation paid to victims.

Following retirement from my position as Associate Director for Research and Disputes for the Division of the Practitioner Data Bank at the U.S. Department of Health and Human Services, I have often worked with Public Use Data File version of National Practitioner Data Bank (NPDB), the federal database that receives information about all malpractice payments for physicians and other practitioners. The NPDB also maintains records on all disciplinary actions taken by the state licensing boards for physicians and other providers, as well as records of disciplinary actions taken by hospitals and other facilities against practitioners. Before I retired, I designed the Public Use Data File for research use. It contains information from all NPDB reports but does not identify the reported practitioners.

In Maryland, my analysis of the Public Use Data File shows that over a 20-year period, only 1.68 percent of the state's physicians were responsible for half of all the money paid out for medical malpractice. Most of these physicians had multiple malpractice payments. If action were taken to restrict or retrain this very small proportion of Maryland physicians, Maryland malpractice payments could be substantially reduced, perhaps even cut in half.

Yet, action was rarely taken against this 1.68 percent of Maryland physicians causing half of the problem. Only 12 percent of them had ever had any reportable action -- not even a slap on the wrist reprimand -- taken against their license by the Maryland Board of Physicians. Only about 4 percent of them had ever had any reportable action taken against their clinical privileges by a Maryland hospital or other health care facility.

Obviously, something is wrong when only about 1/8 of the few physicians with the very worst malpractice records, responsible for half of malpractice dollars paid out, have had any action taken against their licenses and when only about 1/25 of them have had any reportable action taken against their clinical privileges.

There has been much debate recently over the specific issues related to medical malpractice in obstetrics and injuries to infants at birth leading to the proposal to create a birth-injury fund, this year called the Maryland Infant Lifetime Care Trust. While hospitals and physicians claim there is a crisis, over the 10-year period from 2010 through 2019 there were 119 obstetrics-related Maryland malpractice payments for physicians (including settlements and judgments). 103 physicians were responsible for these payments; 89 physicians had only one obstetrics-related payment; 12 had two obstetrics payments; and one physician was responsible for three obstetrics-related payments. The number of obstetrics judgment payments is so small, it would be impossible to say there is any trend either in numbers or payment amounts.

In fact, there were no obstetrics judgments against physicians resulting in payments in 2011, 2013, 2017, 2018, or 2019. There may have been obstetrics judgements rendered against physicians in those years, but they did not result in the judgment-ordered payment and presumably were negotiated down in subsequent settlement discussions or are still being negotiated or appealed with no payment yet made as of the last data of 2019.

It is also possible that there were judgments or settlements against hospitals which did not name physicians or other licensed practitioners and therefore were not reported. This should be rare since hospitals are required to report to the NPDB if a practitioner had any responsibility for the malpractice. It is unethical and potentially illegal for hospitals to require a plaintiff to remove named individuals from a suit, thereby protecting them from being reported, in order to negotiate a settlement.

The number of physician malpractice payments each year in Maryland varies, but has tended downward since 2010 and the fewest number of payments were reported in 2018 and 2019. It is also worth noting that 2018 and 2019 were also the years with the lowest total payments, with total payments of between $60,000,000 and $70,000,000. All the years except 2014 had totals under $100,000,000.

Based on my analysis of the data, I see no evidence of a medical malpractice "crisis" in Maryland for obstetrics or otherwise, as has been claimed. If recent data is indicative, there have been a downward trend in malpractice payments and lower total cost of payments in recent years.

If hospitals and others want to reduce malpractice payments, it would seem that a much more effective strategy would be to ensure the Maryland Board of Physicians has all the resources and legal authority it needs and to require the Board to take action when confronted with physicians who repeatedly have malpractice claims brought against them, especially if payments result. Maryland hospitals should also strongly be encouraged to ensure that peer reviewers take needed actions.

Malpractice isn't a chance or random event. Most physicians never have a malpractice payment. Having even one payment is unusual. The majority of Maryland physicians with obstetrics-related malpractice payments over the last 10 years had at least 2 malpractice payments, including non-obstetrics payments. One had as many as nine payments, most of which were non-obstetrics-related – but no actions against his license or clinical privileges. Only eight physicians in Maryland have worse malpractice records, yet no action has been taken against his license or clinical privileges. The licensing board and peer reviewers need to take action to protect the public from physicians with extremely bad malpractice records.

There are two ways to reduce malpractice payments – reduce malpractice injuries and deaths or cut compensation payments when people are injured or killed. The former is obviously the better solution. Policymakers should act to reduce malpractice-related injury and death rather than simply to cut compensation to injured patients. Reducing injury and death is a lot more important than saving money for malpractice insurance companies and their premium paying physicians and hospitals at the expense of not fully compensating injured victims for their injury.

Robert Oshel, Ph.D, retired as the Associate Director for Research and Disputes for the Division of the Practitioner Data Bank at the U.S. Department of Health and Human Services in 2008. While at HHS he designed the NPDB's Public Use Data File for research use. He can be reached at robert.oshel@gmail.com.

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PLEASE REPLY TO:
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March 2, 2020

Testimony of Michael W. Kessler in Opposition to the Enactment of **SB 879** to the Senate Finance Committee on Thursday, March 5, 2020

EXECUTIVE SUMMARY

- Because the Fund only applies to cases where liability and damages have already been *proven*, it has nothing to do with eliminating "frivolous" or unmeritorious claims.
- The Fund fails to provide for the care that has been proven in court to be required by birth injured children, and creates a bureaucratic quagmire for parents to try to get necessary care and services.
- The New York Fund has current *unfunded* liabilities of almost one billion dollars, and more than two billion dollars over the next eight years, with unfunded liabilities increasing by more than two hundred million dollars *per year* for the next ten years after that.
- There are serious constitutional and other questions of law about the legality of the Fund.

INTRODUCTION

My name is Michael Kessler and I am an attorney in New York State. It is my understanding that you are considering legislation modeled after the New York Medical Indemnity Fund (hereinafter the "Fund") created in 2011. The Fund legislation prohibits children who were injured by *proven* malpractice to recover costs of their care that was also proven and established in court, so that they and their families can make their own critical health care decisions under the guidance of their own physicians.

I am familiar with the proposed legislation before your committee and this legislative body. I have represented a number of the families of birth injured children in the New York Medical Indemnity Fund. In addition, because I have written extensively about the Fund,[1] dozens of families with children in the Fund have reached out to me for assistance in getting care that they require and were promised. Universally they describe the devastating impact that the New York Fund has had on the care provided to their children, and the quality of their lives. As someone who has significant knowledge of the New York Fund, its legal infirmities, how it works in practice, its extraordinarily high

[1] Some of my writings on the New York Medical Indemnity Fund are attached to this submission. It is respectfully hoped that you will consider these materials in deciding whether to enact the very unfair, harmful, and costly proposal before you.

cost, and, most importantly, its harmful impact on the care that the children in the Fund actually receive, I have been asked to share that information with you as you consider this bill.

I am not a member of the Maryland Bar and have no cases pending in this state. However, when I learned that Maryland was considering legislation based on the New York Medical Indemnity Fund [Birth Injury Fund], I felt compelled to travel to Annapolis on my own time and at my own expense in order to help legislators better understand how harmful this legislative scheme has been to the families of catastrophically injured children in New York. I hope that you will not choose to follow the same tragic path taken in New York.

I understand that my time to speak to you is quite limited, so I have prepared these more complete written comments to supplement and give greater context to my testimony. I respectfully hope that you will make them part of the legislative record and consider these thoughts as you decide whether to follow the disastrous humanitarian and fiscal path that was undertaken in New York.

I know that others will speak to issues unique to Maryland, so I will limit my written comments to four key observations about the New York Fund, since our experience there serves as a warning about what will occur in Maryland should the proposed Legislation be enacted: (1) What does the Fund do, and how does it differ from other compensation schemes?; (2) What is the impact of the Fund on the rationing of care to these seriously disabled children?; (3) What effect the enormous insolvency of the Fund will have on those dependent on it for care, as well as on the taxpayers of New York?; and (4): What other fundamental legal issues are raised by the creation of the Fund?

1. What Does the Fund Do and How Does it Differ from Other Compensation Schemes?

It is critical to understand what the New York Fund model does, and how it changes the right to choose and pay for the extensive care that these catastrophically injured children need. It is equally important to understand what the Fund does *not* even purport to do.

There should be no misunderstanding: The Fund has absolutely nothing to do with practice weeding out "frivolous" or unmeritorious lawsuits. To the contrary, it *only* applies to those cases where the aggrieved family has *already proven* malpractice, the severity of the injury, and the need and cost of future care.[2] What the Fund does, however, is take those proven needs, and, at best, arbitrarily reduce the ability of families to choose and pay for care for these children. At its worst, it denies them much, if not all of the extensive care that they so critically need.

Under the Fund, the family of a catastrophically injured child has to hire a lawyer and go through all the steps, expense, and years of delay, to prove the malpractice that

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[2] It also applies to settlements, which by definition are only in situations where the health care providers agree to settle *because* they are concerned that they will be found negligent and will be ordered by a Court to pay even more after a trial.

caused their child's injury, and, among other things the nature and cost of their catastrophically injured child's future care needs. These include medical services and, more importantly, the cost of nursing or care aides when the child's parents or caregivers are unable to take care of the child, therapists, and special equipment.

After hearing all of the facts from both sides, the Court makes a determination, based on the evidence, as to the types and costs of care required, and how long it will be needed. Even then, this finding, based on evidence from expert physicians and rehabilitation specialists, is subject to reduction on appeal.

The system prior to the Fund, though perhaps not without flaws, was pretty fair in determining the nature and cost of the future care. It assured that the care necessary to maximize the brain injured child's quality of life was available, would be paid for, and, as described, there were, and are, numerous safeguards in place to protect the negligent doctor or hospital from "overpaying."

Under the Fund, however, the child's family still has to go through all of the steps described above. But now, instead of requiring the wrongdoer who caused the harm (or its insurance carrier) to pay the *actual* cost of providing care, the obligation to pay for future care is transferred to the Fund, and the *proven* wrongdoer's insurance carrier pays *nothing* for these expensive care costs.

If all that would occur when the law in New York changed, was to transfer the cost of needed future care to the Fund, there might have been no harm done to the child. But that's not what actually happened. Even though the cost of care and the need for it has already been established in Court, now the child and his family have to apply (beg) the Fund *to pay for the care that has already been determined by a physician to be medically necessary, vetted and determined by the Court to be essential.* As a result, a bureaucrat, who is not medically trained, without access to the expert testimony, and without the safeguards inherent in the fact-finding role of the Court, will now decide anew whether the previously determined essential care will be provided.

If the needed care is not approved by the Fund, the family has to go through another round of administrative hearings, in the hope of getting the care that they need *and which the Court already said was appropriate!* If the family's request for care is still denied, the family will be required to embark on yet another trip to Court to get what they have already previously established that their child needs.[3] There are, therefore, only two possibilities: (1) the child and his family gets exactly the same care as they would if the judgment was paid as required (in which case there is no cost saving to anyone -- plus the extra cost of administering the Fund); or (2) the child's care will be rationed and reduced by the Fund, which is exactly what is occurring in New York.

The Fund has taken health care decisions and the means to pay for them out of the hands of Courts, families, and their doctors -- even after they were proven and accepted by a Court -- and then places these critical life-altering decisions at the whim of a Fund bureaucrat who, because there are inadequate resources available to pay anticipated

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[3] *See* e.g. *Matter of Anson v. Zucker*, 162 A.D.3d 1179 (3d Dept. 2018) as an example of what families in New York must go through to get the care they need. This issue is discussed in more detail below.

claims, has every motivation to deny or reduce payments and services. Sadly, it is inevitable that children will suffer and even die because of this legislation.[4]

It should be noted that, unlike Maryland, New York State has no cap on non-economic damages. As a result, New York families are often compelled to use the money they have received for non-economic damages to pay for the *care* that their catastrophically injured child needs which should be paid by the Fund. This occurs because the Fund is unwilling to pay for the needed care that has already been proven in Court. Given the existence of the non-economic damage cap in Maryland, there will be insufficient funds to do even this, and the child will inevitably not receive the care required.

2. How Does the Fund Ration Care and Treat These Catastrophically Injured Children and their Families.

Because, as discussed in detail below, it is financially impossible to create adequate reserves to pay the benefits required (and actually judicially determined), there is no alternative but to deprive children of the care, services and equipment that they were found to require. [5]

Many, if not most of the children who sustained hypoxic brain injury at birth are severely neurologically impaired. Often, they are quadriplegic and require lifetime round-the-clock care, many times by highly skilled health professionals. Even with lesser impairments they usually require significant medical interventions and monitoring, physical, occupational, speech, aquatic, and other therapies, medications, specialized equipment, home modifications to accommodate wheel chairs, handicapped accessible vans, specialized transportation, and electronic equipment to communicate, among other things. The cost of caring for these severely impaired children routinely exceeds several hundred thousand dollars a year, and can be more than one million dollars per year.[6]

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[4] *See* e.g. Charlene Harrington et al., "Nursing Staff Levels and Medicaid Reimbursement Rates in Nursing Facilities, 42 HEALTH SERVICES RES. 1105, 1106–07 (2007). See Joanna Bisgaier & Karin V. Rhodes, Auditing Access to Specialty Care for Children with Public Insurance, 364 NEW ENG. J. MED. 2324, 2325, 2328 (2011) (describing a study which measures the impact of Medicaid coverage on the availability of medical specialty care). Danny Hakim & Russ Buettner, In State Care, 1,200 Deaths and Few Answers, N.Y. TIMES, Nov. 5, 2011, at A1, available at http://www.nytimes.com/2011/11/06/nyregion/at-statehomes-simple-tasks-and-fatal-results.html (describing a case of an individual drowning, because of an allegedly low staffing level due to inadequate funding).

[5] Indeed, if adequate reserves for the projected care cost liabilities were provided, there would be no savings at all.

[6] Already, in its short existence, the New York Fund has almost 50 enrollees who have been paid more than one million dollars in costs each. There are a number of enrollees whose *annual* cost is well into the hundreds of thousands of dollars, and, after a lengthy legal battle, one recipient is costing more than one million dollars *per year*. Since these costs are largely for required nursing care, the Fund's actuaries project that these costs will continue and increase in the future. As a result, as discussed below, the New York Fund will have more than two million dollars in unfunded liabilities over the next eight years. *Report to the New York New York Department of Financial Services, New York State Medical Indemnity Fund, 2nd Quarter 2019 Actuarial Analysis*, Pinnacle Actuarial Resources, August 2019. Excerpts of the report are attached, and the report can be found at: (https://www.dfs.ny.gov/system/files/documents/2019/09/mif_2nd_qtr_2019_report.pdf).

However, despite their proven care needs, many of the New York Fund's children receive no benefits whatsoever.[7]

I have dealt with a number of families who have been forced by law into the Fund instead of being able to collect their lawfully determined damages from the insurance carrier of the person who caused the harm. Without exception, and without prompting, every one of these parents uses the same word to describe their experience in trying to get the necessary services from the Fund: "*It's a nightmare*!"

One mother, whose experience is described below, told me that she devoted approximately 20 hours every week just battling with the Fund for services, and, although she eventually got some of what was needed, she had to use the portion of the child's own recovery for "pain and suffering" to pay for the medical services for which the Fund refused to pay. As noted above, this will not be an option for Maryland families given their statutorily limited recovery for "pain and suffering" damage.

The following is part of what this same mother wrote to the Ways and Means Committee Chair of the New York State Assembly last year. She understood firsthand how poorly the Fund had been treating her son and the families of other children forced into it. She was trying to do something about it. Make no mistake, if you choose to pass this ill-conceived and poorly thought out legislation in Maryland, you *will* hear from families who are denied needed care that they already won in Court and which they desperately need.

> "MIF [New York Medical Indemnity Fund] families have to constantly fight for every single item. Currently without an advocate, we juggle 24-hour caregiving with appeals and endless phone calls to claims. One Hundred percent (100%) of the time hiring a lawyer would cost more than the item we are fighting for.
>
> On June 14, 2017, the NYS Senate Health Committee held a Round Table for parents, attorneys and providers. I testified that fighting the MIF became a part time job. I am unusual MIF parent as I practiced law for a short time and know how to interpret government regulations. **Even with my background, I struggled.** Towards the end our construction appeal I had to hire a lawyer. I acted pro se for three years...How many other parents are also struggling, taking their children to the hospital, working full time, and spending any energy they have left fighting the MIF.
>
> **The MIF: A History of Abuse of Power**
>
> In the spring of 2016 during my request for environmental modification, the MIF **ordered** the independent evaluator, Accessible Options to **recommend nothing.** I got a call from the evaluator crying, as she did not

[7] Indeed, the Fund's actuaries highlight this point. However, recall that these were *all* children who were determined by a Court to have significant future care needs. The fact that many of these children are getting no services at all from the Fund, further underscores the hurdles that the New York Fund imposes on obtaining services.

know what to do. I immediately filed a complaint with the Inspector General against the MIF administrator as this action was inappropriate.

...[T]he administrative judge awarded us 60% of our requested construction items. However, MIF refused to act and I was advised the only way to enforce the order was to file an Article 78 proceeding. It was at this point that the cost of the litigation in the NYS Supreme Court system would cost more than the construction....

One of the benefits the MIF was looking to get rid of in the proposed regulations was recreational and therapeutic assistive technology. Since their attempt to amend the regulations failed, their current practice is to just outright deny items with no reasonable explanation....

Since Luke was enrolled in the MIF in 2014, I had to fight for glasses, a handicapped rental van, dental bills, OTC laxatives, a wheelchair ramp, environmental modifications and most recently assistive technology." (Emphasis in original letter from Heidi Skau attached)

This is just one of dozens of similar experiences of families in the Fund. Many of them are forced to just give up and try to pay for services themselves. If they can't afford it, which is usually the case, the child must go without necessary services. As Ms. Skau notes in her letter, fighting with the Fund to get required care is an ongoing and time-consuming struggle, and "[o]ne Hundred percent (100%) of the time hiring a lawyer would cost more than the item we are fighting for."

Here are a few more examples of what these parents go through, many times to get even the most minimal care for children in the Fund:[8]

In the *Anson* case cited above, the child required a mechanical lift from his wheelchair to a pool for aquatic therapy. Both the therapy and the lift were ordered by his physician as medically necessary for continued home care, and the Fund conceded its medical necessity. Nevertheless, the Fund denied the lift, claiming that it "did not constitute a qualifying healthcare cost," and continued to deny it during an administrative appeal. The Fund arbitrarily determined instead that the child would have to go to a public pool a twenty minute drive away (which was only open one day a week). This public pool also lacked a lift and would have required two adults to be present to lift the child in and out of it. The family was forced to go to Court and, after three years of litigation -- and the legal costs associated therewith -- the Court ordered approval of the lift. The actions of the Fund demonstrate that, in practice, the Fund inevitably tries to unjustifiably ration care in the hope that families will simply give up.

A fifteen-year-old client of mine with a hypoxic brain injury, is functioning at the level of a five-year-old. He cannot be left unsupervised. Yet, the Fund refused payment for fencing and a security gate so that he could be allowed to safely be outside in his yard without an adult being present at all times to prevent him from wandering into the street.

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[8] Attached are comments to proposed New York Fund Regulations that I prepared on behalf of the New York Academy of Trial Lawyers and which describe in more detail both the roadblocks which the Fund imposes to getting services and the experiences of families trying to navigate them.

Many children with these disabilities are quite temperature sensitive, and require a constant environment within limited temperature ranges and oftentimes air filtration. For them, air conditioning is not a luxury but a medical necessity, and having it in a home helps prevent the need for institutionalization. Despite this, the New York Fund simply refused to pay for it because other family members may receive a collateral benefit. Similarly, many of the Fund children require constant access to electrically powered medical appliances, in some cases as a matter of life and death. Yet, one family whom I know was denied a backup generator to power life-critical equipment.

Another family who contacted me had a home with a small garage which would only fit a compact car. It would not fit a handicapped van, which the family required for their child's wheelchair. The Fund denied their request to increase the size of the garage to accommodate the van. Lacking the resources to make this basic logical and necessary accommodation, the family is required to stand outside to get the child and his wheelchair out of the van in the cold, rain, and snow. This unnecessarily exposes an already fragile child to the elements, and is dangerous. Similarly, another family was denied approval for a slight change to the grade of a driveway which, because of the length and configuration of the wheel chair van, was damaging its undercarriage and lift mechanism.

Yet another family was denied a wheelchair accessible path to enable access to the backyard, resulting in the child being stuck inside when at home. A recent decision by the Fund approved by the New York Commissioner of Health denied yard modifications necessary for wheelchair access, simply because they were outside.

The above examples are not merely anecdotal, but sadly are the norm of the life of a family who must rely upon the Fund for the care their child needs. Even when services are approved, the paperwork that the family is required to fill out to get them is overwhelming. Compounding matters further is that the rates of reimbursement make it impossible to find providers.

Providing care to a quadriplegic child is a twenty-four hour a day, seven day a week job. The level of burnout and stress on these families is enormous. The New York Fund arbitrarily restricts respite care to twenty hours a week, regardless of the child's actual needs. This adds to the difficulty of a parent's ability to be employed and imposes additional economic hardship on these families. Implicit in these care-rationing restrictions is the unfounded assumption that families alone have the unpaid responsibility to provide full time care, even to adult enrollees. As such, the child's primary caregiver is precluded from becoming employed to support themselves and their family. In addition, family members, including grandparents, aunts, and uncles -- the people, other than parents, who are most familiar with taking care of the disabled child's needs -- cannot be reimbursed for the time that they provide respite care for the child. Instead, the caregiver must find a stranger, with limited knowledge of caring for the child, who is available – often on short notice – and is willing to undertake this responsibility at the discounted reimbursement rate established by the Fund. Not even Medicaid imposes this restriction on close relatives providing paid respite services. Thus, not only are the number of hours of care limited by the Fund, but, because the reimbursement rates are so low, any caregiver which the family could find at those rates would unlikely have sufficient qualifications to safely care for the child.

Even to apply for equipment, modifications, or services, families must navigate a Byzantine process of contractors, estimates, physicians, and agencies. Many parents have told me that this process requires significant personal out-of-pocket expense. In addition, as Ms. Skau notes, it becomes essentially a job in itself. This is superimposed on the twenty-four hour care that the parents are providing. This extra time precludes them from attempting to supplement family income by being employed in any capacity.

One family who contacted me incurred the expense of a hiring a rehabilitation professional to prepare a detailed fifty-page report supporting their application for home modifications. Nevertheless, despite extensive documentation and proof of medical necessity, the Fund rejected the majority of the needed modifications.

These examples are hardly unique, but rather a consistent fact of life in dealing with the New York Fund. It is undeniable that in most instances the New York Fund is not providing the level of care, therapies, and equipment that these children had *proven* to require in Court, which, absent being forced into the Fund, they would have recovered from the malpractice insurance carrier of the wrongdoer who was *proven* to have caused their injury. Nor has the New York Fund even provided the care and services which its own enabling legislation and regulations require. Part of the reason for this is the nature of the Fund's bureaucracy. More critically, because the Fund is grossly under-reserved to pay for either the promised or necessary care, it has no choice but to dramatically ration and limit care, which is exactly what they have done.

3. The New York Fund Model is Actuarially Unsound, Grossly Underfunded, and Unsustainably Insolvent.

The New York Medical Indemnity Fund [Birth Injury Fund], and any legislation based on this model is structurally unsound, and destined to create massive and increasing unfunded liabilities both currently and over the next thirty years or more. The New York Fund is required to provide regular actuarial reports of its financial status. Excerpts of their most recent public report are attached hereto.[9]

Similar to what is proposed in Maryland, the New York Fund is supported by an increased tax on obstetric hospital services. This tax doesn't come close to funding either the financial obligations undertaken or the promises of future care made to children whose recoveries for such care were taken away from them by their legislators when the Fund was established. Even using the most wildly optimistic projections of payments, usage, medical cost inflation, and life expectancy, the New York Fund, after less than eight full years of existence, has currently amassed *unfunded* liabilities for future care of close to one billion-dollars discounted to present value. That means even under the best-case scenario, as of this moment, the New York Fund is obligated to pay one billion dollars more in in current benefits than it has the money to pay for. In undiscounted dollars, the *current unfunded* liabilities of the Fund are more than two billion dollars.

As bad as that is, the Fund is a ticking fiscal time bomb. This is because the number children in the Fund will continue to increase for the next twenty years. Thus, the

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[9] https://www.dfs.ny.gov/system/files/documents/2019/09/mif_2nd_qtr_2019_report.pdf

unfunded liabilities alone–not the amounts to be paid, but the portion of the payments which are *unfunded*– is currently *increasing by than one hundred million dollars per year* in dollars discounted to present value. This deficit accelerates to increase by more than two hundred million dollars *per year of unfunded* liabilities over the next eight years. By 2028, the discounted *unfunded* liabilities will be $2.2 billion ($5.7 billion undiscounted) and will more than double again over the following ten years.[10]

Tragically, all of this was foreseeable at the time of the Fund's passage to anyone who was willing to actually think through the details and mechanism of how the Fund would be funded and operate. The New York legislature ignored the warnings that this insolvency would inevitably occur. Time has proven that predictions made at the time of its enactment regarding the Fund's inevitable insolvency and its inequitable and unjustified rationing of care to the children it was intended to provide for and protect, were true.[11]

The Fund is operated as a giant Ponzi scheme -- paying out current claims with the dollars it has on hand. Operating as it does, the Fund has no ability to reserve money for the future claims of its current recipients, let alone be able to fund the future obligations of the new, additional children who are forced into it each year. Sadly, this process will not start to level out for thirty years or more.[12]

There is a reason why states do not allow insurance companies to operate with unreserved commitments of billions of dollars.[13] Establishing a Fund for future care that does not have the means to fund its future obligations creates the inevitable need for taxpayer bailout and inequitable and unjustified rationing of care. Yet, that is exactly what is occurring in the New York Fund, and will inevitably occur in any other state that adopts this model. Sadly, there cannot, and will not, be a happy ending to this situation. It will inevitably result in more and more rationing of care, accompanied by eventual complete insolvency and abandonment or an enormous multi-billion dollar state bailout. The New York Fund is in a financial death spiral and will inevitably cease within the foreseeable future without a massive influx of funding. In the meantime, care will continue to be reduced, and eventually the children who are relying on it will be left without the services that they require and were promised.

4. Legal Infirmities of the Fund

It is beyond the scope of these comments to address all the legal and constitutional issues presented by the New York Medical Indemnity Fund, almost all of

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[10] Despite these critical and growing unfunded liabilities, and the fact that New York is receiving the proceeds from the new tax intended to finance the Fund, the New York Governor's 2020 budget makes *zero* appropriation for the Fund, instead pocketing the tax, and further undermining the Fund's insolvency.

[11] *See,* e.g., Kessler and Fahrenkopf, *The New York State Medical Indemnity Fund: Rewarding Tortfeasors Who Cause Birth Injuries by Rationing Care to Their Victims*; 22 Albany Law Journal of Science and Technology 173; http://www.albanylawjournal.org/Documents/Articles/22.2.173-Kessler-Fahrenkopf.pdf

[12] See Department of Financial Services Actuarial Report cited above.

[13] Even with their most optimistic actuarial assumptions, in order to make the Fund fiscally solvent, it would have to place in reserve the present value of all of the future care for each enrollee at the time of enrollment. Since this is at least the same amount as the Court had determined was necessary to provide care, there would be no cost savings under any actuarially stable Fund structure.

which remain unresolved. However, many of these constitutional issues will also be applicable to the proposed Maryland legislation. I am respectfully attaching for your consideration, my law review article which, in part, discusses these issues in more detail.[14] Some, but certainly not all of the Constitutional issues include

(a) Separation of Powers: The Fund interferes with the inherent judicial authority to enter judgment that conforms to the facts of the case as determined by the jury and accepted by the Court. Similarly, the Fund interferes with the Court's inherent judicial power to protect infant's rights and approve settlements in an infant's best interests.

(b) Jury Trial: The Fund infringes on the right of a party to have a jury determine his economic damages including care needs, and to enforce its findings under a judgment.

(c) Due Process: The Fund is an uncompensated taking of a property right to recover the cost of care and, at that, is not for a public purpose, but rather to relieve a private defendant from paying a private judgment.

(d) Equal Protection: The "Fund" improperly discriminates between the victims of obstetric malpractice and other victims of malpractice and other negligence.

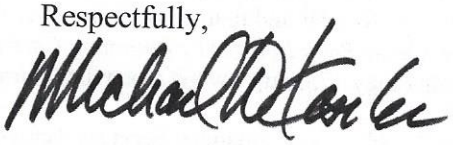
CONCLUSION

After representing dozens of parents of catastrophically impaired children, I can assure you that the last thing they think about before going to sleep each night, and the first thing that they think about each morning, is "how is my child going to be cared for, when I no longer can do so." Prior to the adoption of the Fund in New York, parents were able to rest a bit easier at night, knowing that the resources that they had proved their child needs would continue to be available to their child as long as needed. The adoption of the Fund in New York has robbed parents of that peace of mind, and turned the process of obtaining the care that their children require into an ongoing struggle.

The Hippocratic Oath mandates that the first obligation of a physician is to "do no harm." The creation of a Fund under the New York model does untoward harm to the most vulnerable children in society. It portends devastating consequences to children who have already been victimized by irresponsible medical care.

I hope that this information is helpful to you and I am happy to answer any questions that you might have.

Respectfully,



Michael W. Kessler

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[14] Kessler and Fahrenkopf, *supra.*

EXCERPTS FROM THE FUND ACTUARIAL REPORT

Report to the New York Department of Financial Services

New York State Medical Indemnity Fund

2nd Quarter 2019 Actuarial Analysis

As of June 30, 2019

August 2019

PINNACLE
ACTUARIAL RESOURCES, INC.

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Commitment Beyond Numbers

Executive Summary

Based on our review of available information regarding the New York State Medical Indemnity Fund as of June 30, 2019, Pinnacle has arrived at a number of key conclusions:

- As of June 30, 2019, the Fund has accepted 629 participants (619 living) with expected future benefit payments of approximately $924.3 million and future administrative expenses of $186.3 million, assuming a discount rate of 2.0% and future medical inflation of 3.0%. With a Fund balance as of June 30, 2019 of approximately $229.4 million, this results in an unfunded liability for the Fund of approximately $881.2 million.
    - For the fiscal year prior to the impact of legislation signed on December 31 of 2016 (4/1/16-3/31/17, the 2016-17 fiscal year), the average benefit payments per participant were $12,310 per quarter for a total of $21.100 million paid in benefits during this fiscal year. Living participant counts increased from 400 to 455 over this period. See the Payments Per Participant Summary for more detail regarding these numbers.
    - On December 31, 2016, new legislation was signed expanding eligibility for the Fund to non-hospital births and significantly raising reimbursement rates for the period from July 1, 2017 through December 31, 2019. The period for these increased reimbursement rates was recently extended to December 31, 2020 as part of the recent New York State budget. For the most recent four quarters of the Fund (7/1/2018-6/30/2019), average benefit payments per participant were $17,199 per quarter, representing a 39.7% increase over the average payments in the 2016-17 fiscal year. Total benefits paid were $40.348 million for these four quarters, representing a 91.2% increase in payments over the 2016-17 fiscal period, while living participant counts increased from 556 to 619 over this period. Total annual benefit payments are anticipated to increase annually as more participants are added to the Fund.
    - Our analysis contemplates the "sunset" of the 2016 legislation expected to occur on December 31, 2020. Any legislative action to extend this sunset may have a significant impact on this analysis, similar to the impact of the recent extension noted in our report as of March 31, 2019.

- Total future lifetime benefits for the 619 living Fund participants without discounting is estimated to be $1.848 billion. See Exhibit 2, Page 2.
- The current present value of future benefit payments of $924.3 million does not consider any additional enrollees that may be admitted to the Fund in the future.
- Prior to the beginning of the fiscal year, the Fund was expected to have approximately eighty-four (84.40) additional participants accepted between March 31, 2019 and March 31, 2020. Historically, more participants are admitted in the first quarter of the fiscal year than in successive quarters of the fiscal year; we have incorporated this observation into our expected participant counts per quarter (see Exhibit 3).
  - There were twenty-five (25) new participants to the Fund in the first quarter of fiscal year 2019-20, approximately two (2) less than expected for this period at the beginning of the fiscal year but the largest group admitted since 2017 Q2. This difference is despite updated participant estimates evaluated at March 31, 2019. Prior to this quarter, new participant counts per quarter have varied between eleven (11) and twenty-nine (29) in the last two years.
  - The number of eligible participants is expected to continue increasing for at least thirty years as more eligible participants are admitted to the Fund each year.

- Actual benefit payments in the first quarter of the 2019-20 fiscal year (4/1/19-6/30/19) as of 6/30/19 were $10.605 million. This amount is $1.635 million lower than expected at the prior quarterly analysis. Based on modeled severities and an expected 57.39 additional participants, expected benefit payments in the remaining three quarters of the 2019-20 fiscal year are $39.310. Estimated total benefit payments for the 2019-20 fiscal year (4/1/19 – 3/31/20) are therefore $49.915 million. See Exhibit 3 for more detail regarding these numbers. It is important to recognize that these amounts can vary significantly each quarter due to the inherent uncertainty in benefit payments, the effect of the legislative change on payments, and the transition to a new third party claim administrator in the third quarter of the 2017-18 fiscal year.
- As of September 1, 2018, both the Fund's claims handling and enrollment services are now provided by Public Consulting Group (PCG) instead of Alicare. This change is ultimately

expected to decrease the administrative expenses of the Fund on a per month per member basis. Based on information from the Department, at the March 31, 2019 analysis we projected that $5.449 million would be spent in administrative costs for the 2019-20 fiscal year (see Exhibit 2, Page 1 of our report for 2019 Q1). This number was based on expected, not actual, participant counts. We expect the annual administrative expense to decrease on a per member basis over the next few years due to economies of scale.

- Exhibit 1 summarizes Fund payments by benefit type since 4th quarter of 2012. Compared to the Virginia Birth Related Neurological Injury Compensation Fund, another state-run birth injury fund serviced by Pinnacle, the Fund is having a substantially higher percentage of overall costs in medical and hospital costs, medical equipment and prescription drug costs, and corresponding lower percentages in nursing and long term care costs.
- As of June 30, 2019, thirty-eight (38) participants have received more than $1 million in benefit payments, with eight (8) of these participants receiving more than $2 million in benefit payments. Based on current annual severities by individual member, we expect eight (8) more members to cross the $1 million threshold in the next twelve months. These benefit payments do not include prescription amounts handled in bulk by vendors; see Exhibit 7, page 8 for total prescription drug payments handled in bulk.

Background

"The Medical Indemnity Fund was established in 2011 to provide a funding source for future health care costs associated with birth-related neurological injuries. Enrollees of the Fund are plaintiffs in medical malpractice actions who have received either court-approved settlements or judgments deeming the plaintiffs' neurological impairments to be birth-related."[1] More specifically, a "birth-related neurological injury" is "an injury to the brain or spinal cord...that occurred in the course of labor, delivery or resuscitation, or by the provision or non-provision of other medical services during

[1] Provided by NY DFS

New York Department of Financial Services
Quarterly Analysis of New York Medical Indemnity Fund
Future Fund Balances by Fiscal Year (000s) as of June 30, 2019
With 2.00% Discount

BALANCE SHEET

		Projections as of Fiscal Year-End									
	At 6/30/19	2019-20	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26	2026-27	2027-28	2028-29
Assets											
Fund Balance	229,353.9	242,042.5	241,765.6	259,511.4	273,355.2	282,771.8	287,492.6	287,196.0	281,523.6	270,292.0	253,175.8
Liabilities											
Future Benefits for Current Participants	924,274.7	983,620.0	1,078,392.6	1,197,499.4	1,320,902.8	1,448,182.3	1,578,810.8	1,711,909.0	1,847,701.6	1,985,366.9	2,125,013.0
Future Administrative Expenses	186,260.4	182,279.1	201,192.8	220,050.8	238,759.8	257,030.2	274,756.0	291,798.2	308,214.1	323,871.2	338,811.0
Surplus/(Unfunded Liability)	(881,181.2)	(923,856.6)	(1,037,819.9)	(1,158,038.8)	(1,286,307.5)	(1,422,440.7)	(1,566,074.2)	(1,716,511.2)	(1,874,392.2)	(2,038,946.2)	(2,210,648.2)

INCOME STATEMENT

	At 6/30/19	2019-20	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26	2026-27	2027-28	2028-29
Initial Fund Balance		229,353.9	242,042.5	241,765.6	259,511.4	273,355.2	282,771.8	287,492.6	287,196.0	281,523.6	270,292.0
Annual Funding		52,000.0	52,000.0	52,000.0	52,000.0	52,000.0	52,000.0	52,000.0	52,000.0	52,000.0	52,000.0
Investment Income @ 2.00%		4,152.4	4,275.3	4,448.3	4,761.1	4,991.4	5,131.3	5,175.1	5,116.0	4,948.7	4,668.0
Benefit Payments		39,310.0	50,957.5	32,804.1	36,560.0	40,345.6	44,256.1	48,341.4	52,632.0	56,949.0	61,431.0
Administrative Expenses		4,153.8	5,594.8	5,898.4	6,357.2	7,229.1	8,154.4	9,130.4	10,156.4	11,231.3	12,353.2
Final Fund Balance	229,353.9	242,042.5	241,765.6	259,511.4	273,355.2	282,771.8	287,492.6	287,196.0	281,523.6	270,292.0	253,175.8
Change in Fund Balance		12,688.6	(277.0)	17,745.8	13,843.8	9,416.6	4,720.9	(296.7)	(5,672.4)	(11,231.6)	(17,116.2)
Benefit Payments as % of Initial Fund Balance		17.1%	21.1%	13.6%	14.1%	14.8%	15.7%	16.8%	18.3%	20.2%	22.7%
Number of Participants											
Initial		619	673	754	836	918	1,000	1,080	1,158	1,235	1,309
Expected New		57	86	88	89	91	91	91	92	91	91
Expected Deceased		4	5	6	8	9	11	13	15	17	20
Final	619	673	754	836	918	1,000	1,080	1,158	1,235	1,309	1,381

Notes

Balance Sheet - Assets	Calculated in Income Statement
Balance Sheet - Liabilities	Future Benefits from Exhibit 5, Pages 4-6 discounted to current evaluation Future Expenses based on current administrative costs
Balance Sheet - Surplus	= Assets - Liabilities
Income Statement - Initial Fund Balance	= Final Fund Balance of prior period
Income Statement - Annual Funding	Provided by MIF
Income Statement - Investment Income	Calculated based on 2.0% assumed investment return and assuming average date of benefit and expense payments is the middle of the fiscal period
Income Statement - Benefit Payments	From Exhibit 5, Pages 1-3
Income Statement - Admin Expenses	Calculated based on current and projected participant counts and administrative expense contracts provided by MIF
Income Statement - Final Fund Balance	= Initial Fund Balance + Annual Funding + Investment Income - Benefit Payments - Administrative Expenses
Income Statement - Change in Fund Balance	= Final Fund Balance - Initial Fund Balance
Income Statement - Benefit Payments as % of Initial Fund Balance	= Benefit Payments / Initial Fund Balance
Income Statement - Number of Participants	Initial from Exhibit 7 Expected New from Exhibit 3 Expected Deceased based on assumed increasing rate of deaths for current participants, up to 1.5% Final = Initial + Expected New - Expected Deceased

New York Department of Financial Services
Quarterly Analysis of New York Medical Indemnity Fund
Future Fund Balances by Fiscal Year (000s) as of June 30, 2019
Undiscounted

BALANCE SHEET

		Projections as of Fiscal Year-End									
	At 6/30/19	2019-20	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26	2026-27	2027-28	2028-29
Assets											
Fund Balance	229,353.9	237,890.1	233,337.8	246,635.3	255,718.0	260,143.3	259,732.8	254,261.0	243,472.6	227,292.4	205,508.1
Liabilities											
Future Benefits for Current Participants	1,847,766.5	2,010,887.2	2,266,731.2	2,562,261.2	2,877,398.3	3,211,877.7	3,565,253.2	3,936,267.9	4,326,264.4	4,733,853.2	5,160,045.9
Future Administrative Expenses	352,907.0	348,925.8	392,138.0	436,319.6	481,408.3	526,974.4	572,779.6	618,494.4	664,212.9	709,595.4	754,691.3
Surplus/(Unfunded Liability)	(1,971,319.6)	(2,121,922.9)	(2,425,531.5)	(2,751,945.5)	(3,103,088.5)	(3,478,708.8)	(3,878,300.0)	(4,300,501.3)	(4,747,004.6)	(5,216,156.28)	(5,709,229.04)

INCOME STATEMENT

	At 6/30/19	2019-20	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26	2026-27	2027-28	2028-29
Initial Fund Balance		229,353.9	237,890.1	233,337.8	246,635.3	255,718.0	260,143.3	259,732.8	254,261.0	243,472.6	227,292.4
Annual Funding		52,000.0	52,000.0	52,000.0	52,000.0	52,000.0	52,000.0	52,000.0	52,000.0	52,000.0	52,000.0
Benefit Payments		39,310.0	50,957.5	32,804.1	36,560.0	40,345.6	44,256.1	48,341.4	52,632.0	56,949.0	61,431.0
Administrative Expenses		4,153.8	5,594.8	5,898.4	6,357.2	7,229.1	8,154.4	9,130.4	10,156.4	11,231.3	12,353.2
Final Fund Balance*	229,353.9	237,890.1	233,337.8	246,635.3	255,718.0	260,143.3	259,732.8	254,261.0	243,472.6	227,292.4	205,508.1
Change in Fund Balance		8,536.2	(4,552.3)	13,297.5	9,082.7	4,425.3	(410.5)	(5,471.8)	(10,788.4)	(16,180.3)	(21,784.2)
Benefit Payments as % of Initial Fund Balance		17.1%	21.4%	14.1%	14.8%	15.8%	17.0%	18.6%	20.7%	23.4%	27.0%
Number of Participants											
Initial		619	673	754	836	918	1,000	1,080	1,158	1,235	1,309
Expected New		57	86	88	89	91	91	91	92	91	91
Expected Deceased		4	5	6	8	9	11	13	15	17	20
Final	619	673	754	836	918	1,000	1,080	1,158	1,235	1,309	1,381

Notes

Balance Sheet - Assets	Calculated in Income Statement
Balance Sheet - Liabilities	Future Benefits from Exhibit 5, Pages 1-3 discounted to current evaluation Future Expenses based on current administrative costs
Balance Sheet - Surplus	= Assets - Liabilities
Income Statement - Initial Fund Balance	= Final Fund Balance of prior period
Income Statement - Annual Funding	Provided by MIF
Income Statement - Benefit Payments	From Exhibit 5, Pages 1-3
Income Statement - Admin Expenses	Calculated based on current and projected participant counts and administrative expense contracts provided by MIF
Income Statement - Final Fund Balance	= Initial Fund Balance + Annual Funding - Benefit Payments - Administrative Expenses
Income Statement - Change in Fund Balance	= Final Fund Balance - Initial Fund Balance
Income Statement - Benefit Payments as % of Initial Fund Balance	= Benefit Payments / Initial Fund Balance
Income Statement - Number of Participants	Initial from Exhibit 7 Expected New from Exhibit 3 Expected Deceased based on assumed increasing rate of deaths for current participants, up to 1.5% Final = Initial + Expected New - Expected Deceased

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Comments on The New York Medical Indemnity Fund Proposed Amended Regulations

Introduction

On behalf of the NYS Academy of Trial Lawyers and myself, I am writing to comment on the proposed amendments to the New York Medical Indemnity Fund and urge that these proposed regulations be withdrawn. I am a practicing attorney, and I have studied both the Fund and its regulations. A number of families who have children in the Fund have shared their experiences with me, and therefore I am very familiar with how the Fund operates and how it has treated families since its inception. In 2012, I co-authored a law review article which extensively analyzed the Fund's enabling legislation, as well as what, at that time, were the "Emergency Regulations" under which it was operating.[1] Unfortunately, shortcomings of the Fund, and the difficulties it would impose on these severely disabled children which were predicted in that article, have been more than borne out. The Fund has made life unnecessarily difficult for these families–especially when compared to the compensation that was taken from them to create the Fund. It is respectfully submitted that the currently proposed amendments to the Fund regulations–by further unnecessarily restricting access to care and refusing to approve necessities which would provide therapeutic benefit and improve the quality of life of these severely injured children--will

[1]Kessler and Fahrenkopf, *The New York State Medical Indemnity Fund: Rewarding Tortfeasors Who Cause Birth Injuries by Rationing Care to Their Victims*; 22 Albany Law Journal of Science and Technology 173; http://www.albanylawjournal.org/Documents/Articles/22.2.173-Kessler-Fahrenkopf.pdf

make a bad situation even worse for the families who have been forced into obtaining services from the Fund.

The more than three hundred children now enrolled in the fund require extensive care, equipment, and services, and the effort required by their families to maintain these children twenty-four hours a day is already enormous. These families deserve our support to make their lives easier-- especially since they were forced by law to give up the compensation which would have enabled them to obtain the services themselves-- instead creating more obstacles to get the Fund to pay for necessary services and equipment. The proposed amendments to the regulations will make it more difficult to get the care that the children in the fund were promised, and to which they are entitled.

Because I have written about the Fund,[2] I am regularly contacted by parents of children who suffered neurologic impairment at birth, concerning their experiences in attempting to get the medical care, equipment and services that their children require to maintain their health and improve their quality of life. Based on my conversations with a number of parents, not only is the Fund depriving these children of what they need, but the hurdles imposed by the Fund and the effort required by these families to get even basic services is overwhelming. It is not an exaggeration to say that – without exception – every parent of a Fund child with whom I have spoken over the last several years has used the same one word to describe their Fund experience.

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[2] See e.g.
http://www.rrkslaw.com/Articles-Appearances/Obamacare-and-the-New-York-Medical-Indemnity-Fund-Where-is-the-Outrage-over-Rationing-Care-to-Innocent-Children-Injured-by-Negligent-Doctors-and-Hospitals/
http://www.disabled-world.com/news/america/newyork/indemnity-fund.php
http://www.rrkslaw.com/Articles-Appearances/Disabled-Individuals-Cared-For-by-New-York-State-A-Preview-of-Care-under-The-New-York-State-Medical-Indemnity-Fund/
http://www.rrkslaw.com/articles-appearances/new-yorks-death-panel-lottery-for-children-injured-by-medical-malpractice-at-birth/
http://www.rrkslaw.com/Articles-Appearances/The-Double-Secret-New-York-Medical-Indemnity-Fund-Where-is-the-Information-About-Fund-Operations-and-Where-are-the-Hearings-and-the-Fund-Regulations/
http://www.rrkslaw.com/Articles-Appearances/Challenging-The-New-York-Medical-Indemnity-Fund/

Each one of them calls it a "nightmare."

The new proposed regulations will unfortunately further restrict the care and equipment that these children will receive, lower the amount that the Fund will pay for services, and make the process to obtain equipment and improve handicapped accessibility even more burdensome than it is already. This Memorandum will briefly explore the impact of some of the proposed amendments.

Background

In addressing the impact of the proposed Fund regulation amendments it is important to recall why the Fund was created and what it was promoted to do by its advocates and, indeed, what persons not familiar with its day to day operations may believe that it is accomplishing.[3] Unlike, for example, workers compensation, which applies to all workers injured on the job without regard to the fault of the employer, the Fund is *not* universal to all children who suffered a neurologic injury at birth. To the contrary, the Fund *only* applies to that small number of children who were injured at birth *as the result of the proven medical malpractice* by a doctor or hospital. In order for the Fund to apply, these children must go through all the steps of malpractice litigation, and then *only* after they have either proven and obtained a verdict and judgment against a defendant confirming the deviations from accepted care *and* that such malpractice caused the neurologic injury, or they have convinced a defendant to settle their malpractice claim, does the Fund apply.

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[3] Among the promoted purposes of the Fund when it was enacted was the hope that it would reduce medical malpractice insurance costs by prohibiting children injured at birth from recovering damages for the cost of future care from the hospital or doctor who caused the injury that required care. Whether or not the reduction in medical malpractice insurance costs has been achieved is questionable, but well beyond the scope of these comments. However, one consequence of the Fund is indisputable: Assuming that the cost of future care for birth injured children is reduced by the Fund paying for it instead of the charging the negligent party who caused the injury, that cost reduction can *only* occur by either limiting (rationing) the amount of care, equipment and services that the child receives, or reducing the amount paid for it–which limits access to qualified providers-- or both. Unfortunately, that is exactly what has happened and the situation will be exacerbated by the proposed amendments to the regulations.

At that point, even after obtaining a verdict against the negligent defendant which establishes what future care is required and provides for a sum of money to be paid in installments into a trust to provide for the child's future care needs, the defendant's obligation to pay for that amount is extinguished, and the child is forced into the Fund which, using taxpayer money, is supposed to pay for his or her care.

Thus, even with a judgment against a defendant to compensate the child for the cost of future care, the child receives absolutely no compensation for this proven loss. Nor does the defendant pay any money into the Fund. This scheme is unique among any other malpractice or other tort victim in New York and, indeed, to my knowledge, any tort victim in the United States. It takes away an otherwise enforceable judgment against a defendant after it has been rendered, and in its place requires enrollment in the Fund which is supposed to pay for future care needs. The Fund is not bound by the Court determination of the amount required for future care or the services that the Court had found were required for the child's well-being. Rather, the child must get the Fund to approve the services that it will pay for under a time-consuming and burdensome administrative process. And, if the Fund denies a service, the appeals process is not only difficult and weighted against the child, but time-consuming and expensive. After enduring a successful malpractice litigation, these families are forced into a lifetime of haggling and/or litigating against the Fund, to recover a portion of what was decided necessary in their lawsuit against the tortfeasor.

It would seem that depriving a person of the right to collect a judgment would create a serious constitutional question concerning the taking of a property right,[4] especially, as has proven to be the case, the Fund is not an adequate replacement for the right to the enforce the judgment that has been destroyed by statute. Having been created and promoted as a substitute to provide the

[4]There are a number of other serious constitutional issues raised by the Fund. See, Kessler and Fahrenkopf, *The New York State Medical Indemnity Fund: Rewarding Tortfeasors Who Cause Birth Injuries by Rationing Care to Their Victims*; 22 Albany Law Journal of Science and Technology 173 (2012).

care that would have been paid for by the judgment that has been taken away, it would seem that the Fund's (New York State's) obligation to pay for care should be interpreted in the light most favorable to the child's needs. It would appear that such was the Legislative intent. Indeed, the Regulatory Impact Statement of the Department of Health at the time that the initial Fund regulations were proposed stated that "subdivision 3 of section 2999-h of the PHL sets forth a broad definition of "qualifying health care costs" for services and supplies" and gives the Commissioner of Health authority to further "define" such "qualifying health care costs" by regulation. It does not give the Commissioner the right by regulation to significantly *restrict* such broad definition of "qualifying services." Unfortunately, however, not only do the current regulations fail to comply with what should be the "broad" definition of the services which the Fund will provide, but the proposed amendments create even more onerous restrictions. They further limit care and equipment, and increase the burden on the families of Fund children. As such, they are inconsistent with the purpose of the legislation that created the Fund.

The Proposed Amended Regulations

Based on my conversations with families, their experiences with the Fund has been universally frustrating and unpleasant. It must be kept in mind that taking care of a severely disabled child with cerebral palsy, as most of the Fund enrollees are, is a full time job, even if nursing or respite care is available. The Fund has made the process by which it processes and evaluates requests for services into a maze which even highly educated and sophisticated parents cannot navigate successfully. For less sophisticated caregivers, the Fund has made the process nearly impossible.

The burden of constant applications, requests, compliance, documentation, Fund denials, resubmissions, and appeals makes the already challenging lives of these families even more

difficult – and that is when the family is successful in obtaining the requested services. When they are not, these children are forced to go without. One mother told me recently that dealing with the Fund consumes upwards of twenty hours of her time a week, or more.

By its own Regulations (§69.10-4 (3)-(8)), the Fund is required to provide a "case manager" who is required to establish a "comprehensive case management plan to assist the enrollee to manage all qualifying health services needed by the enrollee…"to assist... the enrollee... to obtain the services set forth in the... plan," and to "assist... the enrollee with any forms necessary." None of the families with whom I have spoken have *ever* received such a plan, or gotten the required assistance. The "case managers" are geographically remote, usually located out of New York State, and have never even seen or otherwise evaluated the child whose care they are supposed to be coordinating. Rather than acting as a "case manager" advocating for necessary care and finding it, their role appears to be to serve as a gate keeper to restrict care and save money.[5] Indeed, at least one parent quoted their case manager as saying that she was specifically told that keeping her job was dependent on denying their application for a requested item of care. So these families are left on their own to find caregivers, equipment, and contractors. Their experience with the Fund consists of begging for services or approvals, and fighting denials. They must contend with an army of Fund and Health Department employees who seek to limit the services that these families receive.

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[5] The Case Management Society of America's Standards of Practice requires "recognition" that a case manager's "primary responsibility is to his/her clients," and also that "[t]he case manager should advocate for the client at the service-delivery, benefits-administration and policy-making levels."
http://www.cmsa.org/portals/0/pdf/memberonly/StandardsOfPractice.pdf)

Similarly the Commission for Case Management Certification requires that "[c]ase managers' first duty is to their clients – coordinating care that is safe, timely, effective, efficient, equitable, and client-centered."
http://stage.cmbodyofknowledge.com/content/case-management-knowledge-2

The "case managers" employed by the Fund do not appear to be acting in accordance with these well-established ethical requirements for professional case managers.

The current Regulations are far more restrictive in providing services and equipment than could have been envisioned when the Fund was created by the Legislature. Unfortunately, the proposed amendments make the situation worse. Here are some examples.

Assistive Technology

Although the description of the amendment to what constitutes "assistive technology" (§69-10 (b)) euphemistically asserts that it is to "clarify" which items will be covered by the Fund, the true impact is to severely limit what they will provide. Under the current regulations an assistive device will be paid for if it is "determined necessary by a physician for purposes of... *habilitation, ability to function, or safety* in his or her current or desired residence." The amended regulation, in contrast, now allows a device *only* if it "is essential for activities of daily living" and now specifically *excludes* anything that is used for recreational or therapeutic purposes. Moreover, under the amended regulations, the Fund will not approve anything that is not designed specifically for a person with a disability or which would be useful in the absence of an injury.

The scope of this proposed restriction is breathtaking. *A severely disabled child will now no longer be entitled to obtain equipment which provides therapy or recreation to her.* So, for example, under this definition, a child who cannot play with traditional toys is prevented from getting special switch operated toys designed for the handicapped, and which are necessary for both therapeutic purposes (switch activation for controlling her environment) as well as enjoyment.

One mother recently told me that her son is able to activate toys only though special sensory switches. These "toys" provide occupational therapy to improve function so that someday he may be able to use learning and recreational toys independently, and thereby improve his ability to control his environment. The proposed amended regulations will not cover these assistive

devices because they are therapeutic and recreational in nature, and not essential for activities of daily living. Similarly, this same child requires a Bluetooth switch that can used to access an iPad with special needs applications. Since the Bluetooth device is for therapeutic and/or recreational purposes, and is not specifically designed for a disabled person – and, even though the applications are designed for the disabled – the switch would not qualify under the amended Fund regulations.

Environmental Modifications

Similarly, the asserted purpose to the proposed amendment to home modifications is to "clarify" what items will be approved. In fact, the purpose is to exclude significant categories of home modifications, and also to limit the purposes for which modifications will be provided by the Fund.

The current regulations (§69-10.1(m)) define an "environmental modification" as an "interior or exterior physical adaptation to the residence where the enrollee lives that is necessary to insure [his] health welfare, and safety... [and] enables him... to *function with greater independence in the community and/or helps avoid institutionalization...* " The proposed amended regulation eliminates "function with greater independence in the community" as a legitimate purpose of home modification. Instead, they seek to limit modifications for the benefit of these children *only to those that enable "activities of daily living."*[6] Therefore, home modifications to allow access to recreation, those that are therapeutic, or which enhance quality of life, are excluded.

[6]Activities of daily living are limited to " basic self care tasks such as dressing and undressing, self feeding, bowel and bladder management, ambulation... communication... functional transfers... and personal hygiene and grooming." (§69-10.1 (a)). Thus anything that is therapeutic, improves function, or quality of life, or is recreational, therefore, is not for an activity of daily living, and therefore prohibited.

The proposed regulations prohibit any modification that adds square footage or even renovations to an existing home if its purpose is for "providing therapy." The list of items that are *not* covered under the proposed amended regulations, even if they are important, include elevators (even if that is the only means of accessing the home); intercoms (even if that is the only method of communication from a child who is not mobile); fencing and security gates; and even bathtubs necessary for aqua therapy.

One quadriplegic cerebral palsy child's family requested but was denied a large inside bathtub in order to provide aqua therapy which was ordered by a physician as essential to moving the child's otherwise immobile limbs. The only alternative source of providing the required aqua therapy was at a rehabilitation center many miles away, and was only available during school hours. This would have required pulling the child out of school frequently, driving many miles, undressing him and redressing him (no simple task with a child with this disability) and then returning him to school. The Fund would presumably pay for the aqua therapy sessions – at a much greater ongoing cost than proving a tub – but not for the tub itself, which not only would have saved money but improved the child's education and quality of life, and decreased the challenges to his caregiver.

A client of mine has a hypoxic brain injury, and though almost fifteen years old, is functioning at the level of a five year old. He cannot be left unsupervised. Yet, the proposed amended regulations will prohibit payment for fencing and a security gate so that he could be allowed to safely play outside in his yard without an adult being present at all times to prevent him from wandering into the street.

Many children with these disabilities are quite temperature sensitive, and require a constant environment within limited temperature ranges and often times air filtration. For them air

conditioning is not a luxury but a medical necessity, and having it in a home may prevent the need for institutionalization. Yet the proposed regulations prohibit this item. Similarly, many of the Fund children require constant access to electrically powered medical appliances, in some cases as a matter of life and death. Yet the proposed amended regulations prohibit upgrades to a home's electrical system unless it is *solely* to provide power to these medical devices. One family whom I know was denied a backup generator to power life critical equipment because it would have served the entire house. Apparently to the Fund, the child's equipment are not allowed to move within the house, or a separate circuit for his equipment could be added and his caregivers would be required to try care for him in the dark even if the equipment remained functional.

The proposed amended regulations also prohibit adding square footage to an existing home. One family who contacted me had a home with a small garage which would only fit a compact car. It would not fit a handicapped van, which the family required for their child's wheelchair. The Fund denied their request to increase the size of the garage to accommodate the van. This requires the family to stand outside to get the child and his wheelchair out of the van in the cold, rain or snow, and expose him to the elements.

Caring for a quadriplegic child requires an enormous amount of specialized and sometimes bulky equipment to keep them functioning. Even if the Fund may pay for the necessary equipment, many of these families have no place put it. Yet the proposed amendments – even where square footage is not increased – *prohibit "renovation of existing rooms... for the purpose of providing therapy, training, education or storage.*" Under the proposed amendments, therefore, a family cannot increase the square footage of an existing residence to provide for room for necessary therapy, training, education and storage, yet neither can they make renovations to that existing structure to provide for such necessities. I have seen many "dining rooms" that are no longer

usable by the family because they have become only the storage place available for such essential equipment.

Another family whom I know was denied a wheelchair accessible path to enable access to the backyard, resulting in the child being stuck inside when at home. A recent decision by the Fund–approved by the Commissioner of Health denied yard modifications necessary for wheelchair access, simply because they were outside. The current regulations (§ 69-10.1 (m) defines an "environmental modification" as

> an interior or *exterior* physical adaptation *to the residence in which an enrollee lives* that is necessary to ensure the health, welfare, and safety of the enrollee, *enables him or her to function with greater independence in the community....* (emphasis added)

Unbelievably, the "exterior" modifications that "enable[d]...her to function with greater independence in the community" was denied by the Fund, and the denial was approved by the Commissioner of Health. In the decision denying the wheelchair accessibility they wrote that modifications are limited

> "to the residence *in which* the enrollee lives. *The enrollee does not reside in her backyard. Her residence is her house.*" (emphasis added)

The proposed amendments to the regulations seek to codify this tortured interpretation and thereby cruelly prevent those home modifications to enable use of the exterior of a home by a disabled child.

The proposed amendments also prohibit modifications to the basement of a home – and even modifications to provide *access* to a basement unless "such access is necessary for an enrollee for an activity of daily living..." Apparently the Fund does not consider therapy or recreation, or simply being able to access the entire house to be with the rest of the family to watch TV or engage in other activities, to be very important. The enrollee will simply not have access to

the entire premises under the proposed amended Fund regulations.

Respite Care

Providing care to a quadriplegic child is a twenty four hour a day – seven day a week job. The level of burnout and stress on these families is enormous. Although the Fund does recognize respite care as appropriate, the proposed regulations place new and unreasonable restrictions on it. Respite care is limited to twenty hours per week (1,080 hours per year). However, the proposed regulations eliminate the possibility of respite care for "substitute care... because the caregiver [parent] is not at home because of work or school." This adds to the difficulty of the parent to become employed and imposes an additional significant economic hardship on these families. Implicit in the regulations is the unfounded assumption that families alone have the unpaid responsibility to provide full time care even to adult enrollees, and that a primary caregiver is precluded from becoming employed to support themselves or their family.

In addition, the proposed amendments provide that "respite care may not be provided by a relative or member of the household." Thus, family members – grandparents, aunts, uncles – the people other than parents who are most familiar with taking care of the disabled child's needs – cannot be paid for respite care. Instead, the caregiver must find a stranger, with limited knowledge of caring for the child, who is available – often on short notice – and willing to undertake this responsibility for the Medicaid rate of reimbursement. (See below). It is my understanding that even Medicaid does not impose this restriction on close relatives providing paid respite services.

Exterior Physical Adaptation

A new definition is proposed for "exterior physical adaptation" which is authorized only if it is to provide two accessible entrances to the premises. The new regulation excludes coverage, among many other things, to "modifications to an existing driveway... or improvement of a

walkway that is not necessary for entrance into or exit from the home." This language appears to seek to codify the unreasonable determination described above whereby it was found that because a child "does not reside in the backyard," she cannot get modifications to enable her access to it.

One family who contacted me had requested approval for a slight change to the grade of a driveway – which because of the length and configuration of the wheel chair van – was damaging its undercarriage and lift mechanism. This would be prohibited under the proposed amendments. As noted above the family who requested alterations to an exterior backyard walkway to make it wheelchair accessible so that the child could utilize the backyard with the rest of the family would be prohibited under the proposed amendments.

Approval of Home Modifications and Assistive Technology

In addition to the already extensive process for Fund approval of home modifications or assistive technology, the proposed amendments create an entire new level of complexity that almost no parent – much less a parent who is providing care to a severely disabled child twenty four hours a day – could navigate by themselves. The process requires hours of time and extensive consultation with professionals – architects, rehabilitation professionals, and construction contractors – in order to even apply for these services, often at great personal expense to the parents of these children. One family who contacted me submitted a detailed fifty page report from a rehabilitation professional to support their application for home modifications, only to see it largely rejected. Another family told me that they have had to retain a rehabilitation professional at their own expense to prepare their application. The process needs to be simplified, not made more challenging, and the Fund needs to provide help in getting these services – as it is required to do by its own regulations (§69-10.4) – instead of imposing more roadblocks.

Rates of Payment

This is a critical issue which has a significant impact on the health and well-being of children in the Fund. The statute creating the Fund (PHL §2999-j) specifically provides that private physicians shall be paid at one hundred percent of the "usual and customary rates." Yet the regulations and the proposed amendments provide for physician payments at the "eightieth percentile of the usual and customary rates for private physician services." I do not understand how this is consistent with the statute. I have had families tell me that their regular physicians will not accept these rates and thus their children's access to medical care is compromised.

Even more concerning is the rate of payment for other than physician services at the "Medicaid rate." Even when nursing care is approved, for example, it is almost impossible to get qualified providers to work at Medicaid rates. One family told me, for example, that they are approved for care aides by Medicaid forty-four hours per week and extra seven hours per day while their child is not in school. At the Medicaid rate of $11.99 per hour, they are fortunate to get aides for twenty hours a week. Because of the child's care needs, the aides need a nursing or special needs background and they cannot just hire a babysitter. The otherwise approved hours are left unfilled. Many other families on have shared similar experiences. By precluding a "relative" from providing paid respite services, the proposed amended regulations exacerbate this situation.

The same is true of other services. For example, I was contacted by the family of a child who, for a number of medical necessity reasons, required various enhancements to his eyeglasses at a cost of almost $250.00, which his mother paid out-of-pocket. She was initially reimbursed at the Medicaid rate of $16.00 before complaining and was eventually being reimbursed the cost.

Nor do the unreasonably low rates of pay to providers merely limit the services that these children can get. They have the significant potential to adversely impact their health and even longevity. Even if the plaintiff is fortunate enough to acquire providers at Medicaid rates, then the issue is whether the quality of care would be sufficient for the plaintiff's needs. A number of studies and articles confirm the fear that Medicaid rates will compromise access to the care that these vulnerable children (and adults) require. A 2011 study published in the *New England Journal of Medicine* established that Medicaid patients (the equivalent of Fund enrollees, since reimbursement for most services are at Medicaid rates) experienced significant delays in getting appointments with medical subspecialists as compared to private pay or private insurance company patients. The delay in getting appointments was about twice as long—an average of forty-two days under Medicaid—compared to twenty days with private insurance. [7]

When care is restricted and inadequate there is legitimate concern that these children may suffer unnecessarily, and likely die prematurely.[8] It is hardly surprising therefore, that investigative reporting discovered that borne out by developmentally disabled individuals. The *New York Times* article cited describes a number of unexplained deaths and other injuries to disabled individuals in state facilities, most of which apparently related to poor care, such as choking and drowning. The *Times* reported "the average age of those who died [from] unknown causes was 40, while the average age of residents dying of natural causes was 54." The State Commission on Quality of Care and Advocacy for Persons with Disabilities found that there had been "concerns about the quality of care in nearly half" of the unexplained deaths. The

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[7] Bisgaier & Rhodes, "Auditing Access to Specialty Care for Children with Public Insurance," 364 *New Eng. J. Med.* 2324, 2325, 2328 (2011); Harrington et al., "Nursing Staff Levels and Medicaid Reimbursement Rates in Nursing Facilities," 42 *Health Services Res.* 1105, 1106–07 (2007).

[8] *See e.g.* Kessler, "Critical Analysis of the Life Expectancy Research from an Attorney's Perspective," in *Pediatric Life Care Planning and Case Management,* (797–799) (Susan Riddick-Grisham ed., 2004); Hakim & Buettner, "In State Care, 1,200 Deaths and Few Answers," *New York Times*, Nov. 5, 2011, at A1, available at http://www.nytimes.com/2011/11/06/nyregion/at-state-homes-simple-tasks-and-fatal-results.html

"unexplained" death rate for individuals cared for by the State of New York was more than four times higher than the rate in Massachusetts and Connecticut.

Thus even if the Fund were to approve nursing care for a certain number of hours, as noted, it is likely that the family would be unable to find nursing staff who would be willing to work in the home at those rates or on all shifts. The same is true with necessary equipment, and certain providers, particularly those who provide more expensive or higher quality equipment, may refuse to provide their goods at Medicaid rates–all of which has the significant potential to compromise the health and well-being of these children and their caregivers.

Cost to Regulated Parties

The proposed amended regulations assert that "there are no costs to regulated parties by these regulations. Qualified plaintiffs will not incur any costs in connection with applying for enrollment in the Fund or coverage by the Fund." That statement is simply untrue. Even a cursory review of the regulations as they exist presently – and made worse by the proposed amendments reveal there are tremendous costs to families – both out- of-pocket and in the time and energy expended to try to obtain benefits. One mother estimated to me recently that, in addition to providing full time care to her child, she spent on average more than twenty hours a week dealing with Fund issues, making it impossible for her to get even a part time job. Based on my discussions with a number of families, this mother is not unique, and who knows how many families just give up because of the difficulties in getting services and payment from the Fund. If a family appeals the Fund's denial of a service or item, they incur significant cost in time and likely require legal counsel at significant expense in order to pursue the appeal. The appeals process is anything but user friendly and the Fund families consider it so stacked in favor of denials that they often just give up rather than pursuing an appeal.

Consumer Advisory Committee

The Fund enabling statute (PHL §2999-j (16) requires the Commissioner to "convene a consumer advisory committee for the purpose of providing information, as requested by the commissioner, in the development of the [Fund] regulations..." I do not know if such a consumer advisory committee exists and, if so, who serves on it, or whether the Commissioner ever requested any information from the Committee about the proposed amendments to these regulations. Certainly none of the parents to whom I have spoken are aware of any such committee, and it is difficult to believe that any reasonable consumer advisory body would be in favor of either the proposed amended regulations or the way these families have been treated even under the current regulations.

Suggestions for Improvement

Based on my discussion with many families over the last several years, it is clear the Fund is not meeting the needs of these children and their caregivers. The process to obtain services is overly and unnecessarily complex, and the rates of payment are inadequate for these families to obtain the services and equipment that these children require. It certainly does not provide an adequate substitute for the right to recover damages for future care pursuant to a judgment so that parents can make health care decisions and provide for their child's needs.

The Fund regulations (§69-10.4) require that enrollees be provided with a qualified case manager who will prepare a "comprehensive written management plan to assist the enrollee... to manage the delivery of all qualified health care services... and also to assist the enrollee to obtain those services and filling out the forms necessary to obtain payment." However, based on my discussion with a number of families, the case managers are geographically remote, they are not

qualified or even aware of the child's needs or services available to these families, and they have not fulfilled their obligation to provide the comprehensive case management plan.

The Fund needs to provide better services to these families. As a start, they should be required to comply with §69-10.4, but more importantly, since the Fund and its contractor's employees primary role seems to be denying payment for services, the Fund should be required to create an ombudsman at the Fund's expense whose sole role is to advocate on behalf of these children for necessary services within the Fund. This ombudsman should not be employed by the contractor but rather should function independently and answer only to the enrollee and his or her family—as the ethical standards for professional case managers require.

In addition, consistent with the Legislative intent that the Fund serve as an adequate substitute for the money judgment or settlement that was taken away from these children, the Regulations should be amended to assure that "qualifying health care services" is "broadly" interpreted, as was stated at the time of the initial adoption "Emergency" regulations. Specifically the regulation should provide that services, equipment or ordered by a child's physician or other professional are presumptively valid, both initially and in any administrative or judicial review proceeding, and the burden should be on the Fund to overcome that presumption to deny a service or item.

There are other remedial measures that would help to level the playing field, and assure that these children have access to the care, equipment and services which they require. These might include penalizing the Fund or its contractor for an unreasonable delay or denial of services, and enhanced and more available judicial review. Legislative action may be necessary to make these changes.

Conclusion

The Fund is not adequately meeting the needs of the children covered by it. It overly and unfairly restricts what it will pay for, and the process to get approval is much too difficult and expensive for these families to navigate–particularly when the deck is stacked against them. The proposed amendments to the regulations make a bad situation worse – much worse. It is respectfully urged that the proposed amendments be withdrawn, and that the regulations be fixed to better meet the needs of these families, as the Fund was intended to do.

Respectfully on behalf of the NYS Academy of Trial Lawyers,

MICHAEL W. KESSLER

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December 16, 2019

Honorable Chairwoman Helene E. Weinstein
Assembly Ways and Means Committee
LOB 923
Albany, NY 12248

Honorable Thomas J. Abinati
LOB 744
Albany, NY 12248

RE: **Bill A2347/A9018-A**

Establishes an office of the state medical indemnity fund ombudsman and a medical indemnity fund advisory panel to advocate for, assist and represent the interests of the qualified plaintiffs

New York State Medical Indemnity Fund (the"MIF") has enrolled over 600 of the most medically fragile children severely injured upon birth born due to medical malpractice

Dear Chairwoman Weinstein:

Please ask your committee to send Assemblyman Thomas J. Abinati's A2347 (the "Bill") to the assembly floor at the start of the 2020 Legislative Session on January 8th. **(See attached as Exhibit A)** This Bill will "establish an office of the state medical indemnity fund ombudsman and a medical indemnity fund advisory panel to advocate for assist and represent the interests of qualified plaintiffs."

My twelve-year old son, Luke, is one of these qualified plaintiffs. He has severe cerebral palsy spastic quadraparesis which caused developmental delays, severe scoliosis, severe reflux and epilepsy.

This MIF was statutorily created back in 2011 to reduce the cost of the medical malpractice insurance specifically for all New York hospitals which have maternity units. Only children who suffered brain or spinal injuries during labor and delivery at these hospitals can be enrolled. To be enrolled in the MIF, the families must give up their rights to pursue a jury trial. **(See attached as Exhibit B, Public Health Law 2999-j (6) (b)).** It is my understanding from our settlement conference that if we had decided to pursue a trial, any award would be expunged

and Luke would have been automatically be enrolled in the Fund by the presiding judge.

After the November 2018 elections, I read your interview with the Legislative Gazette. In this interview you stated that during your new tenure as Chairwoman of the Assembly Ways and Means Committee you wanted to *"find opportunities that lend a solution to the needs facing our families."* This Bill is exactly your opportunity. MIF families have to constantly fight for every single item. Currently without an advocate, we juggle 24-hour caregiving with appeals and endless phone calls to claims. One Hundred percent (100%) of the time hiring a lawyer would cost more than the item we are fighting for.

On June 14, 2017, the NYS Senate Health Committee held a Round Table for parents, attorneys and providers. I testified that fighting the MIF became a part time job. I am unusual MIF parent as I practiced law for a short time and know how to interpret government regulations. **Even with my background I struggled.** Towards the end our construction appeal I had to hire a lawyer. I acted pro se for three years. (**See attached as Exhibit C, In the Matter of Howard Zucker vs. Heidi Skau acting on behalf of L.S. (" the Order"**) How many other parents are also struggling, taking their children to the hospital, working full time, and spending any energy they have left fighting the MIF. No other group needs an advocate more than us, the MIF families.

The MIF: A History of Abuse of Power

- In the spring of 2016 during my request for environmental modification, the MIF **ordered** the independent evaluator, Accessible Options to **recommend nothing.** I got a call from the evaluator crying, as she did not know what to do. I immediately filed a complaint with the Inspector General against the MIF administrator as this action was inappropriate.

  As you can read in the Order, the administrative judge awarded us 60% of our requested construction items. However, MIF refused to act and I was advised the only way to enforce the order was to file an Article 78 proceeding. It was at this point that the cost of the litigation in the NYS Supreme Court system would cost more than the construction.

- On June 20, 2016 the Department of Finance- Health Bureau decided they want to make the NYMIF just another Medicaid program. They promulgated a new set of amendments deleting all the benefits the families were receiving that when beyond the standard Medicaid benefits. State Senator Hannon, the New York Trial Lawyers Association and the families of the MIF banded together to defeat these regulations. (**See attached Exhibit D, the proposed regulations, a scathing letter from Senator Hanon to Commissioner Zucker and the Memorandum of the NY Trial Lawyers**)

- One of the benefits the MIF was looking to get rid of in the proposed regulations was recreational and therapeutic assistive technology. Since their attempt to amend the

regulations failed, their current practice is to just outright deny items with no reasonable explanation. **This scenario is the most pressing example of why an advocate is so desperately needed. (See attached Exhibit E, the MIF's nonsensical denial, my reconsideration argument and finally their approval.**

- This past June, the NYS Court of Appeals, Third Department overturned another MIF denial, in the Matter of Anson v. Zucker, 162 A.D.3d 1179 (3d Dept. 2018) According to the New York Law Journal, " the Third Department found this determination arbitrary and capricious". The MIF family in this case was requesting a lift to get their child in and out of a therapy spa. **(See attached Exhibit F, an excerpt from the article.)**

Since Luke was enrolled in the MIF in 2014, I had to fight for glasses, a handicapped rental van, dental bills, OTC laxatives, a wheelchair ramp, environmental modifications and most recently assistive technology.

In September 2018, the MIF hired a new administer, Public Consulting Group ("PCG"). A new director of Case Management, Michelle Clickner, has done her very best to help me. Unfortunately, she cannot run the MIF all by herself. A statutory advocate and a creation of advisory panel will go far to act a backstop to the abuse of power and indifference we the families have faced over the years.

Please Chairman Weinstein, I just want to focus on my son.
We need an ombudsman.
We need an advisory panel to protect us from harmful amendments.

In the Bill's Justification section, State Senator Hannon specifically referenced me, "One parent, who is a lawyer by trade, testified to the need of a patient advocate". Please assign great weight to this letter as this Bill was created on my behest. Once the Bill is sent to the floor I will make an effort to contact each assemblyman to tell them my personal story. A story that is the same for each and every MIF family!

Doctors Hospital seeking legislative support for new obstetrics program

By: Tim Curtis Daily Record Business Writer February 20, 2020

Doctors Community Hospital in Lanham.

Believing too many Prince George's County residents go outside of the county for health care, Doctors Community Hospital plans to create an obstetrics program, allowing more babies to be delivered in the county.

Doctors and Anne Arundel Medical Center, which recently joined together to form the Luminis Health system, plan to brief the Prince George's County House Delegation in the next few days, according to lawmakers and a hospital spokesman.

Prince George's residents particularly seek care outside the county when it comes time to deliver babies. An estimated 80% of babies born to Prince George's residents are born outside of the county.

Two county hospitals — University of Maryland Prince George's Hospital Center and MedStar Southern Maryland Hospital Center – provide delivery services.

Many Prince George's families go to Anne Arundel Medical Center for baby deliveries. Other hospitals patients choose include those in Montgomery County and Washington.

One of the benefits of Doctors and Anne Arundel joining forces under the Luminis brand, the hospitals said at the time, was to allow Anne Arundel to help Doctors with its community needs assessment and with any opportunities that arose out of that assessment.

It appears as though the obstetrics unit is a place where Anne Arundel's performance can help the Lanham hospital fill a need. A significant majority of the babies delivered outside of the county come from Doctors' service area.

The Doctors' unit would also be able to provide comprehensive women's health care, including breast health and cardiac care.

Convincing patients to stay in Prince George's County over delivering their babies in other counties was also an impetus in building University of Maryland Capital Region Medical Center in Largo, replacing the Prince George's Hospital Center.

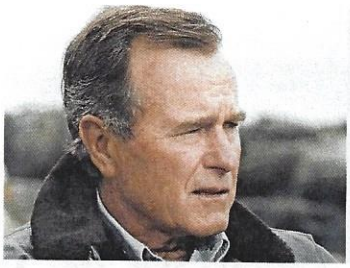
At the hospital's groundbreaking in 2017, U.S. Rep. Anthony Brown and then-County Executive Rushern Baker III, both Democrats, spoke about their difficulties having children in the county.

Brown said he was told by doctors that if he wanted them to deliver his wife's baby, he would have to find a different hospital than the one in Prince George's County. Baker said his plan was to have his first daughter at Providence Hospital, despite living down the road from the Prince George's Hospital Center in Cheverly.

"University of Maryland Capital Region Health supports greater county access for women who experience uncomplicated pregnancies," the system said in a statement. "We also, however, recognize the critical importance of keeping the care of high-risk pregnancies and newborns requiring neonatal intensive care within the county. As the only health system in Prince George's County that provides specialized obstetrics services to residents and their families, we look forward to continuing to provide this high-level of care in a new, state-of-the-art hospital in Largo, the University of Maryland Capital Region Medical Center, which is scheduled to open April 2021."

The two hospital systems have fought over programs in the past. When Anne Arundel Medical Center received a certificate of need to create a cardiac care program, University of Maryland Capital Region Health went to court to try to stop the program, saying it would take patients away from a program meant to be a crown jewel of the new hospital.

A Prince George's County Circuit Court judge ruled against Capital Region Health. The system dropped its appeal last April, allowing Anne Arundel to proceed with its program.



George H. W. Bush | 1924-2018

Leader of a nation, a family

He launched a dynasty, but first this proud public servant stayed true during a tumultuous era.

Washington Post

George H.W. Bush, the 41st president of the United States and the father of the 43rd, was a steadfast force on the international stage for decades, from his stint as an envoy to Beijing to his eight years as vice president and his one term as commander in chief from 1989 to 1993.

The last veteran of World War II to serve as president, he was a consummate public servant and a statesman who helped guide the nation and the world out of a four-decade Cold War that had carried the threat of nuclear annihilation.

His death, at age 94 on Friday, also marked the passing of an era.

Although Bush served as president three decades ago, his values and ethic seem centuries removed from today's acrid political culture. His currency of personal connection was the handwritten letter — not the social media blast.

» See BUSH, 7A

Tampa Bay Times

FLORIDA'S BEST NEWSPAPER | tampabay.com | ★★★★ Sunday, December 2, 2018 | $2

A TIMES INVESTIGATION

Johns Hopkins promised to elevate All Children's Heart Institute. Then patients started to die at an alarming rate.

Leslie Lugo's family visits her grave in September.

HEARTBROKEN

STORY BY KATHLEEN McGRORY AND NEIL BEDI, PHOTOS BY EVE EDELHEIT | *Times Staff*

Sandra Vázquez paced the heart unit at Johns Hopkins All Children's Hospital.

Her 5-month-old son, Sebastián Vixtha, lay unconscious in his hospital crib, breathing faintly through a tube. Two surgeries to fix his heart had failed, even the one that was supposed to be straightforward.

Vázquez saw another mom crying in the room next door. Her baby was also in bad shape.

Down the hall, 4-month-old Leslie Lugo had developed a serious infection in the surgical incision that snaked down her chest. Her parents argued with the doctors. They didn't believe the hospital room had been kept sterile.

By the end of the week, all three babies would die.

The string of deaths in mid 2017 was unprecedented. Nurses sobbed in their cars. The head of cardiovascular intensive care sent an email urging his staff to take care of themselves and each other.

The internationally renowned Johns Hopkins had taken over the St. Petersburg hospital six years earlier and vowed to transform its heart surgery unit into one of the nation's best.

Instead, the program got worse and worse until children were dying at a stunning rate, a *Tampa Bay Times* investigation has found.

Nearly one in 10 patients died last year. The mortality rate, suddenly the highest in Florida, had tripled since 2015.

Other children suffered life-changing injuries. Jean Kariel Viera Maldonado had a heart transplant at All Children's in March 2017. Soon after, the stitching connecting the 5-year-old's new heart to his body broke, and he had a massive stroke. Today, he can no longer walk, speak or feed himself. His parents care for him full time.

» See CHILDREN, 12A

EIGHT CHILDREN: All of these kids went to the Heart Institute and had problems with their care. Four died. Read their stories, beginning on **12A**.

Vol. 135 No. 131

EVE EDELHEIT | Times

Sebastián Vixtha was supposed to be 'completely normal' after surgery.

The doctors who diagnosed Sebastián Vixtha's heart defect told his mother it was serious. But they were hopeful about his long-term prognosis, as long as he underwent three surgeries. "He's going to be normal, completely normal," Sandra Vázquez recalled them saying. At 2 weeks old, Sebastián survived a risky heart surgery at All Children's and returned home. But one month later, he started vomiting and had to return to the hospital. While he was there, his heart stopped. The doctors said his aorta had narrowed. They tried to open it up two different ways. Sebastián seemed to be getting better, so the doctors scheduled another surgery in May. "They clearly told us that this surgery would be less risky than the first," his mother said in Spanish. But after that procedure, Sebastián suffered a second heart attack. He died on June 1, 2017.

EVE EDELHEIT | Times

Leslie Lugo picked up a serious infection in the hospital.

Leslie Lugo was born Jan. 2, 2017, with Down syndrome and a number of serious heart defects often associated with it. Her first procedure on Jan. 12 went well, records show. But after a second surgery that March, she developed an infection deep in her surgical wound. Peer-reviewed research shows such infections occur in fewer than 5 percent of heart surgery cases. The doctors and nurses spent eight weeks treating Leslie's infection with antibiotics and a wound vacuum system. She needed another surgery after that and came out too weak to breathe or pump blood to her body on her own. She died a few days later on May 30.

Leslie's mother, Ma Candelaria Tellez, said her doctors had told her All Children's was the best hospital. In the end, she felt deceived. "I don't recommend this hospital to anyone," she said in Spanish.

Leslie is buried at a cemetery beside the interstate near the family's home in Dover. On a windy afternoon this September, her family visited the grave with two bunches of roses, one red, the other pale peach. Her mother washed her headstone, removing the browned leaves and branches that had blown onto the plot. Her father strung up a balloon with the characters from the movie *Frozen*. The family of five huddled together, the mother's gaze fixed off in the distance. They stayed until it started to rain.

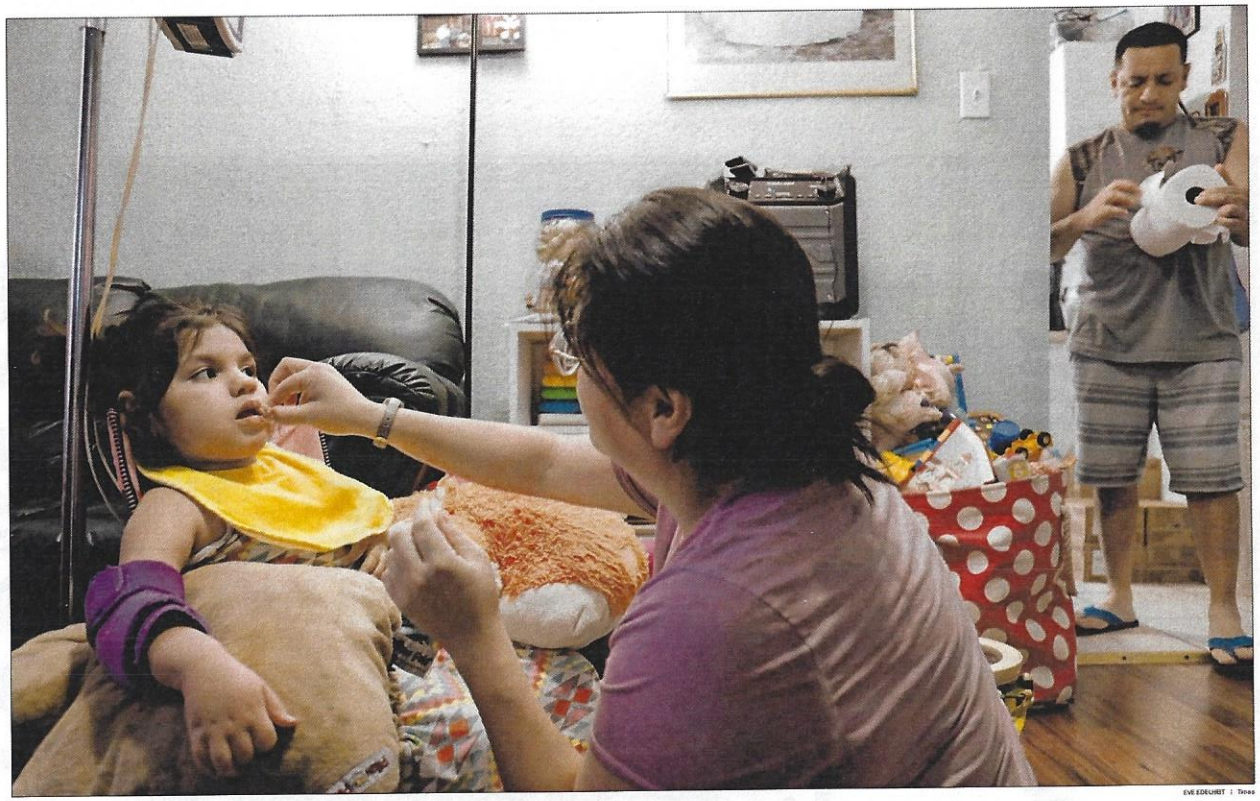
NEIL BEDI | Times

Madeline Rebori traveled 900 miles to be saved.

Not long after Madeline Hope Rebori was born in 2015, a cardiologist at the All Children's Hospital Heart Institute said nothing could save her, her parents recalled. Her family got a second opinion from a Stanford doctor, then took her to Cincinnati Children's Hospital, where surgeons performed a life-saving surgery. Madeline is now 3 years old. She takes tap and ballet. She performed to *I'm a Little Teapot* at a recent recital. Madeline still needs one more surgery for her heart to be fully repaired. Her parents, Brian and Stephanie Rebori, are optimistic. They intend to take her back to Cincinnati.

En español

Para leer en español en Centro Tampa, visite **tampabay.com/corazonroto**



EVE EDELHEIT | Times

» CHILDREN

continued from 1A

Times reporters spent a year examining the All Children's Heart Institute — a small, but important division of the larger hospital devoted to caring for children born with heart defects.

They compared Florida's 10 pediatric heart surgery programs by analyzing a state database of 27 million hospital admissions spanning a decade. Then they reviewed thousands of pages of medical reports, interviewed current and former hospital workers, spoke with top health care safety experts and tracked down families across Central Florida coping with catastrophic outcomes.

They discovered a program beset with problems that were whispered about in heart surgery circles but hidden from the public.

Among the findings:

• All Children's surgeons made serious mistakes, and their procedures went wrong in unusual ways. They lost needles in at least two infants' chests. Sutures burst. Infections mounted. Patches designed to cover holes in tiny hearts failed.

• Johns Hopkins' handpicked administrators disregarded safety concerns the program's staff had raised as early as 2015. It wasn't until early 2017 that All Children's stopped performing the most complex procedures. And it wasn't until late that year that it pulled one of its main surgeons from the operating room.

• Even after the hospital stopped the most complex procedures, children continued to suffer. A doctor told Cash Beni-King's parents his operation would be easy. His mother and father imagined him growing up, playing football. Instead, multiple surgeries failed and he died.

• In just a year and a half, at least 11 patients died after operations by the hospital's two principal heart surgeons. The 2017 death rate was the highest any Florida pediatric heart program had seen in the last decade.

• Parents were kept in the dark about the institute's troubles, including some that affected their children's care. Leslie Lugo's family didn't know she caught pneumonia in the hospital until they read her autopsy report. The parents of another child didn't learn a surgical needle was left inside their baby until after she was sent home.

The *Times* presented its findings to hospital leaders in a series of memos in early November. They declined interview requests and did not make the institute's doctors available to comment.

In a statement, All Children's did not dispute the *Times*' reporting. The hospital said it halted all pediatric heart surgeries in October and is conducting a review of the program.

"Johns Hopkins All Children's Hospital is defined by our commitment to patient safety and providing the highest quality care possible to the children and families we serve," the hospital wrote. "An important part of that commitment is a willingness to learn."

All Children's isn't the first hospital to struggle with pediatric heart surgeries. Several heart programs, including one at St. Mary's Medical Center in West Palm Beach, have shut down after reports of high mortality rates.

Most pediatric heart surgeries involve stopping a child's heart and operating in a space no larger than a walnut shell. But advances in science and technology have made them strikingly safe. In Florida, the survival rate for children who have surgery to correct a heart defect is now 97 percent, the *Times* found.

All Children's had earned a reputation as a community treasure that parents could trust to guide them through the terrifying experience of having a seriously ill child. Under Johns Hopkins, everyone assumed it would only get better.

"You hear Johns Hopkins, there's a sense of prestige," said Rosana Escamilla, whose daughter Alexcia suffered a stroke after heart surgery in 2016. "You think your child is in the best hands."

Instead, operations that surgeons described as low risk began failing.

"Somebody has to do something," Sandra Vázquez remembers one of the other mothers telling her in a quiet corner of the unit, "because they are killing our children."

In interviews in April and May, All Children's CEO Dr. Jonathan Ellen told the *Times* that the Heart Institute had its "challenges" under control. It had slowed surgeries to the lowest level possible without shutting down.

"We've already self-policed our way out," Ellen said, noting that the hospital had been performing only low-complexity heart operations for much of 2017.

It was a tacit acknowledgment that All Children's hadn't been able to perform the hardest heart procedures.

But the hospital couldn't handle the less complicated cases either, records and interviews show.

'Maybe they should have hit the pause button.'

As a newborn in 2013, Alexcia Escamilla survived one of the most difficult procedures in pediatric heart surgery. But after another surgery in 2016 — a procedure that was supposed to be much less risky — Alexcia suffered a stroke that left her unable to walk or speak. Her mother, Rosana Escamilla, never allowed herself to believe the doctors were at fault. A woman of faith, she held a conviction that God had his reasons. Alexcia's father, Oscar, quietly harbored doubts.

Two years later, when Rosana learned other children's surgeries had gone badly, she spread out her daughter's medical records and began closely studying each detail. "If there was such turmoil they should have stopped and said, 'We are going through some changes,'" she said. "Maybe they should have hit the pause button."

NEIL BEDI | Times

Ca'terriunna McGowan needed a new heart.

Twelve days after she was born, Ca'terriunna McGowan went to Johns Hopkins All Children's Hospital in hopes of getting a new heart. She was designated high priority on the transplant waiting list. Ca'terriunna had been sedated for most of her life. As she waited for her new heart, she grew sicker. In January 2018, her blood tested positive for a bacterial infection. In March, her heart rate was erratic. Her new heart came in early May. The transplant was a success, records show, but complications continued. Her kidneys and liver started to fail. "She was going downhill," recalled her father, Glen McGowan, as he stood outside his house and clutched photos of Ca'terriunna before and after her operation. At the end of May, Ca'terriunna was placed on heart and lung support. She died in June.

Bigger ambitions

All Children's Hospital opened in St. Petersburg in 1926 as the American Legion Hospital for Crippled Children. Over the decades, it had grown into a profitable children's hospital, locally run and independent.

But members of its board had bigger ambitions. They wanted a partner to raise the hospital's profile.

In 2011, they effectively gave the hospital to the Baltimore-based Johns Hopkins, which was in the midst of expanding into a $6 billion global health system. All Children's would be its 6th hospital.

Johns Hopkins is considered the birthplace of modern American medicine. At the time, its flagship hospital had held the top spot on *U.S. News & World Report*'s rankings for 21 straight years.

By the end of 2012, two longtime Hopkins faculty members were appointed to key roles in St. Petersburg.

Ellen, the director of pediatrics at the Johns Hopkins Bayview Medical Center in Baltimore, replaced the hospital's CEO. And Dr. Paul Colombani, the director of pediatric surgery at the Johns Hopkins Children's Center, became chief of pediatric surgery.

The new leaders took special interest in the All Children's heart surgery program, already one of the best in the state, but not among the ranks of the country's elite.

The goal was to build a "top-flight, excellent program that could provide unique care for children," Ellen told the *Times* in April.

The hospital's heart surgeons were already performing about 200 procedures annually.

Dr. James Quintessenza, the chief of pediatric heart surgery, took the most cases, including many of the hardest ones. He had consistently good results.

Dr. Jeffrey Jacobs performed surgeries, too, but was a leader outside the operating room. He edited academic journals, spoke at conferences around the world and sat on committees devoted to improving safety.

A third surgeon, Dr. Paul Chai, operated at All Children's only occasionally.

In 2013, Chai left for a job in New York. The hospital's new leaders replaced him with Dr. Tom Karl, then 65, who had spent the previous six years practicing at a children's hospital in Australia.

Karl had worked at some of the nation's best pediatric heart surgery programs and published more than 100 peer-reviewed papers. But in 2008, the University of California San Francisco had suspended his clinical privileges amid allegations he "disrupted patient care and educational activities," he later told the Florida Board of Medicine. He said internal politics were to blame.

After Karl arrived in St. Petersburg, the hospital's administration made a consequential change. For years, All Children's cardiologists sent their most complicated cases to Quintessenza for surgery. Now all cases were to be distributed equally among Quintessenza, Karl and Jacobs.

■ See CHILDREN, 14A

The doctors

Dr. Jonathan Ellen

A longtime Johns Hopkins administrator, Dr. Jonathan Ellen came to All Children's in 2011 as physician-in-chief, and was later promoted to CEO. He set out to turn the Heart Institute into one of the nation's top programs.

Dr. Paul Colombani

Dr. Paul Colombani is the chief of surgery at All Children's. He came to the hospital after 20 years as the chief of pediatric surgery at the Johns Hopkins Hospital in Baltimore. Multiple employees voiced concerns about surgeries to him as early as 2015.

Dr. Jeffrey Jacobs

An editor of multiple medical journals and frequent speaker at conferences, Dr. Jeffrey Jacobs is known for his academic work. Employees started expressing concerns about his surgeries in 2015.

Dr. Tom Karl

All Children's hired veteran heart surgeon Dr. Tom Karl in 2014 from a children's hospital in Australia. Employees started expressing concerns about his surgeries in 2015.

Dr. James Quintessenza

Dr. James Quintessenza was an All Children's pediatric heart surgeon for almost 30 years. After disagreements with Colombani, he was demoted and pushed out in 2016.

Dr. Nhue Lap Do

Dr. Nhue Lap Do joined the All Children's Heart Institute surgical team in mid 2017, straight out of fellowships at the Johns Hopkins Hospital and the Children's Hospital of Philadelphia.

Photos from Times archives, the *Baltimore Sun* (1976), *All Children's* press release, the *San Francisco Chronicle* (2002) and UF Health Care.

EVE EDELHEIT | Times

» CHILDREN
continued from 13A

As Ellen continued to fold All Children's into Johns Hopkins, relationships with teams of private-practice cardiologists and critical care doctors who had played key roles in the unit began to fall away. Johns Hopkins preferred to use its own employees.

"Disrupting a chemistry in that program was what led to the problems that they have today," said Dr. Al Saltiel, who was the president of the critical care group. "You can't replace the entire team at the same time."

The changes troubled Quintessenza. After disagreements with Colombani, he was demoted, then pushed out of the program in June 2016. He had been at the hospital for almost three decades.

By the end of the year, Quintessenza was named chief of pediatric cardiothoracic surgery at Kentucky Children's Hospital. He declined to comment.

Colombani referred questions to an All Children's spokeswoman.

Midway through 2017, All Children's replaced Quintessenza with a young heart surgeon, Dr. Nhue Lap Do, straight out of fellowships at the Johns Hopkins Hospital and the Children's Hospital of Philadelphia.

Karl and Jacobs would handle all of the hardest cases.

'Take her home and love her'

Medical professionals noticed problems with surgeries performed by Karl and Jacobs as early as 2015.

Their patients were returning to the operating room to deal with unforeseen complications, six current and former employees told the *Times*.

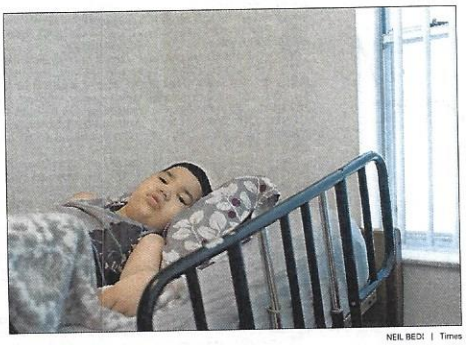
Parents who had chosen the program for its strong reputation began having confounding experiences.

Madeline Hope Rebori was born with a complex heart condition in June 2015. Karl had already met her parents, who recall him saying the condition could be repaired with surgery. But after Madeline arrived, a different All Children's doctor told them nothing could save her, they said.

His instructions to the family: "Take her home and love her."

It is not clear who made the decision. But Brian Rebori was stunned. He asked to speak with Karl. The hospital would not make the surgeon available, he said.

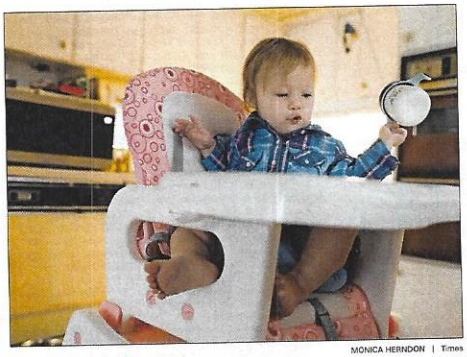
The father found a surgeon at Stanford University Medical Center who agreed to review Madeline's records. In a letter, the surgeon acknowledged that her heart condition was an unusual variant of a defect called Tetralogy of Fallot. But his team had seen dozens like it and had repaired "a great majority" surgically, he said.



NEIL BEDI | Times

Jean Kariel Viera Maldonado's stitches broke, with life-changing results.

Jean Kariel Viera Maldonado first got sick in Puerto Rico, where his family lived. One hospital sent him to another. It was a cardiologist who realized his heart was enlarged and said he might be a candidate for a transplant. For that, however, he would need to leave Puerto Rico. The cardiologist recommended three hospitals: the Children's Hospital of Philadelphia, Boston Children's and Johns Hopkins All Children's. Jean Kariel's parents chose All Children's because they had family in Florida. Before the transplant in 2017, the family visited Walt Disney World. Jean Kariel sprinted through the parks and rode the junior rollercoaster. His parents hold on to that memory. Shortly after the March transplant, the stitching connecting Jean Kariel's new heart to his body broke, and he suffered a debilitating stroke. He can no longer walk. As he keeps growing, it's getting harder to maneuver him around the house and into the car. His parents worry about what's to come.



MONICA HERNDON | Times

Katelynn Whipple left the hospital with a needle in her chest.

Katelynn Whipple needed emergency heart surgery soon after her birth in July 2016. Her aorta, the body's main artery, needed to be lengthened. Her parents thought the surgery went well. But at a followup appointment days after she was discharged, they learned an All Children's surgeon had left a needle in their daughter's chest. Katelynn's parents took her back to the hospital and asked Dr. Tom Karl to remove the needle. Karl said the needle didn't exist, Katelynn's parents told the *Times* earlier this year. The needle was removed during a later surgery at St. Joseph's Children's Hospital in Tampa. All Children's ultimately settled with Katelynn's family. The hospital will give her $5,000 annually for four years beginning on her 18th birthday, and $25,384 on her 25th birthday, records show.

Cash Beni-King's parents begged doctors to fight for him.

Cash Beni-King had multiple surgeries in the five months he was alive. After the first, his tiny heart was too weak to work on its own. After the second, a stroke left him paralyzed. Cash died on July 4, 2017. His younger brother is named Zven, pronounced "seven" and spelled with four letters in memory of the day Cash died. Cash's mother, Yinisi Beni, recently created a remembrance wall in the living room, hanging photos of Cash around words like "family" and "love." Looking at it brings her to tears. His father, Gold King, said he blamed himself for a while. He believes things would be different if he had chosen another hospital for his son. "He would still be here with us," he said.

All Children's later conceded that a procedure could be done, medical records show. Madeline's parents took her to a hospital in Cincinnati, where she had life-saving surgery that August. She turned 3 this year.

"I went from planning a funeral to planning a life," Brian Rebori said.

Surgical intervention is almost always recommended for babies with Madeline's condition, even if the first step is to improve the baby's chance of survival, said Dr. Michael Monaco, a pediatric cardiologist at Morgan Stanley Children's Hospital in New York.

Back at the Heart Institute, things got worse after Quintessenza left in June 2016. With Karl and Jacobs as the only surgeons, the program experienced its highest six-month mortality rate in eight years, the *Times* analysis shows. At least four children died.

Karl and Jacobs each declined to comment when reached by *Times* reporters. They referred questions to the hospital and did not respond to emails outlining the *Times*' findings. The emails did not bounce back.

In one 2016 case, which the *Times* first reported in April, Karl left a surgical needle in the aorta of newborn Katelynn Whipple. Other physicians knew it was there. Nonetheless, Katelynn was discharged with the needle in her body. It was removed three weeks later during an unrelated surgery at St. Joseph's Children's Hospital in Tampa, records show.

Leaving a surgical needle inside a patient is virtually always a serious, preventable mistake. It happened two times that year in the Heart Institute, All Children's acknowledged in April.

In June 2016, Jacobs and Karl operated on 3-year-old Alexcia Escamilla.

Alexcia had been born with a heart condition requiring three surgeries. She had already undergone one of the most challenging procedures in pediatric open-heart surgery as a newborn, performed by Quintessenza. About one in five patients die.

She survived it, and a second surgery by Quintessenza.

Alexcia grew into a happy toddler who danced around the house and chased children at parties. She played with dinosaurs and trains, never dolls. She preferred her hair in a side ponytail. She couldn't wait for the bus that took her to preschool. Some afternoons, when it took her home, she stood firmly on the top step, refusing to climb down.

The final surgery was supposed to be much less risky than the first. The chance of complications — bleeding, infection, stroke, major organ system injury, death — was in the 2 percent to 3 percent range, according to her medical records.

This time, Jacobs took the lead. Karl assisted.

After surgery, blood began pooling around Alexcia's lungs. A vein in her esophagus had burst. It isn't clear why. She had to return to the operating room.

The next day, nurses noticed Alexcia was less responsive. A brain scan showed she had suffered a stroke. Neurosurgeons removed a portion of her skull, so her brain had room to swell. She was put in a medically induced coma.

When Alexcia woke up, she could no longer control her movements or stabilize her neck. She looked "like Gumby," recalled her mother, Rosana Escamilla. Alexcia stared vacantly at her parents.

"She lost everything I loved about her," Escamilla said.

Strokes during or after pediatric heart surgery are rare. One peer-reviewed study found they happen in 5 percent of cases. Another pegged the rate as lower than 1 percent.

A variety of factors can cause a stroke, said Dr. Francisco Puga, professor emeritus of cardiovascular surgery at the Mayo Clinic. He said poor surgical technique is one of them.

Internal warnings

The errors and rising death rates weren't the first indications hospital leaders had that the program was in trouble.

Late in 2015, the four physician assistants who worked in the operating room called for a meeting with their supervisor and Colombani, the chief of surgery. They brought up specific operations that had gone badly and expressed doubt in Karl's and Jacobs' surgical abilities, according to several people with

» See CHILDREN, 15A

Times file (2009)

Eight years ago, All Children's Hospital was an independent and profitable institution. Board members wanted to elevate its reputation and turn it into an academic and research hospital. They effectively gave the hospital to Johns Hopkins in 2011. The new leaders transformed the hospital's heart surgery unit.

» **CHILDREN**
continued from 14A

direct knowledge of the meeting. They spoke on condition of anonymity, worrying that going public could hurt their careers.

That December, the physician assistants had a second meeting about their concerns, this time with the surgeons, the department's leadership team and the hospital's new director of human resources.

Karl and Jacobs continued operating.

Four other medical professionals working in the institute told the *Times* they were so worried about patient safety that they met with their supervisor, human resources or the hospital ombudsman in 2015 or 2016. Three said they named Karl, Jacobs or both surgeons in the conversation.

One former All Children's cardiologist, Dr. Elise Riddle, also noticed poor results. She discussed her experiences in sworn testimony in June 2018 as part of a hearing to determine whether her current employer, Arnold Palmer Hospital for Children in Orlando, should be allowed to open a pediatric heart transplant program.

Riddle testified that she could not access comprehensive data on the All Children's Heart Institute's performance, even as chairwoman of the program's quality improvement committee.

"Essentially all cardiologists were forbidden from looking at our outcomes data," she said.

Riddle added that the administration and the surgeons had "squashed transparency" by prohibiting discussion on ways to improve care.

"Multiple levels of administration had actually tried to hide some outcomes," she said.

Riddle left in 2016. The four physician assistants left, too, along with several doctors, nurses and other medical professionals in the unit. Riddle described it as "a mass exodus."

She declined to be interviewed by the *Times* but provided a statement calling for a "detailed, external review of the cardiovascular surgical outcomes, major complications, deaths, volumes, and the degree of or lack of transparency."

'Suboptimal outcomes'

In early 2017, the hospital's leaders took a step that showed they recognized the program was struggling.

They started sending heart surgery patients younger than a month old to other hospitals, Ellen told the *Times*. Those are often the most difficult cases.

But the Heart Institute kept seeing patients with less complicated conditions.

The hospital said its heart surgery program admitted 106 patients last year. The method the *Times* used to identify cases in the statewide admissions data is conservative; it accounted for 83 patients.

Over the last decade, the program's surgical results had been on par with other Florida hospitals, the *Times* analysis shows. By 2017, that had changed.

Heart surgery patients at All Children's last year were three times as likely to die as those across the state.

They were four times as likely to come out of surgery needing a machine to do the work of their hearts and lungs.

Their surgical wounds were five times as likely to split open.

They took twice as long to recover from surgery.

They were three times as likely to become septic, a potentially deadly response to infection.

Leslie Lugo, Cash Beni-King and Jean Kariel Viera Maldonado all developed infections in the hospital after surgery, their medical records show. The Centers for Disease Control and Prevention considers infections "largely preventable" in a sterile hospital environment. Experts say a spike can indicate broader problems in a surgical unit.

Jean Kariel was 5 in March 2017 when he received a heart transplant. Karl was the lead surgeon. His parents were told the procedure went smoothly, they said. But when Jean Kariel returned from the operating room, he screamed for water.

His blood pressure plummeted. Karl rushed him back into the operating room.

That's when physicians discovered the stitching connecting his new heart to a vein called the inferior vena cava had broken, leaving him bleeding internally for 20 minutes. He had a stroke that damaged much of his brain, his records show.

Jean Kariel's parents said they were told stitches had never broken like that after a heart transplant at All Children's. One critical-care doctor told his family "they were making a sincere attempt to find the cause of this unexpected complication," Jean Kariel's medical records show.

All Children's never told them anything more about it, they said.

Before the procedure, Jean Kariel played soccer and rode horses with his father near their home in the Puerto Rican countryside, his parents said.

Now he's in a wheelchair, mute.

"I had a child who walked and talked, and they returned him to me like this," his mother, Karen Maldonado, said in Spanish.

Later in the spring of 2017, Sebastián Vixtha, Leslie Lugo and another baby died within a week.

The deaths prompted the Heart Institute's nursing director, Lisa Moore, to send an email to the institute's staff about the "suboptimal outcomes in our surgical program." She said the program's leaders recognized "the gravity" of employee concerns and were working on a "structured action plan."

Around that time, 3-month-old Cash Beni-King had a patch sewed over a hole in the center of his heart.

The operation's expected survival rate: 95 percent.

Karl performed the procedure in June 2017; Jacobs assisted. The surgeons believed the hole was closed completely, according to Karl's notes on the procedure. But tests proved otherwise. They reinforced the patch with additional stitches.

Cash came out of the operating room attached to a heart and lung support machine. Multiple attempts to wean him off the machine over the next week failed. Karl performed another surgery to reinforce the stitches around the hole. Shortly after, Cash suffered a serious stroke.

On July 3, 2017, Jacobs told Cash's parents there was no way to save him. The next day, as his parents begged doctors to keep him alive, Cash was disconnected from heart and lung support. Distraught, Cash's father broadcast his son's last moments on Facebook.

At least one other baby died before Ellen had what he described as a "hard conversation" with Karl. They decided Karl should focus on mission work and academics, instead of operating at the hospital, Ellen said in April. Karl remained on staff.

Not long after, in November 2017, a team from the top-ranked Texas Children's Hospital came to St. Petersburg to evaluate the heart surgery unit. Ellen said the hospital asked for the review. He has repeatedly declined to release the team's report.

By the end of December, at least eight children had died.

The hospital could have sent many of those cases to other heart surgery programs. There are five in Central Florida alone, including St. Joseph's in Tampa.

'New heights'

Even as turmoil engulfed the Heart Institute, Ellen announced he wanted to expand it.

In May 2017, he sent an email to hospital staff announcing moves that would support "continued growth of our program," including a promotion for Jacobs to co-director.

"Our combined efforts over the past six years have pushed the quality and safety of our cardiac care forward," Ellen wrote. "The time has come for us to leap to new heights of innovation."

Growing programs like the Heart Institute had been central to Johns Hopkins' strategy from the beginning.

In 2012, Johns Hopkins rolled out an ambitious plan to create new revenue sources that would ultimately double its profit, adding between $150 million and $200 million over the next few years. A portion of the money was expected to come from expanding "high-demand, high-revenue" specialty centers, company newsletters show.

The All Children's Heart Institute fit the bill.

Heart surgery patients represent less than 3 percent of All Children's admissions. But in recent years, they have been responsible for between 13 percent and 17 percent of the hospital's total billing, the *Times* analysis shows. Heart patient billing peaked at $142 million in 2014.

The year that eight children died, the unit's patients were billed $83 million — 10 percent of the hospital's total.

The hospital billed another $28.5 million for 31 admissions to the Heart Institute in the first quarter this year, the latest data available.

How much of that the hospital received is unclear. Private insurers and federal programs like Medicaid and Medicare negotiate or set their own reimbursement rates, typically below full value. The final payments aren't tracked in the state admissions data.

Ellen told the *Times* in May that patient safety and quality — not money — drive the hospital's decision-making.

"I don't actually know how much money the program makes," he said.

In April 2018, the hospital began flying in a surgeon twice a month from the Johns Hopkins Hospital in Baltimore to lead all heart operations, Ellen said. But the arrangement ended after six months, when the surgeon took a job in Chicago.

Although Jacobs and Do are still listed as surgeons on All Children's website, the hospital isn't performing heart surgeries, according to its statement to the *Times*. Karl was removed from the website in July. The hospital didn't answer questions about whether he is still employed.

Public face

The Heart Institute's marketing efforts bore little resemblance to what was actually happening inside the operating room.

Online, as recently as September 2017, the Heart Institute called itself "a leading pediatric cardiac surgery and cardiology program in the United States" that provided the "highest level" of care.

At one point that year, a video on the All Children's Facebook page touted: "Johns Hopkins All Children's Heart Surgery Program performs 1000+ heart surgeries per year."

Actually, the Heart Institute performed 164 procedures on 106 patient admissions last year, Jacobs told the *Times* in April.

Dr. Jorge McCormack, a private-practice cardiologist with privileges at the hospital, sent a screenshot of the video to a state oversight committee in November 2017, raising concerns about "overzealous" and potentially inaccurate marketing efforts.

The hospital removed the video.

Few of the parents the *Times* interviewed were aware of the Heart Institute's struggles at the time of their children's surgeries. None who lost children filed lawsuits, and there is no public sign of any investigations that predated the *Times*' reporting.

Some parents have since learned the hospital withheld information about their children's care.

Katelynn Whipple's parents didn't know a needle had been left in her chest until after she was discharged from the hospital, they told the *Times*. They returned and demanded the needle be taken out. Karl denied it existed, they said.

After the *Times* detailed her case, regulators cited All Children's for not telling Katelynn's parents and for not properly reporting the incident to the state, both violations of state law. Regulators also cited the hospital for not disclosing the second needle incident that year.

Ma Candelaria Tellez said she discovered her daughter Leslie Lugo had picked up pneumonia in the hospital only by reading her autopsy report.

Tellez became suspicious while her daughter was still alive. She said she noticed a milky substance leaking from Leslie's surgical wound after her second heart surgery in March 2017. The doctors denied Leslie had an infection for a week, she said.

Leslie's medical records show that she had mediastinitis, an infection that can develop after heart surgery if a caregiver or instrument is contaminated. It occurs in fewer than 5 percent of pediatric heart surgery cases and can be linked to the expertise of the surgical team, according to published research.

Doctors told Leslie's family that infections were "normal" and "happen all the time," her mother recalled.

What if

Glen McGowan remembers when the doctors at Arnold Palmer Medical Center told him in late 2017 that his newborn daughter, Ca'terriunna, would need a heart transplant.

He will never forget how one doctor reacted when he said he was transferring her to All Children's.

"The doctor grabbed me by the arm and he said, 'Please, don't take your baby there.'" McGowan recalled.

But the family's Jeep was having problems. All Children's was an hour closer than the second nearest option. McGowan felt he had no choice.

Ca'terriunna got a transplant, performed by Do and assisted by the veteran Johns Hopkins surgeon who was flying in from Baltimore. She died at All Children's in June. Medical records show sepsis contributed to her death.

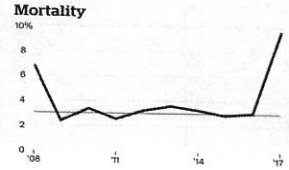
Months later, McGowan stood outside his Avon Park home, clutching two framed photos of Ca'terriunna. His voice got quiet.

"I should have listened to that doctor," he said.

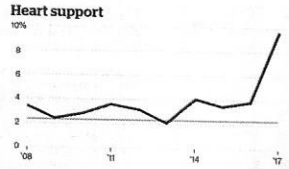
Problems increase

Each of the following charts represents a metric that can indicate problems in a pediatric heart surgery unit. At the All Children's Heart Institute (—) every one spiked in 2017 to be much higher than the 10-year average (---) for programs across the state.

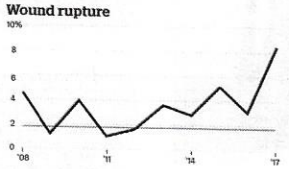
Mortality



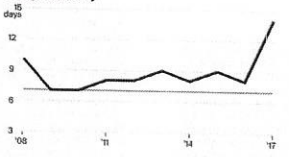
Heart support



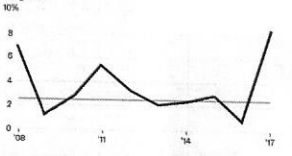
Wound rupture



Length of stay



Sepsis



No one forces children's hospitals to report these outcomes publicly. All Children's publishes four-year mortality averages, but including four years of data can mask recent problems. The *Times* produced single-year figures by analyzing millions of rows of billing data that track individual admissions to hospitals across Florida. For details on how the analysis was performed — including the full results, actual computer code and how it was vetted — visit **tampabay.com/heartdata**.

'She lost everything I loved about her'

Her surgery was supposed to be low risk. But an unusual complication changed Alexcia Escamilla's life. Watch the full video at **tampabay.com/heartvideo**.

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Johns Hopkins to pay nearly $40 million to two families hurt by All Children's heart surgeries

The hospital has been negotiating with 11 families; some were struggling to afford the immense cost of care.

Rosana Escamilla gives her daughter Alexcia tiny pieces of food to taste in their home in August 2018. Alexcia was left paralyzed after a heart surgery at John Hopkins All Children's Hospital. The details of her case match the public filing of a $12.75 million settlement the hospital recently signed with a family. [EVE EDELHEIT | Tampa Bay Times]

By **Kathleen McGrory** and **Neil Bedi**
Published Aug. 23, 2019
Updated Aug. 28, 2019

The families of two children who were paralyzed after heart surgeries at Johns Hopkins All Children's Hospital will receive $26 million and $12.75 million in settlements with the hospital, state records show.

Although the identities of the children are not public, the records describing their cases match two of the patients featured in a *Tampa Bay Times* investigation into the hospital's troubled heart unit. Both families were struggling with the costs of caring for a permanently disabled child with no relief in sight.

A third family that lost a child after heart surgery will receive $750,000.

Last year, the *Times* reported that the death and complication rates in the All Children's heart surgery unit had spiked in recent years, even after frontline workers warned supervisors about problems. The CEO, three other executives and two surgeons and stepped down after the *Times* investigation published and regulators demanded sweeping changes. The hospital has halted heart surgeries while it restructures the department.

RELATED COVERAGE: Johns Hopkins promised to elevate All Children's Heart Institute. Then patients started to die at an alarming rate.

All Children's spokeswoman Danielle Caci said she could not comment on the settlements "due to privacy concerns."

In June, Johns Hopkins Health System CEO Kevin Sowers told the *Times* that he and hospital leaders had reached out to the families of children who died or were injured in the hospital's heart surgery unit.

https://www.tampabay.com/investigations/2019/08/23/johns-hopkins-agrees-to-pay-nearly-40-million-to-two-families-hurt-by-all-childrens-heart-surgeries/

"We made a mistake, and we need to make sure we help support these families and make it right," he said.

The three newly disclosed settlements raise the amount the hospital has paid to families who sought treatment in the Heart Institute to more than $40 million. A fourth family whose daughter died after a heart transplant settled a legal claim for $2.35 million in May.

Additional settlements are expected. The health system disclosed to investors in February that it was negotiating with 11 families, admitting liability in most cases.

RELATED COVERAGE: These eight children went to the All Children's Heart Institute. Here's what happened to them.

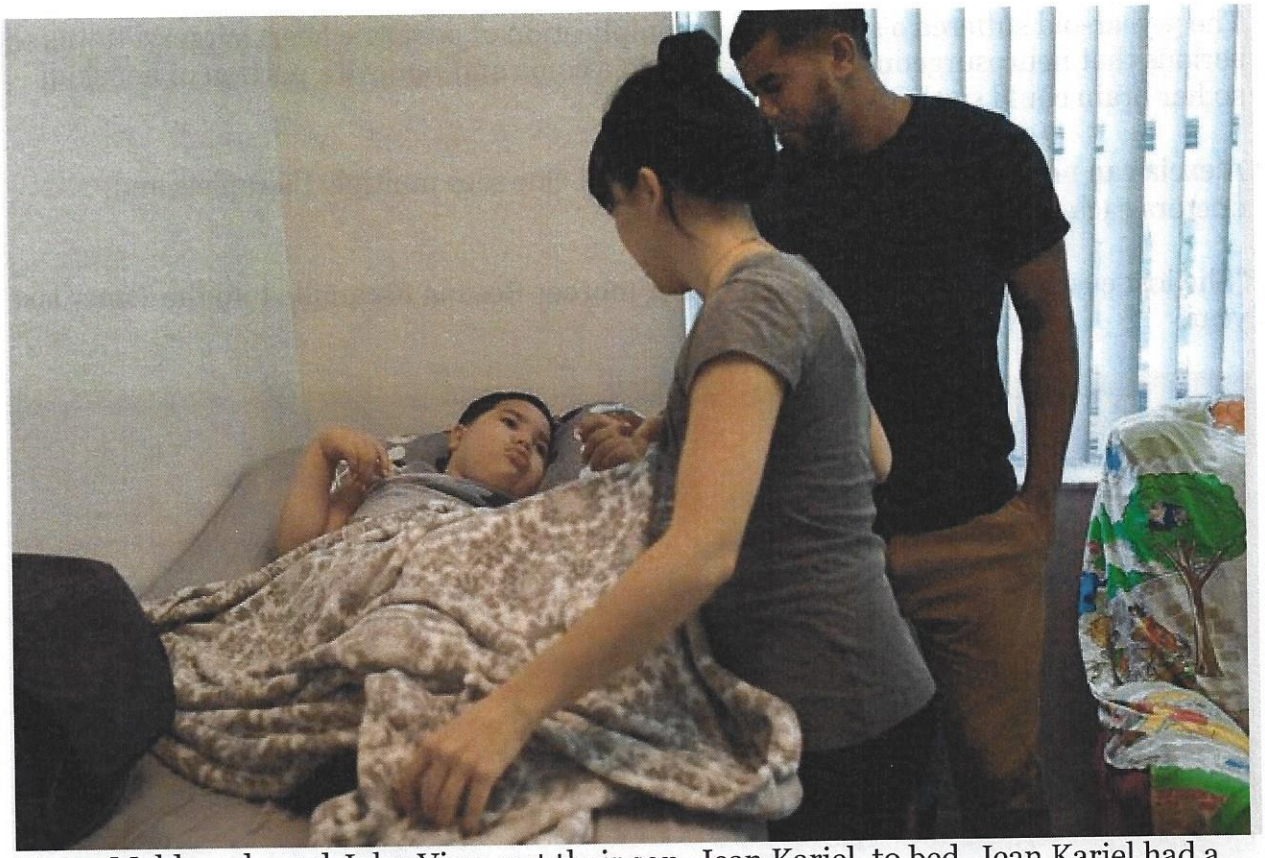
Most of the families featured in the *Times* story didn't know the unit had systemic safety issues before reporters approached them last year. The parents who believed problems had occurred with their children's care said that before the investigation published, they struggled to find lawyers willing to take their cases.

Malpractice settlements often include nondisclosure clauses that prohibit patients and their representatives from discussing the arrangements publicly.

But the settlements were recorded in an online database maintained by Florida's insurance regulator, along with some basic details on each case. Although the database does not typically list patient names, other details match two patients featured in the *Times*' reporting last year.

The $26 million settlement was for a male patient who suffered brain damage and lost the use of his limbs following a March 2017 heart transplant. His principal injury is described as a broken suture, the medical term for a stitch that holds tissues together after an injury or surgery.

Those details match the case of Jean Kariel Viera Maldonado, who suffered a massive stroke after a heart transplant in March 2017. His medical records, which his parents shared with reporters, show that the stitching connecting his new heart to a vein called the inferior vena cava had broken, causing him to bleed internally for 20 minutes.



Karen Maldonado and John Viera put their son, Jean Kariel, to bed. Jean Kariel had a stroke after a heart transplant at All Children's last year. His parents care for him full time. [NEIL BEDI | Tampa Bay Times] [NEIL BEDI | Tampa Bay Times]

Before the surgery, Jean Kariel was a vibrant 5-year-old who played soccer and rode horses. Since the transplant, he has been unable to walk, speak or feed himself.

His mother became his full-time caregiver in their small Central Florida apartment. But 18 months after the surgery, she was already having trouble maneuvering him into the car. She was worried about the day she could no longer lift him.

Reached by phone Wednesday, Jean Kariel's father, John Viera, declined to comment.

The $12.75 million settlement went to a female patient who had had a heart surgery known as a Fontan procedure in June 2016. The settlement record says the patient had internal bleeding and a stroke. She suffered severe brain damage and lost the use of her limbs.

Alexcia Escamilla had a Fontan procedure in June 2016.

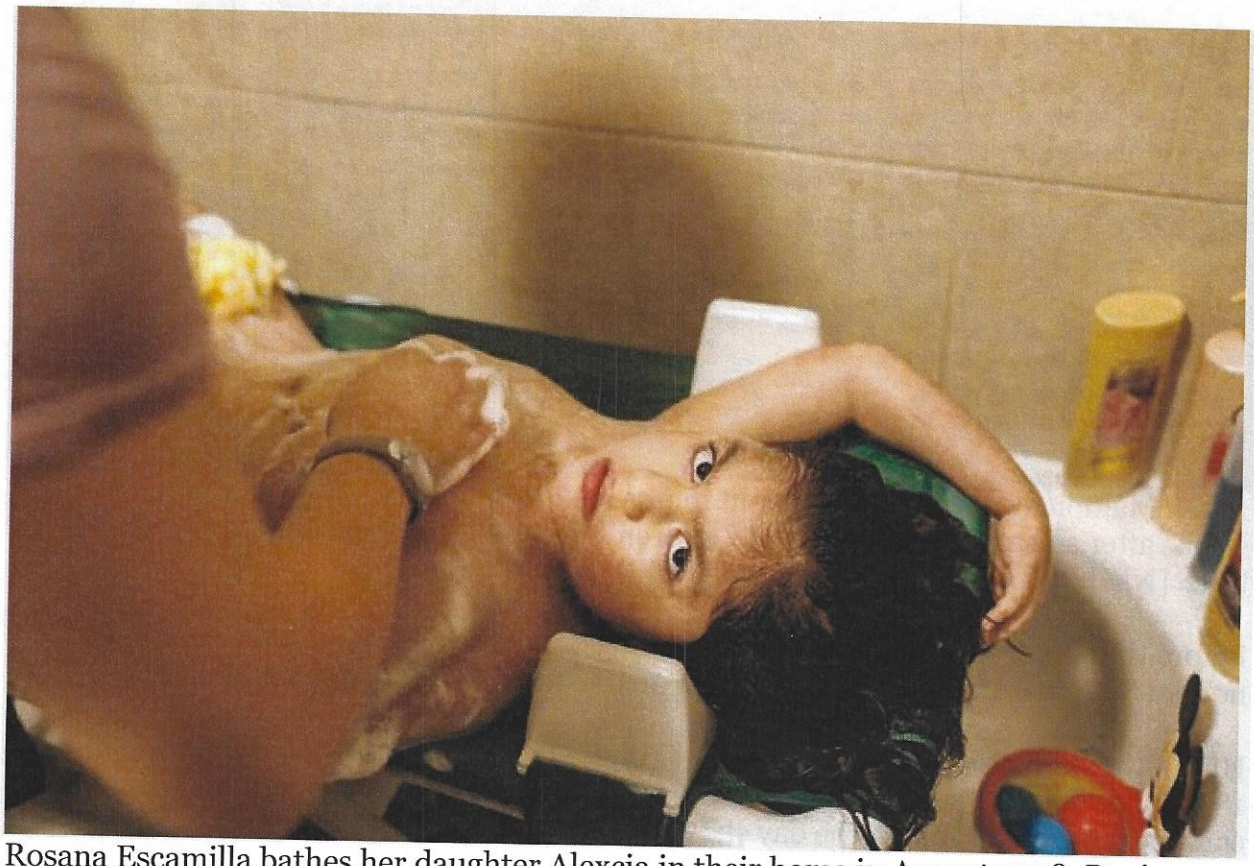
Her medical records, which her family shared with the *Times*, show that the chance of complications was in the 2 percent to 3 percent range. But after the operation, a vein burst and blood began pooling around her lungs.

https://www.tampabay.com/investigations/2019/08/23/johns-hopkins-agrees-to-pay-nearly-40-million-to-two-families-hurt-by-all-childrens-heart-surgeries/

The 3-year-old suffered a stroke, a rare complication of pediatric heart surgery. It was so serious that neurosurgeons had to put her in a coma and remove a portion of her skull so her brain could swell.

Alexcia can no longer speak or control her body. She sees multiple therapists and doctors each week.

"She lost everything I loved about her," her mother Rosana Escamilla told the *Times* last year.



Rosana Escamilla bathes her daughter Alexcia in their home in August 2018. During heart surgery at All Children's, Alexcia suffered from a stroke that left her unable to communicate. Alexcia has a special bed she uses while taking baths because she can't sit up by herself. [EVE EDELHEIT | Tampa Bay Times] [EVE EDELHEIT | Tampa Bay Times]

Escamilla declined to comment this week.

The family that will receive $750,000 lost a child who was injured in the hospital in the spring of 2017. Reporters were unable to identify the child based on the description of the case.

All three settlements, as well as the one from May, were reached outside of court, records show.

https://www.tampabay.com/investigations/2019/08/23/johns-hopkins-agrees-to-pay-nearly-40-million-to-two-families-hurt-by-all-childrens-heart-surgeries/

RELATED COVERAGE: Read all the *Times*' stories on the All Children's Heart Institute.

Experts say settlement amounts are typically based on the injured patient's medical expenses, the cost of future care and lost earning capacity, as well as pain and suffering. They also take into account what a jury might decide if the case went to trial.

Jorge E. Silva, a Miami-based medical malpractice attorney and adjunct professor at Florida International University College of Law, said it isn't unusual for claims involving children who suffered brain damage to result in multi-million dollar awards.

"If you get a life-care planner to say that taking care of this kid who is profoundly disabled is going to cost millions for the rest of their life, and you add to that the pain or suffering of this child, you can easily arrive at $10, $20, $30, $40 million," he said.

Families that lose children tend to receive smaller settlements because they do not have to shoulder the same long-term medical expenses. But each case is different. In 2018, St. Mary's Medical Center in West Palm Beach paid $8.9 million to the family of a child who died in its now-closed children's heart surgery department, records show.

In some high-profile cases, the hospital or doctor has an incentive to settle out of court, said Scott McMillen, an Orlando-based medical malpractice attorney who was not involved in the Heart Institute cases. That's because a jury may also choose to award punitive damages.

"It's what amount of money will it take to get the attention of the defendant," he said.

The problems in the All Children's heart surgery program began after Johns Hopkins took over the hospital in 2011 and made a series of personnel changes. Nurses and other frontline workers began noticing unusual complications as early as 2015 and warned their supervisors that children were being injured or dying after straightforward procedures. But the surgeries continued.

By 2017, All Children's had the highest death rate of any pediatric heart surgery program in the state in the last decade, a *Times* analysis of state data found. The rates of complications such as sepsis and wound ruptures had also spiked.

After the *Times* investigation, the hospital had to enter into a 12-month contract with the government promising additional oversight to avoid losing federal funding. State lawmakers also passed a law increasing oversight for pediatric heart surgery programs.

Johns Hopkins has vowed to make sweeping changes to its policies and structure, including new checks and balances on the hospital's president, more thorough vetting of doctors and improved monitoring of patient safety and quality metrics.

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https://www.tampabay.com/investigations/2019/08/23/johns-hopkins-agrees-to-pay-nearly-40-million-to-two-families-hurt-by-all-childrens-heart-surgeries/

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MARYLAND LAW ALREADY PROTECTS HOSPITALS AND HEALTH SYSTEMS WITH CHARITABLE IMUNITY ABOVE THE LIMITS OF THEIR AVAILABLE INSURANCE

Maryland hospitals and health systems claim that the global market for excess and reinsurance coverage is "hardening," thereby making such insurance coverage more expensive. They claim that large medical negligence judgments would "wipe out" a hospital or health system that didn't have enough medical professional liability insurance to cover the size of the judgment.

In fact, the Maryland Insurance Administration reports that health care professional liability insurance in Maryland is both available and affordable, because of increased competition among insurers who have entered the market to offer such coverage to Maryland physicians:

> The ***stable rate environment and the continuing availability of coverage in the Maryland market*** are positive indicators for health care providers. Likewise, the closed claim and filed lawsuit numbers remain substantially below peak levels of 2012 – 2013. ***This should encourage potential risk bearers that have previously declined to enter or expand their presence in the Maryland market*** during the previous times of less stability to take advantage of growth opportunities within the State.

Md. Ins. Admin., "2019 Report on the Availability and Affordability of Health Care Professional Liability Insurance," at 4 (Sept. 1, 2019) (emphasis added).

Even if a Maryland hospital was faced with extraordinary potential liability, Maryland law affords hospitals with charitable immunity above their available insurance coverage. Section 5-632(c) of the Courts and Judicial Proceedings Article provides:

> A hospital or related institution that is a charitable institution and is insured against this liability in an amount of not less than $100,000 is not liable for damages in excess of the limits of that insurance.

Md. Cts. & Jud. Procs. Code Ann. §5-632(c). Because all hospitals in Maryland are charitable institutions, they enjoy charitable immunity in excess of the limits of their available insurance. If a Maryland hospital or health system could not afford to purchase excess or reinsurance coverage on the global market, charitable immunity would protect against being "wiped out" by extraordinary potential liability.

Within the last decade, for example, The Johns Hopkins Hospital faced an extraordinary class action lawsuit arising from the wrongful conduct of its agent and employee, Nikita Levy, M.D. In court filings in that case, Jane Doe No. 1 *et al.* v. The Johns Hopkins Hospital, *et al.*, Case No. 24-C-13-001041 (Cir. Ct. Baltimore City), the Johns Hopkins Defendants asserted that charitable immunity protected them from liability in excess of their available insurance.

In the Order certifying the class action, the Hon. Sylvester Cox agreed that charitable immunity protected the Johns Hopkins Defendants from liability above $190 million:

(OVER)

10. In connection with the final certification of the Settlement Class, the Court makes the following findings with respect to Maryland Rule 2-231(b)(1)(B):

    a. The Johns Hopkins Defendants are charitable organizations, and therefore ***entitled to immunity*** for third-party tort claims under the Maryland doctrine of charitable immunity, ***except to the extent of available insurance***.

    b. The only assets potentially available to satisfy the Settlement Class members' claims are Johns Hopkins insurance policies, which are wasting policies.

    c. The $190,000,000 Class Action Settlement Amount represents the total assets available to satisfy the Settlement Class Members' claims, considering that:

        i. The limits of Johns Hopkins professional liability insurance would be substantially eroded (and indeed have already been substantially eroded) were Johns Hopkins to continue to defend this class action or, if decertified, lawsuits brought by individual Settlement Class Members; and

        ii. Johns Hopkins' insurers have raised certain defenses to coverage.

    d. In making the findings set forth in paragraphs 10.b and 10.c, the Court has considered the sworn testimony of James R. Murray, Esq., an attorney in the Washington DC office of Dickstein Shapiro, LLP, and a nationally regarded expert in insurance coverage issues. The Court finds that Mr. Murray's testimony is credible.

Order Granting Final Approval of Mandatory Class Settlement Agreement, dated September 19, 2014 (emphasis added). Because Maryland's law of charitable immunity protects hospitals and hospital systems beyond the limits of their available insurance, the liability of Johns Hopkins was limited to its insurance in the Levy Class Action.

In summary, radical and offensive "tort reform" like SB 879, the so-called Maryland Infant Lifetime Care Act, is completely unnecessary, because Maryland's hospitals and health systems are protected by charitable immunity from liability above the levels of their available insurance.

Charitable immunity protected Johns Hopkins from liability above its insurance coverage, and it would do the same for any other hospital threatened with extraordinary liability.

Accordingly, even if excess or reinsurance coverage is temporarily unavailable or unaffordable because of a hardening of the global market for such coverage, ***that would not be a crisis***, and ***hospitals and health systems would have nothing to fear from the tort system***, because Maryland law already provides hospitals and health systems with charitable immunity above their available insurance.

MARYLAND
INSURANCE
ADMINISTRATION

MSAR # 2976

2019 Report on the Availability & Affordability of Health Care Professional Liability Insurance

Submitted to the
Legislative Policy Committee
by the
Maryland Insurance Administration

Al Redmer, Jr.
Commissioner

September 1, 2019

EXECUTIVE SUMMARY

Healthcare professional liability insurance (hereinafter "medical malpractice insurance") covers doctors and other healthcare professionals for liability claims arising from the treatment and care of patients. This annual report is based on data supplied by insurer groups to the Maryland Insurance Administration ("MIA"). The continuous availability and affordability of medical malpractice insurance to practitioners in Maryland is a vital and necessary component of Maryland's health care system.

In 2002 and 2003, rapid and substantial increase in medical malpractice insurance premiums threatened to weaken access to high-quality health care in Maryland. The General Assembly acted in 2004 and 2005 to stabilize the medical malpractice insurance market and to require the MIA to collect relevant data and report annually to the General Assembly on the state of Maryland's medical malpractice market. This data is summarized in Exhibits A through L.

In Maryland, medical malpractice insurance is available to be purchased from admitted insurers, non-admitted (surplus lines) insurers and risk retention groups. All writers of medical malpractice insurance are licensed or authorized by the MIA to conduct business in the state. In 2018, 67 insurer groups wrote medical malpractice insurance policies in Maryland for all types of health care providers. Total medical malpractice premium collected by these insurer groups was $286,320,300, representing a decrease of 1.7 % from the prior year. Admitted insurers accounted for 50% of the total written premium, while surplus lines insurers and risk retention groups accounted for 16% and 34% respectively.

While the number of insurer groups engaged in the medical malpractice market in Maryland is substantial and has not fluctuated significantly over the past ten (10) years, the marketplace remains highly concentrated with respect to premium volume. The leading admitted insurer and the leading risk retention group account for 59% of the total premium volume collectively. That said, the market's premiums remained stable over the past year as evidenced by the fact that only five (5) insurers made a rate increase filing during fiscal year 2019 (July 1, 2018 through June 30, 2019). These filings resulted in average increases of between 2.4% and 10.9 % to a total of 3,147 policyholders. These increases were offset in the market by premium decreases averaging 4.4% impacting over 5,800 policyholders insured by our largest market share insurer group. Our second largest insurer group did not make a rate impact filing in fiscal year 2019. Thus, medical malpractice insurance premiums have again remained affordable and stable in Maryland's market over the past year.

INTRODUCTION

Health care providers are not required by law to purchase and maintain medical malpractice insurance. Providers who elect to not purchase this coverage cannot participate in health care networks supporting preferred provider organizations, health maintenance organizations or managed care organizations.

Medical malpractice insurance premiums began to escalate in 2002 and increased substantially in 2003 and 2004. The General Assembly intervened in 2004 and 2005, including directing the MIA to collect data and report back to the General Assembly on this critical insurance market segment annually. In response, the MIA provides this report each year, including among other metrics, information about the number of active insurers in the medical malpractice insurance market in Maryland, premium rates for selected medical specialties and data for closed medical malpractice claims.

MARYLAND'S MEDICAL MALPRACTICE INSURANCE MARKET

Admitted insurers, surplus lines insurers and risk retention groups all provide medical malpractice insurance policies to a wide variety of health care professionals in Maryland.[1] Exhibits A1 through A5 provide detailed information about these insurer groups. As in the previous year, in 2018, the top two (2) insurer groups operating in Maryland were an admitted insurer created by the General Assembly[2], Medical Mutual Liability Insurance Society of Maryland (MMLIS); and, MCIC Vermont (MCIC), a risk retention group organized under Vermont law operating in Maryland as a non-admitted insurer. These two insurers captured 59% of the market by premium volume, which was a decrease of 3.25% from the prior fiscal year. Exhibit A1 illustrates the 2018 premium and market share data for each insurer group. Exhibit A2 lists the change in written premium for each insurer group by type of license from 2017 to 2018. The small drop in written premium of these top two market share groups contributes to a slightly less concentrated market and confirms that competition exists in the market.

Exhibit A3 is a pie chart showing the 2018 market share of the top nine (9) admitted insurers and a pie chart of the top nine (9) insurers including surplus lines insurers and risk retention groups. Exhibit A4 shows the change in market share of the current top five (5) insurers over the period from 2005 – 2018. MMLIS' share of the market was 30%, a decrease of 4% from last year while MCIC's share of the market increased to 29%. This activity is a continuation of a trend over the past 6 years where it appears that MCIC continues to make inroads into the market share of MMLIS. The total market share of the top two (2) insurer groups remains high at 59% of the market, and continues to be stable.

MEDICAL MALPRACTICE INSURANCE PREMIUMS IN MARYLAND

In response to an increase in medical malpractice insurance premium rates between 2001 and 2005, the General Assembly created the Maryland Health Care Provider Rate Stabilization Fund ("Fund"). Insurance Article, Section 19-802 of the Annotated Code of Maryland established the Fund, effective April 1, 2005.[3] The Fund subsidized medical malpractice insurance premiums paid by eligible health care providers to admitted insurers that elected to participate in the program through calendar year 2008.

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[1] Refer to MIA's *Comparison Guide to Medical Professional Liability Insurance Rates* ("*Comparison Guide*") for a detailed listing of insurers and premiums across the State.

[2] See Chapter 544, Section 1, Laws of Maryland, 1975.

[3] The Fund consists primarily of revenues generated by annual premium tax imposed on health maintenance organizations and managed care organizations pursuant to § 6-102 of the Insurance Article.

Exhibit A5 shows the history of MMLIS' rate changes from 2003 through 2019. Of note is that the sole rate increase since 2009 was 4% in 2012. MMLIS' rates effective January 1, 2018 dropped 2% and its most recent rate filing, effective January 1, 2019, reflects a decrease of 4.4%. The rates of MMLIS, the State's largest writer of medical malpractice insurance by premium volume, have remained stable since 2006.

Medical malpractice insurance premiums vary by specialty, policy limits and practice location. Exhibits B through G provide premium comparisons for twenty (20) different specialties utilizing a base premium for policy limits of $1MM per incident / $3MM annual aggregate for the years 2016 – 2019. Although the premium rates may differ among companies within a specialty, these Exhibits indicate stability in medical malpractice insurance premiums during this time period.

Exhibits B through G also highlight the differences in premiums among insurers. To assist providers in comparing medical malpractice insurance premiums, the MIA publishes the *Comparison Guide to Maryland Medical Professional Liability Insurance Rates* ("*Comparison Guide*") on an annual basis. The *Comparison Guide* is available on the MIA's website (www.insurance.maryland.gov) using the following link:

http://www.insurance.maryland.gov/Consumer/Documents/publications/medicalliabilityrateguide.pdf

The *Comparison Guide* compares general pricing among the major admitted insurers, surplus lines insurers and risk retention groups offering medical malpractice insurance in Maryland.

By law, medical malpractice insurers are required to offer policies with high deductible options of $25,000, $50,000 and $100,000.[4] Exhibits H and I illustrate that high deductible options are not popular among providers. Although policies having a deductible of less than $25,000 are sold, liability insurance policies, including medical malpractice insurance policies, are routinely issued with no deductible.

CLOSED CLAIMS

One factor affecting medical malpractice insurance premium rates is the number of claims filed, also known as claim frequency. Admitted insurers are required to submit certain closed claim information on a quarterly basis to the MIA. A claim is a demand for compensation arising from the alleged malpractice of a health care provider or facility. Exhibit J summarizes the closed claim data provided to the MIA by insurer and Exhibit K summarizes the data by specialty.

[4] Insurance Article, § 19-114 of the Annotated Code of Maryland. This statute was amended in the 2019 legislative session to limit this requirement to policies with annual premiums of $5,000 or more effective October 1, 2019.

Between 2009[5] and 2013 closed claims generally increased among all insurer types (admitted, non-admitted and risk retention groups). The number of closed claims hit a peak for admitted insurers 2013 at 957. The number of closed claims hit a peak for non-admitted insurers in 2012 at 425. The closed claim totals for 2018 were -47%and -20% off these peak totals for admitted insurers and non-admitted insurers respectively.

Exhibit L summarizes the number of lawsuits filed by jurisdiction and venue. The number of lawsuits peaked in 2013 and decreased by 41% in 2014 and again by 7% in 2015. In 2016, the number of lawsuits rose by 2% (22 lawsuits). For 2017, the number of lawsuits increased by 8 %, but was 30% below the peak year of 2014. For 2018, the number of lawsuits was 869, which was a reduction of 6% from the previous year.

CONCLUSION

The MIA continues to monitor concentration, availability and affordability trends for the key medical malpractice insurance market in Maryland. The market continues to be relatively stable but remains concentrated with 59% of the written premium acquired by two (2) insurers. Premium rates were stable or decreasing again this year across the market as a whole and within the two (2) largest market share insurers. The five (5) insurers that entered the market in 2016 – 2017 acquired a collective market share of 1.45% and there are (2) insurers that entered the market in 2017 - 2018.

The stable rate environment and the continuing availability of coverage in the Maryland market are positive indicators for health care providers. Likewise, the closed claim and filed lawsuit numbers remain substantially below peak levels of 2012 – 2013. This should encourage potential risk bearers that have previously declined to enter or expand their presence in the Maryland market during the previous times of less stability to take advantage of growth opportunities within the State.

[5] In 2005, the MIA used one form of on-line reporting, but that tool became unworkable. Since 2009, the data has been collected using a different tool that enables the MIA to access and query the data more easily. This change in systems may have resulted in a change in data collection.

JANE DOE NO. 1, JANE ROE NO. 1, JANE ROE NO. 2, and JANE ROE NO. 3	:	IN THE
Plaintiffs,	:	CIRCUIT COURT
v.	:	FOR
THE JOHNS HOPKINS HOSPITAL, JOHNS HOPKINS COMMUNITY PHYSICIANS, and JOHNS HOPKINS HEALTH SYSTEM CORPORATION	:	BALTIMORE CITY
	:	Case No.: 24-C-13-001041
Defendants.	:	

PROPOSED ORDER GRANTING FINAL APPROVAL OF MANDATORY CLASS SETTLEMENT AGREEMENT

The Plaintiffs, Jane Doe No. 1, Jane Roe No. 1, Jane Roe No. 2, and Jane Roe No. 3, by and on behalf of others similarly situated ("Plaintiffs"), and Defendants, The Johns Hopkins Hospital, Johns Hopkins Community Physicians Inc., and The Johns Hopkins Health System Corporation (together, "Johns Hopkins"), having entered into a proposed Settlement Agreement in this Action, and the Court having duly considered and preliminarily approved the proposed Settlement Agreement, ordered the Parties to provide notice of the Settlement Agreement to the Settlement Class Members, duly considered all objections to Settlement Agreement, and considered the Parties' arguments and submissions in support of final approval,

IT IS ORDERED AS FOLLOWS:

1. For purposes of this Order, the Court adopts the definitions set forth in the Settlement Agreement.

Class Notice

2. The Court previously ordered the Plaintiffs, through the Claims Administrator, to directly mail an approved form of notice of the Preliminary Approval Order to all individuals

who previously received written notice of the October 30, 2013 Conditional Certification Order and all individuals who previously registered as members of the Settlement Class. The Court further ordered the Parties to provide notice to any Settlement Class Members who were minors as of the date of the Preliminary Approval Order but who have not previously registered as Settlement Class Members (a) by mailing written notice to their parents or (b) through alternative means.

3. The Court previously ordered the Plaintiffs, through the Claims Administrator, to provide publication notice of the Preliminary Approval Order pursuant to the approved Class Publication Notice Plan.

4. Through the Claims Administrator, the Plaintiffs subsequently provided notice of the Preliminary Approval Order to the Settlement Class in the manner ordered by the Court, as required by Md. Rule 2-231(h).

5. The Court finds that the notice of Preliminary Approval Order, as well as the manner in which it was provided to Settlement Class Members, fairly and adequately described the proposed class settlement and the manner in which class members could object to the settlement.

6. The Court further finds the Plaintiffs provided valid, due, and sufficient notice to the Settlement Class Members; and complied fully with the Maryland Rules of Civil Procedure, due process, and all other applicable laws. A full and fair opportunity was afforded to Settlement Class Members to object to or to comment on the Settlement and to participate in the hearing convened to determine whether the Settlement Agreement should be given final approval.

7. In making the findings in Paragraphs 4-6, the Court has considered the sworn testimony of Jeanne C. Finegan, the President of HF Media, Inc., which is a division of the

Heffler Group and which has served as the Claims Administrator in this Action. The Court finds Ms. Finegan's testimony to be credible.

Class Certification

8. Pursuant to the Settlement Agreement and for purposes of this settlement only, the Court certifies the following final Settlement Class pursuant to Maryland Rule 2-231(b)(1)(B):

> All former patients of Nikita A. Levy M.D. ("Dr. Levy") or all such persons' personal representatives, heirs or assigns, wherever located, who have or may in the future have any claim against (1) Nikita A. Levy, M.D. ("Dr. Levy") or the Estate of Nikita A. Levy, or (2) The Johns Hopkins Health System Corporation, The Johns Hopkins Hospital or Johns Hopkins Community Physicians (or any other person or entity affiliated with Johns Hopkins), arising out of, based upon, related to, or involving injuries and damages claimed as a result of the Dr. Levy's photographing or videotaping activities or boundary violations while he was an actual or apparent agent, servant, or employee of Johns Hopkins.

9. In connection with the final certification of this Settlement Class, the Court makes the following findings concerning the requirements of Maryland Rule 2-231(a):

a. The Settlement Class consists of over 12,000 former patients of Dr. Levy, and therefore is (i) sufficiently numerous such that joinder of all members is impracticable and (ii) sufficiently ascertainable, in that former patients of Dr. Levy may be identified through Johns Hopkins' medical records.

b. There are questions of law or fact common to the Settlement Class for purposes of determining whether this Settlement should be approved, including but not limited to:

i. Whether Dr. Levy was an actual or apparent agent, servant or employee of the Johns Hopkins Defendants at all times;

ii. Whether the Johns Hopkins Defendants are vicariously liable for Dr. Levy's actions;

iii. Whether the Johns Hopkins Defendants' actions and/or alleged failures to act, including their alleged negligent failure to properly investigate, credential, qualify, select, monitor, and supervise Dr. Levy, directly and proximately resulted in foreseeable injuries or damages to the Settlement Class Members; and

iv. What was the extent and nature of Dr. Levy's alleged misconduct, including his surreptitious photography and videotaping of Settlement Class Members and/or engaging in boundary violations.

c. The claims of the Representative Plaintiffs, Jane Doe No. 1 and Jane Roe Nos. 1, 2 & 3, are typical of the claims of Settlement Class Members, considering that each Representative Plaintiff is a former patient of Dr. Levy, and each seeks to recover damages from the Johns Hopkins Defendants arising from his alleged misconduct under vicarious liability and negligence theories.

d. The class representatives will adequately represent the Settlement Class in that:

i. The interests of the Representative Plaintiffs are sufficiently identical to the other members of the Settlement Class based on their status as former patients of Dr. Levy and the misconduct alleged in the Amended Complaint;

ii. The Representative Plaintiffs have been cognizant of their duties and responsibilities to the Settlement Class Members; and

iii. As previously determined in the Court's October 30, 2013 Order approving Plaintiff's Motion for the Appointment of a Steering Committee, Class Counsel are experienced in class actions and other complex litigation, and have been involved in protracted litigation involving medical malpractice for many years.

10. In connection with the final certification of the Settlement Class, the Court makes the following findings with respect to Maryland Rule 2-231(b)(1)(B):

a. The Johns Hopkins Defendants are charitable organizations, and therefore entitled to immunity for third-party tort claims under the Maryland doctrine of charitable immunity, except to the extent of available insurance.

b. The only assets potentially available to satisfy the Settlement Class members' claims are Johns Hopkins insurance policies, which are wasting policies.

c. The $190,000,000 Class Action Settlement Amount represents the total assets available to satisfy the Settlement Class Members' claims, considering that:

i. The limits of Johns Hopkins professional liability insurance would be substantially eroded (and indeed have already been eroded) were Johns Hopkins to continue defend this class action or, if

decertified, lawsuits brought by individual Settlement Class Members; and

ii. Johns Hopkins' insurers have raised certain defenses to coverage.

d. In making the findings set forth in paragraphs 10.b and 10.c, the Court has considered the sworn testimony of James R. Murray, Esq., an attorney in the Washington D.C. office of Dickstein Shapiro LLP and a nationally regarded expert in insurance coverage issues. The Court finds that Mr. Murray's testimony is credible.

e. The Class Action Settlement Amount, which represents the limited fund set at its maximum, is insufficient in to pay all the claims of the 12,000 Settlement Class Members, considering both the sheer number of the claims and the nature the misconduct alleged in the Amended Complaint.

f. Pursuant to the Settlement Agreement, the entirety of the Class Action Settlement Amount, less any costs, expenses or attorneys' fees awarded by the Court, will be devoted to the satisfaction of the Settlement Class Members' claims.

g. Pursuant to the Settlement Agreement's Allocation Plan, the Class Action Settlement Amount will be distributed to similarly situated Settlement Class Members in an equitable manner. Plaintiffs' counsel will submit the expenses reasonably incurred in the course of the allocation procedure and administration of this matter for payment from the Qualified Settlement Fund, subject to the approval of this Court.

Fairness, Adequacy and Reasonableness

11. The Court finds that the Settlement Agreement, including all exhibits thereto is fair, adequate and reasonable under applicable Maryland law.

12. In connection with the final approval of the Settlement Agreement, the Court makes the following findings with respect to the Settlement Agreement's fairness:

a. The Settlement Agreement is the result of over twenty months of vigorously contested mediation and negotiations between Plaintiffs and the Johns Hopkins Defendants.

b. The mediation was conducted by John W. Perry, Jr., a highly regarded mediator in significant class actions across the country, and Brian Nash, a highly regarded attorney with 40 years of experience litigating and mediating cases in an around Baltimore City. The mediators engaged the Parties in repeated in-person and telephonic sessions in their attempt to reach a settlement.

c. During the mediation, the Parties zealously advanced their arguments, and each side demonstrated a willingness to continue to litigate rather than accept a settlement that was not in their client's interests.

d. Throughout this litigation, the Parties have been represented by highly experienced and competent counsel.

e. In making the findings in paragraphs 12.a-d, the Court has considered the sworn testimony of the mediator, John W. Perry, Jr. and Brian Nash, whose testimony the Court finds is credible.

EXHIBIT 4

JANE DOE NO. 1, JANE ROE NO. 1, JANE ROE NO. 2, and JANE ROE NO. 3 Plaintiffs, v. THE JOHNS HOPKINS HOSPITAL, JOHNS HOPKINS COMMUNITY PHYSICIANS, and JOHNS HOPKINS HEALTH SYSTEM CORPORATION Defendants.	:	IN THE CIRCUIT COURT FOR BALTIMORE CITY Case No.: 24-C-13-001041

AFFIDAVIT OF JAMES R. MURRAY

I, JAMES R. MURRAY, aver that I am over the age of eighteen (18) and that I am competent to be a witness in these proceedings. I declare the following to a reasonable degree of professional certainty, and I would testify as follows:

1. I am a senior partner and the Professional Development Leader of the Insurance Coverage Practice at the law firm of Dickstein Shapiro LLP ("Dickstein Shapiro") in Washington, D.C. Our firm was retained in March of 2013 by Jonathan Schochor of Schochor, Federico & Staton, P.A., counsel for the Plaintiffs, to act as insurance coverage counsel with respect to the Defendants Johns Hopkins Hospital, Johns Hopkins Community Physicians, Inc., and Johns Hopkins Health System Corporation's (the "Johns Hopkins Defendants") claims for insurance for the underlying liabilities of these Defendants arising out of the conduct of Nikita A. Levy, M.D. and allegations of their own direct negligence (the "Levy Claims").

2. The Plaintiffs and the Defendants have reached a settlement agreement providing for a payment of $190,000,000 in cash to the Class Plaintiffs (the "Settlement").

3. I submit this affidavit regarding the fairness and reasonableness of the settlement between the Plaintiffs and the Johns Hopkins Defendants. I also submit this affidavit in support of the Joint Motion for Approval of the Class Settlement. I have been personally and directly involved in the negotiations that led to the Class Settlement. I have personal knowledge of the matters set forth herein.

A. Experience

4. I am the Professional Development Leader of Dickstein Shapiro's Insurance Coverage Practice, which is one of the nation's largest insurance groups representing exclusively policyholders. In 2014, we were named a "Leading Insurance Policyholder Firm" by Chambers USA and by Legal 500: The Clients' Guide to the U.S. Legal Profession and a "Tier-1 National Insurance Law Firm" by U.S. News and Best Lawyers. In 2012, U.S. News named us "Law Firm of the Year (Insurance)." We have frequently been included among the top five insurance practices in the United States by Law360 and our firm has twice been named to the National Law Journal's "Plaintiffs' Hot List" (in 2013 and 2011) due in large part to the success of our insurance coverage attorneys. Our group has helped clients recover more than $5 billion from insurance companies in the last five years alone.

5. A complete copy of my biography is attached as Exhibit A. I have represented policyholders on matters involving nearly every line of insurance over the last 28 years. Law360 designated me as one of only three national "MVPs" for insurance coverage in 2011 and one of only five in 2013 (the only insurance lawyer to have received this recognition twice).

6. Since 2003, I have devoted a significant part of my insurance coverage practice to representing policyholders in pursuit of insurance coverage for claims involving underlying allegations of sexual conduct. I served as insurance coverage counsel to the Roman Catholic Archdiocese of Seattle since 2003. In 2004, the United States Bankruptcy Court for the Eastern

District of Washington appointed me special insurance coverage counsel to the Debtor Roman Catholic Diocese of Spokane. That assignment lasted through 2007 and resulted in court approval of almost $20 million of insurance settlements from the Diocese's historical liability carriers. In 2009, the United States Bankruptcy Court for the District of Oregon appointed me special insurance coverage counsel to the Debtor Oregon Province of Jesuits. That assignment lasted through 2011 and resulted in court approval of almost $120 million in settlements between the Oregon Province of Jesuits and its historical insurance companies. In 2014, the United States Bankruptcy Court for the District of Montana appointed me special insurance coverage counsel to the Debtor the Roman Catholic Diocese of Helena, which resulted in almost $15 million in insurance settlements, subject to court approval and plan confirmation later this year. I most recently served as insurance coverage counsel to the defendant Beebe Medical Center, Inc., and subsequently, with the consent of Beebe Medical Center, to the plaintiffs in litigation involving the conduct of Earl B. Bradley, M.D. a Delaware Pediatrician, which resulted in a $123.1 million settlement. I testified before Hon. Joseph R. Slights III (Delaware Superior Court) at the fairness hearing in that case. I have been qualified as an expert in insurance coverage by the United States Bankruptcy Court for the District of Montana and I testified at trial in *Richardson, Chapter 7 Trustee for Yellowstone Club World LLC et al. v. Cincinnati Insurance Company* (2011).

B. Summary of Opinions

7. These are the salient aspects of my professional opinions regarding the Class Settlement and the insurance settlements in this case. I am prepared to testify to the same.

- The limits of applicable insurance coverage for claims arising out of the acts of Nikita Levy, M.D. and the allegations of direct negligence by the Johns Hopkins Defendants are $224 million dollars;

- The insurance policies applicable in this matter are wasting policies, meaning that any expenses incurred in the defense of this matter by the Johns Hopkins Defendants or on their behalf by their insurance carrier, MCIC Vermont, Inc., would be deducted from the insurance otherwise available to pay judgments or settlements;

- The assets of the Johns Hopkins Defendants are unavailable to the Class Plaintiffs under the Doctrine of Charitable Immunity;

- The Settlement between the Johns Hopkins Defendants and the Plaintiffs is fair and reasonable. Indeed, in view of the limits of available insurance, the Johns Hopkins Defendants' Charitable Immunity, and the "wasting" nature of the available insurance policies, the result in this case is extraordinarily favorable to the Class Plaintiffs.

C. Retention by the Plaintiffs and MCIC Coverage

8. In March of 2013, Schochor, Federico & Staton, P.A. retained me to serve as insurance counsel with respect to the underlying Levy Claims against the Johns Hopkins Defendants and the Johns Hopkins Defendants' claims for insurance for those claims. Following my retention, my team received and reviewed voluminous binders of documents, including the Johns Hopkins Defendants' applicable or potentially applicable insurance policies discussed below, the underlying Class Action complaint setting forth the Levy Claims, expert reports and other additional information regarding the substance of the Levy Claims, and the mediation statements submitted in connection with the settlement process.

9. Our first step in determining the amount of available insurance was to determine what "lines" (or types) of insurance coverage were implicated by the Levy Claims. The Johns Hopkins Defendants maintain a liability insurance program comprised of a primary policy and three excess policies offering potential total coverage "limits of liability" of either: (a) $224 million in Professional Liability insurance, or (b) $205 million in General Liability insurance, depending on the applicable coverage.

10. MCIC Vermont, Inc. ("MCIC") provided all of the Johns Hopkins Defendants' Professional Liability and General Liability insurance on a claims-made basis since 1988, when Dr. Levy began working for the Johns Hopkins Defendants. Because these claims-made insurance policies respond to claims made against the insureds in the policy year in which a claim of wrongdoing is asserted (here, by service of the Class Action Complaint against the Johns Hopkins Defendants) and no historical "occurrence"-based Professional Liability and General Liability insurance policies cover any period of Dr. Levy's employment, only a single year's insurance policies are in play in this case.

11. The Professional Liability and General Liability insurance provide alternative coverage that forecloses the possibility of concurrent recovery under both coverage parts. The policies specify that if a claim implicates both the Professional Liability and the General Liability insurance, only the Professional Liability insurance will apply and provide coverage. As such, the General Liability insurance would be applicable only if the Professional Liability insurance did not afford coverage for the underlying Levy Claims. As a result, in this case, only the Professional Liability insurance applies and provides the Johns Hopkins Defendants coverage.

12. The Johns Hopkins Defendants' liability insurance program includes a primary policy bearing policy number PR 1113, which provides Professional Liability coverage for claims made during the January 1, 2013 to December 31, 2013 period (the "Primary Policy"). The program also includes three excess policies that follow form to the Primary Policy in all relevant respects (the "Excess Policies"). In total, the Primary Policy and the Excess Policies provide combined coverage "limits of liability" of $224 million for any and all Professional Liability claims. Unlike many insurance programs that are comprised of different commercial

insurers participating at each layer, a single insurer, MCIC, issued both the Primary Policy and the Excess Policies. The Johns Hopkins Defendants' Primary Policy and Excess Policies provide Professional Liability coverage for the Levy Claims.

13. In assessing the availability of coverage, the proper analysis focused on the alleged misconduct of the Johns Hopkins Defendants – i.e., whether the "Claims" against the Johns Hopkins Defendants "arise out of . . . any act, error or omission . . . in the furnishing of or the failure to furnish Professional Services." Here, the allegations in the underlying complaint support the argument that the claims against the Johns Hopkins Defendants fall within the terms of coverage. For example, the underlying complaint clearly alleges, and the facts wholly support, that the Johns Hopkins Defendants made errors and omissions in the furnishing of "medical . . . or other professional healthcare treatment or services" that satisfy the first prong of the "Professional Services" definition.

14. Although the "Professional Services" definition was satisfied as to the Levy Claims in my professional opinion, MCIC raised and, absent settlement, could have pursued arguments that the "Professional Services" definition was not satisfied based on the nature of the conduct alleged against Dr. Levy and the Johns Hopkins Defendants. In that case, the General Liability coverage might have applied, but then only if the alleged conduct caused "bodily injury" to Plaintiffs and was not excluded by a "Sexual Misconduct" exclusion applicable only to the General Liability coverage part. These potential arguments, and the likely cost of overcoming them, have informed my professional opinion as to the reasonableness of the Settlement.

D. Other Policies

15. In addition to the Professional Liability and General Liability insurance programs discussed above, the Johns Hopkins Defendants also maintained a directors and officers

("D&O") insurance program comprised of a primary policy and three follow-form excess policies offering total "limits of liability" for Entity Coverage of $25 million (subject to a $500,000 retention). The Johns Hopkins Defendants also maintained a Cyber Liability insurance policy offering total "limits of liability" for Information Security & Privacy Liability of $20 million (subject to a $500,000 retention). Neither of these additional insurance programs is applicable to the Levy Claims, as both contain a clear and specific exclusion for all claims related to or arising from bodily injury, mental anguish, emotional distress, and humiliation -- the specific harms alleged by the Plaintiffs in the underlying complaint for the Levy Claims.

E. "Wasting" Policies

16. Pursuant to the language of the MCIC Primary Policy and Excess Policies, all amounts paid in defense of an underlying lawsuit or separate lawsuits count toward the erosion of the applicable coverage limits. Thus, the sooner that an underlying suit is resolved, the more insurance will remain to pay the underlying victims. In sum, the Primary Policy and Excess Policies at issue would pay a maximum of $224 million, less all defense costs, for a covered claim. Accordingly, all costs for the Johns Hopkins Defendants' defense counsel (local and national, billable by the hour) in addition to all costs for defense medical and other experts as well as all associated costs would be deducted from any available insurance coverage prior to any payments made to the Plaintiffs.

17. On the basis of my experience working on behalf of insureds in matters concerning allegations similar to those at issue in this case, it is my opinion that if these claims were litigated individually, as opposed to through a Class Action, the wasting nature of these insurance policies would result in the vast majority of the available insurance being spent in the defense of these claims, rather than being paid to the Class Plaintiffs. It is my opinion that in any event, significantly less than $190 million would be available for recovery by the Class

Plaintiffs, were these claims litigated individually. That is because a Class Action provides economies of scale, requiring a single defense of the allegations rather than separate defenses of each individual claim, potentially by separate defense attorneys in multiple jurisdictions and with additional costs to coordinate those defenses. For example, if the Johns Hopkins Defendants spent only $25,000 in defending each case individually (which would include all lawyers' fees, experts' fees for liability issues as well as evaluating each Plaintiff for damages, and associated expenses), all insurance proceeds would be paid to the defense attorneys and experts and not the Plaintiffs. Certainly if these cases were litigated individually, a few Plaintiffs might benefit to the detriment of thousands of others.

18. It is also my opinion that even if these claims were litigated to verdict as a class action, and the Plaintiffs prevailed, there would be significantly less than $190 million available for recovery by the Plaintiffs.

F. Charitable Immunity

19. Recovery on behalf of the Class Plaintiffs in this matter is limited to the available insurance coverage. The assets of the Johns Hopkins Defendants are immune from suit pursuant to the doctrine of charitable immunity. Maryland traditionally holds entities that maintain their funds "in trust for charitable purposes" immune from liability in tort, *Perry v. House of Refuge*, 63 Md. 20 (1885). This common law "charitable immunity" doctrine has long since been codified with respect to any "hospital or related institution." Any such entity "that *is a charitable institution and is insured* against this liability in an amount of not less than $100,000 *is not liable* for damages in excess of the limits of that insurance." Md. Code Ann., Cts. & Jud. Proc. § 5-632(c) (West) (emphasis added). Thus, pursuant to Maryland statute, the Johns Hopkins Defendants, as charitable institutions are not liable in excess of their $224 million dollar policy limits.

G. Negotiation

20. I was present for each of the mediation sessions between defense counsel for the Johns Hopkins Defendants, the Johns Hopkins Defendants' insurance carriers, those insurers' reinsurance carriers, Class Counsel, General Counsel, and Risk Managers for the Johns Hopkins Defendants. These negotiations were arms-length, adversarial, and at times, very hotly contested.

H. Conclusion

21. For all the reasons stated in this Affidavit, I believe, based on 28 years of experience, that this settlement is fair, adequate and reasonable. Indeed, it is my opinion that the result is extraordinary, based on all of the factors involved in this litigation. It is my belief that this Settlement constitutes the largest settlement of a Class Action founded upon allegations of sexual abuse, and the third largest sexual abuse settlement of any kind. Insurance coverage litigation would not have resulted in greater recovery in this matter, and the global settlement of this matter has successfully preserved insurance assets for the Class Plaintiffs that would otherwise be spent for the defense of this action. Indeed, if a global settlement had not been reached in this matter, the only future certainty would be many, many years of prolonged litigation with an uncertain outcome. Certainly, significantly less than $190 million would be available to Plaintiffs if this litigation had not been resolved in a Class Action.

James R. Murray

Sworn to before me on this 11th day of September 2014

Notary Public

REGINA M. MATTHEWS
NOTARY PUBLIC
DISTRICT OF COLUMBIA
MY COMM. EXP 02/11/2019

Brian Lancaster_unf_SB879
Uploaded by: Lancaster, Brian
Position: UNF

SB 879 Testimony – oppose

from Brian Lancaster

I recently learned about SB879, and I am very concerned about this bill. Maryland parents whose children are injured at birth should absolutely maintain the right to directly sue the involved healthcare providers and hospitals.

Please oppose this bill.

Thank you.

Sincerely,

Brian Lancaster
Germantown MD

Sandi Lancaster_unf_SB879
Uploaded by: Lancaster, Sandi
Position: UNF

SB 879 Testimony – oppose

I am very concerned about SB879, which would prohibit Maryland citizens from suing their healthcare providers and/or hospitals in the event of birth injuries caused by negligence. This bill reads as though it is looking out for the financial best interest of potentially negligent healthcare providers and hospitals rather than the interests of the citizens of Maryland.

As a Maryland resident, I am strongly opposed to this bill and I urge the committee members to please oppose it as well.

Thank you!

Sincerely,

Sandi Lancaster
Germantown, MD

Meredith Lovell_SB0879 OPPOSE
Uploaded by: Lovell, Meredith
Position: UNF

HB1563/SB0879 OPPOSE

I am writing you as a concerned mother of four, a professional in the human services field for a decade, and a provider of care throughout the childbearing year. Being a birthing woman in Maryland who also serves birthing families **HB1563/SB0879** directly impacts me as birth is always unpredictable. As a human services professional I have seen the lifelong financial impact of birth injuries.

I began my work in the human services field as a direct care respite provider. I worked with families who had children, siblings, and relatives etc. who were developmentally disabled and intellectually impaired. Some of the people I worked with had impairments due to genetic and chromosomal abnormalities. Others were injured during the birth process which caused them to need lifelong care. Their injuries included hypoxia, internal decapitation, cerebral palsy, Hypoxic Ischemic Encephalopathy, and varying degrees of brachial plexus to name a few. Daily care and programs needing to be provided for a lifetime impacts families financially.

The five leading causes of infant death in 2017 were (in order) birth defects, preterm birth/low birth weight, maternal pregnancy complications, SIDS, and injuries. The leading brain-related injury in relation to birth trauma is cerebral palsy. CP is estimated to affect around 800,000 children, with 8,000-10,000 new cases diagnosed each year. In many instances, CP could have been eliminated with the corrective preventative measures by physician. For example, if a physician fails to monitor fetal distress and take the appropriate actions, the infant may develop CP. So we are going to now tell families that their provider's negligence isn't something they or the hospital will be accountable for?

Pitocin is used in the majority of hospital births to induce or augment labor and nearly all to "manage" the third stage. There are risks to using Pitocin. It can cause hyper stimulation of the uterus which causes contractions to be longer, stronger, and closer together. This causes added stress to the baby because it restricts placental flow of oxygenated blood. Restriction of oxygenated blood leads to fetal distress and hypoxia, to name a few. Mismanagement of medication is a common error in hospital births and is a direct contributor to many birth injuries. Providers and the hospitals that employ them should be financially accountable for the injuries they cause.

Birth injuries that arise during delivery is a common occurrence. These types of injuries occur from the use of vacuum extractor or forceps, tools invented to assist in delivery. Other injuries from delivery may include administering the wrong medication, mishandling the infant, resulting in broken bones, lacerations, or skull fractures. When a high level of oxygen is introduced, it interrupts the growth of the vessels and voila – you have Retinopathy of Prematurity. Stevie Wonder was born with sight, but because he received an excessive amount of oxygen, he developed ROP, his retinas detached and he became blind.

Lacerations occur during cesarean sections. I served a family recently whose baby had a laceration to their face. When they spoke with the provider about the injury they were told "The laceration occurred because he was being squeezed so hard in utero during contractions." It doesn't take an expert in birth to know that is completely false. Parents are adjusting to the newness of welcoming life into the world. Then to be hit with the reality of having a child injured during or after the birth process they shouldn't have to struggle with the idea of having a limited cap on a fund of how/when to care for their child. Parents should have a course of action for injuries to their children during or after the birth process. The providers and institutions that caused said injuries should be financially responsible for restitution. To minimize the severity of these injuries by having a limited fund that cannot begin to encompass the financial demands of a lifetime of care is insulting to those parents who are living this daily. It is insulting to parents who will, sadly, be in this position. With infant and maternal mortality rates in the United States climbing annually the providers and institutions where the majority of birth occurs should be financially responsible when their actions cause an injury to an infant in their care.

Meredith Lovell
211 N Lee St
Cumberland MD 21502

Megan Montgomery _unf_sb879
Uploaded by: Montgomery, Megan
Position: UNF

Chairs, Vice Chairs and Members of the Senate Finance Committee. My name is Megan Montgomery. I am very upset with much of this bill, but I will not reiterate what was already. I will instead focus on the one portion of this bill that forces families who feel they have been wrongly denied coverage will now have to go to the Office of Administrative Hearings, essentially RE-LITIGATE their cases every time they're denied. Who pays their attorney's fee's for this? What is the training for these judges going to look like? Who is going to decide what training is important for these judges to learn about?

I have a child with an EIP. We too are forced to go to the OAH when there is a failure on behalf of the school to provide the needed services our children need for the school to meet their constitutionally required mandate of providing quality education. We were told that these judges would be experts and would have expert training. These judges not only do not have expert training, but these judges often do not understand the absolute BASICS of peer-reviewed research. Many of these judges have to have counsel spend hours explaining what a confidence interval is. It's appalling. We were lied to.

I have no doubt that whatever training is going to be done for these OAH judges it will be WOEFULLY inefficient and will lead to harm to the health and well-being of these critically injured victims.

Thank you.

Megan Montgomery

Jennifer Nichols_unf_SB879
Uploaded by: Nichols, Jennifer
Position: UNF

SB 879 Testimony – oppose

Good evening, I am concerned parent and ask that you please vote no to this bill. If your child is injured at birth, you should be able to pursue legal action against the responsible doctor or the hospital directly. This bill proposes letting those responsible “off the hook” for their actions at the cost of the citizens and ultimately the families. When a child is injured by a physician or hospital, the child’s entire family is also injured in a multitude of ways. The affects can be lifelong. Don’t add insult to injury by cutting off a legal remedy for a family to recover through in their effort to be made whole again.

Thank you!

Jennifer Nichols

2351 Maytime Drive

Gambrills, MD 21054

Jenn Rosenthal_unf_879
Uploaded by: Rosenthal, Jenn
Position: UNF

SB 879 OPPOSE

Chairs, Vice Chairs and Members of the Senate Finance Committee. My name is Jenn Rosenthal. I am a citizen of Maryland. A childbearing woman. And a patient at many local hospitals. I have grave concerns about the bill we have before us today. I will touch on only one of the issues that stands out to me.

After the Individual Mandate of the Affordable Care Act was removed under the current administration, no longer do families "HAVE" to get insurance. There are families in Baltimore and all over Maryland that do not have insurance today. If they get pregnant and do not qualify for state insurance they are paying out of pocket. If they have any medical issue they

Under the language of this bill, in order to maintain the $40 million funding requirements and keep the fund solvent, the hospitals are allowed to increase their rates and pass that burden on to consumers. For many families not poor enough to qualify for state coverage and not affluent enough to easily pay out of pocket, this is unacceptable.

Costs of healthcare in Maryland are already some of the highest in the country. It has been an ever increasing cost burden on families and now with this bill the hospital's that have taken an oath to first **do no harm** are in front of the legislature asking to no longer bear the full burden of their failure to do no harm.

When consequences are significantly reduced for bad behavior, where is the incentive to improve outcomes? I urge the committee to stand with your citizens and the future victims and move unfavorable on this bill.

Thank you.

Jenn Rosenthal

Jenn Rosenthal_unf_879
Uploaded by: Rosenthal, Jenn
Position: UNF

SB 879 OPPOSE

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When consequences are significantly reduced for bad behavior, where is the incentive to improve outcomes? I urge the committee to stand with your citizens and the future victims and move unfavorable on this bill.

Thank you.

Jenn Rosenthal

Azara Turaki _unf_SB879
Uploaded by: Turaki, Azara
Position: UNF

Below is my written testimony on **opposing HB1563/SB 879- Maryland Infant Lifetime Care Trust**. Thank you for supporting parental rights!

I would like to share my thoughts on this bill as a citizen of the state. I have also seen the effects where a separate fund obviates the entity for any liability and encourages a sort of recklessness. In addition requirements for receipt of funds would be based on availability of funds and not necessarily on mistake of provider. As we have seen with the Vaccine Injury Fund it takes about 10 years (on average) of litigation. The requirements for the Vaccine Injury fund have become more and more narrow and not necessarily based on the injury but on a sort of risk management. Pharmaceutical companies are not taking the types of precautions with vaccines as compared with other drugs that have litigation risk associated with it.

For this reason I think the Infant Care Trust will remove hospital/doctor liability as well as distance the payout with the type of infraction. The trust would create a board that is very removed from the infraction and will make decision based on an criteria can be dwarfed based on being out of touch with the hospital environment or the real sufferings of the injured families.

If the goal is to limit payouts, I believe Maryland already has a cap of $200 million and what is available from the insurance. "Other research has found that lawsuits also do not lead to doctors leaving the profession in large numbers. One study found 90% of doctors with five or more medical malpractice claims against them continued to practice medicine." Baltimore Sun Jun 4, 2019 Baltimore verdict on Malpractice.

I think this bill will essentially reduce accountability for the hospitals at the expense of every day citizens.

I would suggest working on legislature that assure more equitable payouts but does not distance the providers from the injury. I think it is imperative we hold these hospitals/doctors accountable in a way that is fair to both parties. I would respectfully urge the committees to consider removing this bill.

Thank you for taking the time to read my concerns.

Sincerely,
Colesville, MD
Azara Turaki

Lauren Weir_unf_SB879
Uploaded by: Weir, Lauren
Position: UNF

SB 879 Testimony – oppose

I believe that SB879 will allow for more birth injuries because the doctors and hospitals would be granted immunity from horrific mistakes. The citizens of Maryland should not be responsible for these mistakes! Doctors and hospitals have insurance for this reason and should be on the hook when careful care is not offered.

I respectfully ask you to vote no on this bill.

Thank you,
Lauren Weir
443-926-1998

Peggy Williams _unf_sb879
Uploaded by: Williams, Peggy
Position: UNF

OPPOSED TO SB 879

Chairs, Vice Chairs and Members of the Senate Finance Committee. My name is Peggy Williams. I am disturbed by many parts of this bill. But there is one part in particular that I am confused about. The fund is capped at $40million. Where does this number even come from? I cannot for the life of me understand how the state could decide this number without any idea of what the future will hold for our states seriously birth injured children.

I am the parent of a severely disabled child. Even I have trouble planning for what the expenses will be that he will need as he ages. As would be inevitable, with an increase of these cases coming to this fund because the hospital is no longer settling any of them and instead will be litigating them all, how soon before the rates are increased for all of the birthing citizens of Maryland? This bill expressly permits that in order for the fund to remain solvent, even with treatment rationing, which will occur and has occurred in the very few states who have done this, hospitals may raise their rates on patients.

The cost of birth in Maryland is as follows:

Vaginal birth with insurance: $6,471.87
Vaginal birth without insurance: $12,596.52

C-section with insurance: $9,610.39
C-section without insurance: $16,425.80

With the ballooning cost of healthcare in Maryland, are we really going to tell hospitals they can have essentially immunity at the expense of not only private insurance, but at the expense of state and federal Medicaid and Medicare costs? I find that unconscionable.

Thank you for your time and urge you to please vote against this bill.

Peggy Williams

Olga Yefimov _UNF_SB 879
Uploaded by: Yefimov, Olga
Position: UNF

Please vote NO on SB 879

Dear Senator,

Please vote NO on bill SB 879. Please do not protect hospitals over Maryland children and their families.

Thank you,
Olga Yefimov
15810 Glacier Ct, North Potomac, MD 20878
301-509-1824

MattCelentano_INFO_SB879
Uploaded by: Celentano, Matt
Position: INFO

The League of Life and Health Insurers of Maryland

15 School Street, Suite 200
Annapolis, Maryland 21401
410-269-1554

March 5, 2020

The Honorable Delores Kelley
Chair, Senate Finance Committee
Mille Senate Office Building
Annapolis, MD 21401

Senate Bill 879 – Public Health – Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties

Dear Chairman Kelley,

The League of Life and Health Insurers of Maryland, Inc. (the League) is the State's trade association representing life and health insurance companies doing business in Maryland. The League recognizes the important public policy issues that Senate Bill 879 – Public Health – Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties seeks to address.

While the League does not oppose an attempt to create a Maryland Infant Lifetime Care Trust (Trust) in the State and certainly acknowledges that hospitals as self-insured entities have significant challenges related to the insurability of the market, the League has significant concerns with the funding mechanism as structured under the Senate Bill 879. The bill places the burden of providing ongoing revenue to maintain the Fund on the State's all payor rate setting system. The bill requires the Health Services Cost Review Commission (Commission) to assess a fee on all hospitals that charge for acute obstetrics, neonatal intensive care unit, newborn nursery, premature nursery and normal newborn, or labor and delivery services whose rates have been approved by the Commission to pay for funding the Trust. Though a fee on these hospitals, in reality the cost of the Fund is ultimately paid by rate payors (commercial insurers, Medicaid and Medicare). As a result, the costs of the Fund are fully passed on by the hospitals and *not borne by hospitals themselves*. Under the bill, there is no cap on the amount of funding that may be required and passed on through the rate setting system. Further, there is no ability for the Commission to limit the exposure of rate payors. The Commission is directed to pass the entire cost on- with no ability to protect Maryland rate payors from untenable cost increases. This unlimited cost will ultimately be passed on to each purchaser of health insurance through premium increases, the State budget through Medicaid and the federal government through Medicare. This is of significant concern to the member companies of the League.

The funding also lacks clear accountability measures. If health insurance carriers and other payors in the State are required to support the Trust financially, it is important that the Trust require improvements by hospitals and providers be achieved, and that the Trust demonstrate that it does, in fact, stabilize costs. Such accountability would be required to protect the rate paying public who are bearing the cost of the Trust.

In our opinion, this proposed bill is attempting to shift payment responsibility from the medical provider who committed the wrongful act to the health insurance companies (and thus to the individual insureds through increased premiums). It creates a mechanism whereby the health insured will subsidize the negligent acts of the medical tortfeasor. In an environment of rising health insurance premiums, such legislation would have an even greater adverse impact.

For these reasons, the League respectfully requests that if the Committee chooses to move forward with this legislation, you either 1) spread the costs for the Trust amongst stakeholders beyond rate payors and places a cap on the rates, or 2) adopt an alternate funding mechanism that does not raise the issues identified here.

Thank you for the opportunity to share these concerns with you regarding Senate Bill 879.

Very truly yours,

Matthew Celentano
Executive Director

cc: Members, Senate Finance Committee

HSCRC_INFO_SB879
Uploaded by: Terry, Tequila
Position: INFO

State of Maryland
Department of Health

Nelson J. Sabatini
Chairman

Joseph Antos, PhD
Vice-Chairman

Victoria W. Bayless

Stacia Cohen

John M. Colmers

James N. Elliott, M.D.

Adam Kane

Health Services Cost Review Commission
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Katie Wunderlich
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Population Based Methodologies

Chris Peterson, Director
Payment Reform & Provider Alignment

Gerard J. Schmith, Director
Revenue & Regulation Compliance

William Henderson, Director
Medical Economics & Data Analytics

March 5, 2020

The Honorable Delores G. Kelley
Chair, Senate Finance Committee
3 East, Miller Senate Office Building
Annapolis, MD 21401

Dear Chair Kelley and Committee Members:

The Health Services Cost Review Commission ("HSCRC") submits this letter of information for Senate Bill (SB 879) titled, "Public Health – Maryland Infant Lifetime Care Trust Funded by HSCRC and Maryland Patient Safety Center Duties". SB 879 charges the HSCRC with overseeing the funding of a Maryland Infant Lifetime Care Trust.

We applaud the sponsor for continuing the conversation to produce meaningful reforms to medical malpractice laws and find ways to address rising malpractice costs. As reforms are considered, there needs to be a balanced approach to support patients and their families when injuries occur while also ensuring a sustainable funding mechanism for malpractice insurance and expenses. The following provides considerations for the sponsors of the Lifetime Care Trust that is proposed.

As the Commission has expressed in the past, the HSCRC remains concerned about rising medical malpractice costs and the practice of defensive medicine, which, in combination, increase the cost of hospital care. These costs, particularly costs related to birth injury, have been increasing in Maryland in recent years and threaten access to care for consumers and put additional pressure on the Maryland Total Cost of Care agreement with the federal government.

Birth related malpractice insurance, in particular, is among the most expensive forms of insurance. As malpractice rates climb, both consumers and the State's Total Cost of Care (TCOC) agreement are threatened. From a consumer standpoint, rising malpractice costs contribute to increased hospital costs which are passed onto consumers through higher taxes, premiums, and other out-of-pocket costs. High hospital malpractice insurance premiums and a lack of reinsurance providers for specialty services such as obstetrics also threatens continued access to these services, potentially creating a void of available maternity services for mothers as hospitals are unable to afford the high costs associated with birth-related malpractice.

Over time, higher hospital costs resulting from medical malpractice costs also threaten the State's ability to achieve its goal to build up to $300 million in annual savings under the TCOC Agreement with the federal government. If this savings goal is not met, the benefits that the State's Medicare waiver brings to Marylanders would be jeopardized. These benefits include the equitable funding of Uncompensated Care, which improves access to critical healthcare for Marylanders, as well as enabling a system that links hospital payment to performance on quality measures (which includes malpractice-related measures).

Under the Maryland Health Model, hospitals have strong incentives to reduce malpractice events and expenses since they all are operating within pre-approved global budgets under which they are at risk for costs, including higher malpractice premiums and claims, and the cost of defensive medicine. Therefore, reforms that would reduce costs and improve quality could help the State achieve its TCOC goals and required standards of performance. The Commission and Maryland hospitals are focused on reducing avoidable utilization such as readmissions and complications so the interest of hospitals, physicians, and patients are aligned in this respect. If the cost of malpractice claims continues to increase, there could be an increased incentive for providers to practice defensive medicine that does not provide quality value, thereby subverting the goal to reduce avoidable utilization. Such an increase in costs would impact Maryland's success on meeting the cost growth and quality requirements under the Model.

While the HSCRC is supportive of malpractice reforms, there are a few outstanding strategic and operational points that should be considered in SB 879. First, SB 879 proposes the creation of a new non-governmental organization to administer the birth injury fund. This private entity would have the authority to decide the amount to distribute to patients, the amount needed in the fund, and therefore the amount to be assessed to payers through the hospital rate setting system. This would be an unparalleled level of authority for a non-governmental organization to make decisions about the care of Marylanders and our State's healthcare finance system. This opens questions on whether or not this should instead be a government agency to ensure appropriate oversight and accountability in managing the fund.

Second, the fiscal implications to payers should be considered carefully in planning. SB 879 specifies that up to an additional $40 million could be added to hospital rates annually in order to support the fund as well as the formation and administration costs of the Trust. Using the rate-setting system as a mechanism to generate funding for these items would require increased hospital rates for all payers, including the Maryland Medical Assistance Program (Medicaid).

The bill as currently drafted would assess only obstetric services. However, the federal Centers for Medicare and Medicaid Services (CMS) requires that any provider tax be broad based and applicable to all payers. Therefore, the hospital assessment should be revised to be effectuated on all patient revenues, not just on obstetric services. CMS would most likely not approve the assessment as proposed under SB 879, causing the Department to face federal compliance issues.

Additionally, the HSCRC is required to provide written notice to CMS regarding any new payment methodology that affects the hospital rate-setting system. Under the agreement, CMS then has the authority to accept or reject the change (Section 8. a. iii., pp. 17-18). CMS' authority to make the final decision applies to hospital rate-setting system changes created in legislation

passed through the Maryland General Assembly.

Finally, the creation of the Infant Lifetime Care Trust under SB 879 has significant operational considerations that would require the HSCRC to expend its limited existing resources to support the processes proposed in the bill. To start, HSCRC would be tasked with directing hospital assessments through the rate-setting system into the Fund's account and overseeing payments from the account to cover the costs of the Trust. The HSCRC anticipates that this step would require a similar approach as other processes we manage (e.g., Uncompensated Care). This bill however lays out a distinctly different approach for managing the Fund than we have historically seen as successful. In other similar routines, HSCRC determines payment into and out of the account rather than having a third party, private entity determine payments. We would encourage a similar approach to be adopted in SB 879.

Another operational consideration is that SB 879 would require HSCRC to procure the help of contractors to conduct the following provisions in SB 879:

1. Studying and making available to the public a report "assessing the status of the State's hospital reinsurance market and the cost of self-insurance programs, including the availability, adequacy, and affordability of reinsurance and facilities in the States" (§19-207(b)(6), p. 4 lines 24-29).
2. Compiling "all relevant financial and accounting information" for the rate process, including the costs associated with "medical liability" and "obtaining medical liability insurance" (§19-220(a)(2)(v), pp. 6-7 lines 29 and 5-8).
3. Defining, by regulation, "the methodology used to account for costs associated with medical liability in the rate review process" (§19-220(a)(3), p. 7 lines 9-11).

While the HSCRC is experienced in setting hospital rates and hospital finance, the agency has little experience working on issues related to the reinsurance market or the accounting of medical liability and reinsurance. HSCRC would require a contractor with more in-depth experience in this domain. The contractors would need to have knowledge of Maryland's unique rate-setting system, in addition to extensive expertise in issues of medical liability and reinsurance.

The HSCRC thanks the Committee for allowing us the opportunity to share this additional information on SB 879. We believe that by considering the aforementioned areas, legislative action to reform the malpractice environment can provide many benefits to Maryland's healthcare system. If you have any additional questions, please feel free to contact me at katie.wunderlich@maryland.gov.

Sincerely,

Katie Wunderlich
Executive Director