SB0332 - LoS - BBrookmyer.pdf
Uploaded by: Barbara Brookmyer
Position: FAV

Public Health
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Frederick County Health Department

SENATE BILL 332
Hospitals and Urgent Care Centers – Sepsis protocol (Lochlin's Law)
ORAL TESTIMONY BEFORE THE
Finance Committee
Barbara Brookmyer, MD, MPH, Health Officer, Frederick County Health Department
Position: Support – February 15, 2024

The bill would require each hospital and urgent care center to implement protocols for the early recognition and treatment of a patient with sepsis, conduct periodic training in the implementation of the protocols, and collect and use quality measures.

The Department of Legislative Service's analysis listed the statewide initiatives from 2018 (focused education) and 2015 (a 21 hospital collaborative to reduce mortality). The analysis reported that the 2015 Sepsis Hospital Collaborative reduced the sepsis mortality rate by 25%, saving more than 550 lives.

The components of this bill are the next reasonable step in responding to stalled improvements observed from the prior statewide initiatives. Public education is a key component of a multi-pronged approach, but effective public health strategies are more often those that are focused on the systems and people who are more likely to encounter the undesirable condition, in this case, sepsis, rather than the entire general public population.

Sepsis is the body's extreme response to an infection. It is a life-threatening medical emergency. Sepsis happens when an infection you already have triggers a chain reaction throughout your body. Without timely treatment, sepsis can rapidly lead to tissue damage, organ failure, and death. The local data that is publicly available is for septicemia, defined as a serious bacterial infection (aka "blood poisoning") with three primary complications – sepsis, septic shock, and acute respiratory distress syndrome.

In Maryland septicemia was the 9th leading cause of death in 2021. The 2021 age-adjusted mortality rate in Maryland is higher than that of the US rate, 12.1 per 100,000 population compared to 10.2 per 100,000 population. The reduction in mortality rate observed from 2014 to 2016 appears to have stalled since 2016. Racial disparities are evident in Maryland as Black men die at greater rates (18.9) than Black women (14.3) and White men (12.2) and women (11.1). In Frederick County, 38 people died of septicemia in 2021, **more than** chronic liver disease and cirrhosis (33), suicide (33), breast cancer (22), or motor vehicle accidents (18). Deaths from septicemia most commonly occur in adults over 55 years, but **can occur at any age**. In 2021, in the whole state, 3 children under a year of age died from septicemia.

For more information, please contact Dr. Barbara Brookmyer at BbrookmyerFrederickCountyMD.gov or 301-600-2509.

Maryland
DEPARTMENT OF HEALTH

Barbara A. Brookmyer, M.D., M.P.H. ▪ Health Officer

350 Montevue Lane ▪ Frederick, MD 21702
Phone: 301-600-1029 ▪ Fax: 301-600-3111 ▪ MD TTY: 1-800-735-2258

SB 332 - FIN - MBON - LOI.docx.pdf
Uploaded by: Maryland State of
Position: FAV

Maryland
DEPARTMENT OF HEALTH

Board of Nursing

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

February 1, 2024

The Honorable Pamela Beidle
Chair, Senate Finance Committee
3 East Miller Senate Office Building
Annapolis, MD 21401

RE: SB0332 – Hospitals and Urgent Care Centers - Sepsis Protocol (Lochlin's Law) - Letter of Information

Dear Chair Beidle and Committee Members:

The Maryland Board of Nursing (the Board) respectfully submits this letter of information for Senate Bill (SB) 332 – Hospitals and Urgent Care Centers - Sepsis Protocol (Lochlin's Law). This bill requires, on or before January 1, 2025, each hospital and urgent care center in the State to implement an evidence-based protocol for the early recognition and treatment of a patient with sepsis, severe sepsis, or septic shock that is based on generally acceptable standards of care; and requires hospitals and urgent care centers to require periodic training in the implementation of the protocol for staff with direct patient care responsibilities, and, as appropriate, for certain staff with indirect patient care responsibilities.

Although the Board believes in protocols for sepsis prevention, evaluation, and treatment, this bill may be redundant of existing federal guidelines relating to infection control. In order to receive Medicaid/Medicare reimbursement, hospitals must adhere to requirements outlined in 42 C.F.R. § 482.42. Hospitals must have active hospital-wide programs for the surveillance, prevention, and control of hospital acquired infections and other infectious diseases, and for the optimization of antibiotic use through stewardship.[1]

In addition, due to the variety of hospitals and urgent care centers, developing a standard protocol could prove challenging. In the case of urgent care centers, it may be necessary to develop more structure to absorb new practices related to sepsis prevention and control. Further, it may be difficult for providers to adopt a standardized new approach on top of their already extensive training.

I hope this information is useful. For more information, please contact Ms. Mitzi Fishman, Director of Legislative Affairs, at mitzi.fishman@maryland.gov or Ms. Rhonda Scott, Executive Director, at rhonda.scott2@maryland.gov, or call (410) 585 – 2049.

[1] https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-482/subpart-C/section-482.42

Sincerely,

Gary N. Hicks
Board President

The opinion of the Board expressed in this document does not necessarily reflect that of the Department of Health or the Administration.

Testimony in support of SB0332.pdf
Uploaded by: Richard KAP Kaplowitz
Position: FAV

SB0332_RichardKaplowitz_FAV

2/15//2024

Richard Keith Kaplowitz
Frederick, MD 21703

TESTIMONY ON SB#/0332 – FAVORABLE

Hospitals and Urgent Care Centers - Sepsis Protocol (Lochlin's Law)

TO: Chair Beidle, Vice Chair Klausmeier, and members of the Finance Committee

My name is Richard K. Kaplowitz. I am a resident of District 3. I am submitting this testimony in support of SB#0332, Hospitals and Urgent Care Centers - Sepsis Protocol (Lochlin's Law)

Health care facilities in Maryland have a responsibility to provide an appropriate level of care. The failure of a hospital to recognize and diagnose a case of sepsis in a young child's visit to that hospital resulted in the loss of that child's life. This was a preventable death had there been a protocol in place to have evidence-based protocols for early recognition and treatment of a patient with sepsis of any degree.

This bill will require hospitals and urgent care centers to conduct periodic staff training on protocols for diagnosis and recognition of possible sepsis in a patient. Patient care should always seek to recognize and develop treatment for any patient they are seeing in any possible condition that could degrade the patients' health or result in possible death if untreated. This bill is a good faith attempt to ensure no other parent is faced with the loss of their child when sepsis was present but unrecognized and treated.

My Jewish faith teaches me, in Psalms 82:3-4, "Give justice to the weak and the fatherless; maintain the right of the afflicted and the destitute. Rescue the weak and the needy; deliver them from the hand of the wicked." This bill will retain the rights of the afflicted to access a level of care from whatever medical facility or personnel they encounter. It is both an ethical and moral thing to do and this bill will ensure that it happens; no other child need die from untreated sepsis.

I respectfully urge this committee to return a favorable report on SB0332.

240214_SB332_Hospitals and Urgent Care Centers - S
Uploaded by: Sarah Roth
Position: FAV

DAVID TRONE
6TH DISTRICT, MARYLAND

APPROPRIATIONS COMMITTEE

BUDGET COMMITTEE

JOINT ECONOMIC COMMITTEE

UNITED STATES
HOUSE OF REPRESENTATIVES

2404 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
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@REPDAVIDTRONE

February 14, 2024

The Honorable Pamela Beidle
Chair, Finance Committee
3 East, Miller Senate Office Building
Annapolis, Maryland 21401

The Honorable Katherine Klausmeier
Vice Chair, Finance Committee
3 East, Miller Senate Office Building
Annapolis, Maryland 21401

Dear Chair Beidle and Vice Chair Klausmeier,

I would like to express my full support for *Senate Bill 332 - Hospitals and Urgent Care Centers - Sepsis (Lochlin's Law)*, named after 5 year old Frederick County resident Lochlin DeSantis, who passed away tragically after a rapid-onsetting sepsis infection that was not properly diagnosed.

Sepsis is one of the leading causes of death in U.S. hospitals. Each year 6,800 children die from severe Sepsis. In Maryland, this condition claims the lives of about 1,100 Marylanders. The risk of mortality from this life threatening condition increases 4-9% every hour that treatment is delayed. As many as 80% of Septic Shock patients can be saved with a rapid diagnosis and treatment.

In order to prevent further tragedies at the hands of Sepsis, Maryland needs proper protocols for medical facilities like those laid out in SB332. It lays out a proactive approach that has hospitals and urgent care centers implement evidence based protocols for the early recognition and treatment of patients with Sepsis.

Similar practices have been implemented in New York State. Dr. Jeremy Khan, who published a study on the effect of the regulations said; "these regulations had their intended effect of reducing mortality." The results were published in JAMA, the journal of the American Medical Association. Furthermore, the NIH published an article praising New York's regulations, stating the state's sepsis policy demonstrates that "it is possible to design these policies in ways that are acceptable to hospitals and achieve substantial positive results."

Maryland should not wait any longer to enact policies that can save lives. It is time for all medical facilities in Maryland to use generally acceptable standards of care to recognize and treat Sepsis. The time is now to pass SB332.

Sincerely,

David Trone
Member of Congress

Sepsis Alliance Comments SB0332 (FAV).pdf
Uploaded by: Thomas Heymann
Position: FAV

The Honorable Pamela Beidle
Chair, Finance Committee Maryland General Assembly
3 East
Miller Senate Office Building
Annapolis, Maryland 21401

The Honorable Katherine Klausmeier
Vice Chair, Finance Committee Maryland General Assembly
3 East
Miller Senate Office Building
Annapolis, Maryland 21401

February 15, 2024

RE: Sepsis Alliance Comments on SB0332 (FAV)

Dear Chair Beidle, Vice Chair Klausmeier, and members of the Finance Committee,

On behalf of Sepsis Alliance, please find our comments on SB0332, Hospitals and Urgent Care Centers - Sepsis Protocol (Lochlin's Law).

Sepsis Alliance, the nation's first and leading sepsis education and advocacy organization, represents the 1.7 million individuals diagnosed with sepsis annually in the U.S. This includes 350,000 adults and nearly 7,000 children who die from sepsis each year. More than one million Americans survive sepsis each year, many of whom face physical, psychological, and cognitive after-effects.

Sepsis is a life-threatening emergency that happens when your body's response to an infection damages vital organs and, often, causes death. Rapid identification and treatment with life-saving therapies – like a fast first dose of broad-spectrum antibiotics – provide the best chance for survival and recovery. Studies have shown that for every hour treatment is delayed, patients experience a four to nine percent increased risk of mortality.

Lochlin's Law mandates that life-saving sepsis protocols be followed in hospital settings and urgent care centers, for adults and children alike. It requires, among other protocols: a process for the screening and early recognition of patients with sepsis; guidelines for hemodynamic support; time frame goals; and delivery of early broad-spectrum antibiotics, with timely reevaluation to adjust to narrow-spectrum antibiotics targeted to identified infection sources. These are the types of medical interventions that can save lives and limbs. Studies show that hospital compliance with evidence-based sepsis protocols, like those outlined in Lochlin's Law, is associated with lower 30-day mortality.

The inclusion in SB0332 of urgent care centers is vitally important, as nearly 87% of sepsis cases originate in the community. Many patients experiencing symptoms seek treatment in urgent care centers.

Another vital component of the bill is the requirement that professional staff with both direct and indirect patient care responsibilities, in both hospital and urgent care settings, receive periodic training on sepsis and the implementation of sepsis protocols. Sepsis is a complex condition that presents many clinical challenges. It is fast-moving, deadly, and difficult to manage even for well-trained staff. Its symptoms can easily be missed or confused with those of other conditions. A 2023 study estimates that the proportion of missed or delayed sepsis diagnoses may be as high as 20%.

That's why educating healthcare professionals on sepsis recognition and treatment is one of the main pillars of our organization's work. Sepsis Alliance Institute offers free continuing sepsis education for healthcare professionals across the continuum of care, from home health nurses to emergency department physicians to infectious disease pharmacists. These trainings enable clinicians to rapidly identify sepsis symptoms and confidently implement the life-saving treatments patients need. But there is still no national requirement that healthcare professionals receive training of this kind.

Sepsis Alliance hopes that the Committee will support SB0332, which will codify evidence-based sepsis protocols in both hospital and urgent care settings and standardize comprehensive healthcare professional education on the implementation of these protocols. Lochlin's Law will help to ensure timely recognition and treatment for life-threatening sepsis, reducing suffering and saving many lives throughout the state of Maryland.

Thank you for the opportunity to provide comments.

Sincerely,

Thomas Heymann
President & CEO, Sepsis Alliance
theymann@sepsis.org
3180 University Avenue, Suite 310
San Diego, CA 92104

1a - SB 332- FIN - MDH - LOSWA.pdf
Uploaded by: Jason Caplan
Position: FWA

Maryland
DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

February 15, 2024

Pamela Beidle
Chair, Senate Finance Committee
3 East Miller, Senate Office Building
Annapolis, MD 21401

RE: Senate Bill 332 – Hospitals and Urgent Care Centers – Letter of Support with Amendments

Dear Chair Beidle and Committee Members:

The Maryland Department of Health (Department) respectfully submits this letter of Support with amendments for Senate Bill (SB) 332 – "Hospitals and Urgent Care Centers - Sepsis Protocol (Lochlin's Law)," which requires hospitals and urgent care centers within the State of Maryland to implement a specific protocol establishing treatment for and early detection of sepsis, severe sepsis, or septic shock in patients. HB 84 mandates that hospitals and urgent care centers provide regular staff training to implement sepsis protocols appropriately.

The Department supports the critical health initiative of this bill which requires professional training for sepsis detection and treatment protocols for hospitals and urgent care centers. However, the Department respectfully submits clarifying amendments for special hospitals and urgent care centers to focus on early detection and transfer of a patient with sepsis or suspected sepsis to an appropriate level of care. The amendments will require special hospitals and urgent care centers to train staff to identify sepsis and transfer the individual to a hospital that can provide the appropriate treatment. The Maryland Department of Health believes this clarifying amendment will ensure that patients within a special hospital or urgent care center receive care at an appropriate level of care for treatment of sepsis.

If you would like to discuss this further, please do not hesitate to contact Sarah Case-Herron, Director of Governmental Affairs, at Sarah.Case-Herron@Maryland.gov.

Sincerely,

Laura Herrera Scott, M.D., M.P.H.
Secretary

AMENDMENT TO HOUSE BILL 332

Amendment No. 1:

On page 1, in line 21, strike **"AND"** and insert a comma; in the same line after **"TREATMENT"** insert "**, OR TRANSFER**".

Amendment No. 2:

On page 2, in line 2, after **(I)** insert **"FOR A SPECIAL HOSPITAL OR URGENT CARE CENTER"**; in line 3, strike **"TREATMENT"** and substitute **"TRANSFER"**; in the same line strike the **"AND"** after the semicolon and replace it with **"OR"**, and in line 4 after (**II**) insert **"FOR A HOSPITAL INCLUDE COMPONENTS SPECIFIC TO THE IDENTIFICATION, CARE, AND TREATMENT OF ADULTS AND CHILDREN; AND"**.

Amendment No. 3:
(III).

On page 2, in line 9, after (**I**) insert **"FOR A SPECIAL HOSPITAL AND A URGENT CARE CENTER, A PROCESS FOR THE SCREENING AND EARLY RECOGNITION OF A PATIENT WITH SEPSIS, SEVERE SEPSIS, OR SEPTIC SHOCK, AND PROCEDURES TO TRANSFER THE PATIENT TO A HOSPITAL THAT CAN PROVIDE THE APPROPRIATE LEVEL OF CARE; AND**.

(II) FOR A HOSPITAL:"

Amendment No. 4:

On page 2, in lines 11, 16, 19, 23, and 27, strike **"(II)"**, **"(III)"**, **"(IV)"**, **"(V)"**, and **"(VI)"**, respectively, and substitute **"(1)", "(2)", "(3)", "(4)"**, and "**(5)"** respectively.

Amendment No. 5:
On page 3, in line 11, strike **"AND"** and substitute a comma; in the same line after **"TREATMENT"** insert **", OR TRANSFER";** and in the same line after **"OF" insert "A PATIENT WITH "**.

HB0084.pdf
Uploaded by: Jill Kapper
Position: FWA

Jill Kapper
221 Owings Gate Court T2
Owings Mills MD 21117
HB0084/SB0332- Support W/Amendments

Good afternoon, My name is Jill Kapper and I'm a lifelong resident of Maryland. It seems strange that a required protocol would be put in place by law but there must be an option to opt-out if doing so. During the last few years specifically, we witnessed how medical establishments murdered patient after patient based on protocols. Not all protocols are safe and effective, evidence based or not. Time and time again we see a one-size-fits-all approach as if every patient is identical and has similar needs but this is clearly not the case. I'm all about evidence based medicine but what is evidence based to me may not be the same to you. Again, I'm urging for amendments to be made where patients have the Freedom to decide for themselves which evidence based treatments they would like to pursue.

Thank You for listening!

SB0471 Sepsis Protocol Cover Letter (Lochlin's Law

Uploaded by: Senator Karen Lewis Young

Position: FWA

KAREN LEWIS YOUNG
Legislative District 3
Frederick County

Committee on Education, Energy, and the Environment

James Senate Office Building
11 Bladen Street, Room 302
Annapolis, Maryland 21401
410-841-3575 · 301-858-3575
800-492-7122 *Ext.* 3575
Karen.Young@senate.state.md.us

THE SENATE OF MARYLAND
ANNAPOLIS, MARYLAND 21401

The Honorable Senator Beidle, Chair
The Honorable Senator Klausmeier, Vice Chair
Finance Committee
Maryland Senate
Annapolis, MD

February 15th, 2024

Testimony in Support of SB332: Hospitals and Urgent Care Centers - Sepsis Protocol (Lochlin's Law)

Chair Beidle, Vice Chair Klausmeier, and esteemed members of this committee,

I bring SB332 Lochlin's Law before you today to address a very solvable issue: sepsis testing and training. This bill will do two things: First, require hospitals across the state to perform an inexpensive, noninvasive test for sepsis, and secondly, require staff to be trained in recognition and treatment of sepsis.

What is sepsis? Sepsis is the body's immune system attacking its own organs in response to an infection. Sepsis can be caused by *any infection*, and infections can be caused by viruses, wounds, bacteria, and fungus. Sepsis can quickly cause organ failure, hypertension, septic shock, and death.

Every hour treatment is delayed, mortality rates increase 8 percent[1]. According to the Centers for Disease Control, millions of Americans get sepsis each year and Maryland ranks below 34 other states[2] in sepsis deaths. Indeed, sepsis is the ninth leading cause of death in Maryland. Sepsis has a 20% mortality rate.

How do we stop it? Sepsis is easily identified through a blood sample. With timely identification it can be treated with antibiotics. Anyone can get sepsis, young or old. According

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[1] Sepsis Alliance, "Sepsis Fact Sheet" https://r.search.yahoo.com/_ylt=AwrJ.VhIksZl3E0fzI8PxQt.;_ylu=Y29sbwNiZjEEcG9zAzEEdnRpZANMT0NVSTExNFRfMQRzZWMDc3I-/RV=2/RE=1707541193/RO=10/RU=https%3a%2f%2fsepsis.org%2fwp-content%2fuploads%2f2019%2f08%2fSepsis-FactSheet-v2.pdf/RK=2/RS=Lmlt_Xpl.M7yzfEiKep.SCPzJKE-

[2] Centers for Disease Control. https://www.cdc.gov/nchs/pressroom/sosmap/septicemia_mortality/septicemia.htm. Accessed February 9th, 2024.

to the Maryland Hospital Association, hospitals that voluntarily implemented sepsis protocols saw a 26% reduction in deaths due to sepsis[3]. Other states suggest that number may be even higher — New York's pediatric mortality rate improved by 40 percent, saving over 16,000 lives over five years. Regional healthcare systems have also seen positive results from sepsis protocols such as Intermountain Health Care which reduced the sepsis mortality rates from twenty-five percent to nine percent.[4]

What is the cost? In a tight budget year, that is a question many of us are asking ourselves. According to the National Institute of Health, the costs of treating sepsis after early identification range as high as $16,000 and over $50,000 when identification and, therefore, treatment are delayed[5]. Intermountain Health Care's initiative saved $38 million annually.[6]

This legislation will save lives. It will save money. An ounce of prevention is worth a pound of cure. I urge the committee to return a favorable report.

Sincerely,

Senator Karen Lewis Young

---

[3] Maryland Hospital Association. 2018 Annual Report. https://www.mhaonline.org/docs/default-source/publications/mha's-2018-annual-report.pdf?sfvrsn=f969db0d_0. Accessed February 9th, 2024.

[4] McCaffery et al, "Sepsis-review of screening for sepsis by nursing, nurse driven sepsis protocols and development of sepsis hospital policy/protocols." "https://www.oatext.com/Sepsis-review-of-screening-for-sepsis-by-nursing-nurse-driven-sepsis-protocols-and-development-of-sepsis-hospital-policy-protocols.php#:~:text=Similarly%2C%20Regions%20Hospital%20in%20Minnesota,%2438%20million%20annually%20%5B17%5D.

[5] National Institute of Health. "Epidemiology and Costs of Sepsis in the United States—An Analysis Based on Timing of Diagnosis and Severity Level". National Library of Medicine, National Center for Biotechnology Information. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6250243/. Accessed February 9th, 2024.

[6] McCaffery et al, "Sepsis-review of screening for sepsis by nursing, nurse driven sepsis protocols and development of sepsis hospital policy/protocols." "https://www.oatext.com/Sepsis-review-of-screening-for-sepsis-by-nursing-nurse-driven-sepsis-protocols-and-development-of-sepsis-hospital-policy-protocols.php#:~:text=Similarly%2C%20Regions%20Hospital%20in%20Minnesota,%2438%20million%20annually%20%5B17%5D.

testimony opposing SB332 sepsis- 2024.pdf
Uploaded by: Emily Tarsel
Position: UNF

Emily Tarsell, LCPC

2314 Benson Mill Road
Sparks, Maryland 21152
February 15, 2024

Unfavorable SB 332 (HB 84)

Dear Chairwoman Beidle and Senate Finance Committee Members,

I am Emily Tarsell, a mother, licensed therapist and President of Health Choice Maryland. My heart goes out to the family who lost a child and I understand how they find comfort in this bill. I too lost a child and I too find comfort in raising awareness to prevent others from losing a child. That is what brings me here today.

While it seems reasonable to have protocols for the early recognition and treatment of sepsis, do we really need a law for that? Adequate treatment for sepsis must already exist because the incidence of death from sepsis in the US is very low.[1] Or is it that the pharmaceutical industry sees this as an opportunity to create fear by using "worldwide" data to promote more drugs and/or vaccines by influencing the protocols?

For example, Pharma drove fear of HPV related cancers by hyping "worldwide" statistics to scare us into getting HPV vaccines. Turns out the rates of HPV cancers in the US are less than 1% and we already had safe and effective ways to prevent cervical cancer with Pap screening. They tricked us. My young, healthy daughter got the shots and she died a few days later from a shots she never needed.

So now the incidence of sepsis "worldwide" may be hyped primarily to promote Pharma products here. According to studies, about 85% of sepsis cases occurred in low- income countries**,** primarily among the elderly and those with compromised immune systems.[1]. So why are we not directing resources toward building stronger immune systems with good nutrition and sanitation especially in these marginalized populations?

The best way to deal with sepsis is to prevent it in the first place with a healthy immune system and education about infection prevention. I don't see anything in this bill about that. I do see here the potential for Pharma to exploit the public, especially the most vulnerable, the poor and disadvantaged with protocols for Pharma products that may not be necessary or treatments that are not individualized with no option to op out. This bill does not address these underlying issues.

I respectfully ask for an UNFAVORABLE vote for **SB 332.**

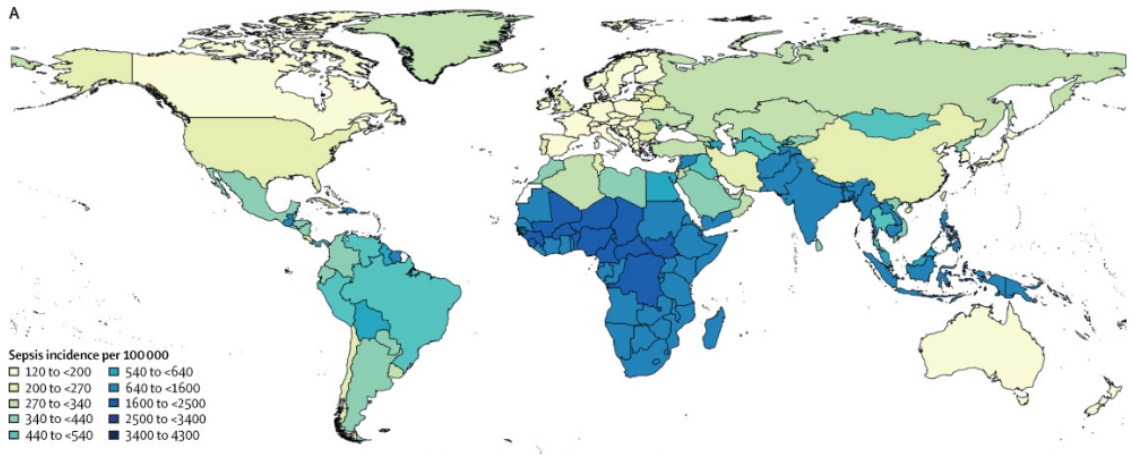
Thank you.
Emily Tarsell, LCPC

[1] Rudd KE, Johnson SC, Agesa KM, Shackelford KA, Tsoi D, Kievlan DR, et al. Global, regional, and national sepsis incidence and mortality, 1990-2017: analysis for the Global Burden of Disease Study. Lancet (London, England). 2020;395(10219):200-11.

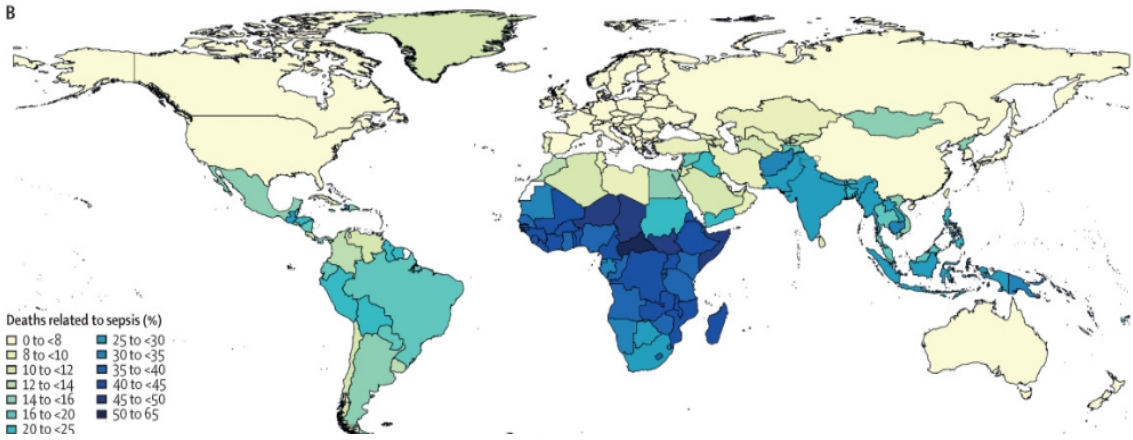
Global, regional, and national sepsis incidence and mortality

Published in the Lancet

Incidence of sepsis in the US 200 to less than 270 per 100,000. (Compared to Africa with as much as 3,400 to 4,300 per 100,000.)



Deaths in the US from sepsis are less than 1 % per 100,000. In Africa, it is as high as 65% per 100,000.



The World Health Organization is planning a Sepsis Awareness Day for September 13th 2024.

While sepsis is clearly a serious problem in low income countries where there are food insecurity and sanitation issues, the US appears to be doing a good job.

Oppose 2024 Senate Bill 0332.pdf
Uploaded by: Eszter Szabo
Position: UNF

Oppose 2024 Senate Bill 0332

Eszter Szabo
Bethesda, MD 20817
February 14, 2024

Dear Chair and Members of the Committee,
https://www.gene.com/download/pdf/tamiflu_patientinfo.pdf

This bill is supported by the Love for Lochlin Foundation in Maryland according to Delegate Kerr who is the sponsor of it in the House. Lochlin was a 5-year-old boy who sadly died from sepsis linked to the flu in 2020, when he was treated with Tamiflu after an urgent care visit. The Foundation is promoting, among other things, vaccination against flu as a solution to flu related sepsis death via free mobile clinics in Frederick County, MD. https://www.loveforlochlin.com/

This bill is condemnable as who would want to see even one more child die at such young age. However, one needs to look a bit further than just assume that the solution to the issue here is either vaccination against the flu or legislative solution with respect to sepsis.

Lochlin was prescribed Tamiflu 2 days after he started his flu symptoms. Tamiflu's side effects according to this study from Japan https://pubmed.ncbi.nlm.nih.gov/22156085/ includes death. "**Conclusions:** These data suggest Tamiflu use could induce sudden deterioration leading to death especially within 12 hours of prescription. These findings are consistent with sudden deaths observed in a series of animal toxicity studies, several reported case series and the results of prospective cohort studies. From "the precautionary principle" the potential harm of Tamiflu should be taken into account and further detailed studies should be conducted."

More on this topic can be found here https://circleofmamas.com/health-news/recent-flu-death-uncovers-more-tamiflu-risks/

"Instead, how about asking these questions?

- What percent of the pediatric influenza deaths every year were administered Tamiflu?
- What percent of these deaths were vaccinated?

The antiviral medication (oseltamivir) was found to cause severe side effects such as hallucinations, severe vomiting and diarrhea, and even death, in it's own clinical trials and post marketing surveillance.

Many people who die of the flu, either were vaccinated, or given Tamiflu:
🙏 Kinsley Sandvik, 8 years old from Maryland, dies on Valentine's Day of 2020 of blood poisoning after being given Tamiflu.
https://www.fox5dc.com/news/8-year-old-maryland-girl-loses-life-from-flu-complications
🙏 Kaylee Roberts, 16 years old, dies from flu after being given Tamiflu.
https://www.cnn.com/…/flu-ohio-teen-kaylee-rober…/index.html

🙏 Luca Calanni, 11 years old dies from the flu. Got a flu shot 2 months prior, and dies after Tamiflu.
https://buffalonews.com/…/death-of-11-year-old-from-flu-ha…/
🙏 Liliana "Lily" Clark, 13 years old dies 2 weeks after she was diagnosed with the flu. Dies after Tamiflu.
https://nypost.com/…/idaho-teen-dies-two-weeks-after-she-w…/
🙏 Jade DeLucia, 4 years old, received a flushot in March 2019 but still came down with the flu in December.
https://www.dailymail.co.uk/…/Four-year-old-girl-not-vaccin…
🙏 Canadian Joanne Ens, 24 years old, dies from flu after taking Tamiflu.
https://winnipeg.ctvnews.ca/manitoba-woman-24-dead-days-aft…

STUDIES
"The mechanisms of sudden-onset type adverse reactions to oseltamivir."
2017 https://www.ncbi.nlm.nih.gov/pubmed/27364959
"Oseltamivir is contraindicated for people aged 10-19 in principle in Japan, due to concern about abnormal behaviours. Sudden death is another concern. This review examines growing evidence of their association and discusses underlying mechanisms of these sudden-onset type reactions to oseltamivir."
"Oseltamivir and early deterioration leading to death: a proportional mortality study for 2009A/H1N1influenza." 2011 https://www.ncbi.nlm.nih.gov/pubmed/22156085
"Of 119 deaths after Tamiflu was prescribed, 38 deteriorated within 12 hours (28 within 6 hours), while of 15 deaths after Relenza, none deteriorated within 12 hours. Pooled OR for early deterioration and overall death were 5.88 (95% CI: 1.30 to 26.6, p = 0.014) and 1.91 (p = 0.031) respectively. Baseline characteristics including risk factors did not contribute to early deterioration after Tamiflu use."
Is oseltamivir (Tamiflu) safe? Re-examining the Tamiflu 'ado' from Japan.
2010. https://www.ncbi.nlm.nih.gov/pubmed/20121561
The author also alarms the potential risk of sudden death related to oseltamivir and foresees how the problem may be solved in the future.
"Fatal neuropsychiatric adverse reactions to oseltamivir: Case series and overview of causal relationships". 2008. https://npojip.org/english/published-paperJRS431.pdf
"This paper reports eight cases in total: five of these died and three survived. Two died as a result of accidents resulting from abnormal behaviour. Three others died suddenly during sleep (two infants and one adult). One of the infants and the adult were found at autopsy to have severe lung oedema. A 14-year-old boy experienced agitation, cyanosis, loss of consciousness and seizures but recovered completely, while a 10-month-old girl showed retarded development and mental retardation after initially appearing to recover from the acute event involving loss of consciousness and seizure. A 15-year-old boy had a delayed onset of complications but developed prolonged neuropsychiatric adverse reactions after taking an almost complete course of Tamiflu; in this case the symptoms lasted for two weeks."

The MD bill itself asks for hospitals and urgent care centers to create diagnosing and treatment protocols for sepsis both in children and adults. The current widely practiced sepsis protocol is using antibiotics, however many infections are antibiotic resistant. It seems there is an interest to use vaccination as a possible way to avoid various infections that may lead to sepsis. However, sepsis mainly develops in individuals with weak immune system or as a result of infections during or following hospital care. This is stated here by the World Health Organization https://www.who.int/news-room/fact-sheets/detail/sepsis

Key facts from this page linked directly above dated July 2023, which is based heavily on a study "funded by The Bill & Melinda Gates Foundation, the National Institutes of Health, the University of Pittsburgh, the British Columbia Children's Hospital Foundation, the Wellcome Trust, and the Fleming Fund" are:

- "A recent scientific publication estimated that in 2017 there were 48.9 million cases and 11 million sepsis-related deaths worldwide, which accounted for almost 20% of all global deaths (1).
- In 2017, almost half of all global sepsis cases occurred among children, with an estimated 20 million cases and 2.9 million global deaths in children under 5 years of age (1).
- Regional disparities in sepsis incidence and mortality exist; approximately 85% of sepsis cases and sepsis-related deaths worldwide occurred in low- and middle-income countries (1).
- Health care-associated infections are one of the most frequent types of adverse event to occur during care delivery and affect hundreds of millions of patients worldwide every year."

Further "To combat this important global health threat, WHO responded with a WHO Secretariat Report and, in May 2017, the Seventieth World Health Assembly adopted Resolution WHA70.7 on *Improving the prevention, diagnosis and clinical management of sepsis*. The key pillars of Resolution WHA 70.7 are to:

1. develop WHO guidance on sepsis prevention and management;
2. draw attention to public health impacts of sepsis and estimate the global burden of sepsis;
3. support Member States to define and implement standards and establish guidelines, infrastructure, laboratory capacity, strategies, and tools for identifying, reducing incidence of, and morbidity and mortality due to sepsis; and
4. collaborate with UN organizations, partners, international organizations, and stakeholders to enhance sepsis treatment and infection prevention and control including vaccinations."

The UN Sustainable Development Goals states: "The prevention and/or appropriate diagnosis and management of sepsis is also linked to adequate vaccine coverage, quality universal health coverage, capacity to comply with the International Health Regulations, preparedness, and water and sanitation services. The challenge, however, remains how to achieve universal prevention, diagnosis and management of sepsis."

Currently there is no gold standard screening protocol to identify sepsis or protocol to treat sepsis, nor is there a meaningful reporting for sepsis events as this scientific study states it here: https://pubmed.ncbi.nlm.nih.gov/31954465/

The following quote is about this issue based on NY state's law about sepsis treatment: https://www.pulmccm.org/p/regulations-sepsis-treatment

"Does Regulating Sepsis Care Improve Outcomes?
New York regulators and its governor tout their state's 16% relative reduction in mortality from sepsis (30% to 25%) from 2014 to 2016, combined with a 20% increase in case identification (11,000 to 13,000/year). That math suggests an unchanged absolute number of about 3,300 deaths from sepsis each year at the observed hospitals. Generally speaking, the most efficient way to improve observed survival from a disease is to identify more cases, which tend to be milder in severity, or false positives.

Any such secular trends are not discernible in the aggregated data in the paper, but 45% of the 49,000 patients (2014-2016) were described as having septic shock. However, in a 2015 New York state health department report, 49% of the patients had septic shock. Were the presenting patients less ill as time went on?

Sepsis mortality has been declining nationwide, in states without such regulations. But the study purporting to show this also admits that depending on which competing epidemiologic case definition is used, observed sepsis incidence in the U.S. during a given time period can arbitrarily be tripled, or reduced by 70%. With the uncertainty in case definition, it's hard to have confidence in national numbers.

There's no way to know, but it seems likely that rapid sepsis identification and delivery of antibiotics at high-performing institutions under the New York regulations saved lives. Whether mandating the other elements of the bundles is helpful or necessary is less clear.

Risks Of Regulation of Sepsis Care
The New York legislation represents a new level of governmental control of medical practice, legislating care for a condition affecting more than one million Americans each year.

Editorialists worried that:
Clinical practice guidelines often make recommendations involving proprietary medical devices and pharmaceuticals. Device and pharmaceutical companies could lobby state governments to include these products in future regulations. If these lobbying efforts are not transparent, conflicts of interest may lead to abuse of the regulatory process."

The story behind the CMS sepsis core measure suggests these concerns are valid:

The National Quality Forum (NQF) is the only guideline-issuing entity in the U.S. whose performance measures result in changes to Medicare and Medicaid rules and thus are backed by state power. The NQF's review process is designed to include industry representation.

According to a slides presented by a physician at the National Institutes of Health, in 2013 the National Quality Forum endorsed an earlier version of its sepsis performance measure, proposed by the original advocates of EGDT for sepsis. The NQF's endorsed measure included a requirement for measuring central venous pressure and central venous oxygenation. This decision came despite objections from multiple professional societies, and disregarded the pending results from the Process, Arise, and Promise trials. (In 2014 and 2015, these three trials together definitively refuted any benefit of standardized measurement of CVP or ScvO2 in sepsis.)

It so happened that in 2013, the co-chair of the NQF steering committee reviewing the sepsis core measure was the vice-president of AdvaMed, a trade association for medical device manufacturers. Also on the board of directors of AdvaMed since 2008: the CEO of Edwards Lifesciences, the manufacturer of a proprietary central venous catheter to measure CVP and ScvO2. Edwards Lifesciences funded the original EGDT trial and subsequently provided hundreds of thousands of dollars in funding and speaker's fees to that study's author and institution.

After publication of the Process trial less than a year later, the National Quality Forum revised its performance measure, changing use of CVP and ScvO2 from required to optional.

The New York regulations were created without suggestions of undue industry influence, but it's worth noting they are grounded in similar history, evidence, and politics as the CMS core measure.

At least three states (Pennsylvania, Washington, and Illinois) are considering similar legislation mandating the use of sepsis bundles, based on New York's model."

The current bill in Maryland doesn't yet mandate one protocol for sepsis but if this would be the case in the future, one wants to oppose this bill. Doctors need to be able to practice medicine based on individual patient needs and not mandated protocols that are influenced by pharmaceutical companies and researchers paid by Big Pharma. I support encouraging the medical community to find working diagnoses for sepsis in children and adults, even though as the above information shows even that is very difficult, but I am against a mandated and codified law which will limit patients' choice for possible treatment at the hospital or urgent care level.

Here is one treatment that might not make a cut for such a protocol even though it successfully worked. IV vitamin C treatment can be used to treat sepsis.
https://www.npr.org/sections/health-shots/2017/03/23/521096488/doctor-turns-up-possible-treatment-for-deadly-sepsis

Please vote against this bill.

Sincerely,

Oppose SB 332.pdf
Uploaded by: John Kelly
Position: UNF

Oppose SB 332

Before the Senate Finance Committee

of the

Maryland General Assembly

Hearing on SB 332

February 15, 2024

Written Testimony in Opposition to Senate Bill 332

John M. Kelly

Bethesda, Maryland

I first want to emphasize that I do not oppose hospitals and urgent care facilities having protocols for identifying and treating sepsis nor for periodic training of such protocols. I oppose ambiguous language in the bill that could easily have unintended consequences of worsening the outcomes of sepsis treatments rather than improving them.

The protocols described in the bill would unduly constrain sepsis treatments to "generally accepted standards of care" ***only*** and, thereby, preclude more recent and effective treatments that have not yet found their way into "generally accepted standards of care".

The bill conflates the terms "evidence-based protocol" and "generally acceptable standards of care". It implies that a protocol is "evidence-based" only if it is regarded as a "generally accepted standard of care". But there are evidence-based protocols that have not been designated as "generally accepted". Therefore, the bill's requirement that the protocols be based on "generally accepted standards of care" can be easily construed as excluding safe and effective protocols that have not yet found their way into conventional definitions of "generally accepted standards of care".

It takes time for safe and effective treatments based on evidenced gathered from clinical experience to be recognized and generally accepted, but this should not exclude them from use or justify any implicit or explicit bias against their use.

The bill biases the treatment of sepsis to "generally accepted standards of care" *only*, and could easily constrain doctors from using effective, evidence-based treatments that have not yet been "generally accepted" simply due to the time it takes for any new treatment to be designated so.

These concerns are not merely hypothetical or speculative. There is convincing evidence that there is an effective and safe sepsis treatment that is far superior to generally accepted protocols but is

not yet a “generally accepted standard of care”. I urge committee member to listen to an interview with Dr. Paul Mari who is one of the persons who developed the new sepsis treatment.” (See: https://www.faim.org/interview-with-dr-paul-marik-on-vitamin-c-protocol-for-sepsis).

In a clinical trial of 150 persons, “Dr. Marik … treated patients with severe sepsis … and septic shock and only person one from that group died from the sepsis itself. Moving from a 30-50 percent mortality utilizing standard treatment protocols for sepsis to achieving a sepsis-related mortality of less than 1% using IV vitamin C / hydrocortosone / thiamine therapy in this small treatment group is nothing short of miraculous. His protocol has since been lab-tested and proven to work. It is now used regularly at Eastern Virginia Medical School to treat sepsis.” (See: Foundation Alternative and Integrative Medicine: https://www.faim.org/)

The above study raises a central questions about current protocols and the major assumption underlying the bill: What is the factual basis for the protocols and for expanding their use? Is the problem of sepsis deaths that not enough health-care facilities are following the current protocols, or is it that the current protocols are not as effective as desired and believed?

The bill implies current protocols are effective. But before the committee considers any legislation regarding such protocols – and in the spirit of the bill’s concern for “evidence-based protocols” -- the committee should find out how effective the current sepsis protocol is in preventing deaths. Then, it should compare the results with the effectiveness of recent sepsis protocols that are not yet considered “generally accepted standards of care”.

The bill continues a troubling trend of taking health care out of the hands of doctors and their patients. Traditional medicine is being turned upside down. Protocols are no longer aides to help doctors treat patients; instead, they are becoming inflexible requirements to follow. And the requirements are promulgated with insufficient regard for the physical health and medical histories of patients.

It is reasonable to be concerned that in an environment of over-reliance on established protocols, doctors would feel constrained from recommending and providing treatments based on their own training, clinical experience and, especially, knowledge of recent advances in health-care that are not yet regarded as “generally accepted”.

Doctors’ traditional role in the “patient-doctor” relationship is seriously diminished. They are becoming agents who administer “protocols” rather than doctors who make judgments about authorizing treatments in consultation with patients about the risks and benefits of health-care

interventions. On on the patient side, adequate informed consent for interventions is diminished or none is provided.

Oppose SB 332.pdf
Uploaded by: Mark Meyerovich
Position: UNF

Oppose SB 332

Dear Chair and members of the committee,

The desire to alleviate suffering and help every patient is commendable. I acknowledge the importance of having comprehensive protocols for treating such serious conditions as sepsis. However, there are several concerning issues about the bill, and thus I respectfully urge you to reject it. Does every problem need a political solution?

To begin with, why should there be a law for a specific medical condition? How many patients are affected? Is this the most pressing medical issue compared to other conditions? Hospitals treat multiple emergencies every hour. Are hospitals not required to make the best of their expertise and assets to save as many patients as they can? Are there no broad laws that hold hospitals accountable for negligence?

Doctors, with their expertise and understanding of individual patient needs, should have the autonomy to tailor treatment plans according to the specific circumstances of each case. However, when protocols prioritize financial gain or legal protection over patient well-being, it undermines the integrity of medical practice and jeopardizes patient outcomes. Mandating adherence to such protocols can lead to the adoption of standardized approaches that may not always align with the best interests of patients, potentially sacrificing optimal care in favor of institutional interests. This lack of flexibility and doctor autonomy not only compromises the quality of care but also erodes trust in the medical profession.

Ignoring the doctor-patient relationship within the proposed protocol presents a significant oversight that could undermine the quality of care provided. The doctor-patient relationship is fundamental to effective healthcare delivery, as it fosters trust, communication, and shared decision-making between healthcare professionals and patients.

There arises a critical question regarding whether the proposed protocol will be deemed a "standard of care," directly linked to reimbursement rates and subsequently mandated across healthcare organizations and jurisdictions. Linking reimbursement rates to protocol adherence could incentivize healthcare institutions to prioritize financial considerations over patient-centered care. This approach risks homogenizing treatment practices and may not necessarily reflect the most effective or appropriate care for all patients.

Increased data collection and reporting, and mandatory training costs, impose additional burden to the health care providers. All of the above points make this bill problematic.

Please vote unfavorably.

Sincerely,
Mark Meyerovich
Gaithersburg, MD
District 15

HB0084_SB332 2024.pdf
Uploaded by: Melissa Burns
Position: UNF

Hello, As a constituent I am writing to ask you to **oppose or amend HB0084/SB0332** - *Hospitals and Urgent Care Centers - Sepsis Protocol (Lochlin's Law)*. While this bill has good intentions, it is overlooking one crucial risk that became evident during the Covid-19 outbreak. This bill intends to codify following "protocol" and risks inhibiting a doctors' ability to use treatments that may not be part of the "protocol". We saw this repeatedly during Covid as doctors were forced to adhere to the protocol of Remdesivir, and were denied the ability to prescribe Ivermectin which has since been proven to effectively treat the disease. Thousands of people died needlessly as a result of these protocols. (See links below)

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10484241/

https://pubmed.ncbi.nlm.nih.gov/34145166/

This bill also increases government control over the doctor-patient relationship, and takes away individuals' rights over their own treatment. The tragic case of Lochlin DeSantis does not seem relevant to the intent of this bill. If this bill wanted to prevent such deaths it would focus on mandatory early screening for sepsis, which Lochlin did not receive. I agree with hospital staff being trained to identify signs of sepsis, and testing early, but it's a terrifying thought that laws are needed to ensure our hospitals and healthcare providers are skilled for the requirements of their jobs. What is medical school for then?

Please use this bill to honor Lochlin, by forcing early detection of sepsis, but please don't let this little boy's death be used as a way to incorporate government interference with the doctor-patient relationship and a doctor's right to treat. FLCCC Alliance has wonderful information about sepsis, they are a group of doctors with a significant amount of expertise in sepsis and its treatment. But a bill like this could risk a doctor's ability to follow their own evidence-based protocols. Please vote UNFAVORABLE or amend this bill to focus solely on early diagnosis. Thank you.

https://covid19criticalcare.com/tools-and-guides/what-is-sepsis/

Melissa Burns
Forest Hill, MD

SB 332 - FIN - HSCRC - LOI.docx.pdf
Uploaded by: State of Maryland (MD)
Position: INFO

maryland
health services
cost review commission

February 15, 2024

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

RE: Senate Bill 332 - Hospitals and Urgent Care Centers - Sepsis Protocol (Lochlin's Law) – Letter of Information

Dear Chair Beidle and Committee Members:

The Health Services Cost Review Commission (HSCRC) submits this letter of information for Senate Bill 332 titled, "Hospitals and Urgent Care Centers - Sepsis Protocol (Lochlin's Law)." HSCRC incentivizes improved treatment of sepsis through hospital pay-for-performance programs and the sepsis bundled payment in the voluntary Episode Quality Improvement Program (EQIP) for specialty physicians. These programs complement SB 332's focus on sepsis prevention.

Maryland hospitals perform well on a key national measure of sepsis treatment. According to CMS, among the 52 States and Territories that reported data to CMS in CY2022, Maryland was ranked 9th from the top. This performance is likely attributable, at least in part, to HSCRC's hospital quality pay-for-performance program, which holds hospitals accountable for their performance on quality measures related to sepsis. This program financially penalizes or rewards hospitals based on their performance compared to other Maryland hospitals and the nation. The resulting payment adjustments to hospital global budgets on revenue (GBRs) are applied on an all-payer basis. The sepsis-related measures used by HSCRC are described below.

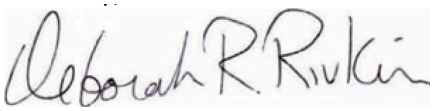
- **Hospital acquired sepsis**: HSCRC uses two measures of hospital-acquired sepsis that are included in payment programs. These measures incentivize hospital processes that minimize the chance that a patient admitted to the hospital will develop sepsis during their admission.
- **Hospital readmissions and mortality:** HSCRC uses all-payer, all-condition readmission and mortality measures in our payment programs. This means that hospital readmissions and deaths due to sepsis are included in the measures. In comparison, the federal Centers for Medicare and Medicaid Services (CMS) hospital payment programs use measures of readmissions or mortality for only a limited number of specific conditions such as heart attack, stroke, and chronic obstructive pulmonary disease (COPD) and the CMS measures are applicable to Medicare patients only.

In addition, the most recent Quality-Based Reimbursement policy approved by HSCRC includes approval for HSCRC staff to develop and implement a Sepsis dashboard for monitoring of statewide and hospital-specific sepsis measures (including measures that are not included in the current hospital quality pay-for-performance program). The HSCRC plans to develop this dashboard over the coming year.

Additionally, the Episode Quality Improvement Program (EQIP) allows specialty physicians to choose to participate in a payment incentive program based on their treatment of episodes of sepsis experienced by patients.

The HSCRC remains committed to using payment incentives to improve outcomes for patients that develop sepsis. SB 332's focus on sepsis prevention complements these efforts to improve outcomes for patients. If you have any questions or if I may provide you with any further information, please do not hesitate to contact me at 410-991-7422 or deborah.rivkin@maryland.gov, or Jon Kromm, Executive Director, at jon.kromm@maryland.gov.

Sincerely,



Deborah Rivkin
Director, Government Affairs