SB754.Whitebagging.MPhA.pdf
Uploaded by: Aliyah Horton
Position: FAV

MPhA
MARYLAND PHARMACISTS ASSOCIATION

Date: February 27, 2024
To: The Honorable Pamela Beidle, Chair
From: Aliyah N. Horton, FASAE, CAE, Executive Director, MPhA, 240-688-7808
Cc: Members, Senate Finance Committee
Re: **FAVORABLE SB 754 - Health Insurance Carriers and Pharmacy Benefit Managers-Clinician Administered Drugs.**

The Maryland Pharmacists Association (MPhA) urges a favorable report for **SB754 - Health Insurance Carriers and Pharmacy Benefit Managers-Clinician Administered Drugs.**

The bill supports the prohibition of payer-mandated white bagging across the state of **Maryland** **in all care settings.**

What is White Bagging? The term describes the distribution of a patient-specific medication from a pharmacy to the physician's office, hospital, or clinic for administration. It is often used in facilitation of oncology treatments and other immunotherapy treatments for immunodeficiencies, hypersensitivity reactions, autoimmune diseases, tissue and organ transplantations, malignancies and inflammatory disorders.

Passage of the bill would prohibit a payer-mandated model where payers dictate where the patient's medication is supplied from and removes incentives for payers to steer patients to affiliated pharmacies in order to, we believe, capture a higher portion of payment for medical services.

MPhA is also concerned about "white bagging" practices due to:

- Drug integrity concerns (e.g., drug storage, temperature controls); and
- Poor communication and coordination among providers, resulting in treatment delays.

In some clinic-based practices, pharmacies are often directly down the hall from a physician or clinician who will be administering the medications. Under white bagging policies they have an extra level of coordination with the patient on treatment scheduling, patient availability, and medication delivery when they could more easily coordinate care with pharmacists/pharmacies, with whom they have a practicing relationship.

This legislation is also supported by the Maryland Pharmacy Coalition, of which MPhA is a member.

SB0754_FAV_MDCSCO, ASCO_HI Carriers & PBMs – Clini
Uploaded by: Danna Kauffman
Position: FAV

February 28, 2024

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

Dear Chair Beidle and Members of the Senate Finance Committee:

The Maryland/DC Society of Clinical Oncology (MDCSCO) and the Association for Clinical Oncology (ASCO) are pleased to support **SB 754**, which would prohibit mandatory white bagging and all brown bagging requirements from insurers so that patients can obtain clinician-administered drugs from their health care providers, thereby preserving timely and consistent delivery of high quality, patient-centered care.

MDCSCO is a professional organization whose members are a community of physicians who specialize in cancer care. ASCO is the world's leading professional society representing physicians who care for people with cancer. With nearly 50,000 members, our core mission is to ensure that patients with cancer have meaningful access to high-quality, equitable cancer care.

Traditionally, the acquisition of anti-cancer drugs is managed in the independent practice or hospital setting where chemotherapy administration is overseen by the treating physician. The practice or hospital pharmacy purchases, stores, and administers these agents under strict handling and administration standards.

Although clinicians prepare detailed treatment plans, drug regimens often change on the day-of treatment due to clinical circumstances. Administration may be adjusted according to criteria, such as patient weight, comorbidities, lab reports, guidelines, and other clinical data. Brown bagging and mandatory white bagging policies remove the physician's ability to control the preparation of drugs. Under a mandatory white bagging policy, insurers require physicians to obtain drugs purchased and handled by payer-owned or affiliated pharmacies, while under a brown bagging policy payers require the drug to be shipped from a pharmacy directly to the patient to bring to the provider's office for administration. Both policies require additional coordination with patients and physicians and could delay or disrupt treatment plans and decisions. Day-of treatment changes can lead to a delay in care if a physician must place a new order, requiring the patient to return on a later date to receive their treatment. This can result in significantly decreased chances of a successful clinical outcome for the patient as well as potential adverse effects on patient health, including toxic reactions.

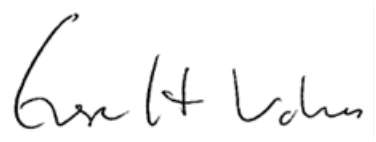
When treatment plans are modified on the day-of treatment, brown bagging and mandatory white bagging policies can also lead to waste if an unused portion of a previously dispensed drug cannot be used for a different patient. Many anti-cancer drugs are highly toxic and require special handling when

discarded. The burden of unnecessary waste related to white bagging and brown bagging falls to practices and hospitals, which must dispose of drugs according to state and federal requirements.

Additionally, MDCSCO and ASCO support language in this bill that prevents pharmacy benefit managers from actively incentivizing or steering patients toward payer-owned or affiliated pharmacies in lieu of a dispensing physician.

MDCSCO and ASCO recognize that white bagging may be necessary in some settings and acknowledge the bill does not ban the practice. However, mandatory white bagging and all instances of brown bagging are not appropriate and can jeopardize the delivery of high-value, high-quality care. For these reasons, we support any efforts to prohibit mandatory white bagging and all instances of brown bagging in Maryland. For a more detailed understanding of our policy on this issue, we invite you to read the ASCO Position Statement on White Bagging and the ASCO Position Statement on Brown Bagging by our affiliate, the American Society of Clinical Oncology. MDCSCO and ASCO welcome the opportunity to be a resource for you. Please contact Nick Telesco at ASCO at Nicholas.Telesco@asco.org or Danna Kauffman, representing MDCSCO, at dkauffman@smwpa.com if you have any questions or if we can be of assistance.

Sincerely



Dr. Paul Celano, MD, FACEP, FASCO
President
MD/DC Society of Clinical Oncology

Dr. Everett Vokes, MD, FASCO
Chair of the Board
Association for Clinical Oncology

SB0754_FAV_MedChi_HI Carriers & PBMs – Clinician-A
Uploaded by: Danna Kauffman
Position: FAV

MedChi

The Maryland State Medical Society

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TO: The Honorable Pamela Beidle, Chair
Members, Senate Finance Committee
The Honorable Shelly Hettleman

FROM: Danna L. Kauffman
Pamela Metz Kasemeyer
J. Steven Wise
Andrew G. Vetter
Christine K. Krone
410-244-7000

DATE: February 28, 2024

RE: **SUPPORT** – Senate Bill 754 – *Health Insurance Carriers and Pharmacy Benefits Managers – Clinician-Administered Drugs and Related Services*

The Maryland State Medical Society (MedChi), the largest physician organization in Maryland, **supports** Senate Bill 754, which would prohibit mandatory "white bagging" and all "brown bagging" requirements from carriers and pharmacy benefit managers (PBMs) to allow patients to obtain clinician-administered drugs from their health care providers, thereby preserving timely and consistent delivery of high quality, patient-centered care.

Brown bagging and mandatory white bagging policies remove the physician's ability to control the preparation of drugs. Under a mandatory white bagging policy, insurers require physicians to obtain drugs purchased and managed by payer-owned or affiliated pharmacies, while under a brown bagging policy payers require the drug to be shipped from a pharmacy directly to the patient to bring to the provider's office for administration. Both policies require additional coordination with patients and physicians and could delay or disrupt treatment plans and decisions. Day-of treatment changes can lead to a delay in care if a physician must place a new order, requiring the patient to return on a later date to receive their treatment. This can result in significantly decreased chances of a successful clinical outcome for the patient as well as potential adverse effects on patient health, including toxic reactions.

When treatment plans are modified on the day-of treatment, brown bagging and mandatory white bagging policies can also lead to waste if an unused portion of a previously dispensed drug cannot be used for a different patient. For example, many anti-cancer drugs are highly toxic and require special handling when discarded. The burden of unnecessary waste related to white bagging and brown bagging falls to practices and hospitals, which must dispose of drugs according to state and federal requirements.

Through years of training and experience in their chosen specialty, physicians are well-informed on the medications that they prescribe to their patients and can advise their patients accordingly. Therefore, MedChi urges a favorable vote on Senate Bill 754 to provide patients with the flexibility to obtain their medications at the venue that they believe will provide them with better care and quality outcomes, which will ultimately benefit the health care system at-large.

Senate Bill 754 - Health Insurance Carriers and Ph

Uploaded by: Jake Whitaker

Position: FAV

Maryland
Hospital Association

Senate Bill 754 - Health Insurance Carriers and Pharmacy Benefits Managers – Clinician-Administered Drugs and Related Services

Position: *Support*
February 28, 2024
Senate Finance Committee

MHA Position

On behalf of the Maryland Hospital Association's (MHA) member hospitals and health systems, we appreciate the opportunity to comment in support of Senate Bill 754. MHA is concerned with the growing prevalence of certain payer-mandated drug distribution models—commonly referred to as "white bagging"—and their negative impacts on access to critical drugs and patient safety. Maryland should join the chorus of states prohibiting payer-mandated white bagging and protect our patients.[1]

Traditionally, hospitals purchase and dispense medication from their own inventory. When a provider reaches a diagnosis and determines a treatment plan, medication orders are promptly entered into the hospital's electronic health records (EHR), which allows for a complete recording of the patient's medication history and safety checks. This integrated approach avoids medication record fragmentation and enhances care coordination.

Once the patient is ready to receive the medication, the hospital's pharmacy prepares the drug from its existing supply and can dispense without delay. If the patient's condition abruptly changes, modifications such as dosage changes can be made quickly to accommodate the patient's needs. This flexibility protects patient safety and expedites access to treatment.

Payer-mandated white bagging, however, disrupts this process and introduces delays and health risks. In a typical scenario, an insurer will require a hospital to send the prescription order to a specialty pharmacy instead of using medication from its own supply. The separate order bypasses the hospital EHR, resulting in record fragmentation. In addition, even if the hospital already has the medication available, the patient still must wait for the drug to be delivered.

The specialty pharmacy then prepares the medication according to the patient's conditions at the time of the order and ships the product to the hospital. If the shipment were to encounter logistical difficulties, patient access to the drug would be delayed. Furthermore, if the patient's condition changes during shipment and requires adjustments to the drug, a new order must be placed with the specialty pharmacy, resulting in additional treatment delays that may worsen the patient's outcome.

[1] Sikora, Kate, and Mary Gens. "White-Bagging Legislation Gains Popularity in State Legislatures." Avalere, April 25, 2022. https://avalere.com/insights/white-bagging-legislation-gains-popularity-in-state-legislatures.

This scenario is only one example of how payer-mandated white bagging can jeopardize access and safety. For these reasons, we request a ***favorable*** report on SB 754.

For more information, please contact:
Jake Whitaker, Director, Government Affairs
Jwhitaker@mhaonline.org

SB754_FAV_Hettleman.pdf
Uploaded by: Shelly Hettleman
Position: FAV

Shelly Hettleman
Legislative District 11
Baltimore County

Chair
Rules Committee

Budget and Taxation Committee

Subcommittees

Health and Human Services

Pensions

THE SENATE OF MARYLAND
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TESTIMONY OF SENATOR SHELLY HETTLEMAN
SB 754 HEALTH INSURANCE CARRIERS AND PHARMACY BENEFITS MANAGERS - CLINICIAN-ADMINISTERED DRUGS AND RELATED SERVICES

As I am sure this committee is already well aware, the price of pharmaceuticals in this country is extraordinarily high and contributes to our high expenditure on health care. High costs mean that many people don't receive the care they need or are experiencing significant financial hardship in order to pay for needed, prescribed drugs.

Whitebagging is one practice in which the price of drugs can be inflated under certain circumstances. Whitebagging is when prescriptions written in a healthcare setting like a hospital are filled by a third-party specialty pharmacy and then subsequently shipped to the provider to prepare and dispense the drug, rather than hospitals procuring drugs directly from manufacturers or distributors. This bill would restrict payers, namely private insurers, from unilaterally mandating that clinician-administered drugs be sourced from an external pharmacy. To be clear, it does not outlaw whitebagging as a practice. The bill's intent is for providers and payers to mutually agree on instances in which whitebagging contributes to lower costs and better outcomes, restricting payers from unilaterally mandating the practice for certain drugs.

Whitebagging often exists when payers restrict their coverage of certain drugs to a narrow network of pharmacists, which can cause delays in care when drugs are harder to procure. According to the American Hospital Association, whitebagging can contribute to safety systems being bypassed, the fragmentation of medical records, and issues with supply chains, which can contribute to drug waste.

Several Boards and Societies of Pharmacists have identified issues with payer-mandates whitebagging. A study in JAMA found that whitebagging can increase patient out-of-pocket costs by $180 per month. For some drugs, it can be a fundamentally inefficient delivery of products that can otherwise be delivered in hospitals, for whom drug rates are regulated. This creates less competition with a smaller group of pharmacies, reducing patients' prompt access to care and fracturing the care delivery process. Further, there is no evidence supporting the claim that restricting whitebagging increases premiums for patients.

Ultimately, the spirit of this bill encourages providers and payers to come together to mutually agree upon the delivery mechanism for drugs that best provides for patients and lowers costs instead of payers restricting their coverage to a short list of specialty pharmacies with whom they have special agreements.

SB 754 - FIN - PHARM - LOS (1).pdf
Uploaded by: State of Maryland (MD)
Position: FAV

Maryland
DEPARTMENT OF HEALTH

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

MARYLAND BOARD OF PHARMACY

2024 SESSION
POSITION PAPER

BILL NO.:	**SB 754 – Health Insurance Carriers and Pharmacy Benefits Managers – Clinician-Administered Drugs and Related Services**
COMMITTEE:	**Finance**
POSITION:	**Letter of Support**

TITLE: **Health Insurance Carriers and Pharmacy Benefits Managers – Clinician-Administered Drugs and Related Services**

Pharmacist

POSITION & RATIONALE:

The Maryland Board of Pharmacy (Board) respectfully submits this letter of support for SB 754 – Health Insurance Carriers and Pharmacy Benefits Managers – Clinician-Administered Drugs and Related Services (SB 754).

Steering – medical necessity and patient choice

SB 754 prevents an entity that provides pharmacy benefits from **steering**, which generally includes increasing the share-of-cost paid by the patient or excluding a drug from coverage unless the patient transfers his or her prescription to a pharmacy affiliated with the entity that provides pharmacy benefits. Accordingly, a patient will select a pharmacy based on medical necessity, rather than financial obligations.

Reimbursement rates – medical necessity and patient choice

SB 754 prevents an entity that provides pharmacy benefits from providing **lower reimbursement rates** to an unaffiliated pharmacy. The reimbursement rate offered to a pharmacy is directly correlated to the final price offered to a patient. When the cost paid by the patient is not drastically different at various pharmacy locations due to reimbursement rates with varying degrees of competitiveness, the decision of a price-sensitive patient is driven by convenience and medical necessity, instead of budget constraints.

-

Specialty pharmacy – timely initiation of pharmaceutical therapy

SB 754 prevents an entity that provides pharmacy benefits from requiring a patient to obtain a clinician-administered drug from a **specialty pharmacy** with the intention that the patient transport the drug to a clinician for administration. When a clinician is enabled to prescribe a medication, obtain the medication from a pharmacy located on-site, and administer the medication during the same appointment, their patient receives timely care, which may lead to improved health outcomes. A patient who obtains a clinician-administered medication from the most convenient pharmacy, rather than a specialty pharmacy, will not unnecessarily experience continuing and persistent symptoms of illness due to the delays of delivery, inconvenience of scheduling multiple appointments, or lack of administration as the severity of his or her condition has changed so as to make the dosage originally prescribed not medically appropriate.

SB 754 prohibits a variety of coverage and benefits limitations that affect the ability of a patient to access clinician-administered prescription medications. Removing unnecessary conditions that prevent a patient from initiating and continuing pharmaceutical therapy is essential to improving the health of Marylanders through disease prevention and management. As the Board routinely receives complaints related to refusal to fill and poor customer service that are ultimately driven by the formulary and coverage decisions of entities that provide pharmacy benefits, the Board supports legislation that enables patients to access necessary pharmaceutical therapies.

Based on the information provided above, the Board respectfully requests a favorable report on SB 754.

If you would like to discuss this further, please do not hesitate to contact Deena Speights-Napata, MA, Executive Director, at deena.speights-napata@maryland.gov or (410) 764-4753.

Sincerely,

Deena Speights-Napata, MA
Executive Director
Maryland Board of Pharmacy

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

20224.02.28 MD SB 754 Specialty Dispensing.pdf
Uploaded by: Heather Cascone
Position: UNF

Heather R. Cascone
Assistant VP, State Affairs
(202) 744-8416
hcascone@pcmanet.org

February 28, 2024

Chairwoman Pamela Beidle
Vice Chair Katherine Klausmeier
Senate Finance Committee Members
Miller Senate Office Building, 3 East
Annapolis, Maryland 21401

UNFAVORABLE: SB 754 – Clinician-Administered Drugs and Related Services

Dear Chairwoman Beidle, Vice Chair Klausmeier, and Members of the Senate Finance Committee:

On behalf of the Pharmaceutical Care Management Association (PCMA), I appreciate the opportunity to comment on a bill allowing dispensing of clinician-administered drugs from certain pharmacies or infusion sites. I respectfully request an unfavorable report on the bill.

PCMA is the national trade association representing America's Pharmacy Benefit Managers (PBMs), which administer outpatient prescription drug plans for more than 266 million Americans with health coverage provided through Fortune 500 large and small employers, labor unions, and government programs. PBMs are projected to save payers over $34.7 billion through the next decade -- $962 per patient per year – as a result of tools such as negotiating price discounts with drug manufacturers and establishing and managing pharmacy networks, in addition to disease management and adherence programs for patients.

There are approximately 80 drugs administered by providers in hospital outpatient departments and physician offices. These drugs are projected to cost about $230 billion in 2023 and $3 trillion for the 10-year period 2023–32.

Price markups of physician-administered drugs are excessive.
SB 754 seeks to disrupt the current system of shipping specialty drugs directly to a site (like a hospital or infusion clinic) for physician administration by allowing these sites to purchase the drugs themselves. In doing so, these administration sites can charge whatever prices they want for physician-administered drugs. When hospitals and providers buy and bill for the drugs they will administer, they mark up the drug far over their acquisition costs, and health plans have had no choice but to accept these excessive charges.

An AHIP analysis of the cost of 10 drugs commonly delivered through a specialty pharmacy for provider administration found that:

- **Hospitals, on average, charged double the prices for the same drugs compared to specialty pharmacies**. On average, physician offices charged 22% higher prices for the same drugs.
- Costs per **single treatment** for drugs administered in hospitals were an average of **$7,000 more** than those purchased through specialty pharmacies. Drugs administered in physician offices were an average of $1,400 higher.

These markups on the price of the drug are in addition to the amounts hospitals and physician offices separately bill for the services required to administer the drugs. AHIP's findings confirm similar studies by the JAMA Internal Medicine,ii Alliance,iii Health Affairs,iv and the Moran Company.v

Patients, families, and employers all bear these unreasonable costs through higher premiums and cost sharing. It is imperative that health plans be allowed to provide these drugs in a manner that is more affordable for patients, but SB 958 takes away these valuable tools. We have offered amendments that would protect patients from facility markups by allowing "white bagging" and "brown bagging" if the treating provider does not accept the health plan's specialty pharmacy contracted reimbursement rate and addressing patient safety concerns.

Specialty pharmacy programs are designed to be safe and seamless to the patient.
Thousands of patients successfully and safely receive their drugs through brown and white bagging each year without issue.

Specialty pharmacies are only used for certain prescription drugs that may be safely delivered in this way. Specialty pharmacies must abide by all state and federal legal and regulatory requirements, in addition to meeting extra safety requirements for specialty drugs imposed by the Food and Drug Administration (FDA) and drug manufacturers.

In addition to the extremely stringent safety requirements for specialty pharmacies, health plans routinely have exception processes in place to address the rare circumstances of quality, safety, medical necessity, and/or care interruption. Health plans develop their specialty pharmacy programs with all potential dosing and treatment dispensing scenarios in mind. In fact, medications are routinely shipped with enough additional supply so that facilities can adjust a dose as required at the time of administration.

The processes for delivering these medications through specialty pharmacies are the same as those used when hospitals acquire the drugs themselves. In fact, many hospitals and physician groups obtain these medications from the same specialty pharmacies that the sponsors of SB 958 claim are "unsafe."
Though the sponsors of this bill have claimed that there are safety issues with these programs, they are not able to point to a pattern of problems beyond a few anecdotes.
Specialty drugs are a leading contributor to drug spending growth and only shared responsibility will address the burden these rising costs put on patients. Instead of pursuing legislative mandates to protect their market power, hospitals can come to the negotiating table and agree to reasonable reimbursement rates for drugs whose prices are already too high. California's health plans, insurers and their designees urge lawmakers to support the use of specialty pharmacies, and to reject policies that take away lower-cost choices from patients.

While the vast majority of shipped prescriptions do not require special handling or packaging, for those that do, mail-service pharmacies use U.S. Pharmacopeia guidelines to determine handling needs and leverage proprietary software to map out the ideal packaging journey, which accounts for the acceptable temperature range, forecasted weather conditions, and destination temperatures. Proprietary software is used by PBMs to map out a delivery path for those prescriptions that must stay within a specific temperature range. Such software accounts for the acceptable temperature range for each prescription, forecasted weather conditions, and destination temperatures. Based on this information, the appropriate shipping time frame and packaging are determined specifically for that prescription. For example, a mail-service pharmacy may package prescription drugs in temperature-protective coolers with gel packs to ensure that the prescriptions stay within a safe temperature range — even accounting for if the package is sitting outside for hours after delivery.

Specialty prescription drugs, including injectable drugs with special handling requirements, are usually shipped through commercial mail and shipping carriers, such as UPS and Federal Express. Specialty

drugs requiring refrigeration are typically shipped for overnight delivery, often through common carriers other than the USPS.

The safety and efficacy of mailed prescriptions are of utmost importance and are well reflected in the level of precision and planning undertaken by mail-service pharmacies in the mailing of prescription drugs, including those with special handling requirements. The precision also reflects the needs and preferences of consumers not only for safe, high-quality products, but also to know when their prescription will be shipped and received. For example, as required by CMS, Medicare Part D plan sponsors require their network mail-service pharmacies to provide enrollees an approximate shipping date range, of within two-to-three days, prior to delivery. Mail-service pharmacies offer enhanced

safeguards for safety and accuracy. Before shipping a prescription to a patient's home, mail-service pharmacies' staff pharmacists electronically review the patient's medications to detect adverse drug reactions, especially any potentially harmful drug-to-drug interactions — even when the patient uses several pharmacies. This information may not be available to a patient's physician without an interoperable health record system.

Specialty pharmacies and mail delivery are tools used in pharmacy networks because they ensure high-quality drug delivery service, avoid waste, and ensure the appropriate use of medications. In limiting a plan sponsor's choices to allow white bagging, this bill is likely to substantially increase costs for Maryland consumers and plan sponsors

I appreciate the opportunity to voice our concerns and am happy to answer any questions you may have.

Sincerely,

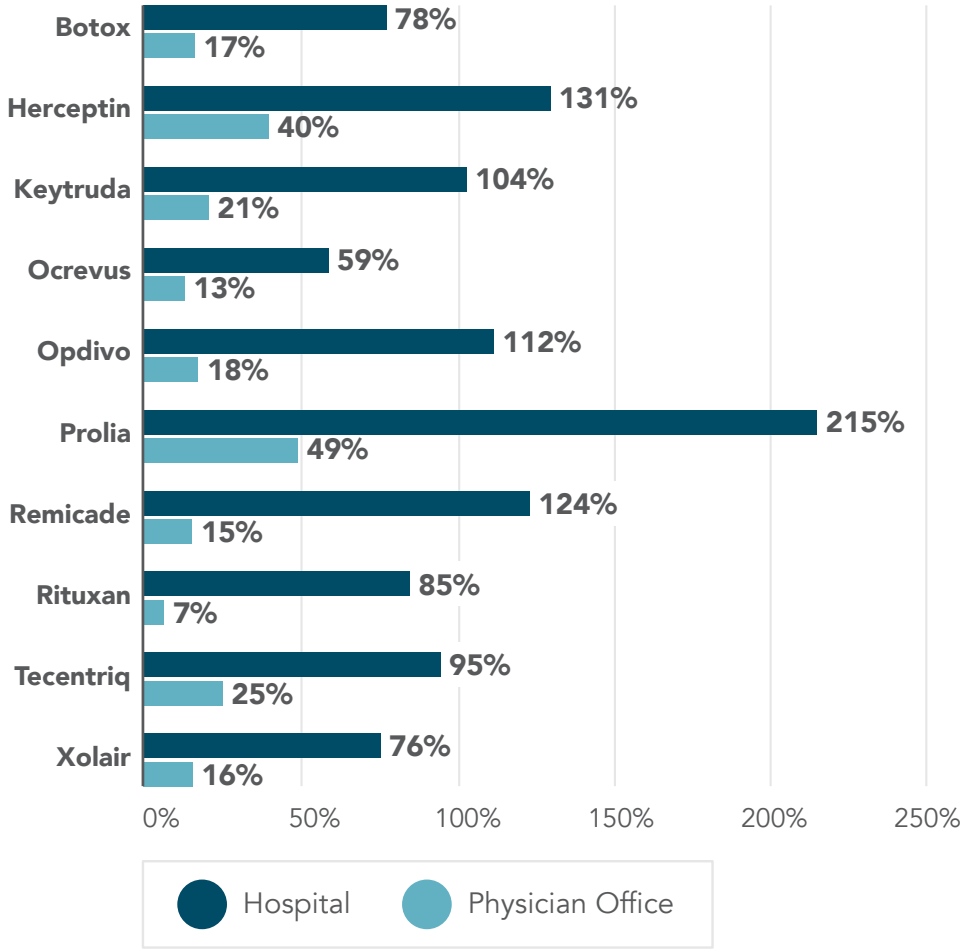
Heather R. Cascone

202202-AHIP_1P_Hospital_Price_Hikes.pdf
Uploaded by: Keith Lake
Position: UNF

Hospital Price Hikes: Markups for Drugs Cost Patients Thousands of Dollars

Everyone should be able to get the medications they need at a cost they can afford. But drug prices are out of control, and hardworking families feel the consequences every day. Health insurance providers have developed innovative solutions to make prescription drugs more affordable, including leveraging lower-cost specialty pharmacies to safely distribute physician-administered drugs (sometimes called "white bagging" or "brown bagging"). These solutions help reduce Americans' out-of-pocket costs and what they pay in premiums – making health care more affordable and accessible for everyone.

Figure 1. Average Markups for Drugs in Hospitals and Physician Offices Over Pharmacies (2018-2020)



Note: Drugs with the highest total spend in 2019, which are also commonly delivered through specialty pharmacies. The drug cost estimate in physician offices and hospitals does not include the cost of administering the drugs

$7,000

Costs per single treatment for drugs administered in hospitals (2018-2020) were an average of $7,000 more than those purchased through pharmacies. Drugs administered in physician offices were an average of $1,400 higher.

108%

Hospitals, on average, charged double (108%) the prices for the same drugs, compared to pharmacies. Physician offices charged 22% higher prices for the same drugs, on average.

Specialty pharmacies lower a patient's health care costs **by preventing hospitals and physicians from charging exorbitant fees to buy and store specialty medicines themselves.** Secure, direct delivery is more efficient and effective and reduces health care costs.

AHIP
Guiding Greater Health

Table 1. Average Markup Amounts for a Single Treatment for Drugs Administered in Hospitals and Physician Offices Over Pharmacies (2018-2020)

Drug	Indication	Physician Office Markup	Hospital Markup
Botox	Chronic Migraine	$204	$935
Herceptin	Cancer	$1,875	$6,091
Keytruda	Cancer	$2,031	$9,956
Ocrevus	Multiple Sclerosis	$4,433	$19,803
Opdivo	Cancer	$1,166	$7,442
Prolia	Osteoporosis	$607	$2,657
Remicade	Crohn's Disease & Psoriasis	$695	$5,601
Rituxan	Rheumatoid Arthritis	$625	$7,926
Tecentriq	Cancer	$2,304	$8,623
Xolair	Asthma	$349	$1,654
Average		**$1,429**	**$7,069**

Note: Markup amounts are estimated for a single treatment. All drugs in the list require multiple treatments.

Innovative Solutions to Keep Drugs Affordable

Specialty pharmacies improve health care affordability while protecting patient safety. AHIP encourages lawmakers to support the use of specialty pharmacies, and to reject policies that take away lower-cost choices from patients.

Methodology

The list of drugs included in the study was obtained as follows. From the list of top 25 drugs by spending in Medicare Part B in 2019,[1] we identified, in consultation with our member plans, the drugs that are also commonly delivered through specialty pharmacies. The resulting list included 10 drugs.

For each drug, all medical and pharmacy claims data were extracted from the IBM® MarketScan® Commercial Database for the period January 1, 2018 to December 31, 2020. Using the claims data, we calculated a 3-year average cost for a single treatment for each drug in 3 different settings: (1) specialty pharmacy, (2) physician office, and (3) hospital. All claims were adjusted for inflation to 2020 dollars.

The average cost for a single treatment in specialty pharmacy setting was obtained by dividing the total claim cost of the drug (including both insurance and out-of-pocket costs) by the metric quantity purchased and then multiplying it by the average adult dose per single treatment. The average adult dose per single treatment was estimated based on the dosing information in the FDA approved label.

The average cost for a single treatment in physician office and hospital setting was obtained as the total claim cost for a single day of treatment. When drugs had multiple dosing regimens for different indications, the most common indication was used in calculation. Medical claims were limited to that indication based on the diagnostic codes and dosing frequency.

The physician office and hospital markups were calculated as a ratio of the average cost for a single treatment in physician office or hospital setting to the average cost for a single treatment in pharmacy setting. Similarly, markup amounts were calculated as the difference between the average cost for a single treatment in physician office or hospital setting and the average cost for a single treatment in pharmacy setting.

1 https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-spending-by-drug

DOCS-#234305-v1-SB_754_League_Oppose.pdf
Uploaded by: Matthew Celentano
Position: UNF

The League of Life and Health Insurers of Maryland

15 School Street, Suite 200
Annapolis, Maryland 21401
410-269-1554

February 28, 2024

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

Senate Bill 754 – Health Insurance Carriers and Pharmacy Benefit Managers – Clinician-Administered Drugs and Related Services

Dear Chair Beidle,

The League of Life and Health Insurers of Maryland, Inc. respectfully **opposes** *SB 754 – Health Insurance Carriers and Pharmacy Benefit Managers – Clinician-Administered Drugs and Related Services* and urges the committee to give the bill an unfavorable report.

SB 754 would:

- Ban nearly every existing tool health plans use to encourage lower cost, higher quality, and more convenient drug administration.
- Expose patients and employers to even higher costs for clinician-administered drugs through higher health insurance premiums and out-of-pocket costs.

SB 754 goes far beyond limiting "white bagging," a practice health plans use in limited circumstances, when there are cost savings for patients and employers, and when clinical evidence indicates the drugs can be safely dispensed and are appropriate for the patient's needs. Nearly every prohibition included in SB 754 raises significant cost concerns, both for individual patients and the commercially insured population.

Individually and collectively, the provisions of SB 754 create an anti-competitive, high-cost clinician-administered drug market in Maryland. Clinician-administered drugs already have high prices, which are then subject to even further, significant markups above hospitals' acquisition costs. Eliminating health insurance providers' existing tools to promote high-quality, lower-cost care will make the drug cost problem worse, not better, for patients and employers.

Our many significant concerns with SB 754 are outlined in the accompanying memo. In light of these issues, we ask that you oppose SB 754

As the stated trade association for the health insurance carriers we are committed to market-based solutions that improve consumer affordability and access to high-quality, high-value health care in Maryland, we appreciate the opportunity to share our serious concerns with and opposition to SB 754, relating to insurance coverage of clinician-administered drugs.

While proponents have characterized SB 754 as "white bagging" legislation, in reality this harmful bill removes nearly every existing tool health insurance providers have to encourage lower cost, higher quality, and more convenient drug administration. Patients and employers bear the unreasonable and growing cost of clinician-administered drugs through higher health insurance premiums and out-of-pocket costs. Health insurance providers are responding to excessive hospital markups and the unsustainable cost of clinician-administered drugs by encouraging lower cost, more convenient settings when it is safe and clinically appropriate.

Before we outline the harmful effects of SB 754, we would like to provide background information on specialty and clinician-administered drugs.

What are Specialty and Clinician-Administered Drugs?

Specialty drugs generally are high-price medications that treat complex, chronic, or rare conditions (e.g., cancer, asthma, multiple sclerosis, rheumatoid arthritis). Specialty drugs can also have special handling and/or administration requirements. Both the number and price of specialty drugs have rapidly increased in recent years[1], and specialty drugs are a leading contributor to drug spending growth[2]. The price of a specialty drug can range from thousands to hundreds of thousands of dollars per regimen.

A growing number of specialty drugs can be taken orally and outside the presence of a medical professional. But many specialty drugs are administered by a clinician intravenously, intramuscularly, under the skin, or via injection. These clinician-administered drugs are given at a variety of sites of care including hospitals, medical provider offices, infusion centers, and by medical professionals during home visits.

What are Specialty Pharmacies?

Specialty pharmacies have evolved to meet the unique requirements for dispensing specialty drugs, such as sophisticated storage conditions and processes for drug handling and dispensing. Like retail pharmacies, specialty pharmacies must abide by all state and federal legal and regulatory requirements – in addition to meeting extra safety requirements for specialty drugs imposed by the Food and Drug Administration (FDA) and drug manufacturers. Specialty pharmacy staff also help coordinate a patient's care by providing close monitoring, collecting data, and sharing that information between the patient's health care providers.

On top of providing these additional, unique services, specialty pharmacies provide drugs at a much lower price, which leads to cost savings for patients, families, and employers.

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[1] The Growing Cost of Specialty Pharmacy-Is it Sustainable? American Journal of Managed Care. February 18, 2013. Available at: https://www.ajmc.com/view/the-growing-cost-of-specialty-pharmacyis-it-sustainable

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What is "White Bagging"?

"White bagging" is the practice in which a specialty pharmacy ships a patient's clinician-administered drug directly to the provider, such as hospital or hospital-affiliated clinic, where it is held until the patient arrives for treatment. In this circumstance, the hospital or clinic does not purchase the drug and bill the patient's insurance benefit for the cost of the prescription, because the drug is provided to them by the specialty pharmacy. However, the hospital or clinic does typically receive payment, such as a percentage of the drug cost, for administering the drug to the patient.

As mentioned previously, specialty pharmacies must follow all relevant laws and guidelines for the storage, handling, dispensing, and shipping of these medications. In other words, the same regulations and standards apply to drugs dispensed via white bagging as to drugs purchased directly by a hospital or clinic.

What are Alternative Sites for Drug Administration?

Patients may be able to receive clinician-administered drugs outside of a hospital setting, such as at an outpatient clinic, infusion center, or in their home under the care of a clinician. These sites of care are lower cost and often more convenient for patients than hospital or hospital-affiliated settings. Even with these benefits, some patients may undergo a "trial period" to ensure therapy safety and tolerance before their drug administration is transitioned to an alternative site, such as their home.

Health insurance providers only select medications for "white bagging" or infusion in non-hospital settings in limited circumstances, when there are cost savings for patients and employers, and when clinical evidence indicates the drugs can be safely dispensed and are appropriate for the patient's needs. It is important to underscore that health insurance providers view patient safety as paramount and want patients to take these critical drugs at the time they are needed. And, when health insurance providers implement specialty drug administration policies, they always have exception processes in place to address circumstances of quality, safety, medical necessity, and/or care interruption.

Why Address the Cost of Clinician-Administered Drugs?

As described above, clinician-administered drugs are a leading contributor to drug spending growth. Clinician-administered drugs have high prices, which are then subject to even further, significant markups above hospitals' acquisition costs. These markups are well-documented, including in several studies released this year:

- Bernstein (2021): This analysis found that some hospitals mark up prices on more than two dozen medicines by an average of 250%. For example, hospitals charged more than five times the purchase price for Epogen, which is used to treat anemia caused by chronic kidney disease for patients on dialysis, and 4.6 times the price for Remicade, a drug that treats a range of autoimmune conditions. According to the analysis, administering treatments to commercially insured patients is 20 times more profitable than administering the same drugs to Medicare patients. The analysis also showed hospitals have been slow to begin using biosimilars, which are nearly identical to brand-name biologic treatments and produce the same health outcome, but at a much lower cost.

- Health Affairs (2021): This study examined the 2019 prices paid for by Blue Cross Blue Shield for certain drugs administered in hospital clinics versus provider offices. The study found the prices paid for hospital outpatient departments were double those paid in physician offices for biologics, chemotherapies, and other infused cancer drugs (99-104% higher) and for infused hormonal therapies (68% higher). Blue Cross Blue Shield – and therefore patients and employers – would

have saved $1.28 billion, or 26 percent of what they actually paid, if the insurer had all patients receive their infusions in a provider's office instead of hospital clinics.

- JAMA Internal Medicine (2021): The median negotiated prices for the 10 drugs studied ranged from 169% to 344% of the Medicare payment limit. The largest variation in markup came from Remicade, an IV drug that treats autoimmune conditions – the median rate paid by commercial insurers at Mayo Clinic's hospital in Phoenix was more than 800% of the Medicare rate.

- AllianceBernstein (2019): Depending on the drug and type of hospital, markups ranged on average from 3-7 times more than Medicare's average sale price.

- The Moran Company (2018): Most hospitals charge patients and insurers more than double their acquisition cost for medicine. The majority of hospitals markup medicines between 200-400% on average.

These markups on the price of the drug are in addition to the amounts hospitals separately bill insurers for the professional services required to administer the drugs.

Patients, families, and employers all bear these unreasonable and growing costs through higher health insurance premiums and out-of-pocket costs. It is imperative that health insurance providers be allowed to help encourage the administration of these drugs in lower cost, more convenient settings when it is safe and clinically appropriate to do so.

SB 754 Decimates Health Insurance Providers' Tools to Encourage Lower Cost, Higher Quality, and More Convenient Care

As we said previously, while proponents have characterized SB 754 as "white bagging" legislation, in reality this harmful bill removes nearly every existing tool health insurance providers have to encourage lower cost, higher quality, and more convenient drug administration. In short, this legislation cuts off at the knees any meaningful, scalable effort to control one of the most significant and fast-growing portions of patients' and employers' health care dollar.

Our specific concerns with and opposition to SB 754 are organized below by the following themes: cost; patient access; patient safety and quality of care; medical necessity; market competition; fraud, waste and abuse; and freedom of contract. Within these themes, we identify provisions of concern and provide the rationale for our opposition. In most instances, a provision is listed under more than one theme due to its broad implications.

Cost Concerns

When it is safe and medically appropriate to do so, patients benefit from drugs being administered in the least restrictive and lowest-cost setting. Nearly every prohibition included in SB 754 invokes significant cost concerns, both for individual patients and the commercially insured population at large, because they prohibit the use of strategies that ensure patients receive the right care, at the right time, and in the right setting.

These provisions effectively ban prior authorization and other utilization management practices for clinician-administered drugs. These practices are put in place to support the delivery of high-value, cost-effective, and evidence-based medicine. For example, health plans can use the prior authorization process to require use of a biosimilar product instead of a brand biologic product, which results in the same clinical outcome at a much lower cost. Utilization management tools also save consumers and employers money

by helping prevent costly inappropriate care and encouraging the delivery of appropriate care in safe, lower-cost settings. Health insurance providers apply utilization management practices across a variety of health care products and services – clinician-administered drugs should be no different.

Patient Access Concerns

Administering drugs in non-hospital settings, when it is safe and medically appropriate to do so, improves patient access and convenience. The health care industry is continuously innovating to safely deliver care in more and less intensive settings, as most recently evidenced by the rise of telehealth and hospital at home models. Continuous innovation in medicine means that safety is not a static benchmark – and locking a fixed view of "safe" drug administration in state law, as SB 754 does, threatens to stall growth and adoption of care delivery methods that are easier, less disruptive, more flexible, and more convenient for patients to access.

Further, if SB 754's prohibitions on health insurance provider strategies to encourage use of less intensive care settings become law, patients are less likely to be made aware of options to receive care at a site like their home or an infusion center – especially given the strong financial incentive providers have to keep care within their facility. Reduced use of these alternative sites also potentially threatens their viability and therefore ability to remain an option for patients.

Finally, because affordability is a key component of access to health care, the cost concerns we identified in the previous section also impact patient access.

The broad construction of the definition of "clinician-administered drug" includes some drugs that can be administered by ancillary health care professionals in the home setting or an infusion center under the indirect supervision of a physician. Taking this definition together with the many prohibitions included in SB 754, some patients may actually lose access to a drug administration method they currently use.

As described previously, health insurance plan designs are essential for encouraging members to utilize high-value, high-quality service providers and locations. In the case of tiered networks, health plans often purposefully establish lower cost-sharing for providers who are of higher quality than their peers. State regulation of health insurance providers should encourage this kind of activity, which is clearly in the patient's best interest – not restrict it, as SB 754 does.

Medical Necessity Concerns

As we have illustrated, SB 754 goes far beyond prohibiting the practice of white bagging and reaches deep into many of health insurance providers' core practices. Another example of this overreach is the bill's removal of the decades-long ability of health insurance providers to define medical necessity in their policies. The definition of "clinician-administered drug" specifies that medical necessity is determined by the prescribing provider. This definition upends established insurance law and regulation and creates a special exception just for clinician-administered drugs. This definition also grants a single clinician the ability to determine the medical necessity of a clinician-administered drug, without any requirement for adherence to medical evidence or clinical practice guidelines.

Further, this aspect of the definition of "clinician-administered drug" would likely incentivize providers to classify as many drugs as clinician-administered as possible, in order to avoid health plan medical necessity reviews. The definition of "clinician-administered drug" eliminates a health insurance provider external review process that ensures appropriate patient care and guards against waste, fraud, and abuse. We have already described how health insurance providers promote the delivery of clinically appropriate, evidence-

based care via utilization management – if health insurance providers also cannot determine medical necessity, we are highly concerned about the likely negative impact on costs, quality of care, and safety.

Market Competition Concerns

Individually and collectively, the provisions of SB 754 create an anti-competitive, high-cost clinician-administered drug market in Maryland. What incentive would providers have to lower their prices and compete on quality if health insurance providers cannot assess medical necessity, are prohibited from using utilization management tools, and cannot use benefit design to reward patients for receiving care at high-quality, lower-cost sites? Eliminating health insurance providers' existing tools to promote high-quality, lower-cost care will make the drug cost problem worse, not better, for patients and employers.

The definition of "participating provider" incorrectly assumes that health insurance providers contract with all facilities or pharmacies within a health system. Under SB 754's definition of "participating provider," these non-contracted facilities or pharmacies would have to be treated the same as contracted facilities or pharmacies – thereby reducing competition and interfering with freedom of contract. The broad construction of this provision seems to indicate that a health plan could not limit coverage or require different cost-sharing for out-of-network pharmacies, which would limit competition, interfere with freedom of contract, and raise costs for the commercially insured population.

While all of SB 754's provisions reveal an attempt to redirect clinician-administered drugs to hospital-based settings, and therefore restricting patient access, this provision is the most difficult to view as anything other than protectionist. To be sure, hospitals would object if their competitors pursued legislation that prevented health insurance providers from requiring patients to receive certain services in a hospital setting. It is also not clear what safety concerns would be alleged to exist with home infusion agencies and infusion centers, as these entities can obtain drugs in a similar manner as hospitals.

Fraud, Waste & Abuse Concerns

Individually and collectively, the provisions of SB 754 create an environment that is ripe for fraud, waste, and abuse due to the prohibition on conventional health insurance provider oversight and controls, complete deference to individual providers, and no guardrails to ensure adherence to standards of practice. Health insurance providers need substantially greater latitude than is provided under this bill to effectively safeguard individual and employer premium dollars, and promote clinically appropriate, evidence-based care.

Freedom of Contract Concerns

We oppose many of SB 754's provisions for a multitude of reasons mentioned elsewhere in this document, but we also oppose these provisions because they represent substantial government interference with freedom of contract. Today, health insurance coverage policies for clinician-administered drugs are the result of contracts that are freely negotiated between private parties. Rather than seeking a legislative remedy to contractual issues, hospitals are invited to raise concerns regarding clinician-administered drugs during negotiations with health insurance providers. Health insurance providers welcome the opportunity to come to agreements that reduce the cost of these expensive drugs for patients, enhance patient access to care, and improve the quality of care provided.

It is also worth noting that, from time to time, health insurance providers may adopt white bagging practices at the request of providers. For example, a provider might find white bagging preferable if they do not stock a drug due to factors such as cost or patient volume, do not have easy access to the drug, or do not have the

ability to adhere to required processes for controlled substances. Under SB 754, this practice likely could not continue.

Conclusion

We appreciate the opportunity to share our perspective on the harmful impact of SB 754. Clinician-administered drugs are a leading contributor to drug spending growth and only shared stakeholder responsibility will address the burden these rising costs put on patients and employers.

Health insurance providers are responding to unreasonable hospital and physician markups and the unsustainable cost of clinician-administered drugs by encouraging lower cost, more convenient settings when it is safe and clinically appropriate. Instead of pursuing legislative mandates to protect their market power, stakeholders that wish to prevent health insurance providers from saving patients and employers money by pursing safe alternatives to drug administration can do so by coming to the negotiating table and agreeing to reasonable reimbursement rates for drugs whose prices are already too high.

For these reasons, the League urges the committee to give Senate Bill 754 an unfavorable report.

Very truly yours,

Matthew Celentano
Executive Director

cc: Members, Senate Finance Committee

2024 SB754 Opposition or Amend.pdf
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Position: INFO

SB754
2024

Opposition Statement SB754
Health Insurance Carriers and Pharmacy Benefits Managers -
Clinician-Administered Drugs and Related Services
Deborah Brocato, Legislative Consultant
Maryland Right to Life

We oppose SB754

On behalf of our 200,000 followers across the state, we respectfully object to SB754. The 2022 session of the Maryland General Assembly significantly lowered the standard of care for women and girls with The Abortion Care Access Act by removing the physician requirement for medical and surgical abortions. This law also requires funding of abortion by the taxpayers through Medicaid and private health insurance. We oppose the additional funding of abortion as part of the "related services" provided by a clinician in the bill. We oppose placing abortion facilites in parity with pharmacies for the purpose of dispensing abortion drugs and requiring Health Insurance Carriers to do the same. Maryland Right to Life requests an amendment excluding abortion purposes from this bill.

D-I-Y Abortions: While the Supreme Court imposed legal abortion on the states in their 1973 decisions Roe v. Wade and Doe v. Bolton, the promise was that abortion would be safe, legal and rare. But in 2016 the Court's decision in *Whole Woman's Health v. Hellerstedt* prioritized "mere access" to abortion facilities and abortion industry profitability over women's health and safety.

The abortion industry itself has referred to the use of abortion pills as "Do-It-Yourself" abortions, claiming that the method is safe and easy. Chemical abortions are 4 (four) times more dangerous than surgical abortions, presenting a high risk of hemorrhaging, infection, and even death. With the widespread distribution of chemical abortion pills, the demand on Emergency Room personnel to deal with abortion complications has increased 250%. The FDA has removed safeguards that prohibited the remote sale of chemical abortion bills leaving pregnant women and girls exposed to the predatory tele-abortion practices of the abortion industry.

In addition to the physical harm of these D-I-Y abortions, consider the psychological harm of chemical abortion. After taking the mifepristone and misoprostol and the contractions begin, the woman or girl is told to expel the baby and placenta into the toilet. This is a very bloody event and the woman and girl will see the remains of their baby in the toilet. If hemorrhaging occurs, the woman or girl will need to get herself to an emergency room.

Maryland is one of only 4 states that forces taxpayer funding of abortion. Maryland taxpayers are forced to subsidize the abortion industry through direct Maryland Medicaid reimbursements to abortion providers, through various state grants and contracts, and through pass-through funding in various state programs. Health insurance carriers are required to provide reproductive health coverage to participate with the Maryland Health Choice program.

Americans oppose taxpayer funding of abortion. Taxpayers should not be forced to fund elective abortions, which make up the vast majority of abortions committed in Maryland. Polls consistently show that 60% of Americans, pro-life and pro-choice, oppose taxpayer funding of abortion.

Funding restrictions are constitutional. The Supreme Court of the United States has ruled that the government may distinguish between abortion and other procedures in funding decisions -- noting that "*no other procedure involves the purposeful termination of a potential life*", and held that there is "*no limitation on the authority of a State to make a value judgment favoring childbirth over abortion, and to implement that judgment by the allocation of public funds*."

Maryland Right to Life requests an amendment excluding abortion purposes from this bill. Without it, we ask for an unfavorable report on SB754.

NIH Abortion Pill Adverse Events.pdf
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Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019

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PMID: 33939340

Abstract

Objectives: Primary: Analyze the Adverse Events (AEs) reported to the Food and Drug Administration (FDA) after use of mifepristone as an abortifacient. Secondary: Analyze maternal intent after ongoing pregnancy and investigate hemorrhage after mifepristone alone.

Methods: Adverse Event Reports (AERs) for mifepristone used as an abortifacient, submitted to the FDA from September 2000 to February 2019, were analyzed using the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAEv3).

Results: The FDA provided 6158 pages of AERs. Duplicates, non-US, or AERs previously published (Gary, 2006) were excluded. Of the remaining, there were 3197 unique, US-only AERs of which there were 537 (16.80%) with insufficient information to determine clinical severity, leaving 2660 (83.20%) Codable US AERs. (Figure 1). Of these, 20 were Deaths, 529 were Life-threatening, 1957 were Severe, 151 were Moderate, and 3 were Mild.

The deaths included: 9 (45.00%) sepsis, 4 (20.00%) drug toxicity/overdose, 1 (5.00%) ruptured ectopic pregnancy, 1 (5.00%) hemorrhage, 3 (15.00%) possible homicides, 1 (5.00%) suicide, 1 (5.00%) unknown. (Table 1).

Retained products of conception and hemorrhage caused most morbidity. There were 75 ectopic pregnancies, including 26 ruptured ectopics (includes one death).

There were 2243 surgeries including 2146 (95.68%) D&Cs of which only 853 (39.75%) were performed by abortion providers.

Of 452 patients with ongoing pregnancies, 102 (22.57%) chose to keep their baby, 148 (32.74%) had terminations, 1 (0.22%) miscarried, and 201 (44.47%) had unknown outcomes.

Hemorrhage occurred more often in those who took mifepristone and misoprostol (51.44%) than in those who took mifepristone alone (22.41%).

Conclusions: Significant morbidity and mortality have occurred following the use of mifepristone as an abortifacient. A pre-abortion ultrasound should be required to rule out ectopic pregnancy and confirm gestational age. The FDA AER system is inadequate and significantly underestimates the adverse events from mifepristone.

A mandatory registry of ongoing pregnancies is essential considering the number of ongoing pregnancies especially considering the known teratogenicity of misoprostol.

The decision to prevent the FDA from enforcing REMS during the COVID-19 pandemic needs to be reversed and REMS must be strengthened.

Keywords: Abortifacient; Abortion Pill; Adverse Event Reports; Adverse Events; DIY Abortion; Drug Safety; Emergency Medicine; FAERS; FDA; Medical Abortion; Medical Abortion Complications; Mifeprex; Mifepristone; Misoprostol; No touch abortion; Post-marketing Surveillance; REMS; RU-486; Risk Evaluation Mitigation Strategy; Self-Administered Abortion.

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