The League of Life and Health Insurers of Maryland

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The Honorable Joseline Pena-Melnyk
Chair, House Health & Government Operations Committee
House Office Building
Annapolis, MD 21401

Senate Bill 1368 – Health Insurance Carriers and Pharmacy Benefit Managers – Clinician-Administered Drugs and Related Services

Dear Chair Pena-Melnyk,

The League of Life and Health Insurers of Maryland, Inc. respectfully **opposes** *HB 1368 – Health Insurance Carriers and Pharmacy Benefit Managers – Clinician-Administered Drugs and Related Services* and urges the committee to give the bill an unfavorable report.

HB 1368 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.

HB 1368 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 HB 1368 raises significant cost concerns, both for individual patients and the commercially insured population.

Individually and collectively, the provisions of HB 1368 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 HB 1368 are outlined in the accompanying memo. In light of these issues, we ask that you oppose HB 1368.

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 HB 1368, relating to insurance coverage of clinician-administered drugs.

While proponents have characterized HB 1368 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 HB 1368, 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.

What is "White Bagging"?

[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

[2] Projections of US Prescription Drug Spending and Key Policy Implications. JAMA Network. January 29, 2021. Available at: https://jamanetwork.com/journals/jama-health-forum/fullarticle/2776040

"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.

HB 1368 Decimates Health Insurance Providers' Tools to Encourage Lower Cost, Higher Quality, and More Convenient Care

As we said previously, while proponents have characterized HB 1368 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 HB 1368 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 HB 1368 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 HB 1368 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 HB 1368'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 HB 1368, 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 HB 1368 does.

Medical Necessity Concerns

As we have illustrated, HB 1368 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 HB 1368 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 HB 1368'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 HB 1368'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 HB 1368 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 HB 1368'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 HB 1368, this practice likely could not continue.

Conclusion

We appreciate the opportunity to share our perspective on the harmful impact of HB 1368. 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 HB 1368 an unfavorable report.

Very truly yours,

Matthew Celentano
Executive Director

cc: Members, House Health & Government Operations Committee