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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