May 5, 2021

Representative Tina Liebling, Chair
Representative Jennifer Schultz
Representative Aisha Gomez
Representative Dave Pinto
Representative Joe Schomacker

Senator Michelle Benson, Chair
Senator Jim Abeler
Senator Paul Utke
Senator Mark Koran
Senator John Hoffman

Re: **HF 2128 / SF 2360 – HHS/HSR Omnibus Budget Bill**
PCMA Issues and Suggestions
Article 5 Prescription Drugs, Sections 8 – 9, 15, and 20 - 22

Dear Chair Liebling, Chair Benson and Members of the HHS/HSR Conference Committee:

The Pharmaceutical Care Management Association, commonly referred to as PCMA, is the national trade association for pharmacy benefit managers (PBMs). PBMs administer prescription drug plans for more than 266 million Americans with health coverage provided by large and small employers, health insurers, labor unions, and federal and state-sponsored health programs.

As the Conference Committee convenes to consider differences in the House and Senate versions of the Omnibus HHS/HSR Bill (HF 2128 and SF 2360), PCMA wanted to express our concerns on the issues in HF 2128 (1st Unofficial Engrossment) and where possible we have also suggested an alternative approach.

○ Article 5 Sections 8 and 20 – [62Q.83] PRESCRIPTION DRUG BENEFIT TRANSPARENCY AND MANAGEMENT. – House Provision

Our industry has significant concerns relative to the language in these Sections which we refer to as "frozen formulary". We believe this will restrict our ability to put downward pressure on prescription drug prices set by pharmaceutical manufacturers to limit the increase of prescription drug costs and work with our clients to effectively manage formularies on their behalf.

PBMs help employers, insurers, and public health programs provide their members access to safe, effective, and affordable medications. Pharmaceutical manufacturers set the price of prescription drugs and pricing in the drug market is volatile. There are very few tools to incent those drug manufacturers to reduce prices. Formulary placement and financial incentives (i.e., lower cost sharing) to use lower-cost generics and brand alternatives are among those tools. The language in this bill threatens these cost saving mechanisms. If specific drugs are mandated to be covered, brand drug manufacturers have no incentive to provide price concessions on their drugs to make them more affordable for patients.

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A recently released report by Milliman shows that **this type of policy would cost Minnesota health care payers $75 million over five years.** HF 58, the frozen formulary bill introduced this session, considered a more holistic approach by marrying a frozen formulary to a prohibition on price changes during a Plan year by drug manufacturers. That bill had a fiscal note of $34 million to SEGIP for 2022-23, and $49 million in 2024-25. It was noted in the fiscal note that:

> "SEGIP expects significant fiscal impact from…Subdivision 3, which describes the changes that a health carrier can make to their formulary during an enrollee's contract term. After consulting with SEGIP's PBM that maintains the formulary, it appears that this legislation would require SEGIP to move from its currently selected formulary to a custom opt-out formulary. SEGIP's current formulary allows for mid-year formulary drug changes that include steering members to drugs with the lowest net cost due to manufacturer rebates from branded drug products, specialty drug management, excluding drugs based on hyperinflation, and utilization management through prior authorization. SEGIP's PBM interprets this Section to limit or outright prevent these mid-year formulary changes."

The language in this section of the bill does not substantively address these cost concerns; rather, if simply exempts SEGIP from the frozen formulary requirements. As highlighted in the Milliman report, the cost of the frozen formulary requirements is very real and significant for all Minnesota health care payers. SEGIP is no different - to keep costs down for SEGIP, their PBM needs to be able to react to drug manufacturers' price increases. Those price increases and the need to respond to them are not unique to SEGIP. They are the same market conditions PBMs work to address for all of their health plan clients. Passage of this language would limit the ability to respond when a manufacturer brings a "me too" drug to market, would stifle competition, and incent a manufacturer to raise their price and ride it all year after they are locked in a formulary because the manufacturer would not need to negotiate with the PBM or health plan.

Significant market forces to drive down the cost of drugs will be eliminated under this bill. For example, imagine that a new generic alternative or competing brand medication were introduced to the market. Under this language, even if these medications offered fewer side effects, a lower risk profile, or came at a lower cost for consumers, PBMs would be unable to encourage patients to use the new medication; favoring the more expensive brand medication and driving up costs for consumers. Hepatitis C drugs offer a powerful example of how real and impactful these market forces are for consumers and health care payers. When hepatitis C drugs Sovaldi, Harvoni, and other competitors came to market, health insurers and PBMs would not have had the leverage to negotiate the deep discounts—around 40% off the list price—on these very expensive drugs in exchange for placement on the formulary as the preferred drug.

Currently, there are appeals processes which health plans and PBMs have in place for patients to access a non-formulary drug. Just last session a comprehensive prior authorization bill was enacted to protect patients' continued coverage of their medications. The health plan or PBM works with a patient and his or her provider to provide access to non-formulary drugs where medically necessary and/or likely to create the best clinical outcome. We believe our appeals

processes are fair and responsive. If the exception is allowed to drive the rule, then costs will go up, not down.

PCMA believes that these Sections will raise prescription drug costs for consumers, employers, and health plans. It removes important tools that PBMs use to deliver high quality services to health plans. The primary effect of "frozen formulary" legislation is not patient protection, but rather increasing costs for patients and health care payers.

- **Article 5 Section 9 – [62W.0751] ALTERNATIVE BIOLOGICAL PRODUCTS. – House Provision**

- **Article 5 Section 21 – STUDY OF PHARMACY AND PROVIDER CHOICE OF BIOLOGICAL PRODUCTS. – House Provision**

Our industry has significant concerns relative to the language in these Sections. It has been stated that the goal of the legislation in this Section is to increase the use of biosimilars and thus decrease the cost for consumers. Increasing competition in this evolving market can surely lead to lower costs to Minnesotans. Years ago, the PBM's were instrumental in supporting the federal law that was enacted to grant the Food and Drug Administration (FDA) the ability to create a framework under which biosimilars and interchangeable biological products can be approved. Today, we continue to strongly support the increase in development and use of these drugs.

Unfortunately, the language in this Section will likely have the opposite effect of its stated goal and will decrease the use of biosimilars and increase costs to consumers. The language in this Section *expressly limits PBM tools* (such as formulary development and management) specific to biosimilars—effectively hamstringing PBMs and plans where these tools are needed most. The language in this Section essentially creates an open formulary for these drugs. This will only lead to increased costs because there will be no incentive for the manufacturers of these drugs to compete on price. Biosimilar manufacturing is in its infancy – the existing incentive structure will drive them to get more efficient in their manufacturing capabilities and thus allow them to compete on price, just as happened with generics over the previous decades. While there are currently no interchangeable biosimilars on the market, there are several biosimilars and each year this list grows, which shows that the market is working. It should also be stated that these types of drugs are the largest growing segment of the market, which makes it even more important to get this right. These types of drugs, only account for approximately 1% of the utilization but they represent close to 50% of the drug spend.

It should be noted that public health care programs and SEGIP are exempted from this Section. While numerous justifications may be proffered, there is a straightforward explanation in line with other costly provisions in this bill which is to avoid a fiscal note and thus move the language forward without considering its true fiscal impact to all health care payers.

- **Suggestion:** The study language in Section 21 would be to evaluate the impact of this legislation AFTER the bill has become law. It is our suggestion to conduct this

research and analysis on the front end to determine the intended and unintended consequences on all stakeholders impacted.

- **Article 5 Section 16 – [151.335] DELIVERY THROUGH COMMON CARRIER; COMPLIANCE WITH TERMPERATURE REQUIREMENTS. – House Provision**

- **Article 5 Section 22 – STUDY OF TEMPERATURE MONITORING. – House Provision**

For PCMA and its member companies, the safety and efficacy of mailed prescriptions is of utmost importance and is 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 such as hemophilia, HIV, and cystic fibrosis medications.

There are federal laws that ensure prescription drugs delivered through the mail are safe for patients. In addition, the Minnesota Board of Pharmacy has oversight of all licensed pharmacies – this includes both in-state and out-of-state. The Board has very specific rules and regulations on prescription delivery which include a process a pharmacy is to use when utilizing the United States Postal Service or other common carriers to deliver a prescription drug. This includes ensuring safe delivery and compliance with temperate requirements as well as providing information to a patient on what they should do if the integrity of the medication they received is compromised in a shipment.

The language in this Section of the bill was discussed at the March 24th meeting of the Board of Pharmacy during which concerns were raised with the language. Thus, the Board of Pharmacy did not vote to support the legislation; rather, they voted to allow Dr. Cody Wiberg to continue to work with the author to further refine the language to better reflect cold-chain technology. Concerns included the efficacy of temperature monitoring strips, including false-positive and false-negative readings leading to pharmaceutical waste, and overly broad language of the bill as it does not narrow the scope to cold-chain and insulin products. Additionally, the language only addresses one segment of the supply chain. When considering temperature monitoring of prescription drugs, it should be inclusive of wholesalers, manufacturers, and retailers, regardless of the pharmacy class.

- **Suggestion:** If a study is included in the final conference committee report, it is our suggestion the study contemplate any significant clinical impact of temperature variation through transit/delivery, not just the existence of temperature variation. We would also suggest a recommendation for an assessment of the impact on returns/replacements and drug trend as a result. Manufacturers should provide extended stability study information for their products so each shipment can be evaluated on its own. This would help in compliance with USP Chapter 1079, in which a “pharmacy should provide on the external package a statement of an acceptable period of delay for delivery”.

Thank you for your time and consideration and please contact me should you have any questions.

Sincerely,

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