April 7, 2022

The Honorable Tina Liebling, Chair, Health Finance and Policy Committee
Minnesota Health Finance and Policy Committee Members
Minnesota House of Representatives
477 Rev. Dr. Martin Luther King Jr. Blvd.
St Paul, MN 55155

The Honorable Jennifer Schultz, Chair, Human Services Finance and Policy Committee
Minnesota Human Services Finance and Policy Committee Members
Minnesota House of Representatives
473 Rev. Dr. Martin Luther King Jr. Blvd.
St Paul, MN 55155

Re: **HF 4706 – Health and Human Services Omnibus Bill**
**PCMA Testimony in Opposition to Article 6 Prescription Drugs,**
**Sections 2 – 3, 6, 18, 32, 40. 43 – 45, , 48 – 49, 53, and 59**

Dear Chair Liebling, Chair Schultz, Members of the Health Finance and Policy Committee, and Members of Human Services Finance and Policy Committee:

My name is Michelle Mack and I represent the Pharmaceutical Care Management Association, commonly referred to as PCMA. PCMA is the national trade association for pharmacy benefit managers (PBMs), which 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.

PCMA appreciates the opportunity to submit written testimony on HF 4706 which is the Health and Human Services Omnibus Bill. PCMA respectfully opposes or expresses areas of concern in Sections 2 – 3, 6, 18, 32, 40, 43 – 45, 48 – 49, 53, and 59 of Article 6 – Prescription Drugs. The language in these Sections will increase costs, have not been fully vetted and we are concerned about the intended and unintended consequences. We have outlined our issues below.

**❍ ARTICLE 6 SECTIONS 2 AND 3 – [62J.497] NCPDP REAL-TIME PRESCRIPTION BENEFIT STANDARD**

Our industry has concerns relative to the language in these Sections. At this time, there is **no** NCPDP Real-Time Prescription Benefit (RTPB) standard. PBMs comply with all other set NCDPD standards around ePrescribing, formulary, etc., but given there is no standard, compliance will be an issue.

**❍ Article 6 Sections 6 and 18 – [62J.84] PBM PRESCRIPTION DRUG SUBSTANTIAL PUBLIC INTEREST REPORTING**

At this time, PBMs are required under 62W.06 (Subd. 2) to report to the Department of Commerce a number of prescription drug information. While PCMA supports meaningful transparency across the supply chain, including transparency that empowers patients, prescribers, clients, and policymakers to make informed decisions that lead to optimal health outcomes and lower costs, we feel this is a duplicative requirement that does not achieve these goals.

**❍ Article 6 Section 32 – [62J.88] PRESCRIPTION DRUG AFFORDABILITY COUNCIL.**

PCMA fully supports efforts to help reduce prescription drug costs and to safely increase access. However, we do want to raise concerns regarding the composition of the proposed Council. While the bill establishes a Prescription Drug Affordability Advisory Council, we would suggest adding a member representing PBMs.

**❍ Article 6 Section 40 – [62Q.1842] PROHIBITION ON USE OF STEP THERAPY FOR ANTIRETROVIRAL DRUGS.**

PCMA applauds the legislature to provide coverage for an enrollee for HIV prevention drugs at the lowest cost share. However, we would request either removing or amending the language in this Section to allow health plans to still be able to perform step therapy and prior authorization based on clinical evidence and rationale. In the case of making available PrEP on the lowest cost sharing tier, prior authorization is needed. Currently, there are drugs available on the market that are unsafe for those assigned female at birth. There is also a drug available that would have adverse health consequences for those with kidney issues. Having a prior authorization in place will ensure the patient receives the appropriate medication for their condition.

**❍ Article 6 Section 43 – [62Q.83] PRESCRIPTION DRUG BENEFIT TRANSPARENCY AND MANAGEMENT.**

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

A recently released report by Milliman shows that **this type of policy would cost Minnesota health care payers $75 million over five-years and the state’s own analysis of a similar bill this year substantiates this**. PBMs help employers, insurers, and public health programs provide their members access to safe, effective, and affordable medications, but pricing in the drug market is volatile, and there are very few tools to incent 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. 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.

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. 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. The health plan or PBM works with a patient and his or her provider to provide access to non-formulary dugs 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 delivery high quality services to health plans. Rather than protecting patients, 'frozen formulary' bills primarily increase costs.

**❍ Article 6 Section 44 – [62W.0751] ALTERNATIVE BIOLOGICAL PRODUCTS.**
**❍ Article 6 Section 59 – STUDY OF PHARMACY AND PROVIDER CHOICE OF BIOLOGICAL PRODUCTS.**

It has been stated that the goal of the legislation in these Sections 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 for 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 still, we strongly support the increase in development and use of these drugs.

Unfortunately, the stated goal of increasing the use of biosimilars and lowering costs to consumers may not be achieved. 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 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. Currently, there is an interchangeable biosimilar on the market, with more interchangeable biosimilars expected to be available in 2023. 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, which only account for approximately 1% of the utilization, represent close to 50% of the cost.

It should be noted that public health care programs and the State Employee Group Insurance Plan are exempted from this bill, and we wonder why the state would not benefit from the suggested cost savings.

Finally, we appreciate the study language to evaluate the impact of this legislation after the bill has become law. However, it might make more sense to conduct this research and analysis on the front end to determine the intended and unintended consequences on all stakeholders impacted by this bill.

- **Article 6 Section 45 – [62W.15] CLINICIAN-ADMINISTERED DRUGS.**
- **Article 6 Section 48 – [151.01].**
- **Article 6 Section 49 – [151.01].**

PBMs and their health plan and employer clients use specialty pharmacies to deliver high quality, accessible pharmacy services while promoting product affordability. Flexibility to continue contracting with these select pharmacies is the key to ensuring access and promoting drug affordability in Minnesota. When an employer or health plan decides to contract with a PBM to administer their pharmacy benefit, they maintain authority over the terms and benefit plan design, including how drugs should be obtained by or delivered to beneficiaries. The employer or plan—not the PBM—makes decisions regarding cost-sharing requirements, formularies, and networks, including the use of mail delivery of a drug to a patient or provider. In limiting a plan sponsor's choices to allow white bagging, this bill will substantially increase costs for Minnesota consumers and plan sponsors. Our research shows that in the first year alone, restricting white bagging has the potential to cost Minnesotans $175 million in excess drug spending.

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. Like the precautions taken with the COVID vaccines moving through cold chain, specialty pharmacies manage specialty drugs in a similar manner to ensure drugs do not spoil.

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. The safety and efficacy of mailed prescriptions is of utmost importance and is well reflected in the level of precision and planning undertaken by specialty pharmacies.

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[1]. 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.[2]

Specialty pharmacies and mail delivery are tools used in pharmacy networks because they ensure high-quality drug delivery service, avoid waste, and ensure appropriate use of the medications.

As stated above, specialty pharmacies are used so patients and employers can continue to afford these very expensive drugs.

**o Article 6 Section 53 – [151.335] DELIVERY THROUGH COMMON CARRIER; COMPLIANCE WITH TERMPERATURE REQUIREMENTS.**

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 additional language in this Section is unnecessary and overly broad, as it would encompass all prescriptions sent via mail including those that are not

[1] CMS, "Clarifications to the 2014 Policy on Automatic Delivery of Prescriptions" (December 12, 2013).
[2] Op. cit, CMS (December 12, 2013).

temperature sensitive. The efficacy of these monitoring devices is debatable; there could be false-positives leading to medical waste, and false-negatives leading to adverse reactions for patients.

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

Sincerely,

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