May 5, 2024

The Honorable Liz Olson, Chair, House Ways and Means Committee
The Honorable Heather Edelson, Vice-Chair, House Ways and Means Committee
The Honorable Pat Garofalo, Republican Lead, House Ways and Means Committee
Minnesota House Ways and Means Committee
Minnesota House of Representatives
479 State Office Building
St. Paul, MN 55155

Re: **PCMA Comments Opposing Prior Authorization Language within Article 4 of HF 4571 – the Health and Human Services Supplemental Budget Bill**

Dear Chair Olson, Vice Chair Edelson, Republican Lead Rep. Garofalo, and Members of the House Ways and Means 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 275 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 provide written testimony. We respectfully submit the following comments for consideration in opposition to the prior authorization language in Article 4 of HF 4571, the House Health and Human Services Supplemental Budget Bill, given the issues with patient coordination of care, significant cost, and safety impacts this bill will have on Minnesota patients.

Industry Concerns with HF 4571

The Fiscal Note for prior authorization (HF 4571-7A) in HF 4571 was released on April 29, 2024, showing a biennial cost of over $32 million. While PCMA has argued that this bill will be costly from the start, we are concerned that the current Fiscal Note did not address various areas of cost. Specifically, it did not address Article 4, Section 28 of the bill, which severely limits prior authorizations for chronic conditions. This section alone could eliminate or reduce medically important coordination of care and lacks necessary definitions and directives for implementation. If this provision becomes law, the increased costs to the state and all payers will be significant. We strongly suggest removing this unvetted section of the bill prior to passage to the floor.

In addition, there were numerous areas in the Fiscal Note where it was noted that things could not accurately be estimated, is not reflected in the Fiscal Note, or not possible to estimate at this time. Some of these are reiterated below:

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmanet.org

> "MMB **cannot estimate a cost for sections 3 and 28 of this bil**l."
>
> "Under section 26, paragraph 3, MMB assumes the Advantage Plan…may see an increased use of higher-cost services, **but we cannot accurately estimate it.**"
>
> "Under section 26, paragraph 4, and the amended § 62Q.1841- Prohibition on use of prior authorization or step therapy protocols, MMB assumes its health plan administrators and pharmacy benefit manager would need to remove all prior authorizations for antineoplastic cancer drugs. **MMB cannot accurately estimate the cost of removing prior authorization for medically administered cancer drugs available through the medical benefit, and therefore it is not reflected in this fiscal note**."
>
> "MMB assumes this bill allows for generic substitution of equivalent brand drugs. If the intent of this bill is to prohibit generic substation of brand drugs, **MMB would assume a large fiscal impact that is not included in this bill."**
>
> "MMB's PBM estimates an Advantage Plan cost of $8,135,000 from removing specialty prior authorization (including antineoplastic cancer drugs) and step therapy/PA based on 2023 Advantage Plan and book of business claims experience. This estimate assumes that the Advantage Plan would forego $8.1M in savings from specialty drug prior authorizations and $35,000 for oral buprenorphine. Additionally, we expect to have lower drug rebates received by the plan…**in addition to potentially lower minimum rebate guarantees, but those specific costs are not possible to estimate at this time**."
>
> "Under section 28, MMB assumes the Advantage Plan's health plan administrators and PBM would be required to not let a prior authorization expire for the treatment of chronic conditions (as defined in section 28 of the bill) and if the treatment of such condition(s) does not change. The bill does not specify what would fall under the bill's definition of chronic conditions, and as a result, **it is unclear how it would be determined whether standard treatment is changing. MMB assumes many conditions and treatments may be affected by this section."**

As a bit of background, on prior authorization, we are including the following:

Prior Authorization Ensures Consistent, Guideline-Based Care While Reducing Costs for Minnesota Payers

Prior authorization is a form of utilization management where a health plan requires pre-approval of a prescription drug. The primary goals are 1) to ensure the appropriateness and suitability of the prescribed medication for the specific patient; 2) to ensure safety; and 3) to reduce costs.

The use of prior authorization in the medical benefit and drug benefit are different. Prior authorization in the medical benefit is for a service and prior authorization use in the drug benefit is for a product – a prescription drug. The difference is important because a drug is typically prescribed for use over a length of time, not just once. Ongoing use of a drug may require monitoring or testing to ensure the drug is safe and effective.
Prior authorization is a tool used for drugs with the following characteristics:

- Dangerous side effects
- Harmful when combined with other drugs
- Should only be used for specific health conditions
- Are often misused or abused
- Have equally, more effective, or more affordable drugs that would work for the majority of patients based on evidence-based drug therapy standards of care

According to the National Academy of Sciences, Engineering, and Medicine (NASEM), "Formularies are used to steer patients and prescribing clinicians toward generic substitutes, biosimilars, drugs with similar therapeutic efficacy for the same disease, or other therapeutic options." Without formulary controls, "insurance premiums would rise," notes NASEM. Prior authorization and step therapy are among the most effective formulary controls, thus prohibiting use of these programs would likely raise premiums. Increased premium costs are passed on directly to Minnesotans who are already feeling the strain from rising costs on their pocketbooks.

Prior Authorization Requirements are Developed by a Panel of Independent Experts.

Health plans and PBMs rely on independent Pharmacy & Therapeutics (P&T) Committees, comprised of independent experts including licensed physicians, pharmacists, and other medical professionals, to develop evidence-based guidelines used in drug management programs—including prior authorization—and to ensure that these management controls do not impair the quality of clinical care.

Every Plan has a Prior Authorization Exceptions Process to Safeguard Coverage of Non-Formulary Drugs when Appropriate.

NASEM has also stated that, "Every plan, whether Part D or an employer-sponsored pharmacy benefit, has an exception process that permits coverage of a drug not on formulary or reduces out-of-pocket cost if a prescriber provides information about side effects the patient has experienced from a lower-tiered drug or offers another medical reason for switching."[1] This process safeguards against the use of prior authorization being too restrictive.

[1] Making Medicines Affordable: A National Imperative," National Academies of Sciences, Engineering, and Medicine (NASEM), Nov. 2017.

It is due to these problematic provisions noted above that we must respectfully oppose the prior authorization language in Article 4 of HF 4571.

Thank you for your time and consideration. Please feel free to contact me should you have any questions.

Sincerely,

Michelle Mack
Senior Director, State Affairs
Phone: (202) 579-3190
Email: mmack@pcmanet.org