March 13, 2024

The Honorable Melissa Wiklund, Chair, Health and Human Services Committee
Minnesota Senate Health and Human Services Committee Members
Minnesota Senate
Room 1100 Minnesota Senate Building
St. Paul, MN 55155

Re: **PCMA Comments Opposing SF 3532 – Prior authorization and coverage of health care services requirements modified, ground for disciplinary action against physicians modified, reports to the commissioner of commerce and the legislature required, data classified, and rulemaking authorized.**

Dear Chair Wiklund and Members of the Health and Human Services 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 and I apologize I am not able to be there in person. We respectfully submit the following comments for consideration in opposition to SF 3532, given the significant patient safety and cost impacts this bill will have on Minnesota patients. We would, however, like to thank Senator Morrison for the changes that have been made.

PBMs exist to make drug coverage more affordable by aggregating the buying power of millions of enrollees through their plan sponsor/payer clients. PBMs help consumers obtain lower prices for prescription drugs through price discounts from retail pharmacies, rebates from pharmaceutical manufacturers, and using lower-cost dispensing channels. Though employers, health plans, and public programs are not required to use PBMs, most choose to because PBMs help lower the costs of prescription drug coverage.

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.

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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.

According to the National Academies of Sciences, Engineering, and Medicines, "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.

Industry Concerns with SF 3532

In 2020, when prior authorization legislation was enacted in Minnesota, the concept was heavily negotiated, and the negotiations took place during the height of the pandemic. A mere four (4) years later, the issue is again at the forefront.

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

This bill, as drafted, puts all prior authorizations into the same bucket when there is a difference between medical benefits and prescription drug benefits. For example, in Section 1, Subdivisions 1 and 2, a prescription drug prior authorization under the prescription drug benefit is never retrospectively denied, nor would it be denied if the "service" has already been received. This is because once a prior authorization is approved for a prescription drug using the prescription drug benefit, a patient receives said prescription drug for the amount of time clinically appropriate for the patient and their condition being treated, taking FDA approved recommendations into account. Also, a prescription drug is not a service.

Another example of this is in Section 6, dealing with an "automated process." Minnesota was one of the first states in the nation to require electronic prior authorization for prescription drugs, which can be found in §62J.497. This became effective in 2011 and mandates all prescribers to submit, and payers to accept, electronic prior authorizations by 2016. This is still in effect and is not used 100% by providers, and the language in SF 3532 does not address this long-standing requirement and appears to set forth a new standard and process.

We also have concerns with Section 7, as it is changing "emergency" exemptions to "certain" exemptions. This includes not being able to use prior authorization for generic drugs, interchangeable biosimilars, and medications to treat substance use disorders. Just because a drug has one of these designations does not mean it will not have dangerous side effects, is not harmful when combined with other drugs, or cannot be misused or abused and doesn't need to be reviewed for appropriate use.

Finally, we have concerns with Section 8, which deals with prior authorization for chronic conditions. As written, this is a very broad and encompassing requirement.

It is due to these problematic provisions noted above that we must respectfully oppose SF 3532.

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

Sincerely,

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