February 15, 2023

The Honorable Judy Lee, Chair Senate Human Services Committee
The Honorable Sean Cleary, Vice Chair Senate Human Services Committee
North Dakota Senate Human Services Committee Members
State Capitol
600 East Boulevard
Bismarck, ND 58505-0360

Re: **SB 2389 – Relating to Prior Authorization for Health Insurance**
PCMA Testimony in Opposition to SB 2389

Dear Chair Lee, Vice Chair Cleary and Committee Members:

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.

At this time, PCMA appreciates the opportunity to provide comments on SB 2389 and respectfully is opposed. This bill is setting in statute the requirements and restrictions that include process, time frames, appeals, etc. for prior authorization.

Prior authorization is a requirement that a health plan pre-approves a prescription drug before a pharmacy can dispense it to an enrollee as a covered benefit. The major goals of prior authorization are to ensure appropriateness and suitability of the prescribed medication for the specific patient, safety, as well as to control costs. Health plans and PBMs rely on independent Pharmacy & Therapeutics Committees, comprised of experts that include 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 health plan has a prior authorization appeals process. According to the National Academies of Sciences, Engineering, and Medicine (NASEM), "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.

Some examples where health plans may require prior authorization for drug products in an effort to ensure appropriate use include:

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

- Growth Hormone and Testosterone prevents use for bodybuilding, anti-aging, and athletic performance while ensuring appropriate use for patients diagnosed with growth hormone deficiencies.
- Opioids: Ensures opioids are prescribed according to guidelines at the lowest dose possible for the shortest time possible, which helps prevent drug diversion and overuse.
- Transmucosal Immediate Release Fentanyl: Encourages appropriate use for the treatment of breakthrough pain in cancer patients who are opioid-tolerant.
- Hepatitis C Direct Acting Antivirals: Helps ensure patient appropriately selected and treated for an appropriate duration of therapy based on current standards of care to include making certain the patient is using the preferred medicine by genotype.
- Diabetes Drugs: Prevents inappropriate use for weight loss.
- Dementia Drugs: Prevents inappropriate use for autism.
- Anti-psychotic Drugs: Prevents inappropriate use for insomnia.
- Thrombopoietin Receptor Agonists: Encourages appropriate, approved use for the treatment of chronic immune (idiopathic) thrombocytopenic purpura in those who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy.
- Biologic Immunomodulators: Encourages use of first-line agents prior to the use of biologic immunomodulators and use of biologic immunomodulators based on indication (i.e., used to treat a particular disease).

Inappropriate use of medicines can be dangerous for patients and result in unnecessary health care expenditures.

According to a study conducted by the Federal Trade Commission (FTC), upon a plan sponsor's request, "[l]arge PBMs and small or insurer-owned PBMs have used step-therapy and prior authorization programs to lower prescription drug costs and increase formulary compliance." The FTC also determined that "[p]rior authorization often involves a clinical justification for the use of drugs that are prone to misuse or are especially costly."[2]

Thank you again for the opportunity to comment on SB 2389 and we urge a "do not pass" vote.

If you have any questions, please do not hesitate to contact me.

Sincerely,

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

[2] Federal Trade Commission, "Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies," August 2005. Available at http://ftc.gov/reports/index.htm#2005. [Emphasis added].