PCMA

April 24th, 2025

The Honorable Donna Bailey
The Honorable Kristi Mathieson
Members, Committee on Health Coverage, Insurance and Financial Services
Cross Building, Room 220
100 State House Station
Augusta, ME 04333

RE: LD 1496 An Act to Ensure Ongoing Access to Medications and Care of Chronic Conditions and Conditions Requiring Long-term Care by Changing Requirements for Prior Authorizations; Opposed

Chair Bailey, Chair Mathieson and Members of the Committee,

On behalf of the Pharmaceutical Care Management Association (PCMA), we wish to share our opposition to LD 1496. PCMA is the national association representing pharmacy benefit managers (PBMs), which administer prescription drug plans for millions of Americans with health coverage provided through large and small employers, health plans, labor unions, state, and federal employee benefit plans, and government programs.

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 prescription drug coverage costs.

Prior authorization requires a health plan to pre-approve a prescription drug before a pharmacy can dispense it to an enrollee as a covered benefit. The primary goals of prior authorization are to protect the patient, to ensure the appropriateness and suitability of the prescribed medication for the specific patient, and 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.

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

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

patients based on evidence-based drug therapy standards of 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 PA being too restrictive.

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

- 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: ensure 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: help ensure the patient is appropriately selected and treated for an appropriate duration of therapy based on current standards of care, including making sure the patient is using the preferred medicine by genotype.
- Diabetes Drugs: prevent inappropriate use for weight loss.
- Dementia Drugs: prevent inappropriate use for autism. • Anti-psychotic Drugs: prevent inappropriate use for insomnia.
- Thrombopoietin Receptor Agonists: encourages appropriate, approved use for treating 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 before 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 harm patients and result in unnecessary healthcare expenditures. Additionally, there are potential unintended cost impacts of proposals to limit or prohibit utilization management tools such as prior authorization.

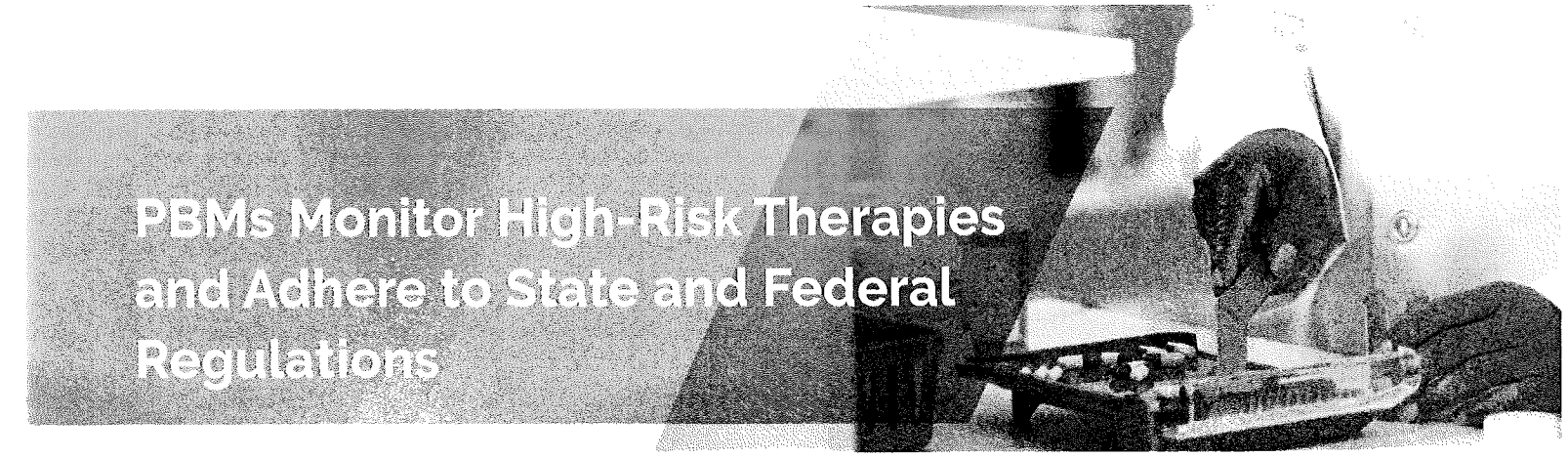
[1] Making Medicines Affordable: A National Imperative," National Academies of Sciences, Engineering, and Medicine (NASEM), Nov. 2017.

PCMA

We must respectfully oppose LD 1496 in the interest of Maine patients and payers because of the problematic provisions noted above.

Sam Hallemeier

Pharmaceutical Care Management Association
(202) 579-7647
shallemeier@pcmanet.org



PBMs Monitor High-Risk Therapies and Adhere to State and Federal Regulations

Pharmacy Benefit Managers (PBMs) help pharmacists monitor high-risk medications.

During the dispensing of a medication, pharmacists rely on PBMs to provide up-to-date information on medications, which includes a PBM review of the patient's medication history. This is a unique value that PBMs can provide because they are often the only entity with a real-time bird's-eye view of the locations and providers involved in a patient's prescription journey. PBMs evaluate a patient's known allergies, health conditions, and available medication history for:

- Dangerous or concerning combinations of drugs.
- Prescriptions filled at multiple pharmacies.
- Morphine Milligram Equivalent (MME) potency for controlled substances.
- Appropriateness of the medication based on a patient's age, known medical conditions, pregnancy status, over- or under-dosing, duration of treatment, clinical misuse or abuse potential, regulatory limitations.
- Information on whether or not the prescriber is authorized to prescribe the specific class of drug.

PBMs use the Centers for Disease Control and Prevention (CDC) or the Food and Drug Administration (FDA) Morphine Milligram Equivalent (MME) guidelines to ensure that a pain medication is safe and appropriate by comparing the dose of the prescribed drug to an appropriate dose of morphine for a similarly situated patient. The PBM evaluates when a patient last filled a medication to make sure the patient does not have an oversupply of the drug, and also uses the prescriber's Drug Enforcement Administration (DEA) or National Provider Identifier (NPI) number to determine if the patient is being treated by an appropriately registered provider. A pharmacy's insurance claim is rejected by the PBM for an invalid prescriber if the prescriber's NPI or DEA number is inactive, or not valid.

All relevant information is sent from the PBM to the pharmacist at the time the medication is filled, and the pharmacist uses this information in combination with their professional judgment to dispense the drug to the patient.

Pharmacies and PBMs must comply with strict standards and laws.

High-risk drugs often have specific compliance requirements for PBMs and pharmacies. Most states have passed laws that require dangerous drug prescriptions to be sent electronically to a pharmacy.[1] Other state mandates include limiting the amount of a drug that a patient can receive the first time they fill a medication, and/or limiting dangerous drugs to a 30-day supply.[2] PBMs develop processes that utilize state laws to assist pharmacists with adherence and enhancement of patient safety.

Additionally, all 50 states have functioning Prescription Monitoring Programs (PMP) that require health care providers and pharmacists to review patient-specific information prior to initiating therapy. Once a prescription has been dispensed to a patient, all state-licensed pharmacies are required to report certain prescriptions to the PMP database.[3] To facilitate the process of getting the information across state lines, the National Association of Boards of Pharmacy (NABP) has created a network that links 48 states together into one database.[4]

more >>

At the federal level, pharmacies that dispense dangerous drugs are required to register with the DEA, and they must follow Title 21 of the Code of Federal Regulations (CFR). Other requirements might include reporting information on dangerous drugs to the federal Risk Evaluation and Mitigation Strategies (REMs) program.[5]

Many PBMs and some pharmacies also receive accreditation to secure business. During the accreditation process, PBMs' and pharmacies' practices are evaluated for compliance with state and federal guidelines. The accrediting organizations often evaluate the drug utilization reviews (DUR) conducted by PBM to validate that the right processes and criteria are in place. These processes include determining when a PBM or pharmacy should reach out to the patient or the prescriber when a concern is identified.

1 https://mdtoolbox.com/eprescribe-map.aspx?AspxAutoDetectCookieSupport=1

2 https://www.cdc.gov/phlp/docs/menu_prescriptionlimits.pdf

3 https://www.fsmb.org/siteassets/advocacy/key-issues/prescription-drug-monitoring-programs-by-state.pdf

4 https://nabp.pharmacy/members/programs-services/industry-information-networks/pmp-interconnect/#:~:text=Download%20flyers%20for%20more%20information%20on%20PMP,more%20that%2045%20jurisdictions%20have%20already%20embraced.

5 https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm