Interested Party Testimony on House Bill 37
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The Ohio House of Representatives Health Committee
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Chairman Lipps, Vice Chair Holmes, Ranking Member Russo, and members of the House Health Committee, my name is Connor Rose, Director of State Affairs for the Pharmaceutical Care Management Association (PCMA). PCMA is the national association representing America's pharmacy benefit managers (PBMs). PBMs administer prescription drug plans and operate mail-order and specialty pharmacies for more than 266 million Americans—including more than 10 million Ohioans—with health coverage through large employers, health insurers, labor unions, and federal and state-sponsored health programs.

As Ohio leaders work tirelessly to address the coronavirus (COVID-19) pandemic, on behalf of the PBM industry, PCMA has continued to support federal, state, and local public health agencies; collaborate with health care providers, first responders, and others; and work closely with American businesses, labor unions, and government programs to ensure working families, older adults, individuals with disabilities, and others get the prescription drugs they need in a timely and cost-effective manner, including at home.

While COVID-19 itself is a new public health challenge, PBMs have substantial experience helping patients access important medications, including in times of emergency or crisis. As patients evaluate their prescription drug needs, following Centers for Disease Control and Prevention (CDC) guidance, PBMs are working with patients and their health care providers to determine if an extra supply of their prescriptions on hand is necessary and safe, as well as to ensure they have an up-to-date supply of their maintenance medications. PBMs also provide guidance to pharmacists and pharmacies to facilitate early refills of maintenance medications due to the COVID-19 pandemic and other public health emergencies, including the documentation needed to request a refill-too-soon override. PBMs' on-staff pharmacists and clinical staff also remind patients to refill their maintenance medications before their on-hand supplies run out, as well as provide safe, reliable, and no-contact options to refill their medications, including by mail.

PCMA has concerns with possible unintended consequences resulting from certain provisions of HB 37, which mandate that employers, retirement systems, and other health plan sponsors provide coverage of emergency refills ***without*** a prescription. While we understand the intent of the legislation is to help ensure patients have access to the medications they need during emergencies, HB 37's scope does not consider the robust range of ways patients currently are able to access their medications in times of emergency, nor is the bill specifically limited to emergencies. The bill also would allow for prescription refills ***without*** a prescription at any time for

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up to a quarter of a year, posing potential patient health and safety risks. The bill also does not contemplate, especially in times of emergency, that full early refills, such as for a 90-day supply, can inadvertently promote inappropriate stockpiling and run counter to private-sector efforts to prevent drug shortages.

As the COVID-19 pandemic has shown, PBMs are committed to promoting high-quality patient care and facilitating continuity, reliability, and safety when patients access medications during times of emergency. For example, **where a prescription has no refills remaining,** PBMs and pharmacies alike have simplified processes for sending new prescriptions from a patient's prescriber directly to their network pharmacy. These processes promote continuity of care for the patient and ensure that, as the patient's health and health care needs change, their prescription regimen matches their needs.

In cases where there is a current prescription with refills remaining, patients generally can refill at day 27 or day 28 (of a 30-day supply). Mail-service pharmacies also may remind patients to *request* their refill earlier, at day 23 for example, with right-timed home delivery. In both cases, these protocols – often referred to as quantity limits – reflect clinical literature and FDA guidelines for how much of a particular drug is safe and clinically appropriate to have on hand.

Reflecting clinical guidelines, CDC recommendations[1], and standard emergency preparedness guidelines[2], PBMs also have in place protocols for pharmacies and pharmacies to fill a requested refill early in cases of emergency.[3] Where it makes clinical sense at the individual patient level, pharmacists currently can and do use their professional judgment to request a waiver of so-called "refill-to-soon" requirements or quantity limits. Under current practice, pharmacists can refill 30 and 90 day supply prescriptions on an emergency or early basis, so long as they are clinically comfortable with doing so and is consistent with *clinical* guidelines to ensure patient safety. Throughout the COVID-19 pandemic, PBMs have been working with patients and their prescribers and pharmacists to address early refill needs.[4]

Behind the scenes, requests for an early refill or extended-days' supply, are evaluated against a patient's complete medication regimen and prescription fill history *across* pharmacies. In cases where it may be clinically inappropriate to fill a prescription early or dispense more than the appropriate supply, PBMs are able to consult with pharmacists to supply the patient with an adequate supply. Similarly, PBMs are able to prevent inappropriate or multiple fill requests *across* different pharmacies that may yield an unsafe supply on hand, and the related risk of diversion or misuse.

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[1] *See* https://www.cdc.gov/cpr/npm/npm2019PrescriptionsBlog.htm
[2] https://www.aarp.org/health/drugs-supplements/info-2020/prescription-drugs-coronavirus.html
[3] For example, https://www.express-scripts.com/art/prc/recentMessagesEmergencyCOVID19.pdf
[4] *See* https://www.pcmanet.org/20914-2/ ; https://www.pcmanet.org/covid-19-how-pbms-are-helping-patients-and-health-plans/covid-19-frequently-asked-questions/; and https://www.pcmanet.org/podcasts-how-pbms-are-helping-patients-during-covid-19/

As written, HB 37 would allow a patient to receive three consecutive, 30-day supply emergency refills *without* having consulted their health care provider during that time. Our industry strongly believes that patient care must be guided and informed by their health care provider, the clinical literature, and the fullness of a patient's prescription regimen and pharmacy care experience; this legislation does not facilitate these important clinical inputs. PCMA is concerned that this would likely lead to improper care and utilization of prescription drugs and worsened health outcomes. Though Schedule II drugs are excluded from HB 37, Schedule III and IV drugs, like suboxone, ketamine, steroids, klonopin, and lorazepam, are not, though they, too, are serious drugs that also can be misused and diverted. If a patient does not have a refill, there could be several reasons as to why, including that the drug is no longer clinically appropriate or that the patient's health care needs have changed.

Especially in cases of emergency, PBMs recognize the importance of balancing undisrupted patient access to medications with efforts to mitigate any risk of drug shortages. In May 2020, the PBM industry convened representative organizations of America's pharmaceutical supply and payment chain, including prescription and over-the-counter brand and generic manufacturers; wholesalers; retail, specialty, and managed care, pharmacies; health insurers; and pharmacists in hospitals and health systems for a joint statement and principles on achieving undisrupted patient access to medications during the COVID-19 pandemic, including that:

> **Policymaking should prioritize patient needs by balancing clinically appropriate drug supplies, efforts to prevent inappropriate stockpiling, substitution and therapeutic interchangeability if shortages occur, and the need to manage drug shortages already occurring and mitigate future drug shortages risks.** For drugs in or anticipating a shortage, there should be flexibility to adjust the supply of medicines to have on hand, which will enable more patients to have access.[5]

With this principle in mind, PBMs have worked closely with states to ensure that there's a thoughtful refill regulatory environment that balances patient needs and safety with the also-important efforts of preventing inappropriate stockpiling, guarding against diversion or misuse, and avoiding unnecessary shortages. As written, HB 37 would limit the ability of the entire pharmaceutical supply and payment chain – from manufacturers to distributors to pharmacies to PBMs to payers, including employers – to adjust in real-time the supply of medicines to have on hand, which will enable *more* patients to have access.

PCMA stands ready to work with the Ohio General Assembly on solutions that effectively balance the needs of patients to obtain their needed prescription drugs during certain emergencies and the importance of clinical patient management considerations. We appreciate your consideration

[5] https://www.pcmanet.org/americas-pharmaceutical-supply-and-payment-chain-collaborating-to-promote-undisrupted-patient-access-to-medications/

of our concerns and look forward to working with Representative Manning on this issue as the dialogue continues.

Sincerely,

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