June 26, 2020

Submitted electronically via PandemicPreparedness@HELP.Senate.gov

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor & Pensions
United States Senate
428 Dirksen Senate Office Building
Washington, DC 20510

RE: "Preparing for the Next Pandemic," a White Paper by Senate Committee on Health, Education, Labor and Pensions Chairman Lamar Alexander (June 9, 2020)

Dear Chairman Alexander:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to offer comments in response to *Preparing for the Next Pandemic*, a white paper released June 9, 2020 of recommendations for consideration by Congress, federal departments and agencies, states, and the private sector to address specific issues and lessons learned as a result of the coronavirus (COVID-19) pandemic.

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 270 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program (FEHBP), and the health insurance exchanges established by the Affordable Care Act (ACA). Our members work closely with employers, health plans, and other issuers to secure lower costs for prescription drugs and promote better individual health outcomes.

Prescription drugs are essential to the health and well-being of hundreds of millions of Americans. During this time of public health emergency, our members have taken action to help patients stay safely at home through convenient, reliable access to their needed prescription drugs, in addition to the vital clinical services and supports to see them through this difficult time. By balancing access – such as through home delivery – with the aim to help alleviate or minimize patient impacts resultant of a strain on the pharmaceutical supply chain, PBMs are facilitating access to needed prescription drugs now and in the days ahead.

PCMA appreciates the thoughtful and collaborative work of the Senate Committee on Health, Education, Labor and Pensions (the committee) to identify the challenges, lessons learned, and opportunities to improve public health preparedness and response.

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Specific to prescription drug access during a pandemic, PCMA supports continued collaboration between the public and private sectors to sustain access to pharmacy care for patients and to help mitigate disruptions, shortages, and related supply challenges. During and after this pandemic, our priority remains enabling everyone to get, as cost-effectively and conveniently as possible, the quality health care they need. PCMA is committed to ongoing dialogue with the committee on promoting affordable, reliable access to prescription drugs.

Our comments in response to the white paper share the actions PBMs have taken to help patients stay safely at home while maintaining safe access to their needed prescription drugs (Issue and Recommendation 4.1). We also address the role of telepharmacy in sustaining access to care during a pandemic, and the value of preserving and building on clearly observable gains in telehealth and telepharmacy (Issue and Recommendation 4.2). Lastly, our comments discuss the importance of policies that foster and encourage competition and quality, to make vaccines and treatment affordable, accessible, and widely available (Questions 1 and 6); and of public-private partnerships to pandemic preparedness and response (Question 8).

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Public Health Capabilities; Issue and Recommendation 4.1: Safe Access to Routine Health Care Services

"Get Americans back to their routine health care safely and develop better plans for the future so that doctors and hospitals can continue to provide health care services and outpatient treatment during a pandemic."

In preparing for and managing patients diagnosed with or experiencing the symptoms of COVID-19, many state executives and public health leaders required or encouraged individuals and families to remain at home and practice physical distancing. Staying safely at home and practicing physical distancing, however, does not mean going *without* access to the routine pharmacy care and prescription drugs on which patients rely. As the following examples illustrate, PBMs have taken action to help patients practice physical distancing and stay at home safely while maintaining convenient, reliable access to their needed prescription drugs during the current pandemic.

Facilitating Reliable, Convenient Access to Needed Prescription Drugs

Since the earliest days of this public health emergency, PBMs have been collaborating with health plans and pharmacies to remove potential barriers to getting prescriptions filled by people staying at home and physical distancing, including encouraging early prescription drug refills and adjusting utilization management programs, where safe and appropriate. PBMs also are advising patients to follow the Centers for Disease Control and Prevention advice relating to an extended days' supply of most maintenance medicines, when clinically appropriate, during an emergency.

PBMs have been a health care leader in facilitating access to home delivery of medications for patients. While mail service pharmacy has always been a convenient and lower-cost option for patients to access their prescription drugs, home delivery has never been as important as it is right now for facilitating routine and safe access to pharmacy care. As part of their pandemic response, PBMs have enhanced home delivery services, including waiving charges for home delivery as well as working with network pharmacies to assist with mailing prescriptions and providing local delivery options for patients.

Promoting Safety of Patients and Pharmacy Staff

Because of the high transmission risk posed by COVID-19, proof-of-receipt and proof-of-delivery requirements may represent an unintentional transmission pathway for pharmacy professionals, patients, and mail carriers alike, and an unintentional barrier to home delivery. To help alleviate both the transmission risk and potential barrier to care posed by such requirements, PBMs are temporarily waiving requirements for pharmacies to obtain proof-of-receipt signatures from patients, except where required by law.

PCMA recommended that states, including their boards of pharmacy and/or Medicaid agencies, as appropriate, temporarily waive proof-of-receipt and proof-of-delivery requirements for the term of the public health emergency and instead consider permitting the industry Best Practice Documentation for Delivery of Prescription Drugs Without a Signature[1] of allowing pharmacists or other delivery personnel to write "COVID delivery," "COVID," or "COVID-19" in the signature line, along with the delivery date and time. In another approach, New York put out Medicaid Pharmacy Guidance that allows pharmacies to confirm delivery through phone call, text, or email, in lieu of a signature.

PCMA also asked the Centers for Medicare & Medicaid Services (CMS) to issue guidance to states clarifying that they may temporarily relax signature log and similar requirements (relating to delivery) without program integrity or audit repercussions.[2] On April 2, 2020, CMS updated its "COVID-19 Frequently Asked Questions (FAQs) for State Medicaid and Children's Health Insurance Program (CHIP) Agencies" to include a new FAQ on signature requirements, specifically encouraging "states to explore ways to ease signature requirements in order to allow beneficiaries to access their medications during the public health emergency."[3] PCMA

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[1] PCMA, "FMI, NACDS, NCPA, NGA and PCMA Announce Best Practices for Signature-Free Access to Prescription Drugs" (June 22, 2020), https://www.pcmanet.org/fmi-nacds-ncpa-nga-and-pcma-announce-best-practices-for-signature-free-access-to-prescription-drugs/.

[2] PCMA, "PBMs Are Taking Action to Promote Patient Access to Prescription Drugs During the COVID-19 Pandemic" (March 2020), https://www.pcmanet.org/wp-content/uploads/2020/03/PBMs-Are-Taking-Action-to-Promote-Patient-Access-to-Prescription-Drugs-During-COVID.pdf. While not expressly required under federal Medicaid regulations, many states' Medicaid signature requirements were established in response to program integrity concerns and to demonstrate services billable to Medicaid were delivered.

[3] CMS, "COVID-19 Frequently Asked Questions (FAQs) for State Medicaid and Children's Health Insurance Program (CHIP) Agencies," last updated May 5, 2020, https://www.medicaid.gov/state-resource-center/downloads/covid-19-faqs.pdf. See FAQ no. 4 on Page 33 of 70 (for the May 5 version) or FAQ no. 11 on Page 11 (for the April 2 version).

appreciates CMS' engagement on this important issue and action to support Medicaid enrollee access to routine pharmacy care.

Helping to Keep the Prescription Drug Supply Chain Functioning Well

This current pandemic's global nature raises the possibility of prescription drug shortages, as drugs normally used by only a few people may suddenly be needed by many, or manufacturing centers may be sidelined by virus outbreaks. PBMs, along with prescription drug manufacturers, wholesalers, pharmacies, and payers, are integral to identifying and managing drug shortages to reduce the prospects of patients being without their medications. PBMs are closely monitoring the global manufacturing environment and using analytics to gauge patients' prescription drug usage trends to anticipate possible disruptions to the supply chain.

Working in concert with the prescription drug supply chain, PBMs also are helping to manage the existing drug supply as equitably as possible among patients who need those prescription drugs. If a shortage or supply disruption results in a specific medication being unavailable, PBMs work with the patient, their prescriber, and their health plan to identify a covered therapeutic substitute and help minimize patient impact. For example, PBMs' real-time benefit tools (RTBTs) allow providers and other prescribers to immediately view covered medications and the patient's cost sharing, as well as send a prescription via e-prescribing to the patient's pharmacy of choice. Should a particular prescription drug be in short supply, RTBTs can help prescribers and pharmacists quickly determine a covered therapeutic alternative for each patient.

To avoid worsening any potential shortages or supply disruptions, not only of medications to treat COVID-19 but other prescription drugs, PCMA recommends federal, state, and local government leaders:

- Avoid policies that may have an unintended impact on the supply of pharmaceuticals in the United States (e.g., stockpiling or hoarding);
- Issue clinical guidelines for health care providers for pandemic-related treatments, based as much as possible on scientific evidence, to help providers, patients, and their health plans and PBMs understand best practices for the treatment of a given pathogen and illness it causes. During the current pandemic, this will help ensure that both COVID-19 patients and those who have been on prescription drug therapies for other U.S. Food & Drug Administration (FDA) approved indications will still have appropriate access should a prescription drug be repurposed for the treatment or prevention of COVID-19;
- Provide timely information on affected products and the expected duration of shortages and/or supply disruptions, so that pharmacies, prescribers, and payers can facilitate adjustments to care and reduce patient disruption; and

- Allow PBMs and health plans to consider individual patient needs and clinical guidelines for early refills, particularly in cases where a greater supply is medically inappropriate and potentially unsafe.

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Public Health Capabilities; Issue and Recommendation 4.2: Telehealth

"Ensure that the United States does not lose the gains made in telehealth."

To help facilitate access to care, state health professional licensing boards, including state boards of pharmacy, moved quickly to allow health care providers, including pharmacists, in good standing in another state to practice in their state. Telepharmacy, or the provision of pharmaceutical care using telecommunications and information technologies to patients at a distance, and electronic prescribing (including for controlled substances) have been essential avenues for many patients to access pharmacy care during the current pandemic.

Specifically, telepharmacy services may include:

- Home delivery of a prescription drug;
- Telephonic and online patient counseling, including access to pharmacists and nurses 24 hours a day, 365 days a year, including for emergency consultations;
- Web-based patient educational resources;
- Texting to patients to support medication adherence, including refill reminders, auto-deliveries, and medication tracking; and
- Pharmacy practice flexibility, such as remote supervision of technician dispensing.

For example, individuals living with diabetes, heart disease, and high blood pressure may be at higher risk of complications from COVID-19. PBMs' mail-service pharmacies can provide these patients with medications that are delivered right to their doorstep, and PBM pharmacists are available by phone 24/7 to answer questions and provide guidance and support.

Throughout the pandemic, PBMs have supported public policies that ease operational barriers and help empower pharmacy professionals to continue delivering needed services, including through telepharmacy, in support of our nation's COVID-19 response. PCMA echoes the recommendations of leading pharmacy associations[4] in recommending states or their boards of pharmacy provide pharmacy professionals and others facilitating access to pharmacy care with increased staffing and worksite flexibility, including by:

[4] National Association of Chain Drug Stories, "Letter to Vice President Mike Pence and Congressional Leaders" (Mach 16, 2020), https://www.nacds.org/pdfs/pharmacy/2020/NACDS-federal-COVID-pharmacy-services-3-16-2020.pdf.

- Allowing pharmacists and pharmacy technicians with valid licenses/certifications to temporarily operate across state lines;
- Authorizing pharmacists and pharmacy staff, including technicians, to conduct routine pharmacy tasks remotely when the technology allows, including those licensed outside the state. In the case of technicians, such remote work would continue to need to be verified electronically by the supervising pharmacist;
- Waiving pharmacy technician ratios or allowing the supervising pharmacist to expand the ratio at their discretion; and
- Ensuring pharmacy professionals are designated essential personnel.

Many of these pharmacy practice flexibilities, which help patients by facilitating continued access to care, were granted through temporary waivers by states or their board of pharmacy for the term of the current public health emergency. As we begin collectively to identify the challenges, lessons learned, and opportunities to improve public health preparedness and response, these waivers and temporary pharmacy practice flexibilities should be evaluated as common-sense measures that can not only help patients in future pandemics and/or emergency response situations, but also preserve the gains made in telehealth.

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Tests, Treatments, and Vaccines; Questions 1 and 6: Incentives

"What incentives can the federal government offer to the private sector to encourage development of more medical countermeasures with no commercial market? What is the appropriate federal role in supporting the manufacturing of medical countermeasures, especially vaccines?"

PCMA strongly supports policies that promote affordable access to prescription drugs, including those for the treatment and prevention of COVID-19 and those that can serve as effective countermeasures against future pandemics. Affordability should not be a barrier to care.

Our member companies harness market forces and competition to facilitate access to high-quality, affordable drug benefits and services for their payer clients and enrollees, including employers and the Medicare and Medicaid programs. To protect against the high prescription drug prices that manufacturers historically have set, PCMA urges policymakers to avoid policies that would allow drug manufacturers to price products without market restraint, including additional data or market exclusivity, for COVID-19 and future pandemic treatments. PCMA encourages the committee to pursue policies that foster competition and quality to make vaccines and treatment affordable, accessible, and widely available during the current pandemic and any future similar public health crises.

Tests, Treatments, and Vaccines; Question 8: Public-Private Partnerships

"How can the United States better leverage public-private partnerships, industry, and academic institutions?"

Throughout the current pandemic, PBMs have worked in partnership with public sector, nonprofit, and pharmaceutical supply and payment chain stakeholders to facilitate Americans' continued access to prescription drugs. For example, to help facilitate access to our nation's nearly 70,000 retail pharmacies, PBMs have actively provided information to www.RxOpen.org, a central hub created after Hurricane Katrina by Healthcare Ready to help promote uniform, consistent supply-chain information for stakeholders during and after disasters. RxOpen is a free public resource open to anyone attempting to locate an open pharmacy during an emergency and is hosted by Healthcare Ready.

In addition, PCMA has forwarded PBM reports of shortages to CMS to help the agency in both policy making and in its work with health care providers and other agencies to understand the pandemic's impact on the health care system and on patients.

To minimize impacts on patient care associated with drug shortages, PCMA is leading a cross-industry collaboration of prescription and over-the-counter drug manufacturers; wholesalers; retail, specialty, and managed care pharmacies; health insurance providers and other payers; and pharmacists in hospitals and health systems. This continuing collaboration has facilitated connections with other health care stakeholders, including patient advocacy groups, and identified and problem-solved shortages and other issues to minimize disruptions to patient care.

The collaboration also has informed a consensus set of policy principles on keeping the pharmaceutical supply chain functioning well as we confront the current and plan for future pandemics.[5] Intended to be helpful to policymakers, including the committee as it considers steps to help mitigate drug access concerns in the event of shortages, whether they result from market, public health, or environmental forces, the principles reflect the importance of public-private partnerships in pandemic preparedness and response.

While we have enclosed the full slate of principles, we would note the following:

- **Both the private and public sectors should work together to sustain access to care for patients and help to mitigate disruptions and shortages.** Supply chain stakeholders continuously assess for shortages or disruptions and collaborate with public health agencies on efforts to sustain access to care. Through FDA-led and industry-supported surveillance efforts, including publicly reported, practitioner-focused

[5] Academy of Managed Care Pharmacy, America's Health Insurance Plans, American Society of Health-System Pharmacists, Association for Accessible Medicines, et al. "Letter to Vice President Mike Pence and Congressional Leaders" (May 27, 2020), https://www.pcmanet.org/wp-content/uploads/2020/05/Pharmaceutical-Supply-Payment-Chain-Letter-May-27-2020.pdf.

shortage information, timely information collection and awareness enables the best management of supply and contingency solutions to minimize the impact on patient care.

- **The pharmaceutical supply and payment chain, including health care providers, should have timely access to information on disruptions and shortages during a public health emergency.** The FDA should continue to provide timely information on affected products and the expected duration, so that pharmacies, prescribers, and payers can facilitate adjustments to care and reduce patient disruption.
- **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.
- **National clinical guidance for health care providers should be issued on potential and approved COVID-19 treatments.** If existing FDA-approved drugs are found to be safe and effective in the treatment or prevention of COVID-19, policymakers must balance broad public health needs while working to maintain access to these drugs for patients who currently rely on them.

An opportunity to further public health preparedness and response, particularly with respect to access to prescription drugs, is to build on these and other public-private partnerships. Forums for collaborative dialogue among public sector, nonprofit, and pharmaceutical supply and payment chain stakeholders can yield practical, real-time solutions and information for pandemic preparedness and response. Data, surveillance, and management of drug shortages during a pandemic may be one such example.

For example, the FDA's drug shortages list has been an invaluable tool to support the management of available prescription drug stock throughout the current pandemic. It is our understanding that the FDA's reporting of shortages primarily reflects manufacturer-reported *supply disruptions* (e.g., a manufacturer experiences an unforeseen breakdown in manufacturing equipment that disrupts production). Other organizations, including the American Society of Health System Pharmacists, track shortages that include smaller-scale disruptions and temporary stock-outs (i.e., where demand exceeds supply). The supply chain is using both reports to manage supply and reduce disruption to patients. The differences between these sources of shortage information demonstrate the value of the public and private sectors collaborating to use data and surveillance to better manage drug shortages and supply disruption risks, particularly during pandemic scenarios. FDA and pharmaceutical supply and payment chain stakeholders, including PBMs, should explore avenues to enable information sharing that would enhance analytics and surveillance of such risks, thereby strengthening preparedness response efforts and sustaining access to pharmacy care.

We appreciate the opportunity to provide comments in response to the committee's white paper, *Preparing for the Next Pandemic*. PBMs support congressional efforts to improve U.S. public health preparedness and response capabilities, including public-private collaboration, and look forward to further working with you and your colleagues on these important questions.

If you or your staff should have need for additional information on our industry's efforts, or specific questions on which we can be helpful, please contact Jonathan Heafitz, vice president of Federal Affairs, at (202) 756-5735 or by email to jheafitz@pcmanet.org.

Sincerely,

Kristin Bass
Chief Policy and External Affairs Officer

Enclosure: Pharmaceutical Supply and Payment Chain Coalition Principles

cc: Jonathan Heafitz, Vice President, Federal Affairs, PCMA
Claire Wulf Winiarek, Vice President, Policy, PCMA

Pharmaceutical Supply and Payment Chain Coalition Principles

Our organizations – those involved in the pharmaceutical supply and payment chains – commit to continue working collaboratively and with the U.S. Food and Drug Administration (FDA) and other federal, state, and local officials to keep the pharmaceutical supply chain functioning well as we confront the coronavirus (COVID-19) pandemic.

Our primary concern is the health and well-being of patients. Medications are essential to millions of Americans. Patients should have the confidence that adequate prescription and over-the-counter drug supplies continue to be available and that our organizations recognize their roles to minimize impacts on patient care associated with drug shortages.

To that end, we agree to the following principles:

- **Patients should have safe, convenient, and reliable access to their medicines.** Following Centers for Disease Control and Prevention's (CDC's) advice, patients may elect to receive an extended days' supply of most maintenance and specialty medicines, when clinically appropriate, including through delivery to their homes. Patients should have the flexibility to decide where they receive infused or injected medicines and may wish to have access to safe treatment at home when clinically appropriate.
- **Both the private and public sectors should work together to sustain access to care for patients and help to mitigate disruptions and shortages.** Supply chain stakeholders continuously assess for shortages or disruptions and collaborate with public health agencies on efforts to sustain access to care. Through FDA-led and industry-supported surveillance efforts, including publicly reported, practitioner-focused shortage information, timely information collection and awareness enables the best management of supply and contingency solutions to minimize the impact on patient care.
- **The pharmaceutical supply and payment chain, including health care providers, should have timely access to information on disruptions and shortages during a public health emergency.** The FDA should continue to provide timely information on affected products and the expected duration, so that pharmacies, prescribers, and payers can facilitate adjustments to care and reduce patient disruption.
- **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.
- **National clinical guidance for health care providers should be issued on potential and approved COVID-19 treatments.** If existing FDA-approved drugs are found to be safe and effective in treating COVID-19, policymakers must balance broad public health needs while working to maintain access to these drugs for patients who currently rely on them.
- **A closely connected, diverse, and resilient global pharmaceutical supply chain is the best means to ensure a consistent and affordable supply of medicines for patients.** As our country addresses the COVID-19 pandemic, reliable patient access to affordable medications remains a significant concern. We support manufacturing in the United States and exploring incentives to maintain, utilize and attract investment in domestic manufacturing. We should avoid measures that could trigger protectionist responses and instead deepen relationships with international trading partners to promote resiliency and diversity of the global pharmaceutical supply chain. Specifically, the U.S. Government should avoid adopting policies that may have an unintended impact on the U.S. pharmaceutical supply, including requirements to buy only drugs, or a percentage of drugs, manufactured in the United States.
- **Logistics and distribution systems that deliver pharmaceuticals should be prioritized to alleviate a potential source of disruption or shortage.** We strongly encourage government officials to engage with the U.S. and global airline, shipping and mail, and logistics industries to ensure prioritization and guaranteed cargo space related to the transport of pharmaceuticals, medical devices, and medical supplies.