

May 27, 2020

The Honorable Mike Pence
Vice President of the United States
The White House
1600 Pennsylvania Avenue, NW
Washington, D.C. 20500

The Honorable Mitch McConnell
Senate Majority Leader
United States Senate
Washington, D.C. 20510

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Charles Schumer
Senate Democratic Leader
United States Senate
Washington, D.C. 20510

The Honorable Kevin McCarthy
House Republican Leader
U.S. House of Representatives
Washington, D.C. 20515

Dear Vice President Pence, Speaker Pelosi, Leader McConnell, Leader McCarthy,
and Leader Schumer:

As representative organizations of the pharmaceutical supply and payment chain, including prescription and over-the-counter brand and generic manufacturers; wholesalers; retail, specialty, and managed care pharmacies; health insurance providers and other payers; pharmacists in hospitals and health systems; and pharmacy benefit managers, we are coming together to work on policy solutions to ensure patients have access to essential medicines during the COVID-19 pandemic.

Our primary concern is the health and well-being of patients, including ensuring that patients with chronic conditions have continued access to the medicines they need. We recognize that all of us in the pharmaceutical supply and payment chain have a responsibility to take action to help prevent and mitigate drug shortages and ensure patient access to care.

As a result of the COVID-19 pandemic, there are serious concerns that disruptions in the pharmaceutical supply chain, which relies on international suppliers, could lead to an increase in drug shortages. In addition, as more people stock up on maintenance medicines and the need for essential medicines increases as a result of COVID-19 hospitalizations, prompt action is necessary to help mitigate and prevent drug shortages for patients.

The companies and organizations we represent continuously assess their supply chains for drug shortages and potential disruptions to supply, and collaborate with federal, state, and local public health agencies to share critical information and partner on efforts to sustain access to care with as little disruption as possible. As a result, and despite challenges, the pharmaceutical supply chain remains strong and resilient, and Americans continue to have access to a safe, effective, and reliable supply of prescription drugs and other medications.

Our organizations have substantial, collective experience in helping to mitigate drug access concerns in the event of shortages – whether the result of market, public health, or environmental forces. And we pledge to continue to work collaboratively with each other and with policymakers

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to identify problems and ensure the supply chain is functioning well as we confront this unprecedented health care system challenge.

As part of our organizations' combined efforts to collaborate with federal and state officials to meet the common goals of a secure and safe supply chain and continued patient access to medicines, we have agreed on a common set of policy principles. We hope policymakers find these useful as they consider steps to address drug shortages.

Sincerely,

Academy of Managed Care Pharmacy
America's Health Insurance Plans
American Society of Health-System Pharmacists
Association for Accessible Medicines
Biotechnology Innovation Organization
Blue Cross Blue Shield Association
Consumer Healthcare Products Association
FMI – the Food Industry Association
Healthcare Distribution Alliance
National Association of Chain Drug Stores
National Association of Specialty Pharmacy
National Grocers Association
Pharmaceutical Care Management Association
Pharmaceutical Research and Manufacturers of America

Enclosure: Pharmaceutical Supply and Payment Chain Coalition Principles

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.