



Pharmacy Readiness for Coronavirus Disease 2019 (COVID-19)

RECOMMENDATIONS FOR FEDERAL POLICYMAKERS

March 2020

Executive Summary

In the United States, our drug supply chain and clinical infrastructure are not generally the subject of deep concern. However, a public health emergency, whether a natural disaster or an infectious disease outbreak, can quickly expose the weak links in our healthcare system. The coronavirus disease 2019 (COVID-19) outbreak highlights potential vulnerabilities in both our drug supply chain and our clinical infrastructure, including the availability of adequate clinician resources.

A. Protect Our Supply Chain from Shortages

The new outbreak highlights the need for the federal government to safeguard our drug supply, to improve transparency in the supply chain, and to ensure contingency plans are in place to mitigate disruptions that can result in drug shortages. However, there are measures the government can take to help mitigate these threats and increase transparency. The following commonsense solutions would enable safer, more consistent drug manufacturing:

- Require manufacturers to provide the Food and Drug Administration (FDA) with more information on the causes of shortages and their expected durations and allow public reporting of this information
- Require manufacturers to publicly disclose manufacturing sites, including use of contract manufacturers, and sources of active pharmaceutical ingredients (APIs)
- Require manufacturers to conduct periodic risk assessments of their supply chains and establish contingency plans to maintain the supply of a drug in the event of a manufacturing disruption
- Require the Department of Health & Human Services (HHS) and the Department of Homeland Security (DHS) to conduct a risk assessment of national security threats associated with the manufacturing and distribution of critical drugs
- Incentivize domestic, advanced manufacturing capacity

B. Ensure Medicare and Medicaid Beneficiaries Have Adequate Access to Pharmacist Care

Ensuring we have sufficient clinician resources to respond to a public health emergency is as essential as protecting our supply of drugs, protective equipment, and other supplies. The following policy recommendations will ensure better access to care during an outbreak, particularly for Medicare and Medicaid beneficiaries:

- Clarify Medicare supervision requirements for pharmacists to align with their state scope of practice
- Clarify Medicare and Medicaid authority to reimburse clinical services provided by pharmacists acting within their state scope of practice
- Clarify Medicare authority to support pharmacy residency programs, including specialized training in infectious disease

C. Provide Resources to Support Clinician Readiness and Resilience

We recommend that Congress provide funding to address the following areas needed to support clinician readiness and resilience for COVID-19 response:

- Infectious disease and emergency preparedness continuing education
- Investment in infectious disease and emergency preparedness clinical education
- Clinician burnout, well-being, and resilience
- Clinician and first responder family support
- Pharmacy readiness assessment

D. Address Emerging Risk Areas

In addition to the concerns we have detailed above, we urge policymakers to consider emerging risk areas that have not received sufficient public consideration:

- Shortage of medication for supportive care
- Shortages of personal protective equipment (PPE) and sterile products
- Hoarding of medical supplies
- False claims and misinformation

Pharmacy Readiness for Coronavirus Disease 2019 (COVID-19)

Recommendations for Federal Policymakers

As the number of confirmed cases and deaths attributed to COVID-19 continue to climb worldwide, policymakers should act quickly to respond.

In the United States, our drug supply chain and clinical infrastructure are not generally the subject of deep concern. However, a public health emergency, whether a natural disaster or an infectious disease outbreak, can quickly expose the weak links in our healthcare system. The COVID-19 outbreak highlights potential glaring vulnerabilities in both our drug supply chain and our clinical infrastructure, including the availability of adequate clinician resources.

Federal policymakers should take the following steps to **ENSURE THE SECURITY OF OUR DRUG SUPPLY CHAIN** and **READINESS OF OUR CLINICAL PHARMACY INFRASTRUCTURE** to respond to outbreaks such as COVID-19:

A. Protect Our Drug Supply Chain from Shortages

This outbreak highlights the need for the federal government to safeguard our drug supply, to improve transparency in the production chain, and to ensure contingency plans are in place to mitigate disruptions. China produces a large portion of the world's active pharmaceutical ingredients (APIs) and finished pharmaceuticals. More than 80% of APIs are produced outside the United States, highlighting the magnitude of the potential risk.¹ Manufacturers have not disclosed which specific drugs are at risk of shortages. This lack of transparency jeopardizes FDA's ability to respond to shortages and exacerbates shortages by causing providers to guess which essential medical supplies might be at risk.

Deprived of clear information, we do not actually know how this outbreak could impact global drug supplies. Without more transparency around drug origins, it is impossible to effectively and accurately plan for possible emergency situations involving the supply chain. As a result, our drug supply chain is left vulnerable, and this vulnerability can result in harm to patients and unsustainable burdens on healthcare providers and the entire healthcare system.

There are reasonable measures the government can take to help mitigate these threats and increase transparency. ASHP believes there are commonsense solutions that would enable safer, more consistent drug manufacturing:

¹ Government Accountability Office, Drug Safety: FDA Has Improved Its Foreign Drug Inspection Program, But Needs to Assess the Effectiveness and Staffing of Its Foreign Offices, GAO-17-143. www.gao.gov/assets/690/681689.pdf.

- **Require manufacturers to provide FDA with more information on the causes of shortages and their expected durations and allow public reporting of this information²**

FDA has already indicated that at least 20 drugs are at risk of shortage and one is confirmed to be in shortage as a result of COVID-19, but the identity of these products is unknown to purchasers.³ It is likely that clinicians will also face a shortage of PPE, particularly masks, if there is a significant coronavirus outbreak. However, there is little visibility into the actual amount of supply available. Unless all manufacturers with products at risk of shortage are required to disclose this information, we are likely to see hoarding of essential medical supplies that could further magnify shortages.

Current law requires manufacturers to notify FDA when there is a discontinuance or interruption in manufacturing. However, manufacturers are not required to disclose the cause of the interruption or provide a time frame for resolution. Some manufacturers do this voluntarily, but inconsistent information hinders FDA's ability to mitigate shortages. Title X of the Food and Drug Administration Safety and Innovation Act should be strengthened to require these notifications be published in the FDA drug shortages database and include the cause of the interruption and a time frame to address the shortage. This requirement should also apply to medical supplies such as masks, syringes, and other devices necessary to safely prepare and administer drugs. Shortages of these items have the potential to cripple the U.S. healthcare system.

- **Require manufacturers to publicly disclose manufacturing sites, including use of contract manufacturers, and sources of APIs²**

FDA and drug purchasers, such as hospitals and pharmacies, lack access to key information that could assist in preparing for regional disasters, geopolitical instability, and manufacturing problems at specific sites. The Food, Drug, and Cosmetic Act (FDCA) should be strengthened to require manufacturers to publicly disclose the location of drug production, including when a contract manufacturer is used, and sources of APIs. This requirement should also apply to manufacturers of masks, syringes, and other devices that are necessary to safely prepare and administer drugs. FDA and purchasers can use this information to more accurately assess the scope and duration of a shortage, identify alternative sources of supply, and identify potential supply disruption for related products, including associated medical devices.

- **Require manufacturers to conduct periodic risk assessments of their supply chains and establish contingency plans to maintain supply of a drug in the event of a manufacturing disruption²**

Manufacturers cannot always predict when a shortage will occur. Manufacturing disruptions can be caused by natural disasters, quality issues, or business decisions, which may include discontinuation of a product. Such shortages negatively impact patient safety and access to care. The FDCA should be amended to include a requirement that manufacturers conduct periodic risk assessments of their supply chains and maintain business continuity contingency plans for future supply disruptions that are reviewed during FDA plant inspections.

² ASHP, along with our partners, the American Hospital Association, American Society of Clinical Oncology, and the American Society of Anesthesiologists, has developed legislative objectives based on the 2017 Drug Shortages Roundtable and the 2018 Summit on Drug Shortages to Examine Impact on National Security and Health Care Infrastructure.

³ U.S. Food and Drug Administration (FDA). FDA Statement: Coronavirus (COVID-19) Supply Chain Update. Feb. 27, 2020. www.fda.gov/news-events/press-announcements/coronavirus-covid-19-supply-chain-update.

- **Require HHS and DHS to conduct a risk assessment of national security threats associated with manufacturing and distribution of critical drugs²**

Relying predominantly on other countries for necessary ingredients to manufacture critical drugs, APIs, and devices required to safely prepare and administer drugs presents a potential threat to the stability of the U.S. drug supply. In addition to drugs, medical devices necessary for the preparation and administration of drugs are a critical part of healthcare infrastructure. Items such as PPE, syringes, needles, and tubing for administration of intravenous drugs have been affected by shortages. To enhance transparency, HHS and DHS should conduct a review of priority risks in pharmaceutical and device manufacturing and distribution systems and identify ways the U.S. government can support preparedness and resilience of critical infrastructure in the pharmaceutical sector.

We also urge the federal government to establish a standing forum for these agencies to engage the private sector, including pharmacists, hospitals, physicians, and manufacturers, to mitigate drug supply chain and clinical infrastructure risks. Working together – not in isolation – to share information and solutions is vital to our success in responding to COVID-19 and building a more resilient system in anticipation of future threats.

- **Incentivize domestic, advanced manufacturing capacity**

FDA has identified advanced manufacturing as a potential alternative to traditional batch manufacturing, which could improve the quality and resilience of drug production.⁴ Investment in domestic, advanced manufacturing, in the form of tax incentives or grants, would reduce our dependence on highly concentrated foreign sources of drug production and would allow manufacturers to more rapidly reallocate manufacturing capacity to products in shortage than is possible through traditional production. Making use of advanced manufacturing technology saves time, reduces the potential for error, and enables a nimbler approach to changing market demands.

B. Ensure Medicare and Medicaid Beneficiaries Have Adequate Access to Pharmacist Care

Pharmacists practicing in hospitals, clinics, physician offices, and community settings are trained to treat infectious diseases and can significantly expand access to care if federal barriers are removed. Pharmacists receive a clinically based doctor of pharmacy degree, and many also complete postgraduate residencies and become board certified in areas of specialty care, including infectious disease. Each year, nearly 4,000 pharmacists complete a pharmacy residency and 1,300 complete an additional residency in a clinical specialty. There are currently more than 800 board-certified infectious disease pharmacists nationwide.

In many communities, pharmacists are the most accessible healthcare providers and the first touchpoint of patient engagement with the healthcare system. In fact, 90% of all Americans live within five miles of a community pharmacy.⁵ In rural and underserved communities and in communities experiencing physician shortages, pharmacists may be the only healthcare provider that is immediately available to patients.

Many states have recognized the training and expertise of pharmacists as clinicians and clarified their state pharmacy practice laws to authorize pharmacists to provide patient care services that will be essential during the response to COVID-19. These services include ordering and administering immunizations, ordering and interpreting point-of-care tests, and initiating medications, such as antiviral therapies that must be initiated in

4 U.S. Food and Drug Administration (FDA). FDA Statement: FDA's modern approach to advanced pharmaceutical manufacturing. Feb. 26, 2019. www.fda.gov/news-events/press-announcements/fda-statement-fdas-modern-approach-advanced-pharmaceutical-manufacturing.

5 See NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.

a limited time from exposure in order to be effective. Some states have also ensured that their residents will have access to these services by clarifying that pharmacists should be reimbursed by health plans, like other providers, when they provide these services.

Forty-nine states and the District of Columbia grant pharmacists the ability to practice collaboratively in some capacity with physicians.⁶ The Centers for Medicare & Medicaid Services (CMS) should ensure that its own regulations do not create a barrier to care that is authorized by state pharmacy practice laws.

To ensure that patients can access pharmacist care during a coronavirus outbreak or other public health emergencies, CMS should implement the following policies:

- **Clarify Medicare supervision requirements for pharmacists to align with their state scope of practice**

To avoid barriers to care for the Medicare population, CMS should provide flexibility in its pharmacist supervision and services requirements so they align with the pharmacy practice law of any state in which a beneficiary is receiving care. This flexibility is necessary to ensure that federal regulations do not prevent pharmacists from providing the same level of care to Medicare beneficiaries that they provide to other patients in the state.

- **Clarify Medicare and Medicaid authority to reimburse clinical services provided by pharmacists acting within their state scope of practice**

To avoid barriers to care for the Medicare and Medicaid populations, particularly those in rural and underserved communities that are experiencing provider shortages, Congress should clarify that Medicare, Medicare Advantage, and Medicaid plans should reimburse clinical services provided by pharmacists acting within their state's scope of practice.

For example, point-of-care testing plays a critical role in the identification and treatment of infectious diseases. Increasing access to testing may help reduce disease spread and improve outcomes through early detection. Recent studies indicate that pharmacist-provided point-of-care testing can increase early identification of infectious disease,⁷ particularly for patients who are not able to see a primary care provider – a group that is likely to grow during a coronavirus outbreak. Further, pharmacist initiation of time-sensitive antiviral therapy can speed care access, improve outcomes and reduce disease spread.⁸ Similarly, once a vaccine becomes available, research shows that pharmacists can significantly improve immunization rates.⁹ To ensure that Medicare and Medicaid beneficiaries can be diagnosed and treated quickly, CMS should reimburse pharmacists for services related to the treatment of infectious diseases, when they are acting within their scope of practice, just as CMS would for other healthcare providers. Failure to do so will leave Medicare and Medicaid beneficiaries with less access to healthcare services than other patients.

6 Centers for Disease Control and Prevention, "Advancing Team-Based Care Through Collaborative Practice Agreements" (2017), www.cdc.gov/dhbsp/pubs/docs/CPA-Team-Based-Care.pdf.

7 M. Klepser, et al. "Effectiveness of a Pharmacist-Physician Collaborative Program to Manage Influenza-like Illness," *J. Am. Pharm. Assoc.* Vol. 56 (2016), available at www.ncbi.nlm.nih.gov/pubmed/26802915.

8 *Id.*; See also See E. Burley et. al, "Opportunities for Pharmacists to Improve Access to Primary Care Through the Use of CLIA-Waived Tests" (2014), available at www.michiganpharmacists.org/Portals/0/resources/poctesting/poctesting0414.pdf.

9 See e.g., N. Hamm, "Pharmacists Increase Vaccination Rates," *Drug Topics* (Aug. 2017), available at www.drugtopics.com/latest/pharmacists-increase-vaccination-rates; T. Steyer, et. al, "The Role of Pharmacists in the Delivery of Influenza Vaccines," *Vaccines*, Vol. 22 (Feb. 2004), available at www.sciencedirect.com/science/article/pii/S0264410X0300673X.

- **Clarify Medicare authority to support pharmacy residency programs, including specialized training in infectious disease**

Rigorous clinician education, including for pharmacists with specialized training to manage infectious disease medication regimens, is the bedrock of a highly trained workforce that is prepared to manage public health emergencies. Unfortunately, Medicare support for these programs is uncertain. CMS should clarify that experts in topics such as infectious disease, who serve on the faculty of educational institutions such as medical schools and schools of pharmacy, can provide training to residents in pharmacy and allied health training programs without jeopardizing Medicare funding of programs.

CMS should also clarify that residents in these training programs may participate in clinical rotations at clinical sites operated by other hospitals or health systems, without jeopardizing Medicare funding, if those rotations are appropriate to strengthen resident training in clinical specialties such as infectious disease.

CMS should further clarify that specialized pharmacy residency programs operated by hospitals or health systems in clinical specialties, such as infectious disease, are eligible for Medicare funding. The current system of relying on community resources to fund these programs is inadequate to maintain a pipeline of infectious disease experts necessary to manage specialized medication regimens during a medical surge event, such as a COVID-19 outbreak.

C. Provide Resources to Support Clinician Readiness and Resilience

We urge Congress to provide funding to support clinician readiness and resilience during a COVID-19 response. At minimum, these programs should focus on increasing preparedness and enhancing the pipeline of infectious disease and public health experts. For instance, programs should center on the following:

- **Infectious disease and emergency preparedness continuing education:** Congress should provide funding for immediate development and dissemination of clinician continuing education and certificate training programs on infectious disease and emergency preparedness, including for pharmacists. Such programs should harness the resources and reach of professional organizations, thereby aiding federal and state public health authorities in disaster response.
- **Investment in infectious disease and emergency preparedness clinical education:** Congress should provide funding to enhance and expand pharmacy, allied health, and medical residency programs and other advanced clinician educational programs focused on infectious disease and emergency preparedness.
- **Clinician burnout, well-being, and resilience:** Congress should provide funding to combat clinician burnout and to support research regarding clinician resilience and well-being. Public health emergencies can create intense strain on our healthcare system, which extends to our clinicians, including pharmacists. Clinicians already face high levels of burnout,¹⁰ and public health emergencies are likely to exacerbate this, adding to the strain on our healthcare system.
- **Clinician and first responder family support:** Congress should provide funding to support the families of clinicians, including pharmacists, and first responders during a pandemic or natural disaster. Given the demands placed on clinicians and first responders in these situations, adequate resources should be

¹⁰ Agency for Healthcare Research and Quality, "Physician Burnout," available at www.ahrq.gov/prevention/clinician/ahrq-works/burnout/index.html; See also M. Durham, P. Bush, A. Ball, "Evidence of Burnout in Health-System Pharmacists," J. AM. HEALTH-SYST. PHARM., Vol. 75 (Dec. 2018) academic.oup.com/ajhp/article-abstract/75/23_Supplement_4/S93/5237667?redirectedFrom=fulltext.

available for those who are caregivers, to ensure they can access backup or emergency child and elder care, at minimum, so they can focus on providing the best possible care to patients.

- **Pharmacy readiness assessment:** Congress should provide funding to provide tools for health systems to assess their readiness to respond to medical surge events and resources to address identified gaps, including disruptions to drug supplies, pharmacy staffing, and ongoing hospital operations.

D. Address Emerging Risk Areas

In addition to the concerns we have detailed above, we would also encourage policymakers to plan for emerging risk areas that have not received sufficient public consideration:

- **Shortages of medications for supportive care:** As outlined above, we remain concerned about disruptions to supply generally, but we are also concerned about whether the market can support sudden steep increases to orders for certain supportive medications. These would include intravenous fluids, pain medications, anti-inflammatories, and other treatments essential to managing patients with COVID-19.
- **Shortages of PPE and sterile products:** The danger of PPE shortages has been documented, but such equipment is also necessary in the compounding and preparation of sterile products. If PPE becomes unavailable for clinicians generally, this may have cascade effects on the safe preparation of medications. If sterile procedures for pharmacist preparation of medications (e.g., USP chapters <797>, <800>) cannot be followed because of a lack of PPE, certain medications may become unavailable for patient care. Similarly, if PPE is not available in other countries, this could impact the production of drugs.
- **Hoarding of medical supplies:** Hospital and clinician preparation for a COVID-19 outbreak necessarily includes ensuring adequate supplies. However, in medical surge events, the risk of hoarding increases. As a result, providers may be more tempted to rely on secondary wholesalers (e.g., gray market) for access to critical medical products, thereby introducing new dangers into the supply chain. The Federal Trade Commission (FTC) and other agencies should exercise enhanced market oversight of price gouging and other practices that take advantage of heightened demand for supplies during a COVID-19 outbreak.
- **False claims/misinformation:** We applaud FDA and FTC for their efforts to stem false and misleading claims about products purporting to treat or prevent COVID-19. We urge the agencies to address such instances aggressively. Further, we encourage the agencies to report bad actors to healthcare providers and, concurrently, to provide clinicians and the public a streamlined reporting method to offer information to the agencies about potential violations.

Additional resources, including ASHP's Pharmacy Competency Assessment Center emergency preparedness and infection prevention modules, are available in the COVID-19 resource center at ashp.org/coronavirus.

For more information, please contact:

Doug Huynh, Director, Federal Legislative Affairs, at DHuynh@ashp.org or 301-664-8806.