

December 24, 2020

Effective and Innovative Approaches/Best Practices in Health Care in Response to the COVID-19 Pandemic; Request for Information (RFI)

A. Health Promotion and Prevention of COVID-19 and Non- COVID-19 Medical Conditions

1. Describe effective innovations/best practices that prevented the transmission of SARS-CoV-2 infections in staff, patients and/or beneficiaries.

Pharmacies remained open, even in the earliest days of the pandemic, and pharmacists and pharmacy personnel have continuously fought on the frontlines for patients. The thoughtful and early implementation of social distancing guidelines, including curbside and drive-through services, at community pharmacies ensured timely access to health care and continuity of care for patients with chronic illnesses. Patient access to services at the pharmacy, including medication dispensing for chronic and acute conditions, adherence support, recommendations for over-the-counter medications, and medication management, demonstrate the important role of pharmacists in chronic disease prevention and management.

3. Describe innovative programs/policies and best practices to ensure timely access to health care and continuity of care for patients with chronic illnesses that increase vulnerability to COVID-19.

Pharmacists practice in many healthcare settings such as hospitals, clinics, physician office practices, long term care facilities, community pharmacies, and federal facilities. Over 90% of Americans live within five miles of a community pharmacy, making pharmacists the most widely accessible health care providers. Evidence suggests pharmacists have more opportunities to interact with patients in the community than other providers. As highly-trained clinicians, pharmacists have the ability to significantly expand patient access to needed care and contribute to addressing/improving public health. However, major barriers restrict pharmacists from fully utilizing their expertise, such as lack of direct payment for services, including those necessary to support the COVID-19 response.

Despite their central role in the healthcare system, pharmacists are not currently eligible to participate in Medicare. As a result, direct reimbursement for pharmacists' services is not available, undermining access to essential services in pharmacies. Many Medicaid and private sector health plans follow Medicare policies resulting in significant impact on the financial sustainability of pharmacists' services and limiting the ability of pharmacists to practice at the top of their license. Further, because the Centers for Medicare & Medicaid Services (CMS) does not directly recognize or reimburse pharmacists under Medicare, the agency often inadvertently excludes pharmacists during rulemaking. To address this issue, we have crafted legislation, the *Pharmacy and Medically Underserved Areas Enhancement Act*, which would allow pharmacists to deliver care within their scope of practice to patients in federally defined medically underserved communities. We urge HHS to exercise full regulatory authority to maximize coverage for pharmacists' services to increase patient access to care during and after the public health emergency.

5. Describe effective programs or practices that helped ensure timely administration of immunizations to pediatric patients and other vulnerable populations including the elderly and individuals with disabilities.

We appreciate the recent action by the Office of the Assistant Secretary for Health (OASH) authorizing pharmacists to order and administer COVID-19 and other vaccines (ages 3 and older)

and Advisory Committee on Immunization Practices (ACIP)-recommended childhood vaccines (ages 3-18), as well as qualified pharmacy technicians and State-authorized pharmacy interns under certain conditions, where this authority did not already exist. This has enhanced the position of community pharmacies and pharmacists as primary access points for patients to receive preventive immunizations and pharmacist-provided patient care services and we strongly urge HHS to make these authorizations permanent.

As valued and vital members of the immunization neighborhood, pharmacists are committed to consistent collaboration, coordination, and communications with other health care professionals and stakeholders to address the public health needs of our patients and communities. Nearly every pharmacist in America has prior experience vaccinating patients. Pharmacists are also the nation's most accessible health care professionals, with 90 percent of Americans living within five miles of a community pharmacy. HHS can increase the number of vaccinated Americans by maintaining pharmacists' immunization authority beyond the pandemic. This practice can be further expanded by implementing payment structures that reimburse pharmacists for administration services.

However, issues have arisen related to pharmacists' ability to enroll as Vaccines for Children (VFC) and Medicaid providers. States have stated they do not have the resources to enroll pharmacies as providers within these programs. Inability to enroll pharmacies limits the ability to optimize the value afforded by HHS' recent authority. Without an adequate/reasonable payment structure in place, providers will not be able to sustain their ability to provide vaccines to patients. Accordingly, APhA urges HHS to provide guidance to our nation's pharmacists and public health in the states to expand the number of VFC sites and pharmacist enrollment in the program.

Inter-disciplinary, drive-up clinics vaccinated hundreds of patients against influenza. One drive-up flu shot clinic at Idaho State University provided 650 people with flu shots, including children and seniors. The event was organized through cooperation with multiple entities who have always had similar goals, but never before worked as collaboratively together: Idaho State University pharmacists, student pharmacists, student nurses and student physician assistants (PAs) through the Idaho Immunization Coalition and their Get Immunized, Idaho program, St. Alphonsus Health System, and Albertsons.

The drive-up flu shot clinic in Pocatello provided just over 100 flu shots on November 21 at Holt Arena to children and adults. Idaho State University pharmacists and student pharmacists again partnered with the Idaho Immunization Coalition and the Get Immunized, Idaho program, along with Albertsons and Southeastern Idaho Public Health.

Additionally, both events were conducted as a feasibility study, to help determine the potential readiness level and response opportunities and challenges for widespread delivery of the COVID-19 vaccine in a drive-up setting, for the Treasure Valley and Southeast Idaho areas.

7. Describe effective health promotion and prevention policies and programs implemented in response to COVID-19, that will continue beyond this pandemic.

As previously mentioned, during the COVID-19 pandemic, pharmacists have overwhelmingly stepped up to contribute to some of the most daunting challenges of this PHE, including shortages of health care staff and burnout of health professionals—which continue to rise and threaten

patient health. HHS has recognized pharmacists' important role in maintaining and addressing the country's economic, health, and safety efforts by authorizing pharmacists to order and administer COVID-19 tests, as well as authorizing qualified pharmacy technicians and state-authorized pharmacy interns to administer COVID-19 tests under certain conditions. In addition, FDA has recognized pharmacies as points of care for COVID-19 testing services. HHS authorized pharmacists to order and administer COVID-19 vaccines (ages 3 y and older) and the Advisory Committee on Immunization Practices (ACIP)—recommended childhood vaccines (ages 3–18 y). HHS also authorized qualified pharmacy technicians and state-authorized pharmacy interns under certain conditions to administer these vaccines, where this authority did not already exist. This has enhanced the position of community pharmacies and pharmacists as primary access points for patients to receive preventive immunizations, point of care tests, and other pharmacist-provided patient care services. However, all of these substantial efforts taken by HHS to maximize the use of pharmacists to increase public health and prevention of COVID-19 are temporary. HHS must take action to make these temporary authorizations permanent to improve access to COVID-19 and other point of care tests, increase childhood and COVID-19 vaccinations and the ability of our public health immunization system, anchored by pharmacists and pharmacies, to meet current and future health crises. We refer HHS to our forthcoming comments on the HHS RFI on Regulatory Relief to Support Economic Recovery regarding authorities that should be maintained (i.e., made permanent) or modified after the expiration of the PHE.

Due to the trusting relationships between pharmacists and their patients, pharmacists have ample opportunities to advance public health through immunization advocacy. Pharmacists are important members of the immunization neighborhood, and that trust will be important in addressing vaccine hesitancy for our nation's most vulnerable populations. APhA strongly recommends that HHS implement a fully-funded component for pharmacists and other accessible health care practitioners to conduct coordinated and consistent community-based education and outreach campaigns supporting recommended vaccinations. These campaigns should focus on eliminating stigma, addressing vaccine hesitancy, and improving prevention and health outcomes for high priority and vulnerable patient populations.

APhA also strongly urges HHS to include a steady funding stream to maintain a quality vaccine curriculum provided by professional associations like APhA and its partnering organizations. For example, HHS could sign a Memorandum of Understanding (MOU) with national immunization professional organizations, such as APhA, which provide professional immunization training programs. For example, APhA has trained more than 360,000 pharmacists through its Pharmacy-Based Immunization Delivery certificate training program, based on national educational and practice standards for immunizations from the Centers for Disease Control and Prevention (CDC), APhA and other reputable entities. This program has prepared pharmacists to assume the roles of educator, facilitator and/or provider of recommended vaccines.

- B. Screening/ Surveillance/Case Identification of COVID-19 and Non-COVID-19 Medical Conditions**
2. Describe efforts to ensure that patients continue to receive United States Preventive Services Task Force-recommended screening procedures on time during the COVID-19 pandemic. Please

include data on the program's ability to prevent negative outcomes due to timely screening and early detection, if available.

Many patients have consulted health care providers via telehealth or cancelled their preventive care appointments, which may leave a gap in chronic disease management, with people missing needed laboratory tests such as blood glucose, HbA1c, or lipid panels. This monitoring gap is an area that needs evaluation as the consequences of the COVID-19 pandemic become clearer. Because people who postpone laboratory tests will continue to receive their medications from their pharmacies, community pharmacists are well positioned to encourage patients to receive these tests to ensure effective chronic disease management. Pharmacists can facilitate a professional triaging and screening process through interviewing patients and assessing their symptoms or lack of symptoms. Engaging pharmacists in this activity provides patients with easier access to a knowledgeable healthcare provider. During public health and other emergencies, pharmacists have the ability to perform health screenings, conduct point of care laboratory tests to collaboratively monitor chronic conditions and disseminate medical information.

C. Treatment for COVID-19 and Non-COVID-19 Medical Conditions

7. Outline novel and effective approaches to ensure compliance with medications, including refills, during the pandemic.

During the PHE, CMS has encouraged insurance plans (both Medicare Advantage and Part D plans) to practice flexibility around prior authorization protocols, refills, deliveries, and pharmacy audits, which has reduced the administrative burden on clinicians and allowed for more efficient patient care. Specifically, CMS has recommended the removal of prior authorization requirements, waiver of prescription refill limits (e.g., for maintenance medications for well-controlled conditions), relaxation of restrictions on home or mail delivery of prescription drugs, and reprioritization of audit activities and reviews. Given the burden reduction of these flexibilities, we recommend that these flexibilities remain in place long term. We are concerned with the potential for decreased medication adherence in vulnerable populations, particularly amongst older adults, after the PHE ends, so proactive support for these flexibilities would help to ensure consistent access to medications in all settings.

As COVID-19 continues to surge and we embark on a nationwide mass immunization campaign, every pharmacist will be needed. The flexible workforce and workflow arrangements provided through 1135 waivers have been essential to supporting healthcare teams. These changes have contributed to a more nimble, responsive healthcare system during the PHE and would provide the same benefits when it ends, including flexibility in license portability and remote tasks. We recommend that the Administration use existing authorities and encourage states and Congress to implement or provide new authorities to permanently allow pharmacists and pharmacy technicians with valid licenses to operate across state lines. Additionally, pharmacists and pharmacy staff should be allowed to permanently conduct routine pharmacy tasks remotely as necessary (i.e., prescription data entry and script verification, medication review and reconciliation), including those licensed outside of a state to ensure business continuity.

On April 20, 2020, the FDA issued additional temporary guidance granting flexibility for pharmacists to compound certain necessary medications under 503A for hospitalized patients without patient-

specific prescriptions to address COVID-19. As this health crisis continues, pharmacies, wholesalers, and manufacturers are experiencing or are likely to experience shortages of critical over-the-counter (OTC) and prescription drug products that are needed for patient care. Accordingly, we urge FDA to permanently allow the flexibility the agency has granted for pharmacists to compound medications in shortage under 503A for hospitalized patients without patient-specific prescriptions to continue to address COVID-19. The FDA should also expand this flexibility to any additional medications in shortage for all other health care conditions. Permitting pharmacists to compound drugs in shortage that are not included under the current guidance will help ensure our nation's hospitals have the medications they need to be able to care for all of their patients without worrying about shortages—a fact that will help hospitals reopen and begin to provide non-emergency services to help alleviate the \$50 billion they are losing per month to restore the economic health of our economy as well as improve the health of our nation's patients.

D. Telehealth

2. Describe best practices and innovations to improve access to care for rural/remote populations using telehealth, during the pandemic.

The rapid shift to telehealth services during COVID-19 has illustrated the value of telehealth long-term, particularly for patients with mobility issues and those in rural and/or medically underserved areas. In order to accommodate the provision of telehealth services during the PHE, CMS relaxed its rule requiring physicians to provide “direct supervision” of auxiliary personnel, including pharmacists, in situations where direct supervision currently is required by regulation. In these situations, during the PHE, physicians may provide supervision of pharmacists using real-time interactive using audio and video technology. This flexibility provided during the PHE, at the very least, should be made permanent regardless of whether there is a declared PHE. Virtual supervision of pharmacist services, where supervision is required, will help meet the growing demand for telehealth services, which will likely extend beyond the COVID-19 pandemic and expand access to coordinated care. Finally, to ensure telehealth services are financially sustainable, physicians and other qualified practitioners must be able to bill for pharmacist-provided telehealth services at a level commensurate with the time and complexity of the services provided when the service meets all applicable billing requirements.

Another example of how telehealth has improved rural/remote populations' access to care is through the provision of diabetes self-management training (DSMT) services via telehealth. APhA appreciates CMS' guidance clarifying that accredited and recognized DSMT programs, eligible to bill Medicare Part B directly for DSMT services, may furnish and bill for DSMT services provided via telehealth during the COVID-19 PHE, and urges the agency to make this authority permanent. Adding DSMT programs to the list of “professionals” eligible to provide telehealth services removes the final regulatory barrier preventing pharmacists in DSMT accredited pharmacies from furnishing DSMT services via telehealth and enhances diabetic patients' access to care.

5. What are some of the key facilitators of telehealth?

The CARES Act (Public Law 116-136) under Sec. 3703. Expanding Medicare Telehealth Flexibilities eliminated requirements in the Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020 (Public Law 116-123) and allows the HHS Secretary to waive telehealth

restrictions under 1834(m) to enable beneficiaries to access telehealth, including in their home, from a broader range of providers—including pharmacists. Given the significant burdens on the health care system posed by the pandemic, we urge the HHS Secretary to use this new authority under Sec. 3703 to specifically include pharmacists as practitioners (providers) for the Medicare Telehealth Benefit in order to fully utilize their expertise during and after the end of the PHE.

E. Mental Health/Behavioral Health and Substance Use Disorder Innovations/Best Practices

2. Describe effective and innovative substance use disorder programs during the COVID-19 pandemic.

The COVID-19 pandemic and its economic, social, and emotional consequences have exacerbated the opioid crisis. Rising overdose rates and decreasing access to treatment have highlighted the inequities in access to evidence-based treatment of opioid use disorder (OUD). Buprenorphine saves lives, but the delivery of effective pharmacotherapy for patients struggling with OUD requires collaborative working relationships between DATA-waivered physicians and pharmacists.

Pharmacists are working to increase access to buprenorphine in embedded models under collaborative practice agreements, but the physician is not able to delegate prescribing authority to the pharmacist because pharmacists are not recognized as DATA-waived providers. There are also efforts underway for physicians to work with community pharmacists to monitor patients taking buprenorphine. Recognizing pharmacists as DATA-waived providers would create increased access to buprenorphine and create efficiencies in the care of patients address opioid use disorder.

3. Describe innovative efforts to provide medication-assisted treatment, including access to counseling and support groups, during the pandemic.

One of the most insidious effects of the COVID-19 crisis is its impact on efforts to fight the opioid epidemic. At the same time patients are facing external stressors that can trigger relapse, the PHE has upended existing medication assisted treatment (MAT) programs, which were already, in many cases, struggling to meet patient need.

The DEA's waiving of the requirement for an in-person visit and allowing a telephone-only consultation with the prescriber in order to initiate buprenorphine treatment has helped to expand access to MAT. To further expand access, we urge HHS to use the authority granted in the Comprehensive Addiction and Recovery Act (CARA) (P.L. 114-198) to revise the "qualifying other practitioner" requirements to allow for pharmacists to receive the requisite waiver (known as an "X- or DATA waiver") necessary to prescribe MAT. In the alternative, we urge the Administration to explore using the Public Readiness and Emergency Preparedness (PREP) Act authority to allow pharmacists who meet certain requirements to prescribe MAT during the opioid public health emergency. At present, the exclusion of pharmacists from X-waiver eligibility has robbed patients of access to MAT at a time when demand for care far outstrips capacity.

F. Population-Level Interventions

2. Provide details on effective, community-based, innovative programs to improve population health during the COVID-19 pandemic (e.g., programs to address social determinants of health).

As the biggest vaccination effort in U.S. history gets underway, several states may not have enough facilities in some areas to administer the COVID-19 vaccine to all residents who want it, according to

a new analysis from the University of Pittsburgh School of Pharmacy and the nonprofit West Health Policy Center.

In what is believed to be the first county-level analysis of the nation's potential COVID-19 vaccine facilities, which include community pharmacies, federally qualified health centers, hospital outpatient departments and rural health clinics, the researchers found that more than a third (35%) of U.S. counties have two or fewer of these facilities and nearly 1 in 10 counties have fewer than one facility per 10,000 residents. Researchers used geographic information system (GIS) software to map more than 70,000 potential COVID-19 vaccine administration facilities and calculate the average driving distance to the closest facility for simulated citizens, including high-risk populations such as people age 65 or older.

The researchers suggest that state and local authorities in areas with short driving distances and low facility density may consider adding vaccination clinics to increase capacity and reduce the time to vaccinate. Conversely, areas with long driving distances may benefit from mobile vaccination clinics to reduce travel-related barriers, and vaccines that require only one dose instead of two may be more effective in ensuring sufficient vaccine uptake. Interactive Map - <https://www.westhealth.org/resource/potential-covid-19-vaccine-locations/>

Dr. Julie Morito, Executive Vice President at the Robert Wood Johnson Foundation and former Commissioner of Chicago's Department of Health, recommended leveraging existing public health immunization infrastructure, including pharmacists and pharmacies, to reduce disparities and inequities in vaccine confidence and acceptance. Dr. Morito noted that Chicago utilized pharmacists and pharmacies as part of 800 provider sites for distribution of the H1N1 vaccine in traditionally underserved areas as a model to improve health equity and build on public trust. Utilization and sustaining of accessible and trusted healthcare providers within identified communities is critical to addressing inequities and health disparities.

We believe broad access to pharmacists' immunization services for all patient populations is fundamental to achieving equitable accessibility to vaccines for our nation's vulnerable populations and to combat vaccination rates that have plummeted nationally since late March when COVID-19 cases started increasing. Accordingly, as mentioned above, we strongly urge HHS to make the new immunization authorizations granted to pharmacists permanent. It is also important to note that data shows there are approximately 21,767 independent pharmacies and 22,812 large national chains. Additional analysis shows that 20.5% of zip codes that have a pharmacy do not have a chain drug store, supporting the case for broad-based utilization of ALL community-based pharmacy practices under equitable distribution of vaccines and additional preventive services to address all underserved communities.

In addition, HHS needs to address barriers related to network inclusion of pharmacists and other accessible immunization providers, and the removal of increased patient out-of-pocket costs for utilizing these providers.

G. Other Topics

1. Please describe effective strategies to address other critical barriers, including work force concerns, provider well-being, supply chain, etc., to ensure continuity of operations in a healthcare system.

Pharmacist Well-Being:

Last July, APhA launched the Pharmacist Well-Being Index (WBI), a validated screening tool invented by the Mayo Clinic, for the pharmacy profession. At last count, 5,927 pharmacy personnel have taken the WBI. Of these, 34.6% overall were at risk of high distress. Since COVID-19, this number has not changed; however, more individuals are reassessing, as well as accessing the WBI resources.

HHS should partner with APhA to assess and address pharmacist well-being during the PHE through the WBI to ensure continuity of care in healthcare systems. Addressing federal recognition of pharmacists as eligible professionals under Medicare with adequate reimbursement aligned with comparable services provided by other health care providers would go a long way to ensuring adequate staffing to help address pharmacists' well-being during and after the PHE.

Supply Chain:

FDA's Essential Medicines List

APhA applauded the FDA's publication of a list of essential medicines, medical countermeasures, and critical inputs that are medically necessary to have available at all times in adequate amounts and dosage forms to serve patient needs. This is the first time FDA has published a list of this kind. FDA noted that this list is intended to ensure that the American public is protected against outbreaks of emerging infectious diseases, such as COVID-19, as well as chemical, biological, radiological and nuclear threats. APhA is reaching out to our members for input on the essential medicines lists. APhA recommends FDA partner with APhA to ensure that medically necessary medications are always available to serve patient needs.

FDA's Dangerous Importation Programs

APhA is disappointed that FDA would risk the safety and security of our nation's drug supply by creating a complex and convoluted program allowing legal importation of certain drugs from Canada. We believe FDA's new drug importation program is not a safe way to reduce drug prices—and puts patients at risk. FDA's final rule jeopardizes patient safety by creating supply chain vulnerabilities that could potentially introduce counterfeit or unsafe drugs into the market. It also undermines the Drug Supply Chain Security Act (DSCSA), which creates "track-and-trace" safeguards that do not exist in Canada. By commingling FDA-approved and imported versions in the marketplace, this program also creates pharmacy operation disruptions and product selection confusion and may limit patient access to medications by complicating insurance coverage and reimbursement at the pharmacy.

Given the additional steps in the supply chain, such as relabeling and laboratory testing requirements, additional reporting systems, and the fact that most high-cost drugs are excluded from the program, it fails to produce significant cost savings to American consumers. APhA strongly urges HHS to end this program of unsafe drug importation schemes that would allow the introduction of risky products into our secure U.S. drug supply chain.