April 22, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services (HHS)
Office of the Secretary
Room 503H-3
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra,

As our nation and the world begin to recover from the COVID-19 pandemic, thanks to more robust vaccine manufacturing, distribution mechanisms, and the nations' pharmacists and healthcare providers, America's pharmacy organizations respectfully urge you to take action and make permanent regulatory flexibilities that have allowed pharmacists to support our nation's public health response to help defeat this pandemic.

During the pandemic, pharmacists have demonstrated the ability to significantly expand access to care and equity in care[1], and they will continue to do so if certain regulatory barriers are permanently removed. In an effort to mitigate and prevent COVID-19, the U.S. Department of Health and Human Services (HHS), the Centers for Medicare and Medicaid Services (CMS), Food and Drug Administration (FDA) and other federal agencies have temporarily removed some of these barriers. If permanently removed, pharmacists could play an even greater role in defending local communities from public health threats, detecting and responding to early pandemics, and ensuring greater health equity for all Americans.

We urge HHS to expeditiously use its authority to make permanent:

- Pharmacists' ability to order, authorize, test, treat, and administer immunizations and therapeutics against infectious diseases;
- Removal of operational barriers that address workforce and workflow issues which previously prevented pharmacists from engaging in patient care;
- Compounding flexibilities to address current and future drug shortages; and
- Reimbursement for specific pharmacist-provided patient care services.

This letter outlines the need for and benefits of making COVID-19-related regulatory flexibility permanent.

[1] National Pharmacy Organizations Unite to Take a Stand Against Racial Injustice. June 5, 2020, available at: https://www.accp.com/docs/news/Pharmacy_Statement_On_Racial_Injustice.pdf

Securing ability of pharmacists to order, authorize, test, treat, immunize, and provide other services

We urge CMS to permanently authorize pharmacists to order, test, treat, immunize, and provide other patient care services, including administration of time-sensitive antiviral therapy for influenza, and when it becomes available, COVID-19.[2] As noted above, pharmacists are expertly trained healthcare practitioners who support public health, greater care access and enhanced health equity, but are only authorized to engage in these types of services in certain states. Recent CMS and HHS guidance provided some consistency across state lines, which has been critical in addressing the current public health crisis. To improve delivery of services and our public health infrastructure, CMS should make a number of temporary policies implemented during the public health emergency (PHE) permanent, including:

- Permitting pharmacists to order and administer all CLIA-waived point of care tests, including COVID-19, influenza, respiratory syncytial virus (RSV), as well as services to treat infectious disease, including administration of time-sensitive antiviral therapy, if available; and
- Granting accelerated CMS certificate of waiver approval to provide CLIA-waived point-of-care tests in all states.

Despite the Public Readiness and Emergency Preparedness Act (PREP Act) and guidance from the HHS Office of the Assistant Secretary of Health (OASH) and Office of General Counsel (OGC), some states still have burdensome restrictive requirements that prevent many pharmacies from accessing CLIA waivers.

- Therefore, our organizations respectfully ask HHS to not only maintain the current policy allowing pharmacists to be granted a CLIA Certificate of Waiver to provide all CLIA-waived point-of-care tests, but also issue clarifying guidance that instructs all states to enact policies and procedures that will expedite allowing pharmacies to follow through on CMS' guidance.

Additionally, CMS issued a May notice[3] that it will use existing evaluation and management (E/M) payment codes to reimburse CMS-eligible providers for counseling services regardless of where the test was administrated. However, this notice does not include pharmacists without "incident-to" relationships. Community pharmacists are well positioned and trained to provide these services but rarely have incident-to relationships with other CMS eligible providers.

- Accordingly, to meet the Administration's COVID-19 testing and vaccination goals, we urge CMS to ensure that all pharmacies have a sustainable mechanism to offer all CLIA-waived point-of-care testing and all associated services (e.g., specimen collection, patient counseling, etc.) and vaccination services (including referrals for well-child visits, COVID-19 referrals, etc.) for all patients, in all patient care settings (e.g., doctor's offices, urgent care clinics, hospitals and community drive-thru,

[2] FDA is reviewing a number of antiviral therapies that could be provided in much the same way as oseltamivir.
[3] https://www.cms.gov/newsroom/press-releases/cms-and-cdc-announce-provider-reimbursement-available-counseling-patients-self-isolate-time-covid-19.

pharmacy testing sites, independent community pharmacies, long-term care, etc.). Given that CMS has found a workable method for reimbursing COVID-19 immunizations, it seems that a similar solution could be found to ensure proper reimbursement for testing as well as other services, such as administration of antiviral therapy.

Finally, under PREP Act authority, pharmacists have been able to provide childhood vaccinations subject to certain requirements. This authority has provided a backstop against sliding pediatric vaccination numbers and we believe maintaining it could provide significant public health benefits, including increased access for underserved populations. However, reimbursement, particularly through the Vaccines for Children program, remains a substantial barrier to uptake. We suggest a modernization of the Vaccines for Children program to transform it from an "office based" model to reflect the current and future immunizers, including pharmacy-based models. In addition, a modernization would better serve those for whom the program was created. Although we recognize some statutory changes may be required, we urge CMS to take any necessary regulatory action to reduce these barriers.

Removal of Operational Barriers for Pharmacists

The COVID-19 pandemic has stressed and strained our healthcare system and revealed generations of health inequities in communities of color, medically underserved, and rural areas. In order to protect public health, detect and respond to future epidemics, and improve the equitable delivery of healthcare, every pharmacist needs to be able to support healthcare teams.

Current 1135 Waivers allow providers, including pharmacists, flexibility and support in providing care. Specifically, these waivers have enabled pharmacists and pharmacy technicians with a valid license to operate across state lines and the ability to conduct routine pharmacy tasks remotely as necessary.

In January 2021, HHS, under the PREP Act, also authorized any healthcare provider, including pharmacists, who are licensed or certified in a state to prescribe, dispense, and/or administer COVID-19 vaccines across state lines, during the public health emergency.

Additionally, CMS has encouraged insurance plans to practice flexibility regarding prior authorization protocols, refills, deliveries and pharmacy audits. These practices have reduced the administrative burden on clinicians and allowed for more efficient patient care, testing and vaccine delivery. Given the benefits to patients and the system, we recommend that CMS encourage all Medicare Advantage (MA) and Part D plans to continue offering these flexibilities to prevent decreased medication adherence in vulnerable populations, especially older adults and people of color. CMS has also issued policies relaxing Medicare Part D audit requirements for signature logs. Accordingly, we recommend the following policies be made permanent for MA, Part D plans and contracted pharmacy benefit managers (PBMs):

- Relaxing to the greatest extent possible prior authorization requirements, where appropriate;
- Suspending plan-coordinated pharmacy audits during any PHE; and

- Waiving medication delivery documentation and signature log requirements to limit unnecessary contact with sick and potentially infectious patients.

Finally, we encourage CMS to include pharmacists under existing and future telehealth flexibilities. Under Medicare Parts B and D, pharmacists already provide comprehensive medication reviews (CMRs), and medication regiment reviews (MRRs) and medication therapy management (MTM), respectively. Within the CMS Innovation Center, clinical pharmacists are already piloting team-based, integrated approaches to comprehensive medication management (CMM) for high-risk, vulnerable patients. These services could be expanded through greater access to the telehealth technologies. Greater access and flexibility would increase the ability of pharmacists to assist patients and improve disparities in health outcomes often related to access to care. Accordingly, we recommend CMS take the following steps to enhance patient access to telehealth services:

- Make permanent the authority allowing direct supervision to be provided using real-time interactive audio and video technology under incident to physician services arrangements;
- Make permanent the authority allowing Medicare-enrolled pharmacies offering accredited diabetes self-management training (DSMT) programs to offer DSMT services via telehealth;
- Designate pharmacists as practitioners (providers) for the Medicare Telehealth Benefit, and add patient care services provided by pharmacists using telehealth to the Medicare Telehealth List;
- Ensure Medicare payment for pharmacist-provided telehealth and in-person services is commensurate with the time and complexity of the services provided;
- Allow for telephonic or video prescription counseling of patients to facilitate contactless care; and
- Make permanent Medicare coverage and payment of audio-only telephone calls for opioid treatment program therapy, counseling, and periodic assessments.

Maintain Compounding Flexibility to Address Current and Future Drug Storages

Beginning in April, FDA issued temporary guidance granting flexibility for pharmacists to compound certain necessary medications under 503A and 503B for hospitalized patients. A month later, two additional drugs were added to the list to address shortages. Throughout this pandemic and looking into the future, we also anticipate potential shortages of critical FDA-approved prescription drugs, including drugs dispensed pursuant to a patient-specific prescription, as well as those distributed to hospitals, clinics, and doctors to administer to patients in a clinical setting. 503A and 503B compounding pharmacies can help meet the increased demands for these products to prevent and mitigate shortages.

- We urge FDA to maintain compounding flexibilities. Compounding drugs in shortages or to mitigate a shortage requires significant investments of time and resources. Because shortages can end suddenly, we urge FDA to provide a reasonable ramp down and up periods for 503As and 503Bs compounding drugs in shortage or to mitigate a shortage to ensure those drugs are available and not wasted.

HHS Support

Although we believe that these changes can be implemented using existing regulatory authority and enforcement discretion of this authority, we urge HHS to support legislative approaches where supporting authority may be needed.

Conclusion

Thank you for your attention to our concerns and request. It is clear that HHS is working hard to quickly end this terrible pandemic, return our nation to normal, and proactively combat long-lingering health disparities. As pharmacists, we support these efforts and stand ready to work with HHS to advance our shared goal of protecting American lives and public health.

Sincerely,

American Association of Colleges of Pharmacy

American College of Clinical Pharmacy

Accreditation Council of Pharmacy Education

American Pharmacists Association

American Society of Consultant Pharmacists

American Society of Health-System Pharmacists

College of Psychiatric and Neurologic Pharmacists

Hematology/Oncology Pharmacy Association

National Alliance of State Pharmacy Associations

National Association of Chain Drug Stores

National Community Pharmacists Association

National Pharmaceutical Association

CC: Sean McCluskie, Chief of Staff
Marvin Figueroa, Director, Intergovernmental and External Affairs
Norris Cochran, HHS Deputy Assistant Secretary of Budget