August 7, 2020

The Honorable Alex Azar II
Secretary
Department of Health and Human Services (HHS)
200 Independence Ave SW
Washington, DC 20201

Re: Executive Order #13924 on Regulatory Relief to Support Economic Recovery

Dear Secretary Azar:

As the nation's economy begins to reopen after the COVID-19 outbreak, America's national pharmacy organizations are respectfully urging that HHS Food and Drug Administration (FDA), Centers for Medicare and Medicaid Services (CMS), etc., take action to make permanent the regulatory flexibilities surrounding pharmacists' ability to test and treat patients for COVID-19 and influenza in "patient care settings" at the point-of-care to help bolster the testing capabilities of our healthcare system and mitigate any potential economic fallout. On May 19, 2020, President Trump issued Executive Order (EO) 13924 "Regulatory Relief to Support Economic Recovery[1]" requiring agencies "to temporarily or permanently rescind, modify, waive, or exempt persons or entities from those requirements, and to consider exercising appropriate temporary enforcement discretion or appropriate temporary extensions of time as provided for in enforceable agreements with respect to those requirements, for the purpose of promoting job creation and economic growth," after the COVID-19 emergency period comes to an end. As you know, pharmacists are trained medical practitioners who have the ability to significantly expand patient access to needed care, should certain regulatory barriers be permanently removed. While there are still barriers in place that restrict pharmacists from fully utilizing their expertise, HHS, CMS, FDA and other federal agencies have begun to address a number of issues to help mitigate and prevent COVID-19, and it is critical that these steps be made permanent to help bolster our nation's economy and protect our country from further economic fallout associated with the ongoing pandemic.

In an effort to accomplish the economic priorities laid out in the EO and get Americans back to work, we urge HHS to expeditiously use its authorities and enforcement discretion to make permanent:

- **Pharmacists' ability to order, authorize, test, and treat infectious diseases;**
- **Reimbursement for specific pharmacist-provided patient care services during public health responses;**
- **Removal of operational barriers that have addressed workforce and workflow issues that have previously prevented pharmacists from engaging in patient care, and;**

[1] The White House. Executive Order on Regulatory Relief to Support Economic Recovery. May 19, 2020. Available at: https://www.whitehouse.gov/presidential-actions/executive-order-regulatory-relief-support-economic-recovery/

- **Maintain compounding flexibilities to address current and future drug shortages.**

Secure Pharmacists' Ability to Authorize, Test-Treat, Immunize, and Provide other Pharmacist Services

We urge CMS to permanently authorize pharmacists to test, treat, immunize, and provide other patient care services. Pharmacists are expertly trained healthcare practitioners, but they were previously only authorized to provide these types of services in specific states. CMS' recent guidance has provided some consistent application across all states which is critical to helping bolster our economy as we navigate the new healthcare landscape. The following CMS actions should be made permanent to help accomplish this mutual goal:

- **The ability of pharmacists to order, collect specimens, and conduct counseling and treatment for critical diseases, like COVID-19.**
- **Allowing pharmacies to be granted a CMS certificate of waiver to provide all CLIA-waived point-of-care tests in all states.**
- **Waived proof-of-receipt requirements in order to limit unnecessary contact with sick patients.**

On April 8, 2020, the HHS Office of the Assistant Secretary of Health (OASH) issued Testing Guidance "authorizing licensed pharmacists to order and administer COVID-19 tests, including serology tests, that the Food and Drug Administration (FDA) authorized."[2] On May 19, 2020 the HHS Office of General Counsel further clarified that "the PREP Act, in conjunction with the Secretary's March 10, 2020 declaration, preempts any state or local requirement that prohibits or effectively prohibits a pharmacist from ordering and administering a COVID-19 diagnostic test that the Food and Drug Administration (FDA) has authorized."[3] Our organizations have also urged the HHS General Counsel to issue a similar authorization for licensed pharmacists to order and administer COVID-19 vaccines, when available, under the PREP Act.[4] CMS has begun to address these issues and has issued a second IFC that "during the COVID-19 PHE, COVID-19 tests may be covered when ordered by any healthcare professional authorized to do so under state law," [5] including pharmacists. Additionally, CMS has issued Medicare Learning Network (MLN) guidance permitting pharmacies and suppliers to enroll temporarily as independent clinical laboratories [NOTE: "Independent Clinical Laboratory," is a different category from "Independent Diagnostic Testing Facility," and "Pharmacy," on the CMS 855B enrollment application and should be clarified by CMS in the MLN] to help address the urgent need for

[2] OASH. OASH's Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act. April 8, 2020, available at: https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf

[3] HHS. Office of the General Counsel. ADVISORY OPINION 20-02 ON THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT AND THE SECRETARY'S DECLARATION UNDER THE ACT. May 19, 2020, available at: https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf

[4] https://www.pharmacist.com/sites/default/files/Pharmacy_COVID_vaccine_guidance_request_FINAL.pdf

[5] CMS. Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program. April 30, 2020, available at: https://www.cms.gov/files/document/covid-medicare-and-medicaid-ifc2.pdf

COVID-19 testing.[6] However, despite CMS guidance granting pharmacists the ability to provide CLIA-waived point-of-care tests in states during the emergency period, some states still have burdensome and restrictive requirements (laboratory director[7], etc.) that prohibit any pharmacy (community, long-term care, etc.) from accessing CLIA waivers. These requirements are incongruent with CMS' other guidance and Advisory Opinions. Therefore our organizations respectfully ask that HHS not only maintain the current policy allowing pharmacies to be granted a CMS certificate of waiver to provide all CLIA-waived point-of-care tests, but to issue guidance that instructs all states to enact policies and procedures that will allow pharmacies to follow through on such guidance.

Additionally, CMS has recently issued a notice that the agency will use existing E/M payment codes to reimburse providers who are eligible to bill CMS for counseling services no matter where a test is administered, including doctor's offices, urgent care clinics, hospitals, and community drive-thru and/or pharmacy testing sites.[8] Our organizations urge CMS to formalize and codify this guidance and Advisory Opinions and consider exercising appropriate enforcement discretion to ensure that all pharmacists and pharmacies have a sustainable mechanism to offer COVID-19 point of care (POC) testing for all patients in all settings, including long-term care settings. CMS has provided an avenue for pharmacies to be reimbursed for conducting POC tests but there is not a feasible and scalable mechanism for pharmacists to be reimbursed for specific COVID-19 testing-related services such as assessment of symptoms, specimen collection, and counseling patients. America's pharmacy workforce has the ability to significantly expand access to care if they are able to test and treat conditions, which will not only help reduce the strain on the health care system but will also allow for more individuals to receive COVID-19 testing and treatment and return to work. This will become more important as the FDA approves point of care antibody tests and a COVID-19 vaccine, which can also be administered by pharmacists in doctor's offices, clinics, long-term care facilities, hospitals, and pharmacy testing cites to reduce the spread of COVID-19 and help uplift our nation as we work through a critical economic recovery.

Permanent Removal of Operational Barriers

The COVID-19 response has strained our healthcare system to the breaking point. In order to mitigate economic dangers, every pharmacist needs to be able to support healthcare teams.

1135 Waivers

The following actions implemented under 1135 waivers should be made permanent to allow providers the maximum flexibility in providing care and to ensure that pharmacists and other clinicians are safe and supported while providing patient care:

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[6] CMS. Medicare Pharmacies and Other Suppliers May Temporarily Enroll as Independent Clinical Diagnostic Laboratories to Help Address COVID-19 Testing. MLN Matters. May 8, 2020, available at: https://www.cms.gov/files/document/se20017.pdf
[7] State of California. Important Information for California State Board of Pharmacy Licensees Related to COVID19 Testing. May 12, 2020 available at: https://www.dca.ca.gov/licensees/pharmacists_covid19_tests_guidance.pdf
[8] https://www.cms.gov/newsroom/press-releases/cms-and-cdc-announce-provider-reimbursement-available-counseling-patients-self-isolate-time-covid-19

- **The ability of pharmacists and pharmacy technicians with valid licenses to operate across state lines;**
- **Pharmacists and pharmacy staff conducting routine pharmacy tasks remotely as necessary (i.e., prescription data entry and script verification, medication review and reconciliation), including those licensed outside the state to ensure business continuity.**

Prior Authorization, Refills, Home Delivery Flexibilities

Since the onset of the emergency period, CMS has encouraged insurance 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. On April 29, 2020 CMS sent information reminding Medicare Advantage and Part D plans of their ability to:

- remove prior authorizations requirements,
- waive prescription refill limits,
- relax the restrictions on home or mail delivery of prescription drugs, and
- reprioritize audit activities and audit reviews[9].

Given the burden reduction of these flexibilities, we recommend that CMS encourage all Medicare Advantage (MA) and Part D plans to continue to offer these flexibilities through the duration of the COVID-19 pandemic and beyond as we are unsure of how long it will take for patients to return to their daily routines (i.e. leaving their homes, picking up medications from their pharmacy). Our organizations are concerned with the potential for decreased medication adherence in vulnerable populations, particularly amongst older adults, after the public health emergency period ends and we urge CMS to proactively support these flexibilities to ensure consistent access to medications in all settings.

Signature Log Flexibility

In addition to the flexibilities that CMS issued on April 29, CMS released a policy relaxing Medicare Part D audit requirements for signature logs on March 20, 2020. The CMS memorandum states "[w]e are making clear that HHS does not require and will not audit for patient signatures as proof of delivery for any medications, including for controlled substances. Part D sponsors should work with pharmacy benefit managers and other entities to continue to utilize tools at their disposal to make sure beneficiaries are receiving controlled substances appropriately."[10] As a COVID-19 vaccine is not yet available we also recommend CMS make this policy permanent for Part D plans and contracted pharmacy benefit managers (PBMs).

[9] CMS. Medicare Advantage and Part D Plans. April, 29, 2020, available at: https://www.cms.gov/files/document/covid-ma-and-part-d.pdf
[10] CMS. Minimizing Face-to-Face Contact for Medication Delivery or Dispensing. March 20, 2020, available at: http://www.ncpa.co/pdf/CPI-OGC-Enforcement-Discretion-FAQ.pdf

Telehealth and Related Flexibilities

On March 17, 2020, CMS announced the expansion of telehealth services on a temporary and emergency basis pursuant to waiver authority added under section 1135(b)(8) of the Act by the Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020 (Pub. L. 116–123, March 6, 2020). Starting on March 6, 2020, Medicare can pay for telehealth services, including office, hospital, and other visits furnished by physicians and other practitioners to patients located anywhere in the country, including in a patient's place of residence. We appreciate CMS' recognition in the Interim Final Rule with Comment (IFC) that "…physicians and *other health care professionals [emphasis added]* are faced with new challenges regarding potential exposure risks, for people with Medicare, for health care providers, and for members of the community at large."[11] Now, distant site practitioners can furnish and receive payment for covered telehealth services (subject to state law), which can include physicians, nurse practitioners, physician assistants, nurse midwives, certified nurse anesthetists, clinical psychologists, clinical social workers, registered dietitians, and nutrition professionals. CMS reiterates in the first IFC that practitioners who may independently bill Medicare should report the evaluation and management (E/M) code that best describes the nature of the care they are providing but excludes any mention of pharmacist-provided patient care services. However, CMS is "revising the definition of direct supervision to allow, for the duration of the PHE for the COVID–19 pandemic, direct supervision to be provided using real-time interactive audio and video technology." More recently, in the 2021 Physician Fee Schedule (PFS) proposed rule CMS stated, "[w]e are proposing to extend this policy until the later of the end of the calendar year in which the PHE ends or December 31, 2021" "to obtain public input on services and circumstances for which this policy might be appropriate on a permanent basis."[12]

Accordingly, we strongly urge CMS to make this flexibility permanent under the EO and clarify that physicians and other qualified practitioners can bill for pharmacist-provided "incident to" services via telehealth to Medicare beneficiaries at higher E/M codes within their state scope of practice and training (99212-99215) when the service provided meets the billing requirements for a specific E/M code. The 2021 PFS clarified that "pharmacists may provide services incident to the services, and under the appropriate level of supervision, of the billing physician or NPP, if payment for the services is not made under the Medicare Part D benefit. This includes providing the services incident to the services of the billing physician or NPP and in accordance with the pharmacist's state scope of practice and applicable state law."[13] However, CMS has still not clarified that "incident to" billing is allowed for pharmacist-provided patient care E/M services for more complex services which pharmacists are trained to perform and are within their scope

[11] CMS. Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency. March 30, 2020, available at: https://www.cms.gov/files/document/covid-final-ifc.pdf

[12] CMS. CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements. Proposed Rule: August 4, 2020, available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-17127.pdf?utm_medium=email&utm_campaign=pi+subscription+mailing+list&utm_source=federalregister.gov

[13] Ibid. CMS also states "Similarly, performing required quality assurance activities consistent with § 423.153(c)(2), such as screening for potential drug therapy problems due to therapeutic duplication, age/gender-related contraindications, potential over-utilization and under-utilization, drug-drug interactions, incorrect drug dosage or duration of drug therapy, drug-allergy contraindications, and clinical abuse/misuse are considered part of dispensing fees under Part D and are not separately reportable services under Part B."

of practice (99212-99215). Recognizing "incident to" services provided by a pharmacist can be billed at E/M codes 99212-15 commensurate with the services delivered will encourage team-based care and free up physicians to treat additional patients, both elective (non-emergency) and non-elective services (emergency), to revitalize our nation's health care systems and improve patient's health care costs which have gone unaddressed during the public health crisis.

In addition, 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, our organizations urge the HHS Secretary 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 this health crisis**.**

Maintain Compounding Flexibilities to Address Current and Future Drug Shortages

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. On May 21, 2020 FDA added morphine sulfate and epinephrine to the list of drugs[14] covered by the earlier guidance documents[15] and to address shortages and access concerns affecting some drugs urgently needed for hospitalized COVID-19 patients. 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. Compounding pharmacists stand ready to provide needed medications for COVID-19 treatment and drugs in shortage in the U.S. as a result of this global crisis. We anticipate potential shortages of critical OTC products used by COVID-19 patients. A number of these products, such as pain relievers, zinc and vitamin C supplements, cough medications, and saline solutions for nebulizers, can be safely compounded by pharmacists. 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 compounding pharmacies can help meet the increased demands for these products to prevent and mitigate shortages. 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 see all of their patients without worrying about

[14] FDA. List of Drugs Used for Hospitalized Patients with COVID-19. Updated May 21, 2020, available at: https://www.fda.gov/media/138279/download

[15] FDA. Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency (Revised). Updated May 21, 2020, available at: https://www.fda.gov/media/137125/download

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[16] to restore the economic health of our economy as well as improve the health or our nation's patients.

Conclusion

Thank you for your attention to our concerns. We support HHS' ongoing efforts to provide the necessary regulatory flexibility and enforcement discretion to maximize the use of pharmacists and other health care practitioners to meet the public health needs of our nation during this pandemic. We stand ready to work with HHS to help protect our nation's economy as we navigate this novel virus and get American back to work.

Sincerely,

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[16] AHA. Hospitals and Health Systems Face Unprecedented Financial Pressures Due to COVID-19. May 2020, available at: https://www.aha.org/system/files/media/file/2020/05/aha-covid19-financial-impact-0520-FINAL.pdf?mod=article_inline

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