

April 17, 2020

The Honorable Seema Verma
Administrator
The Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services (HHS)
Room 314G-01
200 Independence Ave SW
Washington, DC 20201

Re: Urgent Meeting Request to Discuss HHS Testing Guidance Implementation for Pharmacist COVID-19 Response

[Transmitted by email]

Dear Administrator Verma:

As the COVID-19 pandemic continues to put an enormous strain on our nation's health care system and limits the supply of health care providers, our national pharmacy organizations are respectfully urging CMS take actions that will enable pharmacists to fully and effectively support our nation's COVID-19 response, particularly the crucial and urgent testing needs of the country.

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."¹ The pharmacy community is excited about this guidance and accepts the call to action. Pharmacists are trained and experienced and can significantly expand access to care if barriers are removed. While CMS has begun to address a number of issues, there remains a number of logistical, pharmacist and pharmacy payment, and patient access issues that must be addressed in order to fully implement the Testing Guidance and create a pathway for all pharmacies and pharmacists to offer COVID-19 point of care (POC) testing for all patients.

We urge CMS to expeditiously use its authorities and enforcement discretion to provide additional guidance and remove barriers in order to efficiently and effectively implement the HHS Pharmacist Testing Guidance. On behalf of our nation's 300,000 pharmacists, in all practice settings, we request a meeting with you to discuss these issues and barriers in order to urgently meet the public health testing needs of our nation during this pandemic.

¹ 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>

Our questions and issues regarding to implementation relate to:

- **Access and payment under Medicare and Medicaid**
- **Expediting Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waivers**
- **Pharmacist safety and personal protective equipment (PPE) availability and access in alignment with government standards²**
- **Diagnostic and serology/immunity testing pathways, supporting re-engagement and sustainability of the workforce**
- **Logistical pharmacy issues, including reporting and patient follow up**
- **Concomitant influenza and strep point of care testing**

Prior to the meeting we will provide specific questions and recommendations for our discussion.

Additionally, on March 20, 2020, (updated April 3, 2020,) twelve major pharmacy organizations, representing the interests of pharmacists across the United States, released a joint set of policy recommendations critical to addressing the COVID-19 pandemic entitled “*Pharmacists as Front-Line Responders for COVID-19 Patient Care*.” Several of the policy recommendations are directed to CMS. The pharmacy profession urges CMS to immediately implement these measures that are critical to COVID-19 patient care. The attached document contains a full list of the recommendations. They cover the following areas:

- Authorize Test-Treat-Immunize and other pharmacist-provided services
- Ease operational barriers to address workforce and workflow issues that prevent full and effective pharmacist engagement in COVID-19 response
- Address shortages and continuity of care
- Reimburse for services: remove reimbursement barriers that prevent pharmacists from fully and effectively engaging in COVID-19 response

Including these recommendations in CMS’ COVID-19 emergency response will ensure pharmacists can provide patients with accessible testing, medications, and patient care services in their time of need.

As stated by HHS Secretary Azar, the OASH Guidance will “give pharmacists the chance to play a bigger role in the COVID-19 response, alongside all of America’s heroic healthcare workers.” We look forward to meeting with you to discuss elimination of barriers to fully implement the HHS Pharmacist Testing Guidance. Pharmacists are trained, experienced and ready to do more but need your help to provide greater patient access to pharmacist care services for COVID-19 response. Please contact Michael Baxter, Senior Director, Regulatory Policy, at mbaxter@aphanet.org or by phone at (202) 459-8963 to arrange a meeting between CMS and the pharmacy community to engage on these issues.

² See, CDC. Considerations for Pharmacies during the COVID-19 Pandemic. Page last reviewed: April 14, 2020, available at: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/pharmacies.html>. FDA. Emergency Use Authorizations. Content current as of: 04/16/2020, available at: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>. OSHA. COVID-19 Guidance for Retail Workers. April 8, 2020, available at: <https://www.osha.gov/Publications/OSHA3996.pdf>

Sincerely,

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CC: The Honorable Alex Azar II, Secretary, HHS
Brady Brookes, Deputy Administrator & Deputy Chief of Staff, CMS
Kimberly Brandt, Principal Deputy Administrator for Policy & Operations, CMS
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Anita Thomas, PharmD, QIO Program Patient Safety Program, CMS

VADM Jerome M. Adams, MD, U.S. Surgeon General

Ty Bingham, RADM, Chief Pharmacy Officer, U.S. Public Health Service

ADM Brett P. Giroir, MD, Assistant Secretary for Health, HHS

Enclosure: PHARMACISTS AS FRONT-LINE RESPONDERS FOR COVID-19 PATIENT CARE