

May 8, 2020

[transmitted electronically]

The Honorable ADM Brett P. Giroir, M.D.
Assistant Secretary for Health
U.S. Department of Health & Human Services (HHS)
200 Independence Avenue, SW
Room 716G
Washington, DC 20201

Dear Assistant Secretary Admiral Giroir:

America's pharmacists admire and appreciate your tireless efforts leading our nation's COVID-19 response, particularly related to coronavirus testing. Pharmacists in practice settings around the country are delivering front-line patient care as part of the "all-in" effort to prevent, mitigate, and respond to this pandemic. We welcomed your April 8, 2020 [Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act](#), (OASH Guidance) authorizing pharmacists to order and administer certain COVID-19 tests. The pharmacy community is excited about this Guidance and accepts the call to action.

We appreciate the confidence that you have in pharmacists as key providers of testing for pandemic response so we can re-open our country and get our nation fully running again. However, there remains a number of patient access and pharmacist and pharmacy payment issues that must be addressed in order for many pharmacists and pharmacies across the country, especially in underserved communities, to implement the Guidance and provide pharmacist COVID-19 point of care testing. Specifically, we believe legislation would help ensure increased pharmacist testing capacity across the country for Medicare beneficiaries.

While testing is occurring now at some pharmacies, there are significant barriers to ramping up more testing capacity, including a clear pathway to payment for pharmacist testing services. A sustainable business solution for pharmacists and pharmacies must be established for all practice settings, particularly when point-of-care tests become more widely available.

Although the Centers for Medicare and Medicaid Services (CMS) [interim final rule](#) (IFR) addressed several aspects of pharmacist testing, there is a large gap in what was envisioned in your OASH Guidance and the IFR pathway for pharmacist testing. Specifically, it appears that CMS could not outline a testing program in the IFR with direct payment for pharmacists' services as Medicare providers because of current constraints in the law.

Instead, the IFR appears to set up a system that provides direct payment to pharmacies only to the extent that they may be enrolled with CMS as laboratories. The crux of our concern is that pharmacists are not considered to be Medicare providers. For Medicare beneficiaries, we fear that pharmacists and pharmacies would not be directly paid as other health care providers are for any clinical services related to the test, including patient symptom or exposure assessment, specimen collection, interpretation of the results, or

reporting the results to the patient and appropriate state/local authorities. Rather, under the IFR, it appears that these services, which are essential elements of COVID-19 testing, would have to be billed, where applicable, through a physician or other Medicare provider that a pharmacist is under contract with and that provider would bill and receive the payment “incident to” the physician-pharmacist arrangement. Many pharmacists generally do not have arrangements with physician practices that would allow their services to be billed “incident to” a physician or other provider. Without a clearly articulated avenue to directly pay pharmacists and their pharmacies for their clinical testing services in the same manner as other clinicians, our shared public health goal of increasing testing capacity by pharmacists in all communities may not be achieved.

Legislation would help provide clarity to ensure testing access for Medicare beneficiaries in all communities. Congress can fill the gap by authorizing pharmacists as recognized Part B providers of testing services to enable appropriate payment for these services. Without this statutory authority, we fear that many pharmacists and pharmacies may not be able to serve as COVID-19 testing sites. If this gap is filled at the federal level, typically, private payers will follow, further solidifying broader access to testing. As you know, in areas experiencing physician shortages, pharmacists may be the only healthcare provider that is immediately accessible to patients. Pharmacists have trusted relationships with their patients, and it is critical during the pandemic to maintain consistent, accessible delivery of health care.

COVID-19 highlights why we need pharmacists to be recognized by statute as Medicare Part B providers.

We need your help to advocate within the Administration for additional regulatory clarity and for Congress to provide statutory authority recognizing pharmacists as providers of testing services to ensure access for Medicare beneficiaries in all communities across the country. We greatly appreciate your consideration of these concerns and are happy to discuss this further if you have any questions. Together we can help you achieve the Administration’s goal of optimizing testing access by enabling our nation’s pharmacists to respond to the mounting and immediate needs of those impacted by the COVID-19 pandemic. If you have any questions, please follow up with Ilisa Bernstein, Pharm.D., JD., Senior Vice President for Pharmacy Practice and Government Affairs, American Pharmacists Association at ibernstein@aphanet.org or 202-429-7533.

Sincerely,

Jan Engle, PharmD, PhD (HON), FAPhA, FCCP, FNAP
Executive Director
Accreditation Council for Pharmacy Education (ACPE)

Lucinda L. Maine, PhD, RPh
Executive Vice President and CEO
American Association of Colleges of Pharmacy (AACP)

Thomas E. Menighan, BSPHarm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO
American Pharmacists Association (APhA)

Chad Worz, Pharm.D., BCGP
Chief Executive Officer
American Society of Consultant Pharmacists (ASCP)

Paul W. Abramowitz, Pharm.D., Sc.D. (Hon.), FASHP
Chief Executive Officer
American Society of Health-System Pharmacists (ASHP)

Brenda Schimenti
Executive Director
College of Psychiatric and Neurologic Pharmacists (CPNP)

Stacy Sochacki
Executive Director
Hematology/Oncology Pharmacy Association (HOPA)

Rebecca P. Snead, RPh, CAE, FAPhA
Executive Vice President/CEO
National Alliance of State Pharmacy Associations (NASPA)

Steven C. Anderson, IOM, CAE
President and Chief Executive Officer
National Association of Chain Drug Stores (NACDS)

B. Douglas Hoey, RPh, MBA
Chief Executive Officer
National Community Pharmacists Association (NCPA)

Lakesha M. Butler, PharmD, BCPS
President
National Pharmaceutical Association

cc:
Principal Deputy Assistant Secretary for Health RADM Sylvia Trent-Adams, Ph.D., R.N.,
F.A.A.N.
Deputy Assistant Secretary for Health (Medicine & Science) CAPT Paul Reed, M.D.