



November 2, 2020

[Submitted electronically via www.regulations.gov]

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services (“CMS”)
Department of Health and Human Services (“HHS”)
Attention: CMS-3401-IFC
P.O. Box 8016
Baltimore, MD 21244-8013

Re: Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments, and Patient Protection and Affordable Care Act: Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, Interim Final Rule with Comment Period [RIN 0938-AU33]

Dear Administrator Verma:

The American Pharmacists Association (APhA) is pleased to submit these comments regarding the “Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments, and Patient Protection and Affordable Care Act: Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, Interim Final Rule with Comment Period” (“IFC”). APhA represents pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, specialty pharmacies, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

To assist CMS in maximizing the use of pharmacists to respond to the COVID-19 pandemic, APhA respectfully submits the following recommendations with additional information and comments below:

- **Implement a direct payment pathway for COVID-19 testing and related services by pharmacists commensurate with all other healthcare providers, using flexibilities afforded because of the public health emergency.**
- **Expand HHS’ use of flexibility and/or enforcement discretion to offer the same agreement granted to the two national pharmacy chains to ALL pharmacies that are willing and able to contract with Long Term Care (“LTC) facilities for administering COVID-19 vaccines and services.**
- **Utilize pharmacists and pharmacies, who are already providing or could provide services to LTC Facilities, to also provide COVID-19 tests and all testing-related**

services in order to meet the new requirement under the IFC for LTC facilities to test their facility residents and staff.

Limits on COVID-19 and Related Testing without an Order and Expansion of Testing Order Authority (pgs. 54837-54840)

APhA appreciates CMS “establishing a policy whereby tests can be covered when ordered by a pharmacist or other healthcare professional who is authorized to order diagnostic laboratory tests in accordance with state scope of practice and other pertinent laws.” APhA also greatly appreciates HHS’ ongoing recognition of the important role that pharmacists and pharmacies play in maintaining and addressing the country’s economic, health, and safety efforts. However, the IFC also states “[b]ecause pharmacists and certain other healthcare professionals are not considered to be physicians or practitioners under the Medicare statute, they cannot be paid directly under the Medicare program; therefore, pharmacists and other auxiliary personnel still need to be functioning in an incident-to arrangement with a physician or non-physician practitioner for the services they provide to be paid by Medicare under Part B for the front-end assessment and specimen collection associated with the order.” Yet, HHS recently announced the use of enforcement discretion to “allow Medicare-enrolled immunizers, including but not limited to pharmacies working with the United States, *to bill directly and receive direct reimbursement from the Medicare program* [emphasis added] for vaccinating Medicare SNF residents,”¹ during the public health emergency (“PHE”). Thus, while we appreciate CMS’ workarounds to open up potential pathways to utilize pharmacists and pharmacies for COVID-19 testing during the PHE, we respectfully recommend CMS utilize this same flexibility or enforcement discretion to provide direct reimbursement for COVID-19 testing and all testing-related services provided in all eligible pharmacies.

While likely unintended, CMS’ current policy prevents pharmacists from receiving direct reimbursement for specimen collection and other services related to point of care tests, which seems to conflict with the recent clear explanation regarding pharmacies as point of care locations in FDA’s FAQ.² Additionally, CPT code 99211, typically used for specimen collection services provided under incident to billing, in most cases, does not cover the time and complexity of COVID-19 testing and services administered to patients by pharmacists. As with other qualified healthcare professionals, pharmacists would conduct symptom assessment (ruling out influenza virus and respiratory syncytial virus (“RSV”)), specimen collection, reporting of test results (explained under the IFC) and counseling patients on testing results, including potential referrals. Limiting pharmacists’ payment pathways to incident to is also contrary to the HHS Office of General Counsel (“OGC”) Advisory Opinion³ that outlines pharmacists’ ability to order and administer COVID-19 tests and all testing-related services. Therefore, APhA specifically requests CMS use your expanded flexibility under the PHE to identify workable payment pathways and amend and/or use enforcement discretion to implement a direct payment pathway for COVID-19 testing and related services in pharmacies commensurate with all other

¹ CMS. Enforcement Discretion Relating to Certain Pharmacy Billing. October 2020, available at: <https://www.cms.gov/files/document/snf-enforcement-discretion-letter.pdf>

² FDA. FAQs on Diagnostic Testing for SARS-CoV-2. Q: When FDA authorizes under an EUA a SARS-CoV-2 test for use at the point of care, does that mean it is CLIA waived? (Updated 5/9). Content current as of: 10/2/2020, available at: <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2>

³ HHS. Office of the General Counsel. Advisory Opinion. 20-02. May 19, 2020, available at: <https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>

healthcare providers. As demonstrated in HHS' recent contract with two national pharmacies for vaccine administration at LTC facilities, HHS and CMS are able to find creative and flexibility solutions for payment during the PHE.

Requirement for LTC Facilities to Test Facility Residents and Staff for COVID-19 (pgs. 54851-54853)

Under the IFC, CMS is “revising the LTC facility infection control regulations at § 483.80 to establish a new requirement for LTC facilities to test their facility residents and staff, including individuals providing services under arrangement and volunteers.” As mentioned above, CMS recently announced agreements with two pharmacy chains to provide and administer COVID-19 vaccines to residents of LTC facilities nationwide with no out-of-pocket costs.⁴ The Centers for Disease Control and Prevention (“CDC”) also updated its “COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operation,”⁵ to version 2.0, which references that additional pharmacy partners and more retail chain pharmacies and networks of community pharmacists are being considered for this program. In addition, CDC notes that “direct allocation opportunities” will be provided to retail chain pharmacies and networks of independent and community pharmacies (those with a minimum of 200 stores) through Pharmacy Services Administrative Organizations (PSAOs) in Phase 2. Accordingly, APhA strongly recommends HHS and CMS expand the flexibility and/or enforcement discretion to offer the same agreement granted to the two national pharmacy chains to ALL pharmacies willing and able to contract with LTC facilities for administering COVID-19 vaccines and services.

In addition, as CMS understands, all pharmacists are authorized by HHS to “order and administer” COVID-19 tests.⁶ Therefore, APhA recommends CMS also utilize pharmacists and pharmacies, who are already providing or could provide services to LTC facilities, to also provide COVID-19 tests and all testing-related services in order to meet the new requirement under the IFC for LTFs to test their facility residents and staff.

Conclusion

Thank you for the opportunity to provide feedback on the IFC and for your consideration of our comments. We support CMS' and 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 CMS and HHS as we navigate this novel coronavirus to safely re-open America. If you have any questions or require additional information, please contact Michael Baxter, Senior Director of Regulatory Policy, at mbaxter@aphanet.org.

⁴ HHS. Trump Administration Partners with CVS and Walgreens to Provide COVID-19 Vaccine to Protect Vulnerable Americans in Long-Term Care Facilities Nationwide. October 16, 2020, available at: <https://www.hhs.gov/about/news/2020/10/16/trump-administration-partners-cvs-walgreens-provide-covid-19-vaccine-protect-vulnerable-americans-long-term-care-facilities-nationwide.html>

⁵ CDC. COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operation. Version 2.0. October 29, 2020, available at: https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf

⁶ Office of the Assistant Secretary for Health (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>

Sincerely,

A handwritten signature in cursive script that reads "Elisa BG Bernstein".

Elisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice and Government Affairs