



June 1, 2020

[Submitted electronically to www.regulations.gov]

The Honorable Seema Verma
Centers for Medicare & Medicaid Services (CMS)
U.S. Department of Health and Human Services (HHS)
Attention: CMS-1744-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, Interim Final Rule with Comment Period (RIN 0938-AU31)

Dear Administrator Verma:

The American Pharmacists Association (“APhA”) is pleased to submit our comments on the Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, Interim Final Rule with Comment Period (hereinafter “IFC”). Founded in 1852 as the American Pharmaceutical Association, APhA represents nearly 60,000 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, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

APhA supports CMS’ efforts to respond to the pandemic and is happy to continue to serve as a resource to your Agency in assisting the federal government meet the public health challenges of the coronavirus (“COVID-19”) pandemic. Pharmacists are at the front-line providing essential patient care services during this public health crisis. **We can do more with additional flexibility and enforcement discretion from CMS to eliminate regulatory barriers to fully implement the recent HHS pharmacist testing guidance¹ to ensure all pharmacists in every patient care setting can provide all patients with accessible testing, medications, and patient care services in their time of need.**

I. General Comments

Maximize the Use of Pharmacists to Respond to COVID-19

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, APhA is respectfully urging CMS take actions and utilize enforcement discretions 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.

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>

On April 8, 2020, the HHS Office of the Assistant Secretary for 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) has authorized.”² The pharmacy community accepted the call to action. Pharmacists are trained and experienced and can significantly expand access to care if barriers are removed. 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 CMS has begun to address these issues and has issued a second IFC clarifying 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,”⁴ 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 COVID-19 testing.⁵ **However, there still remains a number of logistical, pharmacist and pharmacy payment, and patient access issues that must be addressed in order to fully implement the pharmacist testing guidance and create a pathway for all pharmacies and pharmacists to offer COVID-19 point of care testing for all patients.**

Clarify Telehealth Flexibility for Pharmacist-Provided Patient Care Services

CMS has already granted a number of flexibilities for various providers to provide telehealth services under the IFC. In addition, CMS has now relaxed supervision requirements to permit supervision via audio and video technology as well. However, all other telehealth regulations, including the list of “qualified providers” remain in effect. Our understanding is that pharmacists, as clinical staff, can provide telehealth services incident to a Medicare-eligible provider. **While we have received verbal confirmation in our discussions with CMS, APhA seeks formal clarification from CMS that the IFC’s flexibility on direct supervision also removes the need for pharmacists providing telehealth services under incident to arrangements to be physically present in the same office as supervising physicians or qualified nonphysician practitioners.**

As CMS understands, there are many opportunities to leverage pharmacists in telehealth service delivery across various Medicare programs. Pharmacists, in general, are underutilized for the medication and health-related expertise they can provide to other providers, health care teams and patients, and especially in rural and underserved areas, pharmacists may be the only health care provider accessible to beneficiaries. Many patient care services provided by pharmacists are clinically appropriate for telehealth, including: medication management services (“MMS”), chronic condition management (e.g., diabetes, hypertension), medication reconciliation, transitions of care, pharmacogenomics, interpretation of diagnostic tests and providing test results, and consultations with patients and health care providers. Pharmacists are also actively involved in virtual care delivery for Medicare Part B Chronic Care Management (“CCM”) and Transitional Care Management (TCM) services.

We strongly urge HHS to use the new authority under the recently passed “Coronavirus Aid, Relief, and Economic Security Act” or the “CARES Act” (Public Law 116-136) under Sec. 3703. Expanding Medicare

² Ibid.

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 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>

⁵ 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>

Telehealth Flexibilities that 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. **Accordingly, given the significant burdens on the health care system posed by the pandemic, APhA urges 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.** Specific examples where Medicare beneficiaries can benefit from pharmacists providing telehealth include pharmacist provision of needed evaluation and management (E/M) services using a telehealth format to assist in the management of chronic conditions under supervision via audio and video technology, and allowing pharmacists to provide Diabetes Self-Management Training (DSMT) services via telehealth as part of Medicare-enrolled, accredited DSMT programs that are not affiliated with hospitals or physician clinics. Similarly, as provided for by other health care practitioners in the IFC, CMS should allow pharmacists to provide appropriate level E/M services via telephone for patients who do not have access to technology.

APhA also advocates that HHS review and implement Medicare telehealth policies to promote medication-related services in Part D. With telehealth, pharmacists can provide first-line triage services, counsel patients on potential medication interactions, remotely supervise technicians and oversee medication dispensing, remotely perform final verification of prescriptions, and monitor patient therapies.

II. Provisions in the IFC

APhA thanks CMS for the opportunity to offer our comments on the IFC in order to maximize the use of pharmacists to prevent, treat, and respond to the coronavirus.

Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

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. APhA appreciates CMS recognizes in the 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.” 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. To facilitate the use of telecommunications technology as a safe substitute for in-person services, CMS is, on an interim basis, adding many services to the list of eligible Medicare telehealth services, eliminating frequency limitations and other requirements associated with particular services furnished via telehealth, and clarifying several payment rules that apply to other services that are furnished using telecommunications technologies that can reduce exposure risks. CMS reiterates in the IFC that practitioners who may independently bill Medicare should report the E/M code that best describes the nature of the care they are providing but excludes any mention of pharmacist-provided patient care services. **Accordingly, APhA strongly urges CMS to clarify 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.**

As CMS understands, there are several barriers to physicians billing for pharmacists’ incident to services that CMS can help overcome. Despite previous communications from CMS, when pharmacists’ E/M services

delivered under incident to physician services arrangements are billed to the Medicare program, physicians often encounter barriers to billing higher level E/M codes than 99211, regardless of the complexity of services delivered.

CMS restated the existing regulatory definition of auxiliary personnel and the applicability to incident to physician services in the second IFC without clarifying physicians can bill for higher level pharmacist-provided E/M services:

“We are clarifying explicitly that pharmacists fall within the regulatory definition of auxiliary personnel under our regulations at § 410.26. As such, 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.”⁶

However, CMS also states “[t]his clarification does not alter current payment policy for pharmacist services furnished incident to the professional services of a physician or NPP.”⁷

APhA is concerned that CMS’ current payment policy for pharmacist services furnished in incident to arrangements is unclear and subject to varying interpretations across the healthcare system. Despite the fact that the complexity of most services delivered by pharmacists meets the requirements for physicians to bill at higher levels (E/M codes 99212-215), physicians are often discouraged by Medicare Administrative Contractors (“MACs”) from billing for pharmacists’ services at a level above E/M code 99211 due to concerns of a CMS audit. **Absent CMS clarification and/or enforcement discretion, this issue is unlikely to change.** We have also received reports of reluctance to use higher level E/M billing codes from pharmacists working in value-based models that have a fee-for-service component, which is a detriment to team-based care. It’s inconceivable that a pharmacist providing a 45-minute office visit to manage multiple chronic conditions and multiple medications for a complex Medicare beneficiary under an incident to arrangement with a physician would be limited to having the service billed as a Level 1 visit (99211), that has an anticipated time commitment of 5 minutes. Given pharmacists’ ability to reduce the \$528 billion spent annually on medication-related problems,⁸ it is critical that pharmacists are fully and effectively engaged as part of patient care teams.

In addition, the CY 2020 final Physician Fee Schedule (“PFS”) rule included the intent to adopt in 2021 the American Medical Association’s (“AMA”) revisions to the E/M office visit CPT codes (99201-99215) code descriptors and documentation standards.⁹ While APhA supports CMS’ intent to streamline documentation and billing for E/M services, we have significant concerns that the terminology in the AMA revision could restrict physician incident to billing for pharmacists’ complex E/M services to CPT code 99211 and often does not fit the types of services pharmacists are providing.

Therefore, APhA requests that CMS expressly state in guidance or regulation that “incident to” services provided by a pharmacist can be billed at E/M codes 99212-15 commensurate with the services delivered. Related to the upcoming E/M changes in 2021, pharmacists cannot currently individually report services in

⁶ 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>

⁷ Ibid.

⁸ Watanabe, J.H., McInnis, T. & Hirsch, J.D. (2018). Cost of Prescription Drug-Related Morbidity and Mortality, *Annals of Pharmacotherapy*, available at: <https://doi.org/10.1177/1060028018765159>

⁹ AMA. CPT® Evaluation and Management (E/M) Office or Other Outpatient (99202-99215) and Prolonged Services (99354, 99355, 99356, 99XXX) Code and Guideline Changes. 2019, available at: <https://www.ama-assn.org/system/files/2019-06/cpt-office-prolonged-svs-code-changes.pdf>

Medicare, and therefore are considered clinical staff. CMS could use regulatory authority to implement an individual reporting mechanism for pharmacist services to clarify that pharmacists' services can be billed at levels 99212-15 in 2021 and beyond. CMS could also further communicate this in other public vehicles (e.g., MLN Matters) or in a prominent location on the CMS website. APhA can facilitate distribution of the clarification to our members and provide technical assistance on this issue. Clarifying this issue will help reduce the burden on health care practitioners who are unable to utilize pharmacists for more complex patient care needs. APhA would welcome the opportunity to discuss these issues directly with CMS staff and share documented examples of the services pharmacists are providing.

Communication Technology-Based Services (CTBS)

Non-face-to-face Virtual Check-in and E-Visits are typically only eligible for existing patients and not considered as "telehealth." However, CMS has stated in the IFC "we will not conduct review to consider whether those services were furnished to established patients," during the public health emergency ("PHE"). Thus, CMS is allowing practitioners who may independently bill Medicare for E/M visits (physicians and nurse practitioners) to provide these services to both new or established patients. In addition, now Part B separately pays clinicians who may not independently bill for evaluation and management visits (for example – physical therapists, occupational therapists, speech language pathologists, clinical psychologists) for providing E-Visits, or non-face-to-face patient-initiated communications by using online patient portals, and bill codes (G-2061-G2063). CMS also states in the IFC "[w]e note that this is not an exhaustive list and we are seeking input on other kinds of practitioners who might be furnishing these kinds of services as part of the Medicare services they furnish in the context of the PHE for the COVID-19 pandemic." CTBS services include, for example, certain kinds of remote patient monitoring (either as separate services or as parts of bundled services), and interpretations of diagnostic tests when furnished remotely. These services are different than the kinds of services specified in section 1834(m) in that they are not the kind of services that are ordinarily furnished in person but are routinely furnished using a telecommunications system. Pharmacists can provide a number of these services. For example, pharmacists and pharmacies can deliver continuous glucose monitoring ("CGM") utilizing CTBS services to help reduce the \$327 billion annual cost of diabetes in America.¹⁰ **Thus, APhA strongly urges CMS to use enforcement discretion during the PHE to also allow pharmacists to provide applicable CTBS (i.e, E-Visits, etc.).**

Medicare Clinical Laboratory Fee Schedule: Payment for Specimen Collection for Purposes of COVID-19 Testing

To address the PHE for the COVID-19 pandemic, the IFC includes new level II HCPCS codes for "independent laboratories," which CMS has since clarified can include pharmacies and other independent suppliers,"¹¹ when billing Medicare for the nominal specimen collection fee for COVID-19. However, CMS stated in our recent phone call with the Agency that, under both the first and second IFC, this only applies for collecting specimens from beneficiaries who are homebound or inpatients and not for direct specimens collected in pharmacies for point of care tests.¹² **APhA is concerned that this policy would prevent pharmacists from receiving reimbursement for specimen collection for point of care tests which seems to conflict with FDA guidance and severely limits the ability of the Administration to successfully utilize all pharmacists and pharmacies to meet its national COVID-19 testing goals.** As stated above, on April 8, 2020, the HHS OASH issued Testing Guidance "authorizing licensed pharmacists to order and administer COVID-19 tests, including

¹⁰ American Diabetes Association. The Staggering Cost of Diabetes. March 22, 2018, available at: <https://www.diabetes.org/resources/statistics/cost-diabetes>

¹¹ 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>

¹² 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>

serology tests, that the Food and Drug Administration (FDA) authorized.” FDA’s FAQ states, “we note that the term point of care in the EUAs may include settings such as hospitals, physician offices, urgent care, outreach clinics, *pharmacies [emphasis added]*, and temporary patient care settings that have appropriately trained personnel to perform the test and are operating under a CLIA Certificate of Waiver or Certificate of Compliance.”¹³ Accordingly, for the duration of the emergency declaration, such tests can be performed in a patient care setting that is qualified to have the test performed there as a result of operating under a CLIA Certificate of Waiver or Certificate of Compliance.

In addition, the IFC states “[w]hen COVID-19 tests are furnished without a physician’s or NPP’s order as set forth in this regulation during the COVID-19 PHE, the laboratory conducting the tests is required to *directly notify the patient [emphasis added]* of the results consistent with other applicable laws, as well as meet other applicable test result reporting requirements. Comprehensive and timely reporting of all testing results to local officials is critical to public health management of the pandemic, and we would expect any clinician or laboratory receiving results to report those results promptly, consistent with state and local public health requirements, typically within 24 hours.” Accordingly, APhA requests clarification from CMS that pharmacies enrolled as independent laboratories with a CLIA Certificate of Waiver will directly notify patients of test results.

To further complicate matters, while not included in the second IFC, in the accompanying press release¹⁴ and separate guidance¹⁵ CMS also states:

“Pharmacists can work with a physician or other practitioner to provide assessment and specimen collection services, and the physician or other practitioner can bill Medicare for the services. Pharmacists also can perform certain COVID-19 tests if they are enrolled in Medicare as a laboratory, in accordance with a pharmacist’s scope of practice and state law. With these changes, beneficiaries can get tested at “parking lot” test sites operated by pharmacies and other entities consistent with state requirements. Such point-of-care sites are a key component in expanding COVID-19 testing capacity.”

Because community pharmacists generally do not have incident to arrangements with physician practices that would allow their services to be billed incident to a physician or other provider, **APhA is concerned that without a clear avenue to pay pharmacists for their services including patient assessment, specimen collection (including for/to rule out influenza virus and respiratory syncytial virus (“RSV”), performing the test, interpreting the results, and reporting the results to the patient and appropriate authorities, the Administration’s stated public health goal of widespread and accessible testing in communities by pharmacists will not be achieved. We urge CMS to use regulatory flexibility to address this barrier and provide a clear payment pathway for the services associated with point of care tests at pharmacies during the pandemic.**

Requirements for Opioid Treatment Programs (“OTPs”)

In light of the PHE during the COVID-19 pandemic, CMS is revising § 410.67(b)(3) and (4) to allow the therapy and counseling portions of the weekly bundles, as well as the add-on code for additional counseling or therapy, to be furnished using audio-only telephone calls rather than via two-way interactive audio-video

¹³ FDA. FAQs on Diagnostic Testing for SARS-CoV-2. Content current as of: 05/18/2020, available at: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2?utm_campaign=2020-05-09%20FAQs%20on%20Testing%20for%20SARS-CoV-2%20Update&utm_medium=email&utm_source=Eloqua#5eb6cee7077f9

¹⁴ CMS. Trump Administration Issues Second Round of Sweeping Changes to Support U.S. Healthcare System During COVID-19 Pandemic. April 30, 2020, available at: <https://www.cms.gov/newsroom/press-releases/trump-administration-issues-second-round-sweeping-changes-support-us-healthcare-system-during-covid>

¹⁵ CMS. ADMIN 20-06-CLIA. CMS SARS-CoV-2 Laboratory Testing Comparison. April 30, 2020, available at: <https://www.cms.gov/files/document/admin-info-20-06-clia.pdf>

communication technology if beneficiaries do not have access to two-way audio/video communications technology. **APhA supports this approach to meet treatment needs during the pandemic. APhA also recommends that interactive audio-video and audio only services be permitted for pharmacists who provide medication assisted treatment (“MAT”) services.**

Level Selection for Office/Outpatient E/M Visits When Furnished Via Medicare Telehealth

On an interim basis, CMS is revising Agency policy to specify that the office/outpatient E/M level selection for these services when furnished via telehealth can be based on medical decision making (“MDM”) or time, with time defined as all of the time associated with the E/M on the day of the encounter; and to remove any requirements regarding documentation of history and/or physical exam in the medical record. It remains CMS’ expectation that practitioners will document E/M visits as necessary to ensure quality and continuity of care. APhA supports CMS’ increased flexibility regarding the administrative requirements of documenting the specificity of history and exam.

Conclusion

Thank you for the opportunity to provide comments on the IFC. We support CMS’ 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. Please, also refer to these comments in CMS’ review of our ongoing feedback and forthcoming comments on the second IFC to address the PHE. If you have any questions or require additional information, please contact Michael Baxter, Senior Director, Regulatory Policy, at mbaxter@aphanet.org or by phone at (202) 459-8963.

Sincerely,



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