July 7, 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–5531–IFC
P.O. Box 8016
Baltimore, MD 21244–8016

Re: Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency (RIN 0938–AU32)

Dear Administrator Verma:

The American Pharmacists Association (“APhA”) is pleased to submit our comments on the Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional 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 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.

We are incorporating by reference into the docket for this IFC our comments on the initial/first IFC to address the public health emergency (“PHE”).

I. General Comments

As stated in our previous recommendations, pharmacists can provide essential patient care with additional flexibility and enforcement discretion from CMS to eliminate regulatory barriers to
fully implement the recent HHS pharmacist testing guidance. This would 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. In addition, on May 19, 2020, the HHS Office of General Counsel (“HHS OGC”) 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” (“HHS OGC Advisory Opinion”). CMS has begun to address these issues in the 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,” 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 address this confusion] to help address the urgent need for COVID-19 testing. 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.

On June 30, 2020, HHS announced it was extending its partnership with national pharmacy and grocery retail chains until August 2020. HHS explains “[t]he contract utilizes a federal bundled payment program paid directly to retailers that receive a flat fee for each test administered, with participating retailers responsible for coordinating the full end-to-end testing. That process includes online and telephone registration and appointment scheduling, provider order and notification of result, on-site personnel and security, medical supplies and equipment, and lab testing (on-site or commercial lab) capabilities. Partners are also required to adhere to Centers for Disease Control and Prevention testing criteria.” HHS also states “[p]roviding retailers an option for reimbursement for COVID-19 testing outside of this contract will be essential for the private sector to take over COVID-19 testing once this contract concludes.” APhA agrees and urges HHS provide all pharmacists and pharmacies, including community pharmacies, a clear pathway for direct payment and the same level of payment provided to other healthcare professionals for providing COVID-19 testing services.

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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.

Pharmacists Providing Services Incident to a Physician’s Service

Under the IFC, CMS stated “[m]edication management is covered under both Medicare Part B and Part D.” CMS is “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. Clinical services shall be in accordance with the pharmacist’s state scope of practice and applicable law.” CMS also states they “believe this clarification may encourage pharmacists to work with physicians and NPPs in new ways that expand the availability of health care services during the COVID–19 PHE, and increase access to medication management of individuals with substance/opioid use disorder.” APhA agrees and urges CMS to reference and formally recognize the term and definition of “medication management services” (“MMS”) adopted for the pharmacy practice by the Joint Commission of Pharmacy Practitioners (“JCPP”). The JCPP definition states MMS is “a spectrum of patient-centered, pharmacist provided, collaborative services that focus on medication appropriateness, effectiveness, safety, and adherence with the goal of improving health outcomes.” Pharmacists deliver MMS using the Pharmacists’ Patient Care Process that meet the following elements under the definition:

- Patient-centered approach to care – the service is individualized for a specific patient, focuses on the patient’s needs and concerns, and involves the patient in the care process;
- Assessment of medication appropriateness, effectiveness, safety, and adherence. Consideration should be given to accessibility and cost of medications.
- Collaborative approach to care that involves the patient, caregiver(s), pharmacists, and other healthcare providers; and
- Focus on health outcomes.

It is vital for CMS to recognize MMS to ensure the agency’s regulatory terminology keeps pace with the existing spectrum of pharmacist-provided patient care services, which exceeds the various existing terms that have been codified in disparate federal and state laws and regulations, such as Part D Medication Therapy Management (“MTM”) and Comprehensive Medication Management (“CMM”) as well as those used in private sector programs.

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7 JCPP. The Pharmacists’ Patient Care Process, available at: [https://jcpp.net/patient-care-process/](https://jcpp.net/patient-care-process/)
In addition, while not included in the IFC, in the accompanying press release and separate guidance 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 [emphasis added].”

However, because almost all community pharmacists generally do not have “incident to” arrangements with physician practices that would allow their services to be billed, APhA is concerned that without a clear direct 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. Therefore, we urge CMS to address this barrier and provide a clear payment pathway for the services associated with point of care tests (COVID-19, influenza, RSV) at pharmacies during the pandemic (specimen collection, patient testing, result reporting, assessment, referral, etc.). Furthermore, limiting pharmacists’ ability to order and administer COVID-19 tests to what is permitted under state scope of practice laws is contrary to the HHS OGC Advisory Opinion on preemption. As such, we request that CMS amend 42 CFR §410.32 to appropriately reflect the HHS OASH guidance and HHS OGC Advisory Opinion.

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’ evaluation and management (“E/M”) services delivered under incident to physician services arrangements are billed to the Medicare program, physicians often encounter barriers to billing higher level evaluation and management (E/M) codes than 99211, regardless of the complexity of services delivered.

As mentioned above, CMS restated the existing regulatory definition of auxiliary personnel and the applicability to incident to physician services in the IFC, without clarifying physicians can bill for higher level pharmacist-provided E/M services. Yet, CMS also stated in the IFC “[t]his clarification does not alter current payment policy for pharmacist services furnished incident to the professional services of a physician or NPP.”

APhA members have told us 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

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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 and be inconsistently applied across the country. 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 is 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. In addition, CMS has now relaxed supervision requirements to permit direct supervision of pharmacists providing E/M services by physicians via audio and video technology. Medicare beneficiaries can benefit from pharmacists providing many needed E/M services using a telehealth format to assist in the management of chronic conditions with physician supervision being administered by physicians and other practitioners via audio and video technology. Given pharmacists’ ability to reduce the $528 billion spent annually on medication-related problems, it is critical that barriers be removed so pharmacists are fully and effectively engaged as part of patient care teams.

In addition, the Calendar Year (“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. 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 or use enforcement discretion to recognize “incident to” services provided by a pharmacist can be billed at E/M codes 99212-215 commensurate with the services delivered.** Related to the upcoming E/M changes in 2021, pharmacists cannot currently individually report services in Medicare, and therefore are considered clinical staff. CMS should use regulatory authority to implement an individual reporting mechanism for pharmacist services to clarify that pharmacists’ services can be billed at levels 99212-215 in 2021 and beyond. CMS should 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 specific, higher level E/M services pharmacists are providing.

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Modified Requirements for Ordering COVID–19 Diagnostic Laboratory Tests

APhA thanks CMS for amending the regulation at § 410.32(a) under the IFC to remove the requirement that certain diagnostic tests are covered only based on the order of a treating physician or non-physician practitioner (“NPP”). This interim policy aligns with the recent HHS pharmacist testing guidance,¹² mentioned above, during the PHE to seemingly allow COVID–19 tests to be covered when ordered by any healthcare professional authorized to do so under state law. However, pharmacists continue to encounter additional state barriers to testing despite the HHS OGC Advisory Opinion.¹³ For example, California’s existing state law and regulations will not let the pharmacist at a pharmacy act as the “qualified laboratory director,”¹⁴ as defined by CMS, to get the Certificate of Waiver necessary to conduct the COVID-19 rapid point-of-care test. Various states have similar barriers. Accordingly, APhA strongly urges CMS to immediately act to allow for pharmacists at pharmacies¹⁵ to act as the “qualified laboratory director” in order to receive a CLIA Certificate of Waiver and meet the various state requirements to ensure these pharmacies can conduct COVID-19 testing. Without immediate action, pharmacies will continue to encounter similar barriers that render them unable to conduct the COVID-19 diagnostic and serologic tests necessary to help control the spread of COVID-19 and assist with contact tracing. Furthermore, pharmacists have had challenges with gaining other licensed practitioner (“OLP”) status in states where Medicaid covers OLP services. While a growing number of state Medicaid agencies (Ohio, Alaska, Idaho, Maryland, New York) are paying pharmacists for administering and/or specimen collection for COVID-19 testing, many have encountered barriers to receiving OLP status. Therefore, APhA requests CMS take action to help promote expediting OLP status for pharmacists under a state plan amendment (“SPA”), 1135 waiver or other mechanism in state Medicaid programs to further pharmacists’ contributions to fighting the pandemic. By adding pharmacists as OLPs, CMS could effectively reduce the burden of each state having to submit a SPA or waiver.

As CMS understands, to address the PHE for the COVID–19 pandemic, the first IFC includes new level II HCPCS codes for “independent laboratories,” which CMS has since clarified can include pharmacies and other independent suppliers,”¹⁶ 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. This policy prevents 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. Sample

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¹⁶ Ibid.
collection by pharmacists is performed with the same level of care as other health care providers. Thus, payment for these services should be the same for pharmacists.

Pharmacists should not be treated any differently from physicians for the same activity. As stated above, the HHS OASH testing guidance authorized pharmacists to order and administer COVID-19 tests that FDA authorizes. To follow, 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.” Accordingly, it is only logical that a pharmacist administering point of care tests would be expected to collect samples as a function of administering the test and, as such, pharmacist specimen collection at the point of care from beneficiaries should be covered by Medicare.

Opioid Treatment Programs (OTPs)— Furnishing Periodic Assessments via Communication Technology

The IFC restates that “[i]n the CY 2020 PFS final rule (84 FR 62634), we finalized an add-on code describing periodic assessments furnished by OTPs. The finalized add on code is Healthcare Common Procedure Coding System (HCPCS) code G2077 (Periodic assessment; assessing periodically by qualified personnel to determine the most appropriate combination of services and treatment). The medical services described by this add-on code can be furnished by a program physician, a primary care physician or an authorized healthcare professional under the supervision [emphasis added] of a program physician or qualified personnel such as NPs and PAs.” The IFC also revised “§ 410.67(b)(7) on an interim final basis to allow periodic assessments to be furnished during the PHE for the COVID–19 pandemic via two-way interactive audio-video communication technology. In addition, in cases where beneficiaries do not have access to two-way audio-video communication technology, the periodic assessments may be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology, provided all other applicable requirements are met.” APhA supports the modification and asks for clarification that pharmacists are included as “qualified personnel,” or specifically referenced under the supervision requirement. The CY 2020 PFS final rule also clarified that CMS would “revise § 424.67(b)(1)(i) to include pharmacists [emphasis added] within the scope of the list requirement,” as some pharmacists may be legally authorized to prescribe, order, or dispense medications. For consistency, APhA urges CMS to use enforcement discretion under this new flexibility during the PHE to allow pharmacists, as the medication experts and members of patient care teams, to provide these periodic assessments furnished by OTPs via various communication technologies.

Flexibility for Medicaid Laboratory Services

Under the IFC, CMS states:

“We believe it is vital for Medicaid beneficiaries to have *broad access to tests* [emphasis added] to detect the SARS CoV–2 virus, antibodies to the SARS CoV–2 virus, or COVID–19, so that they can properly monitor their symptoms, make decisions about seeking further care, and take appropriate precautions to prevent further spread of disease. The requirements at § 440.30(a) and (b) could present an obstacle to Medicaid coverage for administering and processing COVID–19 laboratory and diagnostic tests in certain non-office settings, such as parking lots or other temporary outdoor locations, where the setting is intended to maximize physical distancing and thereby minimize transmission of COVID–19. Given the nature and scope of the COVID–19 pandemic, the critical importance of expanding COVID–19 testing to combat the pandemic, and the heightened risk the disease presents to Medicaid beneficiaries, we also would like to accommodate evolving COVID–19 diagnostic mechanisms, such as FDA authorized tests that allow for patients to self-collect a specimen in alternative locations (such as at home) to send to a laboratory, to detect the SARS-CoV–2 virus, antibodies to the SARS-CoV–2 virus, or COVID–19 (sometimes referred to as ‘‘self-collection’’). Accordingly, we are amending § 440.30 to permit flexibility for coverage of COVID–19 tests, including coverage for tests administered in nonoffice settings, and coverage for laboratory processing of self-collected COVID–19 tests that are FDA-approved for self-collection.”

APhA supports this provision allowing Medicaid coverage for self-collection of specimens. However, we note that FDA approval for home specimen collection has been linked to utilizing “appropriately trained personnel” for testing and “health care professionals” for specimen collection, storage and shipping (e.g., see, Kroger EUA19). Accordingly, we would urge Medicare, Medicaid, FDA and the states to ensure that any such self-collection (such as home) are only approved under a model that incorporates trained health care professionals, such as pharmacists, to support patients so that they can properly monitor their symptoms, make decisions about seeking further care, and take appropriate precautions to prevent further spread of disease.

PHE Preparedness

Under the IFC, CMS recognizes “that, during the COVID-19 PHE or any future PHE resulting from an outbreak of communicable disease, and during any subsequent period of active surveillance (as defined above), Medicaid coverage is available for laboratory tests and X-ray services that do not meet conditions specified in § 440.30(a) or (b) so long as the purpose of the laboratory or X-ray service is to diagnose or detect SARS-CoV-2, antibodies to SARS-CoV-2, COVID-19, or the communicable disease named in the PHE or its causes, and so long as the deviation from the conditions specified in § 440.30(a) or (b) is intended to avoid transmission of the communicable disease.” APhA strongly supports this language and urges CMS to codify this

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language for ordering and administering COVID-19 and other tests and related services for additional communicable diseases in any future PHE, which would include pharmacists, and to extend this to Medicare as well as Medicaid coverage.

**Updating the Medicare Telehealth List**

APhA agrees with the comments submitted by the Pharmacy Health Information Technology Collaborative (“PHIT”) requesting that pharmacy services provided by pharmacists using telehealth, particularly pharmacy services provided outside of inpatient settings, be added to the telehealth list. Currently, only one pharmacy service is included on the telehealth list: G0549 Telehealth inpatient pharmacologic management. Although CMS states in the IFC that it is “not codifying a specific process to be in effect during the PHE for the COVID-19 pandemic, we note that we could add services to the Medicare telehealth list on a subregulatory basis by posting new services to the web listing of telehealth services when the agency receives a request to add (or identifies through internal review) a service that can be furnished in full…to a beneficiary in a manner similar to the in-person service. We note that any additional services added using the revised process would remain on the list only during the PHE for the COVID-19 pandemic.” **In this regard, APhA asks CMS to consider making permanent any new pharmacy services that are added to the telehealth list.** Many patient care services provided by pharmacists are clinically appropriate for telehealth, including: 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. Specific examples where Medicare beneficiaries can benefit from pharmacists providing telehealth include pharmacist provision of needed 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.

**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. 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, FAPhA
Senior Vice President, Pharmacy Practice and Government Affairs