



October 5, 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-1734-P
P.O. Box 8016
Baltimore, MD 21244-8013

Re: Medicare Program: CY 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; etc. [RIN 0938–AU10]

Dear Administrator Verma:

The American Pharmacists Association (APhA) is pleased to submit these comments regarding CMS' proposed rule "CY 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements," (hereinafter, the "Proposed Rule"). 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.

General Comments - Maximize the Utilization of Pharmacists for Care Delivery

As communicated previously, APhA strongly agrees with several of the Administration's recommendations in the report "Reforming America's Healthcare System Through Choice and Competition." An important recommendation includes allowing pharmacists and other health care providers to practice at their full practice scope, utilizing their complete skill set and advanced specialized training to augment efforts to improve health outcomes, patient safety, and reduced total cost of care. Further, the report encourages the federal government and states to consider legislative and administrative proposals to facilitate direct and equitable payment to nonphysician providers, including pharmacists, for their clinical services.¹ In addition, Executive

¹ U.S. Departments of HHS, the Treasury, and Labor. Reforming America's Healthcare System Through Choice and Competition. November 30, 2018, available at: <https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf>

Order (“EO”) #13890, “Protecting and Improving Medicare for Our Nation’s Seniors,” recommends the elimination of specific Medicare regulations that require more stringent supervision than existing state scope of practice laws, or that limit health professionals, such as pharmacists, from practicing at the top of their license.² This is particularly important due to the estimated shortage of physicians and patient access to care which has only continued to grow due to workforce aging, population growth and increased demand for health care services that will range from between 54,100-139,000 physicians by 2033.³ During the COVID-19 pandemic, pharmacists have overwhelmingly stepped up to contribute to some of the most daunting challenges of this pandemic, including shortages of health care staff and burnout of health care professionals—which continues to rise and hinder patient outcomes. HHS has recognized the important role that pharmacists play in maintaining and addressing the country’s economic, health, and safety efforts by authorizing pharmacists to order and administer COVID-19 tests⁴ and recognizing pharmacies as points of care for COVID-19 testing services.⁵ In addition, HHS has also authorized pharmacists to order and administer COVID-19⁶ and childhood vaccines⁷ in states where this authority did not already exist—which has enhanced the position of community pharmacies and pharmacists as primary access points for patients to receive preventive immunizations and pharmacist-provided patient care services. As HHS Secretary Alex Azar stated, “the Administration has worked to allow pharmacists—alongside all of America’s heroic healthcare workers—to practice at the top of their license.”⁸ Accordingly, APhA recommends CMS build upon HHS’ substantive work and implement the Administration’s recommendations by fully utilizing enforcement discretion to remove regulatory barriers to the delivery of, and payment for, pharmacist-provided patient care services for our nation’s Medicare beneficiaries.

Team-based, patient-centered care delivery and payment models can help to lower administrative burdens and assist eligible clinicians with achieving maximum quality scores under the Merit-based Incentive Payment System (“MIPS”) and Advanced Alternative Payment Models (“APMs”). Taking action would align Medicare with the many states and Medicaid programs that are already turning to pharmacists to improve patients’ health and outcomes and lower medication-related costs.⁹ In addition, increased recognition of pharmacists and payment for the patient care services they provide would align pharmacists with other health care professionals’ services covered under Medicare Part B. APhA has determined approximately 33% of provider and practice quality metrics under Medicare are impacted by or related to optimal medication

² White House. Executive Order on Protecting and Improving Medicare for Our Nation’s Seniors. October 3, 2019, available at: <https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-nations-seniors/>

³ Association of American Medical Colleges. The Complexities of Physician Supply and Demand: Projections from 2018-2033. June 26, 2020, available at: <https://www.aamc.org/news-insights/press-releases/new-aamc-report-confirms-growing-physician-shortage>

⁴ Office of the Assistant Secretary, “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>

⁵ 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: 09/2/020, available at: <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2>

⁶ OASH. Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act. September 3, 2020, available at: <https://www.hhs.gov/sites/default/files/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf>

⁷ HHS. Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19. August 19, 2020, available at: <https://www.hhs.gov/sites/default/files/third-amendment-declaration.pdf>

⁸ HHS. HHS Expands Access to Childhood Vaccines during COVID-19 Pandemic. August 19, 2020, available at: <https://www.hhs.gov/about/news/2020/08/19/hhs-expands-access-childhood-vaccines-during-covid-19-pandemic.html>

⁹ CMS/ CMCS Informational Bulletin. State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice using Collaborative Practice Agreements, Standing Orders or Other Predetermined Protocols. January 17, 2017, available at: <https://www.medicare.gov/federal-policy-guidance/downloads/cib011717.pdf>

management and treatment safety. Pharmacists are the single most important practitioner who can assist prescribers in achieving and surpassing their medication-related quality outcome measures. Yet, payment models that preclude pharmacists from full participation limit both prescriber and patient access to pharmacist-provided patient care services, particularly for patients in underserved and rural areas.

To assist CMS in fostering patient-care teams, APhA respectfully submits the following recommendations with additional information and comments below:

- **Fully leverage pharmacists in telehealth delivery by adding telehealth care services provided by pharmacists to the Medicare Telehealth List and addressing payment barriers for pharmacists' telehealth services, particularly pharmacy services provided outside of inpatient settings.**
- **Make permanent the recent clarification 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.**
- **Remove any barriers that prevent CMS, beneficiaries and federal taxpayers from garnering the significant avoidance savings available from integrating pharmacists into healthcare delivery and reimbursement models.**
- **Recognize "pharmacists" as "clinicians" that can be utilized by, and collaborate with physicians and non-physician practitioners ("NPPs") under HCPCS Code GPC1X.**
- **Reference and formally recognize the term and definition of "medication management services" ("MMS") adopted for pharmacy practice by the Joint Commission of Pharmacy Practitioners ("JCPP").**
- **Recognize complex "incident to" physician services provided by a pharmacist in team-based health care delivery models that can be billed by physicians and NPPs via Evaluation and Management ("E/M") codes 99212-215 commensurate with the services delivered and consistent with the adopted definitions within the American Medical Association's ("AMA") Current Procedural Terminology ("CPT") Code Set.**
- **Use enforcement discretion to provide a clear payment pathway for the services associated with point of care tests (COVID-19, influenza, respiratory syncytial virus ("RSV")) at pharmacies during the pandemic and beyond, equivalent with that of other qualified healthcare professionals including patient assessment, specimen collection and counseling the patient on the results.**
- **Implement the increase in immunization rates prior to the January 1, 2021 effective date for the physician fee schedule ("PFS") final rule to address the current influenza season and prepare for the COVID-19 vaccine(s).**
- **Create an add-on G-code (HCPCS code GMAT1) for initiation of medication assisted treatment ("MAT") in the emergency department and establish adequate reimbursement.**
- **Add nasal naloxone, auto-injector naloxone, injectable naloxone, and overdose education services to the definition of opioid use disorder ("OUD") treatment services by creating add-on codes and establishing adequate reimbursement.**

- **To enhance Medicare beneficiaries’ access to OUD treatment and care, revise § 410.67(b)(7) to allow periodic assessments to be furnished via two-way interactive audio-video communication technology, and allow OTPs to bill the HCPCS code G2077 add-on code for periodic assessments conducted through the use of audio-only telephone calls after the COVID-19 public health emergency (“PHE”) is over.**
- **Add screening for potential substance use disorders (“SUDs”), including a review of the individual’s potential risk factors for SUD and referral for treatment as appropriate; and a review of any current opioid prescriptions to the Initial Preventive Physical Examination and Annual Wellness Visit, and establish adequate reimbursement.**
- **Require electronic prescribing for controlled substances (“EPCS”) compliance for covered Part D drugs under a Prescription Drug Plan (“PDP”) or an MA–PD Plan using the NCPDP SCRIPT 2017071 standard beginning on January 1, 2022.**
- **Permit any supplier with a Centers for Disease Control and Prevention (“CDC”) assigned National Diabetes Prevention Program (“DPRP”)-recognized supplier organizational code that specifies the service delivery mode of either in-person or combination be eligible to furnish Medicare Diabetes Prevention Program (“MDPP”) services at any time during the PHE or otherwise (permanently).**
- **Maintain the Electronic Prescribing objective’s Query of Prescription Drug Monitoring Program (“PDMP”) measure as an optional measure for the performance period in CY 2021 and increase the bonus points from 5 to 10.**

Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (pg. 50095)

In response to the PHE for the COVID–19 pandemic, CMS undertook emergency rulemaking to add a number of services to the Medicare Telehealth List on an interim final basis. Under the Proposed Rule, CMS would make a number of the services added to the Medicare Telehealth List permanent because these services are similar to the professional consultations, office visits, and office psychiatry services that are already covered on the list. Currently, only one specific medication management service is included on the Telehealth List: G0459 Telehealth inpatient pharmacologic management.

Many patient care services provided by pharmacists are clinically appropriate for telehealth during the PHE and beyond, including: MMS, chronic condition management (e.g., diabetes, hypertension), transitions of care, pharmacogenomics, interpretation of diagnostic tests and providing test results, consultations and referrals with patients and health care providers. While APhA appreciates CMS’ recent recognition of medication management services as a covered benefit in Medicare Part B (see additional comments below), we also encourage CMS to develop mechanisms to better understand how MMS is being delivered both face-to-face and via telehealth delivery and by pharmacists in the Part B program.

Specific examples where Medicare beneficiaries can benefit from pharmacists providing telehealth include pharmacist provision of higher-level E/M services (99212-99215) using a telehealth format to assist in the management of chronic conditions under physician supervision via audio and video technology. Pharmacists are also well-positioned to offer a number of additional services currently on the Medicare Telehealth List (e.g., G0436,7 tobacco use

counseling; G0442 Annual alcohol screen, G0443 Brief alcohol misuse, etc.). Additionally, CMS recently eliminated a significant barrier for Medicare beneficiaries by permitting pharmacists in Medicare-enrolled, accredited DSMT programs not affiliated with hospitals or physician clinics to deliver DSMT services via telehealth due to social distancing requirements and the fact that many DSMT services must be delivered via group session.¹⁰ In order to maintain patient access to DSMT services, APhA strongly encourages CMS to make the delivery of DSMT services via telehealth permanent. APhA also urges CMS to implement mechanisms for pharmacists' services delivered via telehealth to be reimbursed at levels commensurate with the complexity of service delivered, especially for E/M services.

Communication Technology-Based Services (“CTBS”) (pg. 50112, 50114)

Under the Proposed Rule, CMS is proposing to make permanent allowing licensed clinical social workers (“LCSWs”), clinical psychologists, physical therapists (“PTs”), occupational therapists (“OTs”), and speech language pathologists (“SLPs”) to furnish brief online assessment and management services, virtual check-ins, and remote evaluation services, or “CTBS,” as clinical practitioners. CMS also states “[f]or all of these CTBS, we are also making clear that the consent from the patient to receive these services can be documented by auxiliary staff under general supervision, as well as by the billing practitioner.” CMS is “also proposing to allow billing of other CTBS by certain nonphysician practitioners, consistent with the scope of these practitioners’ benefit categories through the creation of two additional HCPCS G codes that can be billed by practitioners who cannot independently bill for E/M services.” One of these codes is “G20X2 (Brief communication technology-based service, e.g. virtual check-in, by a *qualified health care professional who cannot report evaluation and management services* [emphasis added], provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion).” Pharmacists provide these types of services all the time in physician practices and should be formally recognized as a “qualified health care professional,” for providing these services (explained further below).

CMS noted in the Proposed Rule that certain services, such as chronic care management (“CCM”) or remote physiologic monitoring (“RPM”) do not need to be added to the Medicare Telehealth Services List because they fall outside the scope of telehealth services under section 1834(m). CMS seeks comment on other services that are inherently non-face-to-face and do not need to be on the Medicare telehealth services list in order to be billed and paid when furnished using telecommunications technology rather than in person.

Pharmacists are highly involved in the delivery of CBTS services that are inherently non-face-to-face and APhA believes that CMS should clarify that these services, including CCM, RPM, behavioral health integration (“BHI”), and continuous glucose monitoring (“CGM”) fall outside the scope of telehealth services. For example, pharmacists can deliver CGM utilizing CTBS to help reduce the \$327 billion annual cost of diabetes in America.¹¹ Accordingly, APhA strongly

¹⁰ See, CMS, COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing, Question #43, Page #74. Updated 7/28/20, available at: <https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf>

¹¹ American Diabetes Association. The Staggering Cost of Diabetes. March 22, 2018, available at: <https://www.diabetes.org/resources/statistics/cost-diabetes>

urges CMS to use enforcement discretion during the PHE and beyond to also allow pharmacists to provide all applicable CTBS (i.e., E-Visits, etc.).

Remote Physiologic Monitoring/Treatment Management Services (“RPM”) (pgs. 50117-50120)

APhA was pleased when CMS issued a technical correction in 2019 clarifying that RPM under CPT code 99457 may be furnished by pharmacists, working under the direct supervision of the physician or eligible NPP.¹² Similarly, we support CMS’ proposal to make permanent allowing patient consent to be obtained at the time that RPM services are delivered and to allow pharmacists and others to furnish services described by CPT codes 99453¹³ and 99454¹⁴ under the general supervision of the billing physician or practitioner.

Transitional Care Management (“TCM”) (pg. 50120)

For CY 2020, CMS recognized that use of TCM services was low when compared to the number of Medicare beneficiaries with eligible discharges and that increased utilization of medically necessary TCM services could improve patient outcomes and finalized a policy to allow concurrent billing of TCM services, when reasonable and necessary, during the 30-day period covered by TCM services.

In the Proposed Rule, CMS proposes to allow 14 actively priced HCPCS codes, including Complex Care Management Services (“CCCM”) (G2058 – Chronic care management services, each additional 20 minutes of *clinical staff time* [emphasis added] directed by a physician or other qualified healthcare professional, per calendar month) to be billed concurrently with TCM services when reasonable and necessary. As CMS understands, the current restrictions on physicians and nonphysician practitioners from billing for both CCCM and TCM services during the same month places an unnecessary delay on patients who could benefit from these proven services. Pharmacists providing TCM services can easily identify potential patients for CCCM and contribute to CCCM delivery. Accordingly, as payment models continue to shift towards value-based care, APhA urges CMS to remove any barriers that prevent CMS, beneficiaries, and federal taxpayers from garnering the significant avoidance savings available from integrating pharmacists into delivery models proven to reduce hospital readmissions.

¹² CMS. Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; etc.; Correction. March 15, 2019, available at: <https://www.regulations.gov/document?D=CMS-2018-0076-15377>

¹³ Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment – which is valued to reflect clinical staff time that includes instructing a patient and/or caregiver about using one or more medical devices.

¹⁴ Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days – which is valued to include the medical device or devices supplied to the patient and the programming of the medical device for repeated monitoring.

Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient E/M Visits and Promote Payment Stability During the COVID-19 Pandemic - Overview of Policies Finalized in CY 2020 for CY 2021 (pgs. 50121-50124)

Evaluation and Management Changes

In the Proposed Rule, CMS states “[i]n the CY 2020 PFS final rule (84 FR 62844 through 62860), for the office/outpatient E/M visit code set (CPT codes 99201 through 99215), we finalized a policy to *generally* [emphasis added] adopt the new coding, prefatory language, and interpretive guidance framework that has been issued by the AMA’s CPT Editorial Panel...and will be effective January 1, 2021.” However, AMA’s CPT Editorial Panel is a non-governmental body. CMS is the final governmental authority on implementation of any new coding and regulatory guidance. As such, CMS can use its enforcement discretion, within its authority, regarding billing for pharmacist services incident to a physician or NPP that are of a complexity that aligns with higher level E/M codes above 99211 (99212-99215).

In 2014, the American Academy of Family Physicians (“AAFP”) petitioned CMS for clarification on whether a physician may bill for services provided by a pharmacist as “incident to” services.¹⁵ Then CMS Administrator Marilyn Tavenner’s response stated that, “provided all requirements of the ‘incident to’ statute and regulations, including applicable state and local laws, were met, such billing would be wholly permitted.”¹⁶ In 2016, CMS stated in the PFS final rule that eligible providers could bill for auxiliary personnel provided incident-to services “...as if they personally furnished the service [emphasis added].”¹⁷

APhA applauds CMS for clarifying in the second IFC (85 FR 27557) that medication management is covered under both Medicare Part B and Part D (as mentioned below). Pharmacists across the country are sought for their medication and chronic disease management skills, and this clarification resolves longstanding questions about coverage of medication management services in Medicare Part B. CMS also stated that “pharmacists fall within the regulatory definition of auxiliary personnel under our regulations at § 410.26,” and that “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....in accordance with the *pharmacist’s state scope of practice and applicable state law* [emphasis added]. This clarification does not alter current payment policy for pharmacist services furnished incident to the professional services of a physician or NPP.” Finally, CMS declared that “this clarification may encourage pharmacists to work with physicians and NPPs in new ways that expand the availability of health care services during the

¹⁵ American Academy of Family Physicians letter to Centers for Medicare & Medicaid Services, (Jan 2014), available at:

<https://www.accp.com/docs/positions/misc/AAFP%20MTM%20Letter%20to%20CMS%5E2.pdf>

¹⁶ Centers for Medicare & Medicaid Services response to American Academy of Family Physicians, (March 2014), available at: <https://www.accp.com/docs/positions/misc/CMS%20Response%20to%20AAFP%20MTM%20Billing%20Letter.pdf>, stating, “In your letter, you ask that we confirm your impression that if all the requirements of the “incident to” statute and regulations are met, a physician may bill for services provided by a pharmacist as “incident to” services. We agree.”

¹⁷ CMS. Medicare program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to part B for CY2016. (Final rule). Federal Register. 80: 220. (November 16, 2015) p. 71066 <https://www.federalregister.gov/d/2015-28005/p-1578>. Accessed June 22, 2020.

COVID-19 PHE, and increase access to medication management of individuals with substance/opioid use disorder.”¹⁸

While APhA appreciates CMS’ encouragement that the medication management services clarification “may encourage physicians and NPPs to work with pharmacists in new ways,” misaligned Medicare payment policy for pharmacists’ services performed in incident to physician services arrangements continues to be a significant barrier to broad use of pharmacists in team-based care models. Conflicting messages from CMS have caused confusion about physician billing for pharmacists’ services in these arrangements, and CMS application of the AMA Guideline Changes for E/M codes is of great concern related to payment for pharmacists’ services provided under incident to physician arrangements.

To ensure patients have access to critical services, whether provided in-person or via telehealth, CMS must ensure that physicians or NPPs can bill for pharmacists’ services using billing codes reflective of the complexity, duration, and intensity of the services. However, according to the AMA’s Guideline Changes, it appears that lower-level E/M code 99211 is the only code available for time-based billing provided by clinical staff under Part B. The use of 99211 simply is not sustainable for clinical staff, such as highly trained pharmacists providing care to complex patients, who typically provide services with time commitments at the 99212-99214 levels, which would essentially inhibit patients’ access to high quality team-based care that includes pharmacist-provided patient care services. CMS also states in the Proposed Rule the agency’s intention “beginning for CY 2021 to adopt the actual total times (defined as the sum of the component times) rather than the total times recommended by the RUC for CPT codes 99202 through 99215.” If AMA’s Guideline Changes are adopted without any clarification by CMS for pharmacists as members of patient care teams, physicians and NPPs would be significantly challenged to utilize pharmacists to provide complex care services under an “incident to” relationship as E/M code 99211 reflects an average total time of 7 minutes. **It is not feasible that a pharmacist providing a 45-minute office visit to manage multiple chronic conditions and multiple medications for a 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 only has an anticipated time commitment of 7 minutes. Such a provision would eliminate any incentive and/or ability for physicians/ NPPs and pharmacists to partner to provide complex health care services.**

APhA has collected a number of cases from pharmacists working in team-based care arrangements that illustrate the complexity of care being delivered to Medicare-eligible beneficiaries 65 years and older. We would welcome the opportunity to share more of these cases with CMS. The following brief case description highlights a common type of visit pharmacists are providing incident to physician services. Pharmacists often spend 15-60 minutes in visits with patients, depending on the patient’s level of complexity and whether the patient’s visit is an initial encounter with the pharmacist or a follow-up visit.

¹⁸ CMS, Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency. April 30, 2020, available at: <https://www.cms.gov/files/document/covid-medicare-and-medicaid-ifc2.pdf>

- Case example: Patient is a 77-year-old male with type 2 diabetes, heart disease, hypertension, and hyperlipidemia referred by physician to the pharmacist for a follow-up visit. Patient is experiencing increased fatigue, nocturia, and weight loss. Patient is currently taking 6 medications. Pharmacist reviewed symptoms, evaluated the patient’s medication regimen, and discontinued two medications and initiated two new medications in collaboration with physician. The pharmacist provided education on diet and exercise and counseling on the new medications. The patient does not currently conduct self-blood glucose monitoring (“SBGM”), and the pharmacist also worked with the patient to initiate SBGM with a plan to consider continuous blood glucose monitoring to monitor progress in the future. A one-month follow-up visit was scheduled. The pharmacist’s visit details were reviewed and approved by the supervising provider. Total patient visit time: 42 minutes

For reference of Congressional intent, APhA also directs CMS to the House-passed 2nd FY2021 Consolidated Appropriations Act (H.R. 7617)—specifically, the language from H. Rept. 116-450,¹⁹ which states:

“Pharmacists and Patient Care Services.—The Committee is aware that certain Medicare Part B services and care frameworks have provisions to include pharmacists and their patient care services. However, CMS has few, if any, mechanisms to identify and evaluate pharmacists’ contributions to patient care and outcomes or to identify barriers within current service requirements that prevent scalable involvement of pharmacists. The Committee urges CMS to create a mechanism to provide greater visibility into the scope and outcomes of the Medicare services currently provided by pharmacists. In addition, CMS should consider testing such system in a CMMI model to assess barriers to pharmacist participation in current Medicare services and to evaluate the contributions of pharmacists to team-based care and better health outcomes in Medicare beneficiaries.”

In order for CMS to implement HHS’ commitment to advancing team-based care and allow pharmacists to meet HHS Secretary Azar’s goal “to practice at the top of their license,” APhA urges CMS to use enforcement discretion under its existing authority to recognize that complex services provided by pharmacists in team-based health care delivery models under incident to arrangements can be billed by physicians and NPPs via E/M codes 99212-215, **equivalent with the services delivered by all other healthcare providers.** APhA also strongly requests that CMS develop mechanisms to better understand and evaluate how health care practitioners, including pharmacists, whose services are billed by physicians and NPPs under incident to arrangements, contribute to access to care needs and the health outcomes of Medicare beneficiaries.

Comment Solicitation on the Definition of HCPCS Code GPC1X (pg. 50138)

In the CY 2020 PFS final rule (84 FR 62856), CMS finalized the HCPCS add-on code GPC1X which describes the “visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services

¹⁹ See, Page 171- <https://www.congress.gov/116/crpt/hrpt450/CRPT-116hrpt450.pdf>

and/or with medical care services that are part of ongoing care related to a patient’s single, serious, or complex condition.” In the Proposed Rule, CMS acknowledges that the add-on code GPC1X is unclear and comments CMS received stating that the code, as currently described, “could be applicable for every office/outpatient E/M visit.” In response, CMS states the add-on code “reflects the time, intensity, and PE when practitioners furnish services that enable them to build longitudinal relationships with all patients (that is, not only those patients who have a chronic condition or single high risk disease) and to address the majority of patients’ health care needs with consistency and continuity over longer periods of time. For example, in the context of primary care, HCPCS add on code GPC1X could recognize the resources inherent in holistic, patient centered care that integrates the treatment of illness or injury, management of acute and chronic health conditions, and coordination of specialty care in a *collaborative relationship with the clinical care team* [emphasis added]. In the context of specialty care, HCPCS add-on code GPC1X could recognize the resources inherent in engaging the patient in a continuous and active *collaborative plan of care* [emphasis added] related to an identified health condition the management of which requires the direction of a *clinician with specialized clinical knowledge, skill and experience* [emphasis added]. Such collaborative care includes patient education, expectations and responsibilities, shared decision making around therapeutic goals, and shared commitments to achieve those goals.” As “collaborative plans” and “clinicians with specialized clinical knowledge, skill and experience,” may very well include physicians utilizing pharmacists for these services, APhA asks CMS to specifically recognize “pharmacists” as “clinicians” utilized in this context.

Pharmacists Providing Services Incident to Physicians’ Services (pgs. 50146-50147)

Pharmacists May Provide Medication Management Services under Part B

As mentioned above, APhA appreciates CMS reiterating in the Proposed Rule the clarification provided in the Second IFC (85 FR 27550 through 27629) that “pharmacists may provide [medication management] 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 “may free up the time of physicians and NPPs for other work and increase access to medication management services, for individuals with chronic conditions and other conditions.” APhA agrees. Accordingly, we urge CMS to reference and formally recognize the term and definition of “medication management services” adopted for the pharmacy practice by the JCPP^{20,21} that includes the following elements:

- 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.

²⁰ JCPP. Medication Management Services (MMS) Definition and Key Points. March 14, 2018, available at: <https://jcnp.net/wp-content/uploads/2018/05/Medication-Management-Services-Definition-and-Key-Points-Version-1.pdf>

²¹ JCPP. The Pharmacists’ Patient Care Process, available at: <https://jcnp.net/patient-care-process/>

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. MMS encompasses 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.

CMS Use of Enforcement Discretion and Regulatory Flexibility

APhA notes CMS has already used enforcement discretion and regulatory flexibility during the COVID-19 pandemic to relax supervision requirements to permit direct supervision of pharmacists providing E/M services by physicians and NPPs via audio and video technology. CMS confirms this flexibility in the Proposed Rule and restates the recent IFC to extend this supervision flexibility until December 30, 2021 or when the PHE ends. APhA supports CMS’ supervision flexibility and encourages CMS to monitor and evaluate making this flexibility permanent in the long-term.

Given pharmacists’ ability to reduce the \$528 billion spent annually on medication-related problems,²² it is critical that CMS build off this momentum—particularly during the PHE to make this flexibility permanent under the recent Executive Order, “Regulatory Relief to Support Economic Recovery.”²³ As you know, pharmacists are trained healthcare practitioners who have the ability to significantly expand patient access to needed care, should certain regulatory barriers be permanently removed. America’s pharmacy workforce has the ability to significantly expand access to care, which will not only help reduce the strain on the health care system but will also allow for more individuals to receive health care treatments and return to work. Accordingly, APhA urges CMS to remove additional barriers to ensure pharmacists are fully and effectively engaged as part of patient care teams.

Addressing Barriers to Pharmacist-Delivered COVID-19 Testing-Related Services

In the Proposed Rule, CMS also provides an example of how this “clarification may encourage pharmacists to work with physicians and NPPs in new ways where pharmacists are working at the top of their training.” CMS found it “was helpful in recently addressing in the May 1st COVID–19 IFC (85 FR 27550 through 27629), the ability of pharmacies to enroll as laboratories and pharmacists in contractual arrangements with physicians to perform assessment of clinical information, specimen collection and reporting results of COVID–19 clinical diagnostic laboratory tests.” While APhA appreciates the efforts of CMS to provide workarounds to open up potential pathways to utilize pharmacists and pharmacies during the PHE, significant payment barriers still exist for pharmacists’ COVID testing-related services provided in pharmacies, such as symptom assessment and specimen collection. Specimen collection fees for independent clinical laboratories (G2023-24) for COVID-19 tests only apply when collecting specimens from

²² 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>

²³ The White House. Executive Order on Regulatory Relief to Support Economic Recovery. May 19, 2020. Available at: <https://www.whitehouse.gov/presidential-actions/executive-order-regulatory-relief-support-economic-recovery/>

beneficiaries who are homebound or in skilled nursing facilities but not for specimens collected in pharmacies enrolled in Medicare as a laboratory for point of care tests.²⁴

Pharmacists' alternative option to payment for symptom assessment and specimen collection would be to enter into a contract with a physician or NPP under an incident to physician services arrangement and have the physician or NPP bill for the pharmacist's service.²⁵ CMS also states in the Proposed Rule "[i]n cases where the specimen is collected during a visit where the face-to-face interaction only involves clinical staff of the billing professional with whom the patient has an established relationship, these services are generally reported using CPT code 99211. CMS states it is "considering whether to extend or make permanent the policy to allow physicians and NPPs to use CPT code 99211 to bill for services furnished incident to their professional services, for both new and established patients, when clinical staff assess symptoms and collect specimens for purposes of COVID-19 testing, and are soliciting public comments on whether we should continue this policy for a period of time, or permanently, after the COVID-19 PHE ends."²⁶ While APhA supports CMS making permanent the use of codes for specimen collection, because almost all community pharmacists generally do not have "incident to" arrangements with physician practices that would allow their services to be billed, this payment pathway is a significant barrier to sustainable delivery of COVID testing services in pharmacies. In addition, CPT code 99211 in some cases will not cover the time and complexity of COVID-related testing services for some patients that would be commensurate with that of other qualified healthcare professionals including patient assessment, specimen collection (including for/to rule out influenza virus and RSV), and counseling the patient on the results. As a result, the Administration's stated public health goal of widespread and accessible testing in communities by pharmacists will not be achieved. While likely unintended, this 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 in FDA's FAQ.²⁷ Limiting pharmacists' ability to order and administer COVID-19 tests is also contrary to the HHS Office of General Counsel ("OGC") Advisory Opinion on preemption.²⁸ Therefore, APhA specifically requests CMS amend and/or use enforcement discretion of 42 CFR §410.32 to appropriately reflect FDA's FAQ, the HHS Office of the Assistant Secretary of Health ("OASH") guidance²⁹ and HHS OGC Advisory Opinion to implement a direct payment pathway for COVID-19 testing-related services in pharmacies.

²⁴ CMS. Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency. March 1, 2020, available at: <https://www.cms.gov/files/document/covid-final-ifc.pdf>

²⁵ CMS. Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency. September 2, 2020, available at: <https://www.regulations.gov/document?D=CMS-2020-0097-0001>

²⁶ Pg. 50116

²⁷ 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: 10/2/020, available at: <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2>

²⁸ 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>

²⁹ 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>

Immunization Administration (CPT Codes 90460, 90461, 90471, 90472, 90473, and 90474 and HCPCS codes G0008, G0009, and G0010) (pgs. 50162-50163)

APhA thanks CMS for responding to our comments to crosswalk payment rates for immunization administration services at approximately the same rates that were paid in CY 2017 prior to agency revaluation and urges CMS to implement the increase prior to the January 1, 2021 effective date for the PFS final rule to align with HHS’ messages regarding the importance of the public being fully vaccinated with available and recommended vaccines prior to the availability of the COVID-19 vaccine(s) in order to reduce the burden on the healthcare system and public health. Pharmacists are experiencing increased demand during the current influenza season, and increasing the payment rates to providers back to the 2017 rates would help address the increased burden on the healthcare system now and as we prepare for the COVID-19 vaccine(s).

Without CMS’ action, the previously proposed rates for CY 2020 would have represented a 44% decrease for immunization administration.³⁰ CMS also states in the Proposed Rule, “[s]hould a vaccine for COVID-19 or other infectious disease become available during CY 2021, we would anticipate applying the same approach to valuing the administration of such vaccines, regardless of whether separate coding for such services would need to be introduced.” It is imperative that pharmacists and other providers administering immunizations are adequately compensated for efforts being undertaken now to combat seasonal influenza and prepare for the COVID-19 vaccine(s).

APhA also notes that a COVID-19 vaccine(s) is likely to be initially approved by FDA under an emergency use authorization (“EUA”) and not “licensed under section 351,” which would require use of enforcement discretion to comply with Sec. 3713 of the CARES Act. We are aware CMS is exploring coverage options for administrative costs of a COVID-19 vaccine(s) authorized under an EUA. As such, APhA urges CMS to promptly identify the payment pathway, including reimbursement for administrative costs for a COVID-19 vaccine(s) so all authorized immunizers can be assured.

Bundled Payments Under the PFS for Substance Use Disorders (HCPCS Codes G2086, G2087, and G2088) (pg. 50172)

In the Proposed Rule, CMS proposes to expand bundled payments for office-based treatment of OUD (HCPCS Codes G2086, G2087, and G2088) to be inclusive of all SUDs. While all SUDs should be managed, APhA is concerned that including all SUDs within bundled payments for office-based treatment of OUD might be overly broad. The level of care necessary to evaluate, treat, and monitor patients with different SUDs can vary significantly. Therefore, APhA opposes this proposal to expand bundled payments to be inclusive of all SUDs if it would in any way result in inadequate reimbursement for SUD treatment services.

³⁰ See, CMS, Addendum B – Relative Value Units and Related Information Used in CY 2020 Proposed Rule, August 14, 2019, available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-P.html>

If CMS moves forward with this proposal, APhA believes that the agency should require that the diagnosis codes listed on the claim form reflect all SUDs being treated. As APhA members point out, diagnosis codes are used for research as well as quality improvement (“QI”) purposes.

The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (“DSM 5”) recognizes substance-related disorders resulting from the use of 10 separate classes of drugs: alcohol; caffeine; cannabis; hallucinogens (phencyclidine or similarly acting arylcyclohexylamines, and other hallucinogens, such as LSD); inhalants; opioids; sedatives, hypnotics, or anxiolytics; stimulants (including amphetamine-type substances, cocaine, and other stimulants); tobacco; and other or unknown substances. DSM-5 also includes a symptom count-based severity indicator, with two to three symptoms being classified as mild, four to five symptoms classified as moderate, and six or more symptoms being classified as severe.³¹ Given the differences in these SUDs, such as alcohol use disorder, OUD, and tobacco use disorder, as well as the level of care necessary to evaluate, treat, and monitor patients with different SUDs, APhA recommends that CMS consider implementing more stratified coding to describe these services.

Initiation of Medication Assisted Treatment (MAT) in the Emergency Department (HCPCS Code GMAT1) (pgs. 50172-50173)

Presentation in the emergency department (“ED”) for an opioid overdose represents an important opportunity to initiate treatment for OUD and connect patients to care. Accordingly, APhA supports CMS’ proposal to create one add-on G-code (HCPCS code GMAT1) to be billed with E/M visit codes used in the ED setting.

Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (pgs. 50202 – 50209)

APhA is pleased CMS is implementing Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (“SUPPORT”) Act which expands medication-assisted treatment (“MAT”) by establishing a new Part B benefit category for OUD treatment services furnished by an opioid treatment program (“OTP”). Section 2005 also amended the definition of “medical and other health services” to provide coverage of OUD treatment services and established a bundled payment to OTPs for OUD treatment services furnished during an episode of care. Pharmacists are health care practitioners with extensive medication-related education and training. Many pharmacists are actively caring for patients with OUD, yet many barriers prevent patients from receiving care. APhA believes pharmacists can help meet treatment demands but their ability to do so is dependent, in part, on coverage frameworks that encourage better optimization of resources, such as pharmacists. APhA provides the following responses regarding CMS’s proposed regulations related to Section 2005:

³¹ Substance Abuse and Mental Health Services Administration. Impact of the DSM-IV to DSM-5 Changes on the National Survey on Drug Use and Health [Internet]. Rockville (MD): Substance Abuse and Mental Health Services Administration (US); 2016 Jun. 2, Substance Use Disorders. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK519702/>

Definition of OUD Treatment Services

In the Proposed Rule, CMS proposes to extend the definition of OUD treatment services to include opioid antagonist medications, such as naloxone, that are approved by the FDA under section 505 of the Federal Food, Drug, and Cosmetic Act (“FFDCA”) for emergency treatment of opioid overdose. As stated in the *U.S. Surgeon General’s Advisory on Naloxone and Opioid Overdose*, “[r]esearch shows that when naloxone and overdose education are available to community members, overdose deaths decrease in those communities. Therefore, increasing the availability and targeted distribution of naloxone is a critical component of our efforts to reduce opioid-related overdose deaths and, when combined with the availability of effective treatment, to ending the opioid epidemic.”³²

Pharmacists play an important role in proactively identifying and furnishing naloxone to patients who may be at higher risk for an opioid overdose. In order to reduce opioid-related overdose deaths, APhA supports CMS’ proposal to add naloxone to the definition of OUD treatment services and adjust the bundled payment rates by creating two new add-on codes:

- HCPCS code GOTP1: Take-home supply of nasal naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure; and
- HCPCS code GOTP2: Take-home supply of auto-injector naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.

APhA agrees that adding naloxone to the definition of OUD treatment services can help to increase Medicare beneficiaries’ access to naloxone because there are no copayments for services furnished by OTPs and beneficiaries would not need to visit a separate provider to access naloxone.

While APhA supports creating two new add-on codes for nasal naloxone and auto-injector naloxone, the payment rates proposed by CMS are inadequate and need to be further examined. CMS’ proposal of Average Sales Price (“ASP”) + 0 (\$89.63 per 2-pack) for nasal naloxone is inadequate. Based on feedback from APhA members working in OTPs, the current cost of a 2-pack of nasal naloxone is \$115.00 - \$117.00.

For auto-injector naloxone, CMS proposes to use Wholesale Acquisition Cost (“WAC”) + 0 for the *generic* version of the drug (currently \$178.00) [emphasis added]. However, APhA members report that generic auto-injector naloxone is not currently available in the marketplace. In contrast, brand name auto-injector naloxone costs about \$4,000. Accordingly, APhA believes that CMS’ proposed payment rate for auto-injector naloxone is inadequate and should be revised to accurately reflect the true acquisition cost of the drug.

³² Office of the Surgeon General. U.S. Surgeon General’s Advisory on Naloxone and Opioid Overdose. Content last reviewed on April 5, 2018, available at: <https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxoneadvisory/index.html>

Frequency Limit

APhA opposes CMS' proposal to limit Medicare payment to OTPs for naloxone to one add-on code (HCPCS code GOTP1 or GOTP2) every 30 days to the extent that it is medically reasonable and necessary. Naloxone is a life-saving drug, and patient access should not be arbitrarily limited. APhA members report that patients sometimes lose their naloxone or move from one OTP to another and leave it behind, thus needing an additional supply. In order to ensure patient access to this critical overdose-reversing agent, APhA urges CMS to reconsider factors that may require patients to need more than one dispensing of naloxone every 30 days and modify the frequency limit to account for those patients who may need additional naloxone in a 30-day period.

Injectable Naloxone

In addition to nasal naloxone and auto-injector naloxone, APhA believes that CMS should also create a code and establish an add-on payment for injectable naloxone. Ensuring payment for all three forms of FDA-approved naloxone would allow providers to select the most appropriate form of naloxone for the particular Medicare beneficiary and provide options in the case of drug shortages. APhA members note that traditionally injectable naloxone is the least expensive form, but can be more difficult to use in an overdose emergency. While APhA does not have any specific comments on the appropriate payment methodology that CMS should use for injectable naloxone, the payment rate must be adequate.

Overdose Education Services

In addition to naloxone, APhA believes that the definition of OUD treatment services should be expanded to include overdose education, with an appropriate add-on payment for these educational services. As medication experts, pharmacists are well-positioned to educate and counsel patients, friends, and family members about the risk of overdose, the role of naloxone, and how to use it in an emergency in order to obtain buy-in for its receipt and use to prevent opioid-related overdose deaths.

In order to encourage pharmacists and other clinicians to provide overdose education as part of OUD treatment services, the payment rate established by CMS must be adequate in order to appropriately compensate providers for their time spent counseling patients. APhA is concerned that CMS' consideration of crosswalking overdose education services to CPT code 96161 would result in an inadequate payment rate. Instead, APhA recommends that CMS consider use of an appropriate CPT E/M code for overdose education.

Billing and Payment Policies

To enhance Medicare beneficiaries' access to OUD treatment and care, APhA supports CMS' proposal to revise § 410.67(b)(7) to allow periodic assessments to be furnished via two-way interactive audio-video communication technology, provided all other applicable requirements are met. APhA members are using this method of communication to care for their patients, and report many benefits, including reduced costs, convenience, patient privacy, and increased access

to care for patients. For example, two-way interactive audio-video communication technology allows patients taking buprenorphine who are quarantining due to the COVID-19 pandemic, as well as those in treatment programs, to virtually connect with their providers for assessment and safely access buprenorphine.

In addition, APhA recommends that CMS allow OTPs, in appropriate circumstances, to bill the HCPCS code G2077 add-on code for periodic assessments conducted through the use of audio-only telephone calls after the COVID-19 public health emergency is over. APhA believes that audio-only telephone calls can greatly expand access to care for those Medicare beneficiaries with OUD who do not have access to interactive audio-video communication technology, do not want to be on video, or who have privacy concerns with video utilization, such as lack of a private place in their home.

With regard to CMS' question about whether the payment rate for audio-only services should reflect any differences in resource costs, APhA urges CMS to establish parity in payment. The time providers, including pharmacists, spend with their patients is the same regardless of whether the visit is conducted in-person, via two-way interactive audio-video communication technology, or via audio-only telephone calls. Resource costs for various technology options could be considered as part of the payment evaluation.

Comprehensive Screenings for Seniors: Section 2002 of the SUPPORT Act (Section III.E, pgs. 50224 – 50227)

In order to improve SUD and OUD prevention, treatment, and recovery, APhA supports CMS' proposal to add screening for potential SUDs, including a review of the individual's potential risk factors for SUD and referral for treatment as appropriate; and a review of any current opioid prescriptions to the Initial Preventive Physical Examination ("IPPE") and Annual Wellness Visit ("AWV") in § 410.16 and § 410.15, respectively. CMS should adjust the payment values for the IPPE and AWV to adequately compensate practitioners for the additional time spent conducting these screenings.

In addition, APhA notes that SUD and OUD may also become apparent in other care settings, such as a community pharmacy. Therefore, APhA also encourages CMS to consider the community pharmacy when identifying opportunities for patient screening and potential referral, among other services. As we have stated throughout our comments, APhA urges CMS to establish adequate reimbursement for services such as this and if needed, other codes that appropriately compensate pharmacists and other providers for their professional services.

Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan (pgs. 50258 – 50261)

APhA recognizes the advantages of EPCS. EPCS has improved pharmacy workflow and can reduce prescribing errors, eliminate difficulties reading prescribers' handwriting, prevent diversion by eliminating lost, forged, and/or altered paper prescriptions, and be included as part of the integrated electronic health record ("EHR").

However, as CMS notes, while 97 percent of U.S. pharmacies were capable of processing EPCS, only 49 percent of prescribers were capable of electronically prescribing controlled substances. While APhA urges the adoption of EPCS as soon as possible, we believe it is reasonable for CMS to propose requiring EPCS compliance for covered Part D drugs under a Prescription Drug Plan or an MA–PD Plan using the NCPDP SCRIPT 2017071 standard beginning on January 1, 2022. This implementation date should allow sufficient time for prescribers to implement EPCS into their workflows, software systems, and practices. CMS can grant waivers from the EPCS requirement in appropriate circumstances.

With regard to the impact of this EPCS proposal on overall interoperability and on medical record systems, APhA would like to raise the following issues our members brought to our attention for CMS’ consideration:

- E-prescribing of medications that are controlled substances in some states but not others can cause access issues for patients. For example, gabapentin is a controlled substance in some states but not in others. Patients encounter problems when gabapentin is e-prescribed in a state where it is not a controlled substance and sent for pickup to a pharmacy in a state where it is controlled.
- Titrations for some EPCS drugs such as buprenorphine often have complicated directions for use that sometimes result in errors when e-prescribed.
- Tapering of doses of controlled substances also can cause similar problems with directions for use within EPCS systems.

Accordingly, APhA recommends that CMS allow appropriate exceptions to the EPCS requirement when written prescriptions would be clearer and better protect patient health and safety and continue to monitor for unintended consequences.

Medicare Diabetes Prevention Program Expanded Model Emergency Policy (pg. 50273-50275)

APhA supported CMS’ March 31st COVID–19 IFC flexibility that permits certain beneficiaries to obtain the set of MDPP services more than once per lifetime, waives the 5 percent weight loss eligibility requirements and allows certain MDPP suppliers to either pause the delivery of services or deliver virtual MDPP sessions on a temporary basis. We strongly support CMS’ proposal to make many of these provisions permanent for all future applicable 1135 waiver events—in particular the ability to provide MDPP services virtually, effective January 1, 2021, as MDPP services, similar to DSMT, are delivered via group session. We would also like CMS to consider more flexibility in the use of virtual visits beyond make-up sessions for MDPP, especially if combined with face-to-face visits. However, in the Proposed Rule, CMS does not permit beneficiaries who elected to receive MDPP services virtually in accordance with the MDPP Emergency Policy to restart the set of MDPP services at a later date. Due to the substantial billions in annual costs of diabetes on Medicare and society, which was a public health crisis before the PHE, and the unpredictability of COVID-19 and future PHEs, APhA respectfully urges CMS to use enforcement discretion to also allow beneficiaries to continue to receive the benefit of MDPP services more than once per lifetime.

The MDPP is yet another program that may benefit from the increased participation of pharmacists and pharmacies as part of a coordinated approach to help prevent diabetes. A large percentage of Americans live near a pharmacy, and the inclusion of pharmacists and pharmacy staff in the provision of MDPP services offers significant potential, especially in reaching patients in medically underserved communities. We do have concerns about the MDPP fee schedule and whether it is a viable financial model to support a broad scale, high quality, meaningful program. Pharmacies are already present in communities, and thus uniquely available to offer MDPP services to additional communities. APhA offers its assistance to CMS to test and evaluate virtual MDPP services. While we agree with CMS' assertion that "we do not believe it is appropriate to permit virtual-only suppliers to furnish MDPP services when the proposed Emergency Policy is in effect," we recommend that any supplier with a CDC assigned National DPRP-recognized supplier organizational code that specifies the service delivery mode of either in-person or combination be eligible to furnish MDPP services at any time during the proposed PHE or otherwise (permanently).

More generally, APhA encourages CMS to evaluate provider participation in and patient utilization of services through the MDPP model and to make changes, as necessary, such as testing pharmacy specific MDPP pilots, to make certain the expanded model is business sustainable to increase the currently low participation rates (only 1 site per 100,000 Medicare beneficiaries)³³ and achieve its intended goal of benefitting patients.

Transforming MIPS: MIPS Value Pathways (pgs. 50279-50285)

The Proposed Rule recommends postponing the implementation of the Merit-based Incentive Payment System ("MIPS") Value Pathways (MVPs) until 2022. In general, APhA supports CMS' efforts to reduce measure burden and better harmonize and use measures that are most meaningful. We appreciate that CMS will establish a process with stakeholder engagement and collaboration in the development of MVPs. Because pharmacists are integrally involved in efforts to improve quality (performance and patient experience) and impact cost metrics, APhA requests that CMS involve pharmacists in its continued efforts to engage stakeholders in the development of MVP Value Pathways. CMS proposes, beginning with the 2022 performance period, that stakeholders should formally submit their MVP candidates formally utilizing a standardized template, which will be published in the Quality Payment Program ("QPP") resource library for consideration for future implementation. APhA looks forward to reviewing the template. For the MVPs to succeed, pharmacists must be eligible clinicians for the purpose of measure performance, and attribution mechanisms must be in place to evaluate their contributions. APhA appreciates the updates to the Documentation of Current Medications in the Medical Record but also encourages CMS to explore a more robust measure that focuses on ensuring that the best reconciled medication list is available in all of the patient's health care locations. Pharmacists can play a critical role in this effort.

³³ Ritchie, Natalie. Et al. Medicare Diabetes Prevention Program: Where Are the Suppliers? Am J Manag Care. 2020; 26(6):e198-e201, available at: <https://doi.org/10.37765/ajmc.2020.43496>

**Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians
(i) Proposed Changes to the Query of Prescription Drug Monitoring Program (PDMP)
Measure Under the Electronic Prescribing Objective (pgs. 50297 – 50290)**

APhA advocates for nationwide integration and uniformity of PDMPs that incorporate federal, state, and territory databases for the purpose of providing health care providers with accurate and real-time information to assist in clinical decision making when providing patient care services related to controlled substances. Recognizing the importance of utilizing PDMP data to improve patient safety, APhA supports CMS' proposal to maintain the Electronic Prescribing objective's Query of PDMP measure as an optional measure for the performance period in CY 2021. As CMS notes, maintaining the measure as optional would allow time for further progress around EHR-PDMP integration efforts. APhA also supports using Certified Electronic Health Record Technology ("CEHRT") to conduct a query of PDMP for prescription drug history. In addition, APhA agrees that increasing the bonus points from 5 to 10 appropriately reflects the importance of the measure and incentivizes providers to query PDMPs.

Conclusion

Thank you for the opportunity to provide feedback on the Proposed Rule and for your consideration of our comments. As pharmacists continue to work in collaboration with our physician colleagues as vital members of patient care teams, we are happy to facilitate discussions between CMS and our members who currently provide E/M services, CCM, MMS, incident to, and other services. If you have any questions or require additional information, please contact Michael Baxter, Senior Director of Regulatory Policy, at mbaxter@aphanet.org.

Sincerely,



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