September 13, 2021

[Submitted electronically via www.regulations.gov]

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)
Attention: CMS-1751-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Proposed Rule (RIN 0938-AU42)

Dear Administrator Brooks-LaSure:

The American Pharmacists Association (APhA) is pleased to submit comments on the CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Proposed Rule (hereinafter, "proposed rule").

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

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 repeatedly 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 tests[1] and recognizing pharmacies as points of care for COVID-

[1] 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-licensedpharmacists-to-order-and-administer-covid-19-tests.pdf

19 testing services.[2] In addition, HHS also has authorized pharmacists to order and administer COVID-19[3] and childhood vaccines[4] 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. Most recently, as part of the President's "Path Out of the Pandemic Plan," HHS authorized pharmacists to order and administer and pharmacy technicians and pharmacy interns to administer select COVID-19 therapeutics to ensure that more patients can access these lifesaving treatments if they are infected or exposed to COVID-19.[5] Accordingly, APhA recommends CMS build upon HHS' substantive work and utilize enforcement discretion to remove regulatory barriers to the delivery of, and payment for, pharmacist-provided patient care services for our nation's Medicare beneficiaries.

Overarching Comments

Pharmacists' Evaluation and Management Services under Incident to Physician Services Arrangements

APhA appreciates that CMS is engaged with stakeholders in an ongoing review of E/M visit code sets and refinements to current policies.

As you know, Congress recently emphasized in the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations bill, 2022 (H. Rept. 117-96):

> "The Committee appreciates CMS' recognition of the expanding roles of pharmacists with broadened scopes of practice. The Committee requests CMS hear from physicians, pharmacists, and other qualified health professionals on their efforts to work with the American Medical Association (AMA) CPT Editorial Panel to develop mechanisms to attribute, report, and sustain pharmacists' medication management and other patient care contributions to beneficiaries in the Medicare Part B program."

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[2] FDA. FAQs on Diagnostic Testing for SARS-CoV-2. Q: When FDA authorizes under an EUA a SARS-CoV-2 test for use at the point of care, does that mean it is CLIA waived? (Updated 5/9). Content current as of: 09/2/2020, available at: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2

[3] 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

[4] 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

[5] HHS. Ninth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19. September 9, 2021, available at: https://public-inspection.federalregister.gov/2021-19790.pdf

APhA also appreciated CMS's statements in the CY 2021 PFS final rule (FR 84583) that "[w]e agree with certain stakeholders that under the general CPT framework, pharmacists could be considered QHPs or clinical staff, depending on their role in a given service." "We understand and appreciate the expanding, beneficial roles certain pharmacists play, particularly by specially trained pharmacists with broadened scopes of practice in certain states, commonly referred to as collaborative practice agreements. We note that new coding might be useful to specifically identify these particular models of care."

Accordingly, APhA requests the opportunity for an in-person or virtual meeting to educate CMS on pharmacist-provided patient care services that meet the requirements for more complex E/M codes.

- First, AMA's CPT Editorial Panel is a **non-governmental body.** It is important to note that the pharmacy profession is well represented within the CPT structure. Daniel Buffington, PharmD, BCPS, a pharmacist, is one of two nonphysician members from the CPT Health Professionals Advisory Committee who sit on the 17 member CPT Editorial Panel. The rest of the CPT Editorial Panel is comprised of physicians and representatives from 4 designated organizations. CPT codes are structured to account for service delivery by a variety of health care professionals, including pharmacists. CMS is the final governmental authority on implementation of any new coding and regulatory guidance. As such, CMS can and should use its regulatory authority **to permit physicians or nonphysician practitioners (NPPs) to bill for pharmacists' E/M services under incident to arrangements at higher levels of complexity or time than CPT 99211 (e.g., 99212-215), when the care provided supports use of the higher code.**

- Second, pharmacists are currently providing care to complex patients in various state and commercial health plans at a level of complexity or time that aligns with E/M codes 99212-99215.[6]

- Third, APhA has collected a number of case examples 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.

[6] Roshan, Jeff. Credentialing and Privileging 101: Essential Steps to Bill for Patient Care Services. Slide 61. Presentation at APhA2018. March 28, 2018, available at: http://apha2018.pharmacist.com/sites/default/files/slides/Cred_and_Priv_101_3-18-18_104AB_HO.pdf

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.

- 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 the 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 (CGM) 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

APhA also strongly requests that CMS develop mechanisms, in line with congressional intent, 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.

Delays in Payment for Medicare Part B Services

Generally, we have heard from our members about delays from CMS in processing claims for reimbursements for pharmacist-provided patient care services. APhA strongly recommends CMS advance the contributions of pharmacists in team-based health care delivery models by providing timely, sustainable mechanisms to support pharmacists' patient care services proven to improve quality and reduce cost. The federal government continues to look more towards pharmacists to fill the gaps in care 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 due to COVID-19. Accordingly, the federal government should also take concrete steps to invest in pharmacists to maintain Medicare beneficiaries' access to care and improve health care equity, particularly for minority, rural, and underserved populations.

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

- **CMS should use its regulatory authority, to permit physicians or nonphysician practitioners (NPPs) to bill for pharmacists' E/M services under incident to arrangements at higher levels of complexity or time than CPT 99211 (e.g., 99212-215), when the care provided supports use of the higher code.**
- **Develop mechanisms, in line with congressional intent, to better understand and evaluate how health care practitioners, including pharmacists, whose services are billed by physicians and non-physician practitioners (NPPs) under incident to arrangements, contribute to access to care needs and the health outcomes of Medicare beneficiaries.**
- **Make the flexibility for providing "direct supervision" of auxiliary personnel, including pharmacists, via real-time audio/video technology permanent by revising the definition under § 410.32(b)(3)(ii).**
- **Support a reimbursement level that covers the full and complete costs for administration of vaccines (COVID-19 and non-COVID-19 vaccines) in the current COVID-19 environment.**
- **Establish mechanisms to identify what clinical staff, including pharmacists, are providing chronic care management (CCM) and principal care management (PCM) services. This would provide CMS with more insight into how health care is delivered in the Medicare program and guide the development of new care delivery programs based on quality outcomes.**
- **Recognize all chronic pain management and opioid reduction services provided by pharmacists under incident to physician services arrangements and provide parity in payment for the complexity of service delivered as well as in-person and remote services.**
- **Align CMS with congressional intent and recognize pharmacists as providers of remote therapeutic monitoring services (RTM).**
- **Utilize new authority under Sec. 3703 Expanding Medicare Telehealth Flexibilities to enable beneficiaries to access telehealth, including in their home, from a broader range of providers—including pharmacists.**
- **Amend and/or use enforcement discretion of 42 CFR § 410.32 to implement a direct payment pathway for COVID-19 testing-related services in pharmacies that is "equivalent to all other health care professionals."**
- **Permit any supplier with a Centers for Disease Control and Prevention (CDC) assigned National Diabetes Prevention Recognition Program (DPRP)-recognized supplier organizational code that specifies the service delivery mode of either in-**

person or combination of in-person and virtual-only be eligible to furnish Medicare Diabetes Prevention Program (MDPP) services using all delivery modes at any time during the PHE or otherwise (permanently).

- **Restore reimbursement rates for CPT codes for non-COVID vaccine administration so that reimbursement accounts for the cost of the service and continues to encourage providers to offer Medicare beneficiaries ACIP-recommended immunizations at the clinical point-of-care.**
- **Establish an add-on vaccine administration payment similar to the COVID-19 vaccine, for the duration of the pandemic to furnish other preventive vaccines in the beneficiary's home. For example, it is clinically safe to administer both seasonal influenza and COVID-19 vaccines concurrently.**
- **Take action to acknowledge, attribute, and reimburse pharmacist-provided patient care services that can be provided through opioid treatment programs (OTPs).**
- **Issue pharmacist/pharmacy specific guidance on pharmacy billing for monoclonal antibody therapies outlining specific, rapid turn-around of Medicare reimbursements for Medicare Administrative Contractors (MACs) that covers the entirety of administration costs in a pharmacy setting to fully activate and incentivize pharmacists to ensure patients have local access to these lifesaving therapeutics.**
- **Use enforcement discretion during the public health emergency (PHE), and potentially beyond, to waive 1834(m)(4)(C)(ii) and designate pharmacies as originating sites to receive telehealth services.**

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. Please, see our full comments below for detailed feedback on the proposed rule. If you have any questions or require additional information, please contact Michael Baxter, Senior Director of Regulatory Policy, at mbaxter@aphanet.org.

Sincerely,

Ilisa BG Bernstein

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

American Pharmacists Association

Full APhA Feedback and Comments:

Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (Pg. 39130)

CMS added services to the Medicare telehealth services list during the COVID-19 public health emergency (PHE) for which there is likely to be clinical benefit when furnished via telehealth, but there is not yet sufficient evidence available to consider the services for permanent addition. APhA supports allowing these services to remain on the list to the end of December 31, 2023, to allow sufficient time to evaluate whether the services should be permanently added to the telehealth list following the PHE. In addition, APhA recommends that CPT 99441 Non-Face-to-Face Telephone Services (and 99442 and 99443 - the time-based add on codes for 99441) be added to the list on a Category 3 basis to allow for additional data collection.

Similarly, APhA strongly urges the HHS Secretary to use the new authority under the "Coronavirus Aid, Relief, and Economic Security Act" or the "CARES Act" (P.L. 116-136) under Sec. 3703. Expanding Medicare Telehealth Flexibilities to enable beneficiaries to access telehealth, including in their home, from a broader range of providers—**including pharmacists.** The CARES Act eliminated requirements in the Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020 (P.L. 116-123) and allows the HHS Secretary to waive telehealth restrictions under 1834(m) that normally apply only to a "qualified provider" or "practitioner."[7] Given the significant burdens on the health care system posed by the PHE, APhA strongly urges the HHS Secretary to use this new authority under Sec. 3703 to specifically include pharmacists as practitioners (providers) for the Medicare Telehealth Benefit in order to fully utilize their expertise during this ongoing health crisis. HHS should also add pharmacy services provided by pharmacists using telehealth, particularly pharmacy services provided outside of inpatient settings, to the telehealth list.

Many patient care services provided by pharmacists are clinically appropriate for telehealth, including: medication management services, management of chronic conditions[8] (e.g., diabetes, hypertension[9]), substance use disorder treatment, pain management, medication reconciliation,

[7] See, SEC. 3703. INCREASING MEDICARE TELEHEALTH FLEXIBILITIES DURING EMERGENCY PERIOD – which states "Section 1135 of the Social Security Act (42 U.S.C. 1320b– 5) is amended— (1) in subsection (b)(8), by striking ''to an individual by a qualified provider (as defined in subsection (g)(3))'' and all that follows through the period and inserting '', the requirements of section 1834(m).''; and (2) in subsection (g), by striking paragraph (3)," available at: https://www.congress.gov/116/plaws/publ136/PLAW-116publ136.pdf

[8] DeZeeuw EA, Coleman AM, Nahata MC. Impact of telephonic comprehensive medication reviews on patient outcomes. Am J Manag Care. 2018;24(2):e54-e58.

[9] Margolis KL, Dehmer SP, Sperl-Hillen JA, et al. Cardiovascular events and costs with home blood pressure telemonitoring and pharmacist management for uncontrolled hypertension. Hypertension. 2020;76:1097-1103.

transitions of care, pharmacogenomics, interpretation of diagnostic tests and providing test results, education on healthy lifestyle interventions, and consultations with patients and health care providers. NOTE: These are different from medication therapy management under Part D.

In rural areas, health care options can be limited, and community pharmacies are a critical part of providing care and may be one of only a few health care providers in a community. Due to the shortage of health care providers, particularly in rural areas, and the fact that 90% of Americans live within 5 miles of a community pharmacy, APhA strongly urges HHS and CMS to use enforcement discretion during the PHE, and potentially beyond, to waive 1834(m)(4)C(ii) and **designate pharmacies as originating sites to receive telehealth services, such as those described in the paragraph directly above,** for beneficiaries who may not be able to access telehealth services in their homes and beyond the PHE if/when the originating site exception reverts back to the previous restrictions to maintain beneficiaries' convenient access to health care services.

Implementation of Provisions of the Consolidated Appropriations Act, 2021 (CAA) (Pgs. 39145-39150)

Removal of Geographic Location Requirements

APhA strongly supports the removal of geographic location requirements in order to allow patients' homes as originating sites to access telehealth services for the diagnosis, evaluation, and treatment of mental health disorders and other health conditions. During the COVID-19 PHE, telehealth has enabled both providers and patients to stay safe. Allowing patients to receive telehealth services at home greatly enhances access to care by removing barriers such as transportation challenges, childcare needs, or an inability or unwillingness to attend an in-person visit, such as for agoraphobic patients.

APhA members explained that conducting a telehealth visit when patients are home can also provide helpful insights into their patients' lives by enabling them to see their patients' home environment. Patients are more comfortable and therefore, more open and honest when they are in the privacy of their own homes. Allowing patients to access telehealth services from their homes can aid in conducting comprehensive assessments of the patient's medications, because patients can easily collect all of their medications for review by the pharmacist. This increases the likelihood of the pharmacist identifying duplicate therapies, discontinued therapies, over-the-counter products, expired medications, and excessive supplies as these are often forgotten when attending in-person appointments. In fact, a recent study found the expansion of

pharmacist telehealth-delivered comprehensive medication reviews (CMRs) occurred successfully in medically underserved rural areas/populations.[10]

Requirement for an In-person Visit, Without the Use of Telehealth, Within 6 Months Prior to the First Time the Physician or Practitioner Furnishes a Telehealth Service to the Beneficiary, and Thereafter for Mental Health Services

APhA strongly supports CMS's proposal to allow telehealth for mental health services as established in the CAA. However, we believe that requiring an in-person visit within 6 months prior to the first time the physician or practitioner furnishes a telehealth service to the beneficiary might hinder access to care for beneficiaries in need of mental health services. There is no clinical evidence for an arbitrary in-person requirement before a beneficiary can access telehealth services.[11] Requiring an in-person visit often discourages patients from seeking out mental health care due to stigma. For example, patients that live in small rural communities might not want to be seen entering a behavioral health clinic. In addition, as noted above, patients experience barriers to in-person visits, including transportation challenges, the need to make childcare arrangements, and simply accessing a local mental health provider. Therefore, APhA strongly opposes the requirement for an in-person visit within six months prior to the furnishing of a telehealth service. In addition, APhA opposes requiring an in-person visit at least once within six months before any subsequent Medicare mental health telehealth service. The appropriate visit interval – whether in-person or via telehealth – is patient specific.

Payment of Mental Health Services from Different Practitioners in a Group

CMS is seeking comments regarding the extent to which a patient routinely receiving mental health services from one practitioner in a group might have occasion to see a different practitioner of the same specialty in that group for treatment of the same condition, for both telehealth (with a proposed 6 month in-person requirement) and in-person (non-telehealth) services. While it is beneficial for patients to see the same provider, APhA believes that other practitioners of the same specialty/subspecialty within the same group should be allowed to treat the patient in order to provide needed access during vacation, leave, and other instances in which the practitioner is unable to provide needed services.

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[10] Le, L.D., Paulk, I.R., Axon, D.R., & Bingham, J.M. (2021). Comprehensive Medication Review Completion in Medically Underserved Areas and Populations. Journal of Health Care for the Poor and Underserved 32(3), 1301-1311. Available at: https://muse.jhu.edu/article/802262

[11] American Telemedicine Association. Overview of In-Person Requirements, available at https://www.americantelemed.org/wp-content/uploads/2021/06/ATA-Overview-of-In-Person-Requirements-1.pdf

CMS also states "[i]n addition, fee-for-time compensation arrangements (formerly referred to as locum tenens arrangements), as described in section 1842(b)(6)(D) of the Act, allow for payment to be made to a physician for physicians' services (and services furnished *incident to* [emphasis added] such services) furnished by a second physician to patients of the first physician if the first physician is unavailable to provide the services, and the services are furnished pursuant to an arrangement that is either informal and reciprocal, or involves per diem or other fee-for-time compensation for such services."

Pharmacists may provide mental health services incident to the services of the billing physician or non-physician practitioner (NPP), under § 410.26, especially related to the management of medications used to treat mental health conditions. Accordingly, APhA respectfully asks CMS to clarify that this alternative policy will also be applied to pharmacist members of patient care teams providing mental health services under incident to physician arrangements, within the same group to all physicians or practitioners.

Pharmacists are currently providing the following in-person and telehealth-provided services—for a more complete list refer to Appendix 1 (attached to our comments) – Services and Activities Performed by Mental Health Clinical Pharmacists:

- Initial consult appointment through direct patient care via telehealth, face-to-face over video conference, typically lasting 60 minutes
- Comprehensive medication management to include:
    - Assess all of a patient's medications – prescription, nonprescription, vitamins, and supplements;
    - Assess each medication to ensure that it is appropriate, effective, safe, and can be taken as intended;
    - Identify and address medication-related problems;
    - Develop individualized care plans with therapy goals and personalized interventions;
    - Prescribe medications and order laboratory or other diagnostic tests (varies by state);
    - Follow-up appointments at regular intervals (e.g., weekly, biweekly or monthly) to evaluate response, adverse effects, progress toward treatment goals, and to adjust medications as needed; typically lasting 30 minutes;
    - Educate patient and family about medications and lifestyle modifications;
    - Refer to other providers and specialists for services such as diagnostic clarification, psychotherapy, and dietary counseling; and

  Collaborate closely with other mental health team members to clarify diagnoses and discuss complex medication regimens.

Payment for Medicare Telehealth Services Furnished Using Audio-Only Communication Technology (Pg. 39147-39149)

During the COVID–19 PHE, CMS used waiver authority under section 1135(b)(8) of the Act to temporarily waive the requirement, for certain behavioral health and/or counseling services and for audio-only evaluation and management (E/M) visits, that telehealth services must be furnished using an interactive telecommunications system that includes video communications technology.

CMS states in the proposed rule, "[g]iven the generalized shortage of mental health care professionals (https://bhw.hrsa.gov/sites/default/files/bureau-healthworkforce/data-research/technicaldocumentation-health-workforcesimulation-model.pdf), and the existence of areas and populations where there is limited access to broadband due to geographic or socioeconomic challenges, we believe beneficiaries may have come to rely upon the use of audio-only communication technology in order to receive mental health services, and that a sudden discontinuation of this flexibility at the end of the PHE could have a negative impact on access to care."

We agree. Accordingly, we support CMS amending § 410.78(a)(3) to define interactive telecommunications system to include audio-only communications technology when used for telehealth services for the diagnosis, evaluation, or treatment of mental health disorders furnished to established patients when the originating site is the patient's home. Pharmacists are using audio-only communications to deliver telehealth services, especially during the PHE. APhA's May 2021 *Pharmacist Experience in Telehealth Survey* found that 86% of respondents were using audio-only communications to deliver telehealth services.[12] Audio-only communications were used 60% of the time to deliver telehealth services, compared to 36% for audio/video technology.[13]

Audio-only tele-mental health services provided by pharmacists have been proven effective. For example, a 2018 pilot study found that a pharmacist-conducted telephonic assessment of mental health patients' current nutrition, physical activity, and sleep status and subsequent counseling and education improved Duke Health Profile (Duke) scores.[14] Specifically, patients

[12] American Pharmacists Association. May 2021. Pharmacist Experience in Telehealth Survey, Data on file.
[13] Id.
[14] Bingham J., Axon D.R., Scovis N., Taylor A.M. Evaluating the Effectiveness of Clinical Pharmacy Consultations on Nutrition, Physical Activity, and Sleep in Improving Patient-Reported Psychiatric Outcomes for Individuals with Mental Illnesses. Pharmacy (Basel). 2018 Dec 22;7(1):2. doi: 10.3390/pharmacy7010002. PMID: 30583547; PMCID: PMC6473796. Available at: https://pubmed.ncbi.nlm.nih.gov/30583547/

experienced higher Duke physical scores (p = 0.007) and significantly lower anxiety (p = 0.025), depression (p = 0.001) and anxiety-depression scores (p = 0.005) at follow-up.[15]

For documentation purposes, CMS proposes to create a service-level modifier that would identify mental health telehealth services furnished to a beneficiary in their home using audio-only communications technology. APhA believes that such a service-level modifier would be beneficial in tracking utilization of audio-only telehealth services. However, APhA does not believe that additional documentation should be required in the patient's medical record to support the clinical appropriateness of audio-only telehealth services for mental health in the event of an audit or claims denial. Documentation of the use of audio-only mental health telehealth services should be sufficient without imposing an additional burden on practitioners to document the clinical appropriateness of the audio-only services.

To respect patients' preferences, APhA supports CMS's proposal to provide payment for audio-only mental health services only in instances where the beneficiary is unable to use, does not wish to use, or does not have access to two-way, audio/video technology. However, APhA is concerned that CMS's proposal to limit payment for audio-only services to services furnished by practitioners who have the capacity to furnish two-way, audio/video telehealth services inappropriately limits patient access to care by excluding those practitioners – especially rural practitioners – who may not have access to audio/video technology.

Expiration of PHE Flexibilities for Direct Supervision Requirements (Pgs. 39149-39150)

In the CY 2021 PFS final rule (85 FR 84538 through 84540), CMS finalized through the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021 a policy to change the definition of ''direct supervision'' during the PHE for COVID–19 (85 FR 19245 through 19246). This pertains to supervision of diagnostic tests, physicians' services, and some hospital outpatient services, to allow the supervising professional to be immediately available through virtual presence using real-time, interactive audio/video technology, instead of requiring their physical presence. The temporary exception allows the immediate availability for direct supervision through virtual presence, which facilitates the provision of telehealth services by clinical staff of physicians and other practitioners—including pharmacists—incident to their professional services.

CMS is seeking comments on whether this flexibility should potentially be made permanent, where CMS would "revise the definition of ''direct supervision'' at § 410.32(b)(3)(ii) to include immediate availability through the virtual presence of the supervising physician or practitioner

[15] Id.

using real time, interactive audio/video communications technology without limitation after the PHE for COVID–19", or if CMS should continue the policy in place for a short additional time to facilitate a gradual sunset of the policy.

APhA strongly urges CMS to make the flexibility for providing "direct supervision" of auxiliary personnel, including pharmacists, permanent by revising the definition under § 410.32(b)(3)(ii). Supervision via real-time audio/video technology provides flexibility in collaborative care delivery and helps to overcome barriers in access to care. Throughout the pandemic, pharmacists have worked under direct supervision using real-time audio/video technology to deliver a variety of patient care services, including chronic disease management, medication management services, and Annual Wellness visits.

With regard to a service level modifier, APhA does not believe that a service level modifier should be required to identify when the requirements for direct supervision were met using two-way, audio/video communications technology. Supervision is supervision – whether done in-person or via audio/video technology.

Permanent Adoption of the Virtual Check-in Service (HCPCS Code G2252) (Pg. 39150)

In the CY 2021 PFS Final Rule (85 FR 84536), CMS established, on an interim basis, HCPCS code G2252 for an extended virtual check-in (11-20 minutes), which allows healthcare providers to briefly check in with an established patient using any form of synchronous communication technology, including audio-only. APhA supports CMS's proposal to permanently adopt coding and payment for HCPCS code G2252 as described in the CY 2021 PFS final rule.

Remote Therapeutic Monitoring (CPT Codes 989X1, 989X2, 989X3, 989X4, and 989X5) (Pgs. 39173-39174)

CMS is proposing to value new Remote Therapeutic Monitoring (RTM) codes (CPT codes 989X4 and 989X5), used to monitor health conditions, including musculoskeletal system status, respiratory system status, *therapy (medication) adherence* [emphasis added], and *therapy (medication) response* [emphasis added], which includes collection of non-physiologic data. Reportedly, data also can be self-reported as well as digitally uploaded. In contrast, remote physiologic monitoring (RPM) requires that data be physiologic and digitally uploaded.

CMS states that according to AMA's RVS Update Committee (RUC) documents, the new RTM coding was created to allow practitioners who cannot bill RPM codes to furnish and bill for services that look similar to those of RPM. RTM codes are classified as general medicine codes.

CMS is seeking comment on how to remedy the issues related to the RTM code construction in order to permit health care providers who are not physicians or NPPs to bill the RTM codes.

Overall, APhA supports the concept of RTM services and believes that pharmacists have an important role to play in their delivery. As with the introduction of RPM services, there are many clarifications needed to fully evaluate this proposal and provide feedback (e.g., will other conditions beyond musculoskeletal and respiratory be considered; what is the scope of devices and data permitted, what will 989X1-X3 be valued, etc.). APhA strongly advocates that CMS use its authority to permit pharmacists to deliver and bill for RTM services. At a minimum, clinical staff, including pharmacists, should be eligible to deliver RTM services under general supervision, similar to RPM and continuous glucose monitoring (CGM) services. APhA offers the following examples of how pharmacists are currently involved in patient monitoring services, including RPM, and how pharmacists could be leveraged for RTM service delivery.

As the medication experts on patient care teams, pharmacists are uniquely positioned to administer RTM services. For example, pharmacists are currently collaborating with local clinics or through collaborative practice agreements (CPAs) with physicians or NPPs and providing CGM services for CPT codes 95249 (personal CGM training/download), 95250 (professional CGM insertion/download), and CPT 95251 (CGM interpretation). Working collaboratively with the person with diabetes, pharmacists create an action plan that could include keeping a food/activity log prior to the next visit and strategies to reduce hypoglycemia and hyperglycemia, replicate the positive, and improve day-to-day consistency. Pharmacists also make specific medication recommendations or directly adjust medications under a CPA.

As the RTM codes are based on RPM services, current RPM services pharmacists are performing (these fees apply to use of blood pressure monitoring, glucose checks, weight scale, and pulse oximeter) include:

- Blood Pressure Cuff (Auto-pair BP device connected to Phone or Hub)
- Weight Scale (Auto-pair Scale device connected to Phone or Hub)
- Pulse Oximeter (Auto-pair PulseOx device connected to Phone or Hub)
- Blood Glucometer (Auto-pair Glucometer device connected to Phone or Hub)
- International Normalized Ratio (INR) – anticoagulation monitoring
- Hub (Cell connected Hub used if no Phone available)

CPT Codes:

- 99453: Initial set-up and patient education on use of equipment (one-time fee)

- 99454: Supply of devices, collection, transmission and report/summary services to the clinician (monthly)
- 99457: Remote physiological monitoring services by clinical staff/MD/QHCP for first 20 minutes of RPM services (monthly)
- 99458: Remote physiological monitoring services by clinical staff/MD/QHCP that exceeds first 20 minutes of RPM services (monthly)

Pharmacist-provided RTM services CMS should consider include:

- Pharmacogenomics (PGx) counseling services (Note: The Food and Drug Administration (FDA) approved modifications to more than 30 drug labels to include pharmacogenomic information).[16]
    - A patient app can be initiated for storing PGx genetic profile data that can be provided at health care visits to inform prescribing and follow-up monitoring decisions for medication therapies.
- Drug therapy monitoring for toxicity and side effects – e.g., monitoring of direct-acting oral anticoagulants (DOACs)
- Medication adherence checks
    - Initial review
    - Monthly follow-up – this should be done similar to RPM where the clinician is paid for the patient being adherent in time spent of 20-minute increments for their efforts to get the patient adherent. Medication adherence would either be measured by an adherence device, or (less accurately and easily gamed) by refill on time status. Using a device or check-in to make sure the patient is confirming they are taking their medications when they are supposed to on schedule would be ideal.
- Respiratory inhaler use – use of device to monitor inhaled doses to make clinical decisions on whether alternate medications are needed (e.g., overuse of a beta-agonist for asthma may indicate the need for a long-acting inhaler).

As stated in the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations bill, 2022 H. Rept. 117-96, "The Committee encourages CMS to create a mechanism to provide greater visibility into the scope and outcomes of the Medicare services currently provided by pharmacists." RTM services provide the perfect opportunity to align CMS with congressional intent and recognize pharmacists as providers of remote therapeutic monitoring services (RTM).

[16] FDA. Table of Pharmacogenomic Biomarkers in Drug Labels. Content current as of: 03/23/2021. Available at: https://www.fda.gov/drugs/science-and-research-drugs/table-pharmacogenomic-biomarkers-drug-labeling

Principal Care Management and Chronic Care Management (CPT Codes 99490, 99439, 99491, 99X21, 99487, 99489, 99X22, 99X23, 99X24, and 99X25) (Pgs. 39174-39176)

In past comments, APhA requested that CMS expand access to chronic care management services for patients excluded under the current eligibility requirement who have a single high-risk disease or complex chronic condition that is not well accounted for in existing coding and could benefit from these services. Accordingly, APhA and its members strongly supported CMS's proposal allowing physicians to offer Principal Care Management (PCM) services that will pay treating clinicians (G2064) and clinical staff (G2065) for treating patients who need chronic care management, but only have one high-risk chronic condition. Additionally, as of January 1, 2021, Federally Qualified Health Centers (FQHCs)/Rural Health Clinics (RHCs) may now report and receive payment for PCM but must report the service using code G0511. APhA is also appreciative of CMS' efforts to expand the CCM code set to incentivize greater uptake of CCM.

We also strongly support allowing pharmacists and others providing CCM services to continue to obtain beneficiary consent under general supervision. With the ongoing pandemic, this flexibility has permitted CCM services to continue, unimpeded to patients with multiple chronic conditions. Many times, the need for CCM is identified outside of an office visit (when a critical lab, such as an A1c, comes back after a visit and is unexpectedly high, or when a patient calls in reporting high home blood pressure readings, etc). Members of the care team working under general supervision of the physician or NPP should be able to obtain beneficiary consent. Without general supervision, the feasibility and, thus, the reach/impact of CCM will be unnecessarily limited. Additionally, the care team commonly does a comprehensive explanation of the benefits of CCM, the potential costs associated with CCM, and the treatment goals set for the patient.

For CY 2022, the RUC resurveyed the CCM code family, including Complex Chronic Care Management (CCCM) and Principal Care Management (PCM), and added five new CPT codes, to transition all of the PCM G codes to CPT codes. This includes the two codes for utilizing "clinical staff," such as pharmacists, including: 99X24 (Principal care management services, for a single high-risk disease first 30 minutes of *clinical staff time* [emphasis added] directed by physician or other qualified health care professional, per calendar month), and 99X25 (Principal care management services, for a single high-risk disease each additional 30 minutes of *clinical staff time* [emphasis added] directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)). APhA supports these new codes as well as the proposed RUC values for the 10 codes in the CCM family. To realize CMS' goals of "ensuring continued and consistent access to these crucial care

management services," we encourage CMS to continue to examine the reimbursement rates for the CCM family of services, especially as the proposed reduction in the conversion factor for 2022 will offset some of the gains realized by increases to the RUC values.

APhA's members, in collaboration with physicians and other team members, care for patients with a variety of chronic diseases in various practice settings, including patients who experience an exacerbation necessitating more intensive care. Pharmacists' medication expertise can be leveraged for CCM and PCM in clinical staff time activities such as medication management, medication reconciliation, adherence, and chronic care management. From a transparency perspective, APhA urges CMS to find mechanisms to understand the types of clinical staff, including pharmacists, who are providing CCM and PCM services.

Comment Solicitation for Impact of Infectious Disease on Codes and Rate setting (Pg. 39179)

CMS heard from stakeholders about higher costs due to additional supplies, such as personal protective equipment, and increased time that physicians, NPPs and their clinical staff may spend with patients to mitigate further spread of infection when, for example, stakeholders are working to rule out a COVID–19 infection or furnishing other services to a patient with a confirmed COVID–19 infection. CMS's payment systems, including the PFS, are not generally designed to accommodate more acute increases in resource costs. CMS is asking for feedback from stakeholders about additional strategies to account for PHE-related costs, including feedback on the specific types of services and costs that may benefit from further review, such as infectious disease control measures, research related activities and services, or PHE related preventive or therapeutic counseling services. Specifically, CMS is interested in detailed feedback from stakeholders to help inform whether CMS should consider making changes to payments for services or develop separate payments for such services in future rulemaking.

Pharmacists play an essential role in decreasing antimicrobial resistance, implementing infection control processes in their practices, and testing for certain infections, as authorized. Pharmacists' responsibilities for antimicrobial stewardship and infection prevention and control include promoting the optimal use of antimicrobial agents, reducing the transmission of infections, and educating health professionals, patients, and the public.

As CMS understands, pharmacies have remained open during the pandemic to provide care to patients. Yet, with HHS activating pharmacies as COVID-19 testing sites and pharmacists as vaccinators, these pharmacists and pharmacy personnel often continue to serve their communities without proper personal protection equipment (PPE), or often need to finance providing proper protections themselves. Accordingly, APhA recommends CMS develop

separate payments (for pharmacists acting autonomously or as clinical staff for spending additional time mitigating and preventing infection during the PHE), and/or include pharmacists and pharmacies in payments to health care facilities and providers for equipment and PPE so they can continue to serve patients and protect themselves.

Comment Solicitation on Separate PFS Coding and Payment for Chronic Pain Management (Pgs. 39179-39182)

CMS recognizes there are no existing codes that specifically describe the work of the clinician involved in performing the tasks necessary to deliver pain management care. CMS states that there are complexities in treating pain management patients that could include lifestyle discussion, ongoing medication management (such as opioid tapering or discontinuation, when appropriate), behavioral health care, preparation and updating of a care plan, consideration of federal and other opioid prescribing limits and guidelines, Prescription Drug Monitoring Program checks, electronic prescribing requirements, special licensing requirements (controlled substance licenses; buprenorphine ''X-waivers''), interdisciplinary interactions, prescription drug coverage, CMS high-prescriber oversight, consideration of out-of-pocket costs, and other issues.

CMS is soliciting comment on whether it should consider creating separate coding and payment for medically necessary activities involved with chronic pain management and achieving safe and effective dose reduction of opioid medications when appropriate, or whether the resources involved in furnishing these services are appropriately recognized in current coding and payment.

Other activities CMS could consider include toxicology screens, universal precautions, and referral for physical therapy and physical medicine and rehabilitation.

CMS is interested in feedback regarding whether the resource costs involved in furnishing these activities would be best captured through an add on code to be billed with an E/M visit or a stand-alone code.

CMS is also interested in whether any components of the service could be provided ''incident to'' the services of the billing physician who is managing the beneficiary's overall care similar to the structure of the Behavioral Health Integration (BHI) codes.

As CMS states, the high prevalence of pain exacts a substantial economic toll in the United States.[17] In addition, the 2019 HHS Pain Management Best Practices Inter-Agency Task Force (PMTF) report emphasized multi-modal, multidisciplinary approaches that include various modalities for acute and chronic pain. Accordingly, pain management requires an all-hands-on-deck approach. Shortages of pain management specialists and behavioral health providers, and suboptimal or lack of coverage for some treatments recommended in a multi-modal approach to pain care are barriers that impact many patients with chronic pain. APhA supports separate stand-alone codes for chronic pain management and opioid reduction services, both to highlight the importance of chronic pain management services and appropriate patient-centered opioid tapering and to gain further insights into the work required to provide these services, including the work attributed to pharmacists.

As HHS has stated, "[t]aken together, the severe shortage of pain medicine specialists and under-resourced and insufficiently trained PCPs treating pain along with insufficient access to behavioral therapists, pharmacists, and other members of the pain management team has hindered the development of efficient, cost-effective health care delivery models to treat chronic pain."[18]

CMS should recognize all chronic pain management and opioid reduction services provided by pharmacists under incident to physician services arrangements and provide payment parity for the complexity of service delivered and for in-person and remote services. Among others, pharmacists' chronic pain management services include medication management services, interprofessional collaboration and consultation, pain and medication education, support for patients' self-management of pain, and conducting services with an acceptance of responsibility to be culturally responsive and decrease stigma.[19] In addition to the outpatient setting, a 2016 study found that pharmacists' involvement in pain management on an inpatient consult service had a positive impact on pain scores and improvement in functionality.[20] Specifically, patients displayed a significant reduction in their pre- and post-consult pain intensity scores on a 0 to 10 numerical rating scale (6.15 vs 3.25; $p < .001$). Likewise, a significant reduction in pain intensity scores was seen from pre-consult to pre-discharge (6.15 vs 3.6; $p < .001$). Overall functional improvement, specifically sleep, mobility, and appetite, was seen in 86.6% of patients.[21] Pharmacists also play an important role in pain management as patients transition from one

[17] Gaskin DJ, Richard P. The economic costs of pain in the United States. The Journal of Pain. 2012 Aug 1;13(8):715–24.
[18] https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf
[19] Murphy, L., Ng, K., Isaac, P., Swidrovich, J., Zhang, M., & Sproule, B. A. (2021). The Role of the Pharmacist in the Care of Patients with Chronic Pain. *Integrated pharmacy research & practice*, *10*, 33–41. Available at: https://doi.org/10.2147/IPRP.S248699
[20] Mathew, S., Chamberlain, C., Alvarez, K. S., Alvarez, C. A., & Shah, M. (2016). Impact of a Pharmacy-Led Pain Management Team on Adults in an Academic Medical Center. *Hospital pharmacy*, *51*(8), 639–645. Available at: https://doi.org/10.1310/hpj5108-639
[21] Id.

care setting to another by providing such services as medication reconciliation, medication assessment and monitoring, patient and healthcare provider education, discharge counseling, and post-discharge follow-up and planning.[22]

In addition to appropriate coding, CMS also seeks comment on which healthcare settings and stages in treatment transitions from opioid dependence typically occur. These settings include pharmacies, primary care offices, clinics (including urgent care clinics), emergency departments, treatment facilities for substance use disorder/opioid use disorder, mental health step-down facilities, and others.

Evaluation and Management (E/M) Visits (Pg. 39203)

APhA appreciates that CMS is engaged with stakeholders in an ongoing review of E/M visit code sets and refinements to current policies.

As you know, Congress recently emphasized in the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations bill, 2022 (H. Rept. 117-96):

> "The Committee appreciates CMS' recognition of the expanding roles of pharmacists with broadened scopes of practice. The Committee requests CMS hear from physicians, pharmacists, and other qualified health professionals on their efforts to work with the American Medical Association (AMA) CPT Editorial Panel to develop mechanisms to attribute, report, and sustain pharmacists' medication management and other patient care contributions to beneficiaries in the Medicare Part B program."

APhA also appreciated CMS's statements in the CY 2021 PFS final rule (FR 84583) that "[w]e agree with certain stakeholders that under the general CPT framework, pharmacists could be considered QHPs or clinical staff, depending on their role in a given service." "We understand and appreciate the expanding, beneficial roles certain pharmacists play, particularly by specially trained pharmacists with broadened scopes of practice in certain states, commonly referred to as collaborative practice agreements. We note that new coding might be useful to specifically identify these particular models of care."

Accordingly, APhA requests the opportunity for an in-person or virtual meeting to educate CMS on pharmacist-provided patient care services that meet the requirements for more complex E/M codes.

[22] Sourial, M. & Lesé, M.D. (2017). The Pharmacist's Role in Pain Management During Transitions of Care. *US Pharm*. 2017;42(8)HS-17–HS-28. Available at: https://www.uspharmacist.com/article/the-pharmacists-role-in-pain-management-during-transitions-of-care

First, AMA's CPT Editorial Panel is a **non-governmental body.** It is important to note that the pharmacy profession is well represented within the CPT structure. Daniel Buffington, PharmD, BCPS, a pharmacist, is one of two nonphysician members from the CPT Health Professionals Advisory Committee who sit on the 17 member CPT Editorial Panel. The rest of the CPT Editorial Panel is comprised of physicians and representatives from 4 designated organizations. CPT codes are structured to account for service delivery by a variety of health care professionals, including pharmacists. CMS is the final governmental authority on implementation of any new coding and regulatory guidance. As such, CMS can and should use its regulatory 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).

Second, pharmacists are currently providing care to complex patients in various state and commercial health plans at a level of complexity or time that aligns with E/M codes 99212-99215.[23]

Third, APhA has collected a number of case examples 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.

- 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 the 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 (CGM) to monitor progress in the future. A

[23] Roshan, Jeff. Credentialing and Privileging 101: Essential Steps to Bill for Patient Care Services. Slide 61. Presentation at APhA2018. March 28, 2018, available at: http://apha2018.pharmacist.com/sites/default/files/slides/Cred_and_Priv_101_3-18-18_104AB_HO.pdf

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

APhA also strongly requests that CMS develop mechanisms, in line with congressional intent, 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.

Vaccine Administration Services: Comment Solicitation: Medicare Payments for Administering Preventive Vaccines (Pgs. 39220-39224)

CMS is requesting feedback from stakeholders that would support the development of an accurate and stable payment rate for administration of the preventive vaccines described in section 1861(s)(10) of the Act for physicians, NPPs, mass immunizers—including pharmacists—and certain other providers and suppliers.

COVID-19 Vaccine Administration

As of August 5, 2021, more than 108 million doses of COVID-19 vaccines have been administered and reported by community pharmacies across programs in the U.S. (including 8 million doses through Pharmacy Partnership for Long Term Care Program).[24] For context, almost 349 million doses were administered by August 5, 2021. Therefore, those 108 million doses administered and reported by community (retail) pharmacies accounted for about **31%** of vaccinations at that time.

For COVID-19 vaccine administration, Medicare now pays $40 per administration in all settings, with an additional payment if the vaccine is administered under certain circumstances in the beneficiary's home or residence. APhA strongly supports Medicare maintaining the $40 per administration of the COVID-19 vaccine in all settings. In light of the rising delta variant, we need to maintain access to our vaccinator workforce now more than ever. CMS understands the COVID-19 vaccine administration fee rates adequately recognize the costs involved in administering the COVID-19 vaccine. The COVID-19 vaccine is unlike the highly recognized seasonal influenza vaccine in terms of administration requirements. The processes involved in vaccinating under a COVID-19 environment warrant additional requirements and demands on healthcare personnel. As CMS understands, the administrative fees take into account additional

[24] CDC. Understanding the Federal Retail Pharmacy Program for COVID-19 Vaccination. Page last reviewed: August 11, 2021, available at: https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html

costs to pharmacists and other vaccinators, including storage costs that vary based on the vaccine manufacturer (ultra-cold storage, cold storage, refrigeration), personal protective equipment (PPE) and disinfection costs as well as costs for documentation and public health reporting, important outreach and patient education, and the time spent with patients answering any questions they may have about the vaccine. We strongly encourage CMS to support a reimbursement level that covers the full and complete costs for administration of vaccines (COVID 19 and non-COVID vaccines) in the current COVID-19 environment.

Non-COVID-19 Vaccine Administration

Per the CDC, pharmacists were responsible for giving **more** influenza vaccines than physician offices from 2019-2020 through 2020-2021. For example:

- Week 14 Pharmacy 2020-21 = 47.7 million = 59.2%
- Physician Office 2020-21 = 32.8 million = 40.8%.[25]

Clearly, pharmacists continue to serve an integral role in national vaccination efforts. Regarding vaccine administration for non-COVID-19 vaccines. APhA is very concerned with CMS's continued reduction in reimbursement rates for the valuation of CPT codes for vaccine administration—particularly during a national pandemic. Now is not the time to reduce vaccine administration reimbursement rates, with the national goal of getting all vaccination rates to or exceeding pre-COVID rates, as well as meeting target COVID-19 vaccination rates amidst additional burdens on providers and health care systems.

As mentioned in the proposed rule, CMS has proposed to address the ongoing reduction in payment rates for vaccine administration HCPCS codes in the last **two** PFS rulemaking cycles, but has repeatedly failed to do so—during a national pandemic. Most recently, CMS maintained the CY 2019 national payment amount for immunization administration services for CY 2020—which continues an ongoing cut to vaccine administration rates representing a 44% decrease from 2017, when this service was paid at $25.84 (PE RVU of .54). This represents four straight years with a significant decrease to the PE RVU factor for vaccine administration. Work and malpractice factors remain the same. A review of the practice expense cost files does not support any reduction. Practice expense costs were unchanged in 2018 and increased in 2019, 2020 and 2021. In addition, there is no evidence of decreases in any cost component. In fact, APhA anticipates that practice expenses are likely to be higher during the pandemic where

[25] CDC. Influenza Vaccinations Administered to Adults in Pharmacies and Physician Medical Offices, United States. Page last reviewed: May 5, 2021, available at: https://www.cdc.gov/flu/fluvaxview/dashboard/vaccination-administered.html?web=1&wdLOR=c18350690-8CBB-4635-A530-C9AF7982464E

additional PPE continues to be needed. The reductions further exacerbate gaps in immunization access and may have negative long-term impact on providers' ability to offer the CDC's Advisory Committee on Immunization Practices' (ACIP) recommended immunizations to Medicare patients.

Furthermore, HHS has identified influenza vaccination as an important step to limit the harm of COVID-19. Under the Fourth Amendment[26] to the Declaration Under the Public Readiness and Emergency Preparedness Act (PREP Act), HHS noted that covered countermeasures are those that limit the harm that COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom, might otherwise cause. The Eighth Amendment[27] to the PREP Act reinforced this by expanding the scope of vaccinators covered under the PREP Act to pharmacy technicians and interns, in addition to pharmacists, by recognizing that "[h]ealth risks may increase for individuals who contract seasonal influenza concurrently with COVID-19, thus expanding the scope of authorized vaccinators for seasonal influenza lessens the harm otherwise caused by COVID-19." If HHS is so concerned about increasing seasonal influenza vaccination rates, then payment should be increased to serve as an incentive to increase the pool of vaccinators and access sites.

It is important to note that Medicare payment rates for influenza vaccination do not cover the costs incurred by medical practices delivering influenza immunizations in standard settings. Adjusted to 2003 dollars (considering both scheduled and walk-in vaccinations), per shot losses for health care providers ranged from $3.36 to $32.76—**that was 18 years ago**—losses are likely more significant today.[28] In 2003, the labor costs of one influenza vaccination for a solo/partner practice for a scheduled visit was $2.10 in clinical labor cost; $25.47 for non-clinical labor costs for a total labor cost of $27.57. The total labor cost for a walk-in clinic was $26.42.[29]

As CMS understands, immunizations are an important public health imperative and ensuring that immunization providers are properly reimbursed is key to fostering a sustained environment of timely immunization. Vaccine administration by health care providers in their practices, at the point of care, is an opportunity to improve public health. Recent studies show that inadequate reimbursement for vaccination administration results in missed immunization

[26] 85 FR 79190, December 9, 2020.
[27] 86 FR 41977, August 4, 2021.
[28] Coleman, Margaret. Et. al. Estimating medical practice expenses from administering adult influenza vaccinations. Vaccine 23 (2005) 915–923. Received 22 March 2004; received in revised form 21 July 2004; accepted 26 July 2004
Available online 1 September 2004, available at: https://www.izsummitpartners.org/wp-content/uploads/2015/05/COLEMAN-adult-vaccine-cost-article.pdf
[29] Ibid. See, Table 4.

opportunities and declines in immunization rates.[30] This is especially apparent in cases where national and regional payers opt to pay providers **as little as 50% of the federal rate for COVID-19 vaccine administration**, further narrowing margins needed to sustain these clinical services for all patients.[6] Any reimbursement reductions at the physician/pharmacist level could inhibit the ability to achieve HHS's Healthy People 2030 goals. **Accordingly, once again, APhA strongly urges CMS to restore reimbursement rates for CPT codes for non-COVID vaccine administration so that reimbursement accounts for the cost of the service and continues to encourage providers to offer Medicare beneficiaries ACIP-recommended immunizations at the clinical point-of-care. Action is particularly necessary as we prepare to face the upcoming seasonal influenza season during the ongoing national pandemic.**

Payment for COVID–19 Vaccine Administration in the Home (Pg. 39224-39226)

Now, more than ever, innovative solutions to reach the unvaccinated population are vital to ensuring a path to defeat COVID-19. Accordingly, APhA strongly supports CMS continuing to pay an additional amount of $35.50 per dose, geographically adjusted, for administering the COVID-19 vaccine in the home for certain Medicare patients that have difficulties leaving their homes or are hard-to-reach.

To ensure social distancing and adequate space for COVID-19 vaccine set up and administration (disposal, sanitation, changing out PPE, etc.), APhA supports expanding the allowance for the payment for the additional in-home rate for "[a]n apartment in an apartment complex or a unit in an assisted living facility or group home," to a "[c]ommunal space of a multi-unit living arrangement."

We also strongly support CMS's recent announcement to further boost the administration of COVID-19 vaccination – including second and third doses – in smaller group homes, assisted living facilities, and other group living situations by allowing vaccine providers to receive the increased payment up to 5 times when fewer than 10 Medicare beneficiaries get the vaccine on the same day in the same home or communal setting.[31] To simplify and remove administrative barriers, we also support removing the limit of 5 with an add on payment for each patient vaccinated, whether in a communal space in a group living setting as well as individual rooms due to the urgency to defeat COVID-19 and protect our most vulnerable and immunocompromised populations. APhA certainly agrees with CMS that further enhancements

[30] Loskutova, Natalia. Et. al. Missed opportunities for improving practice performance in adult immunizations: a meta-narrative review of the literature. BMC Family Practice (2017) 18:108, available at: https://www.aafp.org/dam/AAFP/documents/patient_care/nrn/loskutova-missed-opportunities.pdf.
[31] https://www.cms.gov/medicare/covid-19/medicare-covid-19-vaccine-shot-payment

will help ensure that at-risk patients in smaller settings have the same opportunities as others to receive the vaccination.

In addition, as CMS notes, the add-on payment is not billable when providers and suppliers, such as pharmacists, furnish a different preventive vaccine (influenza, pneumonia, HBV) in the home. We agree that the same barriers that could prevent a beneficiary from obtaining a COVID-19 vaccine would also prevent them from obtaining other preventive vaccines. The concept of bringing the vaccine to the homebound is an innovative solution to address the 17.2 million missed adult vaccine doses in 2020.[32] Accordingly, APhA strongly supports CMS establishing a similar add-on vaccine administration payment, similar to the COVID-19 vaccine, for the duration of the pandemic, at a minimum, to furnish other preventive vaccines in the beneficiary's home. We also urge CMS to permit the add-on administration payment for concurrent administration of COVID-19 and other preventative vaccines in the home. For example, it is clinically safe to administer both seasonal influenza and COVID-19 vaccines concurrently.

Monoclonal Antibodies Used To Treat COVID–19 (Pg. 39226)

CMS is interested in additional feedback on the resource costs to administer COVID–19 monoclonal antibody products, such as costs associated with infrastructure, clinical labor, and equipment, including personal protective equipment. CMS recognizes that administering monoclonal antibodies used to treat COVID–19 may be complex due to the need to interact with beneficiaries that have active infections and manage the potential for spreading disease. CMS is interested in information on how the costs to furnish monoclonal antibodies used to treat COVID–19 compare with infusions of other complex biologics,
and how the costs to furnish these products may be different when these products are administered in the home.

Pharmacists nationwide are uniquely positioned to increase awareness of and expand access to COVID-19 monoclonal antibody therapies.[33] Frequent patient interactions create opportunities for pharmacists to educate patients about the importance of seeking COVID-19 monoclonal antibody therapies as soon as possible, if eligible. Authority granted under the PREP Act for pharmacists to order and administer COVID-19 tests and more recently, to order and administer monoclonal antibody therapies (via subcutaneous, intramuscular, or oral routes), positions pharmacists to play a significant role in expanding access to these treatments.

[32] Avalere. Updated Analysis Finds Sustained Drop in Routine Vaccines Through 2020. June 9, 2021, available at: https://avalere.com/insights/updated-analysis-finds-sustained-drop-in-routine-vaccines-through-2020

[33] https://pharmacist.com/Practice/COVID-19/Know-the-Facts

Additionally, a growing number of states are permitting pharmacists to order and administer monoclonal antibody therapies intravenously as well. Now, pharmacists can administer a COVID-19 test, and if positive, assess the patient for eligibility to receive therapy, and then administer the therapy or refer the patient for treatment.
For any COVID-19 monoclonal antibody therapy, regardless of how it's administered, pharmacies must invest in a dedicated area for administration and dedicate staff to monitor for adverse reactions. An additional barrier to administration in some pharmacy settings, such as community pharmacies, is the upfront investment needed in supplies for the management of potential adverse reactions. Accordingly, APhA recommends CMS consider a pilot/supplemental funding for community pharmacies to implement the infrastructure to administer these services.

In addition, another significant barrier to maximizing the use of pharmacists to deliver monocolonal antibody therapies is turn-around times on Medicare reimbursement. Our members currently billing Part B as mass immunizers for ordering and administering these therapies have encountered delays from CMS in processing claims for reimbursements. In addition, resource costs for personnel, equipment, and infrastructure for administering monoclonal antibody treatments in pharmacies are estimated to break-even, if not result in a loss if there is an adverse event. Therefore, APhA urges CMS to issue pharmacist/pharmacy specific guidance on pharmacy billing for these therapies outlining specific, rapid turn-around of Medicare reimbursements for Medicare Administrative Contractors (MACs) that covers the entirety of administration costs in a pharmacy setting to fully activate and incentive pharmacists to ensure patients have local access to these lifesaving therapeutics. We also encourage CMS to provide technical assistance to pharmacies along with an evaluation of the costs to administer in a pharmacy. We would be happy to meet with CMS to overview establishing a successful, business sustainable pharmacy-based model to administer and maintain beneficiaries' access to monoclonal antibody treatments.

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)—Telecommunications Technology (Pgs. 39235-39238)

Section 1861(aa)(1) defines RHC services and (3) for FQHCs as physicians' services and such services and supplies that are furnished as an incident to a physician's professional service, and items and services as well as certain vaccines and their administration. It also includes services furnished by a PA, NP, clinical psychologist, or clinical social worker and services and supplies furnished as incident to these services as would otherwise be covered if furnished by a physician or incident to a physician's service.

APhA recommends CMS specify the list of incident to services furnished by pharmacists at RHCs and FQHCs, such as treating patients with depression, anxiety, insomnia, and PTSD. Pharmacists are actively engaged in helping make medication adjustments for their patients with mental health disorders, which are very common for psychiatric conditions.

To ensure that beneficiaries can access services furnished by RHCs and FQHCs in a manner similar to mental health services under the PFS after the PHE, CMS also stated in the proposed rule that it believes it is appropriate to consider modifying the regulatory definition of a mental health visit to provide for remote access to RHC and FQHC services. Therefore, to avoid both the inequities in access to modes of care, and to avoid potentially problematic interruptions to care or the negative consequences of fragmented care, for CY 2022, CMS is proposing to revise the regulatory requirement that a RHC or FQHC mental health visit must be a face-to-face (that is, in person) encounter between a RHC or FQHC patient and a RHC or FQHC practitioner to also include encounters furnished through interactive, real-time telecommunications technology, but only when furnishing services for the purposes of diagnosis, evaluation, or treatment of a mental health disorder.

Additionally, similar to the discussion of proposals for mental health services furnished under the PFS, as described in section II.D. above of this proposed rule, CMS believes that mental health telehealth services furnished via audio-only communications technology would increase access to care, especially in areas with poor broadband infrastructure and among patient populations that either are not capable of, or do not consent to, the use of devices that permit a two-way, audio/video interaction.

APhA supports CMS's proposal to apply the regulatory definition of remote mental health visits to the mental health services provided at RHCs and FQHCs, both through audio/video telehealth as well as audio-only communications technologies.

Medicare Diabetes Prevention Program (MDPP) (Pgs. 39303-39308)

CMS's MDPP has experienced challenges recruiting suppliers to participate in the expanded model, which has limited beneficiary access to the preventive services offered under the expanded model. Existing and prospective suppliers have reported that the length of the set of MDPP services and the payment timing and amounts have made implementation and operation of MDPP burdensome and has hindered participation. Despite limiting the ongoing maintenance sessions phase to 1 year, CMS has heard that the MDPP suppliers find the implementation, operation, and costs of the ongoing maintenance sessions phase burdensome. Currently, more than 1,000 organizations nationally are eligible to become MDPP

suppliers based on their preliminary or full CDC Diabetes Prevention Recognition Program (DPRP) status. However, only 27 percent of eligible organizations are participating in MDPP.

As a CDC DP17-1705 cooperative agreement participant[34] with 4-years of experience in working with providers of the National DPP, the APhA Foundation is considering applying as an MDPP supplier. However, our APhA Foundation team believes that the following items represent key, known challenges for pharmacies as it relates to their participation in MDPP:

1. The requirement to deliver the MDPP in-person is a significant deterrent (particularly within the context of the pandemic, but also otherwise). Our experience indicates that a combination service delivery program that offers DPP in a flexible format that allows for in-person (face-to-face), telehealth (distance learning), and digital (online) options provides a higher likelihood of both engaging and supporting participants in completion of the program.
2. The MDPP program billing complexity and payment/coding process is very labor intensive, complex, and has financial incentives that are sub-optimally aligned in that accountability (and payment retractions) are placed on providers for circumstances that are not within their control. Improving incentive alignment for process measures that are within MDPP provider control along with complexity reduction related to coding should be considered and made to reduce disincentives to participation. In addition, as CMS mentions, payment timing or turnaround on reimbursements for MDPP services significantly hinder participation in the program vs. the resource costs to a supplier.
3. The arduous application process and requirements for organizations to become a MDPP supplier will need technical assistance for onboarding pharmacy practices, particularly if seeking to do this at scale.

In conjunction with the proposed change to remove the ongoing maintenance sessions phase from the MDPP services period, CMS is proposing to redistribute a portion of the ongoing maintenance sessions phase performance payments to certain core and core maintenance session performance payments to address stakeholder concerns that the current MDPP payment structure does not cover reasonable costs of MDPP suppliers to deliver the MDPP set of services. The proposed maximum payment of $661.00 over a 1-year service period is less than the current maximum payment of $704.00 under the original 2-year payment structure. Despite

[34] https://www.cdc.gov/diabetes/programs/stateandlocal/funded-programs/dp17-1705.html

the reduction in the overall maximum payment, CMS believes the proposed payment structure would have a net positive effect on the MDPP suppliers.

CMS data from the DPP model test showed beneficiaries who finished at least nine (9) sessions of the model were considered ''completers'' and had better weight loss and lower Medicare spending than non-completers (those who attended fewer than 9 sessions). The DPP model test showed that beneficiaries who attend nine or more sessions will, on average, experience a 6.24 percentage point increase in weight loss compared to beneficiaries attending fewer than nine sessions. CMS anticipates the proposed changes to the MDPP payment structure, which would pay a total of $61 more per beneficiary who attends at least 9 sessions than what is currently paid, would encourage existing suppliers to retain MDPP beneficiaries given the one-year commitment versus two for the MDPP set of services.

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. Ninety percent of Americans live within 5 miles of a community 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. Even with CMS's modifications in the proposed rule, including the waiver of the $599 provider enrollment application fee, APhA continues to have concerns about the MDPP fee schedule, payment turnaround and whether it is a viable financial model to support a broad scale, high quality, meaningful program. APhA offers its assistance to CMS to test and evaluate virtual MDPP services after the conclusion of the PHE. APhA believes that participants are better able to complete the MDPP if they can attend sessions remotely. To expand participation in the program, APhA recommends 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 of in-person and virtual-only be eligible to furnish MDPP services using all delivery modes at any time during the 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 financially sustainable to increase the currently low participation rates and achieve its intended goal of benefitting patients.

Comment Solicitation on Specimen Collection Fee and Travel Allowance for Clinical Diagnostic Laboratory Tests (Pg. 39308-39310)

CMS states that effective April 1, 2014, the nominal fee that would otherwise apply for a sample collected from an individual in a skilled nursing facility (SNF) or by a laboratory on behalf of a home health agency (HHA) is $5 (see § 414.507(f)), and the relevant HCPCS code is G0471). In 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 by physicians using CPT code 99211.

In the proposed rule, CMS states "we believe that collecting a specimen for COVID–19 testing may incur higher costs than similar specimen collection services, which require a trained laboratory professional, but not additional precautions, to minimize exposure risk." Despite comments that COVID–19 will continue to spread and may become an ongoing and/or seasonal infectious disease event beyond the immediate PHE, CMS continues to believe that the laboratory specimen collection fees for COVID–19 CDLTs established in the context of and for the duration of the PHE for the COVID–19 pandemic should conclude at the termination of the PHE. This statement may have been made before the spread of the ongoing delta variant and clearly does not bode well for identifying, tracking and preventing community spread of COVID-19 and the ongoing pandemic among the unvaccinated which has significantly increased the need for and access to pharmacist and other provider COVID-19 point of care testing.

As you know, in the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations bill, 2022 (H. Rept. 117-96), Congress also stated "CMS' only option for symptom assessment, specimen collection, and patient counseling by pharmacists is to enter into an incident to arrangement with a physician or non-physician practitioner (NPP)." APhA respectfully disagrees. CMS can, and has, used its regulatory discretion, within its own authority, to establish G codes and can do so for pharmacies to provide all COVID-19 testing and specimen collection services for Medicare beneficiaries.

Congress continues under H. Rept. 117-96, to state "[t]he Committee is concerned that most community pharmacists do not have incident to arrangements with physician practices or NPPs, which inhibits the goal of widely accessible COVID–19 testing in community pharmacies. The Committee requests CMS hear from physicians and other qualified health care professionals on their efforts to work with the AMA CPT Editorial Panel to develop coding options for pharmacists' provision of symptom assessment, specimen collection, and patient counseling, when ordering and administering COVID–19 point of care tests at community

pharmacies *equivalent to all other health care professionals*. [emphasis added]." APhA would welcome such a meeting to discuss establishing equivalent coding options for the same COVID-19 testing services provided by pharmacists in line with congressional intent. In addition, APhA again points out that AMA can develop codes for pharmacists, but CMS can and should use its authority to provide coverage for such codes.

Even with the allowance for physicians to use CPT code 99211 for clinical staff conducting specimen collection for COVID-19 testing services, this option does not cover the time and complexity of COVID-related testing services for 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 all of the specimen collection and other services related to point of care tests, which seems to conflict with the clear explanation in FDA's recent FAQ.[35] 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.[36] Therefore, APhA specifically requests CMS amend and/or use regulatory discretion of 42 CFR §410.32 to appropriately reflect FDA's FAQ, the HHS Office of the Assistant Secretary for Health (OASH) guidance[37] and HHS OGC Advisory Opinion to implement a direct payment pathway for COVID-19 testing-related services in pharmacies that is "equivalent to all other health care professionals."

Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs) (Pgs. 39317-39319)

Geographic and Annual Updates to the Adjustment for Weekly Bundled Payments for Take-Home Supplies of Opioid Antagonist Medications

[35] 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 11/16/2020) – which 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." Content current as of: 12/10/2020, available at: https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2

[36] 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

[37] 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

APhA believes it is reasonable for CMS to revise the regulation at § 410.67(d)(4)(iii) to include the adjustment for take-home supplies of opioid antagonist medications in the list of items that will be updated annually using the Medicare Economic Index (MEI). In addition, APhA believes it is reasonable for CMS to revise the regulation at § 410.67(d)(4)(ii) to include the adjustment for take-home supplies of opioid antagonist medications in the list of items for which the non-drug component will be geographically adjusted using the Geographic Adjustment Factor (GAF).

Duplicative Payments

CMS proposes to revise § 410.67(d)(5) to state explicitly that payments for medications that are delivered, administered or dispensed to a beneficiary as part of an adjustment to the bundled payment are considered a duplicative payment if a claim for delivery, administration or dispensing of the same medication(s) for the same beneficiary on the same date of service was also separately paid under Medicare Part B or Part D. APhA urges CMS to evaluate realistic mechanisms to address unanticipated duplication before implementing this provision.

Proposed OTP Coding and Payment for New Nasal Naloxone Product

APhA supports CMS's proposal to create a new add-on G-code describing a take-home supply of a new, higher dose naloxone hydrochloride nasal spray product, and price the code based on the established methodology under the OTP benefit for determining the adjustment for take-home supplies of opioid antagonist medications at § 410.67(d)(4)(i)(E). APhA believes that CMS's proposal to price the drug component of the code based on an assumption of a typical dosage for a take-home supply of this new product to be a box of two 8 mg nasal sprays is appropriate. However, APhA opposes limiting payment for the add-on code to once every 30 days except when a further take-home supply of the medication is medically reasonable and necessary. It would be burdensome for providers to be required to document when a take-home supply is "medically reasonable and necessary." Opioid overdoses lead to deaths when naloxone isn't available, and APhA believes that there should not be limits and/or burdensome restrictions to access to this inexpensive, life-saving drug.

Counseling and Therapy Furnished via Audio-Only Telephone Calls

As previously noted in the Telehealth section of these comments, APhA supports the provision allowing payment for behavioral health services to established patients via audio-only telephone calls when the originating site is the patient's home, including counseling and therapy services provided through OTPs. Accordingly, APhA supports CMS's proposal to

revise the regulations at § 410.67(b)(3) and (4) to allow OTPs to furnish therapy and counseling using audio-only telephone calls rather than via two-way interactive audio/video communication technology after the conclusion of the COVID-19 PHE in cases where audio/video communication is not available to the beneficiary, provided all other applicable requirements are met. We strongly agree with CMS's conclusion that allowing audio-only telephone calls will facilitate broader access to services.

For documentation purposes, CMS proposes to require OTPs to append modifier 95 (Synchronous Telemedicine Service Rendered via Real-Time Interactive Audio and Video Telecommunications System) when two-way interactive audio/video communication technology is used to furnish additional counseling and therapy services billed under the add-on code (HCPCS code G2080). APhA believes that modifier 95 would be beneficial in tracking utilization of audio/video communication technology. However, APhA opposes as burdensome CMS's proposal to require OTPs to document in the beneficiary's medical record the rationale for using audio-only telephone calls as well as the requirement for OTPs to document that they had the capacity to furnish the services using two-way, audio/video communication technology, but instead, used audio-only technology because audio/video communication technology was not available to the beneficiary. In addition to being burdensome, APhA is concerned that CMS's proposal to limit payment for audio-only services to services furnished by OTPs that have the capacity to furnish two-way, audio/video services inappropriately limits patient access to care by excluding those programs – especially rural OTPs – that do not have access to audio/video communication technology. CMS should not be creating additional barriers to care for OUD. APhA supports delaying any documentation requirements to services furnished after the end of the PHE.

Pharmacists Providing Mental Health and SUD/OUD Services Should Receive Attribution, Recognition, and Compensation by CMS

Many pharmacists are actively caring for patients with OUD at OTPs, 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. CMS should take action to acknowledge, attribute, and reimburse pharmacist-provided patient care services that can be provided through OTP programs.

As CMS is aware, patients receiving care in an OTP may have other conditions that require more practitioner time to review medications or coordinate care with other health care practitioners outside of the OTP. APhA encourages CMS to specifically consider how

pharmacists' time devoted to treatment planning and modification, and care coordination can be included among the services covered by Medicare Part B. As CMS understands, pharmacists provide substance use disorder (SUD) and OUD services at OTPs , specialty, and primary care offices, including medication assisted treatment (MAT), and some pharmacists receive additional education and credentialing relevant to SUD/OUD, such as board certification as a psychiatric pharmacist.[38,39,40,41,42,43,44] Pharmacists providing mental health and SUD/OUD services should receive attribution, recognition, and compensation by CMS for providing these 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. 39326-39333)

Delayed Compliance Deadline

Section 2003 of the SUPPORT Act mandates that electronic prescribing of Schedule II-V controlled substances (EPCS) under Medicare Part D begin on January 1, 2021. However, in the CY 2021 PFS final rule, CMS finalized a policy stating the agency would not take compliance actions before January 1, 2022. Given the challenges of the COVID-19 PHE, APhA believes that CMS's proposal to delay the compliance date for EPCS to January 1, 2023 is reasonable.

EPCS in Long-Term Care Facilities

After considering the comments in response to CMS's August 2020 RFI and CY 2021 PFS proposed rule, CMS believes that long-term care (LTC) facilities face additional barriers to EPCS adoption that most prescribers do not face. One such barrier is that the NCPDP SCRIPT 2017071

[38] DiPaula BA, Menachery E. Physician-Pharmacist Collaborative Care Model for Buprenorphine-maintained Opioid-dependent Patients. J Am Pharm Assoc. 2015; 55: 187-192. Available at: https://www.ncbi.nlm.nih.gov/pubmed/25749264
[39] Duvivier H., et al., Indian Health Service pharmacists engaged in opioid safety initiatives and expanding access to naloxone. Journal of the American Pharmacists Association. 57 (2017), S135-S140. Available at: https://www.ncbi.nlm.nih.gov/pubmed/28292501.
[40] Lagisetty, P., Klasa, K., Bush, C., Heisler, M., Chopra, V. & Bohnert, A. Primary care models for treating opioid use disorders: What actually works? A systematic review. PLOS One. Available at: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0186315.
[41] Gilmore Wilson, C. & Fagan, B. Providing Office-Based Treatment of Opioid Use Disorder. Annals of Family Medicine. 2017; 15(5). Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5593733/.
[42] Grgas, M. Clinical psychiatric pharmacist involvement in an outpatient buprenorphine program, Mental Health Clinician, 2013, 3(6), 290-291. Available at: http://mhc.cpnp.org/doi/abs/10.9740/mhc.n183353?code=cpnp-site.
[43] Suzuki et al., Implementation of a collaborative care management program with buprenorphine in primary care: A comparison between opioid-dependent patients and chronic pain patients using opioids non-medically, Journal of Opioid Management, 10(3), 159-168. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4085743/
[44] McCarty et al., Training rural practitioners to use buprenorphine: Using The Change Book to facilitate technology transfer, Journal of Substance Abuse Treatment, 2004, 26(3); 203-8. Available at: https://www.ncbi.nlm.nih.gov/pubmed/15063914

standard lacks appropriate guidance for LTC facilities. As a result, CMS is proposing to revise § 423.160(a)(5) to clarify that compliance actions for prescriptions written for beneficiaries in a LTC facility will not begin until January 1, 2025.

NCPDP has SCRIPT Standard changes in process to address the ePrescribing three-way communication (prescriber, LTC facility, and pharmacy) needs of the LTC community. However, these changes will be included in a future version of SCRIPT. This change request was approved by NCPDP Work Group 11 (ePrescribing and Related Transaction) during its May 2021 meeting and went to ballot in August 2021. Ballot comments will be adjudicated during NCPDP's November 2021 work group meeting. If approved, these changes will be included in the January 2022 version of the SCRIPT Standard (v2022011).

As the proposed changes will necessitate a new version of the SCRIPT Standard, APhA recommends CMS coordinate the timing of its LTC EPCS compliance deadline with its implementation of a new named version of the SCRIPT Standard in 42 CFR 423.160 (b).

70% Threshold and Proposed Exceptions to the EPCS Requirement

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).

Given the benefits of EPCS, CMS's proposed annual compliance threshold of 70% EPCS for Part D controlled substance prescriptions seems arbitrarily low. Whatever threshold CMS chooses, APhA requests that CMS make it clear that pharmacists are not responsible for enforcing the EPCS requirement and can fill valid paper prescriptions for controlled substances.

In addition to the compliance threshold, CMS has also proposed the following exceptions to the EPCS requirement:

- prescriptions issued where the prescriber and dispensing pharmacy are the same entity,
- prescribers who prescribe 100 or fewer Part D controlled substance prescriptions per year,
- prescribers who are prescribing during a recognized emergency like a natural disaster or pandemic declared by a federal, state or local government entity for the geographic area associated with the prescriber's address in the NCPDP database, and
- prescribers who request and receive a waiver from CMS due to extraordinary circumstances.

APhA supports the exceptions where the prescriber and dispensing pharmacy are the same entity; where prescribers are prescribing during a recognized emergency; and where prescribers have been granted a waiver by CMS due to extraordinary circumstances. With regard to the exception for prescribers who prescribe 100 or fewer Part D controlled substance prescriptions per year, APhA members expressed concern that this loophole might collectively result in a large number of paper prescriptions for controlled substances. However, some exception for small prescribers is likely appropriate. For example, a dentist who prescribes a small number of controlled substances might not be in a position to make the financial investment in an EPCS system.

In addition to CMS's proposed exceptions to the EPCS requirement, APhA recognizes that there are other instances in which EPCS might not be the best option. For example, APhA would like to raise the following issues our members brought to our attention for CMS's 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 prescribed as a non-controlled substance in a state where it is not a controlled substance and sent for pickup to a pharmacy in a state where it is a controlled substance, resulting in a rejection at the receiving pharmacy.
- 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.

Closing the Health Equity Gap in CMS Clinician Quality Programs—Request for Information (RFI)) (Pg. 39344-39349)

CMS is evaluating appropriate initiatives to reduce health disparities. CMS plans to use the feedback to inform the creation of a future, comprehensive RFI focused on closing the health equity gap in CMS programs and policies. CMS is seeking public comment on two potential future expansions of the CMS Disparity Methods, including: (1) Future potential stratification of quality measure results by race and ethnicity, and (2) improving demographic data collection.

APhA refers CMS to our joint comments in response to the Office of Management and Budget's (OMB) Request for Information (RFI) on advancing health equity in America.[45]

APhA supports improving demographic data collection and further exploration of stratification and reporting of quality measures by race and ethnicity in order to improve health equity. Provider challenges with mandated collection of race information for COVID-19 vaccinations during the pandemic highlight that it can be burdensome and costly to modify data fields to collect this information. CMS acknowledges these burdens and has also made some progress toward identifying data fields. APhA believes that it is critical to have standardized data fields in place with mechanisms implemented to collect the data before moving to consider quality measure reporting stratified by race and ethnicity.

Addressing our nation's long-lingering health disparities and inequalities will take regular and consistent engagement with health care providers, particularly pharmacists - the most accessible providers. Given the nature of pharmacy, pharmacists engage regularly with patients, including underserved communities, often on a monthly or more frequent basis. The knowledge gained from these conversations gives pharmacists a more robust picture of the challenges, barriers, hurdles, and opportunities facing patients and communities. Combining this access with patient trust and the ability of pharmacists to collaborate and coordinate with other healthcare team members can lead to optimal health outcomes for individuals and communities.

We recommend the inclusion of pharmacists in all forthcoming CMS advisory committees, working groups, and expert panels related to ending health inequalities and advancing health equity. Given the unique expertise and community reach within pharmacy, many pharmacists have the ability to address the special needs of certain patient groups including children, seniors, women, and individuals with disabilities and/or complex medical conditions. As a profession, we would welcome regular engagement with CMS on efforts to end health disparities and achieve health equity.

[45] https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=lbFR17_-Bf8%3d

Updates to the APM Performance Pathways Measure Set/Transforming MIPS: MIPS Value Pathways/Request for Information Regarding the COVID–19 Vaccination by Clinicians Measure (Pg. 39271; 39351;39393-94)

In general, APhA supports CMS's efforts to reduce measure burden and better harmonize and use measures that are most meaningful. However, under the Merit-based Incentive Payment System (MIPS) system, there is not a mechanism to attribute pharmacists' contributions to achieving metrics, of which a significant number are related to or impacted by medications and would benefit from appropriate medication use and pharmacist-provided services. For example, APhA analysis, finds that pharmacists working as part of health care teams directly contribute to over 20% of the current 2021 MIPS quality measures, (APhA can share our analysis with CMS upon request) as well as many of the improvement activities and promoting interoperability measures. Pharmacists can also directly contribute to 77% (10 of 13) of the measures included in the proposed APM Performance Pathway Measure set. In addition, CMS currently utilizes 15 Pharmacy Quality Alliance (PQA) measures that are used throughout CMS programs. APhA predicts as practices move to value-based models and medications become more specialized, the role and the value of pharmacists will be even more critical.

APhA supports CMS's concept to create the MIPS Value Pathways (MVPs) to reduce burden, help patients compare clinician performance, and better inform patient choice in selecting clinicians. We appreciate that CMS is establishing a process with stakeholder engagement and collaboration in the development of MIPs Value Pathways (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. For the Quality Payment Program, including 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 notes CMS' request for information on a proposed COVID-19 Vaccination by Clinicians Measure. This is an important measure in concept, but because pharmacists are not eligible clinicians, their contributions will not be captured in this measure. COVID-19 vaccines are covered in Medicare Part B, including those administered by pharmacists, and notably, pharmacists' contributions to vaccine uptake are estimated to account for approximately 1/3 of all COVID-19 vaccines administered. Due to the significant role pharmacists are playing in COVID-19 vaccination, the COVID-19 Vaccination by Clinicians measure for MIPS represents the perfect opportunity for CMS to allow pharmacists to report on this measure. This is just one example of the lack of visibility pharmacists have within the Medicare system for the many

types of patient care services they deliver. We also agree with the Measure Application Partnership (MAP) the measure should address if the patient population assessed for measure performance is for patients who received 1 dose of a COVID-19 vaccine versus patients who received a complete COVID-19 vaccination series.

Appendix 1: Services and Activities Performed by Mental Health Clinical Pharmacists[46]

Mental health clinical pharmacists provide a wide variety of patient care services as a part of the interprofessional team. These services together allow the mental health clinical pharmacist to provide safe and effective comprehensive medication management and increase patient access to care. This appendix, while not all-inclusive, describes many common types of patient care services performed by this critical team member.

A. **Patient Assessment:** Mental health clinical pharmacists perform assessments to determine appropriate treatment modalities and to monitor efficacy and toxicity. The typical diagnoses of patients evaluated by mental health clinical pharmacists include schizophrenia, depressive disorders, bipolar disorder, ADHD, anxiety disorders, migraine and headache, dementia, sleep-wake disorders, and substance use disorders. They use the same assessment tools as do other mental health professionals, including:
   1. Mental status exams
   2. Suicide risk assessment (e.g., Columbia Rating Scale)
   3. Psychiatric rating scales (e.g., Patient Health Questionnaire-9, PTSD Checklist-17, Generalized Anxiety Disorder-7, Brief Psychiatric Rating Scale, CAGE)
   4. Physical assessments (e.g., weight, blood pressure)
   5. Ordering and interpretation of laboratory tests (e.g., lithium level, complete blood count, basic metabolic panel, hemoglobin A1C)

B. **Medication Prescribing and Monitoring:** Mental health clinical pharmacists provide medication prescribing (e.g. initiation, continuation, change in therapy, discontinuation) and monitoring for medications often utilized in the treatment of mental health disorders as allowed through scope of practice or collaborative practice agreements. These medications include:
   1. Antipsychotics (e.g., Risk Evaluation and Mitigation Strategies [REMS] with clozapine, metabolic adverse effects, abnormal involuntary movement scale)
   2. Antidepressants (e.g., REMS with esketamine, QTc prolongation with citalopram, drug–drug/food interactions with monoamine oxidase inhibitors)
   3. Mood Stabilizers (e.g., levels with lithium, valproic acid/divalproex sodium, carbamazepine, drug–drug interactions)
   4. Stimulants (e.g., verifying the prescription drug monitoring program [PDMP] and managing potential adverse effects)

[46]Board of pharmacy specialties psychiatric pharmacy specialist certification content outline/classification system. 2017. https://www.bpsweb.org/wp-content/uploads/PSYContentOutline2017.pdf. Accessed April 19, 2019.

5. Antiepileptics (e.g., managing therapeutic levels and drug–drug interactions)
6. Benzodiazepines (e.g., initiations and tapers, appropriate use evaluations)
7. Triptans and Anti-Calcitonin Gene-related Peptide (CGRP) Monoclonal Antibodies (e.g., obtainment of medications and efficacy and toxicity of medications)
8. Cholinesterase Inhibitors and N-Methyl-D-Aspartate (NMDA) Receptor Antagonist (e.g., efficacy and toxicity of agents)
9. Non-Benzodiazepine Agents (e.g., verifying the PDMP and managing efficacy and toxicity)
10. Medications Used in Substance Use Disorders

C. **Utilization of Long-Acting Injectable Antipsychotics:** Mental health clinical pharmacists are instrumental in the utilization of long-acting injectable antipsychotics. In addition to the prescribing and monitoring of the injection, they assist in the planning of utilization of the injection, and administration in select states under state law.

D. **Utilization of Pharmacogenomics:** Mental health clinical pharmacists are involved in the utilization of pharmacogenomics to help guide treatment decisions. This includes recommending testing when indicated, interpreting and explaining the results to the patient and other members of the healthcare team, and using the results to make recommendations and optimize medication therapy.

E. **Patient and Caregiver Education:** Mental health clinical pharmacists are heavily involved in medication and treatment adherence education, through techniques such as motivational interviewing. Additionally, they provide medication and disease state education to patients and caregivers. Using the shared decision-making process, mental health clinical pharmacists provide information about various treatment options to patients and their caregivers. This allows for making an informed, collaborative decision that takes into account the patient's preferences, values, and beliefs.

F. **Trainee Education:** Mental health clinical pharmacists provide education to health care trainees (e.g., student pharmacists, pharmacy practice residents, medical residents, fellows) through both didactic education and experiential learning experiences.

G. **Management of Transitions of Care:** Mental health clinical pharmacists are involved in medication reconciliation during the transitions of care that patients with mental health disorders may experience over the course of their lifetime.

H. **Pharmacy-Specific Activities:** Mental health clinical pharmacists are involved in many activities in operating and directing pharmacies, including:
   1. Management of formulary in health care facilities in addition to those for insurance and state Medicaid
   2. Medication utilization review, drug utilization review, and policy standards. Mental health clinical pharmacists perform cost-effectiveness analyses, evaluate National Quality Standards, and fulfill National Accreditation and Regulatory requirements.
   3. Drug information and literature review

I. **Substance Use Disorder Treatment:** Mental health clinical pharmacists have developed many practices in the treatment of those with substance use disorders, including:
   1. Initiation and continuation of buprenorphine, in collaboration with DEA "X"-waivered provider
   2. Monitoring patients on buprenorphine
   3. Naltrexone initiation, monitoring, and continuation
   4. Naltrexone administration in select states
   5. Naloxone prescribing, education, and recommendation
   6. Methadone maintenance therapy

J. **Treatment of Mental Health Disorders in Special and/or Vulnerable Populations**: These populations include:
   1. Pediatrics
   2. Geriatrics
   3. Pregnancy/lactation
   4. Ethnically diverse populations, including refugees
   5. Low-income and homeless
   6. Rural, underserved areas
   7. LGBTQ+ (lesbian, gay, bisexual, transgender, transsexual, 2/two-spirit, queer, questioning, intersex, asexual, ally)
   8. Patients with hepatic/renal impairment and/or absorption issues

K. **Health Promotion Strategies:** Mental health clinical pharmacists are involved in the planning and implementation of a diverse range of health promotion strategies.
   1. Wellness screening (e.g., depression screenings)
   2. Tobacco cessation
   3. Suicide prevention

L. **Development and implementation of models of care:** Mental health clinical pharmacists are leading the way in the utilization of varying models of care, including telepsychiatry, assertive community treatment (ACT) teams, and embedment in primary care clinics.

M. **Research:** Mental health clinical pharmacists are involved in all levels of research, including clinical and laboratory research, with some serving as lead investigators on many types of research, including federal studies.