APhA
American Pharmacists Association

September 6, 2022

[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-1770-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Proposed Rule (RIN 0938-AU81)

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 the pandemic, including shortages of health care staff and burnout of health care professionals—which continues to 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 independently order and administer COVID-19 tests[1] and recognizing pharmacies as points of

[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

care for COVID-19 testing services.[2] In addition, HHS also has authorized pharmacists to independently 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 cementing pharmacists as vital health care infrastructure. Since December 2020, community pharmacists and pharmacy technicians have administered more than 260 million COVID-19 vaccinations (45% of the national total), with more COVID-19 vaccinations administered in community pharmacies than any other practice setting.[5] Most recently, 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.[6] In addition, the Food and Drug Administration (FDA) has independently authorized pharmacists to prescribe Paxlovid, with certain limitations,[7] however, pharmacist prescribing is not occurring due to the lack of a clear, direct payment pathway from CMS to pharmacists for the patient assessment services required to determine if a patient is eligible or not for pharmacist prescribing.

APhA requests real solutions from CMS in addressing barriers to fully utilizing pharmacists' expertise in addressing care access gaps for Medicare beneficiaries and urges the agency to build upon HHS' previous work and utilize public health emergency (PHE) authority, enforcement discretion and demonstration capability to the maximum extent in order to remove remaining regulatory barriers to the delivery of, and payment for, pharmacist-provided patient care services for our nation's Medicare beneficiaries.

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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] CDC. The Federal Retail Pharmacy Program for COVID-19 Vaccination. Page last reviewed: August 9, 2022, available at: https://www.cdc.gov/vaccines/covid-19/retail-pharmacy-program/index.html

[6] 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

[7] FDA. Coronavirus (COVID-19) Update: FDA Authorizes Pharmacists to Prescribe Paxlovid with Certain Limitations. July 6, 2022, available at: https://cacmap.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pharmacists-prescribe-paxlovid-certain-limitations

APhA also notes the proposed rule includes a request for information (RFI) for "Medicare Part B Payment for Services Involving Community Health Workers (CHWs)," [8] to be considered in the same category of "auxiliary staff," where pharmacists are currently categorized by CMS. APhA supports the contributions of CHW's in addressing social determinants of health (SDOH) issues, and, in fact, some community pharmacies are hiring CHW's to assist in connecting patients to community-based services. However, APhA takes this opportunity to remind CMS of the large gap between pharmacists' training, education, licensure, expertise, etc. and other Department of Labor "workforce" categories, (CHWs, etc.). As such, APhA strongly urges CMS, in its ongoing efforts to promote health care equity, to utilize the same effort for collecting information on these other "workforce" categories for "Medicare Part B payment for services," to recognizing and providing Medicare Part B payment for the complex health care services currently provided to Medicare beneficiaries by our nation's pharmacists—recently amplified by the millions of lives and billions of dollars saved from the pharmacist-administered immunizations and health care services provided during the PHE, which the federal government will continue to rely upon for future PHEs.

Overarching Comments

Congressional intent regarding CMS action on pharmacist-provided patient care services

As CMS understands, Congress recently emphasized the following intention for federal funding at CMS regarding pharmacist-provided patient care services in the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations bill, 2023 (H. Rept. 117-403):[9]

> "Ensuring Access to Lifesaving COVID–19 Oral Medications from Pharmacists.—The Committee is concerned with CMS's guidance ''Permissible Flexibilities Related to Oral Antiviral Drugs for Treatment of COVID–19 that May Receive U.S. Food and Drug Administration Emergency Use Authorization and are Procured by the U.S. Government,'' which only encourages, but does not require, Part D ''sponsors to consider paying a dispensing fee for these drugs that may be higher than a sponsor's usual negotiated dispensing fees given the unique circumstances during the public health emergency.'' *The Committee is concerned about patients' access to these lifesaving medications and encourages CMS to review policy options for Part D sponsors to cover all the*

[8] https://www.federalregister.gov/d/2022-14562/p-681
[9] See, https://www.congress.gov/117/crpt/hrpt403/CRPT-117hrpt403.pdf

necessary services to ensure the safe pharmacy dispensing of COVID–19 oral medication [emphasis added]."

"Pharmacists and Patient Care Services.—The Committee is aware that certain Medicare Part B services and care frameworks have provisions to include pharmacists and their patient care services. However, CMS has few mechanisms to identify and evaluate the contributions of pharmacists to patient care and outcomes or to identify barriers within current service requirements that prevent scalable involvement of pharmacists. *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* [emphasis added]."

"Pharmacist-Provided Incident to Physician Services.—The Committee is pleased with CMS's recognition in the calendar year 2021 physician fee schedule (PFS) final rule (FR 84583) that ''pharmacists could be considered QHPs [qualified health care professionals] or clinical staff, depending on their role in a given service,'' and that ''new coding might be useful to specifically identify these particular models of care.'' However, the Committee remains concerned with current CMS PFS requirements restricting physicians' and nonphysician practitioners' (NPPs) utilizing pharmacists under incident to models to bill at the lowest E/M code (99211), with an estimated time commitment of 7 minutes. The Committee understands this restriction has diminished providers' engagement with pharmacists in team-based care models across the country. *CMS should consider how to ensure physicians and NPPs can optimize the use of pharmacists. The Committee encourages CMS identify mechanisms to attribute, report, and sustain pharmacists' patient care contributions to beneficiaries in the Medicare Part B program* [emphasis added]."

APhA again urges CMS to use its full 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. In addition, pharmacists are currently providing care and directly billing for services 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.[10] Pharmacists' medication management services are more time-intensive and complex than described under E/M CPT code 99211. Despite strong evidence to support positive outcomes from pharmacists' care, this restriction is preventing their incorporation into team-based care models due to lack of financial viability and billing coders' concerns that pharmacists' services include medical decision

[10] 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

making, which is not currently included in CPT code 99211. **Accordingly, APhA requests CMS take action, in line with congressional intent, under the direction of the appropriations language mentioned above. APhA also requests the opportunity for an in-person or virtual meeting to educate CMS on pharmacist-provided patient care services, including filling in the knowledge gaps on specific pharmacist-provided patient care services that meet the requirements for more complex E/M codes.**

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 from an APhA member pharmacist in a state where pharmacist services are recognized for direct payment: Patient is a 77-year-old male with type 2 diabetes, heart disease, hypertension, and hyperlipidemia referred by a 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**

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

- **APhA recommends maintaining the pandemic telehealth flexibilities, including location of service and allowable technology for delivery beyond the PHE, and implementing coverage of telehealth audio only services, either through separate payment for CPT codes 99441-99443, or expanding the allowance beyond behavioral health services.**
- **APhA recommends making the flexibility for direct supervision of clinical staff providing incident to services permanent.**

- **APhA supports general supervision of auxiliary personnel/clinical staff, including pharmacists providing incident to behavioral health services.**
- **APhA supports the new chronic pain management (CPM) services and their delivery by auxiliary personnel/clinical staff, including pharmacists, working under general supervision and when these services are provided by pharmacists at Rural Health Centers and Federally Qualified Health Centers (FQHCs).**
- **APhA recommends CMS make a number of policy, payment and procedural changes to reduce obstacles for pharmacists to increase access to a number of underutilized services to promote health equity.**
- **APhA supports the creation of two G codes to include clinical activities that can be furnished by pharmacists and the important role pharmacists can play in the delivery of Remote Therapeutic Monitoring (RTM).**
- **APhA urges CMS to make the additional payment of $35.50 (geographically adjusted) when a COVID-19 vaccine is administered in a beneficiary's home permanent and expand it to all other ACIP-recommended vaccines.**
- **APhA supports a vaccine administration fee for influenza, pneumococcal, and hepatitis B and COVID-19 (at a minimum of $40 to address vaccine hesitancy and assisting patient decision making on vaccine selection) that incentivizes providers to offer vaccinations and encourages Medicare coverage for all ACIP-recommended vaccines.**
- **APhA supports the continuation of the current payment rates for 2023 for administration of a COVID-19 monoclonal antibody product.**

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 and other health care professional 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, PharmD, JD, FAPhA
Interim Executive Vice President and CEO

Full APhA Feedback and Comments:

Implementation of Telehealth Provisions of the Consolidation Appropriations Acts, 2021 and 2022 (pg. 349)

APhA recommends maintaining the pandemic telehealth flexibilities, including location of service and allowable technology for delivery beyond the PHE, and implementing coverage of telehealth audio only services, either through separate payment for CPT codes 99441-99443, or expanding the allowance beyond behavioral health services

In 2020, CMS found that the relative resource costs of furnishing these services via telehealth may not significantly differ from the resource costs involved when these services are furnished in-person and instructed that the telehealth modifier "95" be used for the duration of the COVID-19 PHE. CMS also maintained the facility payment rate for services billed using the general telehealth "place of service" (POS) code "02", should practitioners choose to maintain their current billing practices for Medicare telehealth during the PHE for the COVID-19 pandemic.

In the proposed rule, CMS proposes that the Medicare telehealth services performed with dates of service occurring on or after the 152nd day after the end of the PHE will revert to pre-PHE rules and will no longer require modifier "95" to be appended to the claim, but the appropriate POS indicator will need to be included on the telehealth claim - POS "02" - Telehealth Provided Other than in Patient's Home and POS "10"—Telehealth Provided in Patient's Home. Modifier "93" will be available to indicate that a Medicare telehealth service was furnished via audio-only technology, where appropriate, and only for certain behavioral health services.

CMS also states that "[g]iven that the end date of the PHE is not yet known and could occur before the rulemaking process for the CY 2023 PFS is complete, and that the changes made by these provisions are very specific and concise, we [CMS] are providing notice that we intend to issue program instructions or other subregulatory guidance to effectuate the changes described… to ensure a smooth transition after the end of the PHE for COVID-19."

A number of patient care services provided by pharmacists working in team-based care models during the ongoing PHE have been provided through telehealth services, including audio only communications, e.g., medication management services, management of chronic conditions (diabetes, hypertension, etc.), substance use disorder treatment, pain management, medication reconciliation, etc. Our members report that telehealth visits provide the flexibility to see patients in their homes where access to view and verify medications for medication

management services can make the visit more productive, they can identify factors that could impact patient's health care, and the convenience of telehealth permits patient engagement in visits that can improve the time to control for conditions such as hypertension and diabetes—particularly for underserved populations to promote health equity.

Our members also strongly support making permanent the telehealth flexibilities that have been in place during the pandemic. In addition, APhA also recommends CMS ease the requirements for location of service and allowable technology for delivery. Reverting to pre-pandemic requirements when so many strides have been made in increasing access to care is a step in the wrong direction. APhA supports an evidence-based approach to post-pandemic telehealth services and understands that some services will require the patient to be in-person, but every effort should be made to implement regulations that facilitate delivery of telehealth services, regardless of the originating site.

CMS also notes, at the end of the PHE for COVID-19, these waivers and interim policies will expire, and payment for Medicare telehealth services will once again be limited by the requirements of section 1834(m). Accordingly, APhA continues to strongly urge the HHS Secretary to use the new authority under 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 under 1834(m)—**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."[11] **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 and future health crises.** HHS should also add pharmacy services provided by pharmacists using telehealth to the telehealth list.

Beyond the pandemic, APhA urges CMS to consider implementing CPT codes 99441-99443 as separately payable to pharmacists, or expanding the allowance for a telehealth audio only option beyond behavioral health services to improve access to care, especially in disadvantaged

[11] 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

populations to support SDOH and health equity efforts. APhA's members who work in FQHCs, physician offices, and clinics report that audio only services are critical for their patients who do not have smart phones, internet services, or easy access to transportation. These patients without an audio option may not be able to receive care at all after the PHE. Given the significant national focus on addressing health disparities, SDOH and health equity, further attention to an audio only option is needed.

Expiration of PHE Flexibilities for Direct Supervision Requirements (pg. 368)

APhA recommends making the flexibility for direct supervision of clinical staff providing incident to services permanent

In the proposed rule, CMS reminds stakeholders that after December 31 of the year in which the PHE ends, the temporary exception to allow direct supervision virtually for the provision of telehealth services by clinical staff of physicians and other practitioners, including pharmacists, incident to their own professional services would no longer apply. However, CMS is asking if the flexibility for direct supervision using real-time, audio/video technology should potentially be made permanent, in general, or only for a subset of services.

APhA strongly urges CMS to make the flexibility for providing "direct supervision" of clinical staff, including pharmacists currently classified as auxiliary personnel, 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.

Simply put, supervision is supervision – whether done in-person or via audio/video technology and making the flexibility to allow direct supervision permanent will ensure provider teams, including pharmacists, will be able to continue to meet patients' needs through the use telehealth services. APhA's member pharmacists report that it's easier to communicate, and providers are more responsive, via audio/video technology to address questions. Reverting back to prior supervision requirements will only slow down and complicate care delivery to the detriment of health equity efforts.

Chronic Pain Management and Treatment (CPM) Bundles (HCPCS GYYY1, and GYYY2) (pg. 597)

APhA supports CMS' proposed new CPM services and advocates that CPM requirements include provision by pharmacists as auxiliary personnel/clinical staff working under general supervision

CMS is proposing to add a new CPM benefit with two new codes for CPM services, beginning January 1, 2023, that would be analogous to Chronic Care Management (CCM) services and Principal Care Management (PCM) services and that include "ongoing communication and coordination between relevant practitioners furnishing care." CMS is also seeking comment "on which, if any, CPM elements could be furnished as "incident to" services, and whether to add GYYY1[12] and GYYY2[13] to the list of services for which we allow general supervision as described in our regulation at § 410.26(b)(5)." CMS also recognizes that "[t]he proposed CPM codes may involve arrangements where the physician or other health professional might work in collaboration with other health care providers or members of a care team…where these individuals might furnish certain elements of the service bundle under the direction of the physician or qualified health practitioner, such as assessments, person-centered care planning, including "medication management," referrals to community-based care, and other activities, as appropriate. In addition, how CMS "should structure the proposed CPM code and payment for these services to account for these types of arrangements that could include team-based care."

As CMS has stated, the high prevalence of pain exacts a substantial economic toll in the United States.[14] 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 CMS

[12] HCPCS code GYYY1: Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and maintenance of **a person-centered care plan that includes** strengths, goals, clinical needs, and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health treatment; **medication management;** pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and care coordination between relevant practitioners furnishing care (e.g., physical therapy and occupational therapy, and community-based care), as appropriate. Required initial face-to-face visit at least 30 minutes provided by a physician or other qualified health professional; first 30 minutes personally provided by physician or other qualified health care professional, per calendar month. (When using GYYY1, 30 minutes must be met or exceeded.)

[13] HCPCS code GYYY2: Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month.

[14] Gaskin DJ, Richard P. The economic costs of pain in the United States. The Journal of Pain. 2012 Aug 1;13(8):715–24.

proposal to add a new CPM service and also supports the two new separate stand-alone codes for CPM services, that highlight the critical need for an enhanced focus on chronic pain management and to gain further insights into the work required to provide these services, including the work attributed to pharmacists.

Assuming the design of this service is similar to CCM and PCM, APhA advocates that CMS authorize CPM to be delivered by clinical staff under general supervision from a physician or NPP. Most elements detailed for this service are focused on monitoring, management, and care coordination, and conducive to delivery by clinical staff, including pharmacists. **APhA also requests that CMS align terminology with other services of this type and refer to individuals working under general supervision as "clinical staff" and not "auxiliary personnel."**

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."[15]

Generally, CMS should recognize all chronic pain management and opioid reduction services provided by pharmacists, including both in-person and utilizing telehealth services under general supervision. 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.[16] 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.[17] 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.[18] Pharmacists also play an important role in pain management as patients transition from one care setting to another by providing such services

[15] https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf
[16] 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
[17] 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
[18] Id.

as medication reconciliation, medication assessment and monitoring, patient and healthcare provider education, discharge counseling, and post-discharge follow-up and planning.[19]

In response to CMS' request for feedback on various requirements for CPM, APhA has the following recommendations based on feedback from member pharmacists who provide pain management services:

- CPM should be permitted to be delivered by clinical staff working under general supervision from a physician or NPP. This would leverage various members of the patient's health care team, including pharmacists' expertise in medication management, and provide increased access and flexibility for care delivery. Our members noted that patients in underserved areas to address heath equity efforts and SDOH would especially benefit from a general supervision component.
- APhA supports the proposed elements of CPM, and in response to CMS' request for what elements could be delivered by auxiliary personnel/clinical staff working under general supervision, provides the following elements that can be (and are currently) delivered by pharmacists:
    - Assessment and monitoring;
    - Administration of a validated pain rating scale or tool. APhA members stated that it will be important for CMS to identify evidence-based pain rating scale(s) or tool(s) as there is variability in the marketplace that could limit effectiveness of including this element;
    - Participation in the development, implementation, revision, and maintenance of a person-centered care plan that includes strengths, goals, clinical needs (including "medication management"), and desired outcomes;
    - Medication management (as referenced in the proposed rule under a person-centered care plan); and
    - Health literacy counseling.
- While an in-person initiating visit would be most desirable, our members believe that a telehealth initiating visit is also feasible for this service. After the initiating visit, the monthly visits should allow a telehealth option, as patients with chronic pain would be more likely to participate if there was an option for receiving the service via telehealth, including from pharmacists.
- APhA's member pharmacists report that patient visits for chronic pain management can take an hour or more, depending on the patient's needs. APhA recommends that CMS permit two add-on HCPCS GYYY2 codes for a visit and continue to monitor the time

[19] 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

and resources required to deliver this service. APhA also supports CMS' proposal to permit HCPCS code GYYY1 twice in one month.

- As previously communicated to CMS for CCM and PCM, APhA has concerns about the patient cost sharing requirement for CPM. Many patients with chronic pain have limited income and may be on disability, which could severely impact their ability to participate in this service. APhA also recommends CMS explore mechanisms that waive the cost share for this service.

Finally, as stated in the proposed rule, a multimodal approach to chronic pain management is recommended, but hindered by many barriers, including a lack of behavioral health and other health care practitioners and coverage gaps for some of the recommended services. While the initiation of coverage for CPM is a step forward, continued monitoring is needed to identify and address gaps that prevent patients with chronic pain from receiving the services they need. Also, some of APhA's members working in primary care and internal medicine practices stated that the team-based practices they work in have integrated pain management services incorporated into their standard visits for patients with chronic pain using a whole person approach to care. APhA members expressed concerns about how their contributions would be factored into the overall analysis of CMS' policy to address beneficiaries' pain needs. Accordingly, APhA requests specific clarify from CMS on how pharmacists' contributions will be attributed in CMS' policies to address the pain needs of beneficiaries.

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (pgs. 1,311 and 4,182)

APhA supports inclusion of CPM services in the general care management HCPCS code G0511 when these services are provided by RHCs and FQHCs and advocates that these services be permitted to be delivered by pharmacists working under general supervision. APhA's same recommendations for CPM in physician office practices and clinics apply to CPM in RHCs and FQHCs.

Proposed Revisions to the "Incident to" Physicians' Services Regulation for Behavioral Health Services (pg. 663)

APhA supports general supervision of pharmacists providing incident to behavioral health services

CMS is proposing to amend the direct supervision requirement under its incident to regulations to allow behavioral health services to be furnished under the general supervision of a physician

or NPP when these services or supplies are provided by auxiliary personnel, including pharmacists, incident to the services of a physician or NPP. General supervision does not require the physician's presence during the performance of the procedure.

With the ongoing pandemic, flexibility regarding supervision of pharmacists has permitted services to continue, unimpeded to patients with behavioral health conditions. CMS is correct that amending the direct supervision requirement will increase vital access to beneficiaries in dire need of behavioral health services to help meet the 2022 CMS Behavioral Health Strategy[20] goal to improve access to and quality of mental health care services. Easing supervision to utilize more pharmacists will also help to meet the increased needs for behavioral health treatment and workforce shortages in this field. As CMS is aware, patients receiving behavioral health care services may have other conditions that require more practitioner time to review medications or coordinate care with other health care practitioners. As mentioned above, 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. We also agree there is no risk to this modification since the auxiliary personnel providing the services would need to meet all of the applicable requirements to provide incident to services, including any applicable licensure requirements imposed by the State in which the services are being furnished. As CMS understands, pharmacists provide medication assisted treatment (MAT) services, and some pharmacists receive additional education and credentialing, such as board certification as a psychiatric pharmacist.[21,22,23,24,25,26,27] For an extensive list of behavioral health services and activities performed by mental health clinical pharmacists, please see Appendix #1.

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[20] https://www.cms.gov/cms-behavioral-health-strategy

[21] 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

[22] 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.

[23] 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.

[24] 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/.

[25] 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.

[26] 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/

[27] 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

Easing supervision requirements for pharmacists providing mental health services is a positive step and APhA encourages CMS to provide pharmacists with the attribution, recognition, and compensation for providing these services as the agency does to all other health care practitioners.

Request for Information: Medicare Potentially Underutilized Services (pg. 717)

APhA recommends CMS make a number of policy, payment and procedural changes to reduce obstacles for pharmacists to increase access to a number of underutilized services to promote health equity

CMS is asking for feedback on how to best define and identify high value, potentially underutilized health services, and how specific potential policy, payment, or procedural changes could reduce potential obstacles and facilitate better access to high value health services to promote health equity including a number of services that can be offered by pharmacists, such as preventive services, annual wellness visits (AWVs), diabetes self-management training, screening for diabetes, referral to appropriate education/prevention/training services, immunizations/vaccinations, intensive behavioral therapy for obesity, opioid treatment programs, complex/chronic care management and behavioral health integration services. A number of these underutilized services could have vastly significant uptake if CMS took action to maximize usage of pharmacists as long as appropriate coverage was also provided to incentivize pharmacists to offer these services.

APhA's members report that many of the services on the list of underutilized services are not valued sufficiently (e.g., CCM, complex CCM (CCCM), to account for the overall work required by pharmacists to deliver these services and the onerous documentation requirements, especially considering the work relative value unit (RVU) requirements of physicians and other NPPs for the service. Some of the screening services (e.g., cardiovascular disease screening, depression screening, diabetes screening) detailed in the Medicare Preventive Services list can, and are, delivered in community pharmacies that can provide accessible locations for screening and referral services, including in underserved locations. However, their lack of CMS coverage is a barrier that prevents CMS from leveraging the expertise of pharmacists and convenient access of pharmacies in advancing uptake of these services. Likewise, counseling to prevent tobacco use is a covered pharmacist-delivered service in some states, but lack of CMS coverage is a barrier to patient access to this service in the Medicare program.

Pharmacist-prescribing of Paxlovid:

As CMS understands, the independent FDA has already updated the emergency use authorization (EUA) to permit pharmacists to independently prescribe Paxlovid to treat patients positive from COVID-19. Currently underutilized, especially in underserved communities, APhA provides the following comments on how to increase access to lifesaving Paxlovid test and treat services for beneficiaries who are at high risk for progression to hospitalization and death from COVID-19, especially those in underserved communities.

FDA acted following a new analysis by the Centers for Disease Control and Prevention (CDC), which confirmed APhA's earlier findings of inequitable access of COVID-19 oral antivirals.[28] According to our analysis, as of June 22, 2022, there were over 28,000 community pharmacies located in federally recognized underserved communities, yet only 838 Test to Treat sites had been established in those communities.[29] Tapping the pharmacies in these areas could increase access to treatments up to 3,200%. The data shows that the least vulnerable areas nationwide have access to 75% of Test to Treat locations, limiting the most vulnerable communities to only 25% (666) of these locations. However, these areas—which fall in the top 30% of the social vulnerability index—have an estimated 24,000 community pharmacies, most of which are not Test to Treat points of care for oral COVID-19 antiviral medications.

Removing barriers to pharmacist prescribing of oral antivirals has the potential to be a game changer for addressing health equity and providing timely access to these life-saving treatments in pockets of the country where pharmacists may be the only health care provider for miles—just as they have been available for the administration of COVID-19 vaccines.

However, there is no current federal policy providing coverage for all of the associated clinical services required for pharmacist prescribing, such as consultation to determine patient eligibility, assessing renal and hepatic function, obtaining a comprehensive list of medications (prescribed and nonprescribed), and assessing for potential drug interaction services. Absent coverage for the pharmacist's time to conduct patient eligibility and appropriateness, FDA's authorization will be for naught to reduce our nation's health inequities in accessing this lifesaving medication. These services, which take roughly 15-30 minutes per patient, are reimbursed for every other prescriber, but not for pharmacists.

[28] https://www.cdc.gov/mmwr/volumes/71/wr/mm7125e1.htm
[29] https://www.pharmacist.com/Advocacy/Issues/Inequity-to-COVID-19-Test-to-Treat-Access-Pharmacists-can-help-if-permitted

In APhA's recent Paxlovid pulse survey results, 67% of respondents stated that lack of reimbursement for patient assessment and prescribing, when the patient is eligible, was a"Very significant – my practice will not participate without reimbursement," barrier (42% of respondents), or a "Significant – my practice is unlikely to participate without reimbursement," barrier (25% of respondents).

Separately, pharmacy benefit managers (PBMS) are paying less than $1 in dispensing fees, which does not cover the required patient safety checks necessary simply to dispense this medication. As state above, from Congress, a lot of this race to the bottom in dispensing fees is largely based on CMS's guidance which only encourages, but does not require, Part D ''sponsors to consider paying a dispensing fee for these drugs that may be higher than a sponsor's usual negotiated dispensing fees given the unique circumstances during the public health emergency.''[30] CMS has used various enforcement discretion, waivers and demonstration authority to ensure the provision of lifesaving COVID-19 services. Unfortunately, it is stark that such action was not taken during the PHE with the significant federal investment and remarkable outcomes from prompt use of oral antiviral medications.

Based on our analysis, we recommend a reimbursement rate of **$75/visit** for the clinical assessment. This recommendation is based on Evaluation and Management (E/M) codes that other health care professionals use when providing the patient assessment necessary for prescribing Paxlovid.

From reports by pharmacists evaluating the resources and time required to prescribe Paxlovid, as well information from the limited number of pharmacists currently prescribing Paxlovid under the FDA's EUA, we expect a patient visit to take between **15-45 minutes,** depending on the complexity of the patient. It is anticipated that patient visits will fall into the requirements for CPT E/M codes 99202-99203 (new patient) or E/M 99212-99214 (established patient) range. The Physician Fee Schedule National Average for these codes ranges from $63-$97 for the new patient codes and $49-$110 for the established patient codes. These figures include an adjustment to 85% of the national average fee. We have also conducted outreach to practicing pharmacists separate from this analysis to discuss anticipated resources needed to deliver this service. That feedback is factored into the recommendation. Since information is not available on whether CMS would consider multiple codes or one code, potentially a G code, for this

[30] https://www.cms.gov/files/document/oralantiviralguidance11232021.pdf

service, this recommendation is for an amount that would represent a blended payment rate for the various levels of service.

APhA encourages CMS to explore pathways providing flexibility to reimburse pharmacists for providing Paxlovid test to treat services, including a 402/222 demo and 1135 waiver, options that we believe merit further examination. These options would cover pharmacist patient assessment and prescribing, regardless of pharmacist practice setting (community pharmacy, clinic, physician office practice, telehealth company), as pharmacists in all of these setting are positioned to improve access to Paxlovid via assessment and prescribing services.

AWVs- Authorize General Supervision for Service Delivery:

Pharmacists are permitted to conduct initial and subsequent AWVs under the direct supervision of a physician. While pharmacists may provide the initial or subsequent AWVs as "medical professional - other licensed practitioners," pharmacists cannot provide the Initial Preventive Physical Examination (IPPE).[31] Both types of AWVs must include Personalized Prevention Plan Services (PPPS) that include a personalized prevention plan and health risk assessment (HRA). Studies have found that in a variety of outpatient health centers, AWVs conducted by pharmacists, had a positive impact on patient care, and had high satisfaction rates between patients and physicians.[32]

Given the success of pharmacists in conducting initial and subsequent AWVs, the advancement of technologies and the multiple downstream cost savings from AWVs to beneficiaries, APhA urges CMS to modify AWV requirements to allow pharmacists to provide AWVs under general supervision, including through the utilization of telehealth services. This would expand new models for delivering this service such as through partnerships between physicians and community pharmacists.

Diabetes Self-Management Training (DSMT):

APhA appreciates CMS' interest in addressing barriers to DSMT delivery in community pharmacies in previous proposed PFS rules. As CMS has noted, "many individuals *who actually furnish DSMT services* [emphasis added], such as…*pharmacists* [emphasis added], do not qualify to enroll in Medicare as certified providers."[33] Despite CMS' clarification that accredited

[31] Centers for Medicare and Medicaid Services. Frequently Asked Questions From the March 28, 2012 Medicare Preventive Services National Provider Call: The Initial Preventive Physical Exam and the Annual Wellness Visit. https://www.cms.gov/outreach-and-education/outreach/npc/downloads/ippe-awv-faqs.pdf
[32] https://pubmed.ncbi.nlm.nih.gov/31645170/
[33] https://www.federalregister.gov/documents/2016/07/15/2016-16097/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions

community pharmacies are Medicare-covered entities for DSMT services,[34] and that pharmacists can serve as the certified instructors (as mentioned above), pharmacists report ongoing barriers to billing for DSMT services. This is a significant barrier to pharmacies serving as accessible service locations for DSMT. There is lack of clarity and recognition by CMS in written materials that accredited pharmacies and their certified instructors are permitted to provide DSMT services. This has led Medicare Administrative Contractors (MACs) to deny DSMT claims from accredited pharmacies can bill for DSMT services and problems when pharmacists sign the billing paperwork—even when the service is billed under the pharmacy's NPI. APhA recommends CMS take the following actions to remove some barriers to DSMT access in community pharmacies: listing pharmacies as accredited DSMT providers in the Medicare policy manual; providing information to educate MACs that accredited pharmacies are allowed to deliver and bill for DSMT services under the pharmacy's NPI; and clarifying the billing paperwork can be signed by certified pharmacist instructors.

APhA's member pharmacists also provided feedback that the payment rates for DSMT were insufficient to cover the cost of delivering the service, and there were better incentives to deliver the Medicare Diabetes Prevention Program (MDPP) than DSMT. APhA also received feedback that more flexibility is needed in the mix of individual and group visits in providing care to meet the needs of an individual patient as well expanding the benefit to recognize that patients with diabetes may need re-education over the continuum of managing this chronic condition.

From a service delivery perspective, CMS eliminated a significant barrier for Medicare beneficiaries by permitting pharmacies in Medicare-enrolled, accredited DSMT programs not affiliated with hospitals or physician clinics to deliver DSMT services via telehealth due to social distancing requirements and the fact that many DSMT services must be delivered via group session.[35] In order to maintain patient access and increase access to underutilized DSMT services to promote health equity, particularly in populations heavily impacted by SDOH, APhA strongly encourages CMS to make the delivery of DSMT services via telehealth permanent.

Finally, APhA recommends that CMS change the terminology for DSMT to align with the 2022 Standards of Medical Care in Diabetes, "diabetes self-management education and support" or "DSMES." [36] Patients with diabetes need ongoing support and intensified re-education that can

[34] CMS. COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing. Question #43, Page #74. Updated 7/28/20, available at: https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf
[35]CMS. COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing. Question #43, Page #74. Updated 7/28/20, available at: https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf
[36] American Diabetes Association; *Standards of Medical Care in Diabetes—2022* Abridged for Primary Care Providers. *Clin Diabetes* 1 January 2022; 40 (1): 10–38.

extend beyond the current DSMT benefit. Medicare beneficiaries may need additional benefits CMS should also consider allowing additional hours of DSMT for beneficiaries during the four critical times identified in the Joint Position Statement of the American Association of Diabetes Educators, the American Diabetes Association, and the Academy of Nutrition and Dietetics.[37]

The Medicare Diabetes Prevention Program (MDPP):

MDPP is another underutilized program that may benefit from the increased participation of pharmacists and pharmacies as part of a coordinated approach to help prevent diabetes. According to CMS, out of an estimated 16 million Medicare beneficiaries whose excess weight and risky A1c level make them eligible, only 3,600 have participated since Medicare began covering the MDPP in 2018.[38]

As a CDC DP17-1705 cooperative agreement participant[39] 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

[37] Powers, Margaret. Et. al. A Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. Diabetes Self-management Education and Support in Type 2 Diabetes. 2015, available at: https://www.diabeteseducator.org/docs/default-source/practice/practice-resources/position-statements/dsme_joint_position_statement_2015.pdf?sfvrsn=0.
[38] https://public-inspection.federalregister.gov/2021-14973.pdf
[39] https://www.cdc.gov/diabetes/programs/stateandlocal/funded-programs/dp17-1705.html

CMS mentions, payment timing or turnaround on reimbursements for MDPP services significantly hinders 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.

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. 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 any model is financially sustainable to increase the currently low participation rates and achieve its intended goal of benefitting patients.

Immunizations/Vaccinations:

As stated above, APhA urges CMS to make the additional payment of $35.50 (geographically adjusted) when a COVID-19 vaccine is administered in a beneficiary's home permanent and expand it to all other ACIP-recommended vaccines to increase low vaccination rates to promote health equity—particularly in medically underserved areas.

APhA's members also provided feedback that there can be confusion about where vaccines are covered in the Medicare program, in Part B or Part D. APhA recommends CMS provide more information to clarify Part B and D coverage for all stakeholders.—in particular, to reflect the

recent changes included in the Inflation Reduction Act requiring Medicare Part D plans to cover all ACIP-recommended vaccines with no cost sharing or deductible beginning January 1, 2023.[40]

Non-Face-to-Face Services/Remote Therapeutic Monitoring (RTM) Services (pg. 1,003)

APhA supports the creation of two G codes to include clinical activities that can be furnished by pharmacists and the important role pharmacists play in the delivery of RTM

CMS is proposing to create two HCPCS G codes, one base code and one add-on code, that include clinical labor activities (that is, incident to services such as communicating with the patient, resolving technology concerns, reviewing data, updating and modifying care plans, and addressing lack of patient improvement) that can be furnished by auxiliary personnel under general supervision. These two new G codes, GRTM1 (first 20 minutes of evaluation and management services).and GRTM2 (each additional 20 minutes of evaluation and management services during the calendar month (List separately in additional to code for primary procedure), will include physician work and direct PE inputs as currently described in CPT codes 98980 and 98981 but will allow general supervision of the clinical labor found in the direct PE inputs.

APhA generally supports the creation of two G codes to include clinical activities that can be furnished by pharmacists as auxiliary personnel/clinical staff under general supervision. Pharmacists have the expertise to play an important role in the delivery of RTM. At a minimum, clinical staff, including pharmacists, should be eligible to deliver RTM services under general supervision, similar to Remote Patient Monitoring (RPM) and continuous glucose monitoring (CGM) services.

APhA offers the following examples of how pharmacists are currently involved in patient monitoring services, including RPM, that demonstrate 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

[40] https://www.congress.gov/bill/117th-congress/house-bill/5376/text

reduce hypoglycemia and hyperglycemia and improve day-to-day consistency. Pharmacists also make specific medication recommendations or directly adjust medications under a CPA.

In-Home Additional Payment for Administration of COVID-19 Vaccines (pg. 2,696)

APhA urges CMS to make the additional payment of $35.50 (geographically adjusted) when a COVID-19 vaccine is administered in a beneficiary's home permanent and expand it to all other ACIP-recommended vaccines

APhA supports CMS' proposal to continue the additional $35.50 (geographically adjusted) payment for at-home COVID-19 vaccinations for another year, which is no longer tied to the end of the declaration under section 319 of the PHS Act. We agree it would provide CMS with additional time to track utilization and trends associated with its use to inform the policy for CY 2024. The additional rate is appropriate, as CMS states, "to account for the post-administration time that the health care professional must spend in the home to monitor the patient after administration of the COVID-19 vaccine. Administration of the COVID-19 vaccine typically involves monitoring the patient for at least 15-30 minutes post-injection which is not the general administration protocol for other vaccines. The in-home add-on payment helps to account for the costs associated with special handling of the vaccine and the extra time spent with the patient when a vaccine is administered in the home."

Our members agree "this policy will continue to provide access to beneficiaries who would otherwise have difficulty getting vaccinated, while we [CMS] continue to monitor utilization and receive information to be considered in developing…policy for the future."

While CMS is "not extending the policy to include the other preventive vaccines," "[a]t this time," we strongly recommend that CMS make this policy permanent and extend it to all other ACIP-recommended vaccines. Congress has recognized the enormous public health benefits from making vaccinations more accessible to promote health equity. Most recently, as mentioned above, by removing cost-sharing for all ACIP-recommended vaccines in the Inflation Reduction Act of 2022. Independent analyses has confirmed that preventive vaccines produce significant savings and downstream health care costs.[41] At HHS Secretary Becerra's recent "Virtual Roundtable on Increasing Routine Vaccinations,"[42] APhA recommended HHS extend this additional payment to all ACIP-recommended vaccines to expand beneficiaries' access to the benefits of all preventive vaccinations, particularly to the homebound and those in

[41] https://www.ajmc.com/view/assessing-the-cost-of-vaccinepreventable-diseases
[42] https://www.hhs.gov/about/news/2022/02/24/readout-secretary-becerras-virtual-roundtable-on-increasing-routine-vaccinations.html

medically underserved areas that lack access to primary care providers to promote health equity. The HHS Secretary expressed his support at this meeting and urged us to submit these comments.

COVID-19 Vaccines and Their Administration (pg. 2,750)

APhA supports a vaccine administration fee for influenza, pneumococcal, and hepatitis B and COVID-19 that incentivizes providers to offer vaccinations and encourages Medicare coverage for all ACIP-recommended vaccines

Per the CDC, pharmacists were responsible for giving more influenza vaccines than physician offices from 2019—2021. 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. Considering both scheduled and walk-in vaccinations, per shot losses for health care providers ranged from $3.36 to $32.76—**that was 19 years ago**—losses are more significant today.[43]

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 opportunities and declines in immunization rates.[44]. Accordingly, APhA urges CMS to account for the cost of the service and continue 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.

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

[43] 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

[44] 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.

per administration of the COVID-19 vaccine in all settings. In light of the additional variants, 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 costs to pharmacists and other vaccinators, including the time necessary, which could appropriately be characterized as medical-decision making, navigating the myriad of primary and booster dose scenarios and assisting patients to choose from the various Messenger RNA (mRNA) and non-mRNA vaccines the one that is appropriate for each individual patient, as well as storage costs that vary based on the vaccine manufacturer, personal protective equipment (PPE), 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 that may be causing hesitation about receiving the vaccine. Also, pharmacists are not able to bill an office visit like other CMS-recognized providers, so it is imperative that the vaccine administration fees cover the full spectrum of services involved in providing a vaccine for an individual patient.

Accordingly, APhA strongly encourages CMS maintain the $40 rate for COVID-19 vaccine administration and increase the rate for other ACIP-recommended vaccines, which do not currently cover the full and complete costs for administration and medical decision making required in the current PHE and beyond. We also encourage CMS assess additional adjustments to cover new costs for vaccine administration in the future—in particular to address current and future PHEs (monkeypox, etc.).

Monoclonal Antibody Products Used for Treatment or for Post-Exposure Prophylaxis of COVID-19 (pg. 2,752)

APhA supports the continuation of the current payment rates for 2023 for administration of a COVID-19 monoclonal antibody product

APhA supports CMS' proposal to continue to pay for COVID-19 monoclonal antibody products under the Medicare Part B vaccine benefit through the end of the calendar year in which the EUA declaration under section 564 of the FD&C Act for drugs and biological products. We also urge CMS to reassess continuing this payment for new EUAs for additional monoclonal antibody products given pharmacists' key position to assist with these efforts.

When a monoclonal antibody treatment was found to be very effective against the Delta COVID-19 variant, FDA permitted subcutaneous injection when administered for post-exposure prophylaxis under the original EUA, which, coupled with the Ninth Amendment to Declaration under the PREP Act, permitted pharmacists to provide these treatments subcutaneously and pharmacists were able to quickly administer hundreds of these treatments to patients. To accomplish this, many pharmacies went out of their way retooling and setting up special separate areas, personal protective equipment (PPE), and instituting new patient care processes, at great expense, in order to administer these monoclonal antibodies to uninsured patients and monitor them to ensure patient safety. 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. The speed and success of pharmacists to administer these treatments shows pharmacists' and pharmacies' capabilities as vital parts of our nation's health care infrastructure. Accordingly, CMS needs to ensure that when new EUAs for monoclonal antibody treatments are authorized by FDA against future COVID-19 variants and/or additional pandemics and public health threats that CMS maintains a payment mechanism to easily utilize pharmacists to administer these treatments—particularly in medically underserved areas.

Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan (Pg. 2,909)

CMS is proposing to change the year from which prescription drug event (PDE) data is used from the preceding year to the current evaluated year when CMS determines whether a prescriber qualified for an exception based on the number of Part D controlled substance prescriptions (§ 423.160(a)(5)(ii)). In the 2022 Physician Fee Schedule final rule, CMS finalized several exceptions to the electronic prescribing requirement, including an exception for small prescribers who prescribe less than 100 controlled substances per year. While APhA supports a transition to e-prescribing of controlled substances, our members expressed concerns that CMS' proposal to track prescribing rates in the current year using PDE data may be difficult to translate to meaningful timely information for the prescriber's tracking purposes. In addition, itcould have unintended consequences for patients' access to controlled substances, especially in medically underserved areas if prescribers are reluctant to write prescriptions for controlled substances. Impact on access to buprenorphine for medication assisted treatment for opioid use disorder is another concern in this policy. Specifically, titrations for some EPCS drugs such as buprenorphine often have complicated directions for use that sometimes result in errors when e-prescribed. Accordingly, APhA recommends that CMS allow appropriate exceptions to the

EPCS requirement when certain written prescriptions, such as buprenorphine, would be clearer and better protect patient health and safety.

CY 2023 Modifications to the Quality Payment Program (pg. 3,078)

Overall, APhA supports CMS' 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, our members working in ACOs report that pharmacists are underutilized for their medication expertise, and that even the implementation of medication management practice improvements in the Improvement Activity category is handled as a check the box without implementing evidence-based medication management practices.

APhA analysis finds that pharmacists working as part of health care teams directly contribute to over 25% of the current 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 the majority of measures included in the proposed APM Performance Pathway (APP) measure set. In the proposed rule, CMS acknowledges "the 2022-2024 APM APP measure set (86 FR 65431) may not fully represent the services provided and the patients treated by all clinician types in a group." CMS expects many clinicians who are part of APMs and do not attain QP status will report for MIPS using the APP. Pharmacists' medication and health-related expertise can contribute to varying degrees to most of the seven finalized MIPS Value Pathways (MVPs) for the 2023 performance year and all of the five newly proposed MVPSs in the proposed rule: Advancing Cancer Care; Optimal Care for Kidney Health; Optimal Care for Neurological Conditions; Supportive Care for Cognitive-Based Neurological Conditions; and Promoting Wellness. 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 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's members working within ACO population health management also provided feedback that many efficiencies could be gained if all payers were required to report measure data (e.g. medication adherence data) using a standardized formats and data fields.

Proposal To Change the Query of PDMP Measure Description (Pg. 3,497)

APhA supports CMS' proposal to require Query of the PDMP measure for MIPS providers as part of the Promoting Interoperability MIPS performance category. Most states require query of the PDMP in monitoring use of controlled substances, and the PDMP can be a useful clinical tool for clinicians. APhA also supports CMS' proposed two exceptions to this requirement:

1. Any MIPS eligible clinician who is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period,
2. Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.

APhA also recommends that CMS continue to monitor the impact of this requirement, especially on underserved populations.

Request for Information on Risk Indicators Within Complex Patient Bonus Formula to Continue to Align with CMS Approach to Operationalizing Health Equity (Pg. 3,689)

CMS is proposing a positive adjustment to the quality performance score for an Accountable Care Organization (ACO) that achieves a specified level of quality performance and serves beneficiaries in areas with a high Area Deprivation Index (ADI) or serves a large proportion of dual eligible beneficiaries. CMS is not currently proposing to use the ADI measure within the complex patient bonus, but is asking for public comments on the potential future incorporation of the measure. In considering a potential future definition of "safety net providers" in the context of the complex patient bonus, CMS is interested in input and information related to the definition of "Essential Community Providers" (ECPs) as defined in 45 CFR 156.235.

APhA strongly urges CMS to recognize the need for pharmacists' inclusion and to support policies to include pharmacists as "essential community providers." Pharmacists are among the most accessible health care providers, with nearly 90% of Americans living within five miles of

a community pharmacy. In addition to being medication experts, pharmacists also provide a broad array of services in FQHCs, physician offices, clinics, pharmacies, and other settings, including disease state and medication management, smoking cessation counseling, health and wellness screenings, preventative services, immunizations, and, in some states, women's health services. The inclusion of pharmacists on a patient's care team can have a profound impact on overall quality of care[45], while increasing patient satisfaction and access to essential services, particularly in medically underserved areas (MUAs). Accordingly, APhA agrees with including pharmacists in the definition of "safety net provider" in the context of MIPS eligible clinicians who may receive the complex patient bonus. In addition, APhA urges CMS to consider incentivizing health care professionals that are not currently considered MIPS-eligible clinicians, such as pharmacists to provide care to medically underserved patients to align with CMS' prioritization of heath equity to improve patient access and meet care needs.

[45] *See, e.g.*, Michael E. Porter, Thomas H. Lee, *The Strategy that will Fix Health Care*, HARVARD BUSINESS REVIEW (2013), *available at* http://hbr.org/product/the-strategy-that-will-fix-health-care/an/R1310B-PDF-ENG; C.R. Preslaski , I. Lat, R, MacLaren, J. Poston, *Pharmacist contributions as members of the multidisciplinary ICU team*, CHEST (2013), *available at* http://www.ncbi.nlm.nih.gov/pubmed/24189862; American Diabetes Association,), *Effect of Adding Pharmacists to Primary Care Teams on Blood Pressure Control in Patients with Type 2 Diabetes: A Randomized Controlled Trial*, DIABETES CARE (2010), *available at* http://care.diabetesjournals.org/content/early/2010/10/05/dc10-1294.abstract.

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.