September 9, 2024

[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-1807-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies, Proposed Rule

Dear Administrator Brooks-LaSure:

The American Pharmacists Association (APhA) is pleased to submit comments on the CY 2025 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.

APhA commends CMS' ongoing recognition of pharmacist-provided patient care services and strongly urges the agency to build upon HHS' substantive work maximizing the utilization of public health emergency (PHE) authority, enforcement discretion, and demonstration authority to the maximum extent to remove remaining regulatory barriers to the delivery of, and payment for, pharmacist-provided patient care services for our nation's Medicare beneficiaries.

Overarching Comments

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

As CMS understands, Congress has emphasized the following intent 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 bills, 2023, 2024 (H. Rept. 117-403), and 2025 (H.Rept. 118-585):

117th Congress:

"Pharmacists and COVID–19 Authorities.—The Committee appreciates HHS' recognition under the Public Readiness and Emergency Preparedness (PREP) Act declaration authorities for pharmacists to order, treat, immunize, and provide other patient care services, including the ordering and administration of time-sensitive COVID–19 therapeutics. *The Committee requests a report within 180 days of the date of enactment of this Act on the impact of these authorities on public health and proposed actions and recommendations whether to make these authorities permanent* [emphasis added]."

"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 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]."

<u>118th Congress:</u>

"Convenient Access Standards for Medicare Part D Beneficiaries.— The Committee is concerned that existing convenient access standards for Medicare Part D beneficiaries based on geographic distance do not take into consideration true access to life-saving medications, including those that are less common or facing shortages. The Committee supports efforts by CMS to limit barriers to medication and pharmacist access for Medicare patients and make, as appropriate, updates to the Medicare Part D pharmacy access standards to improve patient access to pharmacy services offered by pharmacies not affiliated with a Pharmacy Benefit Manager. *The Committee urges CMS to consider what updates to Part D network adequacy standards, including those that do not rely on physical distance, could improve patient access to drugs and the expertise of pharmacists* [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]."

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

- **APhA supports extending the existing telehealth flexibilities (audio only and site of care) through and beyond 2025.**
- **APhA urges CMS to continue virtual supervision for incident to for all applicable evaluation and management billing codes beyond 2025, not just the lowest level of 99211.**
- **APhA urges CMS to permit physicians or nonphysician practitioners (NPPs) to bill for pharmacists' evaluation and management (E/M) services under incident to arrangements at higher levels of complexity or time when the care provided supports the use of the higher code and requests the opportunity for an in-person or virtual meeting to fill in the knowledge gaps on specific pharmacist-provided patient care services that meet the requirements for more complex E/M codes.**
- **APhA requests CMS clarify that the new G0013 code for counseling for HIV pre-exposure prophylaxis (PrEP) applies to clinical staff, including pharmacists. Additionally, APhA urges CMS to use CPT code 99213 to crosswalk the relative value units (RVU) for G0013 to more accurately account for the time and complexity of the service provided.**
- **APhA strongly recommends CMS utilize a 6-to-9-month lead-up period for the National Coverage Determination (NCD) moving all PrEP to Part B and utilizing a demonstration pathway for pharmacists to prescribe and bill for PrEP services.**
- **APhA urges CMS to clarify that incident to payment is permitted under general supervision to "clinical staff," including pharmacists for digital mental health treatment devices using new temporary codes GMBT2 (first 20 minutes) & GMBT3 (each additional 20 minutes).**
- **APhA supports CMS' proposed increased telehealth flexibilities and payments for opioid treatment programs (OTPs) and recommends CMS reimburse pharmacist-provided opioid use disorder (OUD) services at OTPs.**
- **APhA urges CMS to continue the existing reimbursement level for the commercial versions of COVID-19 vaccinations through respiratory disease season. APhA also urges CMS to address Part D plans' utilization management of vaccines by pharmacy benefit managers (PBMs) and establish a new add-on CPT code for the administration of combination vaccines that includes payment for patient counseling by pharmacists and other immunizers.**
- **APhA continues to urge CMS to build off the success of the vaccine administration for in-home COVID-19 vaccination to all ACIP-recommended vaccines.**
- **APhA urges CMS to finalize its proposal to expand coverage to those at intermediate risk and no longer require a physician's order for hepatitis B vaccination to facilitate pharmacy roster billing.**

- **APhA also recommends CMS consider maximizing the utilization of pharmacists to fill the gap in primary care providers under CMS' request for information (RFI) on an Advanced Primary Care Management program.**

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, APhA is 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 me at mbaxter@aphanet.org.

Sincerely,

Michael Baxter

Michael Baxter
Vice President, Government Affairs

Full APhA Feedback and Comments:

e. Audio-Only Communication Technology to Meet the Definition of "Telecommunications System (FR 61632)

Beginning January 1, 2025, CMS is proposing to revise § 410.78(a)(3) to state that an interactive telecommunications system may also include "two-way, real-time audio-only communication technology for any telehealth service furnished to a beneficiary in their home if the distant site physician or practitioner is technically capable of using an interactive telecommunications system as defined as multimedia communications equipment."

f. Distant Site Requirements (FR 61634)

CMS will also allow practitioners to continue to use their practice location rather than their home address when providing telehealth services from their home through 2025.

APhA supports these telehealth flexibility extensions and shares CMS' concern about an "abrupt transition" to the pre-PHE policy that defines direct supervision to require the physical presence of the supervising practitioner (below).

(2) Proposal to Permanently Define "Direct Supervision" to Include Audio-Video Communications Technology for a Subset of Services (FR 61634)

CMS is proposing to make permanent virtual supervision for "immediate availability," for the lowest level E/M visit (99211) but would discontinue virtual supervision for other codes, absent congressional action, after December 31, 2025.

Although APhA is pleased with CMS' progress in making virtual supervision of low-level codes, such as 99211, permanent (see, the 117th Congress report language above regarding incident to services), APhA also strongly encourages CMS to expand virtual supervision for all pharmacist-provided incident to services to the list of eligible codes and revise the definition under § 410.32(b)(3)(ii) for "direct supervision" of clinical staff, including pharmacists currently classified as auxiliary personnel.

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. Throughout the pandemic, pharmacists 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.

These services all require a higher-level E/M code but do not rise to the level CMS outlines for "instances where unexpected or adverse events may arise for procedures which may be riskier or more intense," and "the supervising practitioner [may need] to intervene if complications arise."

APhA also strongly urges CMS to use its full regulatory authority to permit physicians or nonphysician practitioners (NPPs) to bill for pharmacists' evaluation and management (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. 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.

APhA 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: 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.**

(37) Preexposure Prophylaxis (PrEP) of Human Immunodeficiency Virus (HIV) (FR 61665)

To facilitate prompt beneficiary access for CY 2025, CMS established 3 HCPCS G codes that describe the service of counseling and administration of Human Immunodeficiency Virus (HIV) pre-exposure prophylaxis drugs. This includes "G0013 (Individual counseling for pre-exposure prophylaxis (PrEP) by clinical staff [including pharmacists], to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence) describe the counseling portion of the service."

APhA strongly supports establishing G0013 for clinical staff, including pharmacists, the medication experts on patient care teams, to provide HIV risk assessment, risk reduction and the medication adherence portion of beneficiary access to PrEP. As one of the most accessible and trusted health care providers in their communities, pharmacists have a significant role to contribute in initiating access to HIV PrEP/Post-exposure prophylaxis (PEP). Nearly 90% of the U.S. population lives within five miles of a community pharmacy and this high level of accessibility allows pharmacists to serve in a unique role as another point of entrance for patients to get integrated into longitudinal and acute HIV preventative services. Programs allowing pharmacists to furnish HIV PrEP/PEP have expanded across the country in the past ten years. Pharmacists have the authority to initiate HIV PrEP in 16 states[1] and HIV PEP in 19 states,[2] via a statewide protocol, standing order, or independent prescriptive authority. Pharmacists in these programs serve as a triage point, established within accessible and familiar community settings, for patients to enter the HIV preventative care system. The accessibility of pharmacists is particularly important for PEP, due to the time-sensitive nature required for the initiation of medication therapy within 72 hours (3 days) of a suspected exposure. Engagement through PEP pharmacist services also establishes a contact point for the transition from PEP to PrEP for high-risk patients, as recommended by the most recent guideline recommendations by the U.S. Public Health Service, allowing for a more seamless entry into the HIV preventative care system.

[1] Arkansas, California, Colorado, Connecticut, Idaho, Illinois, Iowa, Louisiana, Maine, Montana, Nevada, New Mexico, Oregon, Rhode Island, Utah, Virginia

[2] Arkansas, California, Colorado, Connecticut, Idaho, Illinois, Iowa, Louisiana, Maine, Maryland, Montana, Nevada, New Mexico, North Carolina, Oregon, Rhode Island, Tennessee, Utah, Virginia

For G0013, CMS is "proposing a work RVU of 0.18 based on the work and direct PE inputs crosswalked from CPT code 99211 (Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional)." APhA urges CMS to use CPT code 99213 to crosswalk the RVU for G0013 to more accurately account for the time and complexity of the service provided. APhA does not anticipate all encounters, especially with new patients, would realistically reflect an RVU of 0.18. Limiting G0013 to an RVU of 0.18 undervalues the clinical services pharmacists provide and would not reimburse pharmacists for the time providing care to patients with more complex medical histories.

CMS also restates its release of a proposed national coverage determination (NCD) for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention on July 12, 2023. APhA strongly urges CMS reference recommendations submitted by almost 50 HIV advocacy organizations in response to the proposed NCD to mitigate unintended consequences of the proposed transition of PrEP coverage entirely out of Medicare Part D and exclusively into Medicare Part B. A few primary recommendations include:

- Establish a 6- to 9-month lead-in period to allow pharmacists, payors, and patients to adequately prepare for the impact of the change and to ensure that claims processes will be adjudicated in a timely manner. Alternatively, given CMS precedence that when a final NCD is issued that it is effective immediately, issue implementation guidance 6-9 months prior to the final rule that addresses the recommendations included in this letter.
- Utilize current regulatory authority to leverage pharmacies as existing suppliers in Medicare Part B to provide HIV testing and prevention services listed in the recent Fact Sheet, including administering injectable PrEP, similar to how pharmacies bill for vaccination services in Medicare Part B and how pharmacies billed for over-the-counter COVID-19 tests to Medicare Part B during the recent pandemic.

Related to the NCD, CMS has confirmed during a recent Webinar that HIV PrEP prescriptions with a pharmacist listed as the prescriber will not be covered by Medicare Part B. As described above, pharmacists in many states have the authority to prescribe HIV PrEP, and many HIV PrEP clinics are run by pharmacists. As a result of HIV PrEP prescriptions written by pharmacists no longer being covered by Medicare Part B. In addition, there is a risk that many Medicare beneficiaries' care will be interrupted, and they will be forced to establish with another provider to continue to receive their HIV PrEP. APhA strongly urges CMS to allow Medicare Part B to cover HIV PrEP prescribed by pharmacists to not undermine the purpose of the NCD to increase patient access.

b. Payment for Digital Mental Health Treatment (DMHT) Devices (FR 61743)

CMS is proposing Medicare payment to billing practitioners for digital mental health treatment (DMHT) devices furnished incident to or integral to professional behavioral health services used in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care. CMS appears to build these codes on remote patient monitoring (RPM), which pharmacists are currently authorized to bill for under incident to arrangements.

In the description of two of the codes (GMBT2 & GMBT3), it appears that clinical staff, including pharmacists, can provide the DMHT service and the codes can be billed incident to a physician or qualified health practitioner. APhA requests clarification from CMS that GMBT2 and GMBT3 can be billed incident to by clinical staff, including pharmacists.

- GMBT2 (First 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the DMHT device from patient observations and patient-specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month)
- GMBT3 (Each additional 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the DMHT device from patient observations and patient-specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month).

As CMS understands, pharmacists provide medication-assisted treatment (MAT), and can also receive additional education and credentialing, such as board certification as a psychiatric pharmacist.[3,4,5,6,7,8,9]

F. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished By Opioid Treatment Programs (OTPs) (FR 61817)

CMS proposes new flexibilities for OTPs, including permanently allowing audio-only periodic assessments and allowing the OTP intake add-on code to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with methadone when clinically appropriate. Additionally, CMS proposes an increase in payment for OTPs, as well as add-on codes for new Food and Drug Administration-approved opioid agonist and antagonist medications.

APhA supports CMS' proposals to make these OTP flexibilities permanent. 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 as congressional intent mentioned (see, above) 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

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[3] 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

[4] 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.

[5] 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.

[6] 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/.

[7] Grgas, M. Clinical psychiatric pharmacist involvement in an outpatient buprenorphine program, Mental Health Cliniciam, 2013, 3(6), 290-291. Available at: http://mhc.cpnp.org/doi/abs/10.9740/mhc.n183353?code=cpnp-site.

[8] 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/

[9] 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

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 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. Mental health clinical pharmacists have developed many practices in the treatment of those with substance use disorders, including:

1. Prescribing and continuation of buprenorphine.
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.

b. Pneumococcal, Influenza and Hepatitis B Vaccine Administration (FR 61925) and f. Summary of Payment Amounts for CY 2025 (FR 61927)

CMS states in Tables 45 and 46 that the preventive vaccine administration payment for the COVID-19 vaccine under an emergency use authorization (EUA) would remain at $44.99 with a Medicare Economic Index (MEI) adjustment for inflation. However, for COVID-19 vaccines no longer under an EUA vaccine administration is being proposed at $33.74 plus MEI.

APhA strongly supports Medicare maintaining the EUA level of $44.99 per administration of the commercial versions of the COVID-19 vaccine in all settings. At a minimum, during the fall and winter respiratory disease season, which the Centers for Disease Control and Prevention (CDC) defines as a time when viruses that cause respiratory disease usually circulate more heavily in the community. Considering additional COVID-19 variants, we need to maintain access to our vaccinator workforce now more than ever, and inadequate reimbursement for vaccination administration results in missed immunization opportunities and declines in immunization rates. Accordingly, APhA urges CMS to account for the cost of the service and continues to encourage providers to offer Medicare beneficiaries ACIP-recommended immunizations at the clinical point-of-care. As stated above, action is particularly necessary as we prepare to face the upcoming seasonal respiratory condition season for COVID, influenza, and respiratory syncytial virus (RSV).

Utilization management

While not included in the proposed rule, APhA appreciated CMS' letter to plans and pharmacy benefit managers (PBMs) expressing concern "about payment practices that may impede access to recommended vaccinations, and [that] it is imperative that plans and PBMs take immediate steps to ensure adequate payment for and access to vaccines." As APhA and our partners have emphasized to CMS, APhA continues to have serious concern regarding utilization management tactics that are being employed by Medicare Part D plans for vaccine coverage despite the Administration's very clear policy that all Advisory Committee on Immunization Practice (ACIP)-recommended vaccines be made available to Medicare beneficiaries with no copay in implementing requirements of the Inflation Reduction Act. Specifically, the utilization management tactics at issue, such as National Drug Code (NDC) blocks and $0 reimbursement to pharmacies for "less preferred" ACIP-recommended vaccines poses significant and harmful barriers to timely and equitable access to vaccines for Medicare beneficiaries. Accordingly, APhA continues to urge CMS in a final rule to specifically prohibit Part D sponsors from using utilization management tactics for vaccine coverage and to reject any Part D formulary that suggests utilization management for vaccine coverage.

Combination Vaccines

As CMS understands, new combination vaccines against influenza and COVID-19 are advancing through the regulatory process. Combination vaccines, utilizing messenger ribonucleic acid (mRNA) technology, have the potential to reduce the burden of respiratory viruses on CMS, health systems and pharmacies and offer beneficiaries more convenient vaccination options to improve patient compliance and provide stronger protection from respiratory illnesses.

However, it is unclear how to code the administration of influenza-COVID-19 combination vaccines for adults. While there are administration CPT codes that can be used for standalone COVID-19 and influenza vaccine administration, there is no explicit CPT code to bill for the administration of a vaccine containing these two components.

CMS has historically required Medicare providers to bill Part B vaccine administration with vaccine-specific G-codes. For COVID-19, CMS preferred that a unique CPT code (i.e., 90480) be issued in lieu of a G-code. Private payers exclusively use CPT codes for vaccine administration billing. A combination COVID-19-influenza vaccine poses a coding challenge, especially for Medicare patients.

Existing adult vaccine administration coding schemes create provider payment discrepancies between single and COVID-containing combination vaccines. If providers, including

pharmacists, are unable to receive comparable reimbursement for COVID-containing combination vaccine administration, they may favor single-component vaccine administration. This could, in turn, fuel vaccine access barriers for people who may prefer fewer injections or who may be unable to visit their provider more frequently.

APhA supports an add-on CPT code for the administration of a component vaccine within a combination COVID-19/influenza vaccine. The benefits include retaining the current COVID-19 administration code (i.e., 90480); similar code structure used for pediatric combination vaccine administration codes (i.e., 90460-90461); and could be flexible enough to allow for billing of other COVID-19 combination vaccines. It would also ensure providers, including pharmacists, can be reimbursed for patient counseling which is currently not included in 90471 but is included in 90480.

Pharmacy benefit reimbursement is primarily determined via payer/PBM negotiations, rather than a formal valuation process. Accordingly, APhA strongly recommends CMS prepare in the final rule to issue guidance to Medicare Advantage and Part D plans requiring pharmacy benefit managers (PBMs) to implement multi-component billing and payment that covers patient counseling for all practitioners providing these vaccinations.

d. In-Home Additional Payment for Administration of Preventive Vaccines (FR 61926)

The current payment rate for in-home administration of preventive vaccines under M0201 is $39.94 and will be adjusted by MEI. The additional payment is appropriate, as CMS has previously stated, "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."

APhA continues to strongly recommend that CMS makes 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 by removing cost-sharing for all ACIP-recommended vaccines in the Inflation Reduction Act. Independent analyses have confirmed that preventive vaccines produce significant savings and

downstream health care costs.[10] At HHS Secretary Becerra's "Virtual Roundtable on Increasing Routine Vaccinations," 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 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 continue to submit these comments.

Revised Payment Policies for Hepatitis B Vaccine Administration (FR 61929)

CMS is proposing to expand coverage of hepatitis B vaccinations to beneficiaries who are at high or intermediate risk of contracting hepatitis B who have not been previously vaccinated or whose vaccination status is unknown. In addition, CMS will no longer require a physician's order for hepatitis B vaccination to facilitate roster billing.

APhA strongly agrees with CMS that "Medicare coverage of hepatitis B vaccination is outdated in light of recent information about the risks of contracting hepatitis B, and that current research indicates that individuals who remain unvaccinated against hepatitis B are at intermediate risk of contracting hepatitis B virus." CMS also notes that "[i]f the physician's order requirement is eliminated, then we would also change our procedures to allow mass immunizers to use the roster billing process to submit Medicare Part B claims for hepatitis B vaccines and their administration."

All other preventive Medicare Part B vaccines –influenza, pneumococcal, and COVID vaccines – are eligible to be administered by traditional providers and non-traditional providers, or "mass immunizers," including pharmacists, chain drug stores, senior centers, or public health clinics. A physician may send a fee-for-service (FFS) beneficiary from the in-office setting to the pharmacy to receive their HBV vaccines, only for the patient to find that the pharmacist cannot administer hepatitis B vaccines. This is confusing for the patient because they expect to receive their hepatitis B vaccines the same way they receive other preventive Part B-covered vaccines in the pharmacy. These patients, who are elderly or disabled FFS beneficiaries, deemed by their physician at high or intermediate risk of contracting hepatitis B, walk away without receiving their HBV vaccination.

APhA advocated for this proposed change with over 50 other patient organizations and commends CMS on taking this critical step in the proposed rule to fulfill the expanded

[10] American Journal of Managed Care. Assessing the Cost of Vaccine-Preventable Diseases. New Directions in Immunization Awareness and Engagement. December 23, 2019. Available at: https://www.ajmc.com/view/assessing-the-cost-of-vaccinepreventable-diseases

Advisory Committee on Immunization Practices (ACIP) hepatitis B vaccination recommendation, bringing us closer to the elimination of this preventable disease and achieving CMS' goals of vaccine equity and access across the Medicare program.

c. Revisions to Payment Policies for Hepatitis B Vaccinations in Rural Health Clinics (RHC) and Federally Qualified Health Centers (FQHC) (FR 61929)

APhA also supports CMS' proposal to add hepatitis B vaccines to the list of vaccines covered in rural health clinics (RHCs) and federally qualified health centers (FQHCs) at 100 percent of reasonable cost.

APhA is aware of the challenges Medicare beneficiaries face when receiving care in rural and urban areas of shortage. RHCs and FQHCs offer services to vulnerable seniors and the disabled. CMS' proposal encourages parity in reimbursement for hepatitis B vaccination and, allows a consistent, streamlined approach for billing and payments of all Part B preventive vaccines across these critical Part B settings of care.

3. Request for Information: Advanced Primary Care Hybrid Payment (FR61724)

CMS is proposing to create an Advanced Primary Care Management (APCM) program to move primary care away from fee-for-service (FFS) and toward value-based care, combining elements from existing chronic care management (CCM) and principal care management (PCM) programs that also incorporates some communications technology-based services (CTBS), such as virtual check-ins and remote evaluation of images, that have been previously established as separately billable services. Proposed APCM codes are not time-based as CCM codes are, they are broken out by patient risk and include 13 distinct "service elements."[11]

CMS is proposing that APCM services be furnished each calendar month by the practitioner assuming the care management role for a beneficiary with 3 proposed APCM HCPCS codes:

- GPCM1-APCM services "provided by *clinical staff* [emphasis added] and directed by a physician or other qualified healthcare professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month" Proposed valuation: $10 per patient per month

[11] These 13 elements include: 1. Patient Consent; 2. Initiating visit; 3. Continuity of care; 4. Alternative care delivery; 5. Overall comprehensive care management; 6. Patient-centered care plan; 7. 24/7 access to care; 8. Coordination of care transitions; 9. Ongoing communication; 10. Enhanced communication opportunities; 11. Population data analysis; 12. Risk stratification and 13. Performance measurement.

- GPCM2-APCM services "for a patient with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by *clinical staff* [emphasis added] and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the elements included in GPCM1, as appropriate." Proposed valuation: $50 per patient per month.
- GPCM3-APCM services "for a patient that is a Qualified Medicare Beneficiary with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, which place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, provided by *clinical staff* [emphasis added] and directed by a physician or other qualified health care professional who is responsible for all primary care and serves as the continuing focal point for all needed health care services, per calendar month, with the elements included in GPCM1, as appropriate." Proposed valuation: $110 per patient per month.

CMS acknowledges there are care management services/codes that are likely to be viewed as "substantially duplicative" of APCM services and would not be billable alongside APCM (i.e., must be one or the other), including CCM, PCM, and Transitional Care Management (TCM).

CMS' proposal seeks to expand the use of CCM services, which are currently underutilized under FFS to provide patients with a wider range of service options to meet individual needs and create a unified code set for streamlined billing.

CMS considered whether other care management services would be duplicative and stated that community health integration (CHI), Social Determinants of Health (SDOH), principal illness navigation (PIN), remote patient monitoring (RPM), and remote therapeutic monitoring (RTM) "may complement" APCM services and could be billed on top of APCM.

CMS states the new APCM code set "could serve as a chassis to incorporate primary care model learnings" into primary care services and has requested comments on "Advanced Primary Care Hybrid Payments."

CMS includes a 47-question request for information (RFI) for feedback on moving the focus of primary care from evaluation and management (E/M) visits to value-based reimbursement.

Rather than focusing on billing questions such as, "[s]hould CMS limit the types of non-physician clinicians that can bill for an advanced primary care bundle that is larger in scale and scope than APCM," APhA urges CMS to recognize non-physician clinicians, such as pharmacists, that saved millions of lives and over $450 billion in avoidable hospitalizations during the pandemic. In addition, pharmacists and other non-physician clinicians billing at lower levels would not only help address the nation's ongoing primary care shortage but save significant taxpayer funds.

APhA recommends CMS reference our previous comments to HHS on the "Initiative To Strengthen Primary Health Care," and case examples of pharmacists working in team-based care models providing preventive care and wellness services to improve primary care.