APhA
American Pharmacists Association

September 11, 2023

[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-1784-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Proposed Rule (RIN 0938-AV07)

Dear Administrator Brooks-LaSure:

The American Pharmacists Association (APhA) is pleased to submit comments on the CY 2024 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.

General Comments

Pharmacists are one of the leading health care practitioners to have contributed to some of our nation's most daunting health care challenges, including shortages of primary care health care staff—which continues to hinder patient outcomes. As you understand, the United States is projected to face a shortage of up to 124,000 physicians by 2034 as the demand outpaces

supply.[1] The health-care workforce shortage is "more acute" in minority communities,[2] and the cost of the economic burden of health inequities in the United States has cost the nation billions of dollars.[3] The workforce shortage means the United States is not prepared for another pandemic. There are dozens of counties with a staffed pharmacy but no physician. In these communities, pharmacists are caring for patients by monitoring blood pressure, providing diabetes management, and engaging in cardiovascular risk reduction efforts and many other vital services to our nation's public health infrastructure. Many state Medicaid agencies have addressed these issues by filing and approval of state plan amendments to compensate pharmacists for their care services within their state scope of practice and Medicare should follow.

HHS has repeatedly recognized the important role that pharmacists play in maintaining and addressing the country's health with multiple temporary authorizations during the pandemic to test, treat, and immunize Medicare beneficiaries. The HHS Secretary extended many of these medical countermeasures, including certain pharmacy-provided COVID-19 testing, vaccination, and related health care services with the eleventh amendment to the declaration under the Public Readiness and Emergency Preparedness (PREP) Act through December 2024.[4] HHS' action is the result of public health interventions by pharmacists and teammates during the pandemic which averted >1 million deaths, >8 million hospitalizations, and $450 billion in healthcare costs.[5] As HHS understands, patients have come to expect that they can access these vital healthcare services at their local pharmacy, particularly in underserved communities, where the neighborhood pharmacy may be the only healthcare provider for miles.[6]

CMS was one of the many federal agencies to recognize the need to utilize our nation's pharmacists, who have unquestionably proven their role as a permanent part of our nation's health care infrastructure. For example, CMS utilized a variety of administrative pathways, including: section 1135 waivers, enforcement discretion, and demonstration authority under section 402 (a)(1)(B)) to expand coverage of pharmacists' services within Medicare Part B to meet our nation's health care needs. CMS has also previously stated, in the CY 2021 PFS final rule, "[w]e agree with certain stakeholders that under the general CPT framework, pharmacists could be considered QHPs or clinical staff, depending on their role in a given service." "We

[1] https://www.aamc.org/news/press-releases/aamc-report-reinforces-mounting-physician-shortage#:~:text=According%20to%20new%20data%20published,both%20primary%20and%20specialty%20care.
[2] https://www.aamc.org/news/what-s-your-specialty-new-data-show-choices-america-s-doctors-gender-race-and-age
[3] https://jamanetwork.com/journals/jama/fullarticle/10.1001/jama.2023.5965?guestAccessKey=d0ef4664-62ff-4b6d-a816-c450ebc07a08&utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_content=tfl&utm_term=051623
[4] https://public-inspection.federalregister.gov/2023-10216.pdf
[5] https://www.sciencedirect.com/science/article/pii/S1544319122002795?dgcid=author.)
[6] https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2020.01699

understand and appreciate the expanding, beneficial roles certain pharmacists play, particularly by specially trained pharmacists with broadened scopes of practice in certain states, commonly referred to as collaborative practice agreements. We note that new coding might be useful to specifically identify these particular models of care."[7]

In addition, the Food and Drug Administration (FDA) has independently authorized pharmacists to prescribe the oral antiviral Paxlovid, with certain limitations.[8] However, pharmacist prescribing often 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, which is one of the only approved treatments when a patient has contracted COVID-19. 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. Many pharmacy benefit managers (PBMs) are paying less than $1 in dispensing fees for pharmacist-prescribing of Paxlovid, which does not cover the required patient safety checks necessary simply to dispense this medication. Based on our analysis, APhA recommends a reimbursement rate of **$75/visit under the medical benefit** for the clinical assessment (a patient visit takes between **15-45 minutes,** depending on the complexity of the patient).[9] This recommendation is based on evaluation and management (E/M) office or other outpatient services codes that other health care professionals use when providing the patient assessment necessary for prescribing Paxlovid. 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 settings are positioned to improve access to Paxlovid via assessment and prescribing services.

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[7] https://www.federalregister.gov/documents/2020/12/28/2020-26815/medicare-program-cy-2021-payment-policies-under-the-physician-fee-schedule-and-other-changes-to-part

[8] 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

[9] Patient visits fall into the range for CPT E/M codes 99202-99203 (new patient) or E/M 99212-99214 (established patient). 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.

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APhA requests real solutions from CMS to remove barriers to fully utilize pharmacists' expertise to address access gaps in care for Medicare beneficiaries. **APhA strongly urges CMS to build upon HHS' previous work and utilize public health emergency (PHE) authority, enforcement discretion, and demonstration capability to the maximum extent by identifying the full range of E/M services being utilized by pharmacists in the states and any new coding to remove any remaining regulatory barriers to the delivery of, and payment for, the full range of pharmacist-provided patient care services for our nation's Medicare beneficiaries.**

To assist CMS in fostering patient-care teams, APhA respectfully submits our recommendations with additional information in response to the proposed rule (full, comprehensive comments below).

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 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 mbaxter@aphanet.org.

Sincerely,

Michael Baxter

Michael Baxter
Vice President, Federal Government Affairs

Full APhA Feedback and Comments:

(6) Health and Well-Being Coaching FR 52292 and (7) CMS Proposal To Add New Codes to the List FR 52293

For CY 2024, CMS is proposing to add health and well-being coaching services (CPT code 0591-3T) to the Medicare Telehealth Services List on a temporary basis for CY 2024, and Social Determinants of Health Risk Assessments (HCPCS code GXXX5) on a permanent basis.

Providing health and well-being coaching services from pharmacists has been proven to improve patient care. APhA urges CMS to incorporate pharmacist-provider collaborative practice and health coaching for patients with chronic diseases such as diabetes, hypertension, and hyperlipidemia and to allow payment to pharmacists to be able to provide these and other services listed on the Telehealth Services List. The CARES Act eliminated requirements in the Coronavirus Preparedness and Response Supplemental Appropriations Act of 2020 (P.L. 116-123) to allow the HHS Secretary to waive telehealth restrictions under 1834(m) during an emergency that normally apply only to a "qualified provider" or "practitioner"[10] to potentially include pharmacists as practitioners (providers) for the Medicare Telehealth Benefit in order to fully utilize their expertise during the public health emergency. APhA urges CMS to explore additional use of Sec. 3703 Expanding Medicare Telehealth Flexibilities under CARES Act authority during PHEs (e.g., opioid crises, etc.) and enforcement discretion to achieve a similar path to incorporating and paying pharmacists for providing and/or contributing to health and wellbeing coaching services through telehealth.

Addressing our nation's long-standing health disparities and inequalities to begin to address social determinants (SDOH) of health that impact the ability of health care practitioners to identify and/or treat a patient will take regular and consistent engagement with health care providers, particularly pharmacists - the most accessible providers. Given the nature of pharmacy, pharmacists engage regularly with patients, including underserved communities, often on a monthly or more frequent basis. The knowledge gained from these conversations gives pharmacists a more robust picture of the challenges, barriers, hurdles, and opportunities

[10] 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

facing patients and communities. Combining this access with patient trust and the ability of pharmacists to collaborate and coordinate with other healthcare team members can lead to optimal health outcomes for individuals and communities. Accordingly, APhA urges CMS to utilize the same effort explored to permit Medicare reimbursement for SDOH risk assessments for Community Health Workers (CHWs), addressed below, to pharmacists who can also provide telehealth SDOH risk assessments to our patients in underserved communities.

e. Implementation of Provisions of the CAA, 2023 FR 52298

CMS is proposing to implement several telehealth-related provisions of the Consolidated Appropriations Act, 2023 (CAA, 2023), including the temporary expansion of the scope of telehealth originating sites for services furnished via telehealth to include any site in the United States, including an individual's home; the continued payment for telehealth services furnished by rural health centers (RHCs) and federally qualified health centers (FQHCs) using the methodology established for those telehealth services during the PHE; delaying the requirement for an in-person visit with the physician or practitioner within six months prior to initiating mental health telehealth services, and the continued coverage and payment of telehealth services included on the Medicare Telehealth Services List (as of March 15, 2020) until December 31, 2024.

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

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

pharmacist telehealth-delivered comprehensive medication reviews (CMRs) have occurred successfully in medically underserved rural areas/populations.[11]

APhA also reminds CMS that pharmacists may provide mental health services incident to the services of the billing physician or non-physician practitioner (NPP), under § 410.26, especially related to the management of medications used to treat mental health conditions.

Requiring an in-person visit within six months prior to the first time the physician or practitioner furnishes a telehealth service to the beneficiary might hinder access to care for beneficiaries in need of mental health services. There is no clinical evidence for an arbitrary in-person requirement before a beneficiary can access telehealth services.[12] Requiring an in-person visit often discourages patients from seeking out mental health care due to stigma. For example, patients who live in small rural communities might not want to be seen entering a behavioral health clinic. In addition, patients experience barriers to in-person visits, including transportation challenges, the need to make childcare arrangements, and simply accessing a local mental health provider. Therefore, APhA urges CMS to continue to delay the requirement for an in-person visit within six months prior to the furnishing of a telehealth service beyond the statutory deadline of December 31, 2024. In addition, APhA opposes requiring an in-person visit at least once within six months before any subsequent Medicare mental health telehealth service. The appropriate visit interval – whether in-person or via telehealth – is patient-specific.

a. Direct Supervision via Use of Two-Way Audio/Video Communications Technology FR 52301

CMS is proposing to continue to define direct supervision to permit the presence and immediate availability of the supervising practitioner through real-time audio and video interactive telecommunications through December 31, 2024, and whether CMS should consider extending the definition of direct supervision to permit virtual presence beyond December 31, 2024.

APhA strongly urges CMS to make the flexibility for providing "direct supervision" of auxiliary personnel, including pharmacists, permanent by revising the definition under § 410.32(b)(3)(ii). Supervision via real-time audio/video technology provides flexibility in collaborative care delivery and helps to overcome barriers in access to care. Throughout the

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

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

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 (AWV).

(27) Services Addressing Health-Related Social Needs (Community Health Integration services, Social Determinants of Health Risk Assessment, and Principal Illness Navigation Services) FR 52325

For CY 2024, CMS is considering how the agency "could better recognize, through coding and payment policies, when members of an interdisciplinary team, including CHWs, are involved in treatment of Medicare beneficiaries. Currently, there is no separately enumerated statutory Medicare benefit category that provides direct payment to CHWs for their services." This includes proposing new coding to describe and separately value three types of services that may be provided by auxiliary personnel incident to the billing physician or practitioner's professional services, and under the billing practitioner's supervision, when reasonable and necessary to diagnose and treat the patient: community health integration services, SDOH risk assessment, and principal illness navigation (PIN). Specifically, CMS is proposing to create two new G codes describing community health integration (CHI) services performed by certified or trained auxiliary personnel (GXXX1 (60 minutes per calendar month; GXXX2, each additional 30 minutes per calendar month) which may include a CHW, incident to the professional services, and under the general supervision of the billing practitioner furnished monthly, as medically necessary, following an initiating E/M visit (CHI initiating visit) in which the practitioner identifies the presence of SDOH need(s) that significantly limit the practitioner's ability to diagnose or treat the problem(s) addressed in the visit.

APhA notes that CHWs go through a much shorter training period than health care practitioners, such as pharmacists. CMS has previously proposed CHWs for Medicare Part B Payment[13] and to be considered in the same category of "auxiliary staff," where pharmacists are currently categorized by CMS. While APhA supports the contributions of CHWs in addressing SDOH issues, APhA reminds CMS of the large gap between pharmacists' training, education, licensure, expertise, etc. and other Department of Labor "workforce" categories, (CHWs, etc.). APhA prefers pharmacists be referred to as "clinical staff" vs. "auxiliary staff" under current regulations. According to CMS' descriptors for these new payment codes, APhA urges CMS to evaluate when these services could best be delivered by trusted community pharmacists to address community needs as almost 90% of these populations live within 5 miles of a community pharmacy.[14] APhA also notes that community pharmacies are partnering with

[13] https://www.federalregister.gov/d/2022-14562/p-681
[14] https://www.japha.org/article/S1544-3191(22)00233-3/fulltext

CHWs to assist in connecting patients to community-based services and improving patient care.[15] As such, APhA strongly urges CMS, in its ongoing efforts to promote health care equity, to utilize the same effort to provide direct payment to CHWs with agency efforts to recognize and provide Medicare Part B payment for the complex health care services currently provided to Medicare beneficiaries by our nation's pharmacists, as mentioned above, that were recently amplified by the millions of lives and billions of dollars saved from the pharmacist-administered health care services provided during the PHE, which the federal government will continue to rely upon for future PHEs and preventive health care and treatment needs.

3. Diabetes Self-Management Training (DSMT) Services Furnished by Registered Dietitians (RDs) and Nutrition Professionals FR 52360

CMS notes to "interested parties" that "§ 410.72(d) has caused confusion" about whether RDNs can bill for DSMT services provided by other providers. CMS' proposed language will distinguish between when a registered dietician (RD) is providing/billing for medical nutrition therapy services (MNT) and when they are acting on behalf of an accredited DSMT entity and billing for the services of the program provided by multiple professionals. Additionally, CMS proposes "to clarify that an RD or nutrition professional may bill for, or on behalf of, the entire DSMT entity as the DSMT certified provider regardless of which professional furnishes the actual education services."

APhA appreciates CMS seeking to make this technical correction to provide clarity for RD billing for DSMT by adding to § 410.72 Registered Dietitians' and Nutrition Professionals' services. CMS states, "[o]ur regulations and sub-regulatory policies for Medicare telehealth services do not address scenarios involving the furnishing of DSMT services via telehealth when the actual services are personally furnished by individuals who provide them, for example, RNs, pharmacists, or other multidisciplinary team members…" APhA asks CMS to clearly restate that accredited and recognized DSMT programs are eligible to bill Medicare Part B directly for DSMT services, and may furnish and bill for DSMT services provided via telehealth, regardless of the provider type (RNs, pharmacists, registered dietitians, etc.) furnishing the service.

4. DSMT Telehealth Issues FR 52361

(a) Distance Site Practitioners

[15] https://www.japha.org/article/S1544-3191(20)30414-3/fulltext

CMS proposes to "codify billing rules for DSMT services furnished as Medicare telehealth services at § 410.78(b)(2)(x) to allow distant site practitioners who can appropriately report DSMT services furnished in person by the DSMT entity to also report DSMT services furnished via telehealth by the DSMT entity, including when the services are performed by others as part of the DSMT entity.

APhA supports the alignment of regulations for providing/billing for telehealth DSMT with DSMT delivered in person. However, we have concerns with the exact language proposed for 410.78(b)(2)(x) is tied to the term "any distance site practitioner," which seems to mean that DSMT billed under the hospital/clinical NPI, rather than a professional's NPI and may not apply to pharmacy-based programs that submit claims as suppliers. APhA also questions whether the use of "appropriately report DSMT" is the correct terminology and urges CMS to clarify 410.78(b)(2)(x) will also apply to pharmacy-based supplier claims.

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 also strongly encourages CMS to make the delivery of DSMT services via telehealth permanent.

APhA also recommends 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." [16] Patients with diabetes need ongoing support and intensified re-education that can extend beyond the current DSMT benefit. Medicare beneficiaries may need additional benefits and 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.[17]

b. Proposal for Office/Outpatient O/O E/M Visit Complexity Add-On HCPCS Code G2211 FR 32353

CMS is proposing to implement a separate add-on payment for healthcare common procedure coding system (HCPCS) code G2211. This add-on code is designed to better recognize the resource costs associated with evaluation and management visits for primary care and

[16] American Diabetes Association; *Standards of Medical Care in Diabetes—2022* Abridged for Primary Care Providers. *Clin Diabetes* 1 January 2022; 40 (1): 10–38.

[17] 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.

longitudinal care of complex patients. CMS originally finalized this policy in the CY 2021 Medicare Physician Fee Schedule final rule. However, Congress suspended the use of the add-on code by prohibiting CMS from making additional payment under the PFS for these inherently complex E/M visits before January 1, 2024 due to concerns the add-on code will still lead to an additional across-the-board cut to the conversion factor due to budget neutrality requirements.

Overall, APhA agrees with CMS that this add-on payment would improve the accuracy of payment for primary and longitudinal care. As stated in APhA's previous comments to the CY 2021 rule, the add-on code "reflects the time, intensity, and PE when practitioners furnish services that enable them to build longitudinal relationships with all patients (that is, not only those patients who have a chronic condition or single high risk disease) and to address the majority of patients' health care needs with consistency and continuity over longer periods of time. For example, in the context of primary care, the HCPCS add on code could recognize the resources inherent in holistic, patient-centered care that integrates the treatment of illness or injury, management of acute and chronic health conditions, and coordination of specialty care in a collaborative relationship with the clinical care team. In the context of specialty care, the HCPCS add-on code "could recognize the resources inherent in engaging the patient in a continuous and active *collaborative plan of care* [emphasis added] related to an identified health condition the management of which requires the direction of a clinician with specialized clinical knowledge, skill and experience. Such collaborative care includes patient education, expectations and responsibilities, shared decision-making around therapeutic goals, and shared commitments to achieve those goals." As "collaborative plans," may very well include physicians utilizing pharmacists for these services, APhA asks CMS to specifically recognize "pharmacists," and any related pharmacist-provided patient care service utilized in this context.

c. Request for Comment About Evaluating E/M Services More Regularly and Comprehensively FR 52354

CMS is interested in "whether commenters believe that the current AMA RUC is the entity that is best positioned to provide -recommendations to CMS on resource inputs for work and PE valuations, as well as how to establish values for E/M and other physicians' services; or if another independent entity would better serve CMS and interested parties in providing these recommendations."

APhA strongly supports CMS considering another independent entity that would serve CMS in providing recommendations on resource inputs for work and practice expense (PE) valuations and establish values for E/M and other physician services that better reflect team-based care and

the actual services provided by pharmacists and other clinical staff to provide E/M services. AMA's RUC is a non-governmental body and CMS is not obliged to accept the RUC's recommendations. For example, CMS accepted AMA's Guideline Changes that the lower-level E/M code 99211 is the only code available for time-based billing provided by clinical staff under Part B. The use of 99211 simply is not sustainable for clinical staff, such as highly trained pharmacists providing care to complex patients, who typically provide services with time commitments at the 99212-99215 levels, which would essentially inhibit patients' access to high-quality team-based care that includes pharmacist-provided patient care services. Since these statements from CMS, physicians have been significantly challenged to utilize pharmacists to provide complex care services under an "incident to" relationship as E/M code 99211 reflects an average total time of 7 minutes. A growing number of state medical assistance programs, as approved by CMS through state plan amendments, include higher level E/M office and other outpatient services codes on their pharmacist fee schedule.[18,19,20] As APhA has emphasized in the past, **it is not feasible that a pharmacist providing a 45-minute office visit to manage multiple chronic conditions and multiple medications for a Medicare beneficiary under an incident to arrangement with a physician would be limited to having the service billed as a Level 1 visit (99211), that only has an anticipated time commitment of 7 minutes—which has effectively eliminated any incentive and/or the ability for the majority of physicians/ NPPs and pharmacists to partner to provide complex health care services.**

Accordingly, APhA recommends CMS utilize a new entity, including pharmacists and other clinical staff, that represents modern-day health care delivery to more accurately establish values for E/M services.

c. Proposals for CY 2024 and Subsequent Years FR 52499

Based on data that show CMS' additional payment for in-home COVID-19 vaccine administration has helped improve healthcare access to vaccines for underserved Medicare populations, CMS is proposing to maintain this additional payment for the administration of a COVID-19 vaccine in the home ($38.51 for the additional payment for administration in the home in CY 2024). CMS is also proposing to extend this in-home additional payment to the administration of the other three preventive vaccines included in the Part B preventive vaccine benefit — the pneumococcal, influenza, and hepatitis B vaccines — when provided in the home.

[18] https://hcpf.colorado.gov/pharm-serv
[19] https://www.medicaid.nv.gov/Downloads/provider/NV_BillingGuidelines_PT91.pdf
[20] https://portal.ohmits.com/public/Public-Information/Fee-Schedules/Code/RPH/Format/HTML

APhA applauds CMS' recommendations which are in line with HHS Secretary Becerra's "Virtual Roundtable on Increasing Routine Vaccinations,"[21] to promote equity in administering preventive vaccines to underserved populations. APhA continues to recommend 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 additional rate 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 recommends CMS monitor the administration of vaccinations at home and re-examine the agency's current proposal to limit the additional payment to one payment per home visit, even if multiple vaccines are administered during the same home visit.

I. Medicare Diabetes Prevention Program (MDPP) FR 52501

CMS is proposing to extend/allow all MDPP suppliers to continue to offer MDPP services virtually using distance learning delivery through December 31, 2027, if they maintain an in-person CDC organization code. CMS also proposes to remove the requirement for MDPP interim preliminary recognition and replace it with CDC preliminary recognition and to simplify MDPP's current performance-based payment structure by allowing fee-for-service payments for beneficiary attendance.

As a CDC recognized Umbrella Hub Organization (UHO) and a Medicare DPP Supplier for CMS in the Noridian Medicare Administrative Contractor (MAC) region with plans to expand supplier status to all MAC regions in Q4 2023, APhA and the APhA Foundation support CMS' proposed extension of the ability of MDPP suppliers to continue providing MDPP services virtually until 2027. APhA believes that participants are better able to complete the MDPP if they can attend sessions remotely. However, to expand participation in the program, APhA

[21] https://www.hhs.gov/about/news/2022/02/24/readout-secretary-becerras-virtual-roundtable-on-increasing-routine-vaccinations.html

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 a combination of in-person and virtual-only be eligible to furnish MDPP services using all delivery modes at any time.

As stated above, 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. 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 CMS' intended goal of benefitting patients.

2. Medicare Part B Payment for the Administration of Preventive Vaccines FR 53497

In the CY 2022 PFS final rule, CMS finalized a uniform payment rate of $30 for the administration of a pneumococcal, influenza or hepatitis B vaccine covered under the Medicare Part B preventive vaccine benefit (adjusted by geography and Medicare Economic Index (MEI). CMS has also proposed that COVID–19 vaccine administration payment would also be set at a rate to align with the payment rate for the administration of other Part B preventive vaccines ($30 per dose, adjusted by geography and MEI).

APhA strongly supports Medicare maintaining the current $40 per administration of the COVID-19 vaccine in all settings and increasing the rate for other ACIP-recommended vaccines, which do not currently cover the full and complete costs for administration and medical decision-making required. We also encourage CMS to assess additional adjustments to cover new costs for vaccine administration in the future (RSV, Mpox, etc.).

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 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.

In addition, 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. Recent studies show that inadequate reimbursement for vaccination administration results in missed immunization opportunities and declines in immunization rates.[22] 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 the Centers for Disease Control & Prevention (CDC) has recently warned[23] of the potential for a 'tripledemic' this fall – a convergence of rising cases of COVID-19, influenza, and RSV across the country.[24] In recent weeks, the CDC has reported an increase in the number of COVID-19 infections and hospitalizations, an indication of the public health challenges our nation could face this fall and the need for a strong response strategy to protect vulnerable communities.

APhA is also receiving reports from members that Part D plans/PBMs are clawing back vaccine administration fees from pharmacies. These reports are concerns regarding pharmacist participation in immunization efforts as many may not engage because of the payment situation with the Part D plans. APhA would also like to work with CMS to address the different treatment of pharmacists as "mass immunizers," under Medicare versus the way other immunizers are treated anywhere else in the healthcare system. The mass immunizer program does not currently cover all ACIP-recommended vaccines (which is urgent as the new RSV vaccines are ACIP-recommended and covered under Part D but not the mass immunizer program). APhA would like CMS' and the Administration's assistance in maximizing the use of pharmacists as vaccinators and clearly communicating expectations to Part D plans to avoid a situation where pharmacies stop providing Part D vaccines.

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[22] 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.

[23] https://www.nbcnews.com/health/health-news/tripledemic-covid-rsv-flu-winter-cdc-rcna95448

[24] https://covid.cdc.gov/covid-data-tracker/#maps_new-admissions-rate-county

S. A Social Determinants of Health Risk Assessment in the Annual Wellness Visit FR 52548

CMS is proposing to add a new SDOH Risk Assessment as an optional, additional element separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of service as the AWV to enhance patient-centered care and support the effective administration of an AWV.

As stated above, pharmacists are among the most accessible health care providers, with nearly 90% of Americans living within five miles of a community pharmacy and well positioned to provide AWVs and administer SDOH Risk Assessments in order to provide this service to improve health equity for patient care teams.

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).[25] AWVs must include Personalized Prevention Plan Services (PPPS) with a personalized prevention plan and health risk assessment (HRA). Studies have found that AWVs conducted by pharmacists had a positive impact on patient care, and had high satisfaction rates between patients and physicians.[26]

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, and integrate well with CMS' plans to add a new SDOH Risk Assessment.

[25] 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
[26] https://pubmed.ncbi.nlm.nih.gov/31645170/