September 27, 2019

[Submitted electronically via www.regulations.gov]

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)
Attention: CMS-1715-P
P.O. Box 8016
Baltimore, MD 21244-8013

Re: Medicare Program: CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; etc. [RIN 0938–AT72]

Dear Administrator Verma:

The American Pharmacists Association (APhA) is pleased to submit these comments regarding CMS's proposed rule "CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements" (hereinafter, the "Proposed Rule"). APhA, founded in 1852 as the American Pharmaceutical Association, represents 60,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, specialty pharmacies, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

Utilizing Pharmacists for Effective and Efficient Care Delivery

As APhA has stated in previous comments submitted to CMS, physicians and other health care practitioners are similarly challenged to meet the growing demand for patient care services. According to the Association of American Medical Colleges (AAMC), the estimated shortage of physicians due to workforce aging, population growth and increased demand for health care services will range from 40,000 to 90,000 by 2025.[1] The effects of shortages will be

[1] Association of American Medical Colleges, Physician Supply and Demand Through 2025: Key Findings. 2015, available at: https://www.aamc.org/download/450420/data/physiciansupplyanddemandthrough2025.pdf

exacerbated in rural communities which already struggle to meet patient needs.[2] One important mechanism physician practices can employ to greatly increase their capacity to meet patient demand is to use a coordinated, team-based, patient-centered approach to care and delegate appropriate clinical responsibilities to non-physician providers, including pharmacists.[3]

There are more than 300,000 pharmacists in the U.S., many of whom are underutilized in their capacity to contribute to addressing unmet health care needs.[4] Pharmacists currently receive doctoral-level education and/ or practice experience and training, with some pharmacists furthering their training to become specialists with residencies and board certification. Pharmacists' participation on "patient care teams" has been shown to reduce adverse drug events and improve outcomes for patients with chronic diseases.[5] Given pharmacists' ability to reduce the possible $528 billion spent annually on medication-related issues,[6] pharmacists are critical to bending the Medicare cost curve by encouraging the delivery of high-quality, low-cost care. In addition, research has shown coordinated care models involving other health care practitioners, including pharmacists, are essential for realizing the maximum impact of patient care delivery.[7] Improving the utilization of pharmacists in coordinated care models, particularly in rural and medically underserved areas, will help address the need to provide access and care in rural settings and improve quality.

As CMS is aware, almost all pharmacist-provided patient care services are not currently covered by Medicare Part B[8] but are covered by other payers, including several Medicaid programs, cited by CMS guidance.[9] However, certain Medicare Part B services and care frameworks currently leverage pharmacists and pharmacist-provided patient care services, including:

- Incident to physician services in a physician-based practice;[10]
- Incident to physician services in a hospital outpatient clinic;[11]
- Transitional care management (TCM) as part of a team-based bundled payment;[12]

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[2] Petterson S.M., Phillips R.L., Jr., Bazemore A.W. & Koinis G.T.. (2013). Unequal distribution of the U.S. primary care workforce. *American Family Physician* ,87(11), available at: http://www.aafp.org/afp/2013/0601/od1.html.

[3] Bodenheimer, T.D. & Smith, M.D. (2013). Primary Care: Proposed Solutions to the Physician Shortage Without Training More Physicians, *Health Affairs*, available at: https://doi.org/10.1377/hlthaff.2013.0234

[4] Gums, John. Can pharmacists help fill the growing primary care gap? UF News. January 5, 2016, available at: http://news.ufl.edu/articles/2016/01/can-pharmacists-help-fill-the-growing-primary-care-gap.php

[5] Avalere Health. Exploring Pharmacists' Role in a Changing Healthcare Environment. May 2014, available at: http://avalere.com/expertise/life-sciences/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment

[6] Watanabe, J.H., McInnis, T. & Hirsch, J.D. (2018). Cost of Prescription Drug-Related Morbidity and Mortality, *Annals of Pharmacotherapy,* available at: https://doi.org/10.1177/1060028018765159

[7] Mitchell, Pamela. Et. al. Core Principles & Values of Effective Team-Based Health Care. Institute of Medicine. October 2012, available at: https://www.nationalahec.org/pdfs/VSRT-Team-Based-Care-Principles-Values.pdf

[8] Medicare Part B does cover diabetes self-management education/training (DSME/T) programs at pharmacies with facility accreditation. *See,* https://www.cdc.gov/diabetes/dsmes-toolkit/reimbursement/medicare.html. Part B also provides coverage for certain immunizations. *See,* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/qr-immun-billTextOnly.pdf.

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

[10] Centers for Medicare and Medicaid Services, Medicare Learning Network. "Incident to" Services. Revised August 23, 2016, available at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/se0441.pdf

[11] Ibid.

[12] Centers for Medicare and Medicaid Services. Transitional Care Management Services. January 2019, available at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Transitional-Care-Management-Services-Fact-Sheet-ICN908628.pdf. Accessed August 2019.

- Chronic care management (CCM) as part of team-based bundled payment;[13]
- Annual Wellness Visits (AWV);[14]
- Diabetes Self-Management Training (DSMT);[15] and
- Various Advanced Alternative Payment Models (APMs).

APhA strongly agrees with several of the Administration's recommendations in the recent report "Reforming America's Healthcare System Through Choice and Competition." An important recommendation includes allowing pharmacists and other health care providers to practice at their full practice scope, utilizing their complete skill set and training. Further, the report encourages the federal government and states to consider legislative and administrative proposals to allow nonphysician providers, including pharmacists, to be paid directly for their services.[16] Therefore, APhA recommends CMS implement the Administration's recommendations and take full advantage of agency discretion to remove regulatory barriers to payment for pharmacist-provided patient care services.

Team-based, patient-centered payment and delivery models lower the administrative burden and assist eligible clinicians with achieving maximum quality scores. Such action would align Medicare with the many states and Medicaid programs that are already turning to pharmacists to improve patients' health and outcomes and lower medication-related costs.[17] In addition, increased recognition of pharmacists and payment for the patient care services they provide would align pharmacists with other health care professionals' services covered under Medicare Part B. Payment models that preclude participation from health care practitioners with expertise and qualifications to provide care have the unintended consequence of limiting access to care, especially care in underserved areas.

APhA supports CMS's ongoing recognition in the Proposed Rule of the significant contributions of physicians and other health care providers in addressing U.S. health care needs. In addition, APhA supports comments submitted to CMS from the Pharmacy Health Information Technology Collaborative which address "Medicaid Promoting Interoperability Program Requirements for Eligible Professionals."[18] To assist CMS, APhA respectfully submits the following comments:

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[13] American Pharmacists Association, Health Quality Innovators, Atlantic Quality Innovation Network. Chronic Care Management (CCM): An Overview for Pharmacists. March 2017, available at; https://portal.pharmacist.com/sites/default/files/CCM-An-Overview-for-Pharmacists-FINAL.pdf.

[14] Centers for Medicare and Medicaid Services, Medicare Learning Network. The ABCs of the Annual Wellness Visit (AWV). April 2017, available at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Net-work-MLN/MLNProducts/downloads/AWV_chart_ICN905706.pdf. Accessed January 25, 2018.

[15] Indian Health Service. Step-by-Step Guide to Medicare Diabetes Self-Management Training (DSMT) Reimbursement. October 2011, available at: https://www.ihs.gov/MedicalPrograms/Diabetes/HomeDocs/Resources/InstantDownloads/DSMT_Guidebook_508c.pdf. Accessed January 25, 2018.

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

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

[18] See, Pharmacy Health Information Technology Collaborative, Collaborative Outreach: CMS Comments, available at: https://www.pharmacyhit.org/index.php/collaborative-outreach#cms.

I. Direct Practice Expense (Pg. 40485) – Reimbursement Rates for Vaccine Administration

APhA is very concerned with CMS's continued reduction in reimbursement rates for the valuation of CPT codes for vaccine administration[19] under the Proposed Rule. The reductions would further exacerbate gaps in immunization access and may have negative long-term impact on providers' ability to offer Centers for Disease Control (CDC) Advisory Committee on Immunization Practices (ACIP) recommended immunizations to Medicare patients. Under the Proposed Rule, the total payment for vaccine administration in 2020 is set to decrease to $14.42 (Practice Expense (PE) Relative Value Unit (RVU) of .22), representing a 44% decrease from 2017, when this service was paid at $25.84 (PE RVU of .54). For the third year in a row, there is a significant decrease to the PE RVU factor. Work and malpractice factors remain the same. A review of the practice expense cost files does not support this reduction. Practice expense costs were unchanged in 2018 and increased in both 2019 and 2020. In addition, there is no evidence of decreases in any cost component.

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 office, 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.[20] Any reimbursement reductions at the physician/ pharmacist level could inhibit the ability to achieve HHS's Healthy People 2020 goals. Accordingly, **APhA strongly urges CMS to restore reimbursement rates for CPT codes for vaccine administration so that reimbursement accounts for the cost of the service and continues to encourage providers to offer Medicare beneficiaries ACIP-recommended immunizations at the clinical point-of-care.**

II. Physician Supervision for Physician Assistant (PA) Services (Pgs. 40546-40547)

APhA supports the logic of CMS's proposal granting flexibility to non-physician practitioners:

> "…to revise § 410.74(a)(2) to provide that the statutory physician supervision requirement for PA services at section 1861(s)(2)(K)(i) of the Act would be met when a PA furnishes their services in accordance with state law and state scope of practice rules for PAs in the state in which the services are furnished with medical direction and appropriate supervision as provided by state law in which the services are performed. In the absence of state law governing physician supervision of PA services, the physician supervision required by Medicare for PA services would be evidenced by documentation

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

[20] 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.

in the medical record of the PA's approach to working with physicians in furnishing their services."

As CMS states "[t]his proposed change would substantially align the regulation on physician supervision for PA services at § 410.74(a)(2) with our current regulations on physician collaboration for NP and CNS services at §§ 410.75(c)(3) and 410.76(c)(3)." Similar to PAs who may provide a broader array of services than those currently covered by Medicare Part B, recent changes in the practice of pharmacy have resulted in pharmacists practicing more autonomously, like nurse practitioners (NPs) and clinical nurse specialists (CNSs), as members of care teams that often consist of physicians, nonphysician practitioners and other allied health professionals. These changes have resulted in an increasing number of states updating scope of practice laws for pharmacists (e.g, pharmacist prescribing for tobacco cessation, hormonal contraceptives, naloxone, vaccine access, etc., under statewide protocols and collaborative practice authority (CPA) that often includes initiating, modifying, and discontinuing medications and ordering laboratory tests under the parameters of the CPA and delegated by the physician).[21] As stated above, APhA strongly supports the Administration's recommendation to allow pharmacists and other health care providers to practice to the top of their license, utilizing their full skill set and training.[22] Accordingly, **APhA recommends CMS use the same consideration granted to PAs to examine E/M coding (as referenced in section VIII of our comments below) for pharmacists' services provided under incident to physician services arrangements**. Clarification on billing for E/M codes and better utilizing pharmacists in providing care and contributing to value could have a profound, and immediate impact on access, quality, health outcomes and costs for a large portion of the population, particularly in medically underserved communities in these states.

III. Transitional Care Management (TCM) Services (Pgs. 40549-40550)

In the Proposed Rule CMS states "…beneficiaries who received TCM services demonstrated reduced readmission rates, lower mortality, and decreased health care costs." APhA agrees. For example, a recent study of pharmacist involvement in TCM at the University of North Carolina found that hospital readmission rates and interventions in a multidisciplinary team visit coordinated by a clinical pharmacist practitioner vs. physician-only team had a 30-day readmission rate of 14.3% compared with 34.3% by the physician-only team, with addressing nonadherence, initiating a new medication and discontinuing a medication also showing statistical significance.[23]

APhA also supports CMS's efforts in the Proposed Rule to increase utilization of TCM services to positively affect patient outcomes, including the provisions in the Proposed Rule to increase the value of TCM codes and allow concurrent billing with Complex Chronic Care Management (CCCM). As CMS understands, the current restrictions on physicians and nonphysician practitioners from billing for both CCCM and TCM services during the same month places an unnecessary delay on patients who could benefit from these proven services.

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[21] NASPA. Scope of Practice Resources. 2019, available at: https://naspa.us/restopic/scope/

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

[23] Cavanaugh, JJ. Et. al. Pharmacist-coordinated multidisciplinary hospital follow-up visits improve patient outcomes. J Manag Care Spec Pharm. 2015 Mar;21(3):256-60, available at: https://www.ncbi.nlm.nih.gov/pubmed/25726034

Pharmacists providing TCM services can easily identify potential patients for CCCM and contribute to CCCM delivery. Accordingly, as payment models continue to shift towards value-based care, APhA urges CMS to remove any barriers that will allow CMS, beneficiaries and federal taxpayers to garner the significant avoidance savings available from integrating pharmacists into delivery models proven to reduce hospital readmissions.

IV. Non-Complex CCM Services by Clinical Staff (CPT code 99490, HCPCS codes GCCC1 and GCCC2) (Pgs. 40551-40552)

In the Proposed Rule, CMS improves payments for non-complex CCM codes by paying for each 20-minute increment of time spent, instead of for a single 20-minute block of time. APhA has requested that CMS establish codes for non-complex CCM between 20 and 60 minutes. We are pleased CMS is proposing to provide coverage for non-complex CCM services delivered by clinical staff beyond the current 20-minute requirement. The two new temporary "G codes" for non-complex CCM with new increments of clinical staff time (GCCC1 (initial 20 minutes) and GCCC2 (each additional 20 minutes)) will more accurately account for the time required to deliver those non-complex CCM services. APhA's members have indicated the difference between non-complex CCM at 20 minutes and complex CCCM at 60 minutes is an important gap to be addressed. Our members stated that additional 20-minute time-increments for clinical staff may be necessary based on comorbidities that need treatment but do not necessarily require complex CCM. In addition, APhA also urges CMS to evaluate whether the CCM codes are valued correctly to account for the total time and effort of all of beneficiaries' health care team members to appropriately deliver the services and outcomes.

V. Typical Care Plan (Pgs. 40552-40553)

In the Proposed Rule, CMS proposes changing the minimum elements for a comprehensive care plan for all health issues with different content from last year. While APhA generally agrees with most of the elements in the new list which adds "medical management," "cognitive and functional assessment" and "environmental evaluation," we are particularly concerned with the Proposed Rule's removal of "medication management."[24] As medication experts, our members are perplexed how a comprehensive care plan does not include the fundamental element of medication management, especially since medications are a common treatment modality for chronic conditions. As such, **APhA respectfully asks CMS to return "medication management" as a minimum element of the CCM typical care plan to ensure individual patients benefit from this important service focused on medication appropriateness, effectiveness, safety, and adherence with the goal of improving health outcomes.**".[25]

[24] *See,* MLN. Chronic Care Management Services. July 2019, available at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ChronicCareManagement.pdf

[25] The pharmacy profession-wide medication management services consensus definition is located at: https://jcpp.net/wp-content/uploads/2018/05/Medication-Management-Services-Definition-and-Key-Points-Version-1.pdf

VI. Principal Care Management Services (PCM) (Pgs. 40533-40555)

In past comments, APhA has requested that CMS expand access to chronic care management services for patients excluded under the current eligibility requirement who have a single high-risk disease or complex chronic condition that is not well accounted for in existing coding and could benefit from these services. Accordingly, APhA and its members strongly support CMS's proposal allowing physicians to offer Principal Care Management (PCM) services that will pay treating clinicians, most likely specialists, (and clinical staff) via two new G codes for treating patients who need chronic care management, but only have one high-risk chronic condition.

CMS states in the Proposed Rule:

> "While the primary care practitioner may be able to provide care management services for this one complex chronic condition, it is also possible that the primary care practitioner and/or the patient could instead decide that another clinician should provide relevant care management services. In this case, the primary care practitioner would still oversee the overall care for the patient while the practitioner billing for PCM services would provide care management services for the specific complex chronic condition. The treating clinician may need to provide a disease-specific care plan or may need to make frequent adjustments to the patient's medication regimen. The expected outcome of PCM is for the patient's condition to be stabilized by the treating clinician so that overall care management for the patient's condition can be returned to the patient's primary care practitioner."

APhA strongly supports CMS's explanation "…that PCM services include coordination of medical and/or psychosocial care related to the single complex chronic condition, provided by a physician or clinical staff [including pharmacists] under the direction of a physician or other qualified health care professional." APhA also strongly supports CMS adding GPPP2 (at least 30 minutes of clinical staff time (including pharmacists) directed by a physician or other qualified health care professional) to the list of designated care management services that allow general supervision, similar to the treatment of CCM services. In addition, APhA believes it would be appropriate to create an add-on code for additional time spent each month (similar to HCPCS code GCCC2 discussed above) when PCM services are furnished by clinical staff (including pharmacists) under the direction of the billing practitioner.

APhA's members, in collaboration with physicians and other team members, care for patients with a variety of chronic diseases in various practice settings, including patients who experience an exacerbation necessitating more intensive care. Pharmacists' medication expertise can be leveraged for PCM in clinical staff time activities such as medication management, medication reconciliation, adherence, and chronic care management. Many of these patients also live in rural areas. With almost 90% of Americans living within five miles of a community pharmacy,[26] and pharmacists practicing in many different health care settings, pharmacists serve as the most accessible health care practitioner situated to provide health care services and immediate relief to these communities.

[26] NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.

To avoid care fragmentation and duplicative services, APhA supports a requirement "…that the practitioner billing PCM must document ongoing communication with the patient's primary care practitioner to demonstrate that there is continuity of care between the specialist and primary care settings, or…" / and "…requiring that the patient have had a face-to-face visit with the practitioner billing PCM within the prior 30 days to demonstrate that they have an ongoing relationship." APhA also requests that CMS monitor the impact on beneficiary cost-sharing for the cadre of care management and monitoring services that could be delivered concurrently. In addition, APhA believes CMS should fully utilize interoperability of electronic medical records (EMRs) to optimize care delivery, promote care coordination, and avoid duplicative, overlap and fragmented care.

Finally, as Federally Qualified Health Centers (FQHCs) can currently receive payment for CCM or general Behavioral Health Integration (BHI) services, APhA asks for clarification from CMS whether FQHCs can also receive payment for PCM. In addition, APhA also requests clarification from CMS on how PCM services would function under the Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System.

VII. Chronic Care Remote Physiologic Monitoring Services (RPM) (Pgs. 40555-40556)

APhA is very pleased that CMS issued a technical correction on March 14, 2019 clarifying that RPM under CPT code 99457 may be furnished by auxiliary personnel, which can include pharmacists, working under the direct supervision of the physician or eligible nonphysician practitioner.[27] The newest code for remote patient monitoring, CPT code 99457, which took effect in January 2019, offers Medicare reimbursement for "Remote physiologic monitoring treatment management services, 20 minutes or more of *clinical staff* [emphasis added] /physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month." The change now allows RPM services to better mirror CCM services (CPT code 99487, 99489, and 99490). Similarly, APhA is also pleased the Proposed Rule includes a provision clarifying CPT codes 99457 and 994X0 may be furnished as "designated care management services" under general supervision rather than direct supervision. Accordingly, APhA urges CMS to finalize this provision in the Proposed Rule to align RPM with CCM for auxiliary personnel to allow more patients to access the quality-improving benefits of RPM.

VIII. Payment for Evaluation and Management (E/M) Services (Pgs. 40673-40680)

As CMS is aware, pharmacists deliver services under "incident to" physician services arrangements that are billed by physicians or other qualified nonphysician practitioners (NPPs) using E/M codes. Pharmacists are not recognized by CMS as NPPs and fall under the category of "clinical staff" or "auxiliary personnel" depending on the CMS-covered service. APhA supported many of the goals of CMS's previous changes to reduce administrative burdens and

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

improve payment accuracy for E/M physician office visits and associated services. Administrative efficiencies may translate into less billing department staff and more time spent on actual patient care or could provide savings to be used to resource additional team-based, patient care services provided by auxiliary personnel, such as pharmacists. However, APhA has serious concerns regarding potential adoption of the AMA CPT E/M Guideline Changes document,[28] as currently listed in the Proposed Rule. It is our interpretation that CMS's potential adoption of AMA's changes could end the ability for supervising physicians or qualified nonphysician practitioners to use higher level E/M codes for pharmacist-provided patient care services delivered under incident to physician services arrangements. Because the impact of the AMA E/M changes on CMS's requirements for incident to billing is not discussed in the Proposed Rule, APhA requests clarification from CMS on this issue. Provisions from AMA's Guideline Changes that cause concern are noted below.

Under AMA's Guideline Changes, for time based billing,"[f]or office or other outpatient services, if the physician's or other qualified health care professional's time is spent in the supervision of *clinical staff* [emphasis added] who perform the face-to-face services of the encounter, [physicians/ other qualified health care professionals must] use 99211." In addition, AMA's Guideline Changes state:

> "Total time on the date of the encounter (office or other outpatient services [99202-99205, 99212- 99215]): For coding purposes, time for these services is the total time on the date of the encounter. It includes both the face-to-face and non-face-to-face time personally spent by the physician and/or other qualified health care professional(s) on the day of the encounter (includes time in activities that require the physician or other qualified health care professional and *does not include time in activities normally performed by clinical staff* [emphasis added])."

Thus, according to the AMA's Guideline Changes, it appears that lower-level E/M code 99211 is the only code available for time-based billing provided by clinical staff under Part B. APhA emphasizes the lower reimbursement for 99211, with a work RVU of 0.18, is not sustainable for clinical staff, such as highly trained pharmacists providing care to complex patients, and may inhibit access to high quality team-based care. In addition, the Proposed Rule states "[f]or E/M services that require prolonged *clinical staff time* [emphasis added] and may include face-to-face services by the physician or other qualified health care professional, use 99415, 99416." For 99415, AMA's Guideline states "[p]rolonged service of less than 45 minutes total duration on a given date is not separately reported because the *clinical staff time* [emphasis added] involved is included in the E/M codes." Similarly, 99415 and 99416 have low RVUs (PE RVU of 0.27 and 0.12 respectively) that do not accurately reflect the level of care provided by pharmacists. APhA's members indicated low-level reimbursement may disincentivize utilizing pharmacists and could potentially increase pharmacist and physician burnout.

[28]AMA. CPT® Evaluation and Management (E/M) Office or Other Outpatient (99202-99215) and Prolonged Services (99354, 99355, 99356, 99XXX) Code and Guideline Changes. 2019, available at: https://www.ama-assn.org/system/files/2019-06/cpt-office-prolonged-svs-code-changes.pdf - which states "..For office or other outpatient services, if the physician's or other qualified health care professional's time is spent in the supervision of clinical staff who perform the facet o-face services of the encounter, use 99211." Pgs. 1-2. "For E/M services that require prolonged clinical staff time and may include face-to-face services by the physician or other qualified health care professional, use 99415, 99416. Do not report 99354, 99355 with 99415, 99416, 99XXX." Pg. 11.

In addition, the Proposed Rule states that "[w]hen time is used to document, practitioners will document the medical necessity of the office/outpatient E/M visit and that the billing practitioner *personally spent* [emphasis added] the required amount of time face-to-face with the beneficiary. The required face-to-face time will be the typical time for the reported code, except for extended or prolonged visits where extended or prolonged times will apply." APhA is very concerned by requiring the billing practitioner to "personally" spend face-to-face time with the beneficiary, the agency is excluding the ability of physicians to utilize pharmacists and other clinical staff to provide higher-level E/M services under direct supervision, which will discourage, numerous successful team-based care delivery models. APhA members inform us that the care they provide is often aligned with the requirements for the billing of higher-level E/M codes.[29] Accordingly, APhA strongly recommends CMS advance the contributions of pharmacists in team-based health care delivery models by providing sustainable mechanisms to support their patient care services proven to improve quality and reduce cost.

It is important to note CMS does not plan to adopt the AMA CPT E/M codes until 2021, which provides another full cycle on the physician fee schedule to work with CMS to clarify this language before these changes would go into effect. Therefore, APhA respectfully requests that CMS clarify in the final rule that physicians and other qualified nonphysician practitioners can bill for "incident-to" services provided to Medicare beneficiaries by pharmacists at levels higher than E/M code 99211 if the service provided meets the designated E/M requirements and pharmacists' state practice authority.[30] In 2014, the American Academy of Family Physicians (AAFP) petitioned CMS for clarification on whether a physician may bill for services provided by a pharmacist as "incident to" services.[31] Then CMS Administrator Marilyn Tavenner's response stated that, "provided all requirements of the 'incident to' statute and regulations, including applicable state and local laws, were met, such billing would be wholly permitted." Subsequent communication from CMS later in 2014 confirmed this interpretation of "incident to" billing provisions.

Despite the aforementioned guidance from CMS to AAFP, APhA continues to receive reports of difficulties associated with "incident to" billing of E/M services when provided by pharmacists. APhA is concerned these issues stem from a lack of awareness of the clarification CMS provided in 2014 and because Medicare Claims Processing Manuals have not been updated to reflect CMS's interpretation. Consequently, Medicare Administrative Contractors (MACs) have provided differing interpretations of permissible billing practices. Even on an institutional leadership level, there is reluctance from billing and coding departments and legal counsel to permit physicians to bill for pharmacists' services at a level above E/M code 99211, even though the complexity of most services delivered by pharmacists meets the requirements for physicians to bill at higher levels (E/M codes 99212-215). APhA has also received reports of reluctance to use higher level E/M billing codes from pharmacists working in value-based models that have a fee-for-service component. Continued uncertainty is a detriment to desired team-based care. **Therefore, APhA requests clarification from CMS on this issue and continues to request a**

[29] Avalere Health. Exploring Pharmacists' Role in a Changing Healthcare Environment. May 2014, available at: https://avalere.com/insights/exploring-pharmacists-role-in-a-changing-healthcare-environment

[30] CMS. Medicare Learning Network. Evaluation and Management Services. ICN 006764 August 2017, available at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/eval-mgmt-serv-guide-ICN006764.pdf

[31] American Academy of Family Physicians letter to Centers for Medicare & Medicaid Services, (Jan 2014), available at: https://www.accp.com/docs/positions/misc/AAFP%20MTM%20Letter%20to%20CMS%5E2.pdf

meeting with the appropriate individuals at CMS to discuss these issues where we can provide a more detailed overview and examples of these challenges.

APhA urges CMS to look at Washington state in clarifying billing for E/M levels. For example, under Washington State law, pharmacists are recognized as providers by those commercial health plans under the State's purview. Washington pharmacists have billed and been paid for E/M services using the full range of applicable CPT codes (99211-99215) appropriate for the type of service provided.[32] Pharmacists are highly trained professionals with extensive medication expertise to meet the needs of patients with complex conditions and they could be much better utilized to meet the needs of patients through incident to physician services billing with better guidance from CMS. APhA encourages CMS to also clearly convey the 2014 guidance CMS provided to AAFP to all local MACs to avoid any disruptions in the delivery of team-based E/M services. Further, clarifying this issue will also help reduce burden on health care practitioners who are unable to utilize pharmacists for more complex patient care needs.

IX. Transforming MIPS: MIPS Value Pathways Request for Information (Pgs. 40732-40745)

Generally, APhA supports CMS's concept to create the MIPS Value Pathways (MVPs) to reduce burden, help patients compare clinician performance, and better inform patient choice in selecting clinicians. However, under the MIPS system, there is not a mechanism to attribute pharmacists' contributions to achieving metrics, of which a significant number are related to or impacted by medications and would benefit from appropriate medication use and pharmacist-provided services. For example, APhA analysis finds that pharmacists can contribute to over 25% of the more than 270 current quality measures, as well as many of the improvement activities and promoting interoperability measures. 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. For example, our members who practice in APMs and with practices participating in MIPS, note the following select examples of quality measures that pharmacists are currently significantly impacting:

- Hypertension: Controlling High Blood Pressure;[33]
- Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%);[34]
- Risk Standardized, All Condition Readmission;[35]

[32] 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

[33] *See,* Margolis, K. et al. Effect of Home Blood Pressure Telemonitoring and Pharmacist Management on Blood Pressure Control: A Cluster Randomized Clinical Trial. JAMA July 2013, available at: https://www.ncbi.nlm.nih.gov/pubmed/23821088.

[34] *See,* Ip EJ, Shah BM, Yu J, Chan J, Nguyen LT, Bhatt DC. Enhancing diabetes care by adding a pharmacist to the primary care team: an analysis of short term clinical markers and long-term cardiovascular outcomes." Am J Health-Syst Pharm May 2013, available at: https://www.ncbi.nlm.nih.gov/pubmed/23640349.

[35] *See,* ASHP-APhA Medication Management in Care Transitions Best Practices 2013. Pgs. 9-10, 15, 20, 26, 38, 44-45, 60, available at: http://media.pharmacist.com/practice/ASHP_APhA_MedicationManagementinCareTransitionsBestPracticesReport2_2013.pdf.

- Medication Reconciliation Post-Discharge;[36,37,38]
- Statin Therapy for the Prevention and Treatment of Cardiovascular Disease;[39]
- Preventive Care and Screening: Influenza Immunization;[40] and
- Falls: Screening for Falls.

In addition, consideration should be given to how MVP reporting systems can meaningfully capture the contributions of various health care practitioners, including pharmacists, to improving quality outcomes and managing costs. In the RFI, CMS mentions "[w]e plan to engage with clinician professional organizations and front-line clinicians to develop the MVPs." APhA would welcome the opportunity for a face-to-face meeting to share specific information with CMS on our own internal analyses on how and where pharmacists can contribute to the existing MIPS and future MVPs under quality payment program (QPP) metrics. We would include pharmacists in this meeting who are practicing in APMs and working with physicians and other eligible clinicians to influence MIPS measures to share their experiences, successes, and impacts.

X. Merit-based Incentive Payment Program (MIPS) Previously Finalized Measure Proposed for Removal in the 2022 MIPS Payment Year and Future Years (Pgs. 41012, 41060, 41065, 41120, 41155)

In general, APhA supports CMS's efforts to reduce measure burden and better harmonize and use measures that are most meaningful. However, APhA is concerned CMS is considering removal the Medication Reconciliation Post Discharge measure (NQF #0097) with the 2022 MIPS payment year (Orthopedic Surgery, Nephrology, General Surgery, Geriatrics). CMS states "this measure is duplicative of previously finalized measure Q130: Documentation of Current Medications in the Medical Record that also addresses assessment of current medications at the time of a patient and eligible clinician encounter." Q130 (NQF #0419) was adopted by CMS for the 2017 performance period and includes the "[p]ercentage of visits for patients aged 18 years and older for which the *eligible clinician* [emphasis added] attests to documenting a list of current medications using all immediate resources available on the date of the encounter."[41] However, Q130 does not mention the terminology referenced in NQF #0097 which states patients seen "…within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or *clinical pharmacist* [emphasis added] providing ongoing care

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[36] *See*, Kilcup M, Schultz D, Carlson J, Wilson B. Postdischarge pharmacist medication reconciliation: impact on readmission rates and financial savings. Journal of the American Pharmacists Association: JAPhA. 2013;53(1):78-84, available at: https://www.ncbi.nlm.nih.gov/pubmed/23636160.

[37] Kirkham HS, et al. The effect of a collaborative pharmacist-hospital care transition program on the likelihood of 30-day readmission. Amer J Health-Syst Pharm 2014;71:739-45. DOI: 10.2146/ajhp130457, available at: https://www.ncbi.nlm.nih.gov/pubmed/24733137

[38] Zillich AJ, et al. A randomized, controlled pragmatic trial of telephonic medication therapy management to reduce hospitalization in home health patients. Health Serv Res 2014; 49:1537-54. DOI: 10.1111/1475-6773.12176, available at: https://www.ncbi.nlm.nih.gov/pubmed/24712335

[39] *See*, Renner, Hannah M. Et. al. Pharmacist-to-prescriber intervention to close therapeutic gaps for statin use in patients with diabetes: A randomized controlled trial. Journal of the American Pharmacists Association, Volume 57, Issue 3 S236 - S242.e1, available at: https://www.japha.org/article/S1544-3191(17)30155-3/abstract.

[40] *See,* Patel, Anik R. et al. The impact of pharmacy-based immunization services on the likelihood of immunization in the United States. Journal of the American Pharmacists Association, Volume 58, Issue 5, 505 - 514.e2, available at: https://www.japha.org/article/S1544-3191(18)30231-0/fulltext.

[41] MIPS PRA. Appendix A. CMS-5517-P. RR23 – which states "[i]n addition, CMS stated "This measure is being replaced in the Web Interface with the core measure, PQRS #46: Medication Reconciliation Post-Discharge."

for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record."

Removing the measure may preclude utilizing pharmacists due to the Q130 measure's use of the term "eligible clinician," and would be inconsistent with encouraging team-based care as well as other recent CMS policies and changes, such as including the NQF#0097 measure in the 2019 Star Ratings Improvement Measures for Medicare Advantage plans and proposing it as part of a Transitions of Care measure for the 2020 display measure set with possible inclusion in the 2022 Star Ratings.[42] APhA's House of Delegates policy states "APhA recognizes pharmacists as the health care team member responsible for the medication reconciliation process when patients move between practice settings within the continuum of care."[43] Medication reconciliation is not simply documenting a list of medications during an encounter. The Joint Commission recognizes medication reconciliation as "the process of comparing the medications a patient is taking (and should be taking) with newly ordered medications in order to resolve discrepancies or potential problems."[44]

Take, for example, the results of a recent study which found more than half - 242 of the 471 heart patients - had at least one discrepancy between the medications they reported taking, and the ones on their discharge list. Over a quarter left out one or more medications on their list and more than a third were taking something that wasn't on the list. And, 59 percent of patients had a misunderstanding of the purpose, dose or frequency of their medications.[45] Our members believe the medication reconciliation measure should be retained because of its tremendous benefit to patients and avoiding medication errors. [46,47,48] Similarly, CMS needs to continue to explore attribution mechanisms so that various health care practitioners, including pharmacists, can demonstrate their value in improving health outcomes. Accordingly, APhA urges CMS to explore a new measure that focuses on ensuring that the best reconciled medication list is available in all of the patient's health care locations, including post-discharge, and that also includes the role that pharmacists can play as the medication expert on patient care teams.

XI. Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (Section II.G, Pgs. 40518-40542)

APhA is pleased CMS is implementing Section 2005 of the SUPPORT for Patients and Communities Act (SUPPORT Act) which expands medication-assisted treatment (MAT) by establishing a new Part B benefit category for opioid use disorder (OUD) treatment services

[42] *See,* CMS. Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. April 2, 2018. Pgs. 124, 167, available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf
[43] JAPhA NS45(5):580 September-October 2007, available at: https://media.pharmacist.com/hod/APhA_Policy_and_Procedures_2018.pdf
[44] Joint Commission. National Patient Safety Goals effective January 1, 2012. NPSG.03.06.01.
[45] Mixon, Amanda. Et. al. Characteristics Associated With Postdischarge Medication Errors. Mayo Clinic Proceedings. August 2014. Volume 89, Issue 8, Pages 1042–1051, available at: https://www.mayoclinicproceedings.org/article/S0025-6196(14)00387-5/abstract
[46] *See,* Kilcup M, Schultz D, Carlson J, Wilson B. Postdischarge pharmacist medication reconciliation: impact on readmission rates and financial savings. Journal of the American Pharmacists Association: JAPhA. 2013;53(1):78-84, available at: https://www.ncbi.nlm.nih.gov/pubmed/23636160.
[47] Kirkham HS, et al. The effect of a collaborative pharmacist-hospital care transition program on the likelihood of 30-day readmission. Amer J Health-Syst Pharm 2014;71:739-45. DOI: 10.2146/ajhp130457, available at: https://www.ncbi.nlm.nih.gov/pubmed/24733137
[48] Zillich AJ, et al. A randomized, controlled pragmatic trial of telephonic medication therapy management to reduce hospitalization in home health patients. Health Serv Res 2014; 49:1537-54. DOI: 10.1111/1475-6773.12176, available at: https://www.ncbi.nlm.nih.gov/pubmed/24712335

furnished by an opioid treatment program (OTP). Section 2005 also amended the definition of "medical and other health services" to provide coverage of OUD treatment services and established a bundled payment to OTPs for OUD treatment services furnished during an episode of care. Pharmacists are the health care practitioner with extensive medication-related education and training. Many pharmacists are actively caring for patients with OUD, yet many barriers prevent patients from receiving care. APhA believes pharmacists can help meet treatment demands but their ability to do so is dependent, in part, on coverage frameworks that encourage better optimization of resources, such as pharmacists. APhA provides the following responses regarding CMS's proposed regulations related to Section 2005.

A. Opioid Use Disorder Treatment Services

In the Proposed Rule, CMS includes a definition of Opioid Use Disorder Treatment Services and seeks additional feedback regarding whether intake activities, such as a physical exam, initial assessment and preparation of a treatment plan, should be included in the definition of opioid use disorder treatment services. APhA encourages CMS to align the required services described by SAMHSA[49] pertaining to services that must be provided by an OTP, including an initial medical examination, and initial and periodic assessment services with those services considered among opioid use disorder treatment services.

In addition, as CMS is aware, patients receiving care in an OTP may have other conditions that require more practitioner time to review medications or coordinate care with other health care practitioners outside of the OTP. APhA encourages CMS to consider how practitioner time devoted to treatment planning and revision, and care coordination can be included among the services covered by Medicare Part B.

B. SAMHSA Certification

For OUD services provided in an OTP to be covered, CMS indicates SAMHSA certification of the OTP is required. To become SAMHSA certified, an OTP must meet the federal opioid treatment standard in 42 CFR 8.12 which specifically addresses staff credentials as a condition of certification.[50] In addition, the Federal Guidelines for Opioid Treatment Programs recognize that some aspects of medication-assisted treatment services, which are dependent on state law, may be provided by an authorized healthcare professional other than a physician, such as a pharmacist.[51] **APhA encourages CMS to clarify that healthcare professionals working in a SAMHSA-certified OTP may provide care in accordance with state law that will be covered by Medicare Part B.**

[49] 42 CFR Part 8 Subpart C – Certification and Treatment Standards for Opioid Treatment Programs.
[50] 42 CFR 8.12(d) stating "**(d)*Staff credentials.*** Each person engaged in the treatment of opioid use disorder must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. All physicians, nurses, and other licensed professional care providers, including addiction counselors, must comply with the credentialing requirements of their respective professions."
[51] SAMHSA (2015). Federal Guidelines for Opioid Treatment Programs, available at: https://store.samhsa.gov/system/files/pep15-fedguideotp.pdf, at 11, stating "Some aspects of medication-assisted treatment services may be provided by an authorized healthcare professional other than a physician such as an advanced practice nurse, physician assistant, or advanced-practice pharmacist. It is the responsibility of the OTP to review the individual licensing, scope of practice, and supervision requirements of each state with regard to the duties of such an authorized healthcare professional within the OTP beyond the federal roles and limits spelled out in these Guidelines."

C. Quality Improvement

While regulations require OTPs to maintain current quality assurance and quality control plans, APhA members encouraged CMS to consider opportunities to utilize quality measures to improve patient care and treatment goals.

D. Medications Approved by the FDA

APhA supports including the medications approved by FDA for use in the treatment of OUD in the bundled payment, but APhA notes that drug pricing and accessibility of medications may vary over time. For example, drug shortages may prevent access to more affordable medications and certain medications that patients may prefer for personal reasons (e.g., taste) may be more difficult or costly to obtain. To help improve patient adherence, **APhA encourages CMS to carefully evaluate whether flexibility can be provided for the medication portion of the bundled payment to maintain patient access.**

E. Proposed Bundled Payments for OUD Treatment Services

In the Proposed Rule, CMS proposes to establish bundled payments for OUD treatment services provided in an OTP. APhA provides the below responses specific to the bundled payment proposal.

a. Drug Component

To the extent possible, APhA encourages CMS to monitor and evaluate drug pricing and availability to ensure reimbursement is sufficient to cover the cost of medications, particularly considering circumstances that result in increased medication costs.

In addition, APhA encourages CMS to work with the Drug Enforcement Administration regarding opioid production quotas which may need to be proactively modified to account for increased treatment demands stemming from enhanced coverage under the Proposed Rule.

b. Non-Drug Component

In the Proposed Rule, CMS describes coverage of the non-drug component of the bundled payment. As noted above, APhA supports aligning the services included within the bundled payment with those that must be provided by an OTP.

While CMS provides an intensity add-on code, it does not adequately address the additional medication-related services that may need to be provided, particularly for patients with different co-occurring conditions or for those who require additional time for education and medication-related counseling.

As noted above, APhA is also aware that health care practitioners within an OTP may spend additional time working with other health care practitioners to coordinate care and with the patient to discuss their medication use. For example, additional time may be needed to monitor

patients switching formulations or when their dosage changes. Such time is does not appear to be accounted for in the Proposed Rule.

c. Site of Service

CMS proposes to allow the OTP to furnish substance use counseling, individual therapy and group therapy in the bundle via two-way interactivity audio-video communication technology, as clinically appropriate, to increase access to care for beneficiaries. APhA believes other services may be appropriate to provide via telecommunications, such as those provided for other chronic diseases (e.g., medication management) and those related to transitions of care.

d. Education

As CMS finalized the Proposed Rule, APhA strongly recommends the agency provide additional education and resources to OTPs to help them comply with the rule when finalized and regulatory requirements. While APhA appreciates CMS' efforts to learn from Medicaid and Tricare bundled payments, we believe it is crucial for CMS to identify areas for improvement in these programs rather than attempting to only duplicate them. APhA did learn of negative consequences of bundled payments where burdens associated with adhering to requirements resulted in fewer treatment options for patients. Coverage of OUD services within an OTP will have little value to patients if the payment model is too complex or too risky for the OTP to implement. Given the high demand for MAT and the significant changes associated with coverage of OTP services, APhA recommends CMS and SAMHSA work with OTPs to improve their understanding of the rule to support their participation in Medicare and patient access to care.

XII. Medicare Enrollment of Opioid Treatment Programs (Section III.H, Pgs. 40716-40723)

CMS proposes that the OTP must maintain and submit to CMS a list of all physicians and other eligible professionals (as the term "eligible professional" is defined in section 1848(k)(3)(B) of the Social Security Act) who are legally authorized to prescribe, order or dispense controlled substances on behalf of the OTP. APhA raises concerns with CMS' reliance on the term "eligible professional" because pharmacists are not enumerated as an "eligible professional" but may otherwise by legally authorized to prescribe, order or dispense controlled substances on behalf of the OTP. APhA is concerned requiring the OTP to only submit a list of physicians and other "eligible professionals" will imply that other healthcare practitioners, such as pharmacists, legally authorized to perform certain functions may not be included among those who can provide care, such as prescribing, ordering or dispensing of controlled substances on behalf of the OTP. Therefore, APhA recommends CMS modify this section to clarify that pharmacists may be listed among the practitioners included in documentation OTPs must maintain and submit when identifying practitioners who may prescribe, order or dispense controlled substances on behalf of the OTP.

Without providing such clarity, APhA is concerned the payment models implemented in an OTP will not align with Federal opioid treatment standards.[52] Limiting OTP enrollment to practitioners meeting the definition of "eligible professional" does not align with Federal opioid treatment standards pertaining to medication administration, dispensing and use which recognize pharmacists as a practitioner type who must be involved in opioid agonist administration and dispensing.[53] Therefore, APhA is concerned language or forms appearing limiting the types of practitioners who provide information to CMS for enrollment purposes could pose subsequent reimbursement issues for OTPs that utilize pharmacists to provide much needed patient care. **To provide clarity, APhA recommends CMS modify the requirements for enrollment to ensure a range of health care providers, including pharmacists, participate in the bundled payment program.**

XIII. Bundled Payments Under the PFS for Substance Use Disorders (Section II.H. Pgs. 40542-40545)

APhA is pleased CMS proposes a bundled payment for the overall treatment of OUD, including management, care coordination, psychotherapy, and counseling activities. APhA appreciates CMS's efforts to create an avenue for physicians and other health professionals to bill for a bundle of OUD treatment services in a setting other than an OTP. As noted above, pharmacists are medication experts and help provide care to patients with OUD, among other chronic conditions.

a. "Incident to" services

APhA applauds CMS for proposing that the counseling, therapy and care coordination described in the proposed OUD treatment codes could be provided by professionals who are qualified to provide the services under state law and within their scope of practice "incident to" the services of the billing physician or other practitioner. APhA also strongly supports CMS's proposal to allow these "incident to" services to be provided under general supervision.

b. Collaborative Care

APhA is pleased CMS is implementing a bundled payment under the PFS for substance use disorders as it may encourage collaborative care that could otherwise not be provided under fee for service models. However, as noted regarding the OTP bundled payment model, the benefit of these models to patients is largely dependent on uptake by providers. Since office-based treatment programs likely provide OUD treatment services to a smaller portion of the patients than OTPs, APhA is particularly concerned the complexity associated with implementing the model in an office-based setting may discourage participation. Therefore, APhA encourages CMS to monitor uptake and provide education and resources to help improve participation.

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[52] 42 CFR 8.12(h)

[53] 42 CFR §8.12(h) *stating* "OTPs must ensure that opioid agonist treatment medications are administered or dispensed only by a practitioner licensure under the appropriate State law… This agent is required to be a pharmacist, registered nurse…"

Resources CMS provides could include examples of collaborative models that may be employed to reduce burdens on prescribers while optimizing use of community resources and other practitioners, such as pharmacists. For example, in accordance with state law, APhA is aware of pharmacists working under collaborative practice agreements with buprenorphine prescribers to help bridge gaps in care[54] and models where pharmacists may initiate the dispensing and administration of naltrexone.[55] Research also indicates building relationships with a pharmacy regarding the filling of prescriptions is an important element of a successful MAT program.[56] APhA believes providing examples of different ways to structure office-based OUD treatment and build relationships can help reduce burdens with implementation and improve care.

In addition, APhA encourages CMS to work with programs like the Opioid Response Network and Providers Clinical Support System to disseminate education. CMS could also consider working with their partner organizations in developing new resources related to coverage and collaboration that complement the bundled payment models provided in the Proposed Rule.

c. Emergency Department Setting

APhA agrees with CMS that OUD can first become apparent to practitioners in the emergency department setting. APhA supports CMS further contemplating how to provide MAT and referral or follow-up care to patients in an emergency department. APhA also notes that OUD may also become apparent in other care settings, such as a community pharmacy. Therefore, APhA also encourages CMS to consider the community pharmacy when identifying opportunities for patient screening and potential referral, among other services.

Once again, thank you for the opportunity to provide feedback on the Proposed Rule and for your consideration of our comments. As pharmacists continue to work in collaboration with our physician colleagues as vital members of patient care teams, we are happy to facilitate discussions between CMS and our members who currently provide E/M services, CCM, medication management, and "incident to" physician services. If you have any questions or require additional information, please contact Michael Baxter, Director of Regulatory Affairs, at mbaxter@aphanet.org or by phone at (202) 429-7538.

Sincerely,

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

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[54] DiPaula, B.A. and Menachery, E. (2015). Physician-Pharmacist Collaborative Care Model for Buprenorphine-Maintained Opioid-Dependent Patients, *Journal of the American Pharmacists Association,* 55(2), available at: https://www.ncbi.nlm.nih.gov/pubmed/25749264

[55] *See* Kentucky Board of Pharmacy (2018). Opioid Use Disorder Naltrexone Therapy Protocol v2 available at: https://pharmacy.ky.gov/Board%20Authorized%20Protocols/Opioid%20Use%20Disorder%20Protocol%20v2%20Approved%20December%2012,%202018.pdf, last accessed September 20, 2049.

[56] Urban Institute, (2018). Research Report: Implementing an Integrated Medication-Assisted Treatment Program at Community Health Centers, available at: https://www.urban.org/sites/default/files/publication/99009/2018.09.13_ca_camden_complex_care_mat_eval_final_0.pdf.

cc: Mitchel C. Rothholz, RPh, MBA, APhA Chief Strategy Officer
Anne Burns, RPh, Vice President, Professional Affairs