



September 11, 2017

[Submitted electronically via [www.regulations.gov](http://www.regulations.gov)]

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services (CMS)  
Department of Health and Human Services (HHS)  
Attention: CMS-1676-P  
P.O. Box 8016  
Baltimore, MD 21244-8013

**Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program; Proposed Rule [RIN: 0938-AT02]**

Dear Administrator Verma:

APhA is pleased to submit these comments regarding CMS’s proposed rule “Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018” (hereinafter, the “Proposed Rule”). APhA, founded in 1852 as the American Pharmaceutical Association, represents 64,000 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, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

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. As stated in previous APhA comments, physicians and other practitioners are challenged to meet the growing demand for patient care services from the eighty million aging baby boomers and the growing prevalence of chronic diseases such as diabetes and cardiovascular disease—thus, creating a mismatch between demand and capacity. 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 practitioners.<sup>1</sup> There are over 300,000 pharmacists in the U.S.,

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<sup>1</sup> See Bodenheimer, Thomas. Et. al. Primary Care: Proposed Solutions To The Physician Shortage Without Training More Physicians. *Health Affairs*. November 2013 vol. 32 no. 11 1881-1886. Available at: <http://content.healthaffairs.org/content/32/11/1881.full?ijkey=cvPTAIQBTEJ0o&keytype=ref&siteid=healthaff>

many of whom are underutilized in their capacity to contribute to addressing these unmet health care needs.<sup>2</sup> Pharmacists receive doctoral-level education and training, with some pharmacists furthering their training to become specialists with board certification. Pharmacists' participation on "patient care teams" has been shown to reduce adverse drug events and improve outcomes for patients with chronic diseases.<sup>3</sup> 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.<sup>4</sup> As vital members of patient care teams, APhA strongly believes better integration of pharmacists into Medicare is necessary as CMS continues to transition toward value-based payments.

## **I. Utilizing Pharmacists and Pharmacist Services to Reduce Burdens for Physicians and Ensure that Patients and their Providers are Making the Best Health Care Choices Possible**

APhA appreciates CMS's "Request for Information (RFI) on CMS Flexibilities and Efficiencies" to start a "national conversation about improving the healthcare delivery system; how Medicare can contribute to making the delivery system less bureaucratic and complex; and how we can reduce burden for clinicians, providers, and patients in a way that increases quality of care and decreases costs, thereby making the healthcare system more effective, simple, and accessible." As HHS considers regulatory opportunities intended to reduce clinical burdens and improve patient care, APhA emphasizes that pharmacists are the most accessible health care providers and provide care and services in a wide variety of practice settings in communities across our nation. In fact, 91% of all Americans live within five miles of a community pharmacy.<sup>5</sup> In addition to being medication experts, pharmacists also provide a broad array of services beyond dispensing medications, including disease state and medication management, smoking cessation counseling, health and wellness screenings, preventive services, and immunizations. However, due to legislative and regulatory barriers such as references to "provider," "eligible professional," or similar terms that do not include pharmacists in their definition, pharmacists are often an underutilized health care resource. APhA requests CMS employ its regulatory discretion, similar to efforts the agency applied for chronic care management (CCM) and transitional care management (TCM) services, to remove barriers preventing qualified providers, like pharmacists, from being utilized. Such regulatory action has helped alleviate some of the restrictions preventing pharmacists from providing these services, which also positively impacts their inclusion on care teams and in value-based delivery models.

As CMS understands, Sec. 3134 of the Affordable Care Act (ACA) requires the HHS Secretary to periodically identify potentially misvalued services and to review and make appropriate adjustments to the relative values for those services. For example, in the 2017 Physician Fee Schedule (PFS) Final Rule,<sup>6</sup> the HHS Secretary exercised this authority to create

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<sup>2</sup> See 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>

<sup>3</sup> See 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>

<sup>4</sup> See 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>

<sup>5</sup> NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.

<sup>6</sup> CMS. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017. Final Rule. November 15, 2016. 81 FR 80170. Available at: <https://www.federalregister.gov/documents/2016/11/15/2016-26668/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions>

new billing codes to better facilitate the provision of services in the Psychiatric Collaborative Care Model (CoCM). Unfortunately, the Final Rule precluded pharmacists from billing under these new codes based on the reasoning by CMS that the CoCM services provided are “not within the scope of pharmacists or clinical psychologists under Medicare rules.”<sup>7</sup> CMS has previously stated it does not have the authority to authorize Medicare coverage for many pharmacists’ services due to existing statutory limitations. Therefore, APhA requests the HHS Secretary to exercise his/ her maximum regulatory authority to better include qualified practitioners, such as pharmacists, as it has done for other providers, and for needed services, to enhance the infrastructure essential to more effectively deliver health care. Doing so will improve patient access and choice, and increase efficiencies in the delivery of services, which is especially important as health care payment and delivery models become more value-based. In addition, APhA also recommends HHS consider clarifying processes, such as literature reviews of peer-reviewed research, relevant to the creation of new billing codes for pharmacist services to further flexibility and efficiencies.

## II. Improving Care Management Services

APhA agrees with the continued use of CCM services to add value to the health care system through improved patient access and care coordination. APhA appreciates CMS’s past proposals to address barriers to participation in CCM programs. However, we recommend additional changes to enhance participation and improve outcomes.

- Adding HCPCS code G0506 (Care Planning and Chronic Care Management) to the list of telehealth services. APhA supports the addition of G0506 for telehealth services and urges CMS to encourage eligible clinicians to form collaborative and contractual partnerships with pharmacists to provide CCM telehealth services that are within their scope of practice. With the increasing complexity of medications, the role the pharmacist and proper medication management will play under new delivery models, many of which may utilize telehealth services, will be fundamental to allowing CMS to meet its goals of improving quality of care and reducing costs. In addition, CMS estimates that approximately two-thirds of Medicare patients have two or more chronic conditions and an additional means of providing CCM will be necessary to meet the increasing demand for these services and the needs of the medically underserved. Accordingly, to increase patient access and improve outcomes, APhA recommends CMS continue to establish flexible policies that utilize qualified non-physician providers, such as pharmacists, in services, including those provided telephonically.
- Improving the valuation of CCM services. APhA appreciates that CMS is “...interested in the ongoing work of the medical community and other stakeholders to refine the set of codes used to describe care management services” and committed “to continued work with stakeholders on necessary refinements to the code set, especially describing the professional work involved in caring for complex patients in other clinical contexts.” APhA also appreciates CMS’s “continued work with stakeholders to ensure that the coding and valuation of these services accurately reflects the resource costs involved in furnishing these

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<sup>7</sup> *Id.* at 80236., stating “...we agree with the commenters who stated that the role of the psychiatric consultant under these codes is primarily evaluation and management, which is not within the scope of pharmacists or clinical psychologists under Medicare rules.”

services.” Accordingly, APhA offers the following recommendations under the Proposed Rule:

- Refining the CCM codes: APhA members believe there needs to be additional flexibility to account for CCM services that extend beyond the 20-minute visit, but do not reach the 60-minute/moderate to high complexity medical decision making requirements of complex CCM. Accordingly, APhA requests CMS implement codes allowing for the billing of services for regular CCM between 20 and 60 minutes to more accurately account for the time required to deliver the service. In addition, we ask CMS to evaluate and update the codes to reflect the time spent by clinical staff preparing for the patient visit, documenting the care provided, and following up with the patient. An essential step in the CCM process is review of the interaction notes by the provider, intervention, and patient follow-up when required. Consequently, we ask CMS to evaluate whether the codes are valued correctly to account for the total time and effort to appropriately deliver the services and subsequently update the codes to accurately reflect the cost of providing the services.
- Authorize the delegation of CCM care planning for add-on code G0506 (extensive assessment and CCM care planning beyond the usual effort for the initiating visit code): Pharmacists and other qualified health care practitioners are well-suited to provide care planning, a critical component of the CCM service. APhA strongly encourages CMS to develop a flexible framework that allows qualified providers to delegate the CCM care planning to licensed clinical providers who are participating as part of the patient’s care team. Allowing pharmacists to provide these team-based services in coordination with the physician aligns with CMS’s move towards value and emphasis on increasing access through coordinated, team-based care delivery.
- Allowing for billing of more complex CCM service, behavioral health integration and psychiatric CoCM at Rural Health Centers (RHCs) and Federally-Qualified Health Centers (FQHCs). APhA appreciates the Proposed Rule’s provision to adopt Current Procedural Terminology (CPT) codes for CY 2018 and allow FQHCs and RHCs to receive payments for regular and complex CCM services, general behavioral health integration services, and psychiatric CoCM services using two new billing codes created exclusively for RHCs and FQHCs—in addition to the payment for a visit to these sites of care. Consistent with our request above, we ask CMS appropriately value these CCM codes and allow FQHCs and RHCs to bill for regular CCM between 20 and 60 minutes. Clarifying the ability to factor increased time and complexity into the codes will make it more financially feasible for health care practitioners to provide the services at FQHCs, RHCs and all other sites of care to those who need and would benefit from CCM the most—patients with complex conditions. Furthermore, APhA continues to encourage CMS to develop a framework for FQHCs and RHCs to allow auxiliary personnel, including pharmacists, to provide patient care services. Due to their unique regulatory requirements, FQHCs have been prevented from utilizing pharmacists for some services that pharmacists can provide in other health care settings (e.g., Annual Wellness Visits).

- Additional suggestions to optimize the utilization and positive impact of CCM and similar services on patients and the Medicare system:
  - Copays: One administrative difficulty many practitioners face is determining who has or does not have CCM coverage. While fee-for-service patients are covered, some of the Medicare Advantage plans deny the service as “already covered.” APhA members said it is difficult to know whether a patient is enrolled and to determine which plans charge a 20% copayment. Since many patients pay a portion of the cost, APhA asks that it be easier for providers of CCM services to inform beneficiaries how much they will be charged. As CMS understands, copayments can vary greatly (zero to full price), depending on coverage. By the time the patient is notified the service is not covered, they may have several months billed. We suggest CMS encourage insurers and plans to establish better mechanisms to inform patients and providers of the cost and eligibility for CCM and other services.

CMS has determined it does not have the statutory authority to exempt CCM from cost sharing requirements, however, from pharmacist clinician feedback, the monthly cost sharing fee is a significant burden for beneficiaries and an administrative burden for practitioners. Cost has the potential to be an even greater burden for beneficiaries who receive complex CMM. APhA encourages CMS to use maximum regulatory flexibility to explore alternative co-payment relief for beneficiaries by reclassifying CCM services as “preventive.” By addressing the cost barrier, APhA believes patients who can benefit most greatly from CCM services will participate in the program — positively impacting beneficiary health outcomes and costs as well as the Medicare Program.

- CCM/ TCM overlap: APhA continues to hear concerns regarding how CMS interprets and enforces the prohibition on the overlap of CCM and transitional care management (TCM) services. APhA requests CMS identify and implement mechanisms to administratively prevent or minimize TCM and/ or CCM not being provided by practitioners to patients who need the service(s). An understanding of these requirements and what constitutes an overlap situation is critical as the complicated scenarios where coverage is questioned often arise at a time a patient needs more care and coordination.
- Electronic Health Records (EHRs): Our members continue to have concerns that while CMS and private payors have established frameworks to encourage collaboration and team-based care, depending on the practice, pharmacists are frequently blocked from the exchange of relevant clinical information the EHRs. Such restrictions impede the ability of CMS and patients to benefit from coordinated, team-based care. APhA suggests CMS develop policies that facilitate the exchange of relevant health information between the appropriate members of the health care team. The ability to exchange clinical information, including the care plan, is a critical component to coordinating care within CCM practices.
- Evaluation of CCM Service Models: APhA recommends that CMS evaluate the effectiveness of the different CCM service delivery models and facilitate the

sharing of lessons learned to all sites of care, and use the results to make program improvements. As in other value-based programs, it will be important to measure the impact of the different CCM service models on patient outcomes and the health care system in general and develop and implement policies based on sustainable practices that benefit patients and the Medicare system.

### **III. Modifying Evaluation and Management (E/M) Documentation Guidelines**

APhA is generally supportive of CMS's proposal to focus E/M documentation guidelines on medical decision making (MDM) and time for many of the reasons stated in the Proposed Rule, including the reduction of duplicate billing, decreasing the time to report, and minimizing the complexity and length of notes and documentation. Pharmacists deliver services under incident to physician services arrangements that are billed by physicians using E/M codes. APhA has the following member comments/ requests for clarification:

- Currently, E/M codes are primarily applied based on complexity of care provided (e.g., history, exam, medical-decision making) or time, when greater than 50% of the encounter is focused on counseling and/or care coordination. APhA requests further clarification on whether CMS is proposing to revise the documentation guidelines to remove the history and exam component, but keep time as a separate consideration or combine MDM and time into one new documentation guideline.
- As stated previously, our members have concerns regarding the ability for pharmacists to effectively use EHRs to share information and obtain the necessary information needed to provide quality patient care. While an important tool for the efficient and effective sharing of clinical information between providers, pharmacists are frequently blocked from participating in the exchange of this relevant information. Such restrictions impede the ability of CMS and patients to benefit from coordinated, team-based care. A complete electronic patient history, accessible to relevant health care practitioners will be critical to meaningful implementation of CMS proposed changes to the E/M documentation guidelines. APhA suggests CMS develop policies that facilitate the exchange of relevant health information between the appropriate members of the health care team, including pharmacists.

### **IV. Supporting Pharmacists Inclusion in the Medicare Diabetes Prevention Program (MDPP) Expanded Model**

APhA shares CMS's concern regarding the prevalence of diabetes in the U.S. Medicare population, which is growing at an alarming rate<sup>8</sup>—costing \$42 billion more in the single year of 2016 for beneficiaries with diabetes than it would have spent if those beneficiaries did not have diabetes.<sup>9</sup> The expanded MDPP is yet another program that may benefit from the increased participation of pharmacists and pharmacies as part of a coordinated approach to help prevent diabetes. A large percentage of Americans live near a community pharmacy, and the inclusion of pharmacists and pharmacy staff in the provision of MDPP services in pharmacies is of

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<sup>8</sup> R Ashkenazy, MD and MJ Abrahamson. Medicare Coverage for Patients With Diabetes. *J Gen Intern Med.* 2006 Apr; 21(4): 386–392.

Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1484724/>

<sup>9</sup> CMS. Medicare Diabetes Prevention Program (MDPP) Expanded Model. 2017. Available at: <https://innovation.cms.gov/initiatives/medicare-diabetes-prevention-program/>

significant interest in the pharmacy community, especially in reaching patients in medically underserved communities.

APhA is generally supportive of the additional guidance CDC is proposing for implementation of the MDPP program including delaying the start date for service provision until April 1, 2018. We do have concerns about the proposed MDPP fee schedule and whether it is a viable financial model to support a broad scale, high quality, meaningful program. We also would like CMS to consider more flexibility in the use of virtual visits beyond make-up sessions for MDPP, especially if combined with face-to-face visits.

In addition, due to the unique position of local pharmacies to offer MDPP services to additional communities, APhA offers its assistance to CMS's Innovation Center in testing and evaluating virtual MDPP services. More generally, APhA encourages CMS to evaluate provider participation in and patient utilization of services through the MDPP model and make changes, as necessary, such as testing pharmacy specific MDPP pilots, to make certain the expanded model is sustainable to achieve its intended goal of benefitting patients.

While APhA appreciates CMS's acknowledgement in the Proposed Rule that "If a beneficiary progresses to type 2 diabetes, other treatment options, such as Diabetes Self-Management Training (DSMT), may be more appropriate than services that seek to prevent a condition the beneficiary already has," we are disappointed that the agency does not make any further reference to DSMT in the Proposed Rule. While APhA applauded CMS's previous recognition in the 2017 PFS Final Rule of the key role that pharmacists play as instructors "who actually furnish DSMT services...",<sup>10</sup> we reiterate our request for CMS to create a sustainable DSMT model that will increase Medicare beneficiary access to pharmacists.

#### **V. Addressing Pharmacists' Concerns Regarding Healthcare Common Procedure Coding System (HCPCS) Biosimilar Codes and Modifiers**

APhA appreciates that CMS is soliciting comments on the impact of its 2016 payment policy and encourages ongoing review given the emerging nature of the biosimilars market. Assigning the same HCPCS J Code to all like-biosimilars and adding a modifier to distinguish products may have negative implications. APhA is concerned that applying a "modifier" to the J code may lead to coding errors and in the end, do little to improve pharmacovigilance and potentially create coverage issues when miscoded. Given there are few biosimilars on the market, APhA encourages CMS to evaluate and reconsider the implications of the modifier on billing accuracy and patient access when deciding whether to bundle biosimilar billing.

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 medication management, CCM, TCM and incident-to physician services, if that would be helpful. If you have any

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<sup>10</sup> CMS. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017. Final Rule. November 15, 2016. 81 FR 80170. Available at: <https://www.federalregister.gov/documents/2016/11/15/2016-26668/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions>

questions or require additional information, please contact Michael Baxter, Director of Regulatory Affairs, at [mbaxter@aphanet.org](mailto:mbaxter@aphanet.org) or by phone at (202) 429-7538.

Sincerely,

A handwritten signature in black ink that reads "Thomas E. Menighan". The signature is written in a cursive, flowing style.

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

cc: Stacie S. Maass, RPh, JD, Senior Vice President, Pharmacy Practice and Government  
Affairs  
Anne Burns, RPh, Vice President, Professional Affairs