



September 10, 2018

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The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services (CMS)  
Department of Health and Human Services (HHS)  
Attention: CMS-1693-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 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program [RIN 0938-AT31]**

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 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program (hereinafter, the “Proposed Rule”). APhA, founded in 1852 as the American Pharmaceutical Association, represents 62,000 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. We are pleased to provide comments to the Proposed Rule because of its impact on the “Patients Over Paperwork” initiative and how care is delivered to patients.

**I. Effective and Efficient Care Delivery**

As stated in previous APhA comments submitted to CMS, physicians and other practitioners are challenged to meet the growing demand for patient care services due to 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., many of whom are underutilized in their capacity to contribute to addressing 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. In the Proposed Rule, CMS clearly recognizes the value and the benefits of utilizing non-physician personnel and uses its regulatory flexibility to allow and/ or facilitate team-based care delivery and services. APhA appreciates these efforts and encourages CMS to apply this same tenet to pharmacist-provided patient care services to help meet the health care needs of our nation's beneficiaries.

## II. Evaluation and Management (E/M) Visits (Pgs. 330-369)

As CMS is aware, pharmacists deliver services under incident to physician services arrangements that are billed by physicians using E/M codes. APhA is supportive of the goals of CMS's proposed changes to reduce administrative burdens and 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 does note some of flexibilities allowed for in the Proposed Rule may be difficult to take advantage of due to their misalignment with private payor requirements and the EHR and billing system changes needed. APhA has the following comments/ requests for clarification to CMS's proposals.

- **Payment Rates for Office Visits for Established Patients**— Although our members, including those who are working in team-based care arrangements, support the Proposed Rule's goals to reduce administrative time associated with billing, our members have expressed apprehension that the E/M payment/ coding consolidation changes could lead to an increased use of/ volume of lower level E/M visits at the expense of more complex patients. APhA members are concerned lowering payment rates for certain specialties or higher-level services may discourage practitioners from taking on these types of patients. Additionally,

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<sup>1</sup> 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>

<sup>2</sup> 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> 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> Mitchell, Pamela. Et. al. Core Principles & Values of Effective Team-Based Health Care. Institute of Medicine. October 2012. Available at: <https://www.nationalahecc.org/pdfs/VSRT-Team-Based-Care-Principles-Values.pdf>

APhA agrees add-on payments are necessary to reflect the extra time required for more complex and/ or prolonged visits. However, we do not believe the currently proposed amount for the payments will be adequate to incentivize care for complex patients. APhA also requests CMS clarify add-on payments can be used for services provided by “clinical” or “auxiliary staff” working under an incident to physician services arrangements, and consequently, permitting the use of efficient and effective team-based care delivery.

Another related issue of importance to APhA and its members is clarifying the level of E/M services a pharmacist can provide working under a physician’s direct supervision in an incident to physician services arrangement. While CMS has recognized the ability of pharmacists to provide services incident to physician services, there is ambiguity as to what level or complexity of services the pharmacist can provide. Pharmacists’ scope of practice does vary state-by-state, so there may be some state variability as to what services a pharmacist could provide and, therefore, the level of E/M CPT code a physician could bill for an incident to service. However, we have heard from members that some Medicare Administrative Contractors (MAC) have indicated only the lowest level (i.e., 99211) can be billed, which is more limiting than pharmacists’ scope of practice in every state and more limiting than CMS indicated in correspondence with the American Academy of Family Physicians (AAFP).<sup>5</sup> 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.<sup>6</sup> APhA urges CMS to provide further clarification regarding physicians’ ability to bill for pharmacists’ services across the range of CPT codes 99211-215 when incident to requirements are met and urges CMS to look at Washington in clarifying those levels. Pharmacists have the education and training to meet the needs of patients with complex conditions and could be better utilized to meet the demands of system and needs of patients through incident to physician services billing with better guidance from CMS. CMS should also clearly convey this guidance to all local MACs to avoid any disruptions in the delivery of team-based E/M services.

- **Providing Choices in Documentation** — APhA is generally supportive of the Proposed Rule’s easing of various E/M documentation requirements. APhA agrees with CMS’s proposal to offer practitioners the flexibility to choose Medical decision making (MDM), “time” or the current documentation guidelines and the ability to focus documentation on changes by allowing them to review

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<sup>5</sup> AAFP. AAFP, CMS Clarify 'Incident to' Rules Relating to Pharmacists' Services. April 16, 2014. Available at:

<https://www.aafp.org/news/practice-professional-issues/20140416incidenttoltr.html>. Also, *see*,

<https://www.aacp.com/docs/positions/misc/CMS%20Response%20to%20AAFP%20MTM%20Billing%20Letter.pdf>.

<sup>6</sup> 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](http://apha2018.pharmacist.com/sites/default/files/slides/Cred_and_Priv_101_3-18-18_104AB_HO.pdf)

and verify certain medical record information instead of requiring the reentry of repetitive information.<sup>7</sup>

- **Public Comment Solicitation on Eliminating Prohibition on Billing Same-Day Visits by Practitioners of the Same Group and Specialty**— APhA supports CMS’s proposal to eliminate the Medicare Claims Processing Manual requirement that prevents MAC payments for same-day E/M visits by multiple practitioners in the same specialty within a group practice. By implementing the change, CMS is attempting to remove the necessity for practitioners to inconvenience beneficiaries by scheduling E/M visits on two separate days to receive full reimbursement for their services. However, APhA cautions a reduction in the payment under the multiple procedure payment adjustment by 50 percent for the least expensive procedure or visit may be too low and not practical. Although we understand the CMS’s desire to consider potential costs and the sustainability of the Medicare Program, we encourage the Agency to further consider workable reimbursement levels to meet the intended goal.

### **III. Payment for Care Management Services and Communication Technology-based Services (Pgs. 234-239)**

APhA agrees with CMS’s ongoing promotion and facilitation of care management and care coordination services to improve patient and Medicare’s outcomes. APhA generally supports incentivizing and promoting services focused on better monitoring and managing chronic conditions but worry potential additive copays will be a barrier to patient utilization and therefore, any intended benefit. When proposing new services, APhA asks CMS to clarify whether beneficiaries will be responsible for copays and encourages CMS to use maximum regulatory flexibility to explore alternative co-payment relief. With respect to the new care management and communication technology-based services proposed, APhA recommends the following changes to enhance participation and improve outcomes.

- **Chronic Care Remote Physiologic Monitoring (CPT codes 990X0, 990X1, and 994X9)**— With the increasing complexity of medications, the pharmacist and proper medication management will play a key role under new health care delivery models, many of which may utilize remote monitoring services, to allow CMS to meet its goals of improving the quality of care and reducing patients’ health care costs. CMS currently estimates approximately two-thirds of Medicare patients have two or more chronic conditions<sup>8</sup>; therefore, additional means of providing chronic care monitoring will be necessary to meet the increasing demand for these services and the needs of the medically underserved. In order to increase patient’s access and improve outcomes, APhA urges CMS to encourage eligible clinicians to form more

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<sup>7</sup> See, Pg. 334. The Proposed Rule states “Also, we propose that for both new and established patients, practitioners would no longer be required to re-enter information in the medical record regarding the chief complaint and history that are already entered by ancillary staff or the beneficiary. The practitioner could simply indicate in the medical record that they reviewed and verified this information. We wish to be clear that these proposed policy changes would be optional, where a practitioner could choose to continue to use the current framework, and the more detailed information could continue to be entered, re-entered or brought forward in documenting a visit, regardless of the documentation approach selected by the practitioner.”

<sup>8</sup> CMS. Chronic Conditions Among Medicare Beneficiaries. Chartbook. 2012 Edition. Available at: <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/chronic-conditions/downloads/2012chartbook.pdf>

collaborative and contractual partnerships with pharmacists to provide chronic care remote monitoring services within their scope of practice. APhA supported CMS's unbundling of code 99091 (remote patient monitoring) in 2018 to increase the amount of billable Medicare hours available for physicians and clinicians who utilize remote care services. However, it is our understanding remote patient monitoring cannot be subcontracted and all providers must be part of the billing practice/ organization, which would preclude community pharmacists from participating—unlike Chronic Care Management (CCM) services which can be provided by “clinical staff” under general supervision. Accordingly, we are pleased the Proposed Rule specifically mentions “clinical staff” time for 994X9 and ask CMS to clarify the term “clinical staff” and whether this service could be delivered under general supervision in a manner consistent with CCM.<sup>9</sup>

In defining these codes, APhA also urges CMS to build off the Administrator's recent efforts in a separate proposed rule “. . .to modernize Medicare to promote innovation and improve home health by increasing access to remote patient monitoring” to “. . .which will lead to more tailored care and increased positive health outcomes.”<sup>10</sup> APhA recommends CMS expand on last year's changes to 99091 referenced above, and clarify pharmacists, the medication experts on the patient's health care team, play a key role as “clinical staff” in providing remote monitoring of chronic care patients. Including pharmacists in remote patient monitoring will help Medicare leverage resources to help achieve Administrator Verma's goal to “. . .provide state-of-the-art care.”<sup>11</sup>

- **Chronic Care Management Services (CCM) (CPT code 994X7)**— APhA requests clarification from CMS for CPT code 994X7 regarding situations “. . .when the billing practitioner is doing the care coordination work that is attributed to clinical staff in CPT code 99490.” It is not clear from the language whether this code is reimbursing the practitioner for work done in lieu of clinical staff or for additional work done by the practitioner. APhA supports implementing policies which promote efficient and effective care delivery and utilization of team-based care models. It is unclear the impact this new code will have on team-based care.

In addition, we want to re-iterate our request included in our comments to the CY 2018 physician fee schedule for CMS to establish codes for the billing of services for regular CCM between 20 and 60 minutes. The new codes will more accurately account for the time required to deliver CCM services which extend beyond the 20-minute visit, but do not reach the 60-minute/moderate to high complexity medical decision-making requirements of complex CCM.<sup>12</sup> APhA's members indicated the

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<sup>9</sup> 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>

<sup>10</sup> Slabodkin, Greg. CMS proposes reimbursing home health agencies for remote patient monitoring. HealthData Management. Published July 3, 2018. Available at: <https://www.healthdatamanagement.com/news/cms-proposes-reimbursing-home-health-agencies-for-remote-patient-monitoring>

<sup>11</sup> Ibid.

<sup>12</sup> APhA. Comments Submitted on the Proposed Rule: 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 (CMS-1676). September 11, 2017. Available at: <https://www.regulations.gov/document?D=CMS-2017-0092-1278>.

difference between CCM at 20 minutes and complex CCM at 60 minutes in an important gap to be addressed. Consequently, we ask CMS to evaluate whether the 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 update the codes as needed to accurately reflect the cost of providing CCM services.

- **Interprofessional Internet Consultation (CPT codes 994X6, 994X0, 99446, 99447, 99448, and 99449)**— APhA requests clarification from CMS on whether “Interprofessional telephone/Internet assessment and management service” can be delegated by physicians to pharmacists and other “clinical staff”. Specifically, APhA recommends CMS include pharmacists in the term “other qualified health care professionals” as our pharmacist members are consistently consulted by other professionals on the health care team to provide valuable, but unreimbursed, medication and care-related information and services. In addition, CMS should specify when patient consent is required when utilizing these codes.

#### **IV. Proposed Valuation of Specific Codes for CY 2019 (Pgs. 66-70, 244-246)**

APhA supports CMS implementing policies which expand non-face-to-face physicians' services furnished using communication technology that do not fall under telehealth services. The new codes established under the Proposed Rule recognize and incentivize coordinated care and fill important gaps between patient visits through the use of various technologies. APhA urges CMS to include pharmacists as eligible practitioners when establishing applicable non-face-to-face services. As stated above, with the increasing complexity of medications, the pharmacist and proper medication management will play a key role under new health care delivery models, many of which may utilize technology for both non- and face-to-face services. Further, to facilitate utilization of these services, CMS should employ the recent flexibility it granted to Accountable Care Organizations (ACOs) with regard to what qualifies as an “originating sites” for telehealth services and allow beneficiaries to access services from their homes.<sup>13</sup> On the specific new remote monitoring codes in the Proposed Rule, APhA offers the following comments and requests for clarifications.

- **Remote pre-recorded services (HCPCS code GRAS1) e.g., Store-and-Forward**— CMS is “...proposing to value this service by a direct crosswalk to CPT code 93793 (Anticoagulant management for a patient taking warfarin, must include review and interpretation of a new home, office, or lab international normalized ratio (INR) test result, patient instructions, dosage adjustment (as needed), and scheduling of additional test(s), when performed)” because CMS believes the “work described is similar in kind and intensity to the work performed as part of HCPCS code GRAS1.” While APhA sees the value of this proposed service, we are concerned with how code 93793 is being currently applied for anticoagulant management services and how it might impact claims for HCPCS code GRAS1. We have heard from members some claims for

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<sup>13</sup> See, Bipartisan Budget Act of 2018 (Public Law No: 115-123). SEC. 50324(A). Providing Accountable Care Organizations the Ability to Expand the Use of Telehealth. Available at: <https://www.congress.gov/bill/115th-congress/house-bill/1892/text?q=%7B%22search%22%3A%5B%22Bipartisan+Budget+Act+of+2018%22%5D%7D&r=1>

anticoagulant management have been rejected if there is no dosage adjustment required based on INR testing. We ask CMS to clarify claims for longitudinal monitoring of high risk anticoagulant medication should be covered even in the case where medication dosage adjustments are not needed.

- **Brief Communication Technology-based Service, e.g. Virtual Check-in (HCPCS code GVCII)**— APhA requests clarification from CMS whether pharmacists qualify as “other health care professionals” and/ or can offer these virtual services to established patients under physician supervision. These types of services could expand beneficiary access to or encourage beneficiary uptake of opioid or substance abuse treatment regimens amongst other needed services. Some APhA members already communicate with beneficiaries through HIPAA compliant technology for prescription drug refills, medication synchronization and Medication Therapy Management (MTM) and would be well-positioned to offer these services.

**V. Comment Solicitation on Creating a Bundled Episode of Care for Management and Counseling Treatment for Substance Use Disorders (Pgs. 89-92)**

APhA appreciates CMS’s efforts to consider alternative payment models to expand patients’ access to treatment for substance use disorder (SUD). APhA believes such a model could help facilitate coordinated care provided the bundle is made flexible to account for different care models that exist for management and counseling treatment for SUDs and variable patient needs. As CMS finalizes bundled payment policies for SUD, we emphasize medication management as a critical component of MAT treatment and the importance of accommodating patients’ long-term needs based on emerging evidence supporting treatment of SUD similar to other chronic conditions. One option for consideration would be to utilize the framework for CCM services for SUD management and counseling treatment.

**a. Leveraging Pharmacists**

In the Proposed Rule, CMS seeks comments regarding the creation of a bundled episode of care SUD treatment and separate bundles for components of medication-assisted treatment (MAT) (e.g., management and counseling treatment for SUD, including opioid use disorder, treatment planning, and medication management or observing drug dosing for treatment of SUDs). According to the Proposed Rule, a bundled payment model could provide opportunities to better leverage services furnished with communication technology while expanding access to SUD treatment. APhA supports efforts to expand access to MAT, especially by better leveraging resources currently available, such as pharmacists.

APhA believes pharmacists are an underutilized provider when considering SUD treatment in Medicare Part B because of statutory and regulatory barriers. However, by creating a bundled episode of care for management and counseling treatment for SUD, CMS can structure the bundled payment model in a manner that meaningfully expands patient access to care, including pharmacist-provided services and services provided through communication

technology. As CMS is likely aware, pharmacists provide care in all settings, including in opioid treatment programs and primary care offices providing MAT and some pharmacists receive additional education and credentialing relevant to SUD, such as board certification as a psychiatric pharmacist.<sup>14,15,16,17,18,19,20</sup> Pharmacists should be included in any team-based approach to SUD or MAT and if CMS advances a bundled episode of care, APhA urges CMS to allow a wide range of qualified health care practitioners to participate to maximize patient access and benefit.

### **b. Incident to services**

In the Proposed Rule, CMS seeks comment on whether the counseling portion and other MAT components could also be provided by qualified practitioners incident to the services of the billing physician who would administer or prescribe any necessary medications and manage the overall care, as well as supervise any other counselors participating in the treatment. APhA supports CMS expanding access to treatment and better distributing workload among qualified practitioners by considering incident to approaches to service delivery and billing including through telehealth mechanisms. APhA recommends CMS further expand access by allowing pharmacists to be an eligible practitioner to provide MAT components incident to physician services and use the general supervision requirements as permitted with CCM services. Pharmacists working in team-based models perform many different roles in SUD treatment, including induction (required before MAT with buprenorphine), oral challenge (required before MAT with naltrexone), physical exam and assessment, intake, treatment planning, medication management, drug administration, comprehensive care management, care coordination, management of care transitions and health promotion and should not be excluded from providing MAT or other SUD-related services.

### **c. Identification of Non-Opioid Alternative for Pain Treatment and Management**

CMS is also seeking “...comment on methods for identifying non-opioid alternatives for pain treatment and management, along with identifying barriers that may inhibit access to these nonopioid alternatives including barriers related to payment or coverage.” APhA encourages CMS to consider models or payment of services in which pharmacists’ medication expertise is

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<sup>14</sup> DiPaula BA, Menachery E. Physician-Pharmacist Collaborative Care Model for Buprenorphine-maintained Opioid-dependent Patients. *J Am Pharm Assoc.* 2015; 55: 187-192. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/25749264>

<sup>15</sup> Duvivier H., et al., Indian Health Service pharmacists engaged in opioid safety initiatives and expanding access to naloxone. *Journal of the American Pharmacists Association.* 57 (2017), S135-S140. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/28292501>.

<sup>16</sup> Lagisetty, P., Klasa, K., Bush, C., Heisler, M., Chopra, V. & Bohnert, A. Primary care models for treating opioid use disorders: What actually works? A systematic review. *PLOS One.* Available at: <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0186315>.

<sup>17</sup> Gilmore Wilson, C. & Fagan, B. Providing Office-Based Treatment of Opioid Use Disorder. *Annals of Family Medicine.* 2017; 15(5). Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5593733/>.

<sup>18</sup> Grgas, M. Clinical psychiatric pharmacist involvement in an outpatient buprenorphine program, *Mental Health Clinician*, 2013, 3(6), 290-291. Available at: <http://mhc.cpnpp.org/doi/abs/10.9740/mhc.n183353?code=cpnp-site>.

<sup>19</sup> Suzuki et al., Implementation of a collaborative care management program with buprenorphine in primary care: A comparison between opioid-dependent patients and chronic pain patients using opioids non-medically, *Journal of Opioid Management*, 10(3), 159-168. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4085743/>

<sup>20</sup> McCarty et al., Training rural practitioners to use buprenorphine: Using The Change Book to facilitate technology transfer, *Journal of Substance Abuse Treatment*, 2004, 26(3); 203-8. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/15063914>

utilized to help inform other care team members of safer and alternative prescribing options.<sup>21</sup> Physicians in community practices and Veterans Administration medical settings who received services such as academic detailing from a pharmacist regarding safer opioid prescribing later reported adopting safer prescribing behaviors.<sup>22</sup> Currently, no reimbursement model exists for academic detailing in Medicare Part B. APhA encourages CMS to consider approaches to enable academic detailing or other related services by pharmacists for health care practitioners serving Medicare beneficiaries in need of non-opioid pain treatment and management.

#### **d. Multiple MAT Treatment Guidelines**

APhA notes variable treatment guidelines exist for different products used to provide MAT, such as those relying on buprenorphine and naltrexone. Because of variable treatment guidelines and treatments, CMS may need to consider different structures for bundled payment models based on the therapeutic option used.<sup>23</sup> Patients suffering from SUD often have different goals for treatment, which may include long-term use of medications. Therefore, APhA encourages CMS to remain flexible in allowing for different types of treatment under bundled models and align quality measures with patient goals.

#### **e. Complexity**

The Proposed Rule does not contemplate varying treatment needs of patients suffering from SUD and other concomitant conditions. Patients with SUD commonly suffer from mental health disorders and chronic medical conditions which can add complexity to treatment plans.<sup>24</sup> Complex SUD patients may require more counseling sessions, additional medication management, or other supportive services. While the Proposed Rule indicates CMS is considering dividing portions of care into bundled payments, APhA encourages CMS to also consider how bundled payment models can be structured to provide care to more complex patients and offset such risk.

#### **f. Separate Payment for a Bundled Episode of Care**

APhA appreciates CMS's efforts to consider the need for a separate payment for bundled episodes of care for treatment of SUDs. APhA believes bundled episodes of care for SUD treatments should include medication management as a required component because medications are a core element of MAT and other SUD treatments, and these patients often have concomitant conditions requiring medications. If this episodic payment mirrors that used for surgical procedures, APhA is concerned the time-period may not be sufficient for the longitudinal

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<sup>21</sup> See Trotter Davis, M., Bateman, B. & Avorn J. Educational Outreach to Opioid Prescribers: The Care for Academic Detailing, *Pain Physician*, 2017, 20:S147-S:151. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/28226336>.

<sup>22</sup> Larson, M.J., Browne, C., Nikitin, R.V., Wooten, N.R., Ball, S., Adams, R.S. & Barth, K. (2018). Physicians report adopting safer opioid prescribing behaviors after academic detailing intervention, *Substance Abuse*, Apr 2:1-to 7. Available at: [https://www.researchgate.net/publication/324172121\\_Physicians\\_report\\_adopting\\_safer\\_opioid\\_prescribing\\_behaviors\\_after\\_academic\\_detailing\\_intervention](https://www.researchgate.net/publication/324172121_Physicians_report_adopting_safer_opioid_prescribing_behaviors_after_academic_detailing_intervention).

<sup>23</sup> Connery, H. S. Medication-Assisted Treatment of Opioid Use Disorder: Review of the Evidence and Future Directions (2015), 23(2), 63-75. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/25747920>.

<sup>24</sup> Walker, E.R. & Druss B.G. Cumulative burden of comorbid mental disorders, substance use disorders, chronic medical conditions, and poverty on health among adults in the U.S.A. *Psychology, Health & Medicine*, 2017, 22(6), 727-735. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/27593083>.

management required by patients with SUD and stresses SUD care and payment models must accommodate patients' long-term needs.

## **VI. Measure Proposals for the e-Prescribing Objective (Pgs. 636-648)**

CMS is proposing to add two new measures to the e-Prescribing objective: Query of PDMP and Verify Opioid Treatment Agreement. APhA appreciates CMS's efforts to encourage practitioners to utilize different resources in response to the opioid epidemic and offers the following recommendations.

### **a. Proposed Measure: Query of Prescription Drug Monitoring Program (PDMP)**

According to the Proposed Rule, for at least one Schedule II opioid electronically prescribed using Certified EHR Technology (CEHRT) during the performance period, the Merit-based Incentive Payment System (MIPS) eligible clinician is to use data from CEHRT to conduct a query of a PDMP for prescription history, except where prohibited by law. The query is expected to be completed before electronic transmission of the Schedule II opioid prescription. APhA supports appropriate system query of the PDMP by registrants. APhA pharmacist members also support EHR vendors integrating PDMP checks automatically in software systems. Should CMS continue to include this measure, APhA agrees with CMS that this measure should be optional and encourages CMS to study whether high rates of PDMP querying have a meaningful impact on prescribing decisions. In addition, APhA recommends CMS identify opportunities, including partnership with professional associations and states, to better educate practitioners regarding strategies for effective PDMP queries.

### **b. Proposed Measure: Verify Opioid Treatment Agreement**

According to the Proposed Rule, the verify opioid treatment agreement measure is intended to encourage eligible clinicians to identify whether there is an existing opioid treatment agreement when they electronically prescribe a Schedule II opioid using CEHRT if the total duration of the patient's Schedule II opioid prescription is at least 30 cumulative days. The MIPS eligible clinician is also to incorporate the agreement into the patient's EHR using CEHRT. We have concerns about the construct of the measure and whether it will result in the opioid treatment agreement being developed unnecessarily because opioid treatment agreements are generally applicable when treating patients with chronic pain (e.g., 3 months or longer) and used when medications are prescribed on a chronic basis.

In addition, the Proposed Rule states "[t]he treatment agreement is intended to support and enable further coordination and the sharing of substance use disorder (SUD) data with consent, as may be required of the individual." While this measure may increase certain practitioners' awareness of an opioid treatment agreement, a common barrier is pharmacists often do not have access to a patient's EHR, and, therefore, will continue to be unaware of the existence and content of an opioid treatment agreement. Such information would be relevant to pharmacists providing care to patients with an opioid treatment agreement and could impact pharmacists' dispensing decisions. APhA requests CMS consider and implement policies

enabling pharmacists' access to EHRs and other methods where prescribers can share opioid treatment agreements with pharmacists.

CMS also seeks feedback regarding the content of an opioid treatment agreement. While APhA does not have a position regarding model agreements, we encourage CMS to consider including in the agreement opportunities for patients to provide consent for their prescriber to share the opioid treatment agreement with pharmacists.

## **VII. Measure Proposal for the Health Information Exchange Objective (Pgs. 658-671)**

APhA appreciates CMS's efforts to reduce burdens on practitioners by considering the effect of measures on current program priorities and how information can be better communicated across the care continuum. Pharmacists play an important role in transmitting information during transitions of care. Because pharmacists currently are not MIPS eligible clinicians, APhA appreciates CMS's new measures which encourage information sharing with providers other than MIPS eligible clinicians and hopes the Agency will further encourage such information be provided to pharmacists.

## **VIII. Part B Drugs: Application of an Add-on Percentage for Certain Wholesale Acquisition Cost (WAC)-based Payments (Pgs. 1029-1031)**

For pharmacists and pharmacies, obtaining reimbursement for the Part B drugs which they are able to provide is administratively burdensome, delayed and often fails to cover the actual cost of the product. Patient access to many of these needed Part B medications is hindered because pharmacies cannot provide many of these products due to inadequate reimbursement. In addition to reimbursement rates not being adjusted since 2006,<sup>25</sup> some Part B medications are extremely expensive, making it difficult for small and independent pharmacies to float the inventory expense of these products for an extended period. Lowering reimbursement payments for new Part B drugs, without Average Sales Price (ASP) data, from Wholesale Acquisition Cost (WAC)+ 6% to up to 3% based on MACs will only exacerbate this problem. Any reductions in reimbursement will only reduce access for patients. For example, a number of APhA members providing Part B medications for nebulizer and post-transplant patients indicate they currently provide monthly prescriptions at a significant loss and undergo a complicated and time-consuming audit process requiring dozens of pages of documentation. In addition, any reforms to Part B prescription drug coverage must contain requirements whereby products and related services are adequately reimbursed. Unfortunately, payers' reimbursement to pharmacies are all too often failing to recognize both the product's cost and the service related to providing the medication or treatment. The sustainability of community pharmacies, and therefore, patient access, is at risk as pharmacies, many of which are small businesses, cannot withstand reimbursement levels that do not even cover their actual cost of the product, let alone any related service.

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<sup>25</sup> CMS Manual System. Pub 100-04 Medicare Claims Processing. Transmittal 754. November 10, 2005. Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R754CP.pdf>.

**IX. Request for Information (RFI) on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers (Pgs. 908-913)**

In the RFI, CMS is "...interested in hearing from stakeholders on how we could use the CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs (that is, the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities) to further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers." Since MACRA was signed into law, CMS has stated every MIPS eligible clinician must attest that the certified EHR technology used was "[i]mplemented in a manner that allowed for the timely, secure, and trusted bi-directional exchange of structured electronic health information with other health care providers", [including pharmacists] (as defined by 42 U.S.C. 300jj(3))<sup>26</sup>, including unaffiliated providers, and with disparate CEHRT and health IT vendors."<sup>27</sup> However, pharmacists are frequently blocked from the exchange of relevant clinical information which is critical to maximize the benefit of coordinated team-based care, including safe and appropriate medication use; adherence for the elderly and other populations; medication reconciliation; wellness and prevention; chronic disease management programs; and case management for beneficiaries with multiple medications that require complex medication dosing regimens. Therefore, APhA strongly recommends CMS require under COP, CfC, RfP and LTC that pharmacists are granted access to relevant patient information through interoperable HIT and certified EHRs under Medicare to improve patient care and help practitioners deliver effective care. Additionally, APhA supports the comments submitted by the Pharmacy Health Information Technology (HIT) Collaborative on the Proposed Rule. Implementing the Proposed Rule without addressing pharmacists' need for and reporting of information limits the integration of pharmacists into care teams, fails to utilize pharmacists' expertise and experience to positively impact patients and the health care system, and is inconsistent with the principles underpinning CMS's value-based and coordinated care models.

**X. TABLE Group D: Measures with Substantive Changes Proposed for the 2021 MIPS Payment Year and Future Years - D.1. Medication Reconciliation Post-Discharge (Pg. 1440), D.2. Pneumococcal Vaccination Status for Older Adults (Pg. 1441) and Medicare Shared Savings Program (Pgs. 481-482)**

In general, APhA supports CMS's efforts to reduce measure burden and better harmonize and use measures that are most meaningful. APhA is pleased CMS is retaining the Medication Reconciliation Post Discharge measure (NQF #0097) in the Medicare Part B Claims Measure

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<sup>26</sup> See 42 U.S.C. 300jj(3) defining health care provider as "The term "health care provider" includes a hospital, skilled nursing facility, nursing facility, home health entity or other long term care facility, health care clinic, community mental health center (as defined in section 300x-2(b)(1) of this title), renal dialysis facility, blood center, ambulatory surgical center described in section 1395l(i) of this title, [1] emergency medical services provider, Federally qualified health center, group practice, a pharmacist, a pharmacy ... and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary." Available at: <https://www.law.cornell.edu/uscode/text/42/300jj>.

<sup>27</sup> See, CMS, Quality Payment Program. The Merit-based Incentive Payment System (MIPS) Advancing Care Information Prevention of Information Blocking Attestation: Making Sure EHR Information is Shared. Pg. 3. October 2017. Available at: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/ACI-Information-Blocking-fact-sheet.pdf>.

Specifications and MIPS clinical quality measures (CQMs) Specifications collection types, which will allow clinicians to choose this measure as one of the six measures generally required to report to meet the quality performance category requirements. However, APhA disagrees with removing the measure for the CMS Web Interface Measure Specifications as such a move would be inconsistent with other CMS policies and recent changes, such as including this 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.<sup>28</sup> Our members strongly believe the measure should be retained because of its benefit, especially given the enormous cost of medication-related problems to patients and the health care system.<sup>29</sup> We also have similar concerns regarding the proposed removal of the measure ACO-12 (NQF #0097) in the Shared Savings Program. APhA believes the medication reconciliation measure could be improved to include assessment and plan of action, much like the proposed ACO-47 measure Falls: Screening, Risk-Assessment, and Plan of Care to Prevent Future Falls (NQF# 0101).

Additionally, we agree with the comments submitted by Adult Vaccine Access Coalition (AVAC) stating concern regarding the proposed removal of the Pneumonia Vaccination Status for Older Adults measure (ACO-15) in MSSP, but greatly appreciate the addition of zoster, pneumococcal and influenza measures in several APMs as well as a number of specialty provider measure sets.

## **XI. Pharmacists Ability to Impact Quality and Outcomes**

A significant number of MIPS measures are related to or impacted by medications and would benefit from appropriate medication use and pharmacist-provided services. For example, pharmacists can also 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 critical. 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;<sup>30</sup>
- Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%);<sup>31</sup>
- Risk Standardized, All Condition Readmission;<sup>32</sup>

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<sup>28</sup> 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>

<sup>29</sup> Watanabe, Jonathan H. Et. al. Cost of Prescription Drug-Related Morbidity and Mortality. *Annals of Pharmacology*. First Published March 26, 2018. Available at: <http://journals.sagepub.com/eprint/ic2iH2maTdI5zfN5iUay/full>.

<sup>30</sup> 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>.

<sup>31</sup> 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>.

<sup>32</sup> 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\\_MedicamentManagementinCareTransitionsBestPracticesReport2\\_2013.pdf](http://media.pharmacist.com/practice/ASHP_APhA_MedicamentManagementinCareTransitionsBestPracticesReport2_2013.pdf).

- Medication Reconciliation Post-Discharge;<sup>33</sup>
- Statin Therapy for the Prevention and Treatment of Cardiovascular Disease;<sup>34</sup>
- Preventive Care and Screening: Influenza Immunization;<sup>35</sup> and
- Falls: Screening for Falls.

In the Proposed Rule, CMS discusses its consideration of the value of and ability to measure additional clinicians, such as physical therapists, occupational therapists, and clinical social workers to be eligible clinicians for integration into MIPS. CMS has consistently recognized the benefit of utilizing non-physician practitioners in providing care to beneficiaries. APhA supports inclusion of non-physician providers into MIPS as an important component of optimizing coordinated, team-based care. While pharmacists are positively impacting beneficiary care and MIPS measures, because pharmacists are not MIPS “eligible clinicians” per statute, their ability to impact the effective and efficient delivery of quality care is severely impeded. With the increasing complexity of medications and the role proper medication management will play under MIPS, Alternative Payment Models (APMs), and Advanced APMs, recognizing the unique and essential contributions pharmacists make on patient care teams is fundamental to achieving successful APMs and will assist CMS to meet its triple aim goals. In line with CMS’s consideration of adding additional clinicians into MIPS, APhA suggests CMS use its “authority under section 1848(q)(1)(C)(i)(II) [of the Social Security Act] to expand the definition of MIPS eligible clinician to include “...such other eligible professionals (as defined in subsection (k)(3)(B)) as specified by the Secretary...”<sup>36</sup> to pharmacists in its planned Year 3 expansion under the Proposed Rule to physical therapists, occupational therapists, clinical social workers and clinical psychologists.

Given pharmacists’ unique access to, and relationship with, the patient community, and their ability to reduce the possible \$672 billion spent by the U.S. annually on medication-related problems, many of which are preventable,<sup>37</sup> pharmacists are critical to APMs “bending the Medicare cost curve by encouraging the delivery of high-quality, low-cost care” — a stated objective of CMS. As CMS may know, 89 percent of Americans live within five miles of a community pharmacy.<sup>38</sup> In addition, pharmacists are providing services in physician offices practices and hospital-based clinics. 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. APhA recommends CMS incorporate and/or test an APM model focused on optimizing medication use and health outcomes as part of coordinated care delivery through the use of pharmacists. Moreover, absent a statutory change, APhA recommends CMS take advantage of any regulatory discretion to remove regulatory barriers preventing physicians and

<sup>33</sup> 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>.

<sup>34</sup> 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](https://www.japha.org/article/S1544-3191(17)30155-3/abstract).

<sup>35</sup> 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](https://www.japha.org/article/S1544-3191(18)30231-0/fulltext).

<sup>36</sup> See, Social Security Act. §1848 (q)(1)(C)(i)(II). Available at: [https://www.ssa.gov/OP\\_Home/ssact/title18/1848.htm](https://www.ssa.gov/OP_Home/ssact/title18/1848.htm)

<sup>37</sup> Watanabe, Jonathan H. Et. al. Cost of Prescription Drug–Related Morbidity and Mortality. *Annals of Pharmacology*. First Published March 26, 2018. Available at: <http://journals.sagepub.com/eprint/ic2iH2maTdI5zfN5iUay/full>

<sup>38</sup> NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.

eligible clinicians from utilizing pharmacists under team-based, patient-centered payment and delivery models. Pharmacists are often an underutilized resource, which cannot only help achieve the objectives of better outcomes through MIPS and APM but can also help ease the transition of physician and other eligible clinician practices to QPP participation.

In addition, consideration should be given to how reporting systems can meaningfully capture the contributions of various health care practitioners, including pharmacists, to improving quality outcomes and managing costs. 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 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.

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](mailto:mbaxter@aphanet.org) or by phone at (202) 429-7538.

Sincerely,



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