

September 12, 2025

The Honorable Mehmet Oz, MD
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)
Attention: CMS-1832-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: [Docket No. CMS-1832-P] Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, Proposed Rule

Dear Administrator Oz,

The American Pharmacists Association (APhA) is pleased to submit comments on the "CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program; Proposed Rule (hereinafter, "proposed rule").

APhA is the only organization advancing the entire pharmacy profession. It represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including—but not limited to—community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

APhA commends CMS's ongoing recognition of pharmacist-provided patient care services and strongly urges the agency to build upon these efforts, utilizing enforcement discretion and demonstration authority to the maximum extent to remove remaining regulatory barriers to the delivery of, and payment for, pharmacist-provided patient care services for our nation's Medicare beneficiaries.

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

As CMS understands, Congress has emphasized the following intent for federal funding at CMS regarding pharmacist-provided patient care services in the Departments of Labor, Health

and Human Services, and Education, and Related Agencies Appropriations bills, 2023, 2024 (H. Rept. 117-403), 2025 (H.Rept. 118-585), and most recently 2026 (<u>H.Rept. 119-XXX</u>) report language:

"Pharmacists and Patient Care Services.—The Committee is aware that certain Medicare Part B services and care frameworks have provisions to include pharmacists and their patient care services. However, CMS has few mechanisms to identify and evaluate the contributions of pharmacists to patient care and outcomes or to identify barriers within current service requirements that prevent the scalable involvement of pharmacists. The Committee encourages CMS to create a mechanism to provide greater visibility into the quality and outcomes of the Medicare services currently provided by pharmacists. [emphasis added]."

Medicare could also learn a lot from the private sector's utilization of pharmacists. For example, a recent study of the impact of a clinical pharmacist-led and artificial intelligence supported medication adherence program found medication adherence improved in all disease states measured, including Medicare Star ratings also improved, the percentage of patients with diabetes who reached their A1c goal also increased; and reductions in overall health care expenditures were seen per member per month in patients who were adherent in comparison with those who were nonadherent for a savings of \$3,388 per member per year for diabetic population:

Hypertension: 31% cost savingsHyperlipidemia: 25% cost savings

• Diabetes: 32% cost savings.<sup>1</sup>

The proposed rule also solicits public input on President Trump's "Unleashing Prosperity Through Deregulation" executive order (EO 14192), which states the Administration's policy to significantly reduce the private expenditures required to comply with Federal regulations to secure America's economic prosperity and national security and the highest possible quality of life for each citizen." APhA submitted deregulatory comments to <a href="CMS">CMS</a> and <a href="HHS">HHS</a> over the past year in response to their requests for information (RFI). Within these linked comments, APhA has provided the agencies with recommendations to meet the Administration's goals through the utilization of America's pharmacies and pharmacist-provided services.

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

<sup>1</sup> Charles Worrall, et al., *Impact of Clinical Pharmacist-Led, Artificial Intelligence- Supported Medication Adherence Program on Medication Adherence Performance, Chronic Disease Control Measures, and Cost Savings,* 65 Journal of the American Pharmacists Association 102271 (2025). Available at: <a href="https://www.sciencedirect.com/science/article/pii/S1544319124003029">https://www.sciencedirect.com/science/article/pii/S1544319124003029</a>.

- As CMS evaluates alternatives to the emergency room, APhA stresses the accessibility of
  pharmacies and the expertise of pharmacists as a solution. Considering the health
  conditions CMS aims to address, including common respiratory illnesses and bacterial
  infections, pharmacists are already providing these services in many states. In at least 24
  states, pharmacists are capable of testing and treating common respiratory illnesses,
  including influenza, RSV, strep throat, and COVID-19.
- APhA strongly urges CMS to use its full regulatory authority to permit physicians or non-physician practitioners (NPPs) to bill for pharmacists' evaluation and management (E/M) services under incident to arrangements at higher levels of complexity or time than CPT 99211 (e.g., 99212-99215), when the care provided supports use of the higher code.
- APhA supports the expansion of appropriate services via telehealth, as telehealth can be
  an essential step in expanding access to care to specific patient populations. APhA
  encourages CMS to include pharmacists in the expansion of telehealth services under
  Medicare, as pharmacists are the only appropriate providers of pharmacy-provided
  telehealth services.
- APhA supports the expansion of virtual supervision for all pharmacist-provided incident to services. By incorporating "immediate availability" through real-time audio/video communications into the definition of direct supervision, provider teams, including pharmacists, can continue to meet patient needs through telehealth services.
- APhA urges CMS to ensure these potential coding and billing issues are prevented by providing administration codes for COVID-19 combination vaccines before the 2026-2027 season.
- APhA asks CMS to reconsider its decision to make CPT codes 90XX1, 90XX2, and 90XX3 not valid.
- APhA urges CMS to ensure that pharmacists are heavily involved in the remote monitoring of physiological parameters, therapy adherence, therapy response, and digital therapy intervention.
- Regarding HCPCS codes G0552, G0553, and G0554, pharmacists can provide the DMHT services, and the codes can be billed incident to a physician or a qualified health care provider.
- APhA asks CMS to review the scope of practice and training of pharmacists, which is
  extensive in comparison to "clinical social workers" or CSWs, to ensure that pharmacist
  authority to bill or provide services under Medicare matches or exceeds direct or
  incident to billing services recognized for CSWs.

- APhA encourages CMS to incentivize RHCs and FQHCs through incident to billing rates that adequately compensate pharmacists' time to ensure pharmacists can continue to participate in these processes, particularly with more complex patients.
- APhA supports CMS preserving the COVID-19 PHE flexibilities for RHCs and FQHCs to provide these services to Medicare beneficiaries through telecommunications technology.
- APhA recommends CMS include pharmacists in the ASM model.
- APhA supports the extension of the COVID-19 flexibilities for pharmacies participating
  in the MDPP through December 31, 2029, and asks CMS to consider making these
  flexibilities permanent. Additionally, APhA urges CMS to recognize pharmacists as
  eligible providers of the Medicare Diabetes Prevention Program (MDPP) via telehealth
  that corresponds with these COVID-19 flexibilities to maximize efficiencies and meet
  CMS's goal to increase MDPP participation.
- APhA also strongly urges CMS to work with the Assistant Secretary for Technology Policy (ASTP) and the Office of the National Coordinator for Health Information Technology (ONC) to prohibit other health care providers and developers of health IT from blocking electronic health information from being transmitted to pharmacists (i.e., information blocking).

Thank you for the opportunity to provide feedback on the proposed rule and for your consideration of our comments. Please see our full comments below for detailed feedback regarding the proposed rule. If you have any questions or would like to meet with APhA to discuss our comments, please contact Corey Whetzel, APhA's Senior Manager, Regulatory Affairs, at <a href="mailto:cwhetzel@aphanet.org">cwhetzel@aphanet.org</a>.

Sincerely,

Michael Baxter

Vice President, Government Affairs

Michael Baster

#### **Full APhA Feedback and Comments**

## **Determination of PE RVUs (FR 32354)**

#### Payment for Services in Urgent Care Centers

CMS has previously "sought comment on urgent care centers, noting that interested parties describe that hospital emergency departments are often used by beneficiaries to address nonemergent urgent care needs that could be appropriately served in less acute settings, but where other settings, such as physician offices, urgent care centers, or other clinics, are not available or readily accessible." <sup>2</sup> CMS notes that "[p]atients enter EDs to treat common conditions like allergic reactions, lacerations, sprains and fractures, common respiratory illnesses (for example, flu or RSV), and bacterial infections (for example, strep throat, urinary tract infections or foodborne illness) ... [that] often can be treated in less acute settings." 3 CMS "stated that [they] were interested in system capacity and workforce issues broadly and are interested in hearing more on those issues, including how entities such as urgent care centers can play a role in addressing some of the capacity issues in emergency departments."4 Following the receipt of comments from CY 2025 PFS proposed rule and request from interested parties this year, CMS is "consider[ing] adopting a new Place of Service code for "enhanced" urgent care centers as well as create a new add-on G-code to describe the resource costs involved when practitioners furnish certain services in enhanced urgent care centers that offer extended hours and certain diagnostic and therapeutic services." 5 As CMS evaluates alternatives to the emergency room, APhA stresses the accessibility of pharmacies and the expertise of pharmacists as a solution. Considering the health conditions CMS aims to address, including common respiratory illnesses and bacterial infections, pharmacists are already providing these services in many states. In at least 24 states, pharmacists are capable of testing and treating common respiratory illnesses, including influenza, RSV, strep throat, and COVID-19.6 Utilizing pharmacists to test for and treat these conditions can keep Medicare beneficiaries out of expensive urgent care facilities and emergency departments, lowering overall healthcare spending and increasing access to care.

<sup>&</sup>lt;sup>2</sup> Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 32352, 32374. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-258">https://www.federalregister.gov/d/2025-13271/p-258</a>.

<sup>&</sup>lt;sup>3</sup> *Id*.

<sup>&</sup>lt;sup>4</sup> *Id*.

<sup>&</sup>lt;sup>5</sup> *Id.* at 32375. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-260">https://www.federalregister.gov/d/2025-13271/p-260</a>.

<sup>&</sup>lt;sup>6</sup> E. Michael Murphy, Congress Could Expand Access to Essential Services Provided by Pharmacists, The Ohio State University College of Pharmacy. Available at: <a href="https://pharmacy.osu.edu/practice-advancement#:~:text=At%20the%20time%20of%20writing,treat%20only%20for%20COVID%2D19">https://pharmacy.osu.edu/practice-advancement#:~:text=At%20the%20time%20of%20writing,treat%20only%20for%20COVID%2D19</a>.

## Potentially Misvalued Services Under the PFS (FR 32375)

Under section 1848(c)(2)(B) of the Social Security Act, the Secretary is required "to conduct a periodic review, not less often than every 5 years, of the relative value units (RVUs) established under the PFS." Additionally, pursuant to section 1848(c)(2)(K) of the Social Security Act, the Secretary is required "to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services." Further, section 1848(c)(2)(K)(ii) of the Social Security Act directs the Secretary to examine potentially misvalued services that are within specific categories. One of those categories is "Codes that have experienced substantial changes in PE." Another one of those categories is "Codes as determined appropriate by the Secretary."

CPT code 99211 may be misvalued, as it falls within the category of "Codes that have experienced substantial changes in PE." Looking at PE, clinical and non-clinical staff salaries are included in the analysis. As such, CPT code 99211 may be misvalued when pharmacists provide care to complex patients. If incident to billing under CPT code 99211 does not meet any of the other codes within this list, APhA asks the Secretary to examine this code as one that does not reflect the true value of the service being provided. Providing appropriate value to this code may increase the number of pharmacists offering these services, helping address the chronic disease epidemic the country is currently facing.

APhA also strongly urges CMS to use its full regulatory authority to permit physicians or non-physician practitioners (NPPs) to bill for pharmacists' evaluation and management (E/M) services under incident to arrangements at higher levels of complexity or time than CPT 99211 (e.g., 99212-99215), when the care provided supports use of the higher code. Pharmacists are currently providing care to complex patients in various state and commercial health plans at a level of complexity or time that aligns with E/M codes 99212-99215. An example of the types of visits pharmacists routinely provide incident to physician services is below, where the pharmacists often spend 15 to 60 minutes with the patient, depending on whether it is an initial visit or a follow-up visit.

• Case example: Patient is a 77-year-old male with type 2 diabetes, heart disease, hypertension, and hyperlipidemia referred by a physician to the pharmacist for a follow-up visit. Patient is experiencing increased fatigue, nocturia, and weight loss. Patient is currently taking six medications. The pharmacist reviewed symptoms, evaluated the

<sup>&</sup>lt;sup>7</sup> Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 32352, 32375. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-262">https://www.federalregister.gov/d/2025-13271/p-262</a>.

<sup>&</sup>lt;sup>8</sup> *Id*.

<sup>&</sup>lt;sup>9</sup> *Id.* at 32376. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-265">https://www.federalregister.gov/d/2025-13271/p-265</a>.

<sup>&</sup>lt;sup>10</sup> *Id.* Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-267">https://www.federalregister.gov/d/2025-13271/p-267</a>.

<sup>&</sup>lt;sup>11</sup> *Id.* Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-281">https://www.federalregister.gov/d/2025-13271/p-281</a>.

patient's medication regimen, and discontinued two medications and initiated two new medicines in collaboration with the physician. The pharmacist provided education on diet and exercise, as well as counseling on the new medications. The patient does not currently conduct self-blood glucose monitoring (SBGM), and the pharmacist also worked with the patient to initiate SBGM, with a plan to consider continuous blood glucose monitoring (CGM) in the future to monitor progress. A one-month follow-up visit was scheduled. The pharmacist's visit details were reviewed and approved by the supervising provider. **Total patient visit time: 42 minutes.** 

#### Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (FR 32386)

Following the CY 2024 PFS final rule, CMS "implemented a revised 5-step process for making additions, deletions, and changes to the Medicare Telehealth Services List (5-step process), beginning for the CY 2025 Medicare Telehealth Services List." 12 The five steps are: "(1) Determine whether the service is separately payable under the PFS; (2) Determine whether the service is subject to the provisions of section 1834(m) of the Act; (3) Review the elements of the service as described by the HCPCS code and determine whether each of them is capable of being furnished using an interactive telecommunications system as defined in § 410.78(a)(3); (4) Consider whether the service elements of the requested service map to the service elements of a service on the list that has a permanent status described in previous final rulemaking; and (5) Consider whether there is evidence of clinical benefit analogous to the clinical benefit of the inperson service when the patient, who is located at a telehealth originating site, receives a service furnished by a physician or practitioner located at a distant site using an interactive telecommunications system." <sup>13</sup> CMS is now assigning services a "permanent" or "provisional" status rather than as "Category 1," "Category 2," or "Category 3." 14 The proposed rule provides that "[a] service is assigned a 'provisional' status if it meets steps 1, 2, and 3 of our review process, and, if, while there is not enough evidence to demonstrate that the service is of clinical benefit, there is enough evidence to suggest that further study may demonstrate such benefit."15 When discussing the changes to this process, CMS noted that "the 5-step process insufficiently accounts for the vital role of professional judgment exercised by physicians and other practitioners" and "they believe that physicians and other practitioners, given their in-depth knowledge of their beneficiaries' clinical needs, are best positioned to exercise their professional judgment in determining whether a service can be safely furnished via telehealth and whether furnishing a service via telehealth will provide clinical benefit justifying its use."16

This is aligned with President Trump's "Executive Order 13890 on Protecting and Improving Medicare for Our Nation's Seniors," which called for the removal of Medicare program requirements that are "more stringent than applicable Federal or State laws require and that

<sup>&</sup>lt;sup>12</sup> *Id.* at 32387. Available at: https://www.federalregister.gov/d/2025-13271/p-386.

<sup>&</sup>lt;sup>13</sup> *Id*.

<sup>&</sup>lt;sup>14</sup> *Id*.

<sup>15</sup> Id

<sup>&</sup>lt;sup>16</sup> *Id.* Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-388">https://www.federalregister.gov/d/2025-13271/p-388</a>.

limit professionals from practicing at the top of their profession." <sup>17</sup> The Reforming America's Healthcare System Through Choice and Competition report from HHS, the Department of the Treasury, and the Department of Labor also echoed this call by promoting the creation of policies that remove unnecessary barriers to care. <sup>18</sup>

APhA supports the expansion of appropriate services via telehealth, as telehealth can be an essential step in expanding access to care to specific patient populations. APhA encourages CMS to include pharmacists in the expansion of telehealth services under Medicare, as pharmacists are the only appropriate providers of pharmacy-provided telehealth services, and it allows pharmacists to practice at the top of their profession. APhA reminds CMS that pharmacists are authorized to bill the following CPT codes 99202-99205, 99211-99215, 99453-99454, 99091, 99473-99474, and 99457-99458 by other payors, including a number of state Medicaid programs. Further, APhA supports the use of a practitioner's professional judgment in determining if a service can be provided via telehealth, as practitioners, including pharmacists, have a more comprehensive knowledge of their patients to ensure that the care they are providing is not just safe, but also effective.

#### Requests to Add Services to the Medicare Telehealth Services List for CY 2026

CMS "received several requests to add various services to the Medicare Telehealth Services List, effective for CY 2026, some of which [they] believe would meet the proposed revised criteria for being added to the Medicare Telehealth Services List." <sup>19</sup> Some of the requests for added services to the Medicare Telehealth Services List include Group Behavioral Counseling for Obesity (CPT code G0473), Infectious Disease Add-On (CPT code G0545), and Home INR Monitoring (HCPCS code 60248). <sup>20</sup> Pharmacists can be of benefit to physicians and other practitioners who are providing these services via telehealth.

The Group Behavioral Counseling for Obesity code "includes a 30-minute group session that consists of a dietary assessment, counseling, and behavioral therapy, as well as one face-to-face visit per week for each week for the first month, one face-to-face visit every other week for months two through six, and one face-to-face visit per month for months seven through twelve

<sup>&</sup>lt;sup>17</sup> Protecting and Improving Medicare for Our Nation's Seniors, Executive Order 13890, 84 Fed. Reg. 53573, 53574 (Oct. 8, 2019). Available at: <a href="https://www.federalregister.gov/documents/2019/10/08/2019-22073/protecting-and-improving-medicare-for-our-nations-seniors#p-16">https://www.federalregister.gov/documents/2019/10/08/2019-22073/protecting-and-improving-medicare-for-our-nations-seniors#p-16</a>.

<sup>&</sup>lt;sup>18</sup> Reforming America's Healthcare System Through Choice and Competition, U.S. Department of Health and Human Services. Available at: <a href="https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf">https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf</a>.

<sup>&</sup>lt;sup>19</sup> Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 32352, 32389. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-401">https://www.federalregister.gov/d/2025-13271/p-401</a>.

<sup>&</sup>lt;sup>20</sup> *Id.* at 32390. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-403">https://www.federalregister.gov/d/2025-13271/p-403</a>.

(if an individual loses 3kg in the first six months)."<sup>21</sup> Studies have shown that "[p]harmacist-led interventions, such as behavioral counseling, have resulted in patients losing 5%-10% of initial body weight."<sup>22</sup>Additionally, "pilot programs in which pharmacists have collaborated with physicians to conduct annual wellness visits, follow-up after medication initiations, and to provide disease state education and management have resulted in improved patient outcomes, such as weight loss, decreased blood pressure, and decreased cholesterol."<sup>23</sup>

The Infectious Disease Add-On code "include[s] service elements such as disease transmission risk assessment and mitigation, public health investigation and analysis, and complex antimicrobial therapy counseling." As medication experts, pharmacists should be the preferred health care provider when it comes to complex antimicrobial therapy counseling. Additionally, there are over 2,000 BPS Board-Certified Infectious Diseases Pharmacists, who have validated their advanced knowledge and experience to develop antimicrobial therapies, provide direct patient care, lead antimicrobial stewardship, and improve public health."<sup>24</sup>

The Home INR Monitoring "encompasses a face-to-face demonstration of the use and care of the INR monitor, obtaining at least one blood sample, providing instructions for reporting home INR test results, and documenting the patient's ability to perform testing and report results." <sup>25</sup> Pharmacists play a critical role in INR monitoring as it relates to the management of warfarin therapy. Studies have shown that a "pharmacist-managed anticoagulation program within a family practice clinic compared to usual care by the physicians achieved significantly better INR control as measured by the percentage of time patients' INR values were kept in both the therapeutic and expanded range." <sup>26</sup> APhA stresses to CMS that pharmacists are an integral part of health care teams and are trained to provide many of these services that Americans need but are unable to obtain due to current health care provider shortages. APhA provides examples of services pharmacists provide similar or the same services as those provided by other practitioners referenced within the PFS proposed rule here and throughout the rest of our comments.

<sup>&</sup>lt;sup>21</sup> *Id.* Available at: https://www.federalregister.gov/d/2025-13271/p-405.

<sup>&</sup>lt;sup>22</sup> Kayce M. Shealy, *The "5 A's" of Weight Management Counseling*, 58 Journal of the American Pharmacists Association 241, 242 (2018). Available at: <a href="https://www.japha.org/article/S1544-3191(18)30180-8/fulltext">https://www.japha.org/article/S1544-3191(18)30180-8/fulltext</a>. <sup>23</sup> *Id*.

<sup>&</sup>lt;sup>24</sup> *Infectious Diseases Pharmacy Specialty Certification (BCIDP)*, Board of Pharmacy Specialties. Available at: <a href="https://bpsweb.org/infectious-diseases-pharmacy/">https://bpsweb.org/infectious-diseases-pharmacy/</a>.

<sup>&</sup>lt;sup>25</sup> Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 32352, 32391. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-410">https://www.federalregister.gov/d/2025-13271/p-410</a>.

<sup>&</sup>lt;sup>26</sup> Stephanie Young, et al., Comparison of Pharmacist Managed Anticoagulation with Usual Medical Care in a Family Medicine Clinic, 12 BMC Family Practice 1 (2011). Available at: <a href="https://bmcprimcare.biomedcentral.com/articles/10.1186/1471-2296-12-88#:~:text=Once%20a%20test%20result%20was,testing%2C%20and%20provided%20patient%20counsellin">https://bmcprimcare.biomedcentral.com/articles/10.1186/1471-2296-12-88#:~:text=Once%20a%20test%20result%20was,testing%2C%20and%20provided%20patient%20counsellin</a>

## Direct Supervision Via Use of Two-Way Audio/Video Communications Technology

The proposed rule provides that "[u]nder Medicare Part B, certain types of services, including diagnostic tests described under § 410.32 and services incident to a physician's (or other practitioner's) professional service described under § 410.26 (incident-to services), are required to be furnished under specific minimum levels of supervision by a physician or other practitioner."<sup>27</sup> Section 410.32(b)(3) defines three different levels of supervision – general supervision, direct supervision, and personal supervision.<sup>28</sup> Historically, direct supervision has "required the physician (or other supervising practitioner) to be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the service" and meant "in-person, physical, not virtual availability." <sup>29</sup> The public health emergency associated with the COVID-19 pandemic and the subsequent extensions altered this definition to mean "that the necessary presence of the physician (or other practitioner) for direct supervision includes virtual presence through audio/video real-time communications technology."30 This new definition "permitted a supervising physician (or other practitioner) to be considered "immediately available" through virtual presence using two-way, real-time audio/visual technology for diagnostic tests, incident-to services, pulmonary rehabilitation services, and cardiac and intensive cardiac rehabilitation services."31 Within last year's PFS final rule, CMS "acknowledged the utilization of this flexibility and stated [they] recognized that many practitioners have stressed the importance of maintaining it."32 To this point, CMS has provided that an incremental approach for changes following the public health emergency would be needed to ensure that care is not disrupted.33 CMS states "we finalized the revision of the regulation at § 410.26(a)(2) to state that for the following services furnished after December 31, 2025, the presence of the physician (or other practitioner) required for direct supervision shall continue to include virtual presence through audio/video real-time communications technology (excluding audio-only): services furnished incident to a physician's service when they are provided by auxiliary personnel employed by the physician and working under his or her direct supervision and for which the underlying HCPCS code has been assigned a PC/TC indicator of '5'; and services described by CPT code 99211 (office and other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional)."34

<sup>&</sup>lt;sup>27</sup> Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 32352, 32393. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-433">https://www.federalregister.gov/d/2025-13271/p-433</a>.

<sup>28</sup> Id. at 32393-32394.

<sup>&</sup>lt;sup>29</sup> Id. at 32394.

<sup>&</sup>lt;sup>30</sup> *Id.* Available at: https://www.federalregister.gov/d/2025-13271/p-434.

<sup>31</sup> *Id* 

<sup>&</sup>lt;sup>32</sup> *Id.* Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-436">https://www.federalregister.gov/d/2025-13271/p-436</a>.

<sup>&</sup>lt;sup>33</sup> *Id*.

<sup>&</sup>lt;sup>34</sup> Id.

CMS is now proposing to continue to build on this incremental approach to allow certain services to be furnished under direct supervision that allows "immediate availability" of the supervising practitioner using audio/video real-time communications technology (excluding audio-only)" and "permanently adopt a definition of direct supervision that allows "immediate availability" of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), for all services described under § 410.26, except for services that have a global surgery indicator of 010 or 090." APhA supports the expansion of virtual supervision for all pharmacist-provided incident to services. By incorporating "immediate availability" through real-time audio/video communications into the definition of direct supervision, provider teams, including pharmacists, can continue to meet patient needs through telehealth services. Pharmacists have been providing chronic disease management, medication management services, and Annual Wellness visits via telehealth since the pandemic, helping to ensure that their patients are living healthier lives.

## Valuation of Specific Codes (FR 32397)

The proposed rule provides that "[e]stablishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS." It further provides that, "[s]ince the inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations." The proposed rule also "highlight[s] ... that there are often many years between a code's introduction and revaluation within the RUC process, with only a few hundred out of the more than 9,000 codes paid under the PFS considered for revaluation annually by the RUC" and "there is significant variability in how often codes are reviewed by the RUC, on average, CMS estimates that there are 25.49 years since a code valuation has been reviewed by the RUC (this includes 5382 out of 9970 codes which were never reviewed)." CMS provides that "the average is 17.69 years since the last review of a code by the RUC."

On top of the inefficiencies of the RUC highlighted within the proposed rule, the American Medical Association's (AMA) influence over the RUC amounts to a clear conflict of interest, given their significant financial ties to the management of the RUC and revenue from the licensing of CPT codes. Secretary Kennedy has sought to explore alternatives to AMA's billing codes.<sup>40</sup> The proposed rule provides "[f]or several kinds of PFS services, [CMS is] proposing to deviate from the use of the AMA survey data, and instead utilize data from auditable, routinely updated hospital data to either set relative or absolute rates, especially for technical services

<sup>&</sup>lt;sup>35</sup> *Id.* Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-437">https://www.federalregister.gov/d/2025-13271/p-437</a>.

<sup>&</sup>lt;sup>36</sup> *Id.* at 32397. Available at: https://www.federalregister.gov/d/2025-13271/p-450.

<sup>&</sup>lt;sup>37</sup> *Id*.

<sup>&</sup>lt;sup>38</sup> Id. at 32400. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-476">https://www.federalregister.gov/d/2025-13271/p-476</a>.

<sup>&</sup>lt;sup>39</sup> Id.

<sup>&</sup>lt;sup>40</sup> *RFK Jr. Wants to Change How Medicare Pays Doctors*, Advisory Board (Dec. 2, 2024). Available at: <a href="https://www.advisory.com/daily-briefing/2024/12/02/rfkjr-medicare-payments">https://www.advisory.com/daily-briefing/2024/12/02/rfkjr-medicare-payments</a>.

paid under the PFS."<sup>41</sup> CMS notes that "[t]his approach promotes price transparency across settings, offers more predictable rate-setting outcomes, and limits the influence of anecdotal/survey data."<sup>42</sup> In fact, seven former chairs and vice chairs of the Medicare Payment Advisory Commission (MedPAC), who served on MedPAC between 2006 and 2025, issued a rare joint letter on September 8, 2025 endorsing the Trump administration's plan to overhaul how Medicare sets physician payment rates by adopting an "efficiency adjustment" and relying more on empirical data rather than specialty surveys conducted by the AMA's RUC. APhA looks forward to discussing how your team can help CMS unlock the full value of our nation's pharmacists, including Secretary Kennedy's exploration of reducing AMA's monopoly over medical billing codes.

#### Combination COVID-19 Vaccine Administration (CPT Codes 90480 and 9X16X)

Last year, the CPT Editorial Board established 9X16X as an add-on code "to report when each additional non-COVID vaccine component is administered with the COVID-19 vaccine.<sup>43</sup> Within this proposed rule, CMS is proposing to maintain procedural status "X" for CPT code 90480, because the RUC recommendations "suggest that the work and PE is already included in the administration base code and this add-on code is intended for tracking purposes of the second vaccine." APhA is concerned that maintaining procedural status for this CPT code will result in issues with coding and payment when practitioners, including pharmacists, administer COVID-19 combination vaccines, which could become available during the 2026-2027 season. Additionally, APhA notes that the administration of COVID-19 combination vaccines will result in pharmacists spending more time counseling patients than with typical vaccines. As such, APhA urges CMS to ensure these potential coding and billing issues are prevented by providing administration codes for COVID-19 combination vaccines before the 2026-2027 season. CMS should consider creating a G-code for the administration of COVID-19 combination vaccines and utilizing a payment rate greater than the current administration code to account for the increased time required for patient counseling.

### Immunization Counseling (CPT Codes 90XX1, 90XX2, and 90XX3)

Last year, "the CPT Editorial Panel created three new time-based CPT codes 90XX1, 90XX2, and 90XX3 to report vaccine counseling performed where a vaccine is not administered." <sup>45</sup> CPT code 90XX1 related to "[i]mmunization counseling by physician or other qualified health care professional when immunization(s) is not administered by provider on the same date of service

<sup>&</sup>lt;sup>41</sup> Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 32352, 32374. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-257">https://www.federalregister.gov/d/2025-13271/p-257</a>.

<sup>&</sup>lt;sup>43</sup> *Id.* at 32431. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-656">https://www.federalregister.gov/d/2025-13271/p-656</a>.

<sup>&</sup>lt;sup>44</sup> *Id.* Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-658">https://www.federalregister.gov/d/2025-13271/p-658</a>.

<sup>&</sup>lt;sup>45</sup> *Id.* Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-660">https://www.federalregister.gov/d/2025-13271/p-660</a>.

[for] 3 up to 10 minutes."46 CPT code 90XX2 concerned "[i]mmunization counseling by physician or other qualified health care professional when immunization(s) is not administered by provider on the same date of service [for] greater than 10 minutes up to 20 minutes." <sup>47</sup> CPT code 90XX3 provided for "[i]mmunization counseling by physician or other qualified health care professional when immunization(s) is not administered by provider on the same date of service [for] greater than 20 minutes." 48 The creation of these codes and subsequent survey and review of them at the September 2024 RUC meeting followed "CMS creat[ing] six new HCPCS codes so that Medicaid providers could bill for stand-alone vaccine counseling, "State Health Official Letter #22-002 "Medicaid and CHIP Coverage of Standalone Vaccine Counseling"" in 2022.49 CMS is "proposing to assign status indicator (I") to each of these three services, as not valid for Medicare purposes, against the RUC's request to delete the HCPCS codes and replace them with the three CPT codes.<sup>50</sup> CMS reasons that "Medicare uses other coding for reporting of, and payment for immunization counseling."51 There is value in immunization counseling even when a vaccine is not administered to a patient, as trust between the patient and the health care provider is fostered, and also to determine if immunization is not recommended. Immunization counseling also ensures that patients are informed about the risks and benefits of vaccines and allows the health care provider to address any patient concerns. The trust built between a health care provider and a patient during these conversations keeps the door open to patients returning to future appointments with the pharmacy as their health care home. As such, APhA asks CMS to reconsider its decision to make CPT codes 90XX1, 90XX2, and 90XX3 not valid.

Remote Monitoring (CPT Codes 98975, 98976, 98977, 98978, 98980, 98981, 98XX4, 98XX5, 98XX6, 98XX7, 99091, 99453, 99454, 99457, 99458, 99473, 99474, 99XX4, and 99XX5)

Within the proposed rule for CY 2026, "the CPT Editorial Panel created two new RPM [remote physiologic monitoring] codes to describe RPM services that describe less than 16 days of data transmission per 30-day period and less than 20 minutes of interactive communication per month [in] CPT codes 99XX4 and 99XX5" and "made edits to specify the minimum days of data transmission per 30-day period for CPT code 99454." 52 CMS also noted that "[n]one of the RPM codes (CPT codes 99091, 99474, 99XX5, and 99458) met the minimum survey requirements established by the RUC for the January 2025 RUC meeting," causing "CPT codes 99091, 99474, 99XX, 99457, and 99458 be resurveyed after 1 year of utilization data is available for this CPT 2026 code structure." CMS provides that RPM "represents the remote monitoring of parameters such as weight, blood pressure, and pulse oximetry to monitor a patient's condition and inform

<sup>&</sup>lt;sup>46</sup> Id.

<sup>&</sup>lt;sup>47</sup> *Id*.

<sup>&</sup>lt;sup>48</sup> *Id*.

<sup>&</sup>lt;sup>49</sup> *Id.* Available at: https://www.federalregister.gov/d/2025-13271/p-661.

<sup>&</sup>lt;sup>50</sup> *Id.* Available at: https://www.federalregister.gov/d/2025-13271/p-669.

<sup>&</sup>lt;sup>51</sup> *Id*.

<sup>&</sup>lt;sup>52</sup> *Id.* at 32433. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-690">https://www.federalregister.gov/d/2025-13271/p-690</a>.

their management."<sup>53</sup> Regarding remote therapeutic monitoring (RTM), the CPT Editorial Panel created new RTM "codes to describe RTM services that describe less than 16 days of data transmission per 30-day period and less than 20 minutes of interaction communication per month [for] CPT codes 98XX4, 98XX5, and 98XX7" and "made edits to specify the minimum days of data transmission per 20-day period for CPT codes 98976, 98977, and 98978."<sup>54</sup> RTM is "the monitoring of adherence to at-home therapeutic interventions" and involves respiratory system, cognitive behavioral therapy, and musculoskeletal system monitoring.<sup>55</sup> Pharmacists are in the perfect position to monitor patient health information, especially information sent back from wearable health technologies, and work with patients and their care teams to implement changes to a patient's medication regimen to improve patient outcomes. The accessibility and expertise of pharmacists continue to be underutilized by CMS, and this is an area that is ripe for innovation on both the technological side and the health care provider side. As such, APhA urges CMS to ensure that pharmacists are heavily involved in the remote monitoring of physiological parameters, therapy adherence, therapy response, and digital therapy intervention.

One example where pharmacists are already playing an important role in remote monitoring is continuous glucose monitoring. Studies have shown that pharmacist-driven continuous glucose monitoring is associated with absolute mean reductions in A1C between -0.47% and -1.8%, more patients meeting their glycemic goals, increased time spent within their glycemic range, and improved health behaviors.<sup>56</sup>

Other payors, such as state Medicaid programs, already cover these services provided by pharmacists; however, Medicare beneficiaries in the same states have less access to these services. For example, in Wisconsin, pharmacists are a recognized provider type by the state Medicaid program, and their services are covered under the <u>medical benefit</u>. Pharmacists are authorized to bill for CPT codes, including, but not limited to, the following:

- 99202-99205: Evaluation and Management Office or Other Outpatient Services New Patient
- 99211-99215: Evaluation and Management Office or Other Outpatient Services Established Patient
- 99453-99454, 99091, 99473-99474: Digitally Stored Data Services / Remote Physiologic Monitoring
- 99457-99458: Remote Physiologic Monitoring Treatment Management Services

<sup>&</sup>lt;sup>53</sup> *Id*.

<sup>&</sup>lt;sup>54</sup> *Id.* Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-691">https://www.federalregister.gov/d/2025-13271/p-691</a>.

<sup>55</sup> Id

<sup>&</sup>lt;sup>56</sup> Angelina Vascimini, et al., *Pharmacist-Driven Continuous Glucose Monitoring in Community and Ambulatory Care Pharmacy Practice: A Scoping Review*, 63 Journal of the American Pharmacists Association 1660 (2023). Available at: <a href="https://www.japha.org/action/showPdf?pii=S1544-3191%2823%2900251-0">https://www.japha.org/action/showPdf?pii=S1544-3191%2823%2900251-0</a>.

Accordingly, APhA encourages CMS to incorporate pharmacist involvement in remote monitoring to help patients manage and prevent chronic disease.

## **Enhanced Care Management (FR 32496)**

## Integrating Behavioral Health Into Advanced Primary Care Management

CMS "believe[s] that the physicians and practitioners who furnish APCM services should be able to provide BHI services and CoCM without needing to document their time spent performing the service because this would help facilitate a more holistic, team-based approach to care coordination and reduce burden."57 Thus, CMS is "proposing to create optional add-on codes for APCM services that would facilitate providing complementary BHI services by removing the time-based requirements of the existing BHI and CoCM codes."58 CMS notes that by reducing the burden of the documentation requirements for billing, more practitioners will be able to offer these services and patient access to these services will be expanded.<sup>59</sup> The proposed rule states that "[t]hese proposed optional add-on codes for APCM services would be considered a "designated care management service" under § 410.26(b)(5) and, as such, could be provided by auxiliary personnel under the general supervision of the billing practitioner."60 Pharmacists can provide APCM services incident to a billing provider for the HCPCS codes G0556, G0557, and G0558. Medication management and care plan development are just two ways in which pharmacists can make an impact under APCM. APhA strongly urges CMS to utilize pharmacists to provide these services. In particular, psychiatric pharmacists are needed to assist with the 32% shortage of psychiatrists by 2030<sup>61</sup>, with at least 25% of the 66.7 million Medicare beneficiaries affected by behavioral health conditions in 2023.62

### Behavioral Health Integration Add-On Codes for APCM (HCPCS Codes GPCM1, GPCM2, GPCM3)

CMS is "proposing the establishment of three new G-codes to be billed as add-on services when the APCM base code (HCPCS codes G0556, G0557, and G0558) is reported by the same

<sup>&</sup>lt;sup>57</sup> Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 32352, 32501. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-727">https://www.federalregister.gov/d/2025-13271/p-727</a>.

<sup>&</sup>lt;sup>58</sup> Id.

<sup>&</sup>lt;sup>59</sup> Id.

<sup>&</sup>lt;sup>60</sup> *Id*.

<sup>&</sup>lt;sup>61</sup> Anand Satiani, et al., *Projected Workforce of Psychiatrists in the United States: A Population Analysis*, 69 Psychiatric Services 710 (2018). Available at:

https://psychiatryonline.org/doi/pdf/10.1176/appi.ps.201700344.

<sup>&</sup>lt;sup>62</sup> Behavioral Health: Information on Cost-Sharing in Medicare and Medicare Advantage, U.S. Government Accountability Office (Sept. 11, 2024). Available at: <a href="https://www.gao.gov/products/gao-24-106794">https://www.gao.gov/products/gao-24-106794</a>.

practitioner in the same month."<sup>63</sup> The proposed rule provides "HCPCS code GPCM1, an addon code based on CPT code 99492, HCPCS code GPCM2, an add-on code based on CPT code 99493 for CoCM services delivered to patients also receiving APCM services, and HCPCS code GPCM3, an add-on code for general behavioral health integration services based on CPT code 99484."<sup>64</sup>

- "HCPCS code GPCM1: Initial psychiatric collaborative care management, in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional, initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan, review by the psychiatric consultant with modifications of the plan if recommended, entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant, and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies (list separately and in addition to the Advanced Primary Care Management code)."65
- "HCPCS code GPCM2: Subsequent psychiatric collaborative care management, in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate documentation, participation in weekly caseload consultation with the psychiatric consultant, ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers, additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant, provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies, monitoring of patient outcomes using validated rating scales, and relapse prevention planning with patients as they achieve remission of symptoms and/or other

<sup>&</sup>lt;sup>63</sup> Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 32352, 32501. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-728">https://www.federalregister.gov/d/2025-13271/p-728</a>.

<sup>64</sup> Id.

<sup>&</sup>lt;sup>65</sup> *Id.* Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-730">https://www.federalregister.gov/d/2025-13271/p-730</a>.

treatment goals and are prepared for discharge from active treatment(list separately and in addition to Advanced Primary Care Management code)."66

• "HCPCS code GPCM3: Care management services for behavioral health conditions, directed by a physician or other qualified health care professional, per calendar month, with the following required elements: initial assessment or follow-up monitoring, including the use of applicable validated rating scales, behavioral health care planning in relation to behavioral/psychiatric health problems, including revision for patients who are not progressing or whose status changes, facilitating and coordinating treatment such as psychotherapy, pharmacotherapy, counseling and/or psychiatric consultation, and continuity of care with a designated member of the care team (list separately and in addition to Advanced Primary Care Management code)." 67

APhA urges CMS to recognize non-physician clinicians, such as pharmacists, who are qualified and often trained to perform these services. <sup>68</sup> Pharmacists have the skills and knowledge to monitor, facilitate, and coordinate pharmacological treatment and subsequent care for patients with behavioral or psychiatric health problems. There are also over 1,500 BPS Board-Certified Psychiatric Pharmacists "who have advanced knowledge, skills, and experience to optimize safety and outcomes for persons with mental health challenges. <sup>69</sup> Additionally, pharmacists and other non-physician clinicians directly billing at lower levels would not only help CMS and HHS address the nation's ongoing primary care shortage but also save significant taxpayer funds.

#### Policies To Improve Care for Chronic Illnesses and Behavioral Health Needs (FR 32503)

### *Updates to Payment for DMHT*

Last year, CMS "established Medicare payment to billing practitioners for digital mental health treatment (DMHT) devices furnished incident to professional behavioral health services used in conjunction with ongoing behavioral health care treatment under a behavioral health treatment

<sup>66</sup> Id. at 32501-32502. Available at: https://www.federalregister.gov/d/2025-13271/p-731.

<sup>67</sup> Id. at 32502. Available at: https://www.federalregister.gov/d/2025-13271/p-732.

<sup>&</sup>lt;sup>68</sup> Jay L. Martello, et al., *Survey of Psychiatric Pharmacy Education at U.S. Schools of Pharmacy*, 8 Currents in Pharmacy Teaching and Learning 782 (2016). Available at:

https://www.sciencedirect.com/science/article/abs/pii/S1877129715300976. Marshall E. Crites, et al., *Mental Health and Psychiatric Pharmacy Instruction in US Colleges and Schools of Pharmacy*, 15 American Journal of Pharmaceutical Education 1 (2007). Available at:

https://pmc.ncbi.nlm.nih.gov/articles/PMC1847556/pdf/ajpe04.pdf.

<sup>&</sup>lt;sup>69</sup> *Psychiatric Pharmacy Specialty Certification (BCPP)*, Board of Pharmacy Specialties. Available at: <a href="https://bpsweb.org/psychiatric-pharmacy/">https://bpsweb.org/psychiatric-pharmacy/</a>.

plan of care."<sup>70</sup> CMS "use[s] the term "DMHT device" to include the term digital cognitive behavioral therapy we used in prior rulemaking (88 FR 79012 through 79013) and in general to refer to software devices cleared, approved, or granted De Novo authorization by the Food and Drug Administration (FDA) that are intended to treat or alleviate a mental health condition, in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care, by generating and delivering a mental health treatment intervention that has a demonstrable positive therapeutic impact on a patient's health."<sup>71</sup> In January of this year, CMS "finalized three HCPCS G-codes for DMHT devices, to be billed by physicians and practitioners who are authorized to furnish services for the diagnosis and treatment of mental illness."<sup>72</sup> Those three codes are:

- HCPCS code G0552: "Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan),"
- HCPCS code G0553: "First 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the DMHT device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month)," 74 and
- HCPCS code G0554: "Each additional 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (DMHT) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the DMHT device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month)."<sup>75</sup>

CMS previously "finalized that the billing practitioner must diagnose the patient with a mental health condition and prescribe or order the DMHT device." Within the proposed rule, CMS is

<sup>&</sup>lt;sup>70</sup> Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 32352, 32503. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-747">https://www.federalregister.gov/d/2025-13271/p-747</a>.

<sup>&</sup>lt;sup>71</sup> *Id*.

<sup>&</sup>lt;sup>72</sup> *Id.* at 32503. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-749">https://www.federalregister.gov/d/2025-13271/p-749</a>.

<sup>&</sup>lt;sup>73</sup> *Id*.

<sup>&</sup>lt;sup>74</sup> Id.

<sup>&</sup>lt;sup>75</sup> *Id*.

<sup>&</sup>lt;sup>76</sup> *Id.* at 32503. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-750">https://www.federalregister.gov/d/2025-13271/p-750</a>.

"clarifying [] that the patient must have a mental health condition diagnosis, but the billing practitioner does not need to be the practitioner who made the diagnosis {emphasis added}."<sup>77</sup> CMS notes that "payment may only be made for DHMT devices for mental health treatment in accordance with the use indicated in their FDA classification at § 882.5801" and provides that indicated uses include insomnia, substance use disorder, depression, and anxiety."<sup>78</sup> CMS is "proposing to expand [their] payment policies for HCPCS codes G0552, G0553, and G0554 to also make payment for DMHT devices cleared under section 510(k) of the FD&C Act or granted De Novo authorization by FDA and in each instance classified at § 882.5803 Digital therapy device for Attention Deficit Hyperactivity Disorder (ADHD)."<sup>79</sup>

Regarding HCPCS codes G0552, G0553, and G0554, pharmacists can provide the DMHT services, and the codes can be billed incident to a physician or a qualified health care provider. Pharmacists can educate the patient about the DMHT device at the initial onboarding in line with the HCPCS code G0552. Additionally, pharmacists can monitor the patient's response to DMHT devices, evaluate those results, and adjust the patient's medication regimen and therapies accordingly. Thus, pharmacists can play an integral role in HCPCS codes G0552 and G0554 when monitoring the data from the DMHT device and communicating the results with the patient. As CMS notes within the proposed rule, Medicare beneficiaries may have limited access to behavioral health services due to an "ongoing nationwide behavioral health workforce shortage combined with increasing demand for behavioral health care services." Utilizing pharmacists to monitor DMHT devices and adjust patient therapies may be a way to meet this gap in care across the country. APhA also reminds CMS that pharmacists can receive additional education and credentialing in this area, including board certification as a psychiatric pharmacist.

### Prevention and Management of Chronic Disease – Request for Information

CMS is "broadly soliciting feedback to help us better understand how we could enhance our support management for prevention and management of chronic disease." 82 CMS notes that "[s]ix in ten Americans have at least one chronic disease, and four in ten have two or more chronic diseases." 83 APhA notes that 90% of Americans live within 5 miles of a community

<sup>&</sup>lt;sup>77</sup> Id.

<sup>&</sup>lt;sup>78</sup> Id.

<sup>&</sup>lt;sup>79</sup> Id. at 32504. Available at: https://www.federalregister.gov/d/2025-13271/p-755.

<sup>80</sup> *Id.* Available at: https://www.federalregister.gov/d/2025-13271/p-757.

<sup>&</sup>lt;sup>81</sup> *Psychiatric Pharmacy Specialty Certification (BCPP)*, Board of Pharmacy Specialties. Available at: <a href="https://bpsweb.org/psychiatric-pharmacy/">https://bpsweb.org/psychiatric-pharmacy/</a>.

<sup>&</sup>lt;sup>82</sup> Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 32352, 32507. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-783">https://www.federalregister.gov/d/2025-13271/p-783</a>.

<sup>83</sup> Id. at 32507. Available at: https://www.federalregister.gov/d/2025-13271/p-776.

pharmacy.<sup>84</sup> Given the expertise and accessibility of pharmacists, APhA urges CMS to incorporate pharmacist-provided services in its goal to make Americans healthier. Numerous studies have shown that pharmacist interventions can lead to significant improvements in several chronic conditions, including diabetes, hypertension, and dyslipidemia.<sup>85</sup>

Within this RFI, CMS is "considering whether to create additional coding and payment for motivational interviewing" as part of their focus on preventing and managing chronic disease. 60 CMS provides that "[m]otivational interviewing is a collaborative, goal-oriented style of communication with particular attention to the language of change." Pharmacists are playing a growing role in motivational interviewing, especially as it relates to chronic disease management and behavioral health. 88 As such, APhA encourages CMS to create additional codes and payment pathways for motivational interviewing, as health care providers, including pharmacists, can utilize it to make a positive impact on the health of their patients. As a part of creating these new pathways, APhA recommends CMS review APhA's Comprehensive Motivational Interviewing Training (ComMIt) as a ready-to-use training module that educates pharmacists on integrating motivational interviewing into pharmacy practice.

<sup>&</sup>lt;sup>84</sup> Lucas A. Berenbrok, et al., *Access to Community Pharmacies: A Nationwide Geographic Information Systems Cross-Sectional Analysis*, 62 Journal of the American Pharmacists Association 1816, 1816 (2022). Available at: <a href="https://www.japha.org/action/showPdf?pii=S1544-3191%2822%2900233-3">https://www.japha.org/action/showPdf?pii=S1544-3191%2822%2900233-3</a>.

<sup>&</sup>lt;sup>85</sup> See Rahma M. Alabkal, et al., Impact of Pharmacist-Led Interventions to Improve Clinical Outcomes for Adults with Type 2 Diabetes at Risk of Developing Cardiovascular Disease: A Systematic Review and Meta-Analysis, 36 Journal of Pharmacy Practice 888 (2022). Available at:

https://journals.sagepub.com/doi/epub/10.1177/08971900211064459. See also Dave L. Dixon, et al., Effect of Pharmacist Interventions on Reducing Low-Density Lipoprotein Cholesterol (LDL-C) Levels: A Systematic Review and Meta-Analysis, 14 Journal of Clinical Lipidology 282 (2020). Available at:

https://www.sciencedirect.com/science/article/abs/pii/S193328742030074X. See also Manual P. Morgado, et al., Pharmacist Interventions to Enhance Blood Pressure Control and Adherence to Antihypertensive Therapy: Review and Meta-Analysis, 68 American Journal of Health-System Pharmacy 241 (2011). Available at: <a href="https://academic.oup.com/ajhp/article-abstract/68/3/241/5129645">https://academic.oup.com/ajhp/article-abstract/68/3/241/5129645</a>.

<sup>&</sup>lt;sup>86</sup> Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 32352, 32508. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-795">https://www.federalregister.gov/d/2025-13271/p-795</a>
<sup>87</sup> Id.

<sup>&</sup>lt;sup>88</sup> See Jamie Spears, et al., A Pharmacist-Led, Patient-Centered Program Incorporating Motivational Interviewing for Behavior Change to Improve Adherence Rates and Star Ratings in a Medicare Plan, 26 Journal of Managed Care & Specialty Pharmacy 35 (2020). Available at:

https://www.jmcp.org/doi/epdf/10.18553/jmcp.2020.26.1.35. See also Katie Kinsey, et al., Exploratory Analysis of Pharmacist Involvement in Motivational Interviewing Intervention for Patients with Prescription Opioid Misuse Behaviors, JAPhA 100044 (2025). Available at:

https://www.sciencedirect.com/science/article/pii/S2949969025000193.

#### Community Health Integration and Principal Illness Navigation for Behavioral Health

Within "the CY 2025 PFS final rule (89 FR 97822), [CMS] clarified that when [CMS] refer[s] to "certified or trained auxiliary personnel" in the following codes: G0019, G0022, G0023, G0024, G0140, G0146, this also includes clinical social workers (CSWs)."89 The proposed rule provides that "[m]arriage and family therapists (MFTs) and mental health counselors (MHCs) have a similar statutory benefit as CSWs and may also connect individuals with community-based resources to address unmet social needs that affect the diagnosis and treatment of medical problems."90 Further, "[l]ike CSWs, MFTs and MHCs can bill Medicare directly for services they personally perform for the diagnosis or treatment of mental illness and substance use disorders, but are not authorized by statute to bill under the PFS for services that are provided by auxiliary personnel incident to their professional services."91 Additionally, the proposed rule notes that "CHI and PIN services are typically provided by auxiliary personnel supervised by the billing practitioner, and MFTs and MHCs could serve as auxiliary personnel, as the codes do not limit the types of auxiliary personnel that can perform CHI and PIN services incident to the billing practitioner's professional services, so long as they meet the requirements to provide all elements of the service included in the code, consistent with the definition of auxiliary personnel at § 410.26(a)(1)."92 CMS is now "proposing to allow for CPT code 90791 (Psychiatric diagnostic evaluation) or the Health Behavior Assessment and Intervention (HBAI) services that CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168 (and any subsequent HBAI codes) to serve as initiating visits for CHI [for CSWs, MFTs, and MHCs], as [CMS] believe[s] these codes are the most analogous codes to the E/M codes that are currently used as initiating visits for CHI that are utilized by practitioners in a specialty whose covered services are limited by statute to services for the diagnosis and treatment of mental illness."93 Pharmacists routinely provide services to their patients similar to the CHI and PIN services offered by these other providers and should be able to do so as "clinical staff," under CMS's current regulations. Pharmacists are also trained to assist patients with these types of issues to ensure that patients' care is coordinated and managed appropriately. As such, APhA asks CMS to review the scope of practice and training of pharmacists, which is extensive in comparison to CSWs, to ensure that pharmacist authority to bill or provide services under Medicare matches or exceeds direct or incident to billing services recognized for CSWs.

<sup>&</sup>lt;sup>89</sup> Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 32352, 32509. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-813">https://www.federalregister.gov/d/2025-13271/p-813</a>.

<sup>90</sup> Id. Available at: https://www.federalregister.gov/d/2025-13271/p-814.

<sup>&</sup>lt;sup>91</sup> *Id*.

<sup>&</sup>lt;sup>92</sup> Id.

<sup>&</sup>lt;sup>93</sup> *Id.* at 32510. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-817">https://www.federalregister.gov/d/2025-13271/p-817</a>.

#### Drugs and Biological Products Paid Under Medicare Part B (FR 32538)

## Average Sales Price: Price Concessions and Bona Fide Service Fees (§ 414.804 and 414.802)

Within the proposed rule, CMS is "proposing to add a definition of bundled arrangement at § 414.802 and to update § 414.804(a)(2) to provide guidance to manufacturers regarding pricing of bundled price concessions" and "new regulatory text at § 414.804(a)(2)(i) to specify when certain fees are considered price concessions." 4 CMS is also planning to revise the definition of bona fide service fees (BFSFs) and "revising § 414.804(a)(5) to update requirements for ASP [average sales price] data submissions as they relate to reasonable assumptions and evidence that BFSFs are not passed on." 5 These proposals may impact the price pharmacies receive for dispensing Medicare Part B drugs, as reimbursement is tied to the drug's ASP plus a six percent markup and the price patients pay for these medications. As such, APhA encourages CMS to ensure that any changes to these provisions do not jeopardize patient access to these drugs by reducing Medicare reimbursement to the point where pharmacies will not be able to stock them or patients will not be able to afford their portion of the cost-sharing.

#### Average Sales Price: Units Sold at Maximum Fair Price

The proposed rule also notes that the Medicare Drug Price Negotiation Program (MDPNP) is designed "to negotiate a maximum fair price (MFP) for certain high expenditure, single source drugs payable under Medicare Part B and covered under Part D." During the third year of the MDPNP, "initial price applicability year 2028, CMS will select for negotiation up to 15 high expenditure, single source drugs payable under Part B and/or covered under Part D." At that point, when Part B drugs are first included in the MDPNP, the payment limit will be set as 106 percent of MFP. APhA emphasizes its previous concerns expressed to CMS regarding the MDPNP. Additionally, APhA has concerns regarding pharmacies stocking these medications if the pharmacy's acquisition costs are higher than the MFP.

### Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

The proposed rule provides that "RHC and FQHC visits generally are defined as face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which one or more RHC or FQHC qualifying services are furnished." <sup>99</sup> It lists "physicians, NPs, PAs, CNMs, clinical psychologists (CPs), licensed marriage and family therapists, mental health counselors, and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse that is furnishing care to a homebound RHC or FQHC patient in an area verified as

<sup>94</sup> Id. at 32541. Available at: https://www.federalregister.gov/d/2025-13271/p-1089.

<sup>95</sup> Id.

<sup>&</sup>lt;sup>96</sup> Id. at 32545. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-1090">https://www.federalregister.gov/d/2025-13271/p-1090</a>.

<sup>97</sup> I.d

<sup>98</sup> *Id.* Available at: https://www.federalregister.gov/d/2025-13271/p-1092.

<sup>99</sup> Id. at 32547. Available at: https://www.federalregister.gov/d/2025-13271/p-1118.

having shortage of home health agencies" as RHC and FQHC practitioners. <sup>100</sup> However, the proposed rule does provide that "[s]ervices furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment." <sup>101</sup> Pharmacists are valuable members of the health care teams in RHCs and FQHCs throughout the country, and can currently assist as "clinical staff," and would recommend referring to pharmacists as such in this capacity rather than "auxiliary personnel," assisting RHC and FQHC practitioners every day to provide the best quality care for the patients receiving care in these facilities. APhA urges CMS to unlock the true value of pharmacists nationwide by permitting pharmacists greater authority to bill directly under Medicare, to align with the President's Executive Order 13890, to practice "at the top of their profession' (mentioned above).

#### Payment for Care Coordination Services

Within the proposed rule, CMS "noted that payment for office visits may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries, such as those who are returning to a community setting following discharge from a hospital or skilled nursing facility (SNF) stay." 102 CMS states that "[o]ver the last decade, they have updated RHC and FQHC payment policies as appropriate, and we remain committed to improving how Medicare payment recognizes the resources involved in furnishing covered services that encompass aspects of advanced primary care furnished by interprofessional care teams and typically concentrating on the delivery of appropriate preventive care to patients and the management of individuals' chronic conditions as they progress over time."103 CMS "reaffirmed [their] support of primary care and recognized care management as one of the critical components of primary care by implementing significant changes aimed at better capturing the resources required for care management services, including chronic care management (CCM), principal care management (PCM), general behavior health integration (BHI), chronic pain management (CPM), transitional care management (TCM), remote physiologic monitoring (RPM), remote therapeutic monitoring (RTM), community health integration (CHI), principal illness navigation (PIN), PIN-peer support services and Advanced Primary Care Management (APCM)."104 Pharmacists are regularly involved in the coordination of care of complex patients presenting to RHCs and FQHCs. For example, the Ohio project alone documented nearly 1,700 care plans developed by pharmacists. Given the expansion of pharmacist roles in FQHCs nationwide, especially in chronic disease and preventive care, this translates to thousands of care plans actually being

<sup>&</sup>lt;sup>100</sup> *Id*.

<sup>101</sup> Id

<sup>&</sup>lt;sup>102</sup> *Id.* at 32548. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-1122">https://www.federalregister.gov/d/2025-13271/p-1122</a>.

<sup>&</sup>lt;sup>103</sup> Id. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-1123">https://www.federalregister.gov/d/2025-13271/p-1123</a>

<sup>&</sup>lt;sup>104</sup> *Id*.

written annually across the U.S. by our nation's pharmacists. <sup>105</sup> In an effort to ensure that patients receive the highest quality of care and future medication-related issues are prevented, payment to these entities should reflect the services provided by pharmacists on their teams. Until pharmacists can bill under Medicare directly, APhA urges CMS to ensure that pharmacists billing incident to a physician or non-physician practitioner under many of the programs listed above, including CCM and TCM, are adequate and representative of the time spent by the pharmacist in completing these services, especially in the more complex patient cases to lower health care costs and save the taxpayers money.

#### Aligning with the PFS for Care Coordination Services

The proposed rule provides that "under the PFS, certain care management/coordination services are categorized as designated care management services and assigned general supervision for purposes of 'incident to' billing." 106 CMS states that, "generally, [they] do not believe it is clinically necessary for the individuals on the team who provide these services other than the treating practitioner (namely, clinical staff [emphasis added]) to have the treating practitioner immediately available to them at all times, as would be required under a higher level of supervision."107 They also previously "discussed how the regulations under § 410.26(b), at that time, provided for an exception to assign general supervision to CCM services (and similarly, for the non-face-to-face portion of TCM services), because these are generally nonface-to-face care management/care coordination services that would commonly be provided by clinical staff when the billing practitioner (who is also the supervising practitioner) is not physically present; and the CPT codes comprise solely (or to a significant degree) non-face-toface services provided by clinical staff." 108 CMS, "in an effort to better define general supervision and to assign general supervision not only to CCM services and the non-face-toface portion of TCM services, but also to the then proposed codes ... amended § 410.26(a)(3) to better describe general supervision in the context of these services[] and amended § 410.26(b) to assign general supervision to "designated care management services."" 109 As the number of care coordination services continues to grow, CMS is set to "review and evaluate the new care coordination codes each year as established under the PFS to determine their applicability to RHCs and FQHCs."110 At RHCs and FQHCs, pharmacists play a role in this "behind the scenes and not in the presence of the patient" coordination of care. APhA encourages CMS to

<sup>&</sup>lt;sup>105</sup> Pharmacists in Federally Qualified Health Centers: Models of Care to Improve Chronic Disease, Centers for Disease Control and Prevention (Nov. 21, 2019). Available at: <a href="https://www.cdc.gov/pcd/issues/2019/19">https://www.cdc.gov/pcd/issues/2019/19</a> 0163.htm.

<sup>&</sup>lt;sup>106</sup> Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 32352, 32554. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-1138">https://www.federalregister.gov/d/2025-13271/p-1138</a>.

<sup>&</sup>lt;sup>107</sup> *Id*.

<sup>&</sup>lt;sup>108</sup> *Id*.

<sup>&</sup>lt;sup>109</sup> *Id.* Available at: https://www.federalregister.gov/d/2025-13271/p-1139.

<sup>&</sup>lt;sup>110</sup> *Id.* Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-1143">https://www.federalregister.gov/d/2025-13271/p-1143</a>.

incentivize RHCs and FQHCs through incident to billing rates that adequately compensate pharmacists' time to ensure pharmacists can continue to participate in these processes, particularly with more complex patients.

#### Services Using Telecommunications Technology

CMS states that "[u]nder Medicare Part B, certain types of services are required to be furnished under specific minimum levels of supervision by a physician or practitioner."111 The proposed rule provides that "[s]imilar to services furnished in physician office setting, RHC and FQHC services and supplies furnished incident to physician's services are limited to situations in which there is direct physician supervision of the person performing the service, except for certain care coordination services which may be furnished under general supervision."112 During CY 2024, CMS "continued to define "immediate availability" as including real-time audio and visual interactive telecommunications through December 31, 2024, and solicited comment on whether we should consider extending the definition of "direct supervision" to permit virtual presence beyond December 31, 2024; specifically, we solicited comment on potential patient safety or quality concerns when direct supervision occurs virtually in RHCs and FQHCs."113 CMS "[i]n the CY 2025 final rule ... finalized [their] policy to maintain the virtual presence flexibility on a temporary basis, that is, the presence of the physician (or other practitioner) would include virtual presence through audio/video real-time communications technology (excluding audio-only) through December 31, 2025 as such a policy continues to support access and preserve workforce capacity." 114 Following comments from the CY 2025 PFS final rule, CMS noted "direct supervision provided via two-way real time audio-video telecommunications technology meets the statutory requirements specific to RHCs and FQHCs at section 1861(aa)(2)(B) of the Act regarding necessary physician supervision and guidance."115 CMS now "believe[s] that [they] should permanently adopt this flexibility in RHCs and FQHCs as it continues to support access and preserve workforce capacity."116 CMS is proposing "to define "Direct Supervision" to mean that the physician (or other supervising practitioner) must be present in the RHC or FQHC and immediately available to furnish assistance and direction throughout the performance of the service." <sup>117</sup> Further, CMS provides that direct supervision "does not mean that the physician (or other supervising practitioner) must be present in the room when the service is performed" and "[t]he presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only)."118 APhA supports the adoption of virtual supervision for all pharmacist-provided incident to services. By incorporating "immediate availability" through real-time audio/video

<sup>&</sup>lt;sup>111</sup> *Id.* at 32556. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-1156">https://www.federalregister.gov/d/2025-13271/p-1156</a>.

<sup>&</sup>lt;sup>112</sup> *Id.* at 32556. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-1157">https://www.federalregister.gov/d/2025-13271/p-1157</a>.

<sup>&</sup>lt;sup>113</sup> *Id*.

<sup>&</sup>lt;sup>114</sup> *Id*.

<sup>&</sup>lt;sup>115</sup> *Id.* at 32557. Available at: https://www.federalregister.gov/d/2025-13271/p-1160.

<sup>&</sup>lt;sup>116</sup> *Id.* Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-1161">https://www.federalregister.gov/d/2025-13271/p-1161</a>.

<sup>&</sup>lt;sup>117</sup> *Id*.

<sup>&</sup>lt;sup>118</sup> *Id*.

communications into the definition of direct supervision, provider teams, including pharmacists, can continue to meet the needs of the patients of RHCs and FQHCs through telehealth services.

#### Payment for Medical Visits Furnished via Telecommunications Technology

The proposed rule provides that "RHCs and FQHCs heavily utilized the temporary authority to be paid for their services when provided as Medicare telehealth services during the PHE."119 Further, CMS notes that "[e]liminating flexibilities under which RHC and FQHC services have been furnished to beneficiaries via telecommunications technology for over 5 years and resuming payment solely for in-person, face-to-face medical visits, would cause disruptions in access to services from RHC and FQHC practitioners." 120 Thus, CMS "believe[s] that [they] need to preserve the flexibilities under which RHC and FQHC services have been furnished to beneficiaries via telecommunications technology temporarily and to do so through an approach that these settings are familiar with to mitigate burden while we consider how to incorporate services furnished through telecommunications technology on a more permanent basis." 121 Because of this, "in the event that Congress no longer authorizes payment to be made for telehealth services furnished via a telecommunications system by RHCs and FQHCs using a payment methodology based upon payment rates that are similar to the national average payment rates for comparable telehealth services under the PFS, [CMS is] proposing, on a temporary basis, to facilitate payment for non-behavioral health visits ... furnished via telecommunications technology using an approach that closely aligns with this methodology."122 This methodology will be similar to what RHCs and FQHCs utilized during the PHE, and "RHCs and FQHCs would continue to bill for RHC and FQHC medical visit services furnished using telecommunications technology, including services furnished using audio-only communications technology."123 The continuation of these flexibilities for practitioners of RHCs and FQHCs, including pharmacists, is needed to ensure patient care is not disrupted. As such, APhA supports CMS preserving these flexibilities for RHCs and FQHCs to provide these services to Medicare beneficiaries through telecommunications technology.

#### Ambulatory Specialty Model (ASM) (FR 32558)

CMS is "proposing the implementation and testing of the Ambulatory Specialty Model (ASM), a new mandatory alternative payment model with 5 performance years that would begin January 1, 2027[,] and end December 31, 2031." The proposed rule provides that "ASM would test whether adjusting payment for specialists based on their performance on targeted measures of quality, cost, care coordination, and meaningful use of certified electronic health record

<sup>&</sup>lt;sup>119</sup> *Id.* Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-1162">https://www.federalregister.gov/d/2025-13271/p-1162</a>.

<sup>&</sup>lt;sup>120</sup> *Id*.

<sup>121</sup> *Id* 

<sup>&</sup>lt;sup>122</sup> *Id.* Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-1163">https://www.federalregister.gov/d/2025-13271/p-1163</a>.

<sup>123</sup> Id.

<sup>&</sup>lt;sup>124</sup> *Id.* at 32558. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-1168">https://www.federalregister.gov/d/2025-13271/p-1168</a>.

(EHR) technology (CEHRT) results in enhanced quality of care and reduced costs through more effective upstream chronic condition management." <sup>125</sup> Pursuant to the ASM model, "select specialists to Medicare beneficiaries with the chronic conditions of heart failure and low back pain ... would be required to report a select set of measures and activities clinically relevant to their specialty type and the chronic condition of interest." <sup>126</sup> CMS notes that quality, cost, interoperability, and care coordination practices will be assessed during throughout the testing of this model. <sup>127</sup> Further, CMS states they "have designed ASM with a focus on clinicians who commonly treat patients in the ambulatory setting, develop longitudinal relationships with patients, and co-manage beneficiaries with primary care clinicians." <sup>128</sup> Pharmacists are in the prime position to play an important role in ASM, as there are thousands of pharmacists specializing in cardiovascular disease and pain management, including hundreds of Board-Certified Cardiology Pharmacists and pharmacists with Pain Management Pharmacy Specialty Certification. <sup>129</sup> Accordingly, APhA recommends CMS include pharmacists in the ASM model.

#### Controlling High Blood Pressure (MIPS Q236)

CMS is proposing to include "Controlling High Blood Pressure (MIPS Q236) in the heart failure measure set for ASM because optimal blood pressure management is a critical part of heart failure management[,] and uncontrolled blood pressure can contribute to complications and progression." As noted earlier, the utilization of pharmacists in the ASM can help CMS improve the quality of care being provided, lower overall health care costs, and enhance the coordination of care being provided. A recent meta-analysis looking at pharmacist interventions found that "[s]ystolic and diastolic BP [blood pressure] were reduced after pharmacist intervention by -5.3 mmHg ... and -2.3 mmHg, respectively." Another major study has shown that pharmacist-led blood pressure monitoring and prescribing interventions can lead to significant cost savings and improved health outcomes across the U.S. healthcare system.

• Per-person savings: Pharmacist interventions saved an average of \$10,162 per patient over a lifetime, primarily by reducing cardiovascular events.

<sup>&</sup>lt;sup>125</sup> *Id*.

<sup>&</sup>lt;sup>126</sup> *Id.* Available at: https://www.federalregister.gov/d/2025-13271/p-1169.

<sup>127</sup> I.A

<sup>&</sup>lt;sup>128</sup> *Id.* at 32559. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-1175">https://www.federalregister.gov/d/2025-13271/p-1175</a>.

<sup>&</sup>lt;sup>129</sup> BPS Specialty Certifications, Board of Pharmacy Specialties. Available at: <a href="https://bpsweb.org/bps-specialties/">https://bpsweb.org/bps-specialties/</a>.

<sup>&</sup>lt;sup>130</sup> Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 32352, 32579. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-1381">https://www.federalregister.gov/d/2025-13271/p-1381</a>.

<sup>&</sup>lt;sup>131</sup> Viktoria Gastens, et al., *Pharmacists Delivering Hypertension Care Services: A Systematic Review and Meta-Analysis of Randomized Controlled Trials*, Frontiers in Cardiovascular Medicine (2025). Available at: <a href="https://pmc.ncbi.nlm.nih.gov/articles/PMC11949927/">https://pmc.ncbi.nlm.nih.gov/articles/PMC11949927/</a>.

- National impact: If 50% of eligible patients received pharmacist-led care, the U.S. could save \$1.137 trillion over 30 years.
- Health outcomes: Prevented 15 million heart attacks, 8 million strokes, and 4 million cases each of angina and heart failure.
- Gained 30.2 million life years and 30 million quality-adjusted life years (QALYs) across the population. 132

Accordingly, APhA urges CMS to prioritize the utilization of pharmacists within the ASM, especially as it relates to helping patients lower their blood pressure.

## <u>Use of High-Risk Medications in Older Adults (MIPS Q238)</u>

CMS is also "propos[ing] to include the Use of High-Risk Medications in Older Adults (MIPS Q238) measure in the low back pain quality measure set." Within the proposed rule, CMS notes that "[f]orty percent of individuals 65 and older filled at least one prescription for a potentially inappropriate medication and 13 percent filled two or more, leading to as much as \$7.2 billion spent per year on inappropriate medications in older adults." Additionally, they cited studies highlighting the potentially inappropriate use of skeletal muscle relaxants and tricyclic antidepressants and the impact they can have on elderly patients, including the greater risk of falls and fractures. As the medication experts on every health care team, pharmacists play an instrumental role in ensuring that patients are taking the medications best aligned with their treatment plan. APhA encourages CMS to utilize pharmacists to help reduce the number of patients taking potentially inappropriate medications. Investing in pharmacist-provided care in this area could not only improve the lives of Medicare beneficiaries nationwide but also lower the costs CMS is spending to correct inappropriate prescribing and associated adverse events.

## Proposed Promoting Interoperability ASM Performance Category

CMS provides that its "long-term for Promoting Interoperability performance category is to ensure the meaningful use of CERHT and information exchange throughout the year, for all data, all clinicians, and all patients." <sup>136</sup> CMS states that they "believe it is important to leverage the Promoting Interoperability ASM performance category for scoring adjustments to the final

<sup>&</sup>lt;sup>132</sup> Dave L. Dixon, et al., *Cost-Effectiveness of Pharmacist Prescribing for Managing Hypertension in the United States*, 6 JAMA Network Open e2341408 (2023). Available at: <a href="https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2811317">https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2811317</a>.

<sup>&</sup>lt;sup>133</sup> Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 32352, 32580. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-1402">https://www.federalregister.gov/d/2025-13271/p-1402</a>

<sup>&</sup>lt;sup>134</sup> *Id*.

<sup>&</sup>lt;sup>135</sup> *Id*.

<sup>&</sup>lt;sup>136</sup> *Id.* at 32593. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-1564">https://www.federalregister.gov/d/2025-13271/p-1564</a>.

score." <sup>137</sup> As such, APhA encourages CMS to consider utilizing metrics and measures that include the sharing of information with the patient's pharmacy and pharmacist in the ASM. By providing a patient's pharmacist with access to their electronic health record, pharmacists in every setting will be able to make a greater impact on the patient's overall health. Requiring the sharing of this information as part of a model is one step towards ensuring that all clinicians, including pharmacists, have access to meaningful use of CERHT and easier exchange of patient electronic health information. As stated in previous comments from APhA to HHS, CMS should require other health care providers and developers of CERHT to be prohibited from information blocking EHI to pharmacists and penalize developers for doing so. APhA reiterates these points as it is urgent that pharmacists gain real-time access to essential electronic health information of their patients because information blocking causes delays in patient care and prevents health care providers from having a complete picture of the patient's health, which can lead to inefficient and ineffective care.

#### Medicare Diabetes Prevention Program (MDPP) (FR 32627)

The MDPP "is a non-pharmacological behavioral intervention consisting of up to 22 intensive sessions furnished over 12 months, which consists of 16 core sessions delivered weekly over 6 months followed by core maintenance sessions delivered monthly in the following 6 months." 138 These "sessions are delivered by a trained Coach who provides training on topics that include long-term dietary change, increased physical activity, and behavior change strategies for weight control and diabetes risk reduction." 139 CMS states that "[t]he primary goal of the MDPP expanded model is to help Medicare beneficiaries reduce their risk for developing type 2 diabetes by achieving at least 5 percent weight loss from the first core session." <sup>140</sup> The utilization of pharmacists can help CMS achieve this goal, but the program's incentives and structure must account for the expertise and value of pharmacists. As CMS notes within the proposed rule, "[p]articipation in MDPP has been low, with less than 1 percent of eligible beneficiaries participating in the program." 141 CMS provides that "[w]hile an estimated 9.3 million Medicare FFS beneficiaries are potentially eligible for the program (that is, have a prediabetes diagnosis but not a diabetes diagnosis in claims), fewer than 5,000 Medicare FFS beneficiaries have participated in MDPP during the first six years of the program." <sup>142</sup> As CMS looks to "[i]ncreasing the uptake of MDPP among both suppliers and beneficiaries ... to increase the impact and success of the program,"143 they should consider how best to utilize pharmacies, pharmacists, and pharmacy technicians.

<sup>137</sup> Id

<sup>&</sup>lt;sup>138</sup> *Id.* at 32627. Available at: https://www.federalregister.gov/d/2025-13271/p-1926.

<sup>139</sup> Id.

<sup>140</sup> *Id* 

<sup>&</sup>lt;sup>141</sup> *Id.* at 32628. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-1944">https://www.federalregister.gov/d/2025-13271/p-1944</a>.

<sup>142</sup> Id.

<sup>&</sup>lt;sup>143</sup> *Id*.

Within the proposed rule, CMS is proposing several changes to increase involvement, including extending flexibilities permitted during the COVID-19 PHE through December 31, 2029, and testing asynchronous delivery modality. 144 These measures may expand access to MDPP by decreasing barriers for certain patients, especially those living in rural areas or where there may be a limited number of in-person MDPP suppliers. However, additional changes may be needed to the design or promotion of the program to achieve CMS's goal of increasing the impact this program has on patients across the country. A clear solution is to get patients involved at their pharmacy, with pharmacists and pharmacy technicians taking an active role in operating the program. To ensure that pharmacies can implement the MDPP, pharmacists must be adequately reimbursed for their time and expertise. APhA supports the extension of the COVID-19 flexibilities for pharmacies through December 31, 2029, and asks CMS to consider making these flexibilities permanent. Additionally, APhA urges CMS to recognize pharmacists as eligible providers of MDPP via telehealth that corresponds with these COVID-19 flexibilities to meet CMS's goal to maximize efficiencies and increase MDPP participation.

Additionally, these flexibilities will allow providers to meet patients where they are, especially those who are only able to commit to audio calls due to transportation issues, technical problems, or other barriers that prohibit their involvement. APhA supports the addition of online delivery as one of the delivery mechanisms for MDPP for Medicare beneficiaries. However, APhA notes that not permitting a combination of online delivery with other modalities will limit participation in MDPP. To better align with CMS's goal of improving access and participation in MDPP, 145 APhA encourages CMS to allow combination delivery, especially for patients who may currently struggle to enroll in the program.

APhA also encourages CMS to review the <u>work and success</u> of the APhA Foundation, as it relates to diabetes research. <u>Project Impact: Diabetes Prevention</u> has shown that pharmacist-led diabetes care can result in statistically significant improvements in A1C control, LDL cholesterol, total cholesterol, and triglycerides. <sup>146</sup> Additionally, the program has also seen improvements, although not statistically significant, in HDL cholesterol, blood pressure, and body mass index (BMI). <sup>147</sup> Accordingly, APhA recommends allowing Medicare recipients access to all CDC-recognized delivery modalities, including "combination with an online component."

<sup>&</sup>lt;sup>144</sup> *Id.* Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-1945">https://www.federalregister.gov/d/2025-13271/p-1945</a>.

<sup>&</sup>lt;sup>145</sup> Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 32352, 32628. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-1945">https://www.federalregister.gov/d/2025-13271/p-1945</a>.

<sup>&</sup>lt;sup>146</sup> *Project IMPACT: Diabetes*, APhA Foundation. Available at: <a href="https://www.aphafoundation.org/project-impact-diabetes">https://www.aphafoundation.org/project-impact-diabetes</a>.

#### *Proposal to Establish a Medicare Part D Claims Data 340B Repository*

CMS "propose[s] c to the repository, data elements ... from all claims with dates of service during the relevant period which the covered entity determined utilized a drug for which the manufacturer provides a discount under the 340B program ... for all covered Part D drugs billed to Medicare Part D."148 CMS states that "the 340B repository would allow covered entities to submit these data directly to CMS (or a contractor), rather than through claims that dispensers submit to Part D plan sponsors" and "the 340B repository would not further verify the 340B status of a claim but rather would serve solely to store these data." 149 CMS also "intends to require a certification from covered entities that the covered entity has submitted all Part D 340B claims with dates of service during the relevant time period and that the data elements from all claims submitted to the 340B repository are from verified 340B claims and, to the best of the covered entity's knowledge, their submission includes all Part D 340B claims for the covered entity at the time of submission for the applicable period." <sup>150</sup> APhA has concerns that the creation of the 340B repository could result in new administrative burdens for pharmacies and potentially conflict with existing HRSA guidance on administering the 340B program. Accordingly, APhA asks CMS to consult HRSA and provide educational resources and training that would lower and not increase any unfunded mandates and administrative burdens on pharmacists. APhA also shares with CMS that our members have expressed privacy concerns related to submitting this data to the 340B repository.

## Proposal for Covered Entities to Submit 340B Claims Data to the 340B Repository

CMS is "proposing that covered entities would optionally begin submitting the fields specified by CMS below to the 340B repository beginning in 2026 for Part D 340B claims with dates of service on or after January 1, 2026 to allow for CMS to begin usability testing for the 340B repository." <sup>151</sup> Within the proposed rule, CMS states that it expects certain hospitals, including those receiving Medicare Disproportionate Share Hospital (DSH) payments, FQHCs, and critical access hospitals, "to submit data elements to the 340B repository during the testing period [and] ... strongly encourages all covered entities to submit data elements to the 340B repository during the testing period beginning in 2026." <sup>152</sup> CMS later notes that they "will address the possibility of mandatory reporting of data elements to the 340B repository by covered entities in future years in future rulemaking." <sup>153</sup> CMS acknowledges that "covered entities that choose to submit data to arrange for their TPAs [third-party administrators] or other vendors to submit certain data elements to the 340B repository on their behalf." <sup>154</sup> While CMS states that this program is not yet mandatory, APhA encourages CMS to provide those

<sup>&</sup>lt;sup>148</sup> *Id.* Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-2071">https://www.federalregister.gov/d/2025-13271/p-2071</a>

<sup>149</sup> **I**d

<sup>&</sup>lt;sup>150</sup> *Id.* at 32642. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-2072">https://www.federalregister.gov/d/2025-13271/p-2072</a>.

<sup>&</sup>lt;sup>151</sup> *Id.* Available at: https://www.federalregister.gov/d/2025-13271/p-2073.

<sup>&</sup>lt;sup>152</sup> *Id*.

<sup>&</sup>lt;sup>153</sup> *Id*.

<sup>&</sup>lt;sup>154</sup> *Id.* Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-2074">https://www.federalregister.gov/d/2025-13271/p-2074</a>.

covered entities with educational resources to help implement this change, as the reporting may result in an unfunded mandate and increased administrative burden on the covered entities as they work with their TPAs and would need to educate staff on how to submit this data.

## Medicare Shared Savings Program (FR 32645)

The proposed rule provides that "[a]s of January 1, 2025, the Medicare Shared Savings Program ... has 477 accountable care organizations (ACOs) with over 650,000 healthcare providers and organizations providing care to over 11.2 million assigned beneficiaries." <sup>155</sup> As CMS "continue[s] to gain experience with and observe the impact of changes to the Shared Savings Program's quality performance standard and other quality reporting requirements, financial methodology, beneficiary assignment methodology, participation options, and availability of new payment options, among other changes, finalized in recent years through the annual PFS rulemaking process." <sup>156</sup> APhA wants to remind CMS of the integral role that pharmacists play in ACOs within the Medicare Shared Savings Program. Pharmacists work to drive down costs and unnecessary hospital visits and readmissions by managing chronic diseases and optimizing transitions of care. Additionally, as medication experts, pharmacists work to identify medication-related problems and improve medication adherence to ensure their patients' drug therapy regimen is appropriate. The interventions made by a pharmacist are key in ensuring that ACOs meet both their financial and quality goals.

# <u>Toward Digital Quality Measurement in CMS Quality Programs – Request for Information (FR 32710)</u>

Within this RFI, CMS is "soliciting comments on our anticipated approach to the use of Health Level Seven® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®) in electronic clinical quality measure (eCQM) reporting." <sup>157</sup> CMS notes that "[h]aving immediate access to electronic health information, in near real-time, supports quality measurement efforts, provides patients the ability to use these data for care considerations, and may lead to improved clinical outcomes." <sup>158</sup> Additionally, the RFI states "[a]ligning technology requirements for healthcare providers, payers, public health agencies, and health IT developers allows for advancement of an interoperable health IT infrastructure that ensures providers and patients have access to health data when and where it is needed." <sup>159</sup> APhA agrees with both of those statements and urges CMS to work towards ensuring that pharmacies and pharmacists have access to electronic health records. Further, APhA urges CMS to work with the Assistant Secretary for Technology Policy (ASTP) and the Office of the National Coordinator for Health Information Technology (ONC) to prohibit other health care providers and developers of health IT from blocking electronic health information from being transmitted to pharmacists (i.e., information blocking).

<sup>&</sup>lt;sup>155</sup> *Id.* at 32645. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-2091">https://www.federalregister.gov/d/2025-13271/p-2091</a>.

<sup>&</sup>lt;sup>156</sup> *Id.* Available at: https://www.federalregister.gov/d/2025-13271/p-2093.

<sup>&</sup>lt;sup>157</sup> *Id.* at 32710. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-2711">https://www.federalregister.gov/d/2025-13271/p-2711</a>.

<sup>&</sup>lt;sup>158</sup> *Id.* Available at: https://www.federalregister.gov/d/2025-13271/p-2713.

<sup>&</sup>lt;sup>159</sup> *Id.* at 32711. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-2715">https://www.federalregister.gov/d/2025-13271/p-2715</a>.

#### Well-Being and Nutrition Measures Request for Information (FR 32703)

CMS is "seeking input on well-being and nutrition measures for future years in the QPP [Quality Payment Program]."160 CMS notes that "[w]ell-being is a comprehensive approach to disease prevention and health promotion, as it integrates mental and physical health while emphasizing preventative care to proactively address potential health issues."161 More specifically, CMS states they are "seeking comments on tools and measures that assess overall health, happiness, and satisfaction in life that could include aspects of emotional well-being, social connections, purpose, and fulfillment" and "would like to receive input and comments on the applicability of tools and constructs that assess for the integration of complementary and integrative health, skill building, and self-care." 162 Pharmacists can play a role in nutrition counseling and education, as well as preventive and lifestyle support. Additionally, the frequent touch points with patients put pharmacists in an ideal position to provide nutritional advice, which will help prevent and treat chronic diseases. As such, CMS should consider utilizing pharmacists to address these concerns, including encouraging pharmacies and pharmacists to take integral roles in the Food is Medicine initiative. One example APhA recommends CMS reference of how pharmacists are embracing the Food is Medicine initiative and ensuring that patients understand the role diet has on chronic disease is the Nourish My Health campaign. 163 This program "encourages the public to ask [their] pharmacist how to check [their] baseline health numbers; use this information to understand [their] risk for dietrelated disease; and work with [their] health-care provider to make a plan to reduce [their] risk, as appropriate." 164 Pharmacists can play a crucial role in educating patients nationwide about the importance of a balanced diet and how a healthy diet can help reduce their risk of chronic disease.

Proposals to Update Subcategories Beginning with the CY 2026 Performance Period/ 2028 MIPS Payment Year (FR 32723)

<u>Proposals to Modify Existing Improvement Activities Beginning with the CY 2026 Performance Period/</u>
2028 MIPS Payment Year

Within the proposed rule, CMS is proposing to modify IA\_BMH\_1, currently titled "Diabetes Screening," to "broaden the relevant patient population by requiring a comprehensive physical health screening on all patients taking anti-psychotic medications," not just diabetic patients

<sup>&</sup>lt;sup>160</sup> *Id.* at 32703. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-2646">https://www.federalregister.gov/d/2025-13271/p-2646</a>.

<sup>&</sup>lt;sup>161</sup> *Id*.

<sup>&</sup>lt;sup>162</sup> *Id*.

<sup>&</sup>lt;sup>163</sup> Sara Roszak, *Pharmacies Are Key in Food Is Medicine Initiatives*, Milken Institute (Oct. 11, 2023). Available at: <a href="https://milkeninstitute.org/content-hub/power-ideas-essays/pharmacies-are-key-partners-food-medicine-initiatives">https://milkeninstitute.org/content-hub/power-ideas-essays/pharmacies-are-key-partners-food-medicine-initiatives</a>.

<sup>&</sup>lt;sup>164</sup> *Id*.

taking anti-psychotic medications. <sup>165</sup> CMS notes that "[w]hile diabetes remains a key focus due to its significant association with anti[-]psychotic use, the expanded title reflects the inclusion of additional monitoring components, such as obesity, hypertension, dyslipidemia, movement disorders (for example, tardive dyskinesia), and other relevant physical health conditions." <sup>166</sup> APhA commends CMS for proposing this change, as more patients will have access to these additional assessments and routine monitoring. APhA urges CMS to ensure that pharmacists continue to play an important role in these patient care services.

APhA has also received feedback from practitioners and pharmacists that Table F-B2 does not include Parkinson's psychosis as one of the conditions to which this proposed change would apply. APhA asks CMS to consider its inclusion in this change, as access to this additional monitoring and assessments will significantly impact the care being provided to these patients.

# Requests for Information Regarding the Query of Prescription Drug Monitoring Program (PDMP) Measure (FR 32747)

The proposed rule provides that "PDMPs are critical decision support tools for addressing prescription drug use, misuse, and diversion." <sup>167</sup> CMS believes that "improved technology approaches and increased PDMP integration into EHR systems can enable increased utilization of PDMPs and associated positive outcomes for patients." <sup>168</sup> Thus, CMS is "interested in continuing to make improvements to the Promoting Interoperability performance category that promote patient safety and encourage appropriate prescribing of controlled substances while minimizing provider burden." <sup>169</sup> CMS is "seeking public comment through this RFI to potentially inform future rulemaking for the Query of PDMP measure related to the following policy considerations: (1) changing the Query of PDMP measure from an attestation-based measure ("Yes" or "No") to a performance-based measure (numerator and denominator), as well as alternative measures designed to more effectively assess the degree to which participants are utilizing PDMPs; and (2) expanding the types of drugs to which the Query of PDMP measure could apply." <sup>170</sup> For the second point, CMS is "considering proposing in future rulemaking to expand the Query of PDMP measure to include all Schedule II drugs, rather than only including Schedule II opioids." <sup>171</sup>

<sup>&</sup>lt;sup>165</sup> Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 32352, 32725. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-2926">https://www.federalregister.gov/d/2025-13271/p-2926</a>.

<sup>&</sup>lt;sup>167</sup> *Id.* at 32747. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-3056">https://www.federalregister.gov/d/2025-13271/p-3056</a>.

 $<sup>{}^{168}\</sup>textit{Id.} \textit{ at 32749}. \textit{ Available at: } \underline{\textit{https://www.federalregister.gov/d/2025-13271/p-3070}}.$ 

<sup>&</sup>lt;sup>169</sup> *Id*.

<sup>&</sup>lt;sup>170</sup> *Id.* Available at: https://www.federalregister.gov/d/2025-13271/p-3071.

<sup>&</sup>lt;sup>171</sup> *Id.* at 32751. Available at: <a href="https://www.federalregister.gov/d/2025-13271/p-3101">https://www.federalregister.gov/d/2025-13271/p-3101</a>.

Regarding the change of the query of the PDMP measure from an attestation-based measure to a performance-based measure, APhA appreciates CMS's efforts to promote patient safety and the appropriate prescribing of controlled substances. Accordingly, APhA encourages CMS not to create additional administrative burdens or implement changes that significantly hinder pharmacy operations when changing the query of the PDMP measure. With respect to including all Schedule II drugs in the query of the PDMP measure, APhA has heard concerns regarding the lack of methadone reporting to the PDMP. APhA acknowledges the stigma that can be associated with using methadone for treatment of opioid use disorder and recognizes the importance of protecting the confidentiality of patients in substance use disorder treatment programs as required by federal law. APhA member pharmacists in the inpatient setting are having difficulty confirming if a patient is taking methadone before their admission, and the dose if they are taking methadone when the patient is unable to report their current medications or the methadone clinic is closed. One pharmacist reported that methadone clinics are often inaccessible in the evenings and on the weekends, thus there is frequently a gap in treatment, and the patient may experience increased agitation secondary to withdrawal. These gaps are often seen when a patient comes to the hospital on a Friday evening or after a traumatic event, where the patient is intubated or non-responsive, and there is no indication of methadone use from the patient's medical history.