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Sept. 12, 2025

The Honorable Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1832-P
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: 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 [CMS-1832-P]

Administrator Oz,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to CMS on its proposed rule *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* (CY 2026 PFS proposed rule).

NCPA represents America's community pharmacists, including 18,900 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members employ 205,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

Medicare Diabetes Prevention Program (MDPP)

In this proposed rule, CMS is proposing several changes which are aimed towards increasing the uptake of this important prevention-focused program while empowering beneficiaries and promoting further alignment between MDPP and the CDC Diabetes Prevention Recognition Program (DPRP) Standards. Specifically, CMS is proposing changes to 42 CFR 410.79(b) to add definitions for the following terms: Live Coach interaction, Online delivery period, and Online session while modifying the definition of ''Online.'' CMS is also proposing amending § 410.79(c)(1)(ii) and (e)(3)(iii)(C) to address operational questions and barriers related to weight collection requirements. CMS also proposes to extend flexibilities allowed during the PHE for COVID–19 through December 31, 2029 by modifying the definition of extended flexibilities period

in § 410.79(b). Finally, CMS is proposing to test the inclusion of an asynchronous delivery modality by modifying § 410.79, by revising paragraph (b), adding paragraph (f), and amending § 424.205(c)(10), (f)(2)(i), and (f)(5), which will allow MDPP suppliers to deliver the Set of MDPP services Online through December 31, 2029, clarify that MDPP suppliers are not required to maintain in-person delivery capability through December 31, 2029, and introduce a new G-code and payment for Online sessions. CMS states that these changes are expected to expand beneficiary access to MDPP, reduce barriers to participation, improve MDPP session attendance and retention, and promote safety.

NCPA supports the expansion of the Medicare Diabetes Prevention Program (MDPP) to serve more beneficiaries. However, to fully utilize the MDPP and its potential, CMS must fully leverage pharmacies and pharmacists as critical access points for diabetes prevention. Pharmacies are critical stakeholders in managing and preventing chronic conditions, including diabetes, and in particular in underserved and rural communities, and forty-two percent of community pharmacists provide diabetes training.[1]

Specifically, NCPA advises that CMS should:

- **Explore regulatory and programmatic changes that would allow pharmacists and pharmacies to more easily participate in the MDPP and offer broader access to Medicare beneficiaries;**
- **Incentivize broader participation of pharmacists and pharmacies by reducing administrative barriers and creating clear pathways for billing; and**
- **As part of MDPP participation, allow suppliers and pharmacies to bill for necessary diabetes testing required by the program (i.e., hemoglobin A1C testing).**

<u>Services and Supplies Incident to a Physician's Professional Services (§ 410.26)</u>

In the CY 2025 PFS final rule (89 FR 97763), CMS 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).

In response to overwhelming support and requests to extend this policy permanently for a wider set of services than the ones that were finalized in the CY 2025 PFS Final Rule, CMS is 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). CMS is proposing to

[1] 2024 NCPA Digest, page 15.

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. **NCPA supports this proposal.**

NCPA also strongly encourages CMS to expand virtual supervision for all pharmacist-provided incident to services to the list of eligible codes and revise the definition under § 410.32(b)(3)(ii) for "direct supervision" of clinical staff, including pharmacists currently classified as auxiliary personnel. Throughout the pandemic, pharmacists worked under direct supervision using real-time audio/video technology to deliver a variety of patient care services, including chronic disease management, medication management services, and Annual Wellness visits.

NCPA strongly urges CMS to use its full regulatory authority to permit physicians or nonphysician 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.

Remote Physiologic Monitoring (RPM) and Remote Therapeutic Monitoring (RTM)

CMS has proposed new RPM and RTM codes allowing reimbursement for fewer than 16 days of data transmission per month and fewer than 20 minutes of monthly treatment management services. Previously, CMS has required 16 days of data transmission in a 30-day period to bill the RPM and RTM device supply codes (99454 and 98976–98978).

CMS is now proposing to adopt the following codes:

Remote Physiologic Monitoring (RPM)

Device Supply Code for <16 Days of Monitoring

- **CPT 99XX4** – *Remote physiologic monitoring treatment management services, device(s) supply with daily recording(s) and/or programmed alert(s) transmission to monitor one or more physiologic parameters (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), for fewer than 16 days (minimum of 2 days) in a 30-day period; each 30-day period*

Treatment Management Code

- **CPT 99XX5** – *Remote physiologic monitoring treatment management services, 10–19 minutes of clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month*

Remote Therapeutic Monitoring (RTM)

Device Supply Codes for <16 Days of Monitoring

- **CPT 98XX4** – *Remote therapeutic monitoring treatment management services, device(s) supply with daily recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system status, for fewer than 16 days (minimum of 2 days) in a 30-day period; each 30-day period*
- **CPT 98XX5** – *Remote therapeutic monitoring treatment management services, device(s) supply with daily recording(s) and/or programmed alert(s) transmission to monitor respiratory system status, for fewer than 16 days (minimum of 2 days) in a 30-day period; each 30-day period*

Treatment Management Code

- **CPT 98XX7** – *Remote therapeutic monitoring treatment management services, 10–19 minutes of clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month*

CMS provided the following chart in the physician fee schedule:

TABLE 18: PROPOSED CY 2026 REMOTE MONITORING CODES

Code	Long Descriptor
99453	No changes for CY 2026
99XX4	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial: device(s) supply with daily recording(s) or programmed alert(s) transmission, 2-15 days in a 30-day period
99454	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, 16-30 days in a 30-day period
99091	No changes for CY 2026
99XX5	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring 1 real-time interactive communication with the patient/caregiver during the calendar month; first 10 minutes
99457	No changes for CY 2026
99473	No changes for CY 2026
99474	No changes for CY 2026
99458	No changes for CY 2026
98975	No changes for CY 2026
98XX4	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, 2-15 days in a 30-day period
98976	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, 16-30 days in a 30-day period
98XX5	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 2-15 days in a 30-day period
98977	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 16-30 days in a 30-day period
98XX6	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, 2-15 days in a 30-day period
98978	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, 16-30 days in a 30-day period
98XX7	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least 1 real-time interactive communication with the patient or caregiver during the calendar month; first 10 minutes
98980	No changes for CY 2026
98981	No changes for CY 2026

NCPA is supportive of these proposed changes, and also supports greater participation of pharmacists in participating and being reimbursed for remote monitoring.

Prevention and Management of Chronic Disease — Request for Information (RFI)

Pharmacists are uniquely positioned to prevent and manage chronic disease. Today, many pharmacies offer screenings for elevated glucose levels, blood pressure, and cholesterol to help

identify people who are at-risk of common chronic diseases, and help link them to follow up care as needed. Pharmacists can help better identify at-risk people and support linkage to primary care to help prevent and manage early stages of chronic diseases. This helps reverse harms before late stages of disease require more expensive, potentially life-long treatments. Pharmacists also provide chronic disease management programs that help manage and treat people who have already been diagnosed with chronic diseases.

Request for Information (RFI) Questions

How could we better support prevention and management, including self-management, of chronic disease?

Pharmacies offer a powerful solution to prevent and manage chronic disease. Ninety-four percent of independent community pharmacies offering med sync services report synchronizing all chronic medications to a single monthly pick-up date, and 63 percent report that a pharmacist meets with a patient as needed to review medication use.[2] **To meaningfully combat chronic diseases, CMS should examine ways that pharmacists can be reimbursed for providing screenings, disease state education and counseling, nutrition information, lifestyle recommendations, and expert medication advice.**

Are there technical solutions that would enhance the uptake of the annual wellness visit (AWV), or the improving accessibility, impact, and usefulness of the AWV? How can CMS better support practitioners and beneficiaries related to the AWV?

Published literature indicates that Annual Wellness Visits performed by pharmacists are comparable to those performed by physicians,[3, 4] with high patient satisfaction and patient comfortability receiving this service from pharmacists. However, instances of pharmacists performing Annual Wellness Visits remain limited because of requirements and restrictions, such as the requirement for initiating visits and billing challenges. Additionally, published examples highlight challenges pharmacies encounter in working with medical offices to develop collaborative relationships to advance access to AWVs.[5] **To promote access and uptake, ultimately to garner better health outcomes and value in Medicare, CMS should pursue policy changes that remove requirements for initiating visits and promote direct billing opportunities for pharmacists to perform AWVs.**

[2] NCPA 2024 Digest, page 13.

[3] Sewell MJ, Riche DM, Fleming JW, Malinowski SS, Jackson RT. Comparison of Pharmacist and Physician Managed Annual Medicare Wellness Services. J Manag Care Spec Pharm. 2016;22(12):1412-1416. doi:10.18553/jmcp.2016.22.12.1412

[4] Sherrill CH, Cavanaugh J, Shilliday BB. Patient Satisfaction with Medicare Annual Wellness Visits Administered by a Clinical Pharmacist Practitioner. J Manag Care Spec Pharm. 2017;23(11):1125-1129. doi:10.18553/jmcp.2017.23.11.1125

[5] Taylor A. et al. Community pharmacist–delivered Medicare Annual Wellness Visits within a family medicine practice Evans. Journal of the American Pharmacists Association, Volume 57, Issue 3, S247 - S251. 10.1016/j.japh.2017.02.015

Claims-Based Methodology to Remove 340B Units from Rebate Calculations

NCPA has concerns with CMS' proposal to remove 340B claims from the Medicare Drug Inflation Rebate Program using National Provider Identifiers (NPIs) for prescribers and contract pharmacies, as this will likely result in significant confusion and mistaken identification of claims. Prescribers may be associated with a number of facilities, making it difficult to determine with any specificity that a claim is 340B-eligible even when cross-walking between a prescriber's NPI and the Medicare claims data. Similarly, contract pharmacies handle non-340B claims just as prescribers can practice in both 340B and non-340B facilities. Further, as CMS acknowledges, not all contract pharmacies are correctly identified in the Office of Pharmacy Affairs Information Service (OPAIS), which further undermines CMS' proposed methodology.

NCPA also asks CMS if it has tested the above methodology and validated it, i.e., has CMS looked to see how accurate this methodology is by looking at a sample of claims? If not, NCPA asks that CMS do this before making the methodology final. And if CMS finalizes it, CMS should also conduct an ongoing assessment of its accuracy.

NCPA would support the above methodology so long as additional administrative burden is not placed on contract pharmacies. NCPA also advises that CMS should use appropriate data sources.

Proposal To Establish a Medicare Part D Claims Data 340B Repository

CMS proposes to establish a repository to receive voluntary submissions from covered entities of certain data elements from Part D 340B claims to allow CMS to assess such data for use in identifying units of Part D rebatable drugs for which a manufacturer provides a discount under the 340B Program in a future applicable period. CMS intends to allow covered entities to submit data on units of Part D rebatable drugs for which a manufacturer provides a discount under the 340B Program beginning in 2026 to begin testing the usability of the 340B repository. CMS proposes that the 340B repository would receive, via submission by covered entities that choose to submit data 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 (''Part D 340B claims'') for all covered Part D drugs billed to Medicare Part D. 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. CMS would consider all data elements received by the 340B repository to be associated with Part D 340B claims; that is, the 340B repository would not further verify the 340B status of a claim but rather would serve solely to store these data. **NCPA supports this proposal, but seeks clarity from CMS on certain concerns as stated below.**

NCPA requests clarity from CMS as to its deadline on when the repository will be live, and if there will be any testing of the repository. NCPA also asks CMS if this repository will merge with the Medicare Transaction Facilitator (MTF-DM) of the Medicare Drug Price Negotiation. NCPA seeks clarification from CMS that pharmacies are not required to actively provide any information directly to this repository, and that it is only the covered entities that are voluntarily providing this information.

Additionally, NCPA advises that CMS should make it clear that PBMs and health plans will not receive 340B related information on claims as part of this repository. NCPA is concerned that PBMs and health plans would use this information to discriminate through payments or contracting with pharmacies based on 340B utilization.

NCPA supports CMS not requiring pharmacies to identify 340B claims, and re-emphasizes the infeasibility of pharmacies identifying those claims either proactively or retroactively. NCPA has found that the N1 transaction is not feasible as it is not adopted by pharmacy information systems. For details of NCPA's position, see our July 2024 comments to CMS' *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027*, as well as our March 2023 comments to CMS' *Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D-14B of Social Security Act, and Solicitation of Comments*.

Regarding the 340B proposals in the proposed rule, NCPA:

- **Appreciates that CMS is not asking pharmacies to be directly involved in identifying 340B claims either directly or indirectly in the data matching process or the repository process;**
- **Believes the data matching should be tested, and that CMS should report on its accuracy in identifying 340B claims both before implementation and on an ongoing basis;**
- **Believes the data matching and repository data should not be shared with Part D plans or PBMs; and**
- **Believes the repository could be integrated with the MTF-DM such that it helps identify 340B claims and prevents duplication of 340B and MFP, as this would be a much simpler and more efficient process than what has been established for deduplication through the MTF.**

Conclusion

NCPA appreciates the opportunity to share with CMS our comments and suggestions on the CY 2026 PFS proposed rule. Please let us know how we can assist further, and should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

Steve Postal, JD
Senior Director, Policy & Regulatory Affairs
National Community Pharmacists Association