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Sept. 9, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1807-P
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments [CMS–1807–P]

Administrator Chiquita Brooks-LaSure,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to CMS on its proposed rule *Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments* (CY 2025 PFS proposed rule).

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care (LTC) services and play a critical role in ensuring patients have immediate access to medications in both community and LTC settings. Together, our members represent a $94 billion health care marketplace, employ 230,000 individuals, and provide an expanding set of health care services to millions of patients every day. Our members are small business owners who are among America's most accessible health care providers. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

Services and Supplies Incident to a Physician's Professional Services (§ 410.26)

CMS is proposing to revise 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 office and other outpatient visits for the evaluation and management

of an established patient that may not require the presence of a physician or other qualified health care professional. **NCPA supports this proposal.**

Medicare Coverage And Payment Of Opioid Use Disorder Treatment Services Furnished By Opioid Treatment Programs (§ 410.67)

CMS proposes new flexibilities for OTPs, including permanently allowing audio-only periodic assessments and allowing the OTP intake add-on code to be furnished via two-way audio-video communications technology when billed for the initiation of treatment with methadone when clinically appropriate. Additionally, CMS proposes an increase in payment for OTPs, as well as add-on codes for new Food and Drug Administration-approved opioid agonist and antagonist medications. **Many pharmacists treat patients with OUD at OTPs. NCPA believes pharmacists can help meet treatment demands but their ability to do so is dependent, in part, on coverage frameworks that encourage better use of pharmacists. CMS should acknowledge and reimburse pharmacist-provided patient care services that can be provided through OTP programs. NCPA supports CMS' proposed increased telehealth flexibilities and payments for opioid treatment programs (OTPs), recommends CMS reimburse pharmacist-provided opioid use disorder (OUD) services at OTPs, and encourages CMS to implement policy changes that leverage pharmacists to deliver clinical care services for patients with opioid use disorder (OUD).**

340B Provisions Under § 428.203(b)(2)

CMS proposes that under § 428.203(b)(2), for claims with dates of service on or after January 1, 2026, and with respect to an applicable period, CMS would exclude from the total number of units used to calculate the total rebate amount for a Part D rebatable drug those units of the Part D rebatable drug for which a manufacturer provided a discount under the 340B Program. To determine the total number of such units for which a manufacturer provided a discount under the 340B Program, CMS would use data reflecting the total number of units of a Part D rebatable drug for which a discount was provided under the 340B Program and that were dispensed during the applicable period. CMS may apply adjustment(s) to these data as needed. CMS is also soliciting comments on alternative policies for collecting and using 340B data to calculate rebate amounts for Part D rebatable drugs.

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*.

Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

CMS is proposing that prescriptions written for a beneficiary in a LTC facility would not be included in determining compliance under the CMS EPCS Program until January 1, 2028, and that compliance actions against prescribers who do not meet the compliance threshold based on prescriptions written for a beneficiary in a LTC facility would commence on or after January 1, 2028. CMS estimates that without this provision, that if it keeps the existing date of January 1, 2025, as in the current regulatory text at § 423.160(a)(5) for the CMS EPCS Program, CMS estimates at least 6,800 prescribers would become non-compliant due to CMS including prescriptions written for beneficiaries in LTC in the CMS EPCS Program compliance threshold calculation. This estimate is based on data from calendar year 2022 and is prior to considering emergency and disaster exceptions and waivers, which could reduce these numbers. This proposal, should CMS finalize it, would allow prescribers additional time to adopt the new e-prescribing standard, NCPDP SCRIPT standard version 2023011, and utilize EPCS. Additionally, this proposal would prevent an increased number of prescribers from potentially applying for a waiver for circumstances beyond their control due to difficulty of reliably conducting EPCS for beneficiaries in LTC facilities by the current deadline of January 1, 2025. **NCPA supports this policy.**

Other Services Proposed for Addition to the Medicare Telehealth Services List: Preexposure Prophylaxis (PrEP) of Human Immunodeficiency Virus (HIV)

CMS is proposing national rates for HCPCS codes G0011 (Individual counseling for pre-exposure prophylaxis (PrEP) by physician or QHP to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence, 15–30 minutes) and G0013 (Individual counseling for pre-exposure prophylaxis (PrEP) by clinical staff to prevent human immunodeficiency virus (HIV), includes: HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence) pending the future finalization of the NCD for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection. CMS has asked for interested parties to provide feedback on the most accurate way to value these services.

CMS' proposals fail to recognize the independent authority of pharmacists across at least 30 states to initiate PrEP and/or administer injectable medications at convenient and accessible community pharmacy locations. Pharmacies are valuable partners in HHS' ongoing initiative to end the HIV epidemic, and public-private partnerships across the healthcare continuum will be fundamental to effectively scaling up HIV prevention and treatment strategies. NCPA urges CMS to partner with pharmacies to leverage their unique accessibility, clinical expertise, and destigmatizing environment to collaboratively reach the nation's goal to reduce new HIV infections by 90% by 2030. **NCPA advocates that CMS ensure that it maximizes access, affordability, and effective and efficient delivery of HIV PrEP services. To that end, NCPA advocates that CMS:**

- **Clarify that the new G0013 code for counseling for HIV pre-exposure prophylaxis (PrEP) applies to clinical staff, including pharmacists. Additionally, NCPA urges CMS use CPT**

code 99213 to crosswalk the relative value units (RVU) for G0013 to more accurately account for the time and complexity of the service provided.

- **Expand equitable access to PrEP services for all patients, regardless of geographic location or socioeconomic status is needed. CMS should ensure that pharmacies across the country can participate in PrEP delivery without undue administrative burdens so that pharmacies can reach communities who need it most.**
- **Streamline billing processes to enable pharmacists to bill for PrEP services under their own National Provider Identifier (NPI). Simplifying this process would help improve access by reducing delays and enhancing the efficiency of service delivery.**
    - **Note: Currently, CMS requires the pharmacy to include the name and NPI of the ordering/referring provider on the claim when billing Medicare Part B.**
- **Ensure fair reimbursement rates to enable pharmacists to continue providing or expand essential HIV prevention services. Fair compensation helps maintain the sustainability of life-saving HIV prevention services.**
    - **This includes sufficient reimbursement (appropriate and commiserate with other health professionals) for both the drugs and the service of dispensing/supplying those drugs, whether oral or injectable.**
- **Allow pharmacists to perform a broader range of services related to PrEP, such as HIV testing, assessment, and counseling, without undue restrictions, to expand equitable access. CMS should enable pharmacists to provide these services to enhance patient access to comprehensive, convenient, and potentially less stigmatizing HIV prevention services.**
    - **A more integrated approach that includes preventive services, as well as drug administration, aligns with CMS's broader goals for value-based care and reducing care fragmentation.**
- **Simplify codes for PrEP drugs and supply fees. Simplifying billing procedures with PrEP specific codes will reduce administrative burdens and ensure patients receive timely access to PrEP services. CMS's proposed rule outlines specific codes for PrEP drugs and supply fees. It is crucial that these processes are straightforward and easy to navigate for pharmacies of all sizes.**

Proposal To Permanently Define ''Direct Supervision'' To Include Audio-Video Communications Technology for a Subset of Services

CMS is proposing to make permanent virtual supervision for "immediate availability," for the lowest level E/M visit (99211) but would discontinue virtual supervision for other codes, absent congressional action, after December 31, 2025. Although NCPA is pleased with CMS' progress in making virtual supervision of low-level codes, such as 99211, permanent (see, the 117th Congress report language above regarding incident to services), **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.

Vaccine Administration

CMS states in Tables 45 and 46 that the preventive vaccine administration payment for the COVID-19 vaccine under an emergency use authorization (EUA) would remain at $44.99 with a Medicare Economic Index (MEI) adjustment for inflation. However, for COVID-19 vaccines no longer under an EUA vaccine administration is being proposed at $33.74 plus MEI.

TABLE 45: CY 2025 Part B Payments for Preventive Vaccine Administration if the EUA Declaration for Drugs and Biologicals with Respect to COVID-19 Continues into CY 2025

Category of Part B Product Administration	Part B Payment Amount (Unadjusted)	Annual Update[6]	Geographic Adjustment
Influenza, Pneumococcal, Hepatitis B Vaccines[1,4]	$33.74	MEI	GAF
COVID-19 Vaccine[2,4]	$44.99	MEI	GAF
In-Home Additional Payment for Part B Vaccine Administration (M0201)[4]	$39.94	MEI	GAF
COVID-19 Monoclonal Antibodies (for Treatment or Post-Exposure Prophylaxis)[3,4,5]	N/A	N/A	N/A
COVID-19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis)[3,4]			
Intravenous Infusion: Health Care Setting	$450	N/A	GAF

[1] HCPCS Codes G0008, G0009, G0010.
[2] CPT code 90480.
[3] *https://www.cms.gov/monoclonal.*
[4] Beneficiary coinsurance and deductible are not applicable.
[5] As of the issuance of the CY 2025 PFS proposed rule, there are no monoclonal antibodies approved or authorized for the treatment or for post-exposure prophylaxis of COVID-19
[6] The proposed CY 2025 percentage increase of the 2017-based MEI is 3.6 percent based on IGI's first quarter of 2024 forecast with historical data through the 4th quarter of 2023.

TABLE 46: Part B Payments for Preventive Vaccine Administration Beginning January 1, 2025, if the EUA Declaration for Drugs and Biologicals with Respect to COVID 19 is Terminated on or Before December 31, 2024

Category of Part B Product Administration	Part B Payment Amount (Unadjusted)	Annual Update[6]	Geographic Adjustment
Influenza, Pneumococcal, Hepatitis B[1,4]	$33.74	MEI	GAF
COVID-19[2,4]	$33.74	MEI	GAF
In-Home Additional Payment for Part B Vaccine Administration (M0201)[4]	$39.94	MEI	GAF
COVID-19 Monoclonal Antibodies (for Treatment or Post-Exposure Prophylaxis)[3]	Medicare payment under the applicable payment system		
COVID-19 Monoclonal Antibodies (for Pre-Exposure Prophylaxis)[4,5]	TBD[5]	N/A	GAF

[1] HCPCS Codes G0008, G0009, G0010.
[2] CPT code 90480
[3] Payment is in accordance with the applicable payment system of the setting in which the product is administered. Beneficiary coinsurance and deductible are applicable.
[4] Beneficiary coinsurance and deductible are not applicable.
[5] Please see section III.H.1.e. of this proposed rule.
[6] The proposed CY 2025 percentage increase of the 2017-based MEI is 3.6 percent, based on IGI's first quarter of 2024 forecast with historical data through the 4th quarter of 2023.

NCPA urges CMS to continue the existing reimbursement level for the commercial versions of COVID-19 vaccinations through respiratory disease season. NCPA also urges CMS to address Part D plans' utilization management of vaccines by pharmacy benefit managers (PBMs) and establish a new add-on CPT code for the administration of combination vaccines that includes payment for patient counseling by pharmacists and other immunizers.

<u>In-Home Additional Payment For Part B Vaccine Administration</u>

Additionally, as Table 45 and 46 indicate, the current payment rate for in-home administration of preventive vaccines under M0201 is $39.94 and will be adjusted by MEI. **NCPA continues to urge CMS to build off the success of the vaccine administration for in-home COVID-19 vaccination to all ACIP-recommended vaccines.**

Conclusion

NCPA appreciates the opportunity to share with CMS our comments and suggestions on the CY 2025 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
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National Community Pharmacists Association