



December 2, 2024

*[Transmitted Electronically by E-Mail]*

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services (CMS)  
U.S. Department of Health & Human Services (HHS)  
Hubert H. Humphrey Building, Room 445-G 200  
Independence Avenue, SQW  
Washington, DC 20201

**Subject: Concerning Medicare Part B Denials of Pharmacist-Prescribed HIV PrEP Items and Services**

Dear Administrator Brooks-LaSure:

On behalf of the American Pharmacists Association (“APhA”), we write to express our concern over CMS’s proposed administration of the Final National Coverage Determination for Pre-Exposure Prophylaxis (“PrEP”) for Human Immunodeficiency Virus (“HIV”) Prevention (NCD 210.15) (the “NCD”), which became effective September 30, 2024. Specifically, we are alarmed that CMS has indicated in informal guidance concerning the NCD that Medicare-enrolled pharmacies are unable to bill for HIV PrEP items or services that have been prescribed by pharmacists despite that pharmacists are legally authorized by states to prescribe these items. We are concerned about the impact of this policy on patients who rely on pharmacists to prescribe HIV PrEP particularly given the goal of the NCD to broaden access to and coverage of these critical drugs and services and the important role pharmacists play in that effort in areas where prescribers and/or access to primary care services are limited.

Not only does this policy infringe on state authority to define and regulate the practice of pharmacy and medicine, but no statute or regulation requires ordering providers of “additional preventive services” such as HIV PrEP to be enrolled in Medicare, and CMS has not engaged in the requisite notice-and comment rulemaking process to implement such a requirement. Further, such a requirement would amount to arbitrary and capricious action on the part of CMS as prescriber enrollment is not always required in other similar situations, particularly in the case of drugs used for HIV PrEP that were previously billed under Medicare Part D.

***There is no legal basis to exclude pharmacists as prescribing practitioners of HIV PrEP eligible to bill Medicare Part B.***

The NCD itself does not address pharmacists' ability to prescribe or order HIV PrEP items and services billed to Medicare Part B. However, as we raised in our September 25, 2024 [letter](#) to you, CMS has provided informal guidance on this issue, stating in [technical guidance](#) to pharmacies and on a HIV PrEP office hours [webinar](#) that pharmacists are ineligible to bill Medicare Part B directly for HIV PrEP items and services, and that Medicare-enrolled pharmacies are unable to bill for PrEP items or services that were prescribed by pharmacists. CMS stated that it will require prescribers of HIV PrEP to enroll in Medicare Part B and that pharmacists are not among the practitioners permitted to enroll as an ordering/referring provider.

There is no legal basis to exclude pharmacists as prescribing practitioners for HIV PrEP items and services. CMS's position seems to be grounded in confusion about authorization to bill for those services, on the one hand, and authorization to prescribe those services, on the other hand. CMS's stated rationale for not permitting pharmacists to order HIV PrEP items and services billed to Medicare Part B is that pharmacists are not included in the definition of "eligible professional" under Section 1848(k)(3)(B) of the Social Security Act. That term is defined by statute as: "(i) A physician, (ii) A practitioner described in section 1842(b)(18)(C), (iii) A physical or occupational therapist or a qualified speech-language pathologist, and (iv) Beginning with 2009, a qualified audiologist." Section 1842(b)(18)(C), in turn, describes "practitioners" as "(i) A physician assistant, nurse practitioner, or clinical nurse specialist, (ii) A certified registered nurse anesthetist, (iii) A certified nurse-midwife, (iv) A clinical social worker, (v) A clinical psychologist, (vi) A registered dietitian or nutrition professional, (vii) A marriage and family therapist, and (viii) A mental health counselor."

In the case of HIV PrEP items and services, the pharmacy would be the enrolled supplier billing to Part B, and the pharmacist would serve as the ordering/referring/prescribing practitioner. Section 6405(a) and (b) of the Affordable Care Act requires ordering practitioners to be enrolled in Medicare for purposes of ordering Durable Medical Equipment, Prosthetics/Orthotics & Supplies (DMEPOS) items, and home health services. Section 6405(c) of the Affordable Care Act also gives CMS discretion to extend the enrollment requirement to all other categories of items or services covered by Part B. Relying on this authority, CMS adopted regulations in 2012 requiring practitioners who order imaging, laboratory testing, and specialist services to also be "eligible professionals" enrolled in Medicare. In other words, under Section 6405 of the Affordable Care Act and 42 CFR § 424.507(a), pharmacists, who are not "eligible professionals" under Section 1848(k)(3)(B) of the Social Security Act, are not permitted to order or refer items or services in the following Medicare benefit categories: DMEPOS items, home health services, and imaging, laboratory testing and specialist services.

HIV PrEP items and services, however, fall into a different Medicare benefit category of "additional preventive services" in accordance with the NCD. Although Section 6405(c) of the

Affordable Care Act authorized CMS to extend the provider enrollment requirement to orders or referrals of items and services under any Medicare benefit category, including “additional preventive services,” CMS chose to extend the enrollment requirement only to imaging, laboratory testing and specialist services via the formal rulemaking process (in addition to statutory enrollment requirement for DMEPOS items and home health services).

*CMS has not engaged in the requisite rulemaking process to implement a requirement that prescribers of HIV PrEP enroll in Medicare.*

In order for CMS to extend the enrollment requirement to other benefit categories, CMS must follow various procedural requirements. The Medicare Act requires CMS to “provide for notice of [a] proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.” 42 U.S.C. § 1395hh(b)(1). Moreover, the Medicare Act provides that CMS must undertake notice-and-comment rulemaking before issuing any “rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under” Medicare. *Id.* at § 1395hh(a)(2). More generally, the Administrative Procedure Act also requires an agency involved in informal rulemaking to give the public notice and an opportunity to comment on the proposed rulemaking. 5 U.S.C. § 553.

A CMS policy imposing Medicare enrollment requirements for prescribers of “additional preventive services” such as HIV PrEP establishes a legal standard regarding payment for services and the eligibility of individuals to furnish or order those services, and is therefore subject to notice-and-comment rulemaking, which CMS has not undertaken. The U.S. Supreme Court has held that an informal Medicare payment policy posted on CMS’s website must be vacated because it established a substantive legal standard regarding payment and had not gone through the requisite notice-and-comment rulemaking process required by the Medicare Act. *Azar v. Allina Health Services*, 587 US 566 (2019). Further, although there is an exception to the Medicare Act’s notice-and-comment rulemaking requirement for national coverage determinations, CMS stated explicitly in the final decision memo for the NCD (the “NCD Memo”) that the issue of covering pharmacist services related to HIV PrEP is outside the scope of the NCD. Centers for Medicare & Medicaid Services, “Final National Coverage Determination for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention,” (Administrative File CAG-00464N) (September 30, 2024).

In other words, there is no basis under Section 6405 of the Affordable Care Act, CMS regulations, or the NCD Memo to restrict orders and referrals of “additional preventive services,” such as HIV PrEP, to only “eligible professionals” enrolled in Medicare, and CMS has not undertaken the

requisite rulemaking process to impose such a requirement. As such, CMS denials of payment for HIV PrEP items and services ordered by pharmacists, as non-enrolled practitioners, are not supported by law. Additionally, CMS's denial of coverage based on restrictions on who may prescribe HIV PrEP items and services billed to Part B is tantamount to a violation of the NCD, which imposes no such restrictions.

***CMS's determination that only enrolled providers may order HIV PrEP items and services billed to Medicare Part B is arbitrary and capricious.***

Further, CMS's adoption of a policy that pharmacists may not order HIV PrEP items and services that are reimbursable by Medicare Part B is arbitrary and capricious. Prior to publishing the final NCD Memo on September 30, 2024, CMS published a proposed NCD decision memo on July 12, 2023 and offered the opportunity for public comments. Numerous commenters to the proposed memo, including APhA, raised concerns that CMS's failure to recognize pharmacists as ordering practitioners of HIV PrEP items and services would limit access to this important care and would prevent the improvement of long-standing health inequities. In the final NCD Memo, CMS responded to these comments in part, stating that pharmacists are not eligible to be paid directly for furnished services. But CMS did not address its position, as described in prior informal CMS guidance, that pharmacists may also not *order* HIV PrEP items or services billed to Medicare, other than to say that such considerations are outside the scope of the analysis. CMS did not consider the impact that its position would have on beneficiaries that rely on pharmacists to prescribe HIV PrEP services, nor did it consider whether there was any valid rationale for its position. Courts have held that addressing comments to rulemaking in "only a conclusory manner" is fatal to agency action, and is a hallmark of agency action that is arbitrary and capricious. *See, e.g., Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29 at 41, 43 (1983); *see also Ass'n of Priv. Sector Colls. v. Duncan*, 681 F.3d 427 at 449 (D.D.C. 2013). Further, it is the right of the State, not CMS or any other federal agency, to determine the practice scope and authority of pharmacists and other healthcare practitioners. CMS's determination to reject claims of HIV PrEP prescribed by pharmacists is an insertion of the federal government into a matter protected by and belonging to the state governments.

***CMS's determination that only enrolled providers may order HIV PrEP item and services billed to Medicare Part B is arbitrary and capricious because CMS offers insufficient reasons for its position when enrollment is not always required in other similar situations.***

In addition, CMS has offered insufficient reasons for requiring ordering practitioners of HIV PrEP items and services to be enrolled in Medicare, when enrollment is not always required in similar situations. For example, CMS has the authority under Section 6405(c) of the Affordable Care Act

to require ordering/prescribing practitioners of Medicare Part D covered drugs to be enrolled in Medicare. Although CMS originally imposed this enrollment requirement in 2014, it published an interim rule in 2015 expanding coverage to Part D drugs ordered by “other authorized prescribers,” in addition to enrolled physicians and “eligible professionals,” out of concern that “beneficiaries who have been receiving necessary prescriptions from prescribers who are not Medicare-enrolled or opted-out physicians or eligible professionals will no longer be able to obtain Part D coverage for these prescriptions,” and that these changes were “necessary to preserve beneficiaries’ ability to obtain prescriptions for covered Part D drugs prescribed by certain practitioners ineligible to enroll in Medicare.” 80 FR 25958, 25960 (May 6, 2015). In 2018, CMS did away with the enrollment requirement altogether in order to “reduc[e] the burden of the Part D enrollment requirement on prescribers, Part D plan sponsors, and beneficiaries,” and instead established a preclusion list whereby prescribers who are deemed to pose an elevated risk to beneficiaries and the Medicare program are not permitted to order Part D drugs. 83 FR 16440, 16641 (April 16, 2018); 42 CFR § 423.120(c)(6).

CMS’s recognition of the burden of the enrollment requirement with respect to Part D covered drugs stands in sharp contrast to its failure to address the same issue with respect to Part B covered HIV PrEP items and services. Despite concerns raised by commenters to the proposed NCD, CMS has not considered beneficiaries’ ability to obtain prescriptions from practitioners ineligible to enroll in Medicare, a particularly egregious incongruity given the at-risk nature of the beneficiary population in the case of HIV PrEP items and services. Moreover, the anti-retroviral therapy (“ART”) drugs that are a key component of HIV PrEP covered under Part B are also used to treat active HIV infections and are covered under Part D in that context. Not only does CMS have incongruous policies regarding practitioner enrollment for Part B versus Part D generally, it also applies this disparate policy to the exact same drugs billed under those programs: for Medicare Part D claims for ART drugs, CMS does not require prescribers to be enrolled, however, CMS asserts that providers must be enrolled for ART drug claims submitted to Part B. CMS has not acknowledged or explained the difference in approach between Part D- and Part B-covered ART drugs. CMS’s refusal to allow pharmacists to order Part B covered HIV PrEP items and services when it allows pharmacist ordering of drugs covered under Part D is therefore arbitrary and capricious.

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We believe CMS’s position to require prescribers of HIV PrEP items and services to be enrolled in Medicare is an oversight and a misinterpretation of Medicare enrollment policies. Nevertheless, we urge CMS to take prompt action to clarify this mistake with stakeholders and to ensure that Part B claims for these items and services will not be denied if they have been prescribed by non-enrolled practitioners such as pharmacists. APhA stands ready to assist you in



protecting and expanding Medicare patients' access to pharmacist-prescribed HIV PrEP. If you have any questions or would like to speak further about this request, please contact Michael Baxter at [mbaxter@aphanet.org](mailto:mbaxter@aphanet.org).

Sincerely,

A handwritten signature in black ink, which appears to read 'Michael D. Hogue', is positioned below the 'Sincerely,' text.

Michael D. Hogue, PharmD, FAPhA, FNAP, FFIP  
Executive Vice President and Chief Executive Officer  
American Pharmacists Association

cc:

The Honorable Xavier Becerra, Secretary, HHS  
Rachel Pryor, Counselor to the Secretary, HHS  
Neera Tanden, Director, White House Domestic Policy Council  
Erin Richardson, Chief of Staff, CMS  
Will Harris, Senior Advisor, Office of the Administrator, CMS  
Jonathan Blum, Principal Deputy Administrator and Chief Operating Officer, CMS  
Dora Hughes, MD, Acting Chief Medical Officer and Acting Director, Center for Clinical Standards and Quality, CMS  
Joseph Chin, MD, Medical Officer for Coverage and Analysis and Director, Coverage and Analysis Group, CMS  
Francisco Ruiz, Director, White House Office of National AIDS Policy  
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