Congress of the United States

Washington, DC 20515

March 19, 2026

The Honorable Mehmet C. Oz, MD
Administrator
Centers for Medicare & Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Oz:

As Chairmen of House Committees with jurisdiction of federal health care oversight and appropriations for the Department of Health and Human Services (HHS), we are continuing to investigate the role of Pharmacy Benefit Managers (PBM) in pharmaceutical markets. The House Committee on Oversight and Reform's July 2024 staff report and accompanying hearing found that the three largest PBMs controlling approximately 80 percent of the market used prior authorizations, fail-first policies, rebate-driven formulary manipulation, among other tactics to steer patients toward preferred products regardless of physician judgment, with "significant detrimental impacts on Americans' health outcomes." [1] At that hearing, PBM executives declined to commit to deferring to a treating physician's drug selection over cost considerations, even when directly asked.[2] Congress responded: the FY2026 Labor-HHS Appropriations Act, signed February 3, 2026, includes bipartisan PBM reforms such as flat-fee compensation requirements and enhanced disclosure mandates, which reflect Congress's ongoing concern about these practices.[3] As these reforms are implemented, we urge Centers for Medicare & Medicaid Services (CMS) to use its oversight authority to prevent benefit designs that create barriers to appropriate care.

Medicare Part D's "six protected classes" are intended to guarantee meaningful access to clinically critical therapies.[4] Plans must cover "all or substantially all" drugs in these categories to include antineoplastics (cancer drugs), immunosuppressants, antiretrovirals, and others precisely because the clinical consequences of access failures in these areas are severe and often irreversible.[5] That protection is hollow if plans can use step therapy or prior authorization to block access to the physician's chosen agent. Where utilization management delays or prevents the doctor's selected treatment, it functions as a de facto exclusion, and CMS should treat it as one. The Part D appeals process is not a meaningful substitute: high overturn rates demonstrate

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[1] HOUSE COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM, THE ROLE OF PHARMACY BENEFIT MANAGERS IN PRESCRIPTION DRUG MARKETS, STAFF REPORT, 118TH CONG., 4 (July 23, 2024).
[2] *The Role of Pharmacy Benefit Managers in Prescription Drug Markets Part III: Transparency and Accountability: Hearing Before the H. Comm. on Oversight and Gov't Reform*, 118th Cong.
[3] Consolidated Appropriations Act, 2026, Pub. L. No. 119 - 75 (2026).
[4] Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit Manual, Pub. 100-18, Chapter 6: Part D Drugs and Formulary Requirements (v.01.19.16).
[5] *What Medicare Part D Must Cover | Required Drug Coverage Explained*, Medicare Planning (Nov. 27, 2025), https://www.medicareplanning.com/what-medicare-part-d-must-cover/.

that initial criteria utilized by PBMs and insurers are routinely too restrictive, and in serious illness, weeks of delay can cause significant harm to patients.[6]

Drug selection must be individualized. A physician chooses a specific therapy based on a patient's diagnosis, comorbidities, prior treatment history, drug interactions, and tolerability risk. Blanket step therapy requirements that force patients to try and fail on a PBM-preferred agent before accessing the prescribed one substitute cost and contracting preferences for clinical judgment. Bruton's tyrosine kinase inhibitor (BTKi) therapy for chronic lymphocytic leukemia (CLL) is one clear example. There are three FDA-approved covalent BTKi agents indicated for first-line treatment, but they are not interchangeable and have varying toxicity profiles.[7] National Comprehensive Cancer Network (NCCN) Guidelines require individualized selection based on patient-specific factors and toxicity profiles, yet PBMs are implementing blanket step therapy requirements.[8] Utilization management is intended to maintain high-quality care, not to override clinical decision-making by forcing a CLL patient with cardiac risk to fail on medications, which can cause serious and irreparable harm.[9] The same logic applies wherever step therapy overrides a physician's individualized clinical judgment in a protected class.

As negotiated drugs become cheaper for payers, insurers and PBMs gain new financial incentives to impose those drugs as mandatory first steps, regardless of individual patient clinical profiles. This dynamic will expand as additional drugs across therapeutic classes enter negotiation cycles. CMS must ensure that its own pricing reforms are not used to drive clinical sequencing decisions that contradict established guidelines and expose patients to preventable harm. The time to establish clear guardrails is now.

Within its existing authorities, we request that CMS take the following steps:

1. Clarify and enforce that step therapy requiring a patient to fail a different medication before accessing the physician-chosen first-line agent constitutes a de facto exclusion impermissible under the CMS protected class rule.

2. Affirm that a treating physician's written attestation documenting patient-specific reasons such as cardiovascular risk, prior intolerance, or drug interactions is sufficient to satisfy prior authorization requirements for first-line medication selection, without requirement of a trial-and-failure period.

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[6] Medicare Rights Center, *Medicare Part D Appeals: Problems and Options to Correct Them* (Mar. 16, 2023).
7 U.S. Food & Drug Administration, Drug Approval Package for ibrutinib (NDA 205552); acalabrutinib (NDA 210259); zanubrutinib (NDA 213756). Jennifer Brown, et al. *Zanubrutinib or Ibrutinib in Relapsed or Refractory Chronic Lymphocytic Leukemia*, 388 N Engl J Med. 2023 319-332 (December 13, 2022).
[8] National Comprehensive Cancer Network, *NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma*, Version 2.2026, https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1478 .
[9] Centers for Medicare & Medicaid Services, Medicare Prescription Drug Benefit Manual, Pub. 100-18, Chapter 6: Part D Drugs and Formulary Requirements (v.01.19.16).

3. Conduct a focused review of CY26 Medicare Part D plan requirements to identify and correct step therapy edits, prior authorization criteria, and specialty-pharmacy routing requirements that delay or block first-line access. This review should examine whether formulary designs reflect anticompetitive patterns including rebate-driven product selection or steering to affiliated channels.

4. Issue near-term CY26 guidance and pursue longer-term Part D Manual (Chapter 6) regulatory updates to clarify and define "clinical appropriateness" as a standard for formulary management activities. CMS should establish the definition and parameters of clinical appropriateness to ensure that coverage restrictions, utilization management tools, and dispensing channel requirements are grounded in patient care considerations rather than financial or contractual incentives.

The Committees further request CMS enforce existing protected-classes and formulary adequacy standards, which are core program integrity functions fully compatible with the Part D non-interference clause. We appreciate CMS's stewardship of the Part D program and our shared goal is to ensure that beneficiaries receive the best care possible, to improve outcomes and patients' quality of life. We look forward to CMS's response and working together to ensure Medicare beneficiaries can begin physician-directed treatment without delay. Finally, we request a briefing on the planned actions and above concerns by April 17, 2026.

Sincerely,

James Comer
Chairman
Committee on Oversight and Government Reform

Robert B. Aderholt
Chairman
House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

cc: The Honorable Robert Garcia, Ranking Member
Committee on Oversight and Government Reform

The Honorable Rosa DeLauro, Ranking Member
House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies