DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

**CENTER FOR MEDICARE**

**DATE:** April 16, 2025

**TO:** All Prescription Drug Plans, Medicare Advantage-Prescription Drug Plans, Section 1876 Cost Plans, and PACE Organizations

**FROM:** Vanessa S. Duran
Director, Medicare Drug Benefit and C & D Data Group

**SUBJECT:** CY 2026 Part D Formulary Submission Information

This memorandum provides information to assist Part D sponsors with the submission of Contract Year (CY) 2026 formularies.

## Formulary Instructions

The CY 2026 Health Plan Management System (HPMS) Formulary Submission and Reports Technical Manual was released on March 24, 2025 and posted in the memos section of HPMS. The Formulary Outlier Justification Submission (OJS) Module User Manual will be released with the Formulary Submission Module and posted in the documentation section of the OJS module in HPMS on May 12, 2025.

## Formulary Reference File

The initial CY 2026 Formulary Reference File (FRF) is posted in the CY 2025 HPMS Formulary Submission Module. An updated CY 2026 FRF will be posted in the CY 2026 Formulary Submission Module in mid-to-late May.

## Annual Formulary and Benefits Submission Window Dates

Important dates regarding the CY 2026 formulary submission are listed below. We encourage Part D sponsors to submit formulary files in advance of the deadline to provide time to address any technical issues with their submissions that may arise. Please note that an initial formulary must be submitted and successfully validated prior to the formulary submission deadline. The initial formulary and transition policy submissions may be revised and updated until the June 2, 2025 submission deadline.

Important dates related to CY 2026 formulary submissions:

- May 12, 2025 – CY 2026 HPMS Formulary Submission Module released

- June 2, 2025 at 11:59 p.m. PDT – Deadline for the following submissions:
    - Initial formulary submission
    - Transition attestation and policy submission
    - Formulary attestations (Pharmacy and Therapeutics Committee and Prior Authorization/Step Therapy)
    - Formulary crosswalk
- On or about June 3, 2025 – Supplemental formulary file submission window opens
- June 6, 2025 at 11:59 a.m. EDT – Supplemental formulary submission deadline
- On or about June 9, 2025 – Stage 1 Review concerns are communicated
- On or about June 27, 2025 – Stage 2 Review concerns are communicated
- On or about July 18, 2025 – Stage 3 Review concerns are communicated
- Early August 2025 – Summer limited formulary update window
- Late September 2025 – Formulary update window for limited enhancements and immediate substitution-type changes only

***New for CY 2026***

**Prior Authorization (PA) Submission**

Prerequisite Therapy Required for Prior Authorization: The PA file record layout includes a new required field, 'Prerequisite Therapy Required', to indicate if prerequisite therapy is required as part of the PA criteria (Paperwork Reduction Act: CMS-R-262; OMB control number: 0938-0763). When a sponsor submits PA criteria for a drug that includes prerequisite drug therapy requirements that must be met by a beneficiary prior to approving coverage for the drug, sponsors should enter a '1' in the 'Prerequisite Therapy Required' field on the PA submission file. If the PA criteria does not include any prerequisite Part D drug requirements, sponsors should enter a '0' in the 'Prerequisite Therapy Required' field on the PA submission file.

**Selected Drug Formulary Sub-Review**

As outlined in Section 110 of the Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, CMS will use its formulary review process to assess formulary placement of selected drugs in the following ways.[1] Starting in CY 2026, CMS will include a new formulary review in HPMS to identify whether selected drugs are missing from formularies. The review will also determine whether selected drugs are on a preferred tier, and/or are on a lower cost-sharing tier than formulary alternative brand drugs in the same therapeutic class. Additionally, CMS will review formularies to identify instances where a Part D sponsor requires utilization of a formulary alternative brand drug prior to a selected drug (i.e., step therapy), and instances where a Part D sponsor imposes more restrictive utilization management (UM) requirements (i.e., step therapy and/or prior authorization) on selected drugs relative to a formulary alternative brand drug in the same therapeutic class. CMS intends for this review to

[1] CMS, Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 (June 30, 2023), available at https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

occur during the stage 1 and stage 2 reviews. CMS will communicate review concerns related to selected drugs that are not included on formularies during stage 1, and the remaining tiering and/or UM review concerns during stage 2.

If a Part D sponsor receives one or more review concerns and does not address those concerns by resubmitting their formulary, CMS will expect the sponsor to submit a justification (or justifications) in response to the review concerns. CMS expects these justifications to support the submitted plan benefit design and formulary that includes any of the practices noted above during the annual bid review process. Each justification should address applicable clinical factors, such as clinical superiority, non-inferiority, or equivalence of the selected and non-selected brand drugs, as well as the plan design's compliance with applicable statutory and regulatory requirements (e.g., the requirement to have a cost-effective drug utilization management program that bases decisions on the strength of the clinical evidence and standards of practice). CMS will evaluate these justifications for compliance with applicable statutory and regulatory requirements and will only approve a Part D plan bid submitted by a Part D sponsor if the benefit design and formulary complies with those requirements.

If you have questions regarding the CY 2026 formulary submission process, please email PartDFormularies@cms.hhs.gov. If you have questions regarding CY 2026 supplemental files, please email PartDBenefits@cms.hhs.gov.