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CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262)

Comment On: CMS-2025-1857-0001
CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262)

Document: CMS-2025-1857-DRAFT-0015
Comment on CMS-2025-1857-0001

Submitter Information

Name: Anonymous Anonymous

General Comment

Dear CMS,
Thank you for the opportunity to comment on the CY2027 Final Part D Bidding Instructions and proposed formulary/PA submission changes. I am a pharmacist with 17 years of experience, including 8 years managing our Part D formulary. We have significant concerns that may become problematic if CMS proceeds with the proposed changes.
1. Requirement to Ensure Medically Accepted Indications (MAI)
a. CMS requires plans to ensure Part D drugs are used only for MAI. Chapter 6 states that plans must apply UM to drugs likely to be used for non-Part D or non-MAI uses, and that PA is the consistent mechanism for doing so.
b. Restricting diagnostic criteria in PA will increase the risk of non-MAI utilization. While some diagnostic elements evolve, most MAI supporting diagnostics (genotypes, enzyme levels, culture results, pulmonary testing, etc.) are well established standards of care. These are essential for confirming MAI. Examples:
• Orkambi/Symdeko are ineffective for heterozygous F508del patients.
• Arikayce requires sputum cultures confirming MAC.
• Prolastin requires AAT levels, genotype testing, and functional testing.
Removing the ability to require diagnostics undermines the statutory obligation to ensure MAI and contradicts longstanding regulatory practice.
c. Plans will still be legally responsible for MAI even without CMS approved diagnostic criteria and will therefore continue requesting diagnostics outside the formal criteria. This will create industry-wide inconsistency and audit risk.
d. Our plan has successfully integrated diagnostic requirements into ePA and PA review automation. We would welcome the opportunity to share our experience.
2. Formulary Submission File Layout – PA Group Structure
a. CMS proposes limiting PA groups so that only RxCUIs sharing the same “RxNorm ingredient” can be grouped together. Currently, we consolidate multiple drugs with similar criteria into a unified PA group (e.g., one “behavioral health” PA group with 9 drugs/35 RxCUIs). This reduces CMS review volume, minimizes update requests, and streamlines prescriber/patient communication.
Under the proposal, this single group would be split into 9 separate PA groups with nearly identical criteria. For plans, CMS, prescribers, and members, this results in:
• More criteria gates requested and more manual review
• Redundant criteria
• Increased chance of inconsistency

• Dramatically longer published PA documents (our 183 page PDF would likely exceed 300 pages)
Beneficiaries and prescribers would have to navigate multiple repetitive PA groups instead of one consolidated, clinically logical set.
b. "RxNorm ingredient" is not a standardized field. FRF fields like “Related SCDC” include ingredient + strength + dosage form. It is unclear whether different salt forms or combination products count as separate ingredients. "RxNorm Description" is a standard FRF field but also contains strength and dosage form and has a 1:1 relationship with RxCUI, so this is not the same as "RxNorm ingredient." Without a standard reference, enforcement becomes unworkable.
3. Step_Therapy_Total_Groups
Reporting the number of ST groups a drug appears in is not new, but its purpose remains unclear.
4. PA File Record Layout Concerns
a. Prescriber_Restrictions: If CMS requires standardized prescriber codes, these codes are unintelligible to beneficiaries and burdensome for prescribers and plans’ software vendors. Submission file codes would need to differ from the plain language text displayed publicly, doubling work, adding confusion, and increasing the opportunity for error.
b. Prior_Authorization_Group_Indication: Similar concerns to prescriber type code(s) section above. If not displayed in plain English without needing any further translation, this is overly burdensome to the beneficiary, prescriber, and software vendor. It will also be confusing and time-consuming to any human reviewers/managers at CMS and at the plans.
c. Coverage_Duration: A 5-character limit cannot support common duration terms such as “Lifetime,” “Plan Year,” “1 year,” “6 months,” etc.

Thank you for your consideration.

A Health Plan Medicare Part D Formulary Manager

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CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262)

Comment On: CMS-2025-1857-0001
CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262)

Document: CMS-2025-1857-DRAFT-0020
Comment on CMS-2025-1857-0001

Submitter Information

Name: Anonymous Anonymous

General Comment

Comments on individual fields
Prior_Authorization_Group_Desc – This information is not readily available to users on the formulary files that are available to the public. Question to CMS: is there a list of Prior Authorization Groups? Could it be provided what the groups are and then on this file it would have to be one of those groups? At the very least, should likely be less than 100 characters since it is likely more free text which causes issues with matching and data validity.

Prior_Authorization_Group_Indication - The directions are unclear, in that they say all subsequent fields should be filled in for each additional indication. I think it would be easier if the forms were 1 drug 1 indication format and 1 main file that described all the indications or there should be an additional field on the file that has count of indications provided. Additionally, is indications intentionally vague? Or should it be a code set such as ICD-10? Should it generally be ICD-10 code and then if not can be provided as an exception?

Exclusion Criteria - I think these should be separate categories to get information from such as those described and then could be codified based on that. Comorbid diseases - ICD 10 codes, Lab values - specific numbers, etc. This is also a place where asking for questions used to ascertain criteria could be asked.

Required Medical Information – This can also be asked for by which questions/question sets but also included as attachments. Lab Values could be Numeric Range. Diagnostic is its own field to use Diagnosis. Imaging attachment (too large to send - fax).

Prescriber Restrictions – Is there a code set that should specifically be used here? Naming it would help clarify.

Additionally, as Prior Authorizations are determined via question sets for Part D drugs, Asking for the question sets specifically within the document would provide much more additional information to CMS.

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Docket: CMS-2025-1857
CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262)

Comment On: CMS-2025-1857-0001
CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262)

Document: CMS-2025-1857-DRAFT-0001
Comment on CMS-2025-1857-0001

Submitter Information

Name: Anonymous Anonymous

General Comment

I am writing to express concerns with the proposed changes to the PA File Record Layout. As a pharmacist who have developed and reviewed PA criteria for over 10 years, I believe this places an excessive burden on the health plans with insufficient time for implementation. While I appreciate incorporating efficiencies for CMS and transparency for providers and beneficiaries, the burden this places on health plans may unintentionally harm beneficiaries by potentially omitting PA requirements that are in place to ensure safe medication use and appropriate monitoring and increasing costs of premiums due to additional administrative requirements. It appears that a PA record will be required for each drug-indication combination rather than each drug based on the addition of the PA Group Indication field. For some drugs, this will not significantly change the current process. For other drugs, the administrative burden will increase significantly. For example, many biologic drugs have at least 4 indications with some up to 9 FDA approved indications plus off-label uses. One drug will now require 9 or more PA records to be submitted for a single drug rather than 1 with many of the same requirements shared between records. This will cause unnecessary duplication of efforts where the information in a specific PA element is the same and an increase in time and effort for both the health plan in developing the criteria and CMS as they review and approve the proposed PA criteria.

The addition of the PA Criteria Change Indicator field appears that CMS is being lazy and not wanting to review previously submitted criteria in 2026; however, the change to addition of the new fields means that the criteria content changed for every group description in 2027 compared to 2026. This field is irrelevant and excessively increases the burden on health plans.

A decrease in character limits for Required Medical Information and Other fields may be ok with only 1 indication associated with the group; however, this may be insufficient due to the level of specificity CMS has been requiring in criteria in the past year. CMS has required us to include specific label contraindications for prerequisite therapy, such as triptans, and detailed required diagnostic information, such as specific tests and labs, rather than general terms like documentation to support the diagnosis or genetic tests that prescibers would be well aware of if they are prescribing a medication for the indication.

Dividing the Age Restriction information into 2 fields creates an unnecessary administrative burden that does not improve clarity or add value to providers or beneficiaries.

I do appreciate the simplified coverage duration options, but recommend changing this to a dual dropdown option with a number first followed by a time period (days, weeks, months) to choose rather than a lettered option with a number required for some options but not all. I feel for your contractor that needs to build this in HPMS. This doesn't seem to be practical to implement as proposed since there is a 5 character limit. I see some plans entering the first 5 characters of what the letter means, others submitting the letter and forgetting to include a number for months or

days, and many just entering Other and including details in the Other field. This also does not allow simplification of submitting what CMS has previously told us to submit when it comes to hepatitis C drugs that IDSA/AASLD guidelines will be followed. At minimum, add an option for weeks since many product labels recommend monitoring after so many weeks.

In general, I think CMS has good intentions, but this adds significant burden on health plans to be able to implement by the time formulary, PA and ST submissions are done in May and June. Can the HPMS even incorporate these updates by then as they are fairly extensive? Will we be able to download our reports from HPMS with at least a 40-50% increase in the amount of data (estimating that the number of PA groups will increase from 1 per drug to an average of 4 per drug, plus another field for each - as it appears there are 2 new ones and removal of the off-label uses field). I assume Indication-Based Coverage will still be an option?

If the goal is to decrease CMS burden, try being transparent with the plans so we can stop doing rework and guessing at what is ok. It seems like there is no room for cost-conscious therapy even when treatment guidelines state older, cheaper drugs are effective. Specific biologics must be used because a guideline says they are more effective than other biologics, yet the guideline still lower efficacy ones and we have no idea what guidelines to follow because CMS doesn't tell us which ones they consider best practice. Coverage durations for chronic diseases can't be 90 days as we have previously been told, yet no communication this isn't acceptable. CMS has some internal issues that need to be flushed out and clearly communicated to us.

CY 2027 Prior Authorization File Record Layout
Comments

Field Name	Field Type	Maximum Field Length	Field Description	Comment
Prior_Authorization_Group_Desc	CHAR Always Required	100	Only RxCUIs with the same RxNorm ingredient can be included within the same Prior_Authorization_Group_Desc.	What is an example of rxcui's with different RxNorm ingredient?
Prior_Authorization_Group_Indication	CHAR Always Required	500	Enter the indication code for which the prior authorization applies. If the prior authorization applies to more than one indication, the subsequent fields should be repeated for each indication, and the information entered should correspond only to that specific indication.	1) By "code" is CMS referring to ICD-10 codes for each indication we plan to cover? 2) Confirming 2nd sentence: if we have 10 covered indications, regardless if there is anything different in subsequent fields, we have to enter all the subsequent fields for each indication? In this example, we would have 10 separate "lines" with all fields for ONE PA Group
Required_Medical_Information	CHAR If applicable	1000	Enter laboratory, diagnostic, or other medical information required for initiation or continuation of the drug(s).	**Regarding the maximum field length:** This is a much lower (half of) character limit that we are allowed today. However, if this field is suppose to be entered and specific only for each indication

				that we cover, then the low character count may not be a concern.
Coverage_Duration	CHAR Always Required	5	Enter the duration for which the prior authorization will be approved. a. Lifetime b. 1-year c. Plan Year d. Months, (number of months) e. Days, (number of days) Other (enter information in the Other criteria box)	**Regarding the maximum field length:** Confirming we are only submitting the letters: a, b, c, d, or e? How exactly are we submitting 6 months or 28 days if only 5 characters total? Do we put "d.6" or d(6) or e(28)?
Other_Criteria	CHAR If applicable	1000	Enter any other relevant criteria.	**Regarding the maximum field length:** This is a much lower character count than 2026 (1/3 of character limit that we are allowed today). However, if this field is suppose to be entered and specific only for each indication that we cover, then the low character count may not be a concern.

Section/Title	Commentor	Functional Area
PBP Change: Formulary Changes	Emily Lee	CPS Formulary Strategy (with input from CPS PA Ops)

Comment(s)

Based on our current interpretation of “PBP Change: Formulary Changes ” related to prior authorization file changes, CMS appears to be recommending splitting out PA criteria at an indication level. This could potentially lead to more complexity and confusion for members and providers to find the criteria by drug and indication, particularly for drugs with multiple indications. Splitting out criteria by indication as proposed (vs by drug as currently designed), can make the PA criteria PDF more cumbersome for end users by increasing the document size by 5X or more.

In addition, we request guidance from CMS on how an "indication" is defined, as not all drugs have distinct indications and some are extensions (e.g., subclass of a disease or a related condition) of existing indications. For example, with hepatitis C agents require a separate criteria by virus genotype, or would disease status of cirrhosis vs. compensation vs. prior treatment status be considered an indication?

February 19, 2026

The Honorable Mehmet Oz, MD
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850
Sent electronically via: http://www.regulations.gov

RE: CMS-R-262, CMS Plan Benefit Package (PBP) and Formulary CY 2027

Dear Administrator Oz,

Priority Health, a division of Corewell Health, appreciates the opportunity to comment on proposed revisions to the CMS Plan Benefit Package (PBP) and Formulary information collection for CY 2027. Corewell Health is a non-profit health system that provides health care and coverage with an exceptional team of 60,000+ dedicated people comprised of more than 11,500 physicians and advanced practice providers, over 15,000 nurses offering services in 21 hospitals, 300+ outpatient locations, and numerous post-acute facilities. In addition, Priority Health serves over 1.3 million members primarily in Michigan and is the second largest health plan in Michigan, offering an extensive portfolio of health benefits options for employer groups and individuals, including Medicare and Medicaid plans. With over thirty years in business, Priority Health continues to be recognized as a leader for quality, customer service, transparency and product innovation.

Through experience and collaboration, we are reimagining a better, more equitable model of health and wellness. It is from the perspective of an integrated health system that we offer the following comments.

As a threshold matter, we recognize CMS's ongoing efforts to promote standardization and transparency in prior authorization; however, **the level of complexity introduced appears inconsistent with the Administration's stated priorities of streamlining and reducing regulatory burden.** As currently proposed, these changes introduce substantial administrative burden on plans and employer groups who offer Employer Group Waiver Plans (EGWPs) without clearly improving the accuracy and actionability of data. We believe the proposed changes introduce unnecessary and unclear data elements into the prior authorization (PA) and formulary documentation process with unclear benefit to providers or beneficiaries. **These proposed changes conflict with the February 19, 2025 executive order on easing administrative burdens as well as multiple CMS and HHS requests on implementing this order.**

Further, CMS proposes that requirements within a Prior Authorization Group Description (PAGD) apply to all RxCUIs associated with the PAGD, which would force a one-size-fits-all PA criteria model that disregards clinical nuance. **Requiring PA criteria submission at the ingredient and indication level would impose significant operational and administrative burden on health plans**. Most plans build PA workflows at the drug product or therapeutic class level and forcing a single ingredient or indication level model would require reporting system reengineering and significant redundancy. Under the proposed structure, a drug that previously required a single PA record could now require multiple submissions, many of which would repeat identical clinical criteria. **This**

approach creates substantial duplicative work for plans and CMS in their review without adding meaningful insight or utility for CMS.

We are also concerned about the proposed decrease in character limits for the "Required Medical Information" and "Other Criteria" fields. We acknowledge CMS's effort to shift from narrative descriptions toward structured, codified fields. However, **character limits constrain the ability to adequately convey and document clinical appropriateness requirements, which are essential to ensuring complete submissions and avoiding unnecessary delays in plan decisions.**

Given the significant operational implications of these proposed changes, we respectfully request further clarification and additional guidance to ensure plans can implement them accurately and feasibly.

Formulary Changes

- Reference document: CY 2027 List of Changes – 60 Day PRA Package

  CMS proposes moving the PA Criteria Change Indicator to the Formulary File and adding a validation requiring Option 2 for drugs subject to indication-based coverage. **However, there does not appear to be a new field matching this description in the supplied CY 2027 Formulary Submission File Record Layout document.** In addition, the formulary file layout includes a new field labeled "PA_Indication_Indicator", but this is different from both the proposed change description and the referenced "PA_ Criteria_Change_Indicator".

We request clarification:

- What will the new formulary file layout be for HPMS submissions?
- What is the purpose of the "PA_Indication_Indicator" field and how does it relate to the proposed change?

Prior Authorization File Changes

- Reference document: CY 2027 Formulary Submission File Record Layout

  PA Group Description
  In the description for the field "Prior_Authorization_Group_Desc", the document states that "only RxCUIs with the same RxNorm ingredient can be included within the same Prior_Authorization_Group_Desc".

  We request clarification:

  - Does CMS intend to prohibit plans from grouping multiple drugs with different ingredients under a single set of shared criteria, such as those used for high-risk medications and B vs. D determinations, including Immune Globulins?

  Prior Authorization Group Indication
  The new field "Prior_Authorization_Group_Indication" has a description of "Enter the indication code for which the prior authorization applies. If the prior authorization applies to more than one indication, the subsequent fields should be repeated for each indication, and the information entered should correspond only to that specific indication."

  We request clarification:

- Does this mean that when a PA group, or individual drug as proposed, has multiple applicable indications, the PA group name must be repeated in the PA submission file, resulting in a separate row for each indication? Or should all associated indications be entered on a single row in the "Prior_Authorization_Group_Indication" field and separated by a comma or another delimiter?
- If the indications are supposed to be on multiple rows, can the PA criteria be different for the PA group name by indication (making PA Group Name + Indication Code now the primary key for the file)?
    - If the above is the case, the field length for this new field is 500, which is long for a single indication code.
- How should indications without single or exact codes be handled? There are several indications (major cardiovascular event, arthritis, etc.) for which stating specific codes will exponentially increase the reporting requirements and may result in confusion among providers regarding diagnosis and coding requirements to receive approval from the health plan.
- Where will indication codes come from? Will this field utilize the same indications in the Indication Reference File used for Indication Based formularies?

Prior Authorization Criteria Change Indicator
The field "PA_Criteria_Change_Indicator" has a description that states, "If the PA criteria content did not change for this group description compared to CY 2026, please place a "0" in this field. If this group description is new, or the criteria content changed in any way (e.g. additional restrictions), please place a "1" in this field."

We request clarification:
- The structure of the data is changing from CY 2026 to CY 2027. How should plans evaluate if the PA criteria are different from CY 2026?
- What conditions should be used?

Prescriber Restrictions
- Reference document: CY 2027 Prior Authorization File Record Layout

  The field "Prescriber_Restrictions" now has a description that states, "Enter the required prescriber type code(s) for prior authorization approval. If multiple prescriber codes, enter as a comma delimited field."

We request clarification:
- Where will the list of valid prescriber type codes come from?
- If there are multiple prescriber codes to be entered, how should the values be formatted? For example: "07,09,23" vs "7,9,23".

Coverage Duration
- Reference document: CY 2027 Prior Authorization File Record Layout

  In the field "Coverage_Duration", the description states the plan should enter the duration for the PA with the options being: "a. Lifetime", "b. 1-year", "c. Plan Year", "d. Months, (number of months)" and "e. Days, (number of days)".

We request clarification:
- Is the expected submitted value to be a, b, c, d, or e?
- The length for this field is now only 5 characters long. If the duration is d or e, how should the number of months or days be submitted?

        - Would it be submitted as “d(18)” or “e(90)”?
        - What if the number of days is 100+? Which is more than 5 characters total [i.e. “e(180)” = 6 char].
    - Is “Other” a valid value (with the details submitted in the “Other_Criteria” field)?

Conclusion

Thank you for your consideration of our comments. We support the Administration’s goals of transparency and standardization and respectfully ask CMS to reconsider the proposals and explore alternative approaches that advance these goals while reducing administrative burden and complexity for providers, plans, and CMS. Should you have any questions regarding these comments or if you would like any additional information, please contact Lan Le, Principal, Public Policy at lan.le@priorityhealth.com.

Sincerely,

Ryan Nolan, PharmD, MBA
Interim Vice President, Pharmacy
Priority Health

CENTER FOR REGULATORY FREEDOM
PROJECT OF CPAC FOUNDATION

515 KING STREET, ALEXANDRIA VA 22314

M E M O R A N D U M

To: **Hon. Robert F. Kennedy, Jr., Secretary, US Department of Health and Human Services**
Dr. Mehmet Oz, Administrator, Centers for Medicare and Medicaid Services
From: **Andrew Langer, Director, Center for Regulatory Freedom**
Date: **February 19, 2026**
Re: **Comments to US Department of Health and Human Services Centers for Medicare and Medicaid Services (CMS) in response to a Notice Regarding CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262), Docket #CMS-2025-1857, Fed. Reg. 2025-23582, Published December 22, 2025**

Below are comments of the American Conservative Union Foundation's (d/b/a. Conservative Political Action Coalition Foundation) (hereinafter "CPAC Foundation") Center for Regulatory Freedom (hereinafter "CRF"), in response to a Notice regarding CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262), Docket #CMS-2025-1857, Fed. Reg. 2025-23582, published December 22, 2025.

CRF is a project of the CPAC Foundation, a non-profit, non-partisan 501(c)(3) research and education foundation. Our mission is to inject a common-sense perspective into the regulatory process, to ensure that the risks and costs of regulations are fully based on sound scientific and economic evidence, and to ensure that the voices, interests, and freedoms of Americans, and especially of small businesses, are fully represented in the regulatory process and debates. Finally, we work to ensure that regulatory proposals address real problems, that the proposals serve to ameliorate those problems, and, perhaps most importantly, that those proposals do not, in fact, make public policy problems worse.

Introduction

The Center for Regulatory Freedom (CRF) appreciates the opportunity to comment on the proposed revisions to the Plan Benefit Package (PBP) and Formulary submissions for Contract Year 2027. CRF strongly supports the integrity of the Medicare Advantage (MA) and Part D programs, including transparent benefit design, consistent oversight, and structured data reporting that enables meaningful beneficiary comparison and effective federal review. Medicare

Advantage now serves millions of seniors and individuals with disabilities who depend on stable, predictable coverage. Sound regulatory governance is therefore essential to preserving both program credibility and beneficiary confidence.

At the same time, paperwork and information collection requirements are not administratively neutral. They influence plan design, vendor contracting, compliance staffing, and bid construction. Administrative costs are incorporated into MA bids and ultimately affect premiums, supplemental benefit offerings, and rebate allocation decisions. Information architecture choices—particularly those requiring system redesign—can materially alter operational cost structures across the MA ecosystem. For this reason, reporting changes must be evaluated not only for policy intent but also for their economic and competitive consequences.

CMS's stated modernization objectives are legitimate and important. Structured data, consistent taxonomy, and enhanced electronic comparability can improve review efficiency and beneficiary transparency. However, under the Paperwork Reduction Act, revisions to existing collections must satisfy standards of necessity, practical utility, and burden minimization. Modernization must therefore be disciplined modernization. It must enhance clarity and automation without imposing structural costs that exceed incremental informational gains.

CRF's core concern is not with the goal of standardization, but with the method by which it is pursued. When reporting changes require system architecture redesign, vendor reconfiguration, or large-scale duplication of data entry, the resulting costs may outweigh their intended administrative benefit. Structural redesign is categorically different from incremental refinement. The former implicates capital expenditures, integration timelines, and compliance layering that ripple across all participating organizations. Such changes warrant heightened proportionality review.

CRF submits these comments in the spirit of constructive refinement. We support efforts to improve prior authorization transparency, enhance structured data submission, and strengthen CMS's ability to conduct consistent plan review. At the same time, we urge CMS to ensure that standardization mechanisms preserve clinical precision and operational feasibility. Automation should increase—not decrease—under modernization initiatives.

We further encourage CMS to apply implementation discipline commensurate with the scale of the proposed changes. Phased transitions, structured pilot testing, and stakeholder collaboration can mitigate disruption while preserving policy objectives. Regulatory predictability is particularly important in the Medicare Advantage bid environment, where compressed statutory timelines limit the ability of plans to absorb abrupt structural shifts.

Ultimately, CRF's recommendations are grounded in a straightforward principle: regulatory reform must balance transparency with proportionality, and modernization with affordability. By refining certain structural elements of the proposal while preserving its legitimate objectives, CMS can strengthen program oversight, improve beneficiary comparability, and maintain disciplined compliance with the burden-minimization mandate embedded in federal law.

Executive Summary

The Center for Regulatory Freedom (CRF) supports CMS's ongoing efforts to modernize Medicare Advantage (MA) and Part D reporting through structured, transparent, and automation-ready data submissions. Standardization, comparability, and improved electronic review tools can strengthen program oversight and beneficiary access to clear information. However, information collection changes must remain consistent with principles of proportionality, burden minimization, and operational feasibility. Because administrative requirements materially affect MA bid construction, supplemental benefit flexibility, and beneficiary affordability, structural reporting changes warrant careful calibration.

CRF respectfully offers the following substantive recommendations:

• Support CMS's goals of standardization, transparency, and enhanced automation in MA and Part D submissions, recognizing the importance of consistent review and beneficiary comparability.

• Emphasize that paperwork and reporting architecture are economically material; administrative redesign costs enter plan bids and influence supplemental benefit offerings and overall affordability.

• Raise concerns that the proposed indication-level prior authorization duplication requirement may create redundant data entry, system reconfiguration burdens, and vendor redesign costs without corresponding incremental informational gain.

• Recommend adoption of structured referencing, tagging, or inheritance logic models rather than repeated multi-entry duplication for drugs with multiple indications.

• Highlight limitations of a MeSH-only CUI mapping requirement, particularly in complex clinical areas such as oncology and specialty medicine, where necessary distinctions may not be fully representable.

• Recommend incorporation of supplemental modifier fields and the establishment of a structured taxonomy gap review mechanism to preserve clinical precision while advancing standardization.

• Encourage phased implementation timelines for major system architecture changes, including pilot periods and dual-submission transition phases to mitigate disruption.

• Recommend user-centered redesign of PBP validation sequencing to eliminate unnecessary workflow friction and reduce transaction costs associated with screen-to-screen error loops.

• Support allowing multiple SSBCI packages within a single plan to improve reporting accuracy, reduce forced aggregation, and align structural flexibility with expanded utilization reporting requirements.

• Urge CMS to apply a formal burden-to-utility proportionality framework prior to finalization, assessing incremental engineering, vendor, and compliance costs relative to transparency and automation gains.

CRF's recommendations are intended to strengthen—not impede—CMS's modernization objectives. By refining structural elements of the proposal to ensure proportionality, clinical fidelity, and implementation discipline, CMS can enhance transparency and automation while protecting affordability, competitive stability, and the long-term integrity of the Medicare Advantage and Part D programs.

I. Paperwork, Affordability, and Regulatory Proportionality

Paperwork is not administratively neutral. In the Medicare Advantage (MA) and Part D environment, reporting obligations translate directly into operational expense. Compliance staffing, actuarial review, information technology integration, vendor contracting, and quality assurance processes all reflect the cumulative weight of federal reporting architecture. These costs are incorporated into plan bids and become part of the administrative load embedded in premiums and rebate calculations. As a result, information collection requirements have real economic consequences for beneficiaries.

Administrative overhead influences how plans allocate rebate dollars and design supplemental benefits. Every incremental reporting requirement competes with potential investments in enhanced dental, vision, hearing, transportation, in-home support services, or cost-sharing reductions. When compliance architecture expands, plans must reallocate resources to meet regulatory demands. Even modest per-plan increases in administrative complexity, when scaled across hundreds of contracts and millions of beneficiaries, can materially affect program affordability and benefit richness.

The Paperwork Reduction Act establishes a clear governance framework for evaluating such changes. Information collections must be necessary for the proper performance of agency functions, have practical utility, and be designed to minimize burden. These standards are not procedural formalities; they reflect Congress's recognition that regulatory accumulation can impose meaningful economic costs. Accordingly, structural changes to existing reporting systems must be justified by demonstrable utility gains that exceed their implementation burdens.

It is important to distinguish between incremental reporting refinements and structural system redesign. Minor clarifications to data fields or modest format adjustments generally involve limited transition costs. By contrast, requirements that alter the architecture of data submission—such as reconfiguring prior authorization logic at the indication level or restructuring taxonomy

mapping—may necessitate software redevelopment, vendor reprogramming, data migration, and workflow retraining. These are capital-intensive undertakings, not clerical updates.

CRF recognizes that certain changes may enhance transparency and comparability. Structured data can improve CMS review consistency and beneficiary-facing tools. However, transparency-enhancing reforms must be distinguished from duplicative complexity. Requiring repeated entries of substantively identical information, or compressing clinical nuance into overly rigid taxonomies, risks increasing workload without proportionate informational gain. Regulatory precision should not come at the expense of operational efficiency.

System redesign also carries vendor and ecosystem implications. Many MA organizations rely on third-party formulary management systems, prior authorization engines, and compliance platforms. Architectural changes cascade across these vendors, triggering contract amendments, development costs, testing cycles, and deployment risk. These costs are rarely confined to a single reporting year and often persist through maintenance, updates, and downstream integration requirements. Such impacts must be incorporated into any realistic burden assessment.

The Medicare Advantage bid process operates within compressed statutory timelines. Plans prepare actuarial submissions, finalize benefit designs, coordinate provider networks, and ensure compliance across numerous regulatory domains simultaneously. Layering significant reporting architecture changes onto this already compressed environment heightens operational risk. Implementation compression can result in rushed development, temporary workarounds, and elevated compliance exposure—outcomes that undermine both administrative stability and regulatory credibility.

For these reasons, CRF urges CMS to apply a structured proportionality analysis before finalizing major reporting architecture revisions. Such an analysis should estimate incremental engineering hours, vendor redevelopment costs, compliance staffing impacts, and transitional risk relative to anticipated transparency or automation gains. Where informational value is modest and burden substantial, refinement or phased implementation may better serve program integrity.

Regulatory proportionality strengthens—not weakens—oversight. By ensuring that information collection changes are tightly aligned with practical utility and operational feasibility, CMS can preserve transparency objectives while safeguarding affordability and competitive stability. Disciplined evaluation of burden relative to benefit is consistent with both sound administrative governance and the long-term sustainability of the Medicare Advantage program.

II. Prior Authorization Architecture: Duplication vs. Structured Referencing

CMS proposes to modify the prior authorization (PA) reporting structure by requiring indication-level repetition of PA entries. Under this approach, when a single drug has multiple indications subject to prior authorization, plans would be required to submit separate entries corresponding to each indication rather than a consolidated record. While intended to enhance transparency and

data granularity, this structural shift materially alters how PA data must be entered, maintained, and validated within plan systems.

Under current practice, plans may submit a single PA record encompassing multiple applicable indications. The underlying clinical criteria may be structured to address distinct indications within a unified policy framework, allowing plans to apply consistent logic while maintaining internal clinical nuance. This approach reflects how PA systems are operationalized in practice: a single policy object may incorporate branching logic that applies across multiple indications without requiring discrete duplicative entries.

Requiring separate entries for each indication introduces operational complexity. For drugs with numerous FDA-approved or compendia-supported indications, plans would be compelled to replicate substantially identical information across multiple records. This multiplies data entry workload, increases the potential for clerical inconsistency, and expands quality assurance review obligations. Even where criteria remain identical, the reporting burden expands linearly with the number of indications.

More significantly, the proposed structure may require system engineering redesign. Many formulary management and PA platforms are not architected around indication-specific record objects for submission purposes. Reconfiguring data models to create separate, independently tracked indication-level records may require database restructuring, workflow redesign, and validation rule modification. These are structural system changes rather than incremental form adjustments.

Vendor implications must also be considered. MA organizations frequently rely on external technology vendors for PA administration, formulary management, and electronic prior authorization integration. Structural changes to data submission requirements may necessitate vendor contract amendments, development sprints, regression testing, and deployment timelines that extend beyond a single reporting cycle. Such modifications may generate additional contractual and maintenance costs that persist beyond initial implementation.

CRF respectfully questions whether the informational gains from mandatory duplication exceed the associated burdens. If the same prior authorization criteria apply across multiple indications, requiring repeated entries may not enhance substantive transparency. Instead, it may create redundant data artifacts that increase reporting complexity without materially improving CMS review capacity or beneficiary understanding.

A more proportionate approach would allow structured tagging or inheritance logic. Plans could submit a single PA policy record that includes discrete indication tags, with criteria branching clearly defined within the structured submission. Where criteria are identical across indications, inheritance logic could apply automatically; where criteria differ, distinct subfields could capture those variations. This preserves granularity without imposing duplicative repetition.

CMS could also consider reference-based data linking. Under such a model, a primary PA record could be linked to multiple indication codes through structured references rather than separate

full entries. This approach would allow CMS to maintain visibility at the indication level while minimizing redundant data entry and preserving alignment with existing system architectures.

Before mandating structural redesign, CMS should consider pilot testing or phased implementation. A voluntary pilot allowing dual submission—current structure plus structured tagging—would enable CMS to evaluate whether the revised architecture yields meaningful review efficiencies. Empirical assessment prior to full-scale mandate would reduce transition risk and improve policy calibration.

Modernization should strengthen automation, not inadvertently reduce it. If reporting changes require extensive manual reconfiguration or introduce new opportunities for data inconsistency, automation rates may decline rather than improve. Structured referencing models are more likely to preserve scalable electronic processing than duplicative repetition models.

CRF supports CMS's objective of improving prior authorization transparency and consistency. However, architecture matters. A structured, reference-based approach can achieve indication-level clarity while maintaining operational feasibility, minimizing system redesign costs, and preserving automation integrity. Regulatory modernization should expand efficiency and precision simultaneously, rather than forcing a tradeoff between them.

III. MeSH CUI Mapping: Standardization Without Clinical Compression

CRF recognizes CMS's objective in proposing a MeSH Concept Unique Identifier (CUI) mapping requirement: the creation of a standardized, machine-readable taxonomy that promotes consistent review, structured analytics, and comparability across Medicare Advantage and Part D submissions. A common vocabulary can enhance CMS's ability to analyze prior authorization criteria, identify trends, and support beneficiary-facing transparency tools. The goal of structured taxonomy is therefore reasonable and consistent with modernization efforts.

However, the practical limitations of MeSH as a taxonomy must be acknowledged. MeSH was designed primarily as a biomedical indexing tool for literature classification, not as a fully granular clinical policy framework. In complex fields such as oncology, immunology, rheumatology, and other specialty areas, MeSH categories may aggregate clinically distinct conditions into broad groupings that do not reflect treatment nuance or policy logic.

In oncology in particular, coverage criteria frequently depend on staging distinctions, metastatic status, biomarker expression, prior treatment exposure, and line-of-therapy sequencing. These factors are central to evidence-based clinical decision-making and are routinely embedded in structured prior authorization logic. A taxonomy that collapses these distinctions into a single high-level disease category risks eliminating clinically material differences that drive coverage determinations.

Similarly, specialty therapies often differentiate among subtypes of disease that carry distinct treatment pathways. Collapsing those subtypes into broad categorical codes may obscure differences in step therapy requirements, prior exposure prerequisites, or escalation pathways.

These distinctions are not peripheral; they are the very structure upon which automated approval logic is built.

If a MeSH-only requirement forces plans to omit clinically necessary distinctions because no corresponding CUI exists, the likely operational consequence is an increase in manual review. When structured criteria cannot be encoded accurately, systems default to case-by-case adjudication. Manual review increases administrative burden, lengthens determination timelines, and introduces variability—outcomes directly at odds with modernization objectives.

Reduced granularity can therefore undermine automation. Automated prior authorization systems rely on precise rule sets mapped to structured clinical variables. When taxonomy limitations prevent accurate encoding, automation pathways shrink. The unintended result may be a decline in automated approval rates, even though the proposal's stated aim is to enhance structured processing and transparency.

Standardization must be carefully distinguished from oversimplification. Effective standardization captures complexity in a structured format; oversimplification compresses complexity into categories that lose operational meaning. A taxonomy that is too rigid to reflect real-world clinical criteria does not advance regulatory clarity—it introduces abstraction that obscures substantive distinctions.

CRF therefore recommends adoption of a MeSH-plus model. Under this approach, MeSH CUIs would serve as the base taxonomy, supplemented by structured modifier fields that capture clinically material distinctions such as stage, biomarker status, therapy line, or subtype classification. This layered approach preserves standardization while allowing precision.

CMS should also allow a temporary "unmapped but clinically accepted" designation for indications that lack an appropriate MeSH CUI. Where FDA-approved or compendia-supported uses cannot be fully represented within the current taxonomy, plans should be permitted to identify those uses in structured narrative or supplemental coded fields without being forced to eliminate or compress criteria.

In addition, CMS should establish a formal, recurring taxonomy gap review process. Annual stakeholder engagement to identify areas where MeSH CUIs fail to capture commonly utilized clinical distinctions would allow the agency to refine its structured submission framework over time. Continuous improvement of taxonomy mapping will better align modernization with clinical reality.

The ultimate objective should be to improve electronic comparability without sacrificing clinical fidelity. Structured data must reflect the operational logic that governs coverage determinations. If taxonomy constraints distort that logic, comparability gains are achieved at the expense of accuracy.

By adopting a flexible mapping model that incorporates supplemental modifiers and structured gap identification, CMS can preserve the benefits of standardized data while avoiding clinical

compression. Modernization should enable precise encoding of real-world criteria, not force simplification that reduces automation and increases manual burden.

Maintaining clinical precision while improving electronic comparability is not only feasible; it is essential. A calibrated approach to taxonomy design will strengthen oversight, enhance data utility, and protect the operational efficiency that beneficiaries ultimately depend upon.

IV. Implementation Timing and Systems Modernization Discipline

There is an important distinction between policy intent and systems execution. CMS's objectives—improving standardization, enhancing automation, and strengthening structured review—are policy determinations. Translating those objectives into operational reality, however, requires software development, data architecture redesign, workflow modification, vendor coordination, and extensive testing. Implementation discipline must therefore accompany policy ambition. Without careful sequencing, well-intended reforms can produce operational disruption disproportionate to their intended benefits.

Compressed implementation timelines present particular risk in the Medicare Advantage environment. Plans operate under fixed statutory bid deadlines and must coordinate benefit design, actuarial modeling, compliance validation, and vendor integration simultaneously. Introducing structural reporting architecture changes within tight development windows increases the likelihood of rushed system builds, temporary manual workarounds, and heightened compliance exposure. These conditions do not strengthen program oversight; they increase operational fragility.

The vendor ecosystem further complicates rapid implementation. Many MA organizations rely on third-party platforms for formulary management, prior authorization engines, electronic prior authorization integration, and compliance submission tools. Structural changes cascade across these vendors, triggering contract amendments, development queues, testing cycles, and deployment schedules that extend beyond a single plan year. Smaller plans and regional organizations may face disproportionate challenges if vendor resources are constrained by simultaneous industry-wide system updates.

For these reasons, CRF recommends a phased implementation model. CMS could begin with a voluntary pilot phase, allowing interested plans to test structured enhancements while maintaining existing submission formats. A subsequent dual-submission period would permit CMS to evaluate data consistency and operational feasibility before full integration. Only after empirical assessment of burden, automation performance, and data utility should mandatory transition occur. This staged approach mitigates disruption while preserving modernization objectives.

CRF also encourages CMS to establish structured working groups composed of agency technical staff, plan representatives, and vendor stakeholders. Such collaboration would allow identification of system constraints, taxonomy gaps, validation logic concerns, and transition

risks before enforcement deadlines are imposed. Modernization benefits from iterative design informed by operational expertise.

Before finalizing mandatory timelines, CMS should conduct and publish burden-impact modeling that estimates engineering hours, vendor development costs, testing cycles, and compliance staffing implications. Transparent assessment of transitional cost supports accountability and aligns implementation with proportionality principles. Modernization efforts that acknowledge and plan for capital impacts are more likely to achieve durable success.

Predictability is itself a form of regulatory efficiency. Plans that can anticipate phased transitions and clear technical specifications allocate resources more efficiently and avoid emergency development cycles. Predictable modernization strengthens market stability and reduces compliance volatility.

Modernization should proceed with discipline, sequencing, and collaboration. A capital-aware approach that recognizes the structural nature of system redesign will better protect affordability, preserve automation gains, and sustain program integrity. By pairing policy clarity with implementation prudence, CMS can achieve durable reform rather than short-term structural strain.

V. PBP User Interface and Administrative Friction

CMS's proposed revisions to the PBP data entry system highlight an important but often overlooked dimension of administrative burden: interface logic. The current validation sequencing between the "Reduction in Cost Sharing Packages" (19a) and "Additional Benefits Packages" (19b) fields creates an error message when 19b is left blank, even though users may properly complete the relevant MA Uniformity Flexibility information within 19b thereafter. Because users encounter 19a first when proceeding screen-to-screen, the system generates a circular validation loop that requires backtracking to mark sections complete after the necessary information has already been entered elsewhere.

While seemingly minor, this validation logic creates measurable transaction costs. Each instance of forced navigation between screens consumes staff time, increases the risk of incomplete submissions, and introduces avoidable compliance friction. Administrative personnel must interpret error messages, recheck data entries, and repeat save-and-validate cycles. These steps do not improve data accuracy or transparency; they simply reflect suboptimal sequencing of system logic.

When scaled across hundreds of MA organizations and thousands of submissions, such micro-frictions compound. Even modest additional minutes per submission, multiplied across annual bid cycles, translate into meaningful aggregate administrative hours. Over time, repetitive inefficiencies erode productivity and contribute to broader compliance fatigue within plan operations.

CRF recommends that CMS adjust validation sequencing so that error messages are triggered only after the relevant data entry screen has been completed. Logical sequencing should reflect user workflow: validation should occur at the point where required information is actually entered, rather than preemptively on a preceding screen. Aligning error prompts with natural workflow reduces redundant navigation and enhances submission clarity.

CMS should also incorporate structured user-centered testing prior to finalizing interface changes. Engaging plan administrators in usability testing can identify unintended workflow bottlenecks and ensure that system logic reflects real-world navigation patterns. Interface refinement is often most effective when informed by those responsible for daily operational execution.

Addressing validation logic represents a low-cost, high-return improvement. Unlike structural architecture redesign, user interface sequencing adjustments require relatively modest technical modification yet can yield immediate efficiency gains. Streamlined navigation improves submission accuracy, reduces compliance time, and enhances overall system usability.

Modernization encompasses not only data structure but also user experience. By eliminating unnecessary workflow friction within the PBP interface, CMS can advance administrative efficiency without altering substantive reporting requirements. Such refinements demonstrate that disciplined regulatory governance includes attention to operational detail, not merely high-level policy objectives.

VI. SSBCI Package Flexibility and Reporting Accuracy

CMS's proposed enhancements to Special Supplemental Benefits for the Chronically Ill (SSBCI) reporting requirements reflect an effort to improve transparency and oversight. Requiring plans to report the expected number of enrollees eligible for, and expected to utilize, each SSBCI benefit represents an expansion in structured data collection. Greater visibility into benefit targeting and anticipated utilization can support program evaluation and policy refinement.

However, expanded reporting obligations must be aligned with appropriate structural flexibility. If plans are limited to consolidating multiple SSBCI benefits into a single package within a plan, new reporting fields may require aggregation of distinct benefits that serve different clinical populations. Forced aggregation can obscure meaningful distinctions between benefits designed for separate chronic conditions or structured with different eligibility criteria.

Such aggregation raises reporting accuracy concerns. Combining multiple SSBCI offerings into one package may dilute the precision of projected eligibility and utilization estimates. It may also complicate CMS's ability to evaluate whether specific benefits are appropriately targeted and effectively used. Structural rigidity in package design, when paired with granular reporting requirements, creates internal tension between administrative convenience and data fidelity.

CRF therefore recommends that CMS permit multiple SSBCI packages within a single plan. Allowing discrete packages for distinct benefit designs would better align structural architecture

with the expanded reporting framework. Plans could then provide precise projections tied to each targeted intervention without resorting to artificial consolidation.

Structural flexibility directly supports reporting precision. When benefit packages accurately reflect underlying clinical targeting, eligibility criteria, and design variation, the resulting data are more reliable and analytically useful. Precision in reporting strengthens oversight and reduces the likelihood of misinterpretation arising from aggregated categories.

Moreover, improved structural alignment enhances transparency and beneficiary comparability. When SSBCI offerings are clearly delineated and accurately reported, CMS can more effectively present information to beneficiaries evaluating plan options. Clear differentiation among targeted benefits supports informed enrollment decisions and reinforces the integrity of the Medicare Advantage marketplace.

By pairing expanded reporting requirements with structural flexibility, CMS can achieve its transparency objectives while preserving data accuracy and operational clarity. A calibrated approach ensures that increased visibility into SSBCI offerings enhances comparability without introducing unnecessary reporting distortion or administrative burden.

VII. Institutional Discipline and Burden-to-Utility Review

The Paperwork Reduction Act embodies a clear principle of regulatory proportionality: information collections must be necessary for the proper performance of agency functions, possess practical utility, and minimize burden to the extent feasible. These standards require more than procedural compliance. They call for disciplined evaluation of whether incremental reporting requirements meaningfully advance program integrity relative to their operational and economic cost. As CMS considers structural revisions to the PBP and formulary framework, adherence to this proportionality mandate is essential.

CRF encourages CMS to estimate the incremental engineering hours associated with the proposed changes. Structural reporting revisions often require database redesign, workflow reconfiguration, validation logic updates, regression testing, and system deployment. These efforts consume internal technology resources and external vendor capacity. Quantifying anticipated development hours provides a clearer understanding of the capital implications of modernization initiatives.

Beyond engineering hours, CMS should assess vendor and compliance staffing impacts. Many MA organizations depend on third-party platforms for prior authorization management, formulary administration, and bid submission tools. Structural changes may require contract amendments, software development cycles, and ongoing maintenance updates. Additionally, compliance teams must adapt documentation, training protocols, and quality assurance processes. These staffing implications are real and measurable components of regulatory burden.

A disciplined review should also compare marginal transparency or automation gains against these costs. If a reporting modification produces limited improvement in CMS's analytic

capacity or beneficiary comparability, but imposes significant system redesign expenses, proportionality concerns arise. Conversely, where structured refinements demonstrably enhance oversight efficiency or reduce manual review, the case for implementation strengthens. Such comparative analysis ensures that modernization investments yield commensurate public value.

CRF recommends that CMS publish a burden reassessment reflecting these considerations prior to finalization of major structural changes. Transparent evaluation fosters accountability and allows stakeholders to understand the empirical basis for implementation decisions. Updated burden estimates that incorporate transitional engineering and vendor costs will better align PRA compliance with operational reality.

Alignment with Office of Management and Budget review standards is also critical. OMB oversight exists to ensure that information collection revisions reflect cost-benefit discipline and avoid unnecessary administrative expansion. Proactive cost-benefit alignment at the agency level strengthens the defensibility of final rules and enhances institutional credibility.

Establishing a formal burden-to-utility review framework would represent durable governance reform. Such a framework could be applied consistently to future PBP and formulary modifications, creating predictable standards for evaluating structural changes. Plans would benefit from clearer expectations, and CMS would benefit from improved policy calibration.

Institutional discipline does not impede modernization; it strengthens it. By embedding proportionality analysis into structural decision-making, CMS can advance transparency, automation, and beneficiary comparability while safeguarding affordability and operational stability. A structured burden-to-utility review model ensures that modernization efforts remain economically grounded and administratively sustainable over the long term.

Conclusion

CRF strongly supports the continued integrity, transparency, and consistent oversight of the Medicare Advantage and Part D programs. Structured data submission, standardized reporting, and enhanced electronic comparability are legitimate objectives that can strengthen beneficiary confidence and improve CMS's review capacity. The modernization of reporting architecture, when properly calibrated, can advance both accountability and program stability.

Disciplined paperwork reform strengthens—not weakens—program integrity. The Paperwork Reduction Act reflects a recognition that administrative expansion, if left unchecked, can erode efficiency and distort resource allocation. Careful evaluation of reporting changes ensures that information collected serves a clear and necessary purpose, enhances practical utility, and avoids imposing disproportionate burdens. Such discipline reinforces the credibility of federal oversight.

Automation must increase—not decrease—under modernization initiatives. Structured taxonomy, indication-level clarity, and enhanced reporting frameworks should expand scalable electronic processing and reduce manual review. Where structural changes risk compressing clinical nuance or introducing redundant duplication, automation pathways may contract rather

than grow. Modernization should be measured by improvements in efficiency, accuracy, and predictability.

Administrative costs in Medicare Advantage are economically material. Compliance redesign, vendor reconfiguration, and system architecture changes enter bid development and influence the allocation of rebate dollars and supplemental benefits. Even incremental increases in administrative overhead, when multiplied across hundreds of contracts, affect affordability and competitive stability. Reporting reforms should therefore be calibrated to preserve program value for beneficiaries.

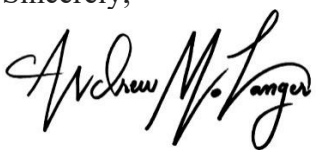
Proportionality and predictability are essential principles of sound governance. Structural reporting changes warrant structured evaluation of incremental benefit relative to transitional and ongoing costs. Phased implementation, stakeholder collaboration, and transparent burden reassessment strengthen policy durability and reduce operational risk. Predictable modernization enhances market stability and compliance confidence.

CRF encourages CMS to refine aspects of the proposed framework where structural duplication, taxonomy rigidity, or interface friction may exceed their practical utility. Precision in architecture design—such as structured referencing for prior authorization, supplemental taxonomy modifiers, phased implementation timelines, and user-centered interface sequencing—can achieve transparency goals without expanding unnecessary complexity.

CRF remains committed to lawful, economically grounded, and affordability-focused regulatory reform. Modernization and burden discipline are not competing objectives; they are complementary pillars of durable governance. By pairing transparency enhancements with proportional implementation and operational realism, CMS can advance program integrity while safeguarding the economic sustainability of Medicare Advantage.

We appreciate the opportunity to provide these comments and look forward to continued engagement that strengthens oversight, improves beneficiary comparability, and ensures that regulatory reform remains anchored in practicality, predictability, and disciplined administration.

Sincerely,



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February 20, 2026

William N. Parham, III
Director
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Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS Plan Benefit Package (PBP) and Formulary 2027 (CMS-R-262)

Dear Director Parham:

CVS Health appreciates the opportunity to comment on the Paperwork Reduction Act Submissions CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262, OMB 0938-0763) released on December 22, 2025.

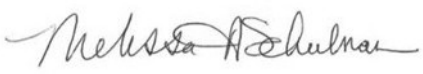
We appreciate CMS' stated objective to reduce provider burden, minimize beneficiary access barriers, and promote adoption of electronic prior authorization (ePA). We share CMS' interest in ensuring that Part D PA criteria are clear, standardized where appropriate, and operationally feasible for sponsors, prescribers, and beneficiaries. We also recognize CMS' concern that overly complex and frequently changing diagnostic criteria can hinder ePA adoption and increase administrative burden.

At the same time, we would ask that CMS consider the level of effort and steps required to implement and maintain the proposed CY 2027 Formulary and Prior Authorization (PA) file layout changes. As described below, the combination of compressed implementation timelines, structural changes to how PA criteria must be reported, and the proposed use of indication code sets, particularly as those code sets have not yet been defined, introduces substantial operational, financial, and compliance risk for all sponsors.

We appreciate CMS' willingness to engage stakeholders through the PRA process and to consider operational realities and impacts alongside policy goals. We respectfully urge CMS to defer implementation to CY 2028 for the Formulary and PA file layout changes or, at a minimum, to finalize these requirements in a manner that minimizes duplicative effort, reduces risk to beneficiaries, and allows sponsors to implement changes thoughtfully and accurately.

We look forward to continued collaboration with CMS to advance shared goals of beneficiary access, provider efficiency, and sustainable program administration. Please see the attached Appendices for further information on the impact of these changes and technical questions and recommendations to the proposed changes to the Formulary and PA files. Please do not hesitate to contact us with any questions regarding these comments.

Sincerely,



Melissa Schulman
Senior Vice President, Government & Public Affairs CVS Health

Appendix I

Implementation Timing and Runway

CMS proposes to require adoption of a substantially altered submission format for Formulary and PA files for CY 2027, with submissions beginning May 8 and closing June 1, 2026. This leaves sponsors fewer than three months to successfully complete the following:

- Design and build significant system enhancements across formulary, utilization management, and downstream platforms
- Convert existing P&T-approved PA criteria into a materially different data structure without affecting the clinical integrity and intent
- Map free-text clinical criteria into new coded and discrete fields
- Develop, test, and validate updated quality assurance processes, and
- Rebuild downstream processes that rely on these data, including public-facing PA criteria documents for beneficiaries and providers.

For all sponsors and PBMs serving Medicare members, this effort is significant. For example, many plans maintain over a thousand distinct Medicare Part D PA criteria sets. Even modest structural changes, when multiplied across this volume, result in many thousands of hours of clinical, operational, and technical work. Importantly, these activities must occur in parallel with other activities such as ongoing formulary maintenance, FDA approval monitoring, ongoing drug compendia monitoring for changes in medically accepted indications for which PA may be approved, and bid- and benefit-related workstreams. This work is highly skilled in nature and requires substantial institutional knowledge and/or clinical expertise to execute accurately.

As such, we respectfully request that CMS consider allowing sponsors to continue using the current Formulary and PA file formats for the CY 2027 submission year, with the updated format becoming mandatory no earlier than CY 2028. This additional runway would allow sponsors to implement the new standard in a deliberate, accurate, and sustainable manner.

If CMS is unable to defer implementation until CY 2028, we strongly urge CMS to communicate the finalized details and clarifications as soon as possible, but no later than March 13, 2026 without additional fields added to the proposed format.

Concerns With Indication-Level Reporting and Duplicative PA Attributes

As we understand the proposed layout, sponsors would be required to submit PA attributes separately for each covered indication for a drug. In practice, many PA attributes—such as approval duration, prescriber requirements, or refill limits—are

identical across all covered indications. Requiring sponsors to submit the same information repeatedly for each indication introduces substantial duplicative effort with little incremental value.

We recommend that CMS allow sponsors to submit PA attributes a single time when those attributes apply uniformly across all covered indications for a drug. Only when PA requirements meaningfully differ by indication should sponsors be required to break out indication-specific records. This approach would:

- Reduce unnecessary data entry and maintenance,
- Lower the risk of internal inconsistencies across otherwise identical criteria,
- Improve data quality for CMS review, and
- Better align with CMS' stated goal of reducing administrative burden.

Absent this flexibility, sponsors will face ongoing operational strain each time a criterion is updated, even when the update has no clinical relevance to individual indications.

Significant Concerns With Use of Indication Code Sets

We have serious concerns about CMS' proposal to require use of a code set to identify covered indications within PA criteria submissions.

Operational and Clinical Risk

If the selected code set is highly granular, sponsors will be required to identify, validate, and submit potentially large numbers of diagnosis codes for each covered indication. This creates several risks:

- Increased likelihood of inadvertently omitting relevant codes, which could result in inappropriate PA denials, delaying care for beneficiaries who should otherwise qualify,
- Greater frequency of updates and resubmissions to address coding inconsistencies, and
- Increased difficulty for clinical reviewers and business users to identify inaccuracies, as codes are far less intuitive than narrative descriptions.

Conversely, if the code set is too high-level, it may not allow sponsors to meaningfully distinguish between clinically distinct indications. For example, differentiating among specific WHO groups of pulmonary hypertension is not straightforward using many common code sets, despite the clinical importance of those distinctions. A similar challenge exists for oncology drugs. Many cancer therapies are indicated only for highly specific clinical scenarios based on tumor

genetics or biomarkers, disease stage, patient functional status, prior lines of therapy, or response to previous treatment. These distinctions are often central to PA criteria but are not readily or reliably captured through diagnosis code sets alone.

Lack of Industry Readiness

Successful adoption of indication coding will require:

- Time for sponsors to understand and interpret the selected code set once it is defined by CMS,
- Iterative clarification and guidance from CMS as questions arise,
- Conversion of existing free-text criteria into codes, and
- Development of robust quality assurance processes to ensure accuracy, consistency, and completeness.

Compression of these activities into the limited timeframe proposed for CY 2027 would create significant risk to data integrity and potentially beneficiary access (e.g. if relevant codes are missed).

Impact on Beneficiary- and Provider-Facing PA Documents

Today, sponsors are able to generate public-facing PA criteria documents by simply extracting the free-text criteria submitted to CMS. This results in a single policy document for a given drug. If this same process is used to generate public facing criteria using the revised format proposed in the PRA:

- Each indication-level PA record could result in a much lengthier and less member-friendly PA criteria document, fragmenting information that is currently presented cohesively;
- If indication codes are submitted without accompanying narrative descriptions, those codes would have to be translated prior to inclusion in the beneficiary- and provider-facing materials, introducing risk and potentially reducing readability and comprehension.

To preserve clear and concise, understandable communications, sponsors would need to build new systems capable of collapsing multiple indication-level records into a single, coherent PA criteria document and translating indication codes back into meaningful, plain-language descriptions.

Appendix II: Technical Questions and Recommendations

1) **PA_Indication_Indicator** (proposed to be moved to the Formulary Submission File Record Layout)
   a) **Reconciling the PA_Indication_Indicator with the Prior_Authorization_Group_Indication Field**
      i) How will CMS reconcile this field with the Prior_Authorization_Group_Indication Field?
      ii) How should this field be populated if both FDA-approved and medically accepted off- label indication(s) apply to the same indication code?
         - If the code encompasses both an FDA-approved and medically accepted off- label use, would this be submitted as a value of 1 or 4?
         - For example, if a drug has an FDA-approved indication for advanced or metastatic non-small cell lung cancer and a medically accepted off label indication for recurrent non-small cell lung cancer, and the Indication Code is M0003440 (Carcinoma, Non-Small-Cell Lung), what PA_Indication_Indicator should be submitted on the Formulary File?

           Recommendation: A value of 4 – All FDA and some medically accepted indications to be submitted on the Formulary File.

2) **Prior_Authorization_Group_Indication Field**
   a) **Source of Indication Codes**
      i) What coding system(s) will CMS require or accept (e.g., SNOMED CT, MeSH, RxNorm, NPPES Taxonomy)?
      ii) Will CMS provide the codes in a reference file (e.g. similar to the Indication Reference File) and if so, when will that be available?
      iii) How often will they be updated (monthly or final list annually)?
      iv) Is a separate code required for each indication? Including FDA-approved indications with no Required Medical Information?

   Recommendation: Indication codes should be made available in a reference file as soon as possible, but no later than March 13 to allow sufficient time to map all criteria. It is critical to have a confirmed source of codes and specific instructions for population of this field as soon as possible to ensure compliance and accuracy. We also recommend that the file should be updated no more than annually except in unique circumstances, such as when a novel drug is newly FDA-approved and no suitable indication code is currently available. Also, if there are ever significant annual updates are made

to the diagnosis code source, ample advance notice will be required to remap all criteria accurately and timely.

b) Inclusion of Code Only vs. Code + Description

i) Please confirm that **only** the indication code is to be included in this field (e.g. M0003440), and not a corresponding description of the indication (e.g. M0003440 Carcinoma, Non-Small-Cell Lung). This is unclear due to the 500-character maximum field length.

c) Requirement for All FDA approved indications

Currently, a value is submitted in the PA_Indication_Indicator field (e.g., 1 = All FDA approved Indications) to describe indications for which the PA will be approved.

i) If all FDA approved indications are covered with either no additional requirements (i.e., no required medical information, no age or prescriber restrictions, etc.) or if all other requirements are identical for all indications, will submission of an indication code be required for each individual FDA-approved indication?

ii) If not, how should this field be populated? For example, will a code be available to indicate "All FDA-approved indications?"

Recommendation: A code should be made available to indicate "All FDA-approved indications" to avoid the need to break out criteria by each individual indication. Today, plans can submit values to describe indications for which the PA will be approved. A requirement to specify each FDA-approved indication and convert them to indication codes will require significant effort and risk to data integrity and beneficiary access (e.g. if relevant codes are missed).

d) Handling Missing Codes

i) If no appropriate indication code exists, how should this field be populated (e.g., "N/A," null, or free text description of the indication)?

Recommendation: Provide a code to indicate "Other" indications when an appropriate indication code is not available. The "Other" indication could be specified in the Required_Medical_Information or Other_Criteria fields.

e) Repetition of subsequent fields when the PA applies to more than one indication

The Field Description provides these instructions: *"Enter the indication code for which the prior authorization applies. If the prior authorization applies to more than one indication, the subsequent fields should be repeated for each indication, and the information entered should correspond only to that specific indication."*

We have discussed multiple interpretations of how this instruction might be translated when more than one indication code is involved. To illustrate, see Appendix 2 for four examples of how two PA Group Indication Codes would be submitted.

i) Please confirm which interpretation aligns with CMS expectations; specifically, the intent if more than one PA group indication code is required. Previous communication with CMS has confirmed Example 4; please confirm this with final guidance.

3) <u>Age_Restrictions Field</u>

a) Submission of age criteria under one year of age

i) Please clarify the format to submit criteria for age restrictions under one year of age. For example, how should age criteria such as "1 month or older" or "3 months or older" be submitted? Should decimal years (e.g., 0.25 for 3 months) be used?

4) <u>Prescriber_Restrictions Field</u>

a) Prescriber Type Code Source

i) Please confirm the coding system(s) CMS expects plans to use (e.g., NPPES Taxonomy).

ii) Please clarify what prescriber type code will be accepted and source of these codes. Will CMS provide the codes in a reference file and if so, when will that be available?

iii) How often will the codes be updated (e.g. an annual list)?

Recommendation: These codes should be made available in a reference file as soon as possible, but no later than March 13 to allow sufficient time to map all criteria. It is critical to have a confirmed source of prescriber type codes and specific instructions for population of this field as soon as possible to ensure compliance and accuracy. We also recommend that the file should be updated no more than annually. Also, if there are ever significant annual updates are made to the prescriber code source, ample advance notice will be required to remap all criteria accurately and timely.

b) Use of Narrative Language for Prescriber Type Codes

i) Our current criteria frequently use phrasing such as "prescribed by or in consultation with [specialty]" or "prescribed by or in consultation with a physician who specializes in the treatment of [disease]." The proposed format does not appear to allow for this language. Will CMS permit continued use of this language, either within this field or elsewhere?

ii) If so, how should this be submitted?

Recommendation: If this language cannot be submitted on the PA criteria file, we recommend that the ability to indicate use by or in consultation with a specialist be permitted on posted PA criteria documents.

c) Handling Missing Codes

i) If no appropriate Prescriber Type code exists, how should plans populate the field (e.g., "N/A," null, or free text description of the Prescriber Restriction)?

Recommendation: Provide a code to indicate "Other" Prescriber Types when an appropriate code is not available. The "Other" Prescriber Type could be specified in the Required_Medical_Information or Other_Criteria fields.

5) <u>Coverage_Duration Field</u>

The draft specification introduces duration categories including **d** = Months, (number of months) and **e** = Days, (number of days).

i) Below are examples needing clarification. What is the required format for submission of the below scenarios? We recommend the first bulleted option (bolded).

<u>Months (Option d)</u>

- **d,10**
- d10
- d (enter information in the other criteria box)

<u>Days (Option e)</u>

- **e,270**
- e270
- e (enter information in the other criteria box)

Other questions:

b) Maintenance process for new FDA approved indications or new medically accepted off- label uses

i) Please provide guidance regarding the maintenance process to submit new indications approved by the FDA or new medically accepted off-label uses. Will there be any changes to the file layout used to request criteria changes or the outlier justification file?

c) Marketing requirements

i) Will these layout changes require any new requirements for marketed documents, including the Part D Model Formulary (Abridged and Comprehensive)?

- For example, would a representation of the submitted value for PA_Indication_Indicator (proposed to be moved to the Formulary Submission File Record Layout) be required to be displayed on the formulary document?
- Will the PA file layout changes result in any new requirements for how PA criteria should be formatted for posting on plan websites?

Appendix III: Examples

Example 1: The two PA group indication codes have their own distinct section on the line:

PA_Change_Type	Prior_Authorization_Grou p_Desc	Prior_Authorization_Grou p_Indication	PA_Criteria_Change_Indicator 1	Exclusion_Criteria 1	Required_Medical_Information 1	Age_Restriction_Modifier 1	Age_Restrictions 1	Prescriber_Restrictions 1	Coverage_Duration 1	Other_Criteria 1	Part_B_Prerequisite 1	Prerequisite_Therapy_Required 1	Prior_Authorization_Grou p_Indication	PA_Criteria_Change_Indicator 2	Exclusion_Criteria 2	Required_Medical_Information 2	Age_Restriction_Modifier 2	Age_Restrictions 2	Prescriber_Restrictions 2	Coverage_Duration 2	Other_Criteria 2	Part_B_Prerequisite 2	Prerequisite_Therapy_Required 2

Example 2: The 2nd PA group indication code is entered after the 1st code, then the two remaining field sets are entered:

PA_Change_Type	Prior_Authorization_Grou p_Desc	Prior_Authorization_Grou p_Indication	Prior_Authorization_Grou p_Indication	PA_Criteria_Change_Indicator 1	Exclusion_Criteria 1	Required_Medical_Information 1	Age_Restriction_Modifier 1	Age_Restrictions 1	Prescriber_Restrictions 1	Coverage_Duration 1	Other_Criteria 1	Part_B_Prerequisite 1	Prerequisite_Therapy_Required 1	PA_Criteria_Change_Indicator 2	Exclusion_Criteria 2	Required_Medical_Information 2	Age_Restriction_Modifier 2	Age_Restrictions 2	Prescriber_Restrictions 2	Coverage_Duration 2	Other_Criteria 2	Part_B_Prerequisite 2	Prerequisite_Therapy_Required 2

Example 3: The 1st and 2nd PA group indication codes are entered into the same field, then the two remaining field sets are entered:

PA_Change_Type	Prior_Authorization_Grou p_Desc	Prior_Authorization_Grou p_Indication 1; Prior_Authorization_Grou	PA_Criteria_Change_Indicator 1	Exclusion_Criteria 1	Required_Medical_Information 1	Age_Restriction_Modifier 1	Age_Restrictions 1	Prescriber_Restrictions 1	Coverage_Duration 1	Other_Criteria 1	Part_B_Prerequisite 1	Prerequisite_Therapy_Required 1	Prior_Authorization_Grou p_Indication 2	PA_Criteria_Change_Indicator 2	Exclusion_Criteria 2	Required_Medical_Information 2	Age_Restriction_Modifier 2	Age_Restrictions 2	Prescriber_Restrictions 2	Coverage_Duration 2	Other_Criteria 2	Part_B_Prerequisite 2	Prerequisite_Therapy_Required 2

Example 4: Although this was not interpreted from the provided field layout, having the two PA group indication codes on their own separate lines would be the most streamlined way for our formulary system to be configured to intake and output the data.

Previous communication with CMS has confirmed Example 4; please confirm this with final guidance.

PA_Change_Type	Prior_Authorization_Grou p_Desc	Prior_Authorization_Grou p_Indication	PA_Criteria_Change_Indicator 1	Exclusion_Criteria 1	Required_Medical_Information 1	Age_Restriction_Modifier 1	Age_Restrictions 1	Prescriber_Restrictions 1	Coverage_Duration 1	Other_Criteria 1	Part_B_Prerequisite 1	Prerequisite_Therapy_Required 1
PA_Change_Type	Prior_Authorization_Grou p_Desc	Prior_Authorization_Grou p_Indication	PA_Criteria_Change_Indicator 2	Exclusion_Criteria 2	Required_Medical_Information 2	Age_Restriction_Modifier 2	Age_Restrictions 2	Prescriber_Restrictions 2	Coverage_Duration 2	Other_Criteria 2	Part_B_Prerequisite 2	Prerequisite_Therapy_Required 2

Submitted via Federal e-Rulemaking Portal: https://www.regulations.gov/

William Parham
Director, Paperwork Reduction Staff
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services

February 20, 2026

Re: CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262, OMB Control Number 0938-0763)

Mr. Parham,

Elevance Health appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed information collection for the CY 2027 Plan Benefit Package (PBP) and Formulary submission requirements.

Elevance Health is a lifetime, trusted health partner fueled by its purpose to improve the health of humanity. The company supports consumers, families, and communities across the entire care journey – connecting them to the care, support, and resources they need to lead healthier lives. Elevance Health's companies serve more than 104 million people through a diverse portfolio of industry-leading medical, digital, pharmacy, behavioral, clinical, and complex care solutions.

Our comments focus on several proposed changes to the formulary and prior authorization (PA) submission files where additional clarification or refinement would meaningfully improve feasibility, reduce unnecessary burden, and help ensure consistent interpretation across plans.

Formulary File Changes – Prior Authorization Indicators

CMS' list of changes indicates a proposal to move the PA Criteria Change Indicator to the Formulary File and to introduce new validation requirements for drugs subject to Indication-Based Coverage (IBC). However, the CY 2027 Formulary File layout does not appear to include a field that aligns with this description.

Specifically:

- The Formulary File layout includes a new field titled PA_Indication_Indicator, which appears conceptually distinct from the PA Criteria Change Indicator described in the list of changes.

- The PA_Criteria_Change_Indicator field continues to appear only in the Prior Authorization File layout.

We request that CMS clarify:

- Whether a new field is intended to be added to the Formulary File specifically for the PA Criteria Change Indicator.
- If a new field will be added for the PA Criteria Change indicator, what will the final Formulary File layout be for HPMS submission.
- How the new PA_Indication_Indicator field relates to, or differs from, the PA Criteria Change Indicator referenced in the PRA materials.

Clear alignment between the list of changes and the final file layouts is critical to avoid inconsistent interpretation and rework during submission.

Prior Authorization File Changes

1. ***Prior Authorization Group Description – Ingredient Limitation***

The Prior Authorization File instructions state that "only RxCUIs with the same RxNorm ingredient can be included within the same Prior Authorization Group Description."

We request clarification on the scope and intent of this requirement, including:

- Whether CMS intends to prohibit PA groupings that span multiple ingredients but share identical clinical criteria (e.g., high-risk medications across different active ingredients).

- Whether CMS is proposing to limit each PA Group Description to a single RxNorm ingredient, even where clinical appropriateness supports broader grouping.

Absent further clarification, this requirement could significantly increase the number of PA groups plans must maintain without providing additional beneficiary or provider value.

2. ***Prior Authorization Group Indication – Structure and Usage***

The new Prior_Authorization_Group_Indication field raises the following operational questions. We request clarification on the following:

- If a PA group applies to multiple indications, should the PA group be repeated across multiple rows, with one indication per row?
- Alternatively, should multiple indication codes be combined within a single row (e.g., comma-delimited)?
- If multiple rows are required, does this effectively make *PA Group Description + Indication* the primary key for the file?
- If criteria may vary by indication, is CMS permitting different PA criteria for the same group description based on indication?

Additionally, we request clarification on:

- The source of valid indication codes (e.g., alignment with the existing Indication Reference File used for indication-based formularies).
- The rationale for a 500-character field length for a single indication code.

Clear guidance on these points is essential to ensure consistent and accurate submissions.

3. ***Prior Authorization Criteria Change Indicator – CY 2026 vs. CY 2027 Comparison***

The PA_Criteria_Change_Indicator requires plans to assess whether criteria have changed relative to CY 2026. Given that the PA data structure itself is changing for CY 2027, plans will be submitting criteria in a different format even where the underlying clinical policy has not materially changed.

We request clarification on:

- How should plans to assess "change" when data elements and structure differ year over year.
- Whether CMS intends this indicator to capture substantive clinical changes only, rather than technical or structural differences resulting from the new layout.

4. ***Prescriber Restrictions – Code Source and Formatting***

For the Prescriber_Restrictions field, CMS indicates that multiple prescriber type codes may be entered as a comma-delimited field.

We request clarification regarding:

- The source of valid prescriber type codes (e.g., National Plan and Provider Enumeration System (NPPES) taxonomy, CMS-defined list).

- Required formatting for multiple values (e.g., leading zeros vs. no leading zeros).

Standardized guidance will help ensure consistent validation and avoid submission errors.

5. ***Coverage Duration – Field Length and Value Format***

The revised Coverage_Duration field is limited to five characters, yet the description references multiple options, including durations defined by months or days.

We request clarification on:

- Whether the expected submission value is the option letter only (a–e).
- Whether "Other" remains a valid option, with details provided in the Other Criteria field.
- How numeric durations should be submitted (e.g., "d18," "e90").
- How durations exceeding two digits (e.g., 100+ days) should be handled within the five-character limit.

Without additional guidance, plans may interpret this field inconsistently.

6. ***Reduction in Field Length for Other Criteria and Required Medical Information***

CMS proposes reducing the maximum field length for Other Criteria and Required Medical Information to 1,000 characters each.

We are concerned that this reduction may limit plans' ability to clearly and accurately describe complex clinical policies, particularly for drugs requiring nuanced criteria to ensure safe and appropriate use. In some cases, reducing this space could hinder effective communication to providers and beneficiaries and constrain Pharmacy & Therapeutics committees' ability to document clinically appropriate policies.

We respectfully request that CMS consider retaining the current character limits or increasing the proposed limits to better accommodate complex PA criteria.

Conclusion

We support CMS' goals of improving efficiency, transparency, and standardization in the PBP and formulary submission process. Addressing the clarifications outlined above would meaningfully improve operational feasibility while preserving CMS' oversight objectives and minimizing unnecessary burden under the Paperwork Reduction Act.

***

We value the partnership that we have developed with CMS and welcome the opportunity to discuss our comments. Should you have any questions or wish to discuss our comments further, please contact Jeremiah McCoy at 202-302-4028, or jeremiah.mccoy@elevancehealth.com.

Sincerely,

Elizabeth P. Hall
Vice President

PUBLIC SUBMISSION

As of: 2/3/26, 8:00 AM
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Status: Draft
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Comments Due: February 20, 2026
Submission Type: Web

Docket: CMS-2025-1857
CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262)

Comment On: CMS-2025-1857-0001
CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262)

Document: CMS-2025-1857-DRAFT-0002
Comment on CMS-2025-1857-0001

Submitter Information

Email: danielle.bulfamante@evernorth.com
Organization: Express Scripts

General Comment

Dear Sir or Madam,

We are writing to request clarification regarding the CMS 2027 proposed changes released within the CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262 | CMS) on December 22, 2025. We appreciate CMS's efforts to streamline and standardize prior authorization (PA) requirements and would like additional guidance regarding the Prior Authorization Group Indication below. Any information you can provide would be greatly appreciated.

1. When will we know what type of code will be used?
2. How would we submit an indication in situations where:
a. The indication does not have a code?
b. There is not an exact code for the indication?
c. Example: Wegovy to reduce the risk of major adverse cardiovascular events. How would CMS expect us to code this?
3. How specific in the hierarchy of coding would we have to be? i.e., Would "arthritis" count for all types?

From Appendix_C_CY2027_PA_Record_Layout (Pg.1):

Formulary Changes (From Appendix B Pg.6 attached):
1. CMS is proposing revisions to the Prior Authorization File to standardize data entry. Fields under consideration for standardization include Age Restriction, Prescriber Restrictions, and Coverage Duration.

As part of these efforts, CMS is also assessing methods to ensure requirements within a Prior Authorization Group Description (PAGD) apply to all RxCUIs associated with the PAGD. This includes limiting the PA criteria submission to a single ingredient and submitting requirements at the indication level. To align with ingredient- and indication-based PA criteria, CMS is proposing movement of the PA Criteria Change Indicator to the Formulary File, removal of the Off-label Uses field, and addition of a Prior Authorization Group Indication field. CMS is also proposing to reduce the character count of the Other Criteria and Required Medical Information fields.
CMS is considering the use of NPPES Taxonomy codes, SNOWMED CT codes, MeSH codes and/or RxNORM data to validate these fields.

Additionally, could you confirm when final guidance on these proposed changes will be released?

We appreciate your time and look forward to your clarification.

Comments for CMS-R-262: CMS Plan Benefit Package (PBP) and Formulary CY 2027

Thank you for the opportunity to provide feedback on the proposed changes to CMS' Plan Benefit Package (PBP) and Formulary for CY 2027. Our comment concerns CMS' proposal to revise the Prior Authorization (PA) File by standardizing data entry and potentially limiting the submission of PA criteria to a single ingredient at the indication level.

Formulary Changes

Document Name: Appendix _C_CY2027_PA_Record_Layout.pdf

We respectfully request that CMS remove the proposed requirement to limit PA criteria submission to a single ingredient and to require submissions at the indication level for the upcoming plan year. We urge CMS to continue allowing plans to submit PA criteria in the current format, as used in CY 2026, to maintain administrative efficiency and minimize the risk of negative impacts as discussed in detail below.

We disagree with CMS' assessment of the impact burden on plans. Restricting PA criteria submissions solely to the indication level would result in significant administrative burdens on plans without providing proportional benefits to beneficiaries or the overall program.

Many Part D drugs are subject to frequent FDA-approved indication expansions. Requiring indication-level submissions would mean plans must file repeated and often duplicative PA updates, even when coverage criteria remain unchanged. This would substantially increase filing volume, elevate compliance risk, and raise the likelihood of technical errors. In most cases, these updates would be administrative in nature and not reflect clinically meaningful changes.

Furthermore, numerous PA requirements, such as prescriber restrictions, safety monitoring, or step therapy, are appropriately applied at the ingredient level across all indications. Mandating the duplication of identical criteria across multiple indications introduces unnecessary complexity and increases the potential for inconsistencies across CMS files, provider systems, and member communications.

The increased frequency of PA updates also brings a greater risk of timing misalignments, beneficiary confusion, and unintended access disruptions.

For these reasons, we respectfully urge CMS to maintain the current approach to PA criteria submissions for CY 2027 and beyond. Thank you for your consideration of our comments.

February 20, 2026

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Document Identifier: CMS-R-262/ OMB Control Number: 0938-0763
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Subject: Comments on Proposed Information Collection Activities: CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262)

Dear Sir/Madam,

Highmark Inc. ("Highmark") is one of America's largest health insurance organizations and an integral part of Highmark Health, an integrated healthcare delivery and financing system. With a commitment to improving the health and well-being of the communities we serve, Highmark provides a wide range of health insurance products and services, including extensive Medicare Advantage and Prescription Drug Plans. Our mission is to deliver high-quality, affordable healthcare solutions that prioritize patient care, innovation, and value.

Highmark appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed information collection activities, specifically those outlined for the CY 2027 Plan Benefit Package (PBP) and Formulary (CMS-R-262). While we acknowledge CMS's objective to enhance standardization and streamline electronic prior authorization (ePA) processes, we have significant concerns regarding the administrative burden and operational challenges these proposed changes will impose on health plans within the extremely tight timeframe for the CY 2027 submission.

The proposed changes to the CY 2027 Part D Formulary and Prior Authorization (PA) submissions represent a fundamental shift from existing descriptive, free-text entries to highly structured, granular, and coded data. This transformation would necessitate a complete overhaul of current processes and systems, impacting various critical areas:

Key Changes and Their Significant Operational Impact:

1. **Stricter Grouping Rules for Prior Authorization:** The requirement that PA groups (across both the Formulary and PA File) must now be restricted to drugs with the same

RxNorm ingredient will force a comprehensive re-segmentation of all existing PA groups. This change alone would exponentially increase the number of data lines to be managed manually. For example, a single PA group for opioids, previously represented by one line, could expand to over 200 lines of data. This creates a massive manual workload that directly contradicts CMS's assessment of "minor impact" for plans.

2. **Granular Indication Specification:** The introduction of new fields demanding explicit "indication codes" for PA, both high-level in the Formulary and specific in the PA Criteria File, requires precise documentation of approval conditions. This level of granularity mandates a sophisticated coding capability that is not typically a core function of pharmacy management or operations teams, necessitating an unreasonably rapid reallocation of resources.

3. **Standardized Coded Data Formats:** The transition of fields such as age restrictions, coverage duration, and prescriber restrictions from free-text to specific codes or structured formats (e.g., Age Modifier + Age; coded duration values; prescriber type codes like NPI Taxonomy) requires extensive re-mapping of existing data and the implementation of new data capture processes.

4. **Reduced Free-Text Capacity:** Significantly reduced character limits for "Required_Medical_Information" and "Other_Criteria" fields compel extreme conciseness, which may inadvertently compromise the clarity and completeness of necessary clinical information for PA decisions.

5. **Removal of "Off-label_Uses" Field:** The elimination of this dedicated field means alternative documentation strategies must be developed, likely within the new structured indication fields or "Other_Criteria," further complicating data entry.

Highmark's Specific Concerns and Operational Challenges:

- **Unrealistic Implementation Timeline:** The proposed changes are significant and far-reaching, requiring extensive data re-mapping, system modifications, and new data capture processes. To mandate the implementation of these comprehensive changes for the CY 2027 submission, due in just over three months, is highly impractical and places an undue burden on health plans. This timeline does not allow for adequate system development, testing, and training.

- **Increased Manual Workload and Risk of Errors:** The breakdown of utilization management (UM) and prior authorization criteria to an individual drug-by-indication basis will lead to an exponential increase in the volume of data. This will result in a massive manual workload, which is highly prone to errors given the complexity and scale

of the required data entry. Many Plans encounter a significant deficiency in certified coding expertise within their pharmacy formulary and prior authorization teams.

- **Lack of Certified Coders:** The new requirement for precise "indication codes" (e.g., ICD-10, SNOMED) poses a significant challenge. Many plans may lack certified coders within their pharmacy formulary and prior authorization teams with the expertise to accurately identify these codes for drug-specific indications. This in combination with the compressed timeframe for compliance creates substantial risk regarding the accuracy and compliance of submissions.
- **Unclear Definition of "Indication":** Without a clear and comprehensive definition of "indication" from CMS, plans face significant uncertainty in data entry and interpretation, increasing the likelihood of inconsistent submissions and potential compliance issues.
- **Impact on External Vendors (ESI):** The proposed changes will directly affect external partners, such as Pharmacy Benefit Managers, which process and build MSD files. This adds another layer of complexity and requires coordination and system updates that cannot be accomplished within the current timeline.

Regulatory Process Concerns:

We question whether CMS is appropriately utilizing a form change (Information Collection Request, or ICR) to implement such a fundamental and far-reaching regulatory requirement change. Such a significant shift, with its widespread implications for health plan operations and compliance, would typically warrant a formal regulatory open comment process to allow for thorough industry feedback and adequate preparation time. The justification for these changes, referencing the Inflation Reduction Act (IRA), also requires further clarification regarding its direct applicability to the scope and nature of these specific data collection modifications.

Inferred CMS Motivation and Potential Provider/System Impact:

While we understand CMS may be aiming to automate its review of clinical criteria and potentially shift data entry burdens from its reviewers to plans, these changes are likely to create a more complex data entry process for provider office staff. This could inadvertently lead to an increase in rejections and appeals, ultimately impacting beneficiary access to care. Concerns also exist regarding the feasibility of building the required system integrations for ePA within the compressed timeframe, which could hinder the very goal of streamlining the process.

In conclusion, the proposed changes for CMS-R-262 represent a significant administrative and operational burden that cannot be reasonably implemented within the stipulated timeframe for the CY 2027 submission. Without changes to this proposal, **many impacted health plans,**

potentially unaware of these significant changes being introduced through an information collection request rather than a more visible regulatory process, could be at risk for non-compliance, or a drastic reduction in utilization management programs to simplify data reporting, which would be detrimental to beneficiary care. We urge CMS to reconsider proposing such fundamental changes through an information collection request and instead utilize a more appropriate and visible process, such as a proposed rule or other formal guidance, to ensure adequate industry awareness and robust public comment.

We strongly urge CMS to:

1. **Delay implementation** of these comprehensive changes to allow health plans sufficient time for system development, data re-mapping, staff training, and the recruitment of specialized coding expertise.

2. **Provide clear and detailed guidance** on the definition of "indication" and acceptable coding standards.

3. **Reconsider the scope and granularity** of the required data elements, potentially phasing in changes or offering more flexible reporting options.

4. **Engage in a formal regulatory open comment process** for changes of this magnitude, ensuring broader industry input and a more collaborative approach to implementation.

Thank you for considering our concerns. We are committed to collaborating with CMS to ensure that program requirements are met efficiently and effectively, without compromising our ability to serve our Medicare beneficiaries.

Respectfully,

Amy Sawyer
Director Health Policy
Highmark, Inc.

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Humana

February 18, 2026

William N. Parham, III
Director, Paperwork Reduction Staff
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: CMS Plan Benefit Package (PBP) and Formulary 2027 (CMS-R-262; Docket ID CMS-2025-1857)

Dear Mr. Parham:

This letter is in response to the Centers for Medicare and Medicaid Services (CMS) agency information collection notice "CMS Plan Benefit Package (PBP) and Formulary 2027 (CMS-R-262)" as issued on December 22, 2025.

Humana Inc., headquartered in Louisville, Kentucky, is a leading health care company that offers a wide range of insurance products and health and wellness services that incorporate an integrated approach to lifelong well-being. Humana currently serves approximately 7 million beneficiaries enrolled in our Medicare Advantage (MA) plans and 3.8 million beneficiaries enrolled in our Medicare Part D Prescription Drug Plans (PDPs). As one of the nation's top contractors for MA, we are distinguished by our long-standing, comprehensive commitment to Medicare beneficiaries across the United States. These beneficiaries – a large proportion of whom depend upon the MA program as their safety net – receive integrated, coordinated, quality, and affordable care through our plans. Our perspective is further shaped by the comprehensive medical coverage we provide for Medicaid beneficiaries in seven states.

PRA List of Changes

Prior Authorization Criteria Change Indicator
CMS is proposing to move the Prior Authorization (PA) Criteria Change Indicator to the Formulary File. As part of these changes, CMS is proposing to require that if the prior authorization applies to more than one indication, the subsequent fields should be repeated for each indication, and the information entered should correspond only to that specific indication.

> **Humana Comment:** While we support CMS's efforts to make the prior authorization submission and review process more efficient and improve the transparency of prior authorization requirements for beneficiaries and providers, we are concerned that CMS's proposed changes to the PA Group Indicator field - even *if* operationally feasible - would necessitate major overhauls

to formulary and prior authorization management systems under a very tight timeline for implementation.

Currently, plans may submit one prior authorization record that includes all applicable indications. However, under CMS's proposal, if a single drug has 10 indications each requiring prior authorization, for example, plans would be required to re-enter the same information 10 separate times for each indication. Not only are the existing platforms not designed to manage prior authorization records at an indication-by-indication level, but this change in itself is also a significant operational lift considering the vast number of drugs and medical conditions that this process would apply to.

Our understanding of the intent of this proposal is to increase the automation of electronic prior authorization reviews, and Humana is fully aligned with this mission and goal. Today, we do not use these txt files for policy integration into our PA tools or for question set development. Humana already achieves a high level of clinical automation within our Medicare PA program: over 70% of our PA policies include at least one automated approval pathway, and for requests submitted via ePA platforms, clinical automation supports approximately 82% of approval determinations. Our current framework already delivers fast, consistent, and scalable automated decisions at a level aligned with CMS's goals for modernization and burden reduction.

The Trump Administration has made it a priority to streamline regulations and reduce administrative burdens on Medicare program stakeholders; however, this change seem counter to that broader intent. Humana anticipates significant costs associated with this change, both for our internal team and our vendors. We encourage CMS to work with plans to explore alternative options for improving the PA process. If CMS insists on pursuing this change, given the scale and complexity of these proposed changes, we request that CMS delay implementation to CY 2028 and work to enhance the current medical coding systems to care for the important clinical scenarios described below.

Humana is also concerned about CMS's proposed MeSH CUI mapping requirement. Below, we outline several examples to illustrate the potential unintended consequences with this proposal.

- **Humana's current Gammunex - IVIG policy includes FDA-approved and compendia-supported indications** that are intentionally incorporated into structured criteria to enable automated, consistent approvals and reduce manual clinical review. Under the proposed CY 2027 requirement that PA criteria map only to MeSH CUIs, several clinically essential IVIG indications – including even the FDA-approved indication for Primary Humoral Immunodeficiency – cannot be represented because no corresponding MeSH CUI exists. Simplifying the policy by removing these criteria would make it appear less complex; however, doing so would actually reduce transparency, slow determinations, and increase provider and plan burden by forcing many previously automatable cases into manual review.
- **Juvenile arthritis illustrates the same taxonomy gap we identified for IVIG.** The MeSH list collapses systemic, polyarticular, and enthesitis-related juvenile arthritis into a single category ("Arthritis, Juvenile"), despite the fact that these subtypes have materially different first-line and escalation pathways (e.g., NSAIDs vs csDMARDs vs early biologics). Our current criteria encode these subtype-specific pathways to support automation and consistent,

timely decisions. Under a MeSH-only submission model, these distinctions cannot be represented, forcing many cases into manual review – reducing transparency, increasing variability, and slowing access. This is a structural limitation of the MeSH subset, not a policy-writing choice, and it runs counter to CMS's goals for streamlined, electronic PA.

- **Oncology therapies** also illustrate limitations of the proposed MeSH CUI model. Cancer indications frequently rely on line of therapy, metastatic status, prior treatment exposure, and biomarker defined subpopulations, none of which can be represented in MeSH. For example, Xtandi (enzalutamide) has distinct FDA approved and compendia supported uses across castration resistant vs. castration sensitive disease, metastatic vs. nonmetastatic states indications. Because MeSH maps all prostate cancer uses to a single broad category, these clinically critical distinctions cannot be encoded, resulting in less transparent criteria and increased reliance on manual review.

Given the concerns highlighted above, we respectfully recommend that CMS allow inclusion of medically accepted indications that lack a MeSH CUI, or, expand the MeSH list to cover key FDA-approved and compendia-supported uses so standardization can be achieved without reducing automation or timely member access.

PBP Data Entry System Screens - Additional Benefits Packages (MA UF/SSBCI) – 19b

CMS is proposing changes to the PBP data entry system.

Humana Comment: Humana offers the following recommendation to improve user navigation and workflow and eliminate unnecessary administrative burden. When a user leaves the 'Additional Benefits Packages' (19b) data entry field blank, 'Reduction in Cost Sharing Packages' (19a) generates an error when the user attempts to click 'Save and Next'. The error message states: "Plans having indicated as offering MA Uniformity Flexibility benefit must offer at least one MA Uniformity Flexibility package in Reduction in Cost Sharing Packages." If the user selects 'OK' and bypasses the error, they are then able to build out the MA Uniformity Flexibility package in 19b. Once the package is built in 19b, the user can go back to 19a and select 'Save & Next' for that section to be marked 'Complete'. This error should likely only generate after hitting 'Save & Next' in 19b, as the MA Uniformity Flexibility benefit only has to be filed in either 19a or 19b, not both sections. Given that the user will always encounter 19a before 19b if working screen to screen, we recommend that CMS address this issue to eliminate unnecessary administrative burden of moving back and forth between screens to ensure 19a is marked 'Complete' after the workaround.

PBP Data Entry System Screens - MA Uniformity/SSBCI Package Selection

CMS is proposing changes to the PBP data entry system.

Humana Comment: Humana recommends that CMS update the PBP to allow plans to create more than one SSBCI package as a single plan may offer multiple SSBCI benefits that target different chronic conditions and utilize varying benefit designs. With the introduction of new fields requiring plans to report the expected number of enrollees eligible for—and expected to utilize—each SSBCI, having multiple SSBCI benefits consolidated into a single package would create unnecessary complexity and reduce reporting accuracy. Allowing multiple SSBCI packages within a single plan would support more precise data submission and better reflect the diversity of SSBCI offerings.

We hope that you consider our comments as constructive feedback aimed at ensuring that together we continue to advance our shared goals of improving the delivery of coverage and services in a sustainable, affordable manner to beneficiaries, focused on improving their total health care experience.

If you have any questions, please do not hesitate to reach out to me at mhoak@humana.com and 571-466-6673.

Sincerely,

Michael Hoak
Vice President, Public Policy

PUBLIC SUBMISSION

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CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262)

Comment On: CMS-2025-1857-0001
CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262)

Document: CMS-2025-1857-DRAFT-0009
Comment on CMS-2025-1857-0001

Submitter Information

Email: gila.williams@ibx.com
Organization: Independence Blue Cross

General Comment

Below are comments related to all sections of the CMS Plan Benefit Package:
The following are comments applicable to all sections of the Plan Benefit Package:
* Making an adjustment to a benefit(s) requires re-saving in order to close out the plan which is time-consuming.
* HPMS data fixes that occur while the plan is working in the tool causes confusion and additional questions and slows down the process as the plan tries to identify what changed during the data input.

Independent Health

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February 20, 2026

Centers for Medicare and Medicaid Services (CMS)
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Submitted via http://www.regulations.gov

Re: Information Collection Request, CMS Plan Benefit Package (PBP) and Formulary CY 2026 (CMS-R-262)

Dear Administrator Oz:

Thank you for the opportunity to comment on the CMS Plan Benefit Package (PBP) and Formulary CY 2026 (CMS-R-262) information collection request. Independent Health Association (IHA) is a not-for-profit health plan located in Western New York serving over 45,500 Medicare beneficiaries in Medicare Advantage (MA) and Part D plans. Our award-winning customer service, dedication to quality health care, and unmatched relationships with physicians and providers have allowed us to be consistently recognized as one of the highest-ranked health plans in the country. For 2026, IHA's Medicare contracts received overall Star Ratings of 5 or 4.5.

Please see our comments below.

Under the subheading CY 2027 Prior Authorization (PA) Criteria Submission, CMS notes that "[d]iagnostic criteria are not static…and…frequent PA submission modifications are necessary when diagnostic information is included." To streamline submissions, CMS is proposing changes to the PA File including limiting PA criteria submission to a single ingredient and submitting requirements at the indication level. In addition, since policies are indication-sensitive, CMS is proposing drastic reductions in character limits in the Required Medical Information and Other Criteria sections. We caution against moving forward with prohibiting plans from grouping drugs together and limiting characters.

Not allowing plans to group drugs together with the same or similar PA criteria will create unnecessary complexity, force plans to maintain many different policies for the same drug, and confuse physicians and beneficiaries who may not realize there are multiple policies for the same drug for different indications. In the latter situation, it may lead to physicians thinking PA is not required for an indication, leading to unnecessary grievances being filed against the plan. Disallowing plans from combining multiple drugs into one policy is likely to achieve the opposite intended effects of reducing administrative burdens and speeding up access to care.

While we agree that diagnostic criteria are ever-changing, sometimes complicated, and that prerequisites for meeting PA criteria can be exhaustive, this is not always within the plan's control. For example, we would be required to detail the reasoning for prerequisite drug therapies tried for asthma if a prescriber was requesting a biologic asthma therapy like Dupixent or Nucala. In order to clarify the plan's position, we are required to note that prerequisite therapies are guideline-driven and should be used in lieu of jumping immediately to a biologic per the guidelines. Reducing character limits makes it much more difficult to detail regulatory requirements tied to coverage standards. Regarding the ever-changing nature of diagnostic criteria, the current system of monthly change requests works well for our plan, and we work with our local physicians and our PA pharmacists to update policies as soon as we can when criteria change or new indications are granted to drugs that already have PA.

Thank you again for the opportunity to comment and thank you for considering IHA's views on the CMS Plan Benefit Package (PBP) and Formulary CY 2026 (CMS-R-262) information collection request. If there are any questions or additional information is needed, please contact Jeremy Laubacker at Jeremy.Laubacker@independenthealth.com.

Sincerely,

Marie a Pero

Marie Pero
Vice President, Medicare Programs

Jefferson Health Plans

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Robert F. Kennedy Jr.
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
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Washington, DC 20201

Submitted via www.regulations.gov

Re: Medicare Program; CMS-R-262 CMS Plan Benefit Package (PBP) and Formulary CY 2027

Dear Secretary Kennedy and Administrator Oz:

Jefferson Health Plans (JHP) appreciates the opportunity to provide feedback on the proposed CY 2027 Plan Benefit Package (PBP) and Formulary Changes to the Medicare Advantage Program. JHP is solely owned by Thomas Jefferson University, and affiliated with Jefferson Health, a 32-hospital integrated delivery and finance system with campuses in Eastern Pennsylvania and New Jersey. Built on a foundation spanning nearly 40 years, JHP is committed to providing members with quality, affordable health coverage. We offer Medicare Advantage-Prescription Drug PPO, HMO, and D-SNP plans in select counties in Pennsylvania and New Jersey and Individual and Family PPO and HMO plans in select counties in Pennsylvania. We also offer Medicaid and CHIP plans statewide in Pennsylvania under the Health Partners Plans brand. We are nationally recognized for our innovations in managed care, including NCQA accreditation for health equity and quality standards, and are committed to building healthier lives and stronger communities through a whole-person approach to health.

Thank you for the opportunity to provide comments on the proposed Prior Authorization (PA), Indication, Prescriber Restriction, and Step Therapy (ST) file layout requirements. JHP strongly supports CMS's goals of improving transparency and member understanding of utilization management criteria. However, several elements of the proposed data structures require additional clarification to ensure accurate, consistent, and operationally feasible implementation.
JHP is respectfully providing our comments and feedback to CMS pertaining to proposed updates to the PA and ST file layout requirements. Our organization appreciates and looks forward to continued partnership with CMS to deliver high quality health care to Medicare Advantage members.

Jefferson Health Plans offers the following comments:

Prior Authorization Group Description — Clarification Needed on "Same RxNorm Ingredient"

CMS states that only RxCUIs with the *same RxNorm ingredient* may be included in a single PA Group Description. Current guidance does not specify whether CMS intends RxNorm Ingredient (IN)–level grouping (e.g., *adalimumab*) or product-specific (SBD/SCD) grouping (e.g., *adalimumab-aaty* vs. *adalimumab-fkjp*).

- The PA file layout requires PA groups to align with formulary RxCUIs but does not define the ingredient-level granularity intended by CMS.
- RxNorm, as maintained by the National Library of Medicine (NLM), provides a clearly defined Ingredient (IN) concept that represents the active moiety, regardless of manufacturer or biologic suffix.

Comment / Request for Clarification:
CMS should confirm that "same RxNorm ingredient" refers to the RxNorm Ingredient (IN) level rather than individual biosimilar products. Without this clarification, sponsors may be forced to create unnecessary, duplicative PA groups for biologics whose suffixes differ but whose clinical criteria are identical.

Therapeutic Category PA Groupings — Need Confirmation on Discontinuation
Under the proposed data structure, therapeutic-class PA groupings (e.g., "PDE5 inhibitors for PAH") appear no longer allowable, since drugs from different ingredients would not meet the requirement to share the same RxNorm ingredient.

- The CY 2027 PA file requires grouping strictly by identical Formulary Group Description, linked to specific RxCUIs, with no allowance for class-based groupings.

Comment / Request for Clarification:
CMS should confirm whether therapeutic-category PA groupings are no longer permitted and must be replaced with separate ingredient-specific PA groups. This change has significant operational implications and should be explicitly stated.

Indication-Level Data Requirements — Need for a Defined "Indication Code" Standard
The proposed layout requires sponsors to submit a separate PA record for each indication, including an "indication code." However:

- CMS has not published a required code system or standardized list for "indication code."
- No fallback approach is specified for conditions lacking a precise coded match.

Comment / Request for Clarification:
We request CMS publish a standard, CMS-maintained Indication Code Reference File (e.g., ICD-10-CM, SNOMED CT, or CMS-specific codes). Without a mandatory code set, PA submissions will be inconsistent, extremely difficult to validate, and burdensome for both sponsors and CMS review teams.

Operational Burden of Requiring Separate PA Records for Each Indication
Many biologics and specialty medications have 5–10+ FDA-approved or medically accepted indications, but the clinical PA criteria are largely identical across indications. CMS's requirement to repeat entire PA records for each indication will create:

- Duplication of nearly identical PA records

- Increased risk of misalignment and version drift
- Increased burden for CMS reviewers
- Increased system complexity without any improvement in member clarity

The current PA layout design (Indicator 1–4 for approved uses) already acknowledges broad indication categories.

Comment / Recommendation:
CMS should allow a single PA record to contain multiple indications, each with its own criteria subsection, or allow "bundled" indication lists within one PA group to prevent unnecessary duplication.

Prescriber Restriction Codes — Need for a CMS-Defined Standard
The file layout requires sponsors to submit "prescriber type codes," but CMS has not defined:

- Which code system must be used (e.g., Medicare specialty codes vs. NPI taxonomy)
- Whether CMS will maintain an official reference file
- How multi-specialty or NP/PA prescriber types should be encoded
- Current PA file layout and CMS sources do not specify a prescriber type coding standard.
- Medicare data systems use multiple prescriber specialty code frameworks (e.g., FFS specialty codes and NPI taxonomy), but none is specified here.

Comment / Request:
CMS should adopt and publish a single, authoritative Prescriber Type Code list in HPMS and require its use across all PA submissions.

Step Therapy (ST) File Layout — Confirm Whether Any CY 2027 Changes Exist
No CMS source to date indicates any proposed changes to the Step Therapy file layout.

- Recent HPMS memos and layout updates focus on PDE file changes, not ST.

Comment / Request:
CMS should confirm whether the ST File Layout remains unchanged for CY 2027, or provide draft specifications if modifications are forthcoming.

Conclusion
We respectfully request CMS clarify or revise the PA and ST file layout requirements to:

1. Confirm RxNorm Ingredient (IN) as the grouping standard.
2. Confirm whether therapeutic-category PA groups are now prohibited.
3. Publish a CMS-maintained Indication Code Reference File.
4. Permit multi-indication PA records to avoid unnecessary duplication.
5. Publish a CMS-standard Prescriber Type Code set.

6. Confirm the status of CY 2027 ST layout changes.

These clarifications will reduce operational burden, improve data quality, and enhance consistency across sponsor submissions while preserving CMS's objectives for transparency and member understanding.

JHP appreciates CMS's continued commitment to strengthening the Medicare Advantage and Part D programs and welcomes ongoing dialogue as these policies are refined. We respectfully request CMS's consideration of the recommendations outlined above to ensure that program requirements accurately reflect member complexity, operational realities, and data readiness, while continuing to promote high-quality, equitable care. JHP remains committed to partnering with CMS to advance policies that support members, plans, and providers alike, and we would be pleased to engage further should additional clarification or discussion be helpful.

Sincerely,

Krista Hoglund

Krista Hoglund, ASA, MAAA, MBA
EVP, President Jefferson Health Plans

PA_Change_Type	Prior_Authorization_Group_Desc	Prior_Authorization_Group_Indication	PA_Criteria_Change_Indicator	Exclusion_Criteria	Required_Medical_Information	Age_Restriction_Modifier	Age_Restrictions	Prescriber_Restrictions	Coverage_Duration	Other_Criteria	Part_B_Prerequisite	Prerequisite_Therapy_Required
ADD	abatacept sq	M0001750	1			1	18		OTHER	INITIAL (6 MONTH APPROVAL): 1) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION, AND 2) TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE CONVENTIONAL SYNTHETIC DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE GREATER THAN OR EQUAL TO 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. RENEWAL (12 MONTH APPROVAL): 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR THE SAME	0	1

PA_Change_Type	Prior_Authorization_Group_Indication	PA_Criteria_Change_Indicator	Exclusion_Criteria	Required_Medical_Information	Age_Restriction_Modifier	Age_Restrictions	Prescriber_Restrictions	Coverage_Duration	Other_Criteria	Part_B_Prerequisite	Prerequisite_Therapy_Required
ADD	M0001748	1			3	2,17	207RR0500X	d,6	NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION.	0	1

PA_Change_Type	Prior_Authorization_Group_Indication	PA_Criteria_Change_Indicator	Exclusion_Criteria	Required_Medical_Information	Age_Restriction_Modifier	Age_Restrictions	Prescriber_Restrictions	Coverage_Duration	Other_Criteria	Part_B_Prerequisite	Prerequisite_Therapy_Required
ADD	M0023901, M0009578	1					207RR0500X, 207N00000X	d,6	NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION.	0	1

Scenario	Description
Example 1	Vertical Expansion - *Prior_Authorization_Group_Desc* is repeated within the PA submission file Separate row per indication(s) Multiple indications included per row when indications share the same set of criteria
Example 2	Horizontal Expansion - *Prior_Autorization_Group_Indication* AND subsequent columns repeated for each indication or group of indications Multiple Indications included within one set of *Prior_Autorization_Group_Indication* AND subsequent columns when indications share same set of criteria

PA_Change_Type	Prior_Authorization_Group_Desc	Prior_Authorization_Group_Indication	PA_Criteria_Change_Indicator	Exclusion_Criteria	Required_Medical_Information	Age_Restriction_Modifier	Age_Restrictions	Prescriber_Restrictions	Coverage_Duration	Other_Criteria	Part_B_Prerequisite	Prerequisite_Therapy_Required
ADD	abatacept sq	M0001750	1				1	18	OTHER	INITIAL (6 MONTH APPROVAL): 1) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION, AND 2) TRIAL OF OR CONTRAINDICATION TO 3 MONTHS OF TREATMENT WITH ONE CONVENTIONAL SYNTHETIC DMARD (DISEASE-MODIFYING ANTIRHEUMATIC DRUG) - IF PATIENT TRIED METHOTREXATE, THEN TRIAL AT A DOSE GREATER THAN OR EQUAL TO 20 MG PER WEEK OR MAXIMALLY TOLERATED DOSE IS REQUIRED. RENEWAL (12 MONTH APPROVAL): 1) CONTINUES TO BENEFIT FROM THE MEDICATION, AND 2) NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES FOR THE SAME	0	1
ADD	abatacept sq	M0001748	1				3 2,17	207RR0500X	d,6	NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION.	0	1
ADD	abatacept sq	M0023901, M0009578	1					207RR0500X, 207N00000X	d,6	NO CONCURRENT USE WITH ANOTHER SYSTEMIC BIOLOGIC OR TARGETED SMALL MOLECULES (E.G., JAK INHIBITOR, PDE-4 INHIBITOR) FOR THE SAME INDICATION.	0	1

PUBLIC SUBMISSION

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CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262)

Comment On: CMS-2025-1857-0001
CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262)

Document: CMS-2025-1857-DRAFT-0005
Comment on CMS-2025-1857-0001

Submitter Information

Email: kirstin.barros@medimpact.com
Organization: MedImpact Healthcare Systems

General Comment

I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' proposed amendments under CMS-2025-1857. The goals articulated in the proposal to enhance formulary transparency, protect beneficiary access, and improve drug price negotiation implementation are important. However, I respectfully urge CMS to consider a delay in the effective date of any new regulations affecting formulary management systems, software requirements, and associated operational requirements until the Plan Year 2028.

I have reviewed other stakeholder comments submitted in this docket, and several also express concern about implementation timing, the depth of IT and process changes required, and the potential to compromise compliance and beneficiary access if implementation schedules are too compressed. Historically, the interval between publication of the final rule and the deadline for formulary submission to CMS spans only a few short months. That period is already heavily constrained by bid development, benefit design finalization, actuarial modeling, vendor configuration, and internal governance review. Introducing sweeping, system-wide formulary requirements during this narrow window creates substantial operational risk. While I strongly support CMS's objectives to enhance transparency around formulary design, the industry's ability to operationalize these changes within existing formulary build cycles and system release schedules is significantly constrained. Requiring accelerated implementation without adequate runway for design, testing, and compliance validation could lead to disruptions in beneficiary access, inaccurate benefit displays, and increased adjudication errors, ultimately undermining the policy goals of the rule.

To align operational realities with the policy intent, I respectfully request that CMS extend the compliance timeline for any requirements that necessitate major software changes or systemic updates to Plan Year 2028. This timeline would allow sufficient lead time for meaningful engagement with stakeholders, comprehensive technical development, broad testing cycles, and effective communication to beneficiaries and network partners prior to implementation.

Thank you for your consideration of this request. Aligning CMS's high-level policy objectives with a realistic implementation timeline will help ensure stable and effective execution that ultimately benefits Medicare beneficiaries and the broader Part D marketplace.

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CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262)

Comment On: CMS-2025-1857-0001
CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262)

Document: CMS-2025-1857-DRAFT-0003
Comment on CMS-2025-1857-0001

Submitter Information

Email: FAS-PartD@medimpact.com
Organization: MedImpact

General Comment

See attached file(s)

Can CMS please clarify which layout in the attached Excel is representative of the new 2027 PA layout (i.e., Example 1, or Example 2)? If neither reflects the intended layout, please provide an example for 2027 PA submissions. We are specifically hoping to understand the following:

A. When a Prior_Authorization_Group_Desc has multiple applicable indications, should the Prior_Authorization_Group_Desc be repeated in the PA submission file with a separate row for each indication (or group of indications if they the same requirements)? [Example 1]
B. OR should the indications ALL be contained within a single row/record? [Example 2]
a. If so, should Prior_Authorization_Group_Indication also be repeated along with all the subsequent indication specific fields?
C. Is CMS intent to permit submission of multiple indications per criteria set? Or does CMS intend to always maintain a 1:1 ratio of indication to criteria sets in the file, even if the criteria content is duplicative? (i.e., if some indications have the same criteria, can those indications be submitted together in a single Prior_Authorization_Group_Indication field, with the corresponding columns only included one time?) See the table below for illustration.

Indication	Distinct Criteria Set	Type
1	A	1:1
2,3,7	B	Many:1
4	C	1:1
5,6	D	Many:1

Attachments

CY2027 PA File Mockup_CMS_2.5.2026

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CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262)

Comment On: CMS-2025-1857-0001
CMS Plan Benefit Package (PBP) and Formulary CY 2027 (CMS-R-262)

Document: CMS-2025-1857-DRAFT-0004
Comment on CMS-2025-1857-0001

Submitter Information

Email: jessica.schiffman@navitus.com
Organization: Navitus Health Solutions

General Comment

I have reviewed the CY 2027 Prior Authorization File Record Layout and have some follow up questions.
1) Prior_Authorization_Group_Indication:
a. What is the "indication code"? What is the source for these codes? What does this field look like if there is multiple indications?
b. When CMS indicates "subsequent fields should be repeated for each indication," could they provide an example? Does this mean fields PA_Criteria_Change_Indicator through Prerequisite_Therapy_Required? How does this look (multiple indications) from a layout standpoint?
2) Prescriber Restrictions:
a. What is the source for the "prescriber type codes"?
3) Coverage Duration:
a. Are the accepted values for this field a; b; c; d, (number of months); e, (number of days); other?
4) Are step therapy criteria allowed in either the Required_Medical_Information or Other_Criteria field? Is it okay to continue to use the Other_Criteria field for overflow due to character limitations?

February 20, 2026

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10913
OMB Control Number: 0938–0763
7500 Security Boulevard
Baltimore, Maryland 21244–1850.

Submitted Electronically: www.regulations.gov

Re: *CMS Plan Benefit Package (PBP) and Formulary CY 2027*

Dear Sir/Madam:

UnitedHealthcare (UHC) is pleased to respond to the CMS*'s* request for comments regarding the *CMS Plan Benefit Package (PBP) and Formulary CY 2027* published in the Federal Register on December 22, 2025 (90 FR 59834).

UnitedHealthcare offers a full range of health benefits, enabling affordable coverage, simplifying the health care experience, and delivering access to high-quality care. UnitedHealthcare is the health benefits business of UnitedHealth Group, a health care and well-being company working to help build a modern, high-performing health system through improved access, affordability, outcomes, and experiences. We are committed to a future where every person has access to high-quality, affordable health care and a modern, high-performing health system that reduces disparities, improves outcomes, and lessens the burden of disease.

Plan Benefit Package (PBP)

PBP Reporting

PBP data entry reporting may be pulled at the contract level/individual PBP level from the Plan Benefit Package -> Reports module. PBP Data Reports found in this module can be useful in aiding organizations with their audits of PBP data entry prior to the initial June bid submissions, Rebid Reallocation, and Desk Review submissions. Under current operational processes, the only option available today to pull PBP Data Excel Reports for multiple plans is to pull one large Excel file. Because the data is not separated out by plan, the current file format creates operational challenges for organizations to audit their plans at the individual plan level.

- UHC recommends that CMS offer an optional feature to generate individual Excel files for each plan to support accurate and efficient review of plan-level submissions. UHC

also requests that this option allow users to download the files in a single ZIP archive, while preserving all existing report download functionality.

In the Data Extract Facility module, organizations can currently download a Plan Information - Plan Version report that has the plan-level information that was entered into the Manage Plans subsection of the Bid Submission module.

- UHC recommends that CMS make this dataset available for download during the PBP data entry window, prior to bid submission and CMS approval. Making this dataset available earlier supports more accurate quality assurance (QA) and audit activities. UHC appreciates having reporting in the Data Extract facility that consolidates HPMS data entry; however, it is currently only available for download in the 'As Submitted' and 'Approved' states. Because the PBP-BPT Submission step occurs at the end of the bid submission process, the delayed availability limits its usefulness for QA. UHC requests that CMS add a third state (e.g., 'Not Yet Submitted') so plans can access this data earlier in the process.

In the Data Extract Facility module, CMS currently provides updates to the data for the Plan Service Area extract once a week and/or upon request.

- UHC requests that CMS address two issues with the 'Service Area – Plan Version' report: (1) the data is not updating in real time despite being labeled as such in the User Interface (UI), and (2) frequent file-size errors prevent self-service downloads. During 2026 bid submission preparations, UHC observed that the report was only updated weekly, and repeated download errors required Help Desk assistance to obtain the data directly from HPMS' backend rather than through the Data Extract Facility. Providing truly real-time data and resolving the file-size limitations would improve efficiency for both CMS and plans as well as help prevent delays in the review process.

Prior to the final bid submissions, UHC conducts multiple quality checks using the reports pulled from the Bid Reports screen of HPMS. Today, most of the reports (such as Service Area Reports and Plan Benefits Reports) are only available for download at the individual plan level. However, for organizations that conduct reviews at the portfolio level with all of their plans, this can make the process of pulling each report for a single plan time-consuming and inefficient.

- UHC requests the ability to download the reports for all / multiple plans in the form of a zip file. Within the zip file, UHC also recommends including the plan ID on each individual file name.

Bids Submission- Supporting Documentation and Bid Pricing Tools (BPTs)

In its current state, the substantiation documentation upload process requires organizations to upload individual zip files to one plan at a time and each zip file can take up to 5 minutes to process per plan.

- Given the number of files that need to be uploaded during the short windows of time before the bid submission and resubmission deadlines, UHC requests that CMS consider a module that would expedite the substantiation documentation upload process.
- An example of an existing HPMS module that supports this capability is the PBP-BPT submission module. CMS could consider using the PBP-BPT submission module as a

model to develop a substantiation document upload module to allow organizations to simultaneously upload different zip files to multiple plans.

During the bid submission process, health plans may upload hundreds of substantiation documents for each HPBP which can result in over 100,000 documents that need to be audited by the health plans to confirm the accuracy of the uploads.

- UHC requests the capability to export an Excel document showing the following: (1) all uploaded supporting documentation, (2) the plans to which they are attached, (3) and the HPMS user who uploaded the documents. UHC does extensive quality checks prior to bid submission of these documents and having the ability to check more than one plan's uploads at one time will substantially improve the efficiency and accuracy of those checks.

Currently, duplicate files sometimes occur due to system lag or user error and are frequently identified during QA. Only the original uploader of the bid substantiation documents has the ability to delete them, and it can be cumbersome to identify the person who needs to log in again to delete the duplicate files.

- UHC requests that CMS allow users, perhaps based on user access level, to delete substantiation documents they did not personally upload. Expanding deletion permissions to additional authorized users would help streamline the process and prevent unnecessary delays.
- UHC also encourages CMS to allow organizations to delete substantiation documents during rebate reallocation, rather than requiring plans to submit a list for CMS to remove - to keep the reallocation process consistent with the process used during initial bid submission. Enabling plans to manage these deletions directly would reduce administrative burden on CMS and improve efficiency and process consistency.

PBP/API Submission

Currently, HPBP service area updates must be entered manually in the Set-Up Plans module. However, for benefit data entry, plans are able to utilize the API process which allows an organization to directly import data from an external source.

- UHC requests that CMS enable APIs for submitting service area updates and other data elements in the Set-Up Plans module, rather than requiring manual data entry. API-based updates would significantly reduce data-entry burden and minimize the risk of errors.

When uploading a PBP via API, any validation error stops the entire upload and requires an organization to clear one error at a time. This set-up slows the process and makes it difficult to triage issues with benefits that show up in multiple sections of the PBP.
Therefore, when uploading an entire plan via the API, UHC requests the following:

- The API uploads all of the sub-sections that have no validation errors regardless of whether some sections do have validation errors.
- The API upload results provide the validation errors for all subsections (e.g., Benefit Details, Benefit Offerings) that have an error.
- The ability to upload only those select subsections of the PBP that need to be re-uploaded (e.g., Benefit Details, Benefit Offerings) instead of having to reupload all of the PBP subsections.

Currently, to retrieve premium data from HPMS we have to: (1) download the report, (2) manipulate it, and then (3) reupload it to UHC's own system.

- While maintaining the current "Review Plan Data Reports", UHC requests the ability to send the premium data directly from HPMS to our system through the API.

During initial bid submissions recently, all plans exported successfully with no validation errors. However, when resubmitting the API for desk-review updates, new validation errors appeared, indicating that CMS changed the API benefit-validation checks without notifying plans.

- UHC recommends that CMS notify plans whenever benefit-validation checks in the API are updated, so plans can proactively adjust their JSON configuration instead of discovering issues only when resubmission windows reopen.

The Out-of-Network (OON) Groups data in the PBP JSON does not display the OON Group Number associated with each benefit. Instead, it shows a backend code (a string of letters and numbers) that does not match the Group Number shown in the PBP UI. This limits our ability to validate OON Group assignments during QA.

- UHC requests that the JSON display the OON Group Numbers by benefit exactly as shown in the PBP UI. This enhancement would allow MA Organizations to more efficiently and comprehensively validate OON Group data during its QA process.

PBP Sandbox Requests

UHC uses the Sandbox environment to test plan data entry and exports to HPMS, but the current Sandbox does not allow plans to create or add new plans within the Sandbox. This prevents MA Organizations from validating new plans' data and identifying export or validation issues before official bid submission.

- UHC requests that CMS allow MA Organizations to create and add new plans in the Sandbox environment, enabling full end-to-end testing of API exports of existing and new plans prior to official submission. UHC requests user quality of life enhancements to the 'Edit Plan Service Area' screen, specifically:
    1. The ability to maximize the service-area picklist windows.
    2. The ability to sort the picklist alphabetically in addition to the current county-code sort.

  These improvements would make navigation and review easier as well as help ensure accuracy.

Other HPMS Modules and Processes

Currently, when an Individual (non-800 Group) plan changes SNP types within the same contract, 800-series Group plans must remove all service areas (counties) and then re-add them after the new SNP type has been approved by CMS. This workflow is time-consuming for the MA Organization and is susceptible to errors.

- UHC recommends that MA Organizations be able to retain all 800-series Group plans in counties on a Plan Benefit Package (PBP) when an Individual plan changes SNP types within the same contract. This enhancement would allow the SNP type change without requiring the removal and re-entry of counties during bid submission setup.

We request that the Medicare Plan Finder (MPF) and Medicare & You (M&Y) Handbook reviews be held a few weeks prior to rebate reallocation. The window for completion of the MPF and M&Y Handbook reviews and the rebates allocation is compressed and occurs simultaneously which can be challenging for the resources dedicated to the review of both of those activities. Changing the timeframe for review would give MA Organizations more time and capacity necessary to better plan for the review of MPF and M&Y modules. Also, more time would be allowed for the CMS team responsible for the modules to correct any issues reported by health plans during round one of the reviews.

UHC also appreciates the additional time CMS gave MA Organizations to conduct the rebate reallocation review in 2025. The additional time allowed MA Organizations to perform quality checks, which in turn helped support stability and consistency in benefit design. UHC asks that CMS continue to give MA Organizations at least 2-3 more business days to conduct this review due to the growing number of plan counts and the increasing complexity of the plan designs.

Recommendation Regarding 11c3 Diabetic Monitors
In the "CY 2027 PBP List of Changes" dated January 5, 2026, CMS introduces 11c3 Diabetic Monitors as a new Medicare covered benefit subcategory for CY 2027, and notes that 11c1 Diabetic Supplies will not be carried forward when using prior year copy functionality.

Under 11c3, plans are now required to specify cost sharing applicable to all diabetic monitors, including both Blood Glucose Monitors (BGMs) and Continuous Glucose Monitors (CGMs). While BGMs and CGMs are grouped within the same benefit category, they frequently differ with respect to manufacturer limitations, cost sharing structures, and utilization management. In the absence of a distinct way to identify BGMs versus CGMs within the PBP, plans may face ambiguity when indicating whether manufacturer limits apply to one type of monitor but not the other, or when reflecting cost sharing that differs between these products. This lack of differentiation may also reduce transparency and clarity for members reviewing plan benefits. Providing distinct data points would allow the PBP to more accurately reflect the underlying benefit design, thereby reducing ambiguity and potential confusion.

To support accurate benefit representation, clear interpretation of manufacturer limitation questions, and consistent member understanding, UHC requests the capability to distinguish between BGMs and CGMs within the PBP. With this recommended differentiation, it would be beneficial to associate the question in the 11c parent category—"Do you limit Diabetic supplies and services to those from specified manufacturers?"—with each relevant category (Diabetic Supplies, BGMs, CGMs) individually. This could be achieved either by placing the question in each applicable subcategory or through checkbox selections within the parent category to clearly indicate applicability.

PBP Data Entry for D-SNPs
On the *Plan Characteristics* screen, the new "This D-SNP" question includes four response options, and UHC requests confirmation whether there will be an option to select multiple options for a PBP. Additionally, UHC requests confirmation that option 3 ("Provides for a buy-down by the Part D Sponsor of the nominal Part D low-income copayments to $0 on any formulary tier(s), thus forfeiting LICS payments") applies when a Part D sponsor reduces the

member Initial Coverage Limit (ICL) cost sharing for an entire formulary tier to $0 on a Basic Alternative (BA), Enhanced Alternative (EA), or Actuarial Equivalent (AE) benefit design.

Formulary

CY 2027 Prior Authorization File Record Layout

UHC appreciates the opportunity to comment on the proposed updates to the Contract Year (CY) 2027 Prior Authorization (PA) Record File layout. UHC recognizes and supports CMS's goal of enhancing standardization and improving the clarity and efficiency of PA File submissions.

However, UHC is concerned regarding the timeline for implementation. The proposed updates represent structural and operational changes to the PA File format—including new standardized fields, movement of key indicators across files, removal and addition of data elements, and introduction of new validation requirements. These changes will require MA Organizations to undertake system reengineering, internal workflow adjustments, and comprehensive training across multiple operational teams to ensure proper and accurate implementation.

UHC respectfully requests that CMS delay the implementation of the proposed PA File layout changes from CY 2027 to CY 2028 to allow adequate time for alignment, system and operational readiness, training, and accurate file submission across MA Organizations. Given the operational impact of the proposed changes and the expected release of the final CY 2027 PA File layout in April 2026, UHC is concerned that there will not be sufficient time for MA Organizations to build, test, and implement the changes prior to the 2027 submission cycle.

Given the scope of the proposed modifications, early access to CMS-led training would greatly assist plans in ensuring accurate implementation and operational readiness. If CMS moves forward with finalizing the proposed changes, UHC respectfully requests clarification on whether CMS plans to offer live and/or recorded training sessions upon the release of the final PA File layout to support plans in understanding and preparing for the new requirements.

UHC requests clarification for some of the proposed field updates in the CY 2027 PA Record File Layout:

Prior Authorization Group Description: The new field description states that *"*Only RxCUIs with the same RxNorm ingredient can be included within the same PA Group Description.*"*

- This field description appears to require plans to create new, separate PA Group Descriptions solely because the drug ingredients differ across products, even when the PA criteria are the same. This would lead to additional, duplicative PA Group Descriptions, increasing administrative burden and reducing efficiency. UHC respectfully asks CMS to provide the logic and intent behind this requirement to better understand the operational impact of this change. Specifically, does this mean that drugs within the same therapeutic class—but containing different active ingredients—may no longer be grouped under the same PA Group Description, even when the clinical criteria are aligned? UHC would appreciate additional clarification or examples illustrating how CMS envisions this requirement being applied in practice.

Prior Authorization Group Indication: This new field requires plans to "enter the indication code for which the PA applies," and specifies that *"*if the PA applies to more than one indication, the subsequent fields should be repeated for each indication."

- Under the current process, plans submit a single line entry per drug that encompasses all applicable indications. The proposed change appears to require separate line entries for each individual indication, potentially resulting in multiple line entries for the same product when criteria apply broadly. This could significantly increase file length and operational complexity, especially for drugs with numerous FDA-approved indications or multiple clinical criteria pathways. Additional clarity and examples from CMS would help plans understand how to operationalize this new field and assess the downstream impacts on workflow, file size, and system configuration.

- UHC respectfully requests that CMS provide a standardized list of allowable indication codes in advance of the PA Record File submission cycle to ensure consistent and accurate reporting across plans. If CMS provides a defined list, how should plans proceed when an indication is not included or not yet added to that list? Will there be an "Other" option to capture indications that fall outside the predefined set?

- UHC seeks clarification on how plans should handle mid-year changes to diagnosis or indication codes. If a code is updated or replaced during the year, will plans be required to resubmit all previously submitted PA groups that used the old code? Clear guidance on mid-year code management would help prevent unnecessary resubmissions and ensure alignment with CMS expectations.

- UHC seeks clarification on whether each indication will require its own line entry, even when PA criteria are identical across indications? Additionally, can CMS clarify whether the submission and CMS approval will be specific to each "PAgroup+RxNormIngredient+IndicationCode", in such a way that each combination is considered a unique submission entry and can be updated and re-submitted independently from another PA group with the same RxNorm Ingredient but a *different* indication code?

Age Restriction Modifier: Based on this proposed new field's description, plans would be required to first select an age restriction modifier (e.g., ≥, ≤, or a range) and then populate the Age Restrictions field with specific age values only when a modifier is used.

- The current process requires plans to enter straightforward age-based criteria in a single free-text field. The proposed change appears to require multiple fields to capture information currently conveyed in one field, even for simple age requirements. Because plans have relatively few age-based criteria, these additional fields may add unnecessary administrative burden across the industry. UHC requests clarification on whether the new Age Restriction Modifier field is intended to be required or optional.

Age Restriction: The proposed updates to the field description require plans to first select an age restriction modifier and then populate the Age Restrictions field with specific age values only when a modifier is used.

- UHC requests clarification on the proposed updates to the field description. The proposed field description does not allow plans to distinguish between initial and reauthorization age-based criteria. In most cases, age restrictions apply only to initial PAs, but there are situations where age criteria differ—or do not apply—at reauthorization. The proposed format does not provide a way to make this distinction, limiting necessary clinical specificity. Given this added complexity and the loss of flexibility compared to the existing free-text format, UHC respectfully asks whether CMS will consider retaining the current Age Restrictions structure, which allows plans to clearly specify age requirements for both initial and reauthorization criteria without adding additional fields or duplicative entries.

Prescriber Restrictions: The proposed updates to the field description instruct plans to identify and submit specific prescriber type codes rather than using the current free-text format.

- UHC requests clarification on the proposed updates to the field description. UHC requests CMS to provide a full list of allowable prescriber type codes and guidance on how CMS expects these codes to be applied. If CMS provides the list of acceptable prescriber codes, how should plans proceed if a prescriber specialty is not or is not yet included in that list? Will there be an "Other" option to account for this scenario?
- UHC respectfully requests that CMS consider allowing plans to retain the current Prescriber Restrictions format, which is more flexible and operationally efficient.

Coverage Duration: The proposed updates to the field description instruct plans to select a single standardized duration option (e.g., lifetime, 1-year, plan year, months, days).

- UHC requests clarification on the proposed updates to the field description. This proposed description does not allow plans to differentiate between initial and reauthorization coverage durations, which frequently differ in practice. When duration varies by PA coverage duration, plans would be forced to select “Other” and describe the duration manually, reducing clarity and leading to more frequent use of non-standard entries. This approach may introduce unnecessary administrative burden compared to the current free-text format, which allows plans to clearly specify distinct initial vs. reauthorization durations within a single field. UHC respectfully requests that CMS consider retaining the current Coverage Duration format or allowing flexibility to capture differing initial and reauthorization durations without relying heavily on the “Other” category.

Thank you for your thoughtful consideration of our comments. Should you have any questions, please do not hesitate to contact me.

Sincerely,

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