

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



**CENTER FOR MEDICARE**

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January 17, 2025

**Warning Letter**

Contract ID: H3204

Formulary ID(s): 25429

Parent Organization Name: Presbyterian Healthcare Services

Legal Entity Name: PRESBYTERIAN HEALTH PLAN

Alejandra Quintana Clyde  
Medicare Compliance Officer  
9521 San Mateo Blvd NE  
Albuquerque, NM 87113

VIA EMAIL: [aquintana30@phs.org](mailto:aquintana30@phs.org)

**RE: FAILURE TO MEET CY 2025 FORMULARY REQUIREMENTS**

Dear Alejandra Quintana Clyde:

The Centers for Medicare & Medicaid Services (CMS) is issuing this warning letter to PRESBYTERIAN HEALTH PLAN, which operates Medicare Part D Contract ID H3204, for failing to comply with the Part D program requirement that Part D plan sponsors submit all required information described in 42 C.F.R. 423, Subpart F, concerning its future year's bid (of which the formulary is an element), [1] according to requirements established by CMS. We are issuing a warning letter because CMS issued a notice of non-compliance to your organization for its failure to comply with similar submission requirements for contract year (CY) 2024.

Part D sponsors may offer only those benefit plans, including formularies, that they have submitted according to the instructions CMS issued pursuant to 42 C.F.R. § 423.265 and which CMS has reviewed and approved pursuant to 42 C.F.R. § 423.272. To ensure the timely review of thousands of bid submissions each year, CMS established a process by which we conduct the formulary review process in stages. Corrections to the formulary requested by CMS during each stage review must be made in order for the formulary to be eligible for the Summer Limited Update Window.

During the annual formulary review process, Part D sponsors must be certain to comply with requirements related to deadlines for re-submission and with limitations on the scope of changes sponsors may make to a formulary during a re-submission. CMS has made clear to sponsors the fact that their failure to meet submission deadlines adversely impacts CMS's review of all sponsors' submitted formularies and, therefore, missed re-submission deadlines may place CMS's approval of a proposed

formulary at risk. For the CY 2025 Stage 1 Review, CMS communicated issues to sponsors on June 10, 2024, and allowed them to justify or correct the identified formulary issues and resubmit by June 13, 2024. For the Stage 2 Review, CMS communicated issues to sponsors on June 28, 2024, and allowed them time to justify or correct and resubmit by July 5, 2024. For the Stage 3 Review, CMS communicated issues to sponsors on July 19, 2024, and allowed them time to resubmit by July 23, 2024.

At each stage of the formulary review process, unless otherwise instructed, sponsors must limit the revisions made to a formulary during re-submission to those necessary to address the issues identified by CMS. Sponsors that use re-submission opportunities to make changes to their formulary beyond the scope necessary to address CMS-raised issues (i.e., “non-allowable” changes) are out of compliance with Part D formulary submission and review requirements.

According to the HPMS Memo entitled “Summer Update Window for CY 2025 Formularies” (dated July 22, 2024), Part D sponsors had the opportunity to make limited updates to their conditionally approved CY 2025 formulary submissions from 12:00 a.m. EDT August 5, 2024 through 5:00 p.m. EDT August 7, 2024. The summer update window cannot be used to make significant enhancements or significant negative changes to existing formulary drugs, since the formulary version that was initially submitted to CMS for review was considered in the bid and Part D benefits review. CMS also offered a final CY 2025 formulary submission window between 12:00 a.m. EDT September 16, 2024 and 5:00 p.m. EDT on September 18, 2024, as outlined in the HPMS Memo entitled “CY 2025 September Formulary Enhancement Submission Window” (dated August 26, 2024).

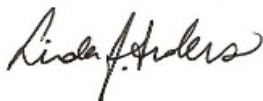
CMS is issuing this compliance notice to your organization because it failed to comply with the CY 2025 Part D formulary submission and review requirements when:

**The plan submitted its Stage 3 formulary resubmission with non-allowable/unsolicited changes in that it changed the therapeutic class from 'Electrolyte/Mineral Modifiers' to 'Electrolyte/Mineral/Metal Modifiers' and changed the therapeutic category from 'Therapeutic Nutrients/ Minerals/Electrolytes' to 'Electrolytes/Minerals/Metals/Vitamins' for RxCUI 2180997.**

Please be aware that this letter will be included in the record of your organization’s past Medicare contract performance, which CMS will consider as part of our review of any application for new or expanded Medicare contracts your organization may submit. CMS deems this instance of non-compliance a Part D issue. CMS notes that we are issuing this compliance notice based exclusively on information that we obtained from sources other than the sponsor’s own self-disclosure.

In the future, please ensure that your organization’s formulary is updated and approved within CMS’s specified timeframes. For questions regarding your formulary submission, please contact the Part D Formulary mailbox at [PartDFormularies@cms.hhs.gov](mailto:PartDFormularies@cms.hhs.gov). If you have questions related to the compliance implications of this notice, please contact Christine Hill at [Christine.Hill@cms.hhs.gov](mailto:Christine.Hill@cms.hhs.gov) and copy your account manager.

Sincerely,



Linda Anders, Division Director  
Division of Benefit Purchasing and Monitoring  
Medicare Drug Benefit and C&D Data Group

CC via email:

Jeff Mouakket, CMS  
Arianne Spaccarelli, CMS  
Brian Martin, CMS  
Christine Hill, CMS

[1] As discussed in the preamble of Final Rule CMS–4068–F, “information that would accompany the bid submission would, at a minimum, include...the plan’s formulary.” See p.4294 at <https://www.govinfo.gov/content/pkg/FR-2005-01-28/pdf/05-1321.pdf>