



CENTER FOR MEDICARE

January 15, 2021

Corrective Action Plan

Contract ID: H3809

Formulary ID(s): 21371

Parent Organization Name: Providence Health & Services

Legal Entity Name: PROVIDENCE HEALTH & SERVICES - OREGON

Cindy Noordijk
Medicare Compliance Officer
4400 NE Halsey, Bldg 1, Suite 200
Portland, OR 97213

VIA EMAIL: cynthia.noordijk@providence.org

RE: FAILURE TO MEET CY2021 FORMULARY REQUIREMENTS

Dear Cindy Noordijk:

The Centers for Medicare & Medicaid Services (CMS) is issuing a request for PROVIDENCE HEALTH & SERVICES - OREGON, which operates Medicare Part D Contract ID H3809, to develop and implement a corrective action plan (CAP) to address the organization's failure to comply with the Part D program requirements concerning formulary submissions. Specifically, your organization failed to 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 this request based on the severity of the issue and because CMS issued a notice of non-compliance to your organization for its failure to comply with similar submission requirements for CY 2020.

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 the 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' review of all sponsors' submitted formularies and, therefore, missed re-submission deadlines may place CMS' approval of a proposed

formulary at risk. For the CY 2021 Stage 1 Review, CMS communicated issues to sponsors on June 8, 2020, and allowed them to justify or correct the identified formulary issues and resubmit by June 12, 2020. For the Stage 2 Review, CMS communicated issues to sponsors on June 23, 2020, and allowed them time to justify or correct and resubmit by June 29, 2020. For the Stage 3 Review, CMS communicated issues to sponsors on July 20, 2020, and allowed them time to resubmit by July 23, 2020.

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 2021 Formularies” (dated July 29, 2020), Part D sponsors had the opportunity to make limited updates to their conditionally approved CY 2021 formulary submissions from 12:00 AM EDT August 6, 2020 through 5:00 PM EDT August 10, 2020. 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 2021 formulary submission window between 12:00 a.m. EDT September 21, 2020 and 5:00 p.m. EDT on September 23, 2020, as outlined in the HPMS Memo entitled “CY 2021 September Formulary Enhancement Submission Window” (dated September 4, 2020).

CMS is issuing this compliance notice to your organization because it failed to comply with the CY 2021 Part D formulary submission and review requirements when **it neglected to indicate that prior authorization was applicable to 266 RXCUIs upon which its bid was based. This resulted in numerous emails and discussions, after which CMS allowed the addition during the August update window.**

Consistent with CMS’ authority under 42 C.F.R. § 423.509(c), we request that your organization take corrective action to come into compliance. The first opportunity for your organization to demonstrate that it has taken the necessary corrective action will be the 2022 bid cycle. Therefore, CMS requests that these areas of noncompliance be addressed in the spring of 2021 leading up to the 2022 bid cycle. CMS will rely on H3809’s 2022 formulary submission to determine whether the corrective action plan has been successfully implemented. CMS will consider the CAP closed once the Division of Formulary and Benefit Operations has determined that H3809’s 2022 formulary submission demonstrates that it has effectively resolved the issues described above.

CMS notes that we are issuing this compliance notice based on information that we obtained from both the sponsor’s own self-disclosure as well as 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’ specified timeframes. For questions regarding your formulary submission, please contact the Part D Formulary mailbox at 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 and copy your account manager.

Sincerely,

A handwritten signature in black ink, appearing to be "A. Hill", with a long horizontal line extending to the right.

Amy Larrick Chavez-Valdez, Director

Medicare Drug Benefit and C&D Data Group

CC via email:

CENK AYRAL, CMS

Scott Nelson, 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>