



CENTER FOR MEDICARE

February 08, 2022

Corrective Action Plan

Contract ID: H5211

Formulary ID(s): 22488, 22489

Parent Organization Name: Marshfield Clinic Health System, Inc.

Legal Entity Name: SECURITY HEALTH PLAN OF WISCONSIN, INC.

Lisa Boero
Medicare Compliance Officer
1515 Saint Joseph Avenue
Marshfield, WI 54449

VIA EMAIL: shp.compliance.dept@securityhealth.org

Re: FAILURE TO MEET CY 2022 FORMULARY REQUIREMENTS

Dear Lisa Boero:

The Centers for Medicare & Medicaid Services (CMS) is issuing a request for SECURITY HEALTH PLAN OF WISCONSIN, INC., which operates Medicare Part D Contract ID H5211, 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 because CMS issued a warning letter to your organization for its failure to comply with similar submission requirements for contract year (CY) 2021.

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 contract year (CY) 2022 Stage 1 Review, CMS communicated issues to

sponsors on June 14, 2021, and allowed them to justify or correct the identified formulary issues and resubmit by June 16, 2021. For the Stage 2 Review, CMS communicated issues to sponsors on July 1, 2021, and allowed them time to justify or correct and resubmit by July 8, 2021. For the Stage 3 Review, CMS communicated issues to sponsors on July 21, 2021, and allowed them time to resubmit by July 26, 2021.

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 2022 Formularies” (dated July 27, 2021), Part D sponsors had the opportunity to make limited updates to their conditionally approved CY 2022 formulary submissions from 12:00 a.m. EDT August 5, 2021 through 5:00 p.m. EDT August 9, 2021. 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 2022 formulary submission window between 12:00 a.m. EDT September 20, 2021 and 5:00 p.m. EDT on September 22, 2021, as outlined in the HPMS Memo entitled “CY 2022 September Formulary Enhancement Submission Window” (dated September 3, 2021).

CMS is issuing this compliance notice to your organization because it failed to comply with the CY 2022 Part D formulary submission and review requirements when:

The plan submitted their September Formulary Enhancement formulary resubmission with non-allowable/unsolicited changes in that they submitted a more restrictive QL on a generic RXCUI (1541890). The QL was submitted as part of an immediate generic substitution so the QL should have been the same or better than the brand.

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 2023 bid cycle. Therefore, CMS requests that these areas of noncompliance be addressed in the spring of 2022 leading up to the 2023 bid cycle. CMS will rely on H5211’s 2023 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 H5211’s 2023 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 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,



Amy Larrick Chavez-Valdez, Director

Medicare Drug Benefit and C&D Data Group

CC via email:

AVALON GORDON, CMS

Michael Neuman, 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#page=33>