



August 16, 2021

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development
Attn: CMS-10305
Control Number: II, Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted Electronically: www.regulations.gov

Re: *Medicare Part C and Part D Data Validation*

Dear Sir/Madam:

UnitedHealthcare (UHC) is pleased to respond to the Centers for Medicare and Medicaid Services (CMS) request for comments regarding the *Medicare Part C and Part D Data Validation* published in the Federal Register on June, 17th, 2021.

UHC is dedicated to helping people live healthier lives and making the health system work better for everyone by simplifying the health care experience, meeting consumer health and wellness needs, and sustaining trusted relationships with care providers. In the United States, UHC offers the full spectrum of health benefit programs for individuals, employers, and Medicare and Medicaid beneficiaries, and contracts directly with more than 1.3 million physicians and care professionals, and 6,500 hospitals and other care facilities nationwide. The company also provides health benefits and delivers care to people through owned and operated health care facilities in South America.

Coverage Determinations

In our review of the *2022 Medicare Part C and D Reporting Requirements Data Validation Procedure Manual, Appendix B* we found a discrepancy on page 24. To improve consistency, we ask for CMS to update sections 6 and 7, *Coverage Determinations*, to match the section E Notes 2. *Coverage Determinations and Exceptions*, bullet 3, on p. 19 of the *2021 Medicare Part D Plan Reporting Requirements: Technical Specifications*.

6. Organization accurately calculates the number of coverage determination (Part D only) decisions made in the reporting period, including the following criteria:
 - a. Includes all coverage determinations (fully favorable, partially favorable, and adverse), including exceptions, with a **date of decision** that occurs during the reporting period, regardless of when the request for coverage determination was received.

7. Organization accurately calculates the total number of [Utilization Management] UM, Formulary, and Tier exceptions decisions made in the reporting period, including the following criteria:
- a. Includes all decisions made (fully favorable, partially favorable, and adverse) with a **date of decision** that occurs during the reporting period, regardless of when the exception request was received.

The quarterly case inclusion criteria should be consistent with the technical guidance: Requests for coverage determinations, including exceptions, are reported based on the date the enrollee/enrollee's representative is notified in writing of the coverage determination decision, see below.

6. Organization accurately calculates the number of coverage determination (Part D only) decisions made in the reporting period, including the following criteria:
- a. Includes all coverage determinations (fully favorable, partially favorable, and adverse), including exceptions, with a **date the enrollee/enrollee's representative is notified in writing of the coverage determination decision that occurs during the reporting period**, regardless of when the request for coverage determination was received.
7. Organization accurately calculates the total number of [Utilization Management] UM, Formulary, and Tier exceptions decisions made in the reporting period, including the following criteria:
- a. Includes all decisions made (fully favorable, partially favorable, and adverse) with a **date the enrollee/enrollee's representative is notified in writing of the coverage determination decision** that occurs during the reporting period, regardless of when the exception request was received.

Redeterminations

Similar to the section above, in our review of the *Medicare Part C and D Reporting Requirements Data Validation Procedure Manual, Appendix B* we found a discrepancy on p. 25. To improve consistency, we ask for CMS to update section 10.ato match section E.3. on p. 20, *Redeterminations of the 2021 Medicare Part D Plan Reporting Requirements: Technical Specifications*.

10. Organization accurately calculates the total number of redeterminations (Part D only), including the following criteria:
- a. Includes all redetermination final decisions for Part D drugs with a **date of final decision** that occurs during the reporting period, regardless of when the request for redetermination was received or when the member was notified of the decision.

Section 10.a, p. 25 *Redeterminations* asks to include all redeterminations, regardless of when the member was notified of the decision. This language does not align with the *2021 Medicare Part D Plan Reporting Requirements: Technical Specifications*. We ask for section 10.a, p. 25 to be updated to include redetermination requests based on the date the enrollee/enrollee's representative is notified in writing of the redetermination decision to be consistent with the technical guidance, see below.

10. Organization accurately calculates the total number of redeterminations (Part D only), including the following criteria:
- a. Includes all redetermination final decisions for Part D drugs with a **date the enrollee/enrollee's representative is notified in writing of the redetermination decision** that occurs during the reporting period, regardless of when the request for redetermination was received.

MTM Data Validation Standards

UHC asks CMS to confirm the process to populate the data for Elements I, J and K, (*Appendix B: Data Validation Standards, 3. Part D Data Validation Standards, Medication Therapy Management (MTM) Programs*) in the scenario below. We understand that Element K will not be validated in the 2022 Data Validation audit.

Element I. Date of MTM program enrollment.

Element J. Date met the specified targeting criteria per CMS – Part D requirements in § 423.153(d)(2). Required if met the specified targeting criteria per CMS – Part D requirements (May be same as date of MTM program enrollment).

Element K. Targeting criteria met. Required if met the specified targeting criteria per CMS – Part D requirements in § 423.153(d)(2) (Multiple chronic diseases/multiple Part D drugs/cost threshold, (Drug management program at-risk beneficiary¹, Both)).

Scenario:

Member meets Medication Therapy Management (MTM) program targeting criteria on 1/5/22 based on having multiple chronic diseases/multiple Part D drugs/cost threshold. Later in the year, on 4/5/22, the member is identified as a Drug Management Program At Risk Beneficiary (DMP-ARB). Given the member meets two reporting categories, please confirm the reporting for this member should be as follows:

- Element I = 1/5/22 (date member met MTM program criteria)
- Element J = 4/5/22 (date the member meets both MTM program and DMP-ARB criteria)
- Element K = “Both”

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

Sincerely,

Amy Hunt Tjornhom

Amy Hunt Tjornhom
Associate Director Regulatory Affairs
(952) 931-4424
amy.hunttjornhom@uhc.com