June 6, 2022

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: OMB Control Number: 0938-1115
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Medicare Part C and Part D Data Validation (42 CFR 422.516(g) and 423.514(j))

Submitted Electronically: https://www.regulations.gov/

Dear Sir/Madam:

UnitedHealthcare (UHC) is submitting comments regarding the information collection request for the Medicare Part C and Part D Data Validation (42 CFR 422.516(g) and 423.514(j)). 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. 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.

Part D Medication Therapy Management Program (MTMP)
Reporting Section Criteria (RSC): Section 5

With respect to the standards listed in Subsection 5, the reference letters used for the section are misaligned (Reporting Section Criteria (RSC) 5 in the 2022 Data Valuation CY 2023 DV Appendix B_Draft_20220308_508). RSC 5b in the 2022 Manual is now RSC 5a in the 2023 Manual. This misalignment of the standards is an error because it is not reflected in Appendix J that is used for scoring. As a result, when the auditors look for RSC 5b in Appendix B, it will not match up to RSC 5b in Appendix J. The sections from the 2022 and 2023 versions are set out below.

> Appendix B, RSC Section 5 in 2022:
>
> 5. Organization accurately reports data by applying data integrity checks listed below and uploads it into HPMS:

a. Date of MTM program enrollment (Data Element I) is within the reporting period (between 1/1/2021 and 12/31/2021).
b. One record is entered for each unique beneficiary, i.e., only one record exists for a unique MBI number (Data Element B).
c. Only reports beneficiaries enrolled in the contract during the reporting period, i.e., MBI (Data Element B) maps to a beneficiary enrolled at any point during the reporting year for the given Contract Number (Data Element A).

Appendix B, RSC Section 5 in 2023:

Organization accurately reports data by applying data integrity checks listed below and uploads it into HPMS:

5. Date of MTM program enrollment (Data Element H) is within the reporting period (between 1/1/2022 and 12/31/2022).
a. One record is entered for each unique beneficiary i.e., only one record exists for a unique MBI number (Data Element B).
b. Only reports beneficiaries enrolled in the contract during the reporting period, i.e., MBI (data Element B) maps to a beneficiary enrolled at any point during the reporting year for the given Contract Number (Data Element A).
c. CMR received date (Data Element P) is within the beneficiary's MTM enrollment period.

Appendix J, RSC Section 5 in 2023:

RSC-5 Organization accurately reports data by applying data integrity checks listed below and uploads it into HPMS:

a: Date of MPM program enrollment (Data Element H) is within the reporting period (between 1/1/2022 and 12/31/2022).

RSC-5b Organization accurately reports data by applying data integrity checks listed below and uploads it into HPMS.

b: One record is entered for each unique beneficiary i.e., only one record exists for each unique beneficiary (Data Element B).

Therefore, the misalignment in Appendix B needs to be fixed. UHC recommends that CMS update the numbering in Appendix B, RSC Subsection 5 so that it will align with Appendix J which is used for auditor scoring.

Reporting Section Criteria (RSC): Section 5q and 5r

In addition to the misalignment mentioned above, RSC 5q is a duplicate of RSC 5r. UHC has concerns about this duplication because it is not reflected in Appendix J that is used for scoring. When the auditors look for RSC 5q in Appendix B, it will not match RSC 5q in Appendix J.

Appendix B, RSC Section 5q and 5r in 2022:

- RSC 5q. If a CMR was received (Data Element Q = Yes), there is a reported date of initial CMR (Data Element R ≠ missing).
- RSC 5r. If a CMR was received (Data Element Q = Yes), there is a reported delivery date(s) (Data Element S ≠ missing).

Appendix B, RSC Section 5q and 5r in 2023:

- RSC 5q. If a CMR was received (Data Element O = Yes), there is a reported delivery date(s) (Data Element Q ≠ missing).
- RSC 5r. If a CMR was received (Data Element O = Yes), there is a reported delivery date(s) (Data Element Q ≠ missing).

Appendix J, RSC Section 5q and 5r in 2023:

- RSC 5q. If a CMR was received (Data Element O = Yes), there is a reported date of initial CMR (Data Element P ≠ missing).
- RSC 5r. If a CMR was received (Data Element O = Yes), there is a reported delivery date(s) (Data Element Q ≠ missing)

UHC recommends that CMS update the numbering in Appendix B, RSC Section 5 and remove the duplicated RSC 5q so that it aligns with Appendix J which is used for auditor scoring.

Reporting Section Criteria (RSC): Section 5v

UHC has identified a gap between RSC 5v in Appendix B and Appendix J as compared to the CY 2022 Reporting Requirements document.

In addition to the misalignment mentioned above under Subsection 5, validations for Element P (If offered a CMR, recipient of (initial) offer) that were removed for CY 2022 in the Reporting Requirements document were not removed in Appendix B and Appendix J. Instead, the data element was updated to Element T (Recipient of initial CMR); however, Element T is for the recipient of the completed CMR, not the CMR offer. This error could cause the auditors to evaluate and score plans incorrectly based on a data element that no longer exists.

Appendix B and Appendix J, RSC Section 5v in 2022:

- RSC 5v. If a CMR was offered (Data Element N), there is a reported recipient of initial offer (Data Element P ≠ missing).

Appendix B and Appendix J, RSC Section 5v in 2023:

- RSC 5v. If a CMR was offered (Data Element M), there is a reported recipient of initial offer (Data Element T ≠ missing).

CY 2022 Reporting Requirements:

Element M. Offered annual CMR. (Y (yes) or N (no)). Required if met the specified targeting criteria per CMS – Part D requirements.

Element O. Received annual CMR with written summary in CMS standardized format. (Y (yes) or N (no)). Required if offered annual CMR.

Element T. Recipient of initial CMR. (Beneficiary, Beneficiary's prescriber; Caregiver; or Other authorized individual). Required if received annual CMR.

Below are two scenarios that show how the data will be reported if we follow the requirements in Appendix B and Appendix J versus the requirements in the CY 2022 Reporting Requirements document.

Scenario 1:

It is possible for a beneficiary to be offered a CMR (Element M) but the CMR is not completed (aka initial CMR, Element O) because the beneficiary declines the CMR or the CMR is deemed invalid because of Return Mail. When this occurs, we cannot use Element T to report the recipient of the offer because it will incorrectly report that a completed CMR occurred.

Incorrectly reported based on Appendix B and Appendix J

- Element M = Y (CMR offer indicator)
- Element O = N (Completed CMR indicator)
- Element T = 01 (Beneficiary - Completed CMR recipient)

Correctly reported based on CY 2022 Reporting Requirements

- Element M = Y (CMR offer indicator)
- Element O = N (Completed CMR indicator)
- Element T = blank (Completed CMR recipient)

Scenario 2:

Another possibility is for the recipient of the CMR offer to be different than the recipient of the completed CMR if the beneficiary is considered cognitively impaired at the time of the CMR or if the beneficiary requests another individual to complete the CMR on their behalf. When this occurs, we cannot report the recipient of the offer as the recipient of the completed CMR because it will incorrectly report who completed the CMR. Additionaly, it will conflict with the name of the CMR recipient that is shown in our required CMR Written Summaries.

Incorrectly reported based on Appendix B and Appendix J

- Element M = Y (CMR offer indicator)
- Element O = Y (Completed CMR indicator)
- Element T = 01 (Beneficiary - Completed CMR recipient)
- Written Summary = Name of caregiver (Completed CMR recipient)

Correctly reported based on CY 2022 Reporting Requirements

- Element M = Y (CMR offer indicator)
- Element O = Y (Completed CMR indicator)
- Element T = 03 (Caregiver - Completed CMR recipient)
- Written Summary = Name of caregiver (Completed CMR recipient)

UHC recommends that CMS update RSC Section 5v in Appendix B and Appendix J to remove the validation for Element T (previously P in CY 2021 - If offered a CMR, recipient of (initial) offer) to align with the removal in the CY 2022 Reporting Requirements.

Reporting Section Criteria (RSC): Section 11c

UHC has identified a gap between RSC 11c in Appendix B and Appendix J as compared to the CY 2022 Reporting Requirements document and the CY 2021 Bene-level MTMP Submission Instructions.

The element letter for the number of medication therapy problem resolutions in Appendix B and Appendix J was incorrectly updated to Element Y (Number of communications sent to beneficiary regarding safe disposal). Per the CY 2022 Reporting Requirements document, the correct element letter is Element X (Number of medication therapy problem resolutions). Element Y is for safe disposal and does not relate to the recommendations made to the beneficiary's prescriber(s). Additionally, per the CY 2021 Bene-level MTMP Submission Instructions, Element X (shown as Element Z for 2021 below) is a subset of Element W (shown as Element Y for 2021) and cannot be greater than Element W (Number of medication therapy problem recommendations). However, it is possible for Element Y to be populated with a number greater than zero while Element X and W are not. When this occurs, it will cause our number of medication therapy problem resolutions to appear higher than our number of medication therapy problem recommendations when this is not the case. UHC has concerns that this update could cause the auditors to evaluate and score plans incorrectly based on the wrong data element.

<u>Appendix B and J, RSC Section 11c in 2022:</u>

- RSC 11c. Properly identifies and includes the number of medication therapy problem resolutions resulting from recommendations made to beneficiary's prescriber(s) as a result of MTM program services within the reporting period for each applicable member. For reporting purposes, a resolution is defined as a change or variation from the beneficiary's previous medication therapy. Examples include, but are not limited to, Initiate medication, Change medication (such as product in different therapeutic class, dose, dosage form, quantity, or interval),

Discontinue or substitute medication (such as discontinue medication, generic substitution, or formulary substitution), and Medication compliance/adherence (Data Element Z).

Appendix B and J, RSC Section 11c in 2023:

- RSC 11c. Properly identifies and includes the number of medication therapy problem resolutions resulting from recommendations made to beneficiary's prescriber(s) as a result of MTM program services within the reporting period for each applicable member. For reporting purposes, a resolution is defined as a change or variation from the beneficiary's previous medication therapy. Examples include, but are not limited to, Initiate medication, Change medication (such as product in different therapeutic class, dose, dosage form, quantity, or interval), Discontinue or substitute medication (such as discontinue medication, generic substitution, or formulary substitution), and Medication compliance/adherence (Data Element Y).

CY 2022 Reporting Requirements:

Element W. Number of medication therapy problem recommendations made to beneficiary's prescriber(s) as a result of MTM services.

Element X. Number of medication therapy problem resolutions resulting from recommendations made to beneficiary's prescriber(s) as a result of MTM recommendations.

Element Y. Number of communications sent to beneficiary regarding safe disposal of medications. Required if met the specific targeting criteria per CMS – Part D requirements.

CY 2021 Bene-level MTMP Submission Instructions

Element Y. Number of medication therapy problem recommendations made to beneficiary's prescriber(s) as a result of MTM services:

- Must be not missing.
- Must be a number from 0-99.

Element Z. Number of medication therapy problem resolutions resulting from recommendations made to beneficiary's prescriber(s) as a result of MTM recommendation:

- Must be not missing.
- Must be a number from 0-99.
- Number of medication therapy problem resolutions resulting from recommendations made to beneficiary's prescriber(s) as a result of MTM recommendations (Data Element Z) must be less than or equal to Number of drug therapy problem recommendations made to beneficiary's prescriber(s) as a result of MTM services (Data Element Y).

UHC recommends that CMS update Element Y in RSC Section 11c to Element X in both Appendix B and J.

Improving Drug Utilization Review Controls

For the Part D Improving Drug Utilization Review Controls, there are discrepancies between data element descriptions. Appeals are inconsistently listed within the criteria in Appendix J and the Part D Reporting Requirements do not include Appeals within the reporting data element description.

- DVA Appendix J 2.e RSC 8, 8.a, and 8.b requires a favorable Coverage Determination or Appeal.
- DVA Appendix J 2.e RSC 8.aii and 8.bii requires a favorable Coverage Determination or Appeal.
- DVA Appendix J 2.e RSC 9.a and 9.b requires a favorable Coverage Determination but does not include Appeals.

The Part D Plan Reporting Requirements for Hard MME Elements do not mention Appeal requests:

> T. Of the total reported in element R and not in element S, the number of unique beneficiaries who requested a coverage determination for the prescription(s) subject to the edit.
> U. Of the total reported in element T, the number of unique beneficiaries that had a favorable (either full or partial) coverage determination for the prescription(s) subject to the edit.

Similarly, the Naïve Safety edit also does not mention appeal request:

> EE. The number of unique beneficiaries with an opioid naïve days supply edit claim rejection who requested a coverage determination for the prescription(s) subject to the edit.
> FF. Of the total in element EE, the number of unique beneficiaries with an opioid naïve days supply edit claim rejection who had a favorable (either full or partial) coverage determination for the prescription(s) subject to the edit.

UHC is seeking clarification if appeal requests should be included when reporting the DUR elements for Hard or Naïve data elements (T, U, EE, FF).

UHC appreciates the opportunity to provide comments and looks forward to CMS's feedback.

Sincerely,

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