PUBLIC SUBMISSION

As of: 5/20/21 1:09 PM
Received: May 18, 2021
Status: Draft
Category: Association - Drug
Tracking No. kou-9c3t-u5os
Comments Due: May 18, 2021
Submission Type: Web

Docket: CMS-2021-0041
Medicare Part D Reporting Requirements (CMS-10185)

Comment On: CMS-2021-0041-0001
Medicare Part D Reporting Requirements (CMS-10185)

Document: CMS-2021-0041-DRAFT-0018
Comment on CMS-2021-0044-0001

Submitter Information

Email: tuan.nguyen@bcbsma.com
Organization: BCBSMA

General Comment

Below are my questions regarding the 2022 reporting requirements for MTM and DUR:
• Element F, K, S, and X - The number of claim rejections overridden by the pharmacy due to an exemption
o What is classified as an exemption?
• Element 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.
o So CMS wants us exclude CD for claims that were overridden at POS?
• Element 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.
o For this element we do not need to exclude members with a POS override or got a paid claim due to reduced supply?

May 18, 2021

William N. Parham
Division of Regulations Development
Office of Strategic Operations and Regulatory Affairs
The Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: Document Identifier CMS-10185/OMB Control Number 0938-0992
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Docket ID: Document Identifier CMS-10185/OMB Control Number 0938-0992 – "Proposed 2022 Medicare Part D Reporting Requirements" Notice

Dear Mr. Parham:

Navitus Health Solutions is providing these comments regarding the Notice of Proposed 2022 "Medicare Part D Reporting Requirements" (CMS-10185/OMB Control Number 0938-0992).[1]

As background, Navitus Health Solutions is a 100% pass-through, fully transparent, pharmacy benefit manager (PBM). Since the founding of our company in 2003, Navitus has relentlessly worked to reduce the overall drug costs paid by our clients, while improving member health, providing superior customer service, and ensuring regulatory compliance. Navitus administers pharmacy benefits for seven million members across our commercial, ACA/Exchange, Medicaid, Medicare Part D, and discount card lines of business.

As indicated by CMS, "[d]ata collected via the Medicare Part D reporting requirements will be an integral resource for oversight, monitoring, compliance, and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries."[2] To ensure that these standards reflect best practices and are also useful in practice, Navitus would like to provide the following feedback regarding newly proposed elements included within "Title IV. Improving Drug Utilization Review Controls" (IDUR) of the proposed reporting requirements.[3]

Collection of Subsequent Paid Claims Per Rejection. While CMS has clarified what constitutes a unique rejection via the technical specifications, we would like to request a definition of what constitutes a subsequent paid claim (or override of) a unique rejection, *i.e.*, would a subsequent paid claim (or override) be required to match on some, all, or none of the pieces of the unique rejection being reported? Additionally, is a single opioid claim able to represent a successful paid claim (or override) for multiple different rejections? While different interpretations may apply—and be equally appropriate—different

[1] Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services; Agency Information Collection Activities: Proposed Collection; Comment Request, 86 Fed. Reg. 14926 (proposed March 19, 2021), *available at* https://www.govinfo.gov/content/pkg/FR-2021-03-19/pdf/2021-05809.pdf.
[2] 86 Fed. Reg. 14927.
[3] Medicare Part D Reporting Requirements at Section IV. Improving Drug Utilization Review Controls (Effective as of January 1, 2022).

approaches will lead to significant differences in reporting elements across different plan sponsors, some more complex to report than others.

Collection of Data Around Timing (24 Hours) of Overrides. We would additionally like to comment on the specific data collected within:

1. **Opioid Care Coordination Safety Edit at 90 MME**

> E. The number of claim rejections overridden by the pharmacy within 24 hours of the initial claim rejection.[4]
>
> J. The number of unique beneficiaries with at least one claim rejection overridden by the pharmacy within 24 hours of the initial claim rejection.[5]

With regard to Elements E and J, rejections that have a National Council for Prescription Drug Programs (NCPDP) response code entered at the point of sale (POS) are usually entered within the same day. Rejections that persist beyond 24 hours will typically result in a new, unique rejection for the following date of service (as defined by the technical specifications). Please note, clarification of the information above regarding the definition of a subsequent paid claim (or override) would assist in addressing this concern. Additional clarification is also needed to determine when the 24 hour clock begins and ends. For example, there are scenarios including, among others, claim reversals, reprocessing efforts, and repeated pharmacy rejections which may result in multiple potential start and stop times. Proper instruction regarding the correct process in these scenarios would be appreciated.

Thank you for the opportunity to provide feedback on this proposed reporting requirements. If we can provide any additional information for your rule-making process, please let us know.

Sincerely,

Carmen Backman
Vice President of Government Programs

[4] *Id*. at 10.
[5] *Id*. at 11.

CVSHealth 1275 Pennsylvania Ave NW, Suite 700
Washington, DC 20004

Submitted electronically via www.regulations.gov

May 18, 2021

Chanelle Jones
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: (CMS-10185; OMB control number: 0938-0992)
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on the proposed Plan Year 2022 Part D Reporting Requirements

Dear Chanelle Jones:

CVS Health appreciates the opportunity to respond to the proposed 2022 Part D Reporting Requirements released on March 19, 2021.

CVS Health is dedicated to becoming the most consumer-centric health company in the world. We're evolving based on changing consumer needs and meeting people where they are, whether in the community at one of our nearly 10,000 local touchpoints, in the home, or in the palm of their hand. Our newest offerings – from HealthHUB® locations that are redefining what a pharmacy can be, to innovative programs that help manage chronic conditions – are designed to create a higher-quality, simpler and more affordable experience.

In response to the proposed 2022 Part D reporting requirements, we address the following reporting measures:

- Medication Therapy Management Programs:
  - Recommended clarifications regarding revised data elements
- Improving Drug Utilization Review Controls:
  - Recommended clarifications regarding revised data elements. Statements and reporting to support the proposed changes for IDUR controls.
- Coverage Determinations Redeterminations, and Reopenings
  - Recommended clarifications regarding the Redeterminations report as it relates to direct member reimbursement.

1275 Pennsylvania Ave NW, Suite 700
Washington, DC 20004

We are also providing additional recommendations regarding the Medicare Part D Reporting process that, if adopted, would improve the quality, efficiency, and accuracy of the reporting data.

We have provided a more detailed discussion of our recommendations in the attached appendix.

CVS Health is committed to working with CMS to provide meaningful reporting requirements. We would be happy to respond to any follow-up questions you may have.

Sincerely,
Chad Wilson
Advisor
Regulatory Affairs
CVS Health

Appendix
Specific Comments on the proposed Medicare Part D Reporting Requirements for Plan Year 2022

Section II. Medication Therapy Management Programs (Pages 7- 8):

Element I: 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 beneficiary; Both; None).

Recommendation: Suggesting clarifying the layout for this element and having one response for the data element with the three different choices. The values we are recommending are:

- Yes = Targeting Criteria Met
- None = Targeting Criteria Not Met
- Both = Both Targeting Criteria and At-Risk Beneficiary

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. (Maybe same as the Date of MTM program enrollment).

Because beneficiaries are automatically enrolled in the MTM program when they meet the targeting criteria, the "date met the specified targeting criteria" is always the date of the MTM program enrollment.

In addition, when a beneficiary is targeted more than once (e.g., met the general criteria and was later is identified as an at-risk beneficiary; or meets the targeting criteria and is enrolled, subsequently changes plans, and then later returns to the original plan, all within the same plan year) we should report the earliest date they are enrolled in the MTM program for the current plan year should be reported.

Recommendation: Update the requirements for this data element to state:

- The date that the beneficiary met the targeting criteria is always the date the beneficiary was enrolled in the MTM program.
- For a beneficiary targeted more than once, report the date for the first time they were enrolled in the MTM program.

Section IV. Improving Drug Utilization Review Controls (Pages 10-12):

Opioid Care Coordination Safety Edit

- K. The number of unique beneficiaries with at least one claim rejection overridden by the pharmacy due to an exemption.
- L. Of the total not in element K, the number of unique beneficiaries with at least one claim rejection overridden by the pharmacy as a result of prescriber consultation.

We question the value of asking how many claims were overridden by the pharmacy for a specific reason (e.g., prescriber consultation, other exemption). We reviewed over 110,000 claims for 2020 that rejected for the Opioid Care Coordination edit and found that 88% were overridden "with prescriber approval"; over 11% were overridden with "filled as is"; and only 0.17% indicated they were filled due to a specific opioid edit exemption. CMS does not require any special documentation on the part of the dispensing pharmacist, and our data suggest that asking for detail on the overrides may not be useful to CMS. The pharmacist can only enter one Result of Service Code per reject reason. We suspect that the overrides "with prescriber approval" included a lot of exemptions that were identified by the prescriber.

Recommendation: CMS should not include elements K or L as the vast majority of pharmacists do not use the specific exemption overrides for this edit.

Hard MME Safety Edit

- S. Of the total reported in element R, the number of unique beneficiaries with at least one claim rejection overridden by the pharmacy due to an exemption.

Pharmacists cannot override a hard reject safety edit, even if the beneficiary met one of the exemption criteria. The pharmacist must contact the plan/Pharmacy Help Desk for an override. These plan overrides do not include the specific reason for the override. Any override that is not the result of a coverage determination request must, by definition, be due to an exemption.

Recommendation: CMS should not include data element S. If CMS includes data element S, please clarify that it is any plan override that was not a coverage determination request.

Opioid Naïve Days Supply Safety Edit

- X. The number of rejected claims overridden by the pharmacy due to an exemption.
- Y. The number of rejected claims overridden by the pharmacy because the beneficiary was not opioid naïve.

- BB. The number of unique beneficiaries with at least one rejected claim overridden by the pharmacy due to an exemption.
- CC. The number of unique beneficiaries with at least one rejected claim overridden by the pharmacy because the beneficiary was not opioid-naive.

Because the opioid naïve safety edit is a hard reject, it may only be overridden by the pharmacy using a SCC. The National Council for Prescription Drug Programs (NCPDP) does not have SCC values to clarify why a pharmacy is overriding an opioid naïve edit. For example, we accept SCC 10: Meets Plan Limitations. Using this SCC value, the pharmacy certifies that the transaction complies with the program's policies and rules pertaining to the particular product being billed. Therefore, it is not possible to differentiate an override due to an exemption versus the beneficiary is not opioid naïve.

Recommendations:

- Combine elements X and Y into a single element – The number of rejected claims overridden by the pharmacy.
- Similarly, combine elements BB and CC into a single data element – "The number of unique beneficiaries with at least one rejected claim overridden by the pharmacy."

Section V. Redetermination Exceptions: Pages 14-15

Direct Member Reimbursement (DMR) requests do not typically include an explicit exception request (except potentially a tiering exception request). If a drug included in the DMR request requires a clinical review for a formulary, utilization management, or tiering exception, the exception would be part of the clinical universes. An appeal of a DMR request would be for the amount reimbursed, which would not include any redetermination exceptions.

Recommendation: Clarify that exception request dispositions are to be excluded from the DMR universes.

Additional recommendations for improvements to the Medicare Part D Reporting Process:

- **Publish the Medicare Part D Reporting file layouts on the CMS Paperwork Reduction Act website.**

Today, CMS publishes the reporting file layouts only on the HPMS portal. However, most plans delegate creating reports to their First Tier, Downstream or Related Entities (FDRs) that perform the services related to the report measures. Many of these FDRs do not have access to the HPMS portal.

This situation forces the FDRs to request that the plans arrange to obtain and send the file layouts to the FDR, creating an unnecessary step that delays the FDR's ability to react quickly to any changes.

Recommendation: Publish the Medicare Part D reporting file layouts on the CMS PRA website along with the Reporting Requirements and Technical Specifications, rather than the HPMS portal.

- **Provide example files for each new or modified report measure**

Today, FDRs that produce and submit reporting to CMS on behalf of plans frequently experience upload errors caused by previously unidentified issues.

These errors most often occur when CMS makes a reporting file layout change and uploads an updated file layout to HPMS. If CMS does not call out the modification to the plans or FDRs, the resulting submission errors could confuse the submitter, delay corrections, and cause untimely submission of the reports to CMS.

For example: For the 2020 reporting year, the Coverage Determinations report and the DUR reports underwent a change that did not allow blank spaces at the end of each row before the carriage return. In prior years, this did not cause report submission difficulties. Because there was no notification that this change occurred, all plans experienced submission failures for these reports.

This situation resulted in the urgent reallocation of resources from other critical projects and increased project costs. It significantly increased the risk of untimely submission.

If CMS had published an example file along with a notification of the file layout changes, the plans and FDRs would have avoided the above situation entirely.

Recommendation: Provide an example file for each report that is modified or new each year, along with the Reporting Requirements, Technical Specifications, and the file layouts on the CMS PRA website as one complete reporting package.

1275 Pennsylvania Ave NW, Suite 700
Washington, DC 20004

1275 Pennsylvania Ave NW, Suite 700
Washington, DC 20004

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

May 17, 2021

RE: 2022 Part D Reporting Requirements Comment Period – 60 Day Comment Period

To whom it may concern,

Blue Cross Blue Shield and Blue Care Network of Michigan appreciate the opportunity to provide feedback on the proposed CY2022 Part D Reporting Requirements.

Largely, our organization feels the proposed reporting requirements are realistic and appropriate. We do request that CMS consider modifying the requirements in relation to the withdrawn and dismissed cases to better reflect the regulations published in the CY2022 MAPD Final Rule.

The CY2022 MAPD Final Rule requires withdrawn cases be dismissed by the plan when a party filing the coverage determination or redetermination submits a timely request to the Part D plan sponsor. As currently proposed, plans are required to report the total number of withdrawn and dismissed coverage determinations and the total number of withdrawn and dismissed redeterminations as distinct categories. Maintaining these distinct categories could cause inconsistent reporting between plans as all timely withdraw requests will be dismissed.

Blue Cross Blue Shield of Michigan and Blue Care Network recommend CMS combine the separate withdrawn and dismissal categories into a single dismissal category to eliminate confusion and to better ensure data integrity in Part D reporting submissions.

Thank you in advance for your consideration of our response. We look forward to receiving the reporting requirements for 2022 once finalized.

Sincerely,

Kaitlin Stretch

Manager, Regulatory Oversight and Compliance
kstretch@bcbsm.com
248-369-7814

PUBLIC SUBMISSION

As of: 5/19/21 12:18 PM
Received: May 17, 2021
Status: Draft
Category: Other - OT001
Tracking No. kot-2pdn-72fj
Comments Due: May 18, 2021
Submission Type: Web

Docket: CMS-2021-0041
Medicare Part D Reporting Requirements (CMS-10185)

Comment On: CMS-2021-0041-0001
Medicare Part D Reporting Requirements (CMS-10185)

Document: CMS-2021-0041-DRAFT-0007
Comment on CMS-2021-0041-0001

Submitter Information

Email: jpmaciaszek@express-scripts.com
Organization: Express-Scripts

General Comment

These questions arise out of the reporting requirements CMS published in late March, specifically clarification for new data elements for CY 2022 Improving Drug Utilization Review Controls to be implemented for CY 2022 Med D reporting.

Questions Re: Document ID: CMS-10185-Part D Reporting Requirements 2022

Question 1:
Element F states:
The number of claim rejections overridden by the pharmacy due to an exemption.
We will be including the following overrides in the element F count:
• Prescriber consulted, dispensed, palliative care
• Prescriber consulted, dispensed, cancer treatment
• Pharmacist consulted other source, dispensed, palliative care
• Pharmacist consulted other source, dispensed, cancer treatment
Is this a complete list of the overrides to include in the Element F count?
If it is not, which other overrides should be included?
Should any of the above overrides not be included?

Question 2:
Element G states:
Of the total not in element F, the number of claim rejections overridden by the pharmacy as a

result of prescriber consultation.
We will be including the following override in the element G count:
• Prescriber consulted, dispensed, with prescriber approval
Is this the correct override to include in the Element G count?
Are there any other overrides that should be included in the element G count and what overrides are they?

Question 3:
Element S states:
Of the total reported in element R, the number of unique beneficiaries with at least one claim rejection overridden by the pharmacy due to an exemption.
We will be including the following overrides in the element S count:
• Prescriber consulted, dispensed, palliative care
• Prescriber consulted, dispensed, cancer treatment
• Pharmacist consulted other source, dispensed, palliative care
• Pharmacist consulted other source, dispensed, cancer treatment
Is this a complete list of the overrides to include in the Element S count?
If it is not, which other overrides should be included?
Should any of the above overrides not be included?

Question 4:
Element X states:
The number of rejected claims overridden by the pharmacy due to an exemption.
We will be including the following overrides in the element X count:
• Prescriber consulted, dispensed, palliative care
• Prescriber consulted, dispensed, cancer treatment
• Pharmacist consulted other source, dispensed, palliative care
• Pharmacist consulted other source, dispensed, cancer treatment
Is this a complete list of the overrides to include in the Element X count?
If it is not, which other overrides should be included?
Should any of the above overrides not be included?

Question 5:
Element Y states:
The number of rejected claims overridden by the pharmacy because the beneficiary was not opioid naïve.
We will be including the following overrides in the element Y count:
• Prescriber consulted, dispensed, patient is not opioid naive
• Pharmacist consulted other source, dispensed, patient is not opioid naive
Is this a complete list of the overrides to include in the Element Y count?
If it is not, which other overrides should be included?
Should any of the above overrides not be included?

Question 6:
Element Z states:
Of the total not in elements X or Y, the number of rejected claims for which up to a 7 day supply (covered by the plan) was dispensed by the pharmacy.
We will be including the following in the element Z count:
• Claims which were paid without a pharmacy override or a favorable or partially favorable

coverage determination for up to a 7 day supply
Is this a complete list of what should be included in the Element Z count?
If it is not, which other claims should be included?

PUBLIC SUBMISSION

As of: 5/19/21 12:16 PM
Received: May 17, 2021
Status: Draft
Category: Health Plan or Association
Tracking No. kot-023d-c28a
Comments Due: May 18, 2021
Submission Type: Web

Docket: CMS-2021-0041
Medicare Part D Reporting Requirements (CMS-10185)

Comment On: CMS-2021-0041-0001
Medicare Part D Reporting Requirements (CMS-10185)

Document: CMS-2021-0041-DRAFT-0006
Comment on CMS-2021-0041-0001

Submitter Information

Email: Keith.Greiner@fallonhealth.org
Organization: Fallon Health

General Comment

Our Medicare Advantage organization seeks clarification from CMS regarding how to populate Elements I and J of the Medication Therapy Management Plan Reporting. If a member is enrolled into MTM due to plan-specific criteria (Some sponsors also offer enrollment in the MTM program to an expanded population of beneficiaries who do not meet the targeting criteria under § 423.153(d)(2).):
Would Element I (Targeting criteria met) be populated with “None” or is there a choice of “N/A”?
Would Element J (Date met the specified targeting criteria per CMS – Part D requirements in § 423.153(d)(2)) be populated with “N/A” or left blank?

PUBLIC SUBMISSION

As of: 5/19/21 12:08 PM
Received: April 13, 2021
Status: Posted
Posted: May 19, 2021
Tracking No. knf-wq61-ap7c
Comments Due: May 18, 2021
Submission Type: Web

Docket: CMS-2021-0041
Medicare Part D Reporting Requirements (CMS-10185)

Comment On: CMS-2021-0041-0001
Medicare Part D Reporting Requirements (CMS-10185)

Document: CMS-2021-0041-0002
Comment on CMS-2021-0041-0001

Submitter Information

Name: Anonymous Anonymous
Email: pregan@gatewayhealthplan.com

General Comment

Part D Enrollment reporting clarification.
• We have agents that use our CRM system to submit the enrollments electronically. Usually either on an iPad or Laptop. We have always captured these as Electronic since that is how we interpreted the guidance. This is under I, "Of the total reported in A, the number of electronic enrollment requests received via an electronic device or secure internet website (if sponsor offers this mechanism". Would this instead fall under K "Of the total reported in A, the number of enrollment requests received from an applicant through an agent broker"?

• If the agent doesn't submit the application via an electronic device but rather faxes in an app, would that be captured as Paper under G, "Of the total reported in A, the number of paper enrollment requests received" or under K, "Of the total reported in A, the number of enrollment requests received from an applicant through an agent broker"?

PUBLIC SUBMISSION

As of: 5/19/21 12:10 PM
Received: May 06, 2021
Status: Posted
Posted: May 19, 2021
Tracking No. kod-50vr-hjs9
Comments Due: May 18, 2021
Submission Type: Web

Docket: CMS-2021-0041
Medicare Part D Reporting Requirements (CMS-10185)

Comment On: CMS-2021-0041-0001
Medicare Part D Reporting Requirements (CMS-10185)

Document: CMS-2021-0041-0004
Comment on CMS-2021-0041-0001

Submitter Information

Name: Anonymous Anonymous
Email: pregan@gatewayhealthplan.com

General Comment

Will the Part D excluded drugs be excluded from the DV count as in the past?

Healthfirst, Inc.

Enrollment:

CY2021 -

Enrollment K: Of the total reported in A, the number of enrollment requests effectuated by sales persons.

CY2022

Enrollment K. Of the total reported in A, the number of enrollment requests received from an applicant through an agent broker.

Is “agent broker” the same as a sales rep/person? We have an internal sales team and external brokers. Are we only reporting the brokers in this field? Or does this include the sales team and brokers?

2022 Part D Reporting Requirements: Healthfirst, Inc. Pharmacy Comments

Opioid Care Coordination Safety Edit

K. The number of unique beneficiaries with at least one claim rejection overridden by the pharmacy due to an exemption.

L. Of the total not in element K, the number of unique beneficiaries with at least one claim rejection overridden by the pharmacy as a result of prescriber consultation.

Healthfirst recommends that CMS not include elements K or L. CMS does not require dispensing pharmacists to include special documentation for these overrides and only one Result of Service Code may be entered per reject reason. Pharmacists may be overriding Opioid Care Coordination edits "with prescriber approval," rather than using specific exemption overrides. For these reasons we question the value in collecting the volume of claims overridden by the pharmacy for a specific reason, given that pharmacists may not be using specific exemption overrides for this edit.

Opioid Naïve Days Supply Safety Edit

X. The number of rejected claims overridden by the pharmacy due to an exemption.

Y. The number of rejected claims overridden by the pharmacy because the beneficiary was not opioid naïve.

BB. The number of unique beneficiaries with at least one rejected claim overridden by the pharmacy due to an exemption.

CC. The number of unique beneficiaries with at least one rejected claim overridden by the pharmacy because the beneficiary was not opioid-naive.

Healthfirst recommends that CMS combine elements X and Y into a single element: The number of rejected claims overridden by the pharmacy. We also recommend the CMS combine elements BB and CC into a single element: The number of unique beneficiaries with at least one rejected claim overridden by the pharmacy.

Hard rejects, like the opioid naïve safety edit, may only be overridden by a pharmacist using a Submission Clarification Code (SCC). "Beneficiary is not opioid naïve" overrides cannot be distinguished from exemption overrides, as SCC values to clarify the reason for an opioid naïve edit override do not exist. For this reason, we recommend CMS combine elements X and Y and elements BB and CC.

PUBLIC SUBMISSION

As of: 5/19/21 12:11 PM
Received: May 15, 2021
Status: Posted
Posted: May 19, 2021
Category: Health Care Industry - PI015
Tracking No. kop-ifg5-3bs7
Comments Due: May 18, 2021
Submission Type: Web

Docket: CMS-2021-0041
Medicare Part D Reporting Requirements (CMS-10185)

Comment On: CMS-2021-0041-0001
Medicare Part D Reporting Requirements (CMS-10185)

Document: CMS-2021-0041-0005
Comment on CMS-2021-0041-0001

Submitter Information

Email: danielle.w.booker@healthpartners.com
Organization: Healthpartners

General Comment

Section IV. Improving Drug Utilizations Review Controls:
Element E. The number of claim rejections overridden by the pharmacy within 24 hours of the initial claim rejection
Question: Can CMS clarify the timeframe for if/when a claim would become an "initial claim rejection" again? For example, if a claim was processed for a particular member on January 1st, rejected for the Care Coordination Safety Edit, and then another claim was processed on April 1st and also rejected for this edit, would they be considered 2 separate "initial claim rejections"? Or is CMS considering the "initial claim rejection" to be counted once per year, upon the first occurrence?

Element J. The number of unique beneficiaries with at least one claim rejection overridden by the pharmacy within 24 hours of the initial claim rejection
Question: In the example above, should the beneficiary be counted only if the January 1st claim (first incidence) was overridden by the pharmacy within 24 hours? Or should the April 1st claim also be reviewed and taken into account?

For Data Element Z, 'Welcome Letter' is listed as an option for the method of delivery. Can you please define 'Welcome Letter'? Is this referring to the invitation/offer communications sent to members who meet our MTMP targeting criteria?"
For the Redetermination section, please provide guidance on how to report RD DMR’s not

related to an exception? For example, which of the new reporting sections would we report RD DMR's related to cost sharing appeals or Self-Administered Drugs where the coverage determination was denied for no proof of payment and the member is now providing documentation of payment?

PUBLIC SUBMISSION

As of: 5/19/21 12:05 PM
Received: May 17, 2021
Status: Draft
Category: Health Plan or Association
Tracking No. kos-uo9n-hxo5
Comments Due: May 18, 2021
Submission Type: Web

Docket: CMS-2021-0041
Medicare Part D Reporting Requirements (CMS-10185)

Comment On: CMS-2021-0041-0001
Medicare Part D Reporting Requirements (CMS-10185)

Document: CMS-2021-0041-DRAFT-0005
Comment on CMS-2021-0041-0001

Submitter Information

Name: Anonymous Anonymous
Email: haines-r@iehp.org

General Comment

1. In Section IV Improving Drug Utilization Review Controls, for element U, would the favorable coverage determination be a coverage determination that fell within the same quarter as the rejected claim edit? What would happen if the rejected claim occurred on the last day of quarter 1 and the coverage determination was approved during quarter 2?

2. In Section IV Improving Drug Utilization Review Controls, for element U, are the favorable coverage determination and the rejected claim edit linked at the National Drug Code (NDC) level for the purposes of including in the reporting?

Independent Health

511 Farber Lakes Drive, Buffalo, New York 14221 716.631.3001 www.independenthealth.com

May 18, 2021

CMS, Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: Document Identifier CMS-10185
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically via www.regulations.gov

Re: Proposed 2022 Medicare Part D Reporting Requirements

Dear Mr. William N. Parham, III:

Thank you for the opportunity to comment on the proposed 2022 Medicare Part D Reporting Requirements (CMS-10185). Independent Health Association (IHA) is a not-for-profit health plan that continually aims to provide our Western New York community with innovative health-care products and services, which enable affordable access to quality health care. Our award-winning customer service, dedication to quality health care and unmatched relationships with physicians and providers has allowed us to be consistently recognized as one of the highest-ranked health insurance plans in the nation. Additionally, IHA's HMO and PPO contracts each received an overall star rating of 4.5 in the 2021 star ratings. IHA offers Medicare Advantage Plans and Prescription Drug Plans. Please see our comments below.

For Section IV. Improving Drug Utilization Review Controls, we ask CMS to add clarifying language to the reporting requirements and/or technical specifications on what is considered an "exemption" for data elements F, S, and X. If the reference to an excepted beneficiary refers to the beneficiary categories at 42CFR 423.100, we recommend that CMS add a link to the regulation, so that plans, pharmacies, and others can easily reference the most up-to date list (since it has changed and may continue to do so). Alternatively, CMS could, on an annual basis, add the list to the specifications from the regulation text.

For Section IV. Improving Drug Utilization Review Controls, we ask CMS to clarify in the reporting requirements and/or technical specifications for data elements F, S, X, and Y whether an override by the health plan for an exemption (or to state the member is not opioid naïve) would count in these data element categories (such as an override entered by the plan's pharmacy help desk) or only an override entered by the dispensing pharmacist. Plans may not allow pharmacies to enter an exemption override at point-of-sale for these elements, in which case there would be no data for those elements if only a dispensing pharmacy override is counted.

For Section V. Coverage Determinations Redeterminations, and Reopenings, under At-Risk Redeterminations, we ask CMS to define in the reporting requirements and/or technical specifications what would fall under this At-Risk Redetermination category. Clarification in the reporting requirements and/or technical specifications as to whether this would be a combination of all redeterminations or only exception redetermination requests would be helpful for achieving the goal of accurate and comparable reporting. Also, is an "at-risk" redetermination based on the drug, type of drug, protected drug class, preauthorization criteria or some other criteria? Although we would suggest not distinguishing between at-risk versus non-at-risk redeterminations, additional background on the purpose behind this reporting distinction could be helpful as well.

Thank you again for the opportunity to comment and thank you for considering IHA's views on the proposed 2022 Medicare Part D Reporting Requirements (CMS-10185) . If there are any questions or additional information is needed, please contact Jeremy Laubacker at Jeremy.Laubacker@independenthealth.com.

Sincerely,

Dawn Odrzywolski
Vice President, Medicare Programs

PUBLIC SUBMISSION

As of: 5/19/21 12:58 PM
Received: May 14, 2021
Status: Draft
Category: Health Plan or Association
Tracking No. koo-w935-bqa5
Comments Due: May 19, 2021
Submission Type: Web

Docket: CMS-2021-0042
CMS Identity Management (IDM) (CMS-10452)

Comment On: CMS-2021-0042-0001
CMS_FRDOC_0001-3047

Document: CMS-2021-0042-DRAFT-0004
Comment on CMS-2021-0042-0001

Submitter Information

Email: Teresa.L.Adkins@kp.org
Organization: Kaiser Permanente

General Comment

"We would like clarification on why CMS removed the following paragraph from section VI "Employer/Union Sponsored Group Health Plan Sponsors:
NOTE: This reporting requirement applies only to individual PDPs and "800 series" PDPs offered to employers. MA-PD plans already report these data as part of the Part C reporting requirements and are therefore exempt from this Part D reporting section.
We would like to understand if this means CMS expects MAPD plans to now follow the Part D Reporting Requirements for this specific section as of 2022 going forward."

PUBLIC SUBMISSION

As of: 5/19/21 1:03 PM
Received: May 14, 2021
Status: Draft
Category: Health Plan or Association
Tracking No. koo-yexh-if7u
Comments Due: May 19, 2021
Submission Type: Web

Docket: CMS-2021-0042
CMS Identity Management (IDM) (CMS-10452)

Comment On: CMS-2021-0042-0001
CMS_FRDOC_0001-3047

Document: CMS-2021-0042-DRAFT-0005
Comment on CMS-2021-0042-0001

Submitter Information

Email: Teresa.L.Adkins@kp.org
Organization: Kaiser Permanente

General Comment

We would like additional clarification on the following for the 2022 Part D Reporting Requirements :
• The previous element D for enrollments indicated, “the number of enrollment requests denied due to the sponsor’s determination of the applicant’s ineligibility to elect the plan.” This version now states, “the number of enrollment requests denied due to the sponsor’s determination that the applicant was not eligible for an election period.” We would like clarification if this means element D should only include election period denials and no other upfront denial reasons such as for outside the service area and element F is for all other denials.
• The previous element K for enrollments stated “the number of enrollment requests effectuated by sales persons.” It now says, “the number of enrollment requests received from an applicant through an agent broker.” We would like clarification whether that means this should only include applications received from 3rd party brokers or if this also includes internal plan sales agents.

Attachments

2021-077_CY2021 to CY2022 Crosswalk_040821

2021-077_CY2022_Part D Reporting Requirements_030821

May 18, 2021

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Department of Health and Human Services
Attention: CMS-10185, Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Re: Information Collection Request on Medicare Part D Reporting Requirements (CMS-2021-0042-0001, CMS-10185)

Dear Sir or Madam:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to the Centers for Medicare and Medicaid Services (CMS) regarding the Information Collection Request on Medicare Part D Reporting Requirements. NCPA appreciates the work of CMS to continue to bring transparency to the Part D pharmacy performance measures currently in use in network contracts by plans and pharmacy benefit managers (PBMs) and to begin the development of a standardized pharmacy performance measure rubric for use in the future.

NCPA represents America's community pharmacists, including 21,000 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a $74 billion healthcare marketplace, employ 250,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits these comments on behalf of community and long-term care pharmacies.

Background

NCPA has repeatedly weighed in with CMS regarding our concerns with direct and indirect remuneration (DIR) and pharmacy price concessions in the Medicare Part D program and the need for the development of standard pharmacy quality measures. The way in which pharmacy quality is currently measured in the Part D program is unfortunately tied to PBM recoupments from the pharmacy post point-of-sale versus a standardized quality payment program. Community pharmacists should be rewarded for efforts to drive performance and not solely penalized, especially when plan sponsors are receiving bonus payments.

Community pharmacy providers have experienced a skyrocketing increase in the amount of post point-of-sale price concessions (often referred to as direct and indirect remuneration fees) extracted from their businesses by Part D plan sponsors and PBMs. The increase in these retroactive fees continues to have a detrimental effect on Part D beneficiaries, the Medicare program, pharmacies, and taxpayers, and the trend is not slowing.

These fees blur the line among the cost of a prescription drug, payment for pharmacy services, quality measures, and pharmacy price concessions. Many of these retroactive fees are marketed by Medicare Part D plan sponsors/PBMs as "quality based." However, these retroactive fees are based on payment methodologies consisting of a withhold of a certain amount with the opportunity for the pharmacy to have the penalties decreased (or "earned back") based on achieving certain arbitrary quality measures implemented by the plan/PBM. Oftentimes the retroactive fees are based on the ingredient cost of drugs dispensed, far from "quality."

For example, one independent pharmacy owner in 2020 paid $215,125.49 in DIR fees. It is difficult for this pharmacy owner to determine exactly how much of this amount was "earned back" in the name of quality, but the best approximation is 7% of the total amount paid in DIR fees was returned. This amount ($15,670.24) is minimal for the pharmacist, based on time/staff commitment to quality, who has already paid $96,475.46 in DIR fees from January 1, 2021, thru April 30, 2021.

Plan sponsors are receiving significant bonus payments for their performance, yet bonus payments are not being passed down to providers to drive performance. Pharmacists are driving performance through their services and relationships directly with patients yet are being penalized for their efforts that contribute to a plan's quality rating.

NCPA Applauds CMS for Requiring Part D plans/PBMs to Disclose Pharmacy Performance Measures

On January 15, 2021, CMS finalized a rule requiring Part D plans to disclose pharmacy performance measures and how they are applied to pharmacies to CMS[1]. CMS will be able to make those measures publicly available to increase transparency in the Part D space and utilize the information to begin development of standardized pharmacy performance measures. The requirement becomes effective on January 1, 2022.

NCPA recognizes this as an important first step in the process of standard pharmacy performance metrics being applied across the industry. NCPA appreciates CMS hearing the issues raised by past comments in the Part D space and for willingly taking the first step in situational awareness around the discrepancies in the application of performance measures by plans/PBMs to pharmacies within the various PBM networks.

NCPA understands this process is nascent and will require additional rulemaking by CMS. NCPA looks forward to continuing to work with CMS and other stakeholders to develop a functioning and transparent system which works for all participants and benefits patients.

[1] https://www.federalregister.gov/d/2021-00538/p-1076

NCPA suggests CMS utilize the work of the Pharmacy Quality Alliance (PQA) in assisting in the development of any standardized metrics.

NPCA urges CMS to utilize a wide scope under their authority to collect information related to how pharmacy "performance" is measured, regardless of whether a plan or PBM utilizes the term "pharmacy performance measures" in contractual language.

NCPA Recommends for Each Pharmacy Performance Metric Being Used by a Plan/PBM to Measure a Pharmacy, CMS Shall Collect:

- The measure developer or entity responsible for development of the measure;
- How the measure was validated and tested;
- If the plan/PBM is using the measure in accordance with published measure specifications which have been validated and tested;
- If the plan/PBM is using the measure according to licensing agreements with measure stewards;
- Adjustments or modifications to measure steward specifications;
- Source of data used to calculate the measure;
- The minimum number of patients required in the denominator to reliably calculate the measure;
- The platform, e.g., EQuIPP, and measurement period used in calculating the measure.
- Thresholds for incentives or other cut points related to pharmacy performance;
- Level of attribution, e.g., individual pharmacy vs. Pharmacy Services Administration Organization (PSAO), and attribution criteria;
- Risk adjustment or stratification included in the measure to account for clinical or socio-economic variables;
- Whether the measure is being utilized to calculate reimbursement, either through recoupment, credit to a deduction in payment or bonus payments, or a combination thereof;
- Claim ID for payor, prescription number, pharmacy NCPCP number, transaction number, or Generic Product Identifier, and fill date to identify the claim(s) being used to determine the measure.
- Where the measure should apply i.e., community pharmacy-based claims, specialty pharmacy-based claims, LTC pharmacy-based claims and if the quality measures are different based on where the patient lives.

It is imperative that such level of detail outlined above be provided to CMS via the Medicare Part D Reporting Requirements. This is because the measures often being applied by plans/PBMs to pharmacies were developed for use in population health measurement at a health plan level, not developed for use in pharmacies with smaller numbers of patients.

There is wide variance and lack of standardization among PBMs and plans with respect to terminology, metrics, timing, and calculation methods. PBMs and plans regularly deviate from the measure specifications when using endorsed measures to determine pharmacy level quality.

PBMs and plans will oftentimes alter the list of drugs used to capture a metric during the evaluation period. There is a lack of transparency as to how PBMs and health plans are implementing their own and/or altering endorsed measure specifications. Moreover, the frequency of changes makes it challenging for pharmacies to consistently track their performance. There is a lack of consistency in attribution methods or number of patients required to capture a metric. PBMs and plans may utilize a measure to determine the entire pharmacy's quality based on as few as one patient.

Pharmacies experience systematic payment reductions based on ambiguous contract terms and no consistency exists among measurement time periods. While CMS and plans should be connecting the patients most in need with medication management with the highest performing pharmacies, there is a disincentive to care for these patients in the current environment of penalties (i.e., lower quality scores equal increased retroactive pharmacy price concessions) and pharmacy performance "goals" are oftentimes unattainable due to unrealistic thresholds and cut points.

Looking to the Future

Community pharmacists sometimes have no insight into their individual pharmacy's quality standing in any given PBM network. A pharmacy may not be given access to a dashboard or data/metrics showing where it stands in relation to other pharmacies in the PBM "quality" network. For these reasons, NCPA strongly urges CMS to require the greatest level of detail when requiring plans/PBMs to report pharmacy performance measures. It is important for community pharmacy that plans and PBMs make all aspects of these measures fully transparent, and CMS ensures plans/PBMs are held accountable for the measures being used. As CMS begins to collect data from the plans/PBMs, NCPA recommends CMS identify potential misuses and unfair applications of pharmacy performance measures, particularly focused on independent pharmacies arbitrarily grouped together within a particular network.

NCPA would also suggest CMS make all the information on pharmacy performance measures collected publicly available as soon as possible so pharmacies can make decisions on their Part D contracts for the upcoming year, increase transparency, and benefit patients. It is important that participating pharmacies are aware of the measures for which they are being held accountable.

Furthermore, NCPA requests CMS develop a system where pharmacies can validate the data submitted by the plans/PBMs. CMS accords plans and PBMs to reconcile, validate, dispute, and review submitted data. Since pharmacies are being judged on similar criteria, they should have the same opportunity to audit the submitted data to correct for mistakes and inaccuracies.

Finally, NCPA supports the natural outgrowth of a Star Ratings system for pharmacies to better provide information to patients when choosing a potential Part D plan and pharmacy partner. NCPA has participated in PQA's creation of pharmacy level measures. Measures are being created that look at a given pharmacy's entire patient population and pharmacy system data, not just patients siloed by plan/PBM or solely using plan/PBM claims data.

In doing so, NCPA requests CMS require the use of pharmacy level measures and develop a verification process to ensure the data being used to measure pharmacy performance is correct and statistically meaningful. However, given the unique needs and the possibility of statistically skewed patient populations, NCPA recommends CMS consider separating long term care and specialty pharmacies from community pharmacies when designing such a Star Ratings system.

Conclusion

Under the Part D program, plans/PBMs have clear and consistent quality measurement rules that are not suitable for pharmacies. Community pharmacies have no such rules. As pharmacies serve patients from multiple health plans and PBMs, there is an inconsistent and untenable application of the definition of "quality" applied to pharmacies among the various payors. This lack of consistency has led to the extraction of billions of dollars in pharmacy DIR fees, and we greatly appreciate CMS taking this first important step to address the problems our members are facing in serving Part D patients.

NCPA greatly appreciates the opportunity to share our views on the data collection for Medicare Part D Reporting Requirements. NCPA looks forward to continuing to work with CMS and other interested stakeholders to develop universal pharmacy performance measures as well as responsible and practicable ratings for pharmacy. Should you have any questions, please contact me at ronna.hauser@ncpa.org or 703-838-2691.

Sincerely,

Ronna B. Hauser, PharmD
Vice President, Policy & Government Affairs

CC: Cheri Rice, Deputy Director, CMS
Amy Larrick, Director, Medicare Drug Benefit and C and D Data Group
Chris Bauer, Director, Medicare Drug Benefit and C and D Data Group, Division of Part D Policy
Craig Miner, Deputy Director, Medicare Drug Benefit and C and D Data Group, Division of Part D Policy
Michelle Ketcham, Director, Medicare Drug Benefit and C and D Data Group, Division of Clinical and Operational Performance
Alice Lee-Martin, Deputy Director, Medicare Drug Benefit and C and D Data Group, Division of Clinical and Operational Performance

PUBLIC SUBMISSION

As of: 5/19/21 12:37 PM
Received: May 18, 2021
Status: Draft
Category: Health Plan or Association
Tracking No. kou-i73f-cyc7
Comments Due: May 18, 2021
Submission Type: Web

Docket: CMS-2021-0041
Medicare Part D Reporting Requirements (CMS-10185)

Comment On: CMS-2021-0041-0001
Medicare Part D Reporting Requirements (CMS-10185)

Document: CMS-2021-0041-DRAFT-0012
Comment on CMS-2021-0041-0001

Submitter Information

Email: mike.eaton@selecthealth.org
Organization: SelectHealth

General Comment

Regarding the updates for the DUR reporting there are requests being made that are not currently captured by Part D Sponsors. For example, the proposal includes capturing the number of claim rejections overridden by the pharmacy due to a beneficiary exemption. Today pharmacies are just placing codes to override claims and are not providing this granular level of detail for a Part D Sponsor to capture. It would require a large amount of network recontracting to require our pharmacies to provide this type of information on their overrides, to the amount of our entire network. This granular level of override will be overly burdensome to capture on a consistent basis as well since pharmacies are not used to providing detail to these overrides; rather they are used to providing a singular code for overrides. This could cause additional rejections at the point of sale and beneficiary dissatisfaction, as well as potential for beneficiaries to go without their medication due to a pharmacy not submitting proper codes, etc. This additional reporting requirement could be a roadblock for beneficiaries and pharmacies a like to provide needed medication.

Organization Name: CalOptima
Organization Contact Name: Annie Phillips
Email Address: aphillips@caloptima.org
Telephone Number:

Proposed 2022 Part D Reporting Requirements

Section Title	Page #	Description of Issue or Question	Suggested Revision/Comment
Section II. Medication Therapy Management	7	For Letter (I) Targeting criteria met, what will be the allowable data responses?	Include allowable data responses Eg. Y (yes) or N (no)
Section II. Medication Therapy Management	8	For letter Y and Z regarding safe disposal of medication, does this only include communications made as part of the MTM program or does the number of communications and method include dates/methods anytime during the calendar year?	Please provide clarification within this section regarding the definition of reportable education events.