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Director
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Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically via http://www.regulations.gov

Re: CMS-10171/OMB 0938-0978, Part D Coordination of Benefits Data

Dear Director Parham:

Thank you for the opportunity to comment on CMS' Information Comment Request CMS–10171, Part D Coordination of Benefits Data ("COB ICR") published by the Centers for Medicare & Medicaid Services (CMS) in the Federal Register on October 21, 2024.[1]

CVS Health serves millions of people through our local presence, digital channels, and our nearly 300,000 dedicated colleagues – including more than 40,000 physicians, pharmacists, nurses, and nurse practitioners. CVS Health offers Medicare Advantage Prescription Drug (MAPD) plans in 46 states and D.C. Aetna also offers robust standalone prescription drug plans (PDPs) to individuals in all 50 states and D.C. Our unique healthcare model gives us an unparalleled insight into how health systems may be improved to help consumers navigate the healthcare system–as well as their personal healthcare–by eliminating disparities, improving access, lowering costs, and being a trusted partner for every meaningful moment of health. We share CMS' overarching goals in developing the model, namely, to increase access to prescription drugs and improve medication adherence and appreciate CMS' seeking feedback through the RFI from stakeholders early while the model is still in development.

Below are our comments and recommendations which we believe will make the coordination of benefits ("COB") process more efficient and streamlined, specifically as it pertains to E1 transaction enhancements and COB-OHI data collection and operational processes.

[1] See 89 Fed. Reg. at 84154 (October 21, 2024).

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I. E1 Transaction Enhancements

The Medicare E1 response provides significant value to pharmacy providers and the beneficiaries they serve, as the detail enhances the ability to efficiently coordinate benefits. As described in further detail below, we recommend certain enhancements to the E1 transaction to improve pharmacy point of service ("POS") transaction processing where prescriptions are dispensed before the patient arrives at the pharmacy to ensure the enrollee's benefits are coordinated and to improve real-time tracking of enrollee True out-of-pocket (TrOOP) expenditures.

A. Remove Age 65 Restriction on E1 Data Sets

Currently, the E1 service excludes enrollees under the age of 65, even though individuals may be enrolled in Medicare based on disability before they reach the age of 65. Specifically, over 10% of all Medicare enrollees served by CVS pharmacies are under the age of 65. Since these enrollees can change plans or eligibility status, it is critical to have the E1 data available at POS to prevent unexpected outcomes. Without the E1 information for these younger enrollees with complex health care needs, there is a greater risk that their prescriptions will not be submitted to the Part D plan for coverage at the point of sale and they will have to pay out-of-pocket and seek reimbursement from the plan. In addition, if they have other coverage, there will be no coordination with that other coverage, such as billing the Part D cost sharing to Medicaid for QMB eligibles. For all of these reasons, we recommend that CMS enhance the Medicare E1 transaction data sets to include all eligible enrollees, regardless of age.

Recommendation:

- **Provide E1 data for all Medicare enrollees, regardless of age.**

B. Provide MA Only 4RX Information

CMS and the Part D Transaction Facilitator (PDTF) recently included the return of MA Only plan information with the E 1 response, but only when this is the only plan information within the CMS data file (e.g., no PDP plan information) and only the name of the MA Only plan. The BIN, PCN, Group ID, Cardholder ID information associated to the MA Only plan is not provided. However, many MA Only plans support NCPDP claim billing transactions, where the 4RX claim routing information is critical for the pharmacy to be able to service these enrollees for prescriptions covered under Medicare Part B. MA Only enrollees may also be enrolled in a separate PDP plan for their prescription drug benefits. Pharmacies need access to both the Part D and Part B/C plan information to appropriately coordinate benefits. This is becoming more critical as Part B coverage rules are expanding, such as covering HIV PrEP, where the claim may be covered under Part B or Part D based on specific conditions. We recommend that CMS include the full 4RX detail for MA Only plans, not only the plan name, so that enrollee benefits can be coordinated appropriately.

Recommendation:

- **Include the full 4RX detail for MA Only plans, not only the plan name.**

C. Provide Medicaid QMB Information

CVS Health requests CMS include Medicaid prescription benefit eligibility information (4RX) as OHI within the E1 data for QMB dual eligibles. At a minimum, the Medicaid 4RX information should be available for those QMB duals who are enrolled in a MA-PD plan as the Medicare automated cross-over through the Coordination of Benefits Agreement (COBA) process does not apply to MA-PD claims, and the pharmacy must bill Medicaid at point of service. Once the Medicaid 4RX is available within the CMS Medicare OHI data files, Part D plans can access this eligibility data and return as OHI on the paid claim covered under the Part B benefit for a QMB, with NCPDP Benefit Stage Qualifier value of 51 - *Not paid under Part D, paid under Part C benefit (for MA-PD plan). Enrollee is a Qualified Medicare Enrollee*. Additionally, to complete benefits coordination for QMBs, Medicaid pharmacy claims processing systems need to support NCPDP COB claims that contain Benefit Stage Qualifier 51. This recommendation was also called out within the NCPDP QMB Duals White Paper.[2]

Recommendation:

- **Include Medicaid prescription benefit eligibility information (4RX) as OHI on the E1 for QMB dual eligibles.**

D. Provide New MBI Information

CVS Health request CMS enhance the Medicare FFS HIPAA Eligibility Transaction System (HETS) to include and return any newly assigned Medicare Beneficiary Identifier (MBI) for enrollees where the prior MBI was compromised. The assignment of new MBIs is impacting over 12% of our Medicare FFS enrollees, causing Medicare Part B claims (e.g., vaccines) to reject as Missing/Invalid Cardholder ID. This is the result of the enrollee's MBI being replaced, where no notification is returned on the HETS eligibility response to indicate this. As a result, the claim may default to a cash claim, as there is no digital message indicating a new MBI has been assigned and more importantly, the updated MBI is not returned to inform the pharmacy on how to submit the claim.

CVS Health recommends HETS support mapping between the enrollee's original MBI and the newly assigned MBI to return the new MBI within the HETS 271 response when the original MBI is submitted on the 270 request. This is currently supported within the CMS Medicare E1 service, allowing pharmacy providers to coordinate benefits for these enrollees. This is particularly critical during peak vaccine seasons.

Recommendation:

- **Enhance the Medicare FFS HETS to include and return any newly assigned MBI for enrollees where the prior MBI was compromised.**

II. COB-OHI Data Collection and Operational Processes

1. Patient Assistance Programs (PAPs)

[2] https://www.ncpdp.org/NCPDP/media/pdf/WhitePaper/WG1-COB-WP-Dual-Eligible-Part-B-Claims-Processing-Barriers-and-Recommendations_1.pdf?ext=.pdf

Over the past few years, the number of manufacturers offering patient assistance programs (PAPs) to Medicare Part D enrollees and the number of patients that participate in such programs has significantly increased. Per Chapter 14 of the Medicare Part D Prescription Drug Manual, Medicare enrollees who receive financial assistance from PAPs should not allow the claims to pay under the Medicare Part D benefit. Plans are required to implement edits to reject claims under the Part D benefit that are covered through a PAP, so that such costs do not count towards patient True Out of Pocket (TrOOP) costs.

There is a current electronic exchange of COB-OHI information available through the CMS Benefits Coordination & Recovery Center (BCRC) whereby manufacturers can electronically report PAP coverage details for Medicare Part D enrollees. This information is then sent to the Part D plan on a COB-OHI data file for the plan to implement its edits to reject claims filled for those products that should not be covered under Part D.

Despite the availability of this electronic process, many PAPs are not utilizing it and are instead mailing letters to Part D plan sponsors with the required information. As a result, plans are receiving thousands of PAP letters each month, which requires time-consuming and expensive manual processes to manage. Some of the challenges imposed by these paper letters include:

- **Manual processes must be in place to open and sort letters**
- **PAP letters are not standardized, so each letter must be reviewed individually with varying levels of detail being provided**
- **In many cases, there is not enough information in the correspondence for Part D plan sponsors to be able to apply the appropriate edits to reject claims due to PAP coverage. This then requires an outbound phone call to the PAP's customer service line to obtain specific details to confirm enrollee eligibility under the Part D benefit, the list of Product IDs that are associated with the PAP, and the date range for which coverage was approved in order to ensure that these claims do not process under the Part D benefit.**

The volume of paper PAP letters has increased by approximately 4,900% in the past four years. In 2020, one Part D sponsor received approximately 100 letters/month from manufacturers related to this process, and currently, they are receiving on average 5,000 letters a month. The average time to work through the process outlined above for *each letter* is approximately 15 minutes, which includes sorting and opening the mail, contacting Customer Service to obtain details, documenting the discussion, and entering the edits into the POS adjudication system. This is a significant and unwarranted burden on Part D plan sponsors, and we respectfully request that CMS consider implementing one or more of the following solutions:

1) **Require, and enforce the requirement, that PAPs send their drug coverage information electronically through the BCRC process and update the 2007 PAP attestation currently posted on the CMS website to specify that this is the required method for communicating this information. The current version of the attestation allows PAP to communicate PAP assistance details for Part D enrollees by any means, including telephone, mail, electronic mail, or fax to the Part D plan sponsor.**
2) **CMS should work with stakeholders to create a standardized template that includes all the information Part D plan sponsors need to operationalize this**

process; CMS must also then require that PAPs use this template to submit their coverage information.

3) **CMS should also consider allowing batch files of electronic email or file exchange of the PAP information to be passed to Part D plans (such as through an E1 transaction or standardized subrogation process) so that Part D plans and/or their PBMs can load multiple records for the same Contract ID at one time, instead of having to do this on an individual and manual basis.**

Recommendations:

- **Require PAPs to submit their drug coverage information electronically through the BCRC process and update the PAP attestation accordingly.**
- **CMS should develop standardized content for the PAP communication that includes all the information required for Part D plans to operationalize the process.**
- **If electronic data exchange through the BCRC is not possible or until it is implemented, CMS should allow batch transfers of the required information for each Part D sponsor so that all the records for a given Part D sponsor from a PAP can be loaded at one time.**

2. Medicare as a Secondary Payer (MSP) cases

With the expansion of Section 111 reporting requirements for non-Group Health Plans (NGHPs) to include prescription drug coverage, we have seen a substantial increase in paper mailings from NGHPs, such as large automobile insurance companies. Although this information should be transmitted electronically to the BCRC or insurers should enter the claim information directly via BCRC web portal, instead, these large insurance companies are mailing letters directly to Part D plan sponsors to notify them of potential coverage for an accident-related incident for a particular Medicare Part D enrollee. Per CMS guidance as outlined in the Plan Communications User Guide related to the COB-OHI file, if the Part D Plan is certain that a claim is incident-related, and that primary insurance for this incident exists, they should reject primary payment and if the Part D Plan makes a conditional primary payment, it must reconcile with the NGHP post-POS.

This has resulted in significant burden, cost, and operational complexities that must be managed manually, and therefore leads to delays. Upon the receipt of a letter, the Part D Plan sponsor must contact the insurance company for each individual enrollee, get routed to the appropriate parties who can sign HIPAA release forms, then provide a list of all drugs that the Part D enrollee is taking so that the insurance company can assess what coverage will be provided and for what timeframe so that edits can be put in place to ensure that Medicare only pays secondary for those drugs until the settlement has been reached. Once the edits are put in place, there is an ongoing communication between the insurer and the plan sponsor to continue to exchange and evaluate any new drugs that the enrollee may take, and then a final reconciliation may be needed to recover any mistaken payments paid for the covered drugs before the letter was received and the process began.

We request that CMS consider implementing the following steps to address this issue:

1. **CMS should enforce the requirement that NGHPs send their information electronically through Section 111 reporting -- including, but not limited to seeking civil monetary penalties -- especially for the larger companies that should have standardized processes in place to electronically transmit data.**
2. **CMS should adopt enhancements to the COB-OHI data file layout to include additional details related to conditional MSP coverage such as incident-specific Diagnosis Codes, incident-specific covered Product IDs or drug classes, attestation that a HIPAA authorization to disclose PHI is on file, and other necessary information that would reduce some of the burden and time-consuming and costly back and forth communications with NGHP insurance companies to collect all the necessary information.**
3. **CMS should work with stakeholders to create a standardized template that includes all the information Part D plan sponsors need to operationalize this process; CMS must also then require that NGHPs use this template to submit their coverage information.**
4. **Allow conditional insurers and Part D plan sponsors to electronically exchange larger files of information at a Contract ID level to expedite the process.**

Recommendations:

- **CMS should improve enforcement of electronic Section 111 reporting and impose meaningful penalties, including by collecting civil monetary penalties, on NGHPs that do not send the Section 111 electronically as required.**
- **CMS should develop standardized content and templates for the NGHP communication that includes all the information required by Part D plans.**
- **Allow NGHPs and Part D plan sponsors to electronically exchange larger files of information at a Contract ID level to expedite the process**

3. Notifying Enrollees Regarding Other Prescription Drug Coverage on File

Per section 50.2 of the Medicare Prescription Drug Benefit Manual (MPDBM), Part D sponsors are required to notify enrollees about other coverage on file and ask the enrollee to notify the plan if updates are required. Based on our experience, the notification requirement to send all complete COB-OHI data to the enrollee may lead to confusion. This is because in the vast majority of cases, the complete, reliable COB-OHI data on file is for State Pharmaceutical Assistance Programs (SPAP) and AIDS Drug Assistance Programs (ADAP) supplemental COB-OHI records which the Part D plan cannot update. Only the SPAP or ADAP can make updates to these records, with the result that the enrollee is then directed to contact the SPAP and/or ADAP directly. Not only may the enrollee have challenges in getting routed to the appropriate contacts to make changes that will then be reflected in their COB-OHI data, but they are often frustrated at being asked to notify the Part D sponsor only to learn that the Part D sponsor cannot make the updates. They also have no way to easily validate if the information was updated as requested until the next notification letter, at which point, they may follow the same path again.

We recommend that CMS revise section 50.2 of Chapter 14 of the MPDBM to allow Part D sponsors to exclude SPAP and/or ADAP COB information from the notifications. Not only will

this reduce enrollee confusion and therefore increase satisfaction, but it would also result in cost-savings due to a reduction in the number of notification mailings.

Recommendation:

- **Revise Section 50.2 of the Chapter 14 of the MPDBM to allow Part D sponsors to exclude information about SPAP and ADAP coverage from the notification of other coverage required to be sent to enrollees.**

Thank you for considering our recommendations and comments. We welcome any follow-up questions you may have.

Sincerely,

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