### **Frequently Asked Questions**

The Centers for Medicare & Medicaid Services (CMS) is conducting a documentation review in support of the Calendar Year (CY) 2022 Part D Improper Payment Measure (Part D IPM). This analysis determines whether drugs prescribed by medical providers were received by beneficiaries and were appropriately submitted to CMS via prescription drug event (PDE) submissions.

During prior years of the document review and validation process, CMS received several questions regarding details and clarification of the submission process. This Frequently Asked Questions (FAQs) document serves to provide answers to commonly asked questions. Additional information pertaining to the CY 2022 Part D IPM, along with a list of best practices, can be found in the CY 2022 Submission Instructions.

#### 1. Document Submission

 Question: We submitted prescription record hardcopy/medication order documentation for a PDE and received an element check result that the PDE was marked "complete." The pharmacy just located and sent us an updated prescription record hardcopy. What should I do?

<u>Answer:</u> If you have already submitted supporting documentation for a PDE and the PDE is marked as "complete," reach out via the Discussion Board on the Health Plan Management System (HPMS) Part D IPM Module to have the PDE reset. Once the PDE is reset, you will receive communication through the Discussion Board that a window for resubmission of the documentation has been established for that specific PDE. <u>DO NOT</u> resubmit any new or additional documentation until after receiving confirmation via the Discussion Board that the PDE has been reset and that a resubmission window has been approved and opened.

• <u>Question</u>: We submitted a Missing Documentation form for a prescription record hardcopy that we could not obtain. Why does our summary status still show "fail" for this PDE?

<u>Answer:</u> A Missing Documentation form does not substitute for valid supporting documentation; it communicates to CMS that the Part D sponsor's attempts to locate the supporting documentation were not successful. Therefore, the status for the PDE will remain as "fail." If you locate supporting documents for a PDE after you submitted a Missing Documentation form and before the final submission deadline, you may submit them.

 <u>Question</u>: The laws of the state in which the pharmacy resides only require pharmacies to keep records for audit purposes for one year. Are Part D sponsors exempt from sending CMS the prescription record hardcopies for those specific PDE(s)?

<u>Answer</u>: No. Part D sponsors must maintain records, documents, books, and other evidence of accounting procedures and practices for 10 years, per 42 Code of Federal



Regulation (C.F.R.) § 423.505. The 10-year records retention requirement also applies to the Part D sponsor's first tier and downstream entities as per 42 C.F.R. § 423.504(i). Part D sponsors' first tier and downstream entities must contractually agree to audits and inspections by CMS and/or its designees; to cooperate, assist, and provide information as requested; and to maintain records for a minimum of 10 years. Although state law may not require a Part D sponsor to participate in any state audits after a specified time period (e.g., 12 months, 18 months) from the date of service, federal regulation mandates participation for 10 years after the date of service.

 Question: We acquired another contract partially into the calendar year. Are we responsible for the PDE data from the previous Part D sponsor, even if it may be housed at a different pharmacy benefit manager (PBM)?

<u>Answer:</u> Yes. If a Part D sponsor or contract is discontinued, merged, or acquired by another Part D sponsor, the gaining Part D sponsor is required to provide access to the prior contract's documents and information for a period of 10 years. These regulations for Medicare Advantage Prescription Drug (MAPD) sponsors are found in 42 C.F.R. § 422.504(d) and (e). The corresponding regulations for prescription drug plan (PDP) sponsors are found in 42 C.F.R. § 423.505(d). Every effort should be made by the gaining Part D sponsor to acquire the required supporting documentation from the discontinued, merged, or acquired Part D sponsor by contacting the appropriate records maintenance department or personnel.

 Question: The CY 2022 Part D IPM Submission Instructions request a scanned image of both the front and back of the prescription record hardcopy. If the back side of the prescription is blank, do you want us to make a notation of that as you might not be able to see it in the scanned image?

<u>Answer</u>: No. A notation is not needed. Send only the front side of the prescription record hardcopy if the back side is blank.

• <u>Question</u>: Is there a naming convention that should be used when uploading the Zip file of documentation?

<u>Answer:</u> Yes. The Zip file must use a specific naming convention, which includes the contract number and contract year. The Part D IPM supporting documents (e.g., prescription record hardcopy or medication order and Claim Detail File) must be labeled correctly with the PDE\_ID and the document type, as shown in the example below.

Part D IPM Document		Example Naming
Retail/Mail Pharmacy	Long-Term Care (LTC) Pharmacy	Convention
Prescription Record Hardcopy	Medication Order	T3513_2022_0019_RxRec
PBM Claim Detail File		T3513_2022_CDF

These naming conventions apply to PDE records processed in LTC and retail/mail pharmacies.



Please see the Document Naming Conventions section in the CY 2022 Part D IPM Submission Instructions for additional information.

### 2. Mapping

• <u>Question</u>: When submitting mail order or retail pharmacy prescription record hardcopies, do we need to map each prescription or provide a mapping key?

<u>Answer</u>: No. Mapping is not requested for mail order or retail pharmacy prescription record hardcopies.

• <u>Question</u>: When submitting LTC medication orders, do we need to map each one of the orders?

<u>Answer</u>: Yes. CMS requests that all LTC medication orders be mapped to ensure that the proper order is reviewed, as multiple medication and ancillary orders may be present.

- 3. LTC Medication Orders and Valid Provider Authorization
  - Question: We had medication orders rejected due to missing/invalid prescriber signature. LTC facilities tell me the prescriber's signature is not required, and the nurse can approve the order. Is approval by the nurse acceptable for submission?

<u>Answer</u>: For LTC medication orders, if you cannot obtain a document that is signed by a provider with prescriptive authority, you will need to submit supplemental documentation (i.e., medical record or Physician/Authorized Prescriber CMS Attestation for LTC Medication Order form) along with the unsigned medication order. Refer to the CY 2022 Part D IPM Submission Instructions for detailed information.

• <u>Question</u>: If a medication order is not signed by a provider with prescriptive authority, what supplemental documentation can we submit along with the medication order so that the PDE is deemed acceptable?

<u>Answer:</u> A medication order that is signed by a provider with prescriptive authority is required for this validation activity; however, CMS will accept multiple types of supplemental documentation and combinations of documentation that serve to validate or authenticate a medication order instead of the signed medication order. An unsigned medication order must be accompanied by supplemental information such as:

- A physician-signed page from the medical chart referencing a review of the order in progress notes or a provider chart review log showing that a provider with prescriptive authority reviewed and approved a beneficiary's medication order
- A dictation note in a Medical Chart stating orders have been reviewed and approved by a physician
- A Physician/Authorized Prescriber CMS Attestation for LTC Medication Order (CMS provides a blank attestation form in the HPMS Part D IPM Module Document Library to be completed and signed by the provider)

Supplemental documentation must be copied together with the medication order into one PDF using the current prescription record hardcopy naming convention (see example at the bottom of page 2).



Refer to the CY 2022 Part D IPM Submission Instructions and Reference Sheet for Documentation From Long-Term Care Pharmacies and Facilities for detailed information.

#### 4. Deadlines

 Question: What is the advantage of submitting documentation before the early submission deadline?

Answer: CMS provides feedback on early submissions that will allow you to correct issues. Part D sponsors that upload Part D IPM documents (e.g., prescription record hardcopy/medication order) to the HPMS Part D IPM Module on or before the early submission deadline will be notified of all verification checks, including element checks, and will receive an Interim Finding Report (IFR). The element checks ensure that all the necessary data elements are included in the Part D IPM documents. CMS will not provide an element check status notification for documents submitted after the early submission deadline (i.e., you will not be informed via email that your documentation has been reviewed). Part D sponsors that submit incomplete data before the early submission deadline may update files with complete documents by resubmitting before the final submission deadline. All Part D sponsors will receive an IFR and can also continue to submit their documentation until the final submission deadline regardless of whether they submitted documentation prior to the early submission deadline. However, the IFR can provide useful suggestions on how to clear potential discrepancies, and CMS encourages early submission of documentation.

Question: If my plan submits some, but not all, of the assigned Part D IPM documents before the early submission deadline, will we receive element check results for the documents that were submitted before the early submission deadline?

<u>Answer</u>: Yes. CMS conducts the element checks on a document-by-document basis. CMS will post element check results to the HPMS IPM Module Summary Status page for all documentation submitted before the early submission deadline.

#### 5. Common CMS Outreach to Part D Sponsors

Part D IPM Contractor Booz Allen Hamilton (Booz Allen) and CMS may reach out to Part D sponsors for clarification of documentation during the review process. Below are examples of common issues and typical outreach to Part D sponsors. These examples are included in this document to help you understand what areas of supporting documentation pose the most problems during the review process and help inform you as to what you can do to avoid these problems.

The date written on the prescription record hardcopy/medication order does not align with the date of service on the PDE. In this instance, CMS would ask Part D sponsors to confirm with the pharmacy if this is, in fact, the prescription record hardcopy/medication order that best aligns to the date of service on the PDE. If there is a prescription record hardcopy/medication order that better aligns to the PDE date of service, CMS would request that Part D sponsors upload that documentation.



- The submitted medication order was not signed by an authorized prescriber. Authorized prescribers include Doctor of Medicine (MD), Doctor of Osteopathy (DO), Physician Assistant (PA), Nurse Practitioner (NP), Certified Registered Nurse Practitioner (CRNP), Advanced Nurse Practitioner (ANP), and Doctor of Dental Surgery (DDS). Practitioners who do NOT have prescriptive authority are Registered Nurse (RN), Licensed Practical Nurse (LPN), or Licensed Vocational Nurse (LVN). CMS requests the Part D sponsor work with the pharmacy to obtain the properly signed medication order from the facility. Refer to FAQ 3 for information on supplemental documentation.
- The following are examples of date discrepancies on the Physician/Authorized Prescriber CMS Attestation for LTC Medication Order forms submitted for the Part D IPM process in prior years:
  - The medication order is from 5 years ago, while the claim date of service is from 2022. Additionally, the date of service filled in on the Physician Attestation in the "Enrollee Information" section is after the PDE date of service. CMS requests the Part D sponsor have the physician attest to the date of service on the PDE.
  - The date of service of the PDE claim is from 2022; however, the physician has inserted a 2024 date as the date of the medication order. CMS requests the Part D sponsor have the physician attest to the date of service on the PDE.
  - The medication order attached to the Physician Attestation is from 2023 for a 2022 date of service. CMS requests that the medication order from the PDE date of service be attached to the attestation, even though it is unsigned or invalid.
- Another example of a discrepancy identified upon review of the Physician/ Authorized Prescriber CMS Attestation for LTC Medication Order forms submitted during the Part D IPM process in prior years was that only the attestation was submitted. Remember that attestations are needed only for medication orders without a signature from a provider with prescriptive authority. The attestation must be scanned together with the medication order as one PDF document corresponding to the PDE date of service. The combination of the medication order—even though it is not signed by the provider—along with the attestation form signed by the physician referencing the PDE date of service on the form will allow CMS to consider the documentation to be complete.

### 6. Reporting

• <u>Question</u>: Where can the measurement of Part D Improper Payments that results from this analysis be found?

<u>Answer</u>: The final results for the Part D IPM review can be found in multiple locations. The results are published in both the Agency Financial Report (AFR) and posted to <u>paymentaccuracy.gov</u>. Additional details can also be found on the Medicare Part D IPM page on <u>cms.gov</u>.



• Question: When will we receive the final results for our sampled PDE records?

<u>Answer</u>: Once the AFR is released, your organization will receive a Final Finding Report (FFR) outlining the final results of the Part D IPM review. The FFR will also provide additional details for any PDEs found to be discrepant through the review process.

#### 7. Contact Information

- Questions related to the HPMS Part D IPM Module should be sent to <a href="mailto:hpms@cms.hhs.gov">hpms@cms.hhs.gov</a>.
- Questions related to the CY 2022 Part D IPM should be sent to <u>PartD\_IPM@cms.hhs.gov</u>, with the subject line "Part D IPM 2022."
- Questions may also be submitted via the Discussion Board on the HPMS Part D IPM Module.

Do not include any protected health information (PHI) and/or personally identifiable information (PII) when you communicate about a PDE record via email or the Discussion Board.