Frequently Asked Questions

The Centers for Medicare & Medicaid Services (CMS) is conducting a documentation review in support of the calendar year 2021 (CY 2021) 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.

1. Document Submission

1.1. ***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?**

Answer: If the supporting documentation for a PDE has already been submitted and marked as "complete," reach out via the discussion board to have the PDE reset. Once the PDE is reset, a window for resubmission of the documentation will be communicated through the discussion board for that specific PDE. DO NOT 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.

1.2. *Question:* 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?

Answer: 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 documents are located after a Missing Documentation Form is submitted and before the final submission deadline, they may be submitted.

1.3. ***Question*****: 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)?**

*Answer***:** 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 CFR §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 or 18 months) from the date of service, federal regulation mandates participation for 10 years after the date of service.

1.4. ***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)?**

Answer: Yes. If a Part D sponsor or contract is discontinued, merged, or acquired by another Part D sponsor, the gaining Part D sponsors are 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.

1.5. ***Question:*** **The CY 2021 Part D IPM Submission Instructions requests a scanned image of both the front and back of the prescription record hardcopy. If the backside 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?**

Answer: No. A notation is not needed. Send only the front side of the prescription record hardcopy if the backside is blank.

1.6. ***Question:*** **Is there a naming convention that should be used when uploading the Zip file of documentation?**

Answer: Yes. The Zip file must have 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 Convention
Retail/Mail Pharmacy	Long-Term Care (LTC) Pharmacy	
Prescription Record Hardcopy	Medication Order	T3513_2021_0019_RxRec
PBM Claim Detail File		T3513_2021_CDF

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

Please see the Document Naming Conventions section in the Submission Instructions for additional information.

2. Mapping

2.1. ***Question*: When submitting mail order or retail pharmacy prescription record hardcopies, do we need to map each prescription or provide a mapping key?**

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

2.2. ***Question:* When submitting LTC medication orders, do we need to map each one of the orders?**

Answer: 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

3.1. ***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?**

Answer: For LTC medication orders, if you cannot obtain a document that is signed by a provider with prescriptive authority, supplemental documentation (i.e., medical record or CMS Physician Attestation Form) will need to be submitted along with the unsigned medication order. Refer to the Submission Instructions for detailed information.

3.2. ***Question:* 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?**

Answer: A medication order that is signed by a provider with prescriptive authority is required for this validation activity; however, multiple types of supplemental documentation and combinations of documentation that serve to validate or authenticate a medication order will be accepted 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 Attestation (a blank Physician Attestation is provided by CMS in the HPMS Part D IPM Module Document Library to be completed and signed by the provider)

Supplemental documentation must be copied together, along with the medication order, into one PDF using the current prescription record hardcopy naming convention. Refer to the Submission Instructions and Reference Sheet for Documentation from Long-Term Care Pharmacies and Facilities for detailed information.

4. Deadlines

4.1. ***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 we find. Contracts that upload Part D IPM documents (e.g., prescription record hardcopy/medication order) to the Health Plan Management System (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. Element check status will not be provided for documents submitted after the early submission deadline (i.e., you will not be informed whether your documentation data elements were deemed complete or which required data elements your documentation is missing). Part D sponsors with incomplete data submitted before the early submission deadline may update files with complete documents by resubmitting before the final submission deadline. Part D sponsors that have not submitted Part D IPM documents by the early submission deadline will not be able to correct any issues discovered during the Element Check process and will not receive an IFR.

4.2. ***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?**

Answer: Yes. The element checks are done on a document by document basis. All documentation submitted before the early submission deadline will have element check results posted to the HPMS IPM Module Summary Status page.

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 Part D sponsors understand what areas of supporting documentation pose the most problems during the review process and help inform them as to what they can do to avoid these problems.

5.1. 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.

5.2. 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). Work with the pharmacy to obtain the properly signed medication order from the facility. 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 the question and Answer 3.2 for information on supplemental documentation.

5.3. The following are examples of date discrepancies on the Physician Attestations submitted for the Part D IPM process in prior years:

- The medication order is from five years ago, while the claim date of service is from 2021. Additionally, the date of service filled in the Physician Attestation in the "Enrollee Information" section is after the PDE date of service.
- The date of service of the PDE claim is from 2021; however, the physician has inserted a 2023 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 2022 for a 2021 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.

5.4. Another example of a discrepancy identified upon review of the Physician Attestation submitted during the Part D IPM process in prior years was that only the Physician Attestation was submitted. Remember that Physician Attestations are only needed for medication orders without a signature from a provider with prescriptive authority. The Physician 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 CMS Physician 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. Contact Information

6.1. Questions related to the HPMS Part D IPM Module should be sent to hpms@cms.hhs.gov.

6.2. Questions related to the CY 2021 Part D IPM should be sent to PartD_IPM@cms.hhs.gov, with the subject line “Part D IPM 2021.”.

6.3. 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 personally identifiable information (PII) when you communicate about a PDE record via email or the discussion board.