SUBMISSION INSTRUCTIONS

January 26, 2024

Submission Deadline:
April 19, 2024 by 11:59 p.m., Pacific Time (PT)

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Introduction

The Centers for Medicare & Medicaid Services (CMS) is conducting a documentation review to validate the accuracy of Calendar Year (CY) 2022 Part D prescription drug event (PDE) data. This analysis determines whether drugs prescribed by medical providers were received by beneficiaries and were billed appropriately to Medicare Part D contracts and, ultimately, to CMS. This process is referred to as the Medicare Part D Improper Payment Measure (Part D IPM).

The Submission Instructions were developed to support those Part D sponsors that have had PDEs selected for the CY 2022 Part D IPM by providing an overview of the process and submission requirements. The purpose of this document is to:

- Describe applicable records maintenance expectations and requirements.
- Provide a Part D IPM overview and timeline for CY 2022.
- Identify Part D IPM supporting documentation required for submission.
- Discuss how to identify selected PDE records.
- Review the submission process.
- Identify best practices.

Records Maintenance Expectations and Requirements

Part D sponsors must maintain books, records, documents, and other evidence of accounting procedures and practices for 10 years, per 42 Code of Federal Regulations (C.F.R.) § 423.505.

The 10-year records retention regulation also applies to the Part D sponsor's first-tier and downstream entities as per 42 C.F.R. § 423.505(i). Part D sponsors' first tier and downstream entities must contractually agree to audits and inspections by CMS and/or its designees and must provide information as requested and maintain records for a minimum of 10 years.

If a Prescription Drug Plan (PDP) or Medicare Advantage Prescription Drug (MAPD) plan is discontinued, merged, or acquired by another Part D sponsor, the "gaining" Part D sponsor is still required to provide access to that Part D sponsor's documents and information for a period of 10 years. All historical records for Part D sponsors that are acquired must be transferred from the old Part D sponsor to the new Part D sponsor. These regulations for PDPs and MAPD plans are found in 42 C.F.R. § 423.505(d). Gaining Part D sponsors should make every effort to acquire the required supporting documentation by contacting the appropriate records maintenance department or personnel.

Federal regulation mandates participation in the audit per 42 C.F.R § 423.505(b)(10).

Federal regulation 42 C.F.R. § 423.322(a) regarding disclosure of information states that CMS' payments to Part D sponsors are conditioned upon provision of information to CMS that is necessary to carry out Subpart G – Payments to Part D Plan Sponsors For Qualified Prescription Drug Coverage, or as required by law. Your cooperation with this data validation activity is required. Organizations that do not comply with this requirement or that have poor performance identified through CMS oversight may be subject to remedies available under law,

including enforcement actions under 42 C.F.R. Parts 423, Subparts K and O, which may include civil money penalties, enrollment sanctions, or contract terminations.

Part D IPM Overview

Each year, CMS conducts a documentation review in support of the Part D IPM. This analysis determines whether drugs prescribed by medical providers were received by beneficiaries and were appropriately submitted to CMS via PDE submissions.

CMS, together with its contractor, collects and reviews documentation from Part D sponsors to substantiate a sample of PDE records selected as part of the Part D IPM. The PDE records in the sample that correspond to the Part D sponsor's contract are made available to Part D sponsors on the Health Plan Management System (HPMS) Part D IPM Module through the PDE Record Identifier spreadsheet. The HPMS Part D IPM Module also allows for sponsors' upload of Part D IPM documents and data (i.e., supporting documentation) for assigned PDE_IDs, such as prescription record hardcopies and Claim Detail Files (CDFs).[1]

Part D Sponsor Responsibilities

Responsibilities for Part D sponsors with PDE records selected for this review include the following tasks:

1. Receive email notification that the PDE Record Identifier spreadsheet, which contains sampled PDE records' identifying data elements, is available for download.

2. Log on to the HPMS Part D IPM Module: hpms.cms.gov.

3. Download the PDE Record Identifier spreadsheet from the HPMS Part D IPM Module.

4. Contact the appropriate pharmacy benefit managers (PBMs) and/or pharmacies to collect the supporting documentation required for each sampled PDE record.

5. Submit the supporting documentation via the HPMS Part D IPM Module.

6. Communicate with CMS and its contractor regarding submission statuses via the HPMS Part D IPM Module Discussion Board.

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[1] Instructions for accessing and using the HPMS Part D IPM Module can be found in the HPMS Plan User Guide.

Part D IPM Timeline

Following is the timeline for the CY 2022 Part D IPM process.

Activity	Date(s)
CMS notifies selected Part D sponsors of participation in the CY 2022 Part D IPM process. Part D sponsors can download the PDE Record Identifier spreadsheet.	January 12, 2024
CMS requests Part D sponsors identify no more than five points of contact (POCs) who will work with CMS throughout the Part D IPM process. Sponsors should submit requests for new users who do **not** have an active CMS user ID and for all users who have an active CMS user ID with access to HPMS, but not the Part D IPM Module, to hpms_access@cms.hhs.gov. Refer to the "Requesting Access to the HPMS Part D IPM Module" document in the Part D IPM Module Document Library for further details.	January 12–25, 2024
Training teleconference held with Part D sponsors to review the submission process and answer questions.	January 24, 2024
HPMS Part D IPM Module is open, and Part D IPM Submission Instructions are available.	January 26, 2024
Submission Window Opens: 12-week submission window begins.	January 26, 2024
Part D sponsors gather supporting documentation from pharmacies and PBMs and submit documentation to the HPMS Part D IPM Module on a rolling basis.	After the submission window begins
Early Submission Deadline: Part D sponsors that have uploaded prescription record hardcopy/medication order supporting documentation to the HPMS Part D IPM Module by this date will receive results from the element checks (see Verification Checks and Resubmission), as well as an Interim Finding Report (IFR) detailing preliminary results. Element checks will not be provided for supporting documents submitted after this date. Part D sponsors that have participated in early submission and find through the elements checks and IFR that they have incomplete supporting documentation may upload additional files with complete documentation by resubmitting before the final submission deadline.	March 8, 2024
Element check status and IFR provided to Part D sponsors that submitted prescription record hardcopy/medication order supporting documentation prior to the early submission deadline.	March 29, 2024
Final Submission Deadline: Part D sponsors complete uploading of supporting documentation to the HPMS Part D IPM Module by this date. Documentation must be received by 11:59 p.m., Pacific Time (PT) on this date to be considered for the Part D IPM validation review.	April 19, 2024

Activity	Date(s)
Ongoing engagement by CMS and its contractor with Part D sponsors via the HPMS Part D IPM Module Discussion Board. Part D sponsors upload additional information, if necessary.	Throughout the submission and review process

Part D IPM Supporting Documentation

Generally, Part D sponsors must submit the following two types of supporting documentation: a CDF and a prescription record hardcopy *or* a medication order. A table with the Part D IPM Document Types is presented below.

Part D IPM Document Type	Frequency
1. **CDF**	One per contract for all PDEs
2. **Prescription Record Hardcopy *or* a Medication Order (for long-term care [LTC] pharmacies)** If the prescription originates from a mail or retail pharmacy, a copy of the prescription record hardcopy must be submitted for that PDE record. If the prescription originates from an LTC pharmacy, a copy of the medication order must be submitted along with any supplemental documents, if applicable, for that PDE record.	One per PDE record
3. **Supplemental Documentation** For an LTC medication order that is not signed by a provider with prescriptive authority, one of the following options for supplemental documentation must be copied together with the medication order into one PDF using the current prescription record hardcopy naming convention: I. Medical Chart: A physician-signed page from the medical chart referencing order in notes, a dictation note in the medical chart stating orders have been reviewed and approved by a physician, etc. The entire medical chart does NOT need to be provided, but supplemental documentation from the medical chart that supports the unsigned LTC medication order should be provided; or II. Attestation: A Physician/Authorized Prescriber CMS Attestation for LTC Medication Order form completed and signed by the provider; or III. Chart Review Log: A patient or provider chart review log signed by a provider with prescriptive authority showing review and approval of the beneficiary's medication order.	One per PDE record when an LTC medication order is not signed by a provider with prescriptive authority

Part D IPM Document Type	Frequency

4. **Optional Documentation**
 	
    I. <u>Medication Administration Record</u>: For LTC pharmacies, the pharmacy-generated Medication Administration Record (MAR) (if the pharmacy generates the MAR for the facility and if one is available) is not required documentation but is useful during the review process. The MAR can be either a copy of a manual MAR or a copy of an electronic MAR (eMAR). The MAR should include the drug name and strength corresponding to the drug name and strength in the PDE sample identifiers. (Note that this optional documentation does not have to be a completed MAR from the facility.)
 	
   II. <u>Micro-Tag</u>**:** Submitting the computer-generated micro-tag is helpful to the review process, if it is available, for both retail/mail order prescription record hardcopies and LTC medication orders. The micro-tag is the computer-generated "sticker" that summarizes the prescription information.
 	
 III. <u>Prior Authorization Records</u>: Submitting approved prior authorization records used to approve the PDE is helpful to validate a proper Part D dispensation.
 	
 IV. <u>Post Reconciliation Adjustment Details</u>: Submitting additional information for any PDEs that have been adjusted post-reconciliation is helpful to validate any differences between the PDE and provided documentation.
	One per PDE record

Best Practices for Supporting Documentation

<u>All</u> supporting documentation submitted by the final submission deadline will undergo the Part D IPM process; thus, please submit the best supporting documentation you can obtain, even if it is incomplete.

Please follow these guidelines when gathering and preparing supporting documentation for submission:

- **All supporting documentation must correspond to the PDE records in the sample.** Do not submit documents or data that correspond to dates of service other than the PDE record date or an adjusted version of the sampled PDE record made after the CMS final PDE submission deadline for Part D reconciliation of June 29, 2023. If the PDE has been adjusted prior to this date, send supporting documentation corresponding to the PDE submitted for reconciliation. See <u>Appendix A</u> for CMS' policy on adjusted PDE records.

- **Supporting documentation must align with the drug name and drug strength on the PDE record.** Drug name and strength will be included in the PDE identifiers provided via the HPMS Part D IPM Module.

- **Data submitted in the CDF must be in .xlsx format.** Use data from the selected PDE, queried from your data warehouse, to assemble the file. Submit data using the template

provided. A data dictionary is also included in the template to provide a description of the data requested in each field.

- **Prescription record hardcopies/medication orders supporting documentation must be legible images (e.g., Adobe PDF, GIF, JPEG, BMP).** Review each document carefully for legibility before uploading and submitting via the HPMS Part D IPM Module. Prescription record hardcopies printed on tamper-proof paper with watermarks are typically used to prevent duplication and deter fraud. These watermarks of "void" or "illegal" appear on photocopies and obscure the prescription writing, making them illegible and rendering them unusable during extraction of required data elements in the review process. In this case, inclusion of a micro-tag can help inform what information is on the prescription hardcopy.

The following sections describe each supporting document, including the format of the document, what the document typically includes, and the minimum data elements that must be included in the document.

Prescription Record Hardcopy (Mail/Retail Pharmacies)

The prescription record hardcopy is the original document from the prescriber (e.g., medical provider). This is the document (paper or electronic) presented to the pharmacy for dispensing. State and federal regulations require that prescription record hardcopies be retrievable by the pharmacy dispensing the prescription.

Attestations submitted by medical providers **do not** serve as valid replacements for the prescription record hardcopy in the retail/mail order setting. Physician attestations will be accepted as supplemental documentation **only** to validate a medication order (LTC pharmacy) not signed by a provider with prescriptive authority.

The prescription record hardcopy submitted for the Part D IPM process **must** include the following data elements:
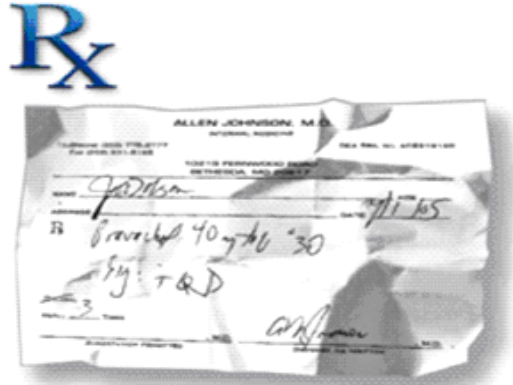
- Patient name
- Drug name (active ingredient)
- Drug strength
- Dispense as Written (DAW) product selection (if applicable)
- Prescriber name
- Prescriber signature (provider with prescriptive authority)
- Prescription date
- Quantity
- Directions for use

This supporting documentation must be provided in the form depicted in Figure 1. Please note, an acceptable prescriber signature may take many different forms. Electronic signatures are acceptable for electronically transmitted documents, while a written signature will be required for written prescriptions. For telephoned prescriptions, a prescriber signature is not needed if the order is phoned directly to the pharmacist. Each signature will be reviewed on a case-by-case basis and compared with the PDE record for accuracy.

Figure 1 shows examples of retail/mail prescription record hardcopies. The front and back of the prescription record hardcopy are requested as they may contain notes that provide documentation of any changes made to the written prescription at the point of service. (There is no need to submit the back of the prescription record hardcopy if it is blank.)

Figure 1: Examples of Acceptable Prescription Record Hardcopies

Note: Fictitious Beneficiary

Note: Fictitious beneficiary

Optional Documentation: Micro-Tags

The micro-tag is the computer-generated "sticker" that summarizes the prescription information. The micro-tag aids reviewers when validating the prescription record hardcopy. **It does not replace the prescription record hardcopy and will not be accepted if submitted without the original prescription record hardcopy.**

If available, a copy of the micro-tag should be submitted. **The micro-tag should be scanned together into one image with the prescription record hardcopy (preferably in PDF format).** See Figure 2 for an example of a micro-tag.

Figure 2: Example of Micro-Tag

Rx#:60999999	DOB: 1/1/1989	FILL DATE: 9/1/2022
Dobson, Joe		233 Elm St, Histown, FL 22222
PRAVACHOL 40 MG	QTY: 30 TAB	11111-2222-33 (Acme Drug)
Johnson, Allen	DEA: BJ1111111	RPh:XXX
Copay: $10.00	Ins. Paid: $45.87	Auth# 1234123456785678

Note: Fictitious beneficiary

The examples depicted in Figure 3 represent examples of acceptable prescription record hardcopy documentation. Figures 4 through 11 depict examples of unacceptable prescription record hardcopy documentation.

Figure 3: Examples of Acceptable Prescription Record Hardcopy Documentation

Name:	Jane Doe			Date: 10/25/2022	

DRUG	MG/CC	SIG	QTY	REFILLS
Amoxicillin	500	PO Q12H	28	0

John Smith, M.D.

_____ _____
Dispense as Written   Substitution Permitted

Note: Fictitious beneficiary

TELEPHONED PRESCRIPTION

NAME: *John Doe*   Date 1/24/22
ADDRESS
PHONED BY ____ Time ___ DELIVER ___ WILL CALL ✓
ORIGINAL Rx No. ____ DO NOT REFILL ___ REFILL ✓ TIMES 12

℞ *Lipitor 40mg*
1t po Qam

LABEL Yes ☐ No ☐   Doctor
Dispense as Written ____
Substitution Permitted ____ *Yes*   Pharmacist
                                          DEA No.

Note: Fictitious beneficiary

Figure 4: Example of Unacceptable Documentation – Prescription History

Prescription History

Doe, Jane

Unacceptable Document

Demographic Detail

Age	Gender	SSN	Alt SSN	Zip
41	F	XXX-XX-XXXX		11111

Prescription Detail

Rx #	Label	Qty	Fill Date	Days Supply	Refill #	Total Refills
1111111	Amantadine 100 mg cap	60	010123	30	0	0
	Prescriber: Smith, J.			Pharmacy: XXX Pharmacy		
2222222	Ambien 10 mg tab	30	010123	30	0	0
	Prescriber: Smith, J.			Pharmacy: XXX Pharmacy		
3333333	Augmentin 500-125 tab	21	010123	7	0	0
	Prescriber: Smith, J.			Pharmacy: XXX Pharmacy		

Prescriber Detail:

Address	Phone	DEA	NPI
2 Elm St, Anywhere, State 11111	111-555-1234	AS1111111	1234567891

Pharmacy Detail:

Address	Phone		NPI	NCPDP
10 Elm St, Anywhere, State 11111	111-555-5678	AS3333333	1234512345	1112223

Drug Detail:

Drug: AMBIEN 10 MG TABLET

Drug Code	Dosage Form	Strength	Route Description	HIC Class
00024542131	TABLET	10 MG	ORAL	Sedative/Hypnotic Non-Barbiturate

Disease Descriptions	Side Effects
Insomnia	Insomnia, Impaired Cognition, Nightmares, Agitation, Depression, Diplopia, Visual Changes, Hypotension, Drowsiness, Amnesia, Vertigo, Dizziness, Skin Rash, Headache, Nausea, Vomiting, Diarrhea, Falling, Allergic Reactions, Irritability

Note: Fictitious beneficiary

Figure 5: Example of Unacceptable Documentation – Pharmacy Attestation

March 5, 2022

In reference to prescription request for Jane Doe

Rx: Atorvastatin 10 mg

Unacceptable Document

Based on the origin code associated with this claim, this order was phoned in. Our internal label was used as a hard copy, therefore no written prescription exists.

The undersigned certifies; (a) that the person for whom the prescription was written is eligible for benefits; (b) that they have received the prescription; (c) that they authorize the release of all information contained in this log, the prescription to which it corresponds and subsequent claims to parties concerned; (d) that they are the patient for whom this prescription is being obtained or are authorized to execute this consent on behalf of such persons; (e) that this medication is not for an on the job injury or covered by any other insurance plan and (f) that they assign payment for this transaction directly to the pharmacy shown above.

Signature: _____

Note: Fictitious beneficiary

Figure 6: Example of Unacceptable Documentation – Pharmacy Transaction File

```
Rx #: 012345              Batch #: 572      Patient Facility: Evergreen
Last Fill:  03/22/2022    Qty: 30           Date:   04/20/2022

                                                   Unacceptable Document

Allergy:  PCN
Product Ordered: Ambien 10 MG Tablet        Package Size: 100
NDC: 00024-5421-31
Product Substituted: Zolpidem 10 MG Tablet  Package Size: 100
NDC: 00054-0087-25
Directions: 1T QD……………………………………………Take one tablet by mouth daily

Qty Dispensed: 30                  Quantity Remaining: 30
# of labels: 1                     PRN (Y/N)?: Y
Expire Date: 04/20/2023            Total Fills: 2      Rx Origin: 0

Label: Zolpidem 10 MG Tablet       Substitution Ok? Y    DAW: 0
Next fill: 05/20/2022              Schedule: C-IV
ICD9:                             RPh1: ABC
```

Note: Fictitious beneficiary

Figure 7: Example of Unacceptable Documentation – Pharmacy Drug Utilization Review (DUR) Report

```
                                    Pharmacy DUR Report
3/2/2022     14:26:54                                    Unacceptable Document    Page 1

Patient Name    Rx No.    Drug Name           Qty   DS   Fill date   Sig
Jane Doe        12345     Amlodipine 10mg     30    30   1/2/2023    One tablet by mouth daily
                12346     Atorvastatin 10mg   30    30   1/2/2023    One tablet by mouth daily
                12347     Zolpidem 10mg       30    30   1/6/2023    One tablet by mouth at bedtime
                12348     Amoxicillin 500mg   30    10   1/10/2023   One capsule by mouth 3x daily
                12349     Nexium 40mg         30    30   1/10/2023   One capsule by mouth daily
                12340     Mirtazapine 15mg    30    30   1/10/2023   One tablet by mouth daily
John Doe        12351     Aricept 10mg        30    30   1/19/2023   One tablet by mouth daily
                12352     Levothyroxine 100mcg 30   30   1/19/2023   One tablet by mouth daily
                12353     Simvastatin 40mg    30    30   1/28/2023   One tablet by mouth daily
                12354     Coreg CR 20mg       30    30   1/28/2023   One tablet by mouth daily
                12355     Tramadol 50mg       90    30   1/28/2023   One tablet by mouth 3x daily PRN
```

Note: Fictitious beneficiary

Figure 8: Example of Unacceptable Documentation – Patient Pickup Signature Log

Rx #	Fill Date	Pickup Date & Time	Decline Counseling	Drug Name	Quantity	Patient Paid	Total	Signature
669230	10/29/22	10/29/22 5:30pm	YES	Simvastatin 20mg	30	$5.00	$5.00	

Note: Fictitious beneficiary

Figure 9: Example of Unacceptable Documentation – Micro-Tags Submitted Without Prescription Record Hardcopy

```
Rx#:60999999          DOB: 1/1/1989              FILL DATE:  9/1/2022
Dobson, Joe                             233 Elm St, Histown, FL 22222
PRAVACHOL 40 MG           QTY: 30 TAB     11111-2222-33 (Acme Drug)
Johnson, Allen           DEA: BJ1111111              RPh:XXX
Copay: $10.00  Ins. Paid: $45.87   Auth# 1234123456785678
```
Unacceptable Document

Note: Fictitious beneficiary

Figure 10: Examples of Unacceptable Documentation – Patient Pickup Signature Log Accompanied by Micro-Tag

Rx #	Fill Date	Pickup Date & Time	Decline Counseling	Drug Name	Quantity	Patient Paid	Total	Signature
669230	10/29/22	10/29/22 5:30pm	YES	Atorvastatin 10mg	30	$5.00	$5.00	

Unacceptable Document

```
        10/29/22

ATORVASTATIN 10MG              #30          Unacceptable Document
NDC# 00591-3774-19    WATSON      REFILLS: 11
TAKE ONE TABLET ONCE DAILY
                  PCS            CHARGE:
```

Note: Fictitious beneficiary

Figure 11: Example of Unacceptable Documentation – Insurance Tax Summary

```
July 1, 2022              Tax Insurance Summary              Page 1

NDC#        Days      Rx#  Dr. J. Smith  N/R   Date   Qty.  Amount

_____      _____    _____  ____  _____  ____  _____

Metoprolol 50mg    30                           06/30/2012   30   $0.00
                          Unacceptable Document
56023-0403-01

Pantoprazole 40mg  30                     N     6/30/2012   15   $5.20

45253-2131-12



Pharmacist: [signature]              Date: 7/01/2022
```

Note: Fictitious beneficiary

Medication Order (LTC Pharmacies)

If the PDE record was processed by an LTC pharmacy, the medication order must be submitted for that PDE record. Part D sponsors should submit any supplemental or optional documentation or explanations as needed. Any supplemental or optional information must be submitted as part of the same image, meaning they should be scanned together (preferably in PDF format). Such optional information includes the MAR and/or computer-generated micro-tag, if available, for that PDE record. Do not send blank MAR template forms used by the facility or MARs containing information not aligning to the specific drug order being reviewed.

LTC pharmacies typically use a prescription record that is different from that used by retail or mail-order prescriptions. The LTC prescription record is usually a page of the patient's medical chart where the prescriber has written the medication order. This page may include other medical directives and may not be as complete or as standardized in format as the prescription record used by retail and mail-order pharmacies.

The medication order submitted for the Part D IPM process **must** include the following data elements:

- Patient name
- Drug name (active ingredient)
- Drug strength
- DAW product selection (if applicable)
- Prescriber name
- Prescriber signature (provider with prescriptive authority)
- Prescription date
- Directions

This documentation must be provided in the following form:

- Image (front and back) of the actual medication order (see Figure 12 for an example).
- If supplemental or optional documentation or explanations are needed, they should be submitted together with the medication order. An example of optional documentation is micro-tag images (see Figure 16 for an example). Make sure to circle or identify the required data elements before creating and submitting the image file. These documents should all be scanned together into one image (preferably in PDF format). Note that electronic history, transaction screenshots, MARs, and refill or packing lists from the pharmacy or LTC facility do not serve as a substitute for the medication order, but may be submitted to provide additional information about the medication order.

Figures 12 through 14 are examples of acceptable medication orders. Figure 15 depicts an example of a mapped medication order. Figure 16 depicts an example of a micro-tag. Figures 17 through 22 show examples of unacceptable medication order supporting documents.

Figure 12: Example of Medication Order

Note: Fictitious beneficiary

Figure 13: Example of Acceptable Medication Order Documentation

PHYSICIAN ORDERS	
Medications	**Orders**

05/04/2022
    Amoxicillin 500mg Oral TID
    Ramipril 5mg Oral QD
06/06/2011
    Lexapro 5mg Oral QD
	05/04/2022 Lifestyle Activities: exercise as tolerated

Physcian Signature: *John Smith*	**Date:** 06/06/2022
Allergies: NKDA	**Diagnosis:** 123.4 561.5 181.2
Resident Name: *Jane Doe*	**DOB:** xx/xx/xxxx

Note: Fictitious beneficiary

Figure 14: Example of Acceptable Medication Order Documentation

Name: Jane Doe			**Date:** 10/25/2022	

DRUG	MG/CC	SIG	QTY	REFILLS
Amoxicillin	500	PO Q12H	28	0

John Smith, M.D.

_____   _____
Dispense as Written   Substitution Permitted

Note: Fictitious beneficiary

Figure 15: Example of Mapped Medication Order

1. Patient Name
2. Drug Dame (Active Ingredient)
3. Drug Strength
4. Dispense As Written (DAW) product selection if applicable
5. Provider with Prescriptive Authority
6. Prescription Date
7. Directions

Note: Fictitious beneficiary

*** *Please note that in this example, #3 is not applicable as the drug is available in only one strength and #4 is not applicable as this is a single source drug.*

Figure 16: Example of Micro-Tag

Rx#:60999999	DOB: 1/1/1989	FILL DATE: 9/1/2022
Dobson, Joe		233 Elm St, Histown, FL 22222
PRAVACHOL 40 MG	QTY: 30 TAB	11111-2222-33 (Acme Drug)
Johnson, Allen	DEA: BJ1111111	RPh:XXX
Copay: $10.00	Ins. Paid: $45.87	Auth# 1234123456785678

Note: Fictitious beneficiary

Figure 17: Example of Unacceptable Documentation – Refill List

REFILL ORDERS   Check ONE box only   X Send today _ Weekly

Unacceptable Document

Facility: XXXXX

Today's Date: 5/26/22

Ordering Staff: Joan

Pages: 1 of 3

Nurse Rec'd	Date	Nurse Rec'd	Date
Amlodipine 10mg	5/20/22	Amlodipine 10mg	5/26/22
Nurse Rec'd	**Date**	**Nurse Rec'd**	**Date**
Amlodipine 10mg	5/21/22		
Nurse Rec'd	**Date**	**Nurse Rec'd**	**Date**
Amlodipine 10mg	5/22/22		
Nurse Rec'd	**Date**	**Nurse Rec'd**	**Date**
Amlodipine 10mg	5/23/22		
Nurse Rec'd	**Date**	**Nurse Rec'd**	**Date**
Amlodipine 10mg	5/24/22		
Nurse Rec'd	**Date**	**Nurse Rec'd**	**Date**
Amlodipine 10mg	5/25/22		

Figure 18. Example of Unacceptable Documentation – MAR Form

2022 Medication Log

Month: _April 2022_

For: _Mary Jane Smith_

Unacceptable Document

Medication	Time to be given	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Metoprolol 100 mg	8:00 AM	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	
	8:00 PM	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	
i tablet BID																																

Start Date: April 1, 2022   **End Date:** April 30, 2022

Prescribed by: Dr. James Jones   **For:** Mary Jane Smith   **Side Effects:** Drowsiness

Medication	Time to be given	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Ampicillin 250 mg	6:00 AM								√	√	√	√	√	√	√	√	√	√	√													
	12:00 PM								√	√	√	√	√	√	√	√	√	√	√													
i capsule QID	5:00 PM								√	√	√	√	√	√	√	√	√	√	√													
	10:00 PM								√	√	√	√	√	√	√	√	√	√	√													

Start Date: April 8, 2022   **End Date:** April 18, 2022

Prescribed by: Dr. James Jones   **For:** Mary Jane Smith   **Side Effects:** Take on an empty stomach Diarrhea

Note: Fictitious beneficiary

Figure 19: Example of Unacceptable Documentation – Refill Request

**Figure 20: Example of Unacceptable Documentation –
Screenshot of Electronic Refills and Order Processing File**


```
Start Dt/Tme 8/16/22  2:35pm        Exp Dt  8/16/23  D/S 30  Disp 30
Stop Dt/Tme 8/17/22  1:34pm         Lst Fl  8/15/22  Ref 11  Rem      Quan 30

Notes:            Auth By         Auth #                        Unacceptable Document

Opt     Rx Number Drug Name     Qty     Org Dt    Lst Dt    Sig Code   Doctor    Price     PC       Rc

F5           ATENOLOL 50MG       30      081611 081711    QD                    10.00
F6           AMOXICILLIN 500MG   28      070211 000000    TID                    7.00
F7           PHENYTOIN 100MG    180      060511 060511    2T TID                10.00
F8
F9
```

Note: Fictitious beneficiary

Figure 21: Example of Unacceptable Documentation – Internal Audit Report


```
12:34                                                                    04/10/2022

                                        Unacceptable Document
Patient:
Physician:
Facility

Rx Date: 02 / 03 / 2022        Prep Date: 02 / 05 / 2022      Rx#:
Expire Date: 05 / 03 / 2022    Start Date:   02 / 05 / 2022   Log# 123446
Discard Date:                                                 Claim ID:


Total Volume per Dose:     1 ML    Days Supply: 30
Total Metric Quantity:     30      Gross Amt Due: $20.00

Rx Description:            OMEPRAZOLE/SODIUM BICARBONATE 20MG
Frequency:                QD
Sig:
Allergies:                None
Dispense:
```

Figure 22: Example of Unacceptable Documentation – Packing Lists

Note: Fictitious beneficiary

LTC Medication Orders – Supplemental Documentation Process

A medication order that is signed by a provider with prescriptive authority is the preferred supporting document for LTC claims for this Part D IPM process. In certain circumstances, supplemental documentation can serve as a substitute for a medication order or to cure a deficient medication order. Supplemental documentation must be copied together with the medication order into one PDF using the appropriate naming convention for the file.

Examples of supplemental documentation include:

- A completed Physician Attestation form together with a medication order that is not signed by a provider with prescriptive authority. (Only the official Physician Attestation forms as provided by CMS to Part D sponsors are acceptable.)

- An unsigned medication order accompanied with supplemental information, such as a physician-signed page from the medical chart referencing review of the order in the progress notes; a dictation note in a medical chart stating orders have been reviewed and approved by a physician; or a patient or provider chart review log signed by a provider with prescriptive authority showing review and approval of a beneficiary's medication order.

Claim Detail File

For every pharmacy claim processed by a PBM, data from the processing/adjudication results are created and stored. These results contain claims adjudication details available for the PBM to review. These data are typically stored in the PBM's computer system.

The CDF submitted for the Part D IPM process must include the following data elements:

- Group ID (pre-populated)
- PDE_ID (pre-populated)
- Medicare Beneficiary Identifier (MBI)

- Beneficiary First Name
- Beneficiary Last Name
- Prescription service reference number (Rx Number)
- Product service ID (National Drug Code [NDC] number)
- Pharmacy National Provider Identifier (NPI)
- Date of service
- Quantity
- Days' supply
- Ingredient cost paid
- Dispensing fee paid
- Sales tax
- Vaccine administration fee
- Gross Drug Cost Below Out-of-Pocket Threshold
- Gross Drug Cost Above Out-of-Pocket Threshold
- Patient Pay Amount
- Other True Out-of-Pocket (TrOOP) Amount
- Low Income Cost Sharing Subsidy Amount
- Patient Liability Reduction due to other payer amount
- Covered D Plan Paid Amount
- Non-Covered Plan Paid Amount
- Estimated Rebate at Point of Service (POS)
- Total Gross Covered Drug Cost Accumulator
- TrOOP Accumulator
- Reported Gap Discount

This supporting documentation must be provided in the following form:

- The CDF must be submitted, unaltered, using the Microsoft Excel® template provided to each Part D sponsor via the HPMS Part D IPM Module, as shown in Figure 23. There is one Excel template for each contract. The HPMS Part D IPM Module will not accept CDFs that have had their format altered in any way.
- All data elements requested for a particular PDE_ID must be present on the CDF (i.e., each row must be completed). The HPMS Part D IPM Module will not accept CDFs with partial information for a specific PDE_ID.
- The quantity data element can include no more than two decimals.
- The CDF is not required to include information for all PDE_IDs in a single CDF (that is, you may upload CDFs one PDE_ID at a time).

Figure 23: Example Claim Detail File

Group_ID	PDE_ID	MBI	Beneficiary First Name	Beneficiary Last Name	Rx Number	NDC	Pharmacy NPI	Date of Service	Quantity	Days Supply	Ingredient Cost Paid	Dispensing Fee Paid	Sales Tax	Vaccine Administration Fee	Gross Drug Cost Below Out-of-Pocket Threshold	Gross Drug Cost Above Out-of-Pocket Threshold	Patient Pay Amount	Other TrOOP Amount	Low Income Cost Sharing Subsidy	Patient Liability Reduction Due to	Covered D Plan Paid Amount	Non Covered Plan Paid Amount	Estimated Rebate at POS	Total Gross Covered Drug Cost Accumulator	True Out-of-Pocket Accumulator	Reported Gap Discount	PDE ID Status
100	E30M_2022_000																										No Response
101	E30M_2022_000																										No Response
102	E30M_2022_000																										No Response
103	E30M_2022_000																										No Response
104	E30M_2022_000																										No Response

Note: Fictitious Beneficiaries

Claim Detail Financial Fields

Beginning in 2010, there were legislative changes to the definition of "negotiated price" that affect the required pricing data elements. Federal Regulation 42 C.F.R. § 423.100 amends the

definition of ''negotiated prices'' (effective for the Part D IPM CY 2010 and forward) to require that Part D sponsors base beneficiary cost-sharing and price reporting to CMS on the price ultimately received by the pharmacy or other dispensing provider, also known as the pass-through price.

The changes to the C.F.R. require that all beneficiary cost shares and accumulators on the PDE be based on the actual drug prices paid to the pharmacy provider. This Part D IPM process identifies discrepancies between the prescription record hardcopy, the CDF, and the PDE record.

Identifying Selected PDE Records

The CY 2022 Part D IPM sample includes PDE records that correspond to the Part D sponsor's contract. The PDE Record Identifier spreadsheet from the HPMS Part D IPM Module identifies which PDE records are in the review sample. An HPMS Part D IPM Module email notification is sent to the Part D sponsor noting that this spreadsheet is ready for download. After identifying the PDE records in the sample, the Part D sponsor gathers the required supporting documentation for these PDE records.

The following discussion describes the content of the PDE Record Identifier spreadsheet.

Tab 1, Instructions: The first tab contains instructions for identifying the PDE records that must be validated and for submission of the corresponding supporting documentation, including the document naming conventions. See Figure 24 for an example of Tab 1 from the PDE Record Identifier spreadsheet.

Figure 24: Tab 1, Instructions

Tab 2, PDE Identifying Data Elements: The second tab of the spreadsheet contains the PDE ID and a set of 10 PDE data elements that uniquely identify the PDE record that must be validated. See Figure 25 for an example of Tab 2 of the spreadsheet.

Each PDE record is given a **PDE ID**. This number is assigned by CMS. It consists of the Part D sponsor Contract ID, the year of the PDE record's date of service, and a final number assigned in sequential order.

This PDE ID is used to name the Part D sponsor's supporting documentation and to communicate about PDE records with CMS and/or its contractor. **Do not use protected health information (PHI) or personally identifiable information (PII) when communicating about a PDE record via email or the HPMS Part D IPM Module Discussion Board.** Please use the PDE ID when communicating with CMS regarding this project.

Figure 25: Tab 2, PDE Identifying Data Elements

The following identifiers are provided on Tab 2:
- Claim Control Number
- PBP Number
- Prescription Service Reference Number
- Date of Service
- Fill Number
- Service Provider ID
- Service Provider ID Qualifier
- Drug Name, Strength & Dosage Form
- MBI
- Process Date

Tab 3, Data Element Reference: This tab provides further details concerning the identifying data elements in the PDE record. See Figure 26 for an example of Tab 3 of the spreadsheet. Column 1, Data Elements, offers a list of data element fields; Columns 2 and 3 provide definitions of the types of values normally found in the fields. See Appendix B for the entire list of 2022 PDE data elements.

Figure 26: Tab 3, Data Element Reference

Data Elements	PDE Field Name	Definitions/Values
PDE_ID	N/A	Field assigned by CMS to identify each unique PDE record. Consists of *Contract ID_Analysis Year_Sequential Number*
Claim Control Number	CLAIM CONTROL NUMBER	Optional Field *
Plan Benefit Packages (PBP)	N/A	Plan Benefit Package Identification Number
Prescription Service Ref Number	PRESCRIPTION SERVICE REFERENCE NO	The field length of 12 will be implemented in the Drug Data Processing System (DDPS) on January 1, 2011 in anticipation of the implementation of the NCPDP D.0 standard in 2012. Field will be right justified and filled with 5 leading zeroes. Applies to all PDEs submitted January 1, 2011, and after.
DOS	DATE OF SERVICE (DOS)	MM/DD/YYYY
Fill Number	FILL NUMBER	Values = 0–99.
Service Provider ID	SERVICE PROVIDER ID	When Plans report Service Provider ID Qualifier = '99' - Other, populate Service Provider ID with the default value "PAPERCLAIM" defined for TrOOP Facilitation Contract.
Service Provider ID Qualifier	SERVICE PROVIDER ID QUALIFIER	The type of pharmacy provider identifier used in field 14. 01 = National Provider Identifier (NPI); 06 = UPIN; 07 = NCPDP Provider ID; 08 = State License; 11 = Federal Tax Number; 99 = Other (Reported Gap Discount must = 0). Mandatory for standard format. For standard format, valid values are 01 - NPI or 07 - NCPDP Provider ID. For non-standard format, any of the above values are acceptable.
Drug Name, Strength, & Dosage Form	PRODUCT SERVICE ID	Root drug name, strength, and dosage form referenced from NDC number found in the product service ID PDE field.

Data Elements	PDE Field Name	Definitions/Values
MBI	MEDICARE BENEFICIARY IDENTIFIER	Replacement for the SSN-based Health Insurance Claim Number (HICN).
Process Date	N/A	Data Process Date, MM/DD/YYYY

* Please note, the Claim Control Number for records obtained through consolidation of a plan or plan sponsor may not match the format of your current claims system.

Submission Process

After downloading the PDE Record Identifier spreadsheet to identify sampled PDE records, requests for supporting documentation must be made for those PDE records from pharmacies and PBMs. As a reminder, all supporting documentation submitted by the final submission deadline will undergo the Part D IPM process. Part D sponsors, CMS, and its contractor communicate via the Discussion Board feature on the HPMS Part D IPM Module if any questions or problems arise regarding the submission process. This manual is available within the Part D IPM Module Documentation link located on the left-hand side of the Part D IPM Module landing page.

Supporting Documentation Submission

Submit all supporting documentation to the HPMS Part D IPM Module during the **12-week submission window**. Submission of documentation through any other avenue is not allowed.

Refer to the HPMS Plan User Guide, located in the HPMS Part D IPM Module, for additional details regarding the submission process.

The following section describes how to name and consolidate supporting documentation. Information regarding what to submit when a certain document cannot be accessed is also provided below.

Document Naming Conventions

Requirements for supporting documentation differ by type of document.

- The CDF must be labeled with Part D sponsor's contract number, the Contract Year (year of service), and "CDF" separated by underscores, as shown in the example below.
- prescription record hardcopies or medication orders must be labeled correctly with the PDE ID followed by "RxRec" separated by underscores, as shown in Figure 27.
    - When ancillary or supplemental documentation is submitted, all documentation must be included together as one document in a PDF file, which must be labeled with the appropriate naming convention. Supplemental documentation may include pages from a medical record or a Physician Attestation to supplement an unsigned medication order.

**Figure 27: Naming Conventions for Prescription Record Hardcopies
or Medication Orders**

Part D IPM Document	Example Naming Convention
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 mail/retail pharmacies.

Document Formats

All prescription record hardcopy/medication order submitted documents must be saved as an image (e.g., PDF, GIF, JPEG, BMP); PDF is the preferred document file format. For the CDF, .xlsx is the required file format.

File Consolidation, Upload, and Verification

There are two acceptable options for uploading supporting documentation:

1) **Single Zip file: all documents for all PDE records consolidated in one Zip file.** All supporting documentation can be zipped within one Zip file. The file should be named after the Part D sponsor's contract number and the Contract Year (year of service).

As Figure 28 demonstrates, this Part D sponsor has two PDE records sampled for one of its contracts. The Part D sponsor is uploading *five* prescription record hardcopies and *one* CDF (one prescription record hardcopy for each of the five PDEs, and one CDF containing all the data for all the PDEs).

Figure 28: Example of Naming Convention and Upload Format for a Single Zip File
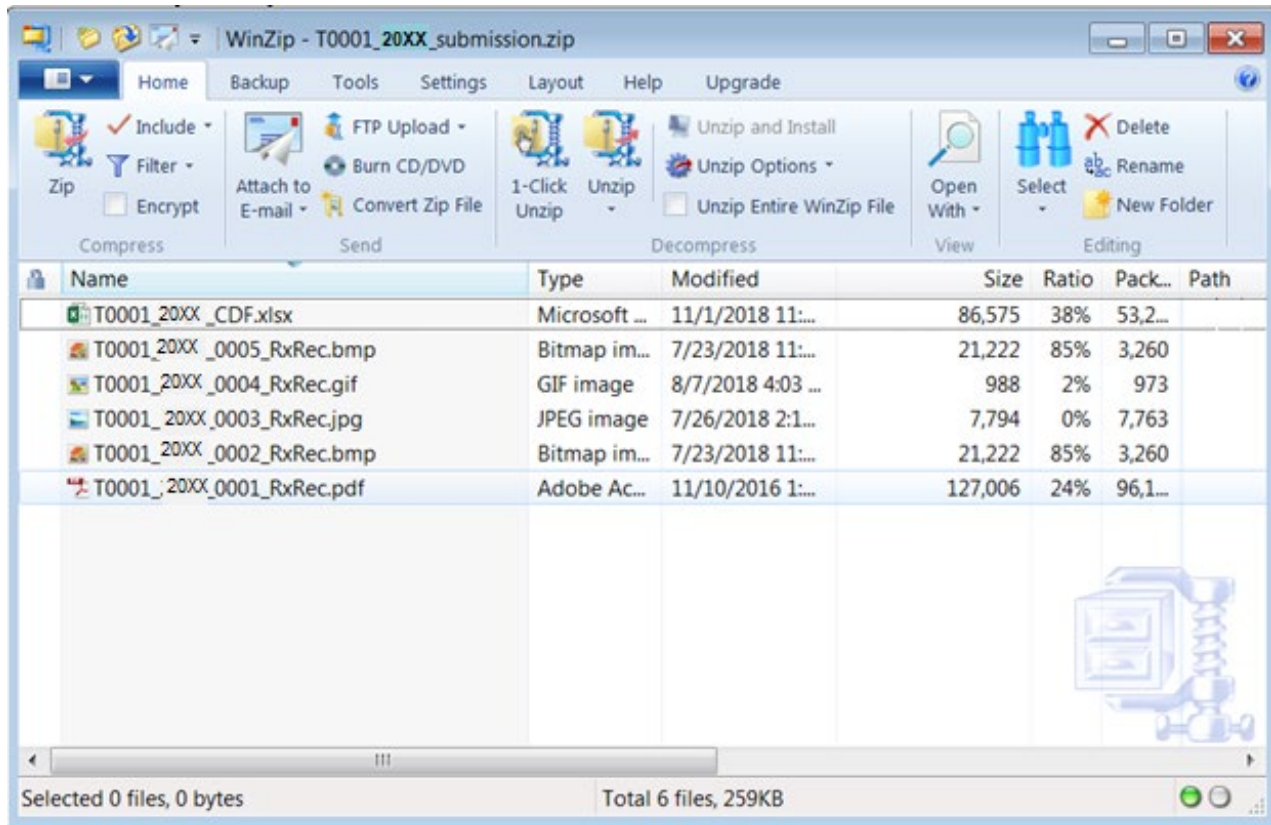
2) **Multiple Xip files; one Zip file for one or multiple PDE records.** If the submission of supporting documentation for PDE records on a rolling basis is preferred, a Zip file for one or multiple PDE records can be uploaded. One or multiple CDFs can be submitted for selected PDEs within a contract (be sure that all the fields for each PDE ID are complete). Each file should be named after the Part D sponsor contract number and contract year (year of service).

Before uploading a file, a radio button must be checked to verify that the documents to be uploaded are accurate to the best of the Part D sponsor's knowledge.

Ancillary Documentation

If ancillary documentation is to be submitted to provide more information or context to a supporting document, it must be included in the supporting document image. This means the documents must be scanned at the same time as one PDF or if there are multiple PDFs, they should be concatenated into one PDF file. The PDF file must be labeled with the appropriate naming convention as described above.

Missing Documents

If a prescription record hardcopy/medication order cannot be obtained, the Part D sponsor must submit a Missing Documentation Form (see Figure 29) in its place. This form allows for an explanation for why the document cannot be accessed and the steps taken to verify that the documentation is not available.

In Section 3 of the form, it is important to specify the source(s) used to verify this information and a detailed explanation on all steps taken. The Missing Documentation Form can be found in the Help Documents folder on the HPMS Part D IPM Module. This document should be named using the same naming convention as the document it replaces. The Module will not accept a Missing Documentation Forms in place of the CDF.

Figure 29: Missing Documentation Form

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

CY 2022 Part D Improper Payment Measure – Missing Documentation Form

If a prescription drug event (PDE) supporting document (prescription record hardcopy/medication order) is not available for the PDE record, please complete and submit this Missing Documentation form in place of <u>each</u> missing document.

You should complete and upload this form only if the **entire** PDE supporting document is missing; <u>do not</u> upload this form to explain missing data elements.

Make sure to name this Missing Documentation form according to the naming convention specified below and in the Submission Instructions.

1. Select the missing documentation type, and complete Sections 2 and 3 below:

Documentation Type		File Naming Convention
Retail/Mail Pharmacy	**Long-Term Care (LTC) Pharmacy**	
☐ Prescription Record Hardcopy	☐ Medication Order	*PDE ID*_RxRec

2. Prescription record hard copy/medication order is missing because:
Document internal and external research performed and actions taken to reach pharmacy/ facility in the comment area below.

☐ **Pharmacy non-responsive**
☐ **Pharmacy sold**
☐ **Pharmacy closed**
☐ **LTC facility closed**
☐ **Pharmacy unable to locate (lost) prescription copy**
☐ **Records destroyed by natural disaster (e.g., storm, flood, fire)**
☐ **Records seized by law enforcement**
☐ **Other (Described in Section 3)**

3. Comments and actions taken (use additional page if necessary):

Examples

Prescription Record Hardcopy:
Consulted internal pharmacy contracting system, pharmacy is inactive. Spoke with Lori at the Maryland State Board of Pharmacy on February 1, 2024 at 4:00 pm. Confirmed pharmacy was closed on August 1, 2023.
Prescription Record Hardcopy:
Spoke with Rich, pharmacy manager on 2/3, 2/5, and 2/9. We faxed the pharmacy a request for records on 2/2 and 2/7. Pharmacy has not responded to our requests for information.

_____

_____

_____

CMS Physician Attestation Forms

Part D sponsors need to submit a separate Physician/Authorized Prescriber CMS Attestation for Long-term Care Medication Order form, along with the original LTC medication order, for each record in which the medication order is not signed by a provider with prescriptive authority and no supplemental documentation is available. Attestation forms are to be used only for medication orders that are not signed by a provider with prescriptive authority or are improperly signed by someone other than an authorized prescriber. The attestation form will allow an authorized prescriber to attest that they approved the LTC medication order in question. Figure 30 is a copy of the CMS-provided attestation form. The form can be found in the Help Documents folder on the HPMS Part D IPM Module.

Figure 30: CMS Physician Attestation Form

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

CY 2022 Part D Improper Payment Measure – LTC Physician Attestation

Physician/Authorized Prescriber CMS Attestation for Long-term Care (LTC) Medication Order

I. Enrollee Information (to be completed by the Part D Sponsor)

Medicare Identification Number (MBI): _____

Last Name: _____   First Name: _____

Date of Birth: _____ (mm/dd/yyyy)

Drug Name: _____   Drug Strength: _____

Date of Service: _____

Calendar Year (CY) 2022 Contract ID: _____

CY 2022 Part D Sponsor Name: _____

II. Attestation Statement (to be completed by the Physician/Authorized Prescriber)

I, _____, confirm that the prescription drugs listed
(print or type full name of the physician/authorized prescriber)

in the long-term care medication order dated _____ (mm/dd/yyyy)
(medication order written date or date of service)

are accurate. These medications were prescribed by me in my capacity as the

_____ when I provided treatment to/diagnosed the
(authorized prescriber credentials, e.g., MD, DO)

Medicare beneficiary mentioned above.

I do hereby attest that this information is true, accurate and complete to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact may subject me to administrative, civil, or criminal liability.

_____
Signature

_____
Date (mm/dd/yyyy)

Verification Checks and Resubmission

Once a Zip file has been uploaded to the HPMS Part D IPM Module, CMS conducts two checks of the file and its contents to verify the documents. The Verification Checks are as follows:

- File Upload Check
- Element checks

Notification of successful upload of the file will be evident within minutes of file upload within the HPMS Part D IPM Module. HPMS sends an email regarding the submission status to the Part D sponsor POC(s).

Refer to the HPMS Plan User Guide for additional information regarding the process status of uploaded files.

CMS will provide element check results by March 29, 2024, to Part D plan sponsors that have submitted supporting documents on or before the early submission deadline of March 8, 2024. These sponsors will also receive an IFR by March 29, 2024, outlining the preliminary results of their sampled and submitted PDE records.

If these sponsors desire to resubmit supporting documentation based on the results of these checks, they can do so before the final submission deadline of April 19, 2024. **Please submit files as early as possible within the <u>first 6 weeks</u> of the submission period window to allow ample time to receive the results of element checks, and to provide time to update any required files to ensure complete and valid documentation and resubmit before the submission deadline.**

CMS and/or its contractor may contact Part D sponsors during or after the submission period to request clarification regarding submitted files. At this time, CMS may request resubmission of supporting documentation.

Refer to the HPMS Plan User Guide, available on the Part D IPM Module, for additional details regarding the resubmission of supporting documentation.

When resubmitting a supporting document that was previously missing or deemed invalid, only resubmit the corrected/valid document. **Do not resubmit other documents that are not missing or invalid.** Also, if asked to resubmit a supporting document because it is missing data elements, the resubmitted file must contain both the <u>newly</u> requested data elements <u>**and**</u> the data elements that were included on the previous document. **Do not submit a document with just the new data elements.**

Furthermore, if you would like to explain why data elements are missing from a document, you can do so on the HPMS Part D IPM Module Discussion Board. **Do not submit a Missing Documentation form or some other document describing why the data elements are missing. Do not use PHI or PII when communicating about a PDE record via the Discussion Board.**

All files submitted by the final submission deadline, whether deemed incomplete or any other issue, will be reviewed during the Part D IPM process.

Best Practices

Part D sponsors must carefully adhere to guidelines regarding required information to ensure their PDE submissions are complete and contain the best possible documentation. CMS recommends the following actions and best practices to help improve adherence to submission guidelines and minimize burden when submitting through the submission window:

- Take note that the final submission deadline of **Friday, April 19, 2024,** is the last date on which you can submit supporting documentation.
- Submit both the CDF and prescription record hardcopy/long-term care medication order as early as possible.
    - o Confirm the prescription record hardcopy/long-term care medication order pertains to the sampled PDE and the associated beneficiary.
    - o Diligently review the CDF to ensure alignment of data with the sampled PDE.
- Compare your supporting documentation against the PDE Record Identifier spreadsheet provided to minimize the need for resubmission.
- Ensure all documentation for all your PDE records are consolidated in one Zip package. The package must contain the requested documentation for the Part D IPM. Please confirm you are not submitting documentation meant for another audit.
- Verify that you are using the correct naming conventions while uploading documentation.
- Recognize that acceptable documentation comes in various forms. Refer to this document for a detailed list of required elements for each supporting document, along with the examples provided of both acceptable and unacceptable documents.
- For necessary attestations, use only the CMS-provided Physician/Authorized Prescriber Attestation for Long-Term Care (LTC) Medication Orders form. (Alternative forms are NOT accepted.)
- Use the HPMS Part D IPM Module Discussion Board to seek clarifications if you are uncertain about submission requirements.
- Delegate the identification of required data elements on the prescription record hardcopy/LTC medication order to personnel familiar with prescription processes. This business process improves key generation and mapping outcomes.
- Seek approval for prepared documents from your Medicare Compliance Officer or other experienced personnel, such as a Pharmacy Director. They should validate that the documents most accurately represent and substantiate the final PDE record.
- Involve knowledgeable personnel from your plan who have information systems access to collect and submit supporting documentation. Ensure they have access to accurate data sources representing the claim data contributing to or forming the Part D sponsor's PDE submission before uploading to HPMS.
- Review all prescription record hardcopies and/or medication orders subject to PDE submission and confirm prior to uploading documentation that the documents are signed by licensed providers.
- Provide explanatory comments or documents when the beneficiary named on the prescription record hardcopy/medication order is not the same as the beneficiary named on the CDF. For example, the beneficiary may answer to a different name (nickname) rather than their given name. As such, the CDF shows the beneficiary's given name while the prescription record hardcopy may refer to the beneficiary's non-given name.

- Submit an explanation/additional information if a pharmacy sends prescription record hardcopy documentation that fails to support the PDE. Common examples include:
  - Prescription record hardcopies for a drug strength that is not commercially available. Part D sponsors submitted an explanation of how the beneficiary received the dose prescribed (e.g., two prescriptions of varying strengths were dispensed, a larger quantity of a lower strength was dispensed) and how this was reflected on the PDE.
  - Prescription record hardcopies for a drug that fails to match the drug listed on the PDE. Part D sponsors submitted an explanation indicating why the prescribed drug misaligns to the PDE (e.g., the pharmacy contacted the physician to change the drug to comply with the Part D sponsor's formulary, the original drug prescribed was unavailable, the original drug prescribed was changed due to interactions with other therapy the beneficiary was receiving).
  - Prescription record hardcopies for a quantity that fails to match the quantity listed on the PDE. Part D sponsors submitted an explanation indicating why the prescribed quantity misaligns to the quantity on the PDE (e.g., a lesser quantity was dispensed due to a Part D sponsor's limitation on days' supply available to a beneficiary at retail or by beneficiary request).

Contact Information

For any questions or concerns regarding the Part D IPM activity, use the email addresses below. Initial responses will be provided within 1 business day; however, resolution of issues may require additional time.

Policy and Teleconference Questions

Questions regarding CMS policies related to the Part D IPM process should be sent to PartD_IPM@cms.hhs.gov. Part D sponsors are also invited to submit questions in advance of the annual teleconference to this mailbox.

Please include "Part D IPM 2022" in the subject line.

Part D IPM Submission Process Questions

Questions posted on the HPMS Part D IPM Module Discussion Board, available at hpms.cms.gov, will be answered by the relevant party depending on the subject matter (i.e., PDE ID-specific questions and submission questions). Please note that only authorized users will be able to access and view the Discussion Board(s) for their authorized contract(s). **Do not use PHI or PII when communicating about a PDE record via email or the Discussion Board. Please use the PDE ID to identify the PDE instead.**

HPMS Help Desk

Send technical questions concerning HPMS, the Part D IPM Module, and the supporting documentation upload process to hpms@cms.hhs.gov.

Appendix A. CMS Policy Regarding Adjusted Claims

The deadline for submission of PDE data for the CY 2022 Part D Payment Reconciliation was June 29, 2023. The PDE records that CMS sampled for the current CY 2022 Part D IPM process were submitted on or before this date. The CY 2022 Part D IPM process validates the PDE record that the Part D sponsor determined was the final PDE record for purposes of the CY 2022 Part D Payment Reconciliation.

In the situation where the sponsor subsequently adjusted the sampled "recon PDE" (adjustment made **AFTER** June 29, 2023), the requirement is as follows:

- The sponsor must submit documentation that **aligns to the PDE submitted to CMS as the "RECON PDE."** This version should align to the PDE identifiers and match the specified fields in the sampled "recon PDE"; and
- The sponsor must submit additional documentation indicating that the sampled PDE record was adjusted following reconciliation.
    - Please be sure this additional documentation is linked to an adjusted PDE *if* it supports the intended field(s) in the "recon PDE." See the earlier section in these Submission Instructions for additional information on submitting optional or supplemental documentation.
- If the sponsor cannot locate documentation for the sampled "recon PDE," upload a Missing Documentation form in place of each missing document. This form and instructions for completion and submission can be found in the Help Documents library on the HPMS Part D IPM Module.

- Data in the CDF must match the PDE record submitted for reconciliation in the 11 fields provided as PDE identifiers (the PDE_ID Number and the 10 unique identifiers associated with the PDE being reviewed and the Part D sponsor Contract ID Number.

Appendix B. PDE Layout

The PDE Inbound Layout File, effective October 24, 2022, can be found on the CMS Customer Service and Support Center (CSSC) website.

END OF DOCUMENT