SUBMISSION INSTRUCTIONS

January 27, 2023

Submission Deadline:
April, 21 2023 at 11:59 p.m. PT

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List of Exhibits

Introduction

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

CMS, together with its contractor, collects and reviews documentation from Part D sponsors to substantiate a sample of PDE records. 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. This HPMS Part D IPM Module also allows for the upload of Part D IPM documents and data (supporting documentation) for assigned PDE_IDs, such as the prescription record hardcopies and Claim Detail Files (CDFs).[1]

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 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 Manager (PBM) and/or pharmacies to collect the supporting documentation required for each 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.

The purpose of the Submission Instructions is to help Part D sponsors: (1) identify supporting documentation required for submission, (2) submit supporting documentation in the correct format, and (3) understand the Part D IPM process.

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

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). Every effort should be made to acquire the required supporting documentation by the gaining Part D sponsor 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 CFR Parts 423, Subparts K and O, which may include civil money penalties, enrollment sanctions, or contract terminations.

Project Timeline

The following is the timeline for the Part D IPM process.

Activity	Date(s)
CMS notifies selected Part D sponsors of participation in the CY 2021 Part D IPM process.	January 13, 2023
CMS requests Part D sponsors identify no more than five (5) 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, as well as 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 13, 2023 – January 26, 2023
Teleconference held with Part D sponsors to review the submission process and answer questions.	January 25, 2023
HPMS Part D IPM Module is open, and Part D IPM Submission Instructions are available. Part D sponsors can download the PDE Record Identifier spreadsheet.	January 27, 2023
12-week submission window begins.	January 27, 2023
Part D sponsors request 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 uploading 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 documents submitted after this date. Part D sponsors with incomplete supporting documentation may upload additional files with complete documentation by resubmitting before the final submission deadline.	March 10, 2023
Element status results and IFR provided to Part D sponsors that submitted prescription record hardcopy/medication order supporting documentation prior to the early submission deadline.	March 31, 2023
Final Submission Deadline: Part D sponsors upload supporting documentation to the HPMS Part D IPM Module by this date. Documentation must be received prior to this date to be considered for the Part D IPM validation review.	April 21, 2023
Ongoing communication with Part D sponsors via the Discussion Board on the HPMS Part D IPM Module. Part D sponsors upload additional information, if necessary.	Throughout the submission and review process

Introduction to Part D IPM Documents

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

Part D IPM Document Type	Frequency
1. **Prescription Record Hardcopy *or* a Medication Order (for Long Term Care [LTC] pharmacies)**	One per PDE record
2. **Claim Detail File (CDF)**	One per Contract for all PDEs
3. **LTC Medication Order that is not signed by a provider with prescriptive authority.** One of the following options for ancillary documentation must be copied together along 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 should be provided that supports the unsigned LTC medication order; or II. A Physician Attestation completed and signed by the provider; or III. A Patient or Provider chart review log signed by a provider with prescriptive authority showing review and approval of a beneficiary's medication order.	One per PDE record when a LTC medication order is not signed by a provider with prescriptive authority
4. Optional Documentation. I. 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 does not have to be a completed MAR from the facility.) II. Submitting the computer-generated micro-tag is helpful to the review process, if 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.	One per PDE record

All 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, 2022. If the PDE has been adjusted prior to this date, send supporting documentation corresponding to the PDE submitted for reconciliation. See Appendix B 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 the 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) or Medication Order (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 a LTC pharmacy, a copy of the medication order must be submitted along with any supplemental documents, if applicable, for that PDE record. Though not required, adding a computer-generated micro-tag to supporting documentation facilitates efficient document review and minimizes multiple submissions for the same PDE record. Each of these supporting documents is described in greater detail below.

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 **only** be accepted as supplemental documentation to validate a medication order (LTC pharmacy) not signed by a provider with prescriptive authority.

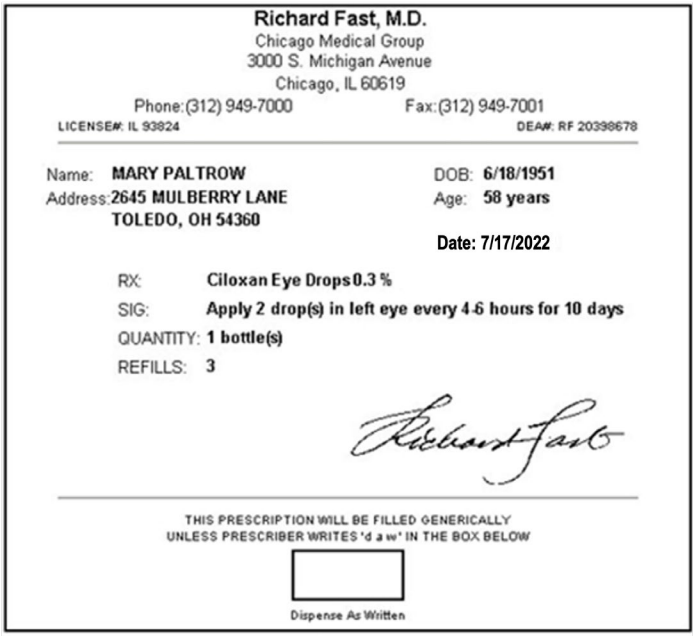
The prescription record hardcopy submitted for the Part D IPM process **must** include the following data elements:

- 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 it 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



Richard Fast, M.D.
Chicago Medical Group
3000 S. Michigan Avenue
Chicago, IL 60619
Phone:(312) 949-7000 Fax:(312) 949-7001
LICENSE#: IL 93824 DEA#: RF 20398678

Name: MARY PALTROW DOB: 6/18/1951
Address: 2645 MULBERRY LANE Age: 58 years
TOLEDO, OH 54360

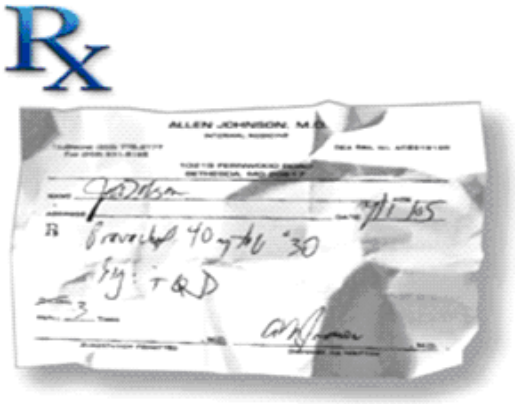
Date: 7/17/2022

RX: Ciloxan Eye Drops 0.3 %
SIG: Apply 2 drop(s) in left eye every 4-6 hours for 10 days
QUANTITY: 1 bottle(s)
REFILLS: 3

THIS PRESCRIPTION WILL BE FILLED GENERICALLY
UNLESS PRESCRIBER WRITES 'd a w' IN THE BOX BELOW

Dispense As Written

Note: Fictitious Beneficiary



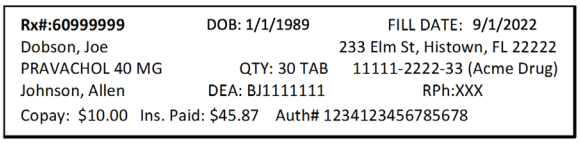
Note: Fictitious Beneficiary

Micro-Tags

The micro-tag is the computer-generated “sticker” that summarizes the prescription information. The micro-tag aids the 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

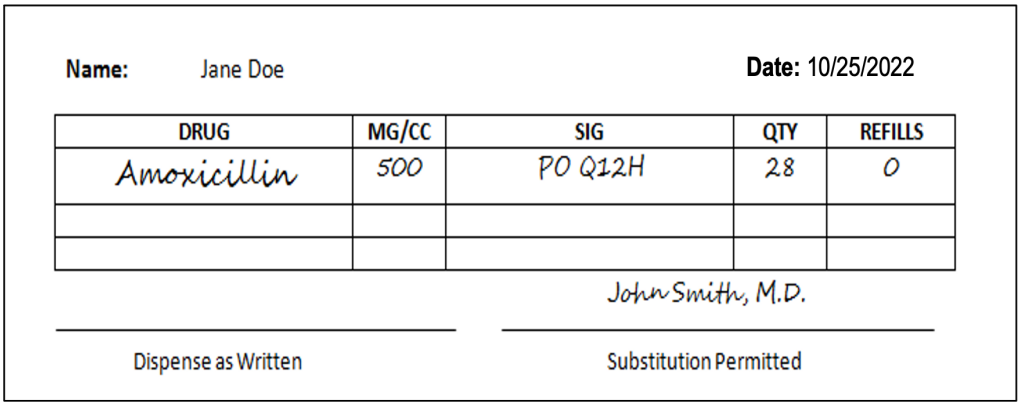


Rx#:60999999 DOB: 1/1/1989 FILL DATE: 9/1/2022
Dobson, Joe 233 Elm St, Histown, FL 22222
PRAVACHOL 40 MG QTY: 30 TAB 11111-2222-33 (Acme Drug)
Johnson, Allen DEA: BJ1111111 RPh:XXX
Copay: $10.00 Ins. Paid: $45.87 Auth# 1234123456785678

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

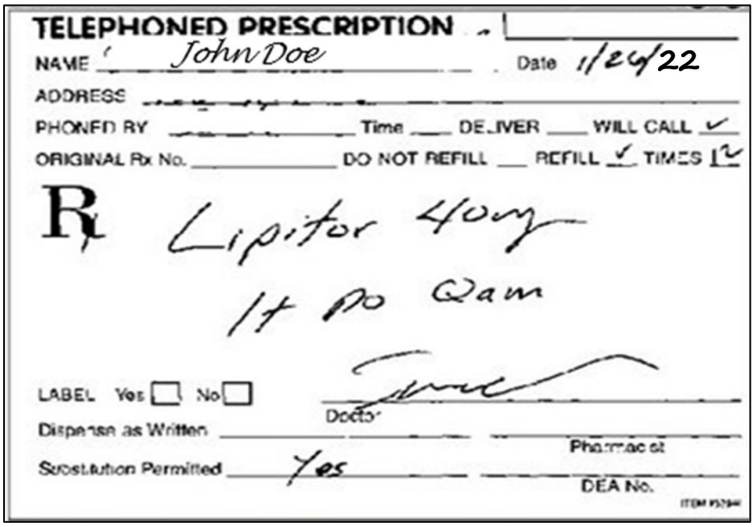
DRUG	MG/CC	SIG	QTY	REFILLS
Amoxicillin	500	PO Q12H	28	0

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

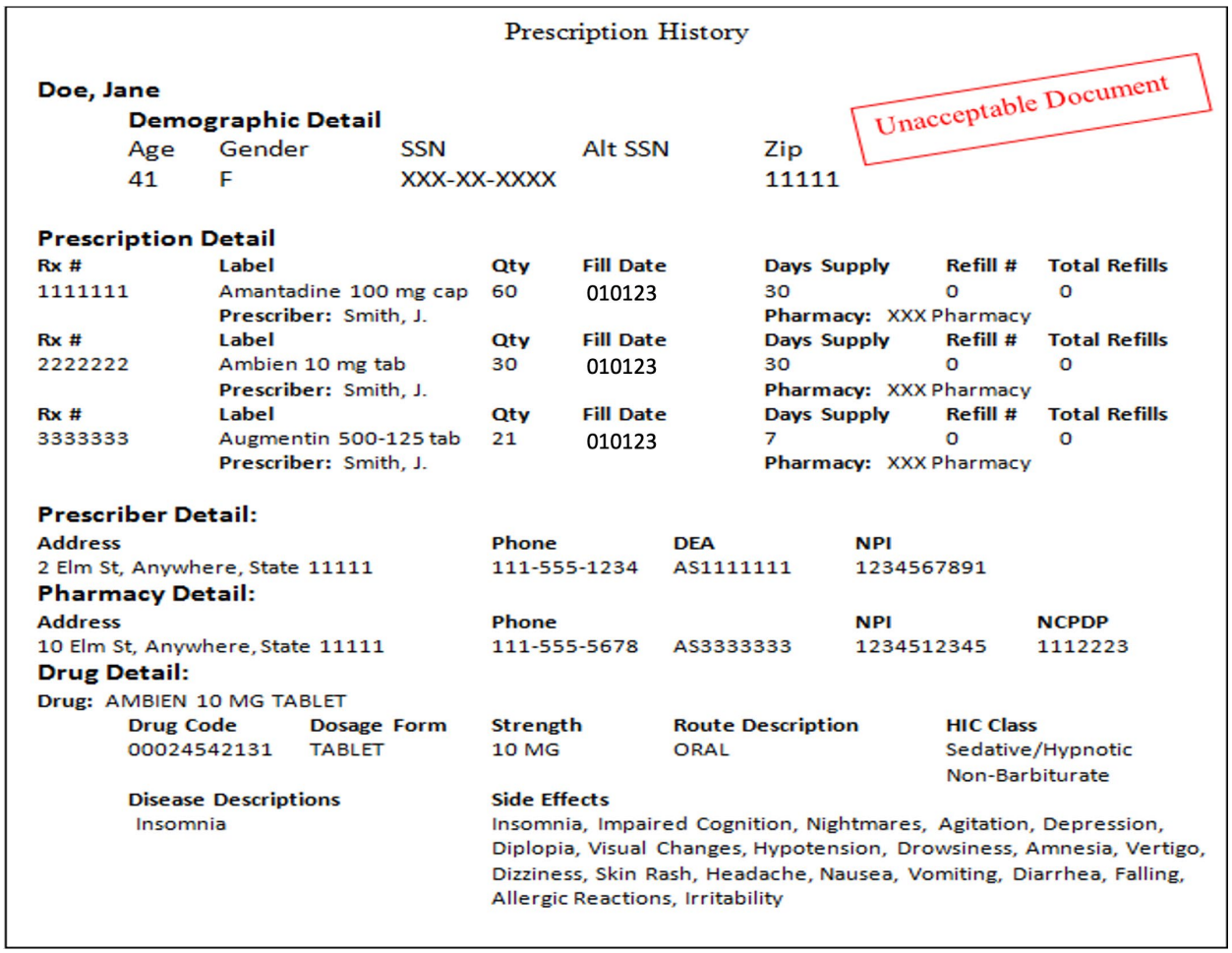
Pharmacist

Substitution Permitted Yes

DEA No.

Note: Fictitious Beneficiary

Figure 4: Example of Unacceptable Documentation – Prescription History



Prescription History

Unacceptable Document

Doe, Jane

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

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:

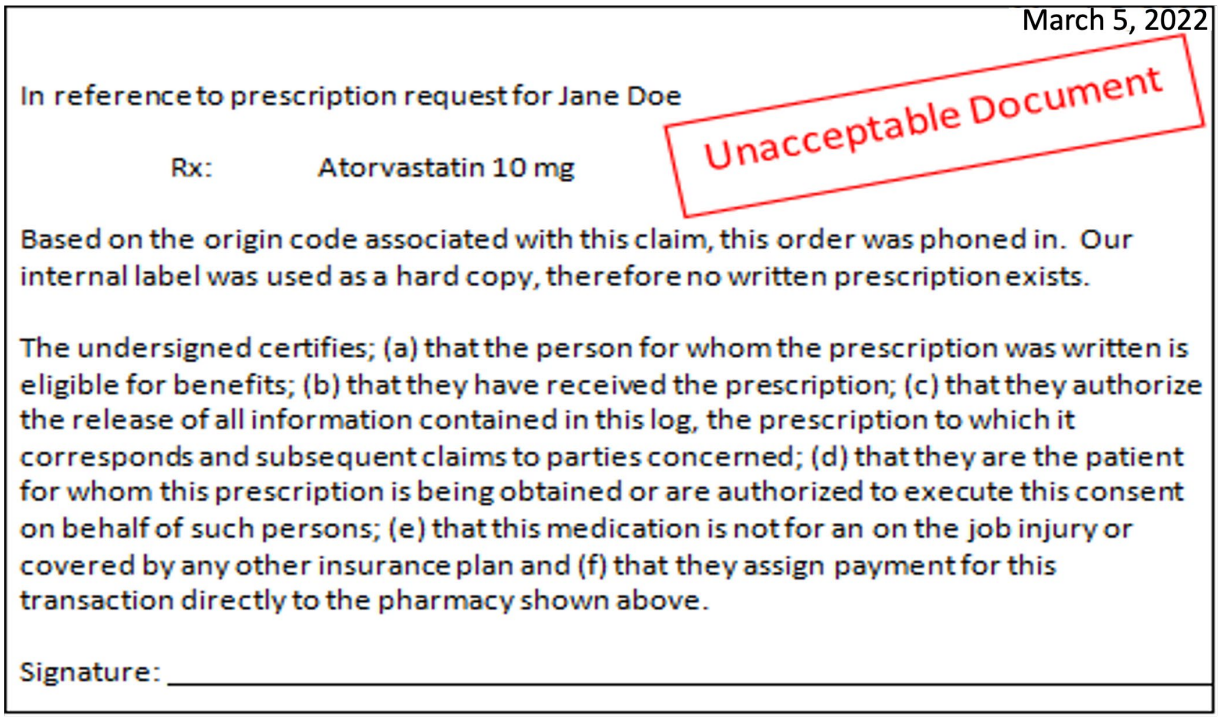
Drug: AMBIEN 10 MG TABLET

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

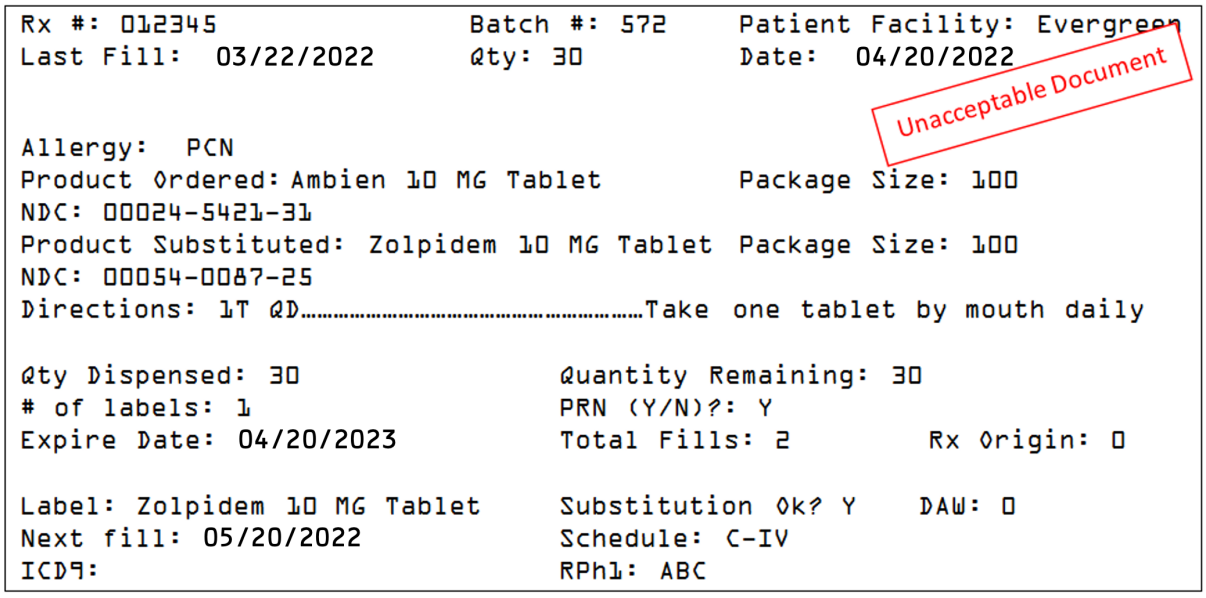
Note: Fictitious Beneficiary

Figure 5: Example of Unacceptable Documentation – Pharmacy Attestation



Note: Fictitious Beneficiary

Figure 6: Example of Unacceptable Documentation – Pharmacy Transaction File



Note: Fictitious Beneficiary

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

Pharmacy DUR Report

3/2/2022 14:26:54 Page 1

Unacceptable Document

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	

Unacceptable Document

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
NDC# 00591-3774-19 WATSON REFILLS: 11
TAKE ONE TABLET ONCE DAILY
PCS CHARGE:

Unacceptable Document

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 56023-0403-01	30				06/30/2012	30	$0.00
Pantoprazole 40mg 45253-2131-12	30			N	6/30/2012	15	$5.20

Unacceptable Document

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 ancillary documentation or explanations as needed. Any ancillary information must be submitted as part of the same image, meaning that they should be scanned together (preferably in PDF format). Such ancillary 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 oedication 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

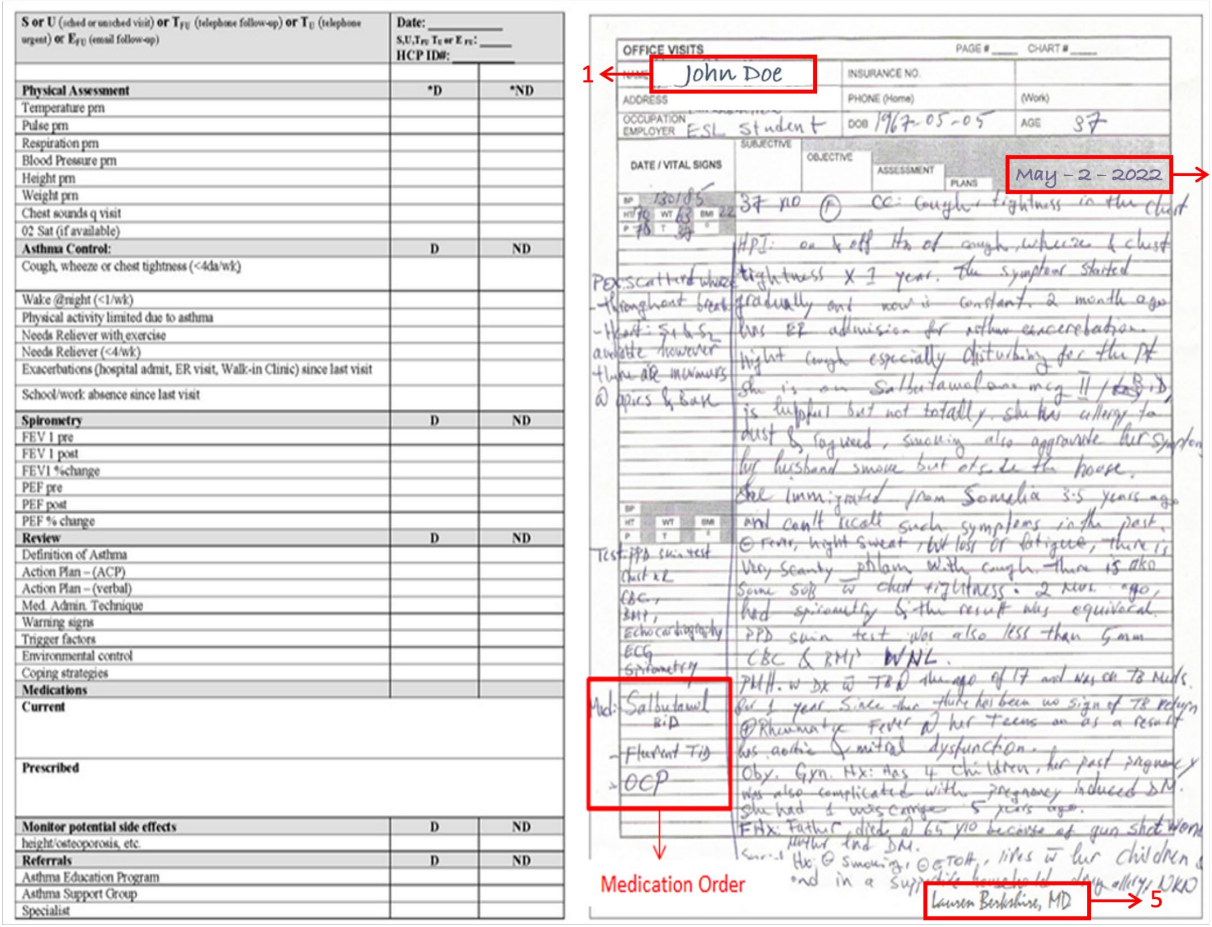
This documentation must be provided in the following form:

- Image (front and back) of the actual medication order (see Figure 12, for example).

- If ancillary documentation or explanations are needed, they should be submitted together with the medication order. An example of ancillary 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 Figures 17 through 22 show examples of **UNACCEPTABLE** medication order supporting documents.

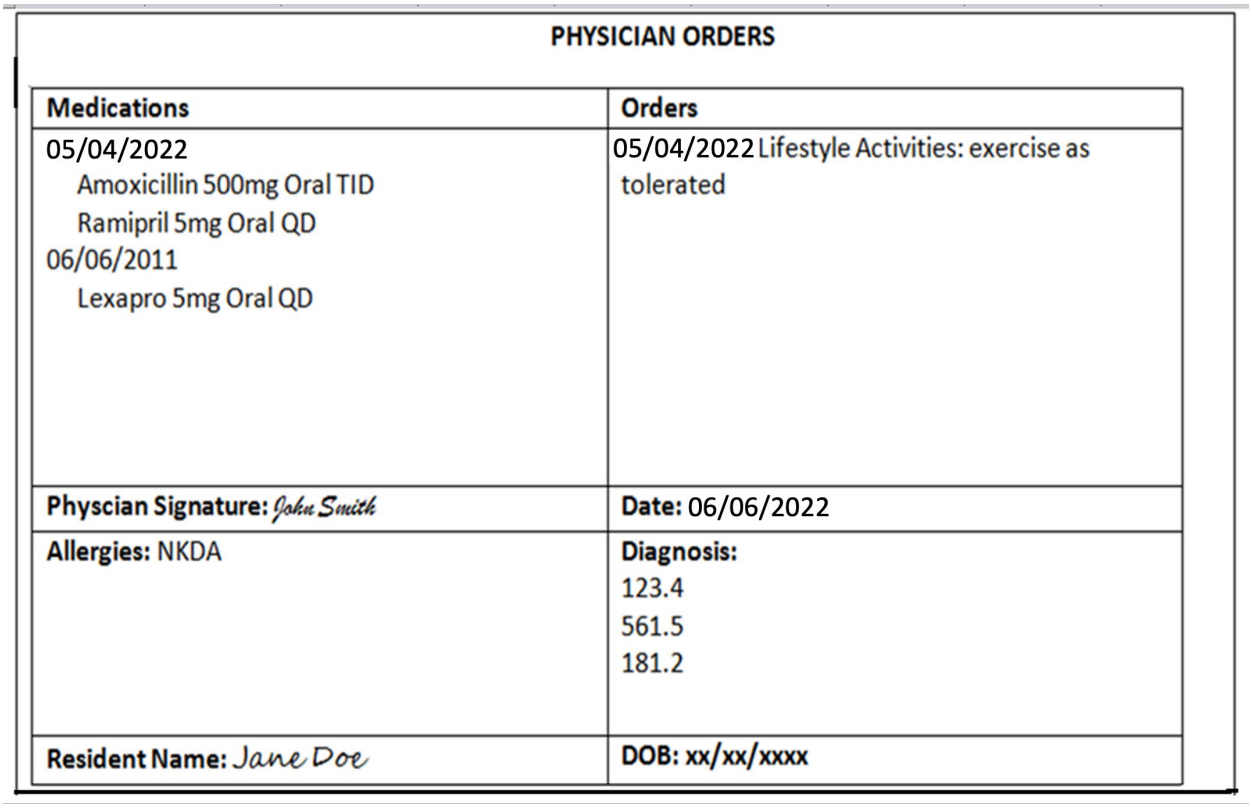
Figure 12: Example of Medication Order



S or U (sched or unsched visit) **or** T_{FU} (telephone follow-up) **or** T_U (telephone urgent) **or** E_{FU} (email follow-up)	**Date:** _____ S,U,T_{FU} T_U or E_{FU}: ____ HCP ID#: _____	
Physical Assessment	*D	*ND
Temperature prn		
Pulse prn		
Respiration prn		
Blood Pressure prn		
Height prn		
Weight prn		
Chest sounds q visit		
02 Sat (if available)		
Asthma Control:	D	ND
Cough, wheeze or chest tightness (<4da/wk)		
Wake @night (<1/wk)		
Physical activity limited due to asthma		
Needs Reliever with exercise		
Needs Reliever (<4/wk)		
Exacerbations (hospital admit, ER visit, Walk-in Clinic) since last visit		
School/work absence since last visit		
Spirometry	D	ND
FEV 1 pre		
FEV 1 post		
FEV1 %change		
PEF pre		
PEF post		
PEF % change		
Review	D	ND
Definition of Asthma		
Action Plan – (ACP)		
Action Plan – (verbal)		
Med. Admin. Technique		
Warning signs		
Trigger factors		
Environmental control		
Coping strategies		
Medications		
Current		
Prescribed		
Monitor potential side effects	D	ND
height/osteoporosis, etc.		
Referrals	D	ND
Asthma Education Program		
Asthma Support Group		
Specialist		

Note: Fictitious Beneficiary

Figure 13: Example of Acceptable Medication Order Documentation

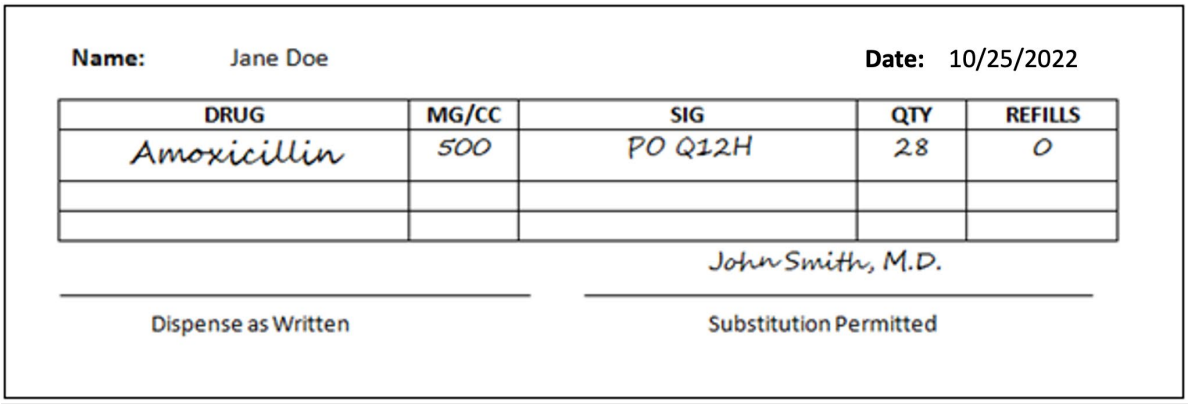


PHYSICIAN ORDERS

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

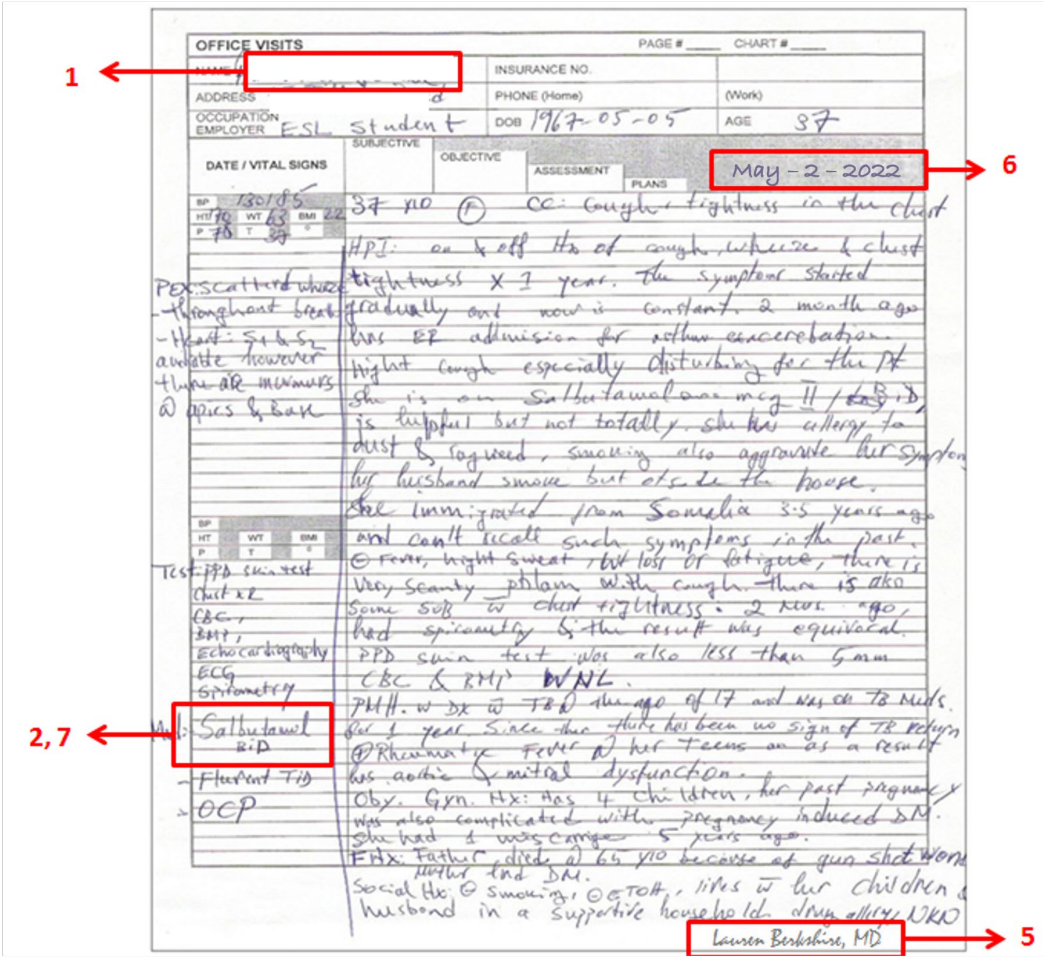
John Smith, M.D.

Dispense as Written

Substitution Permitted

Note: Fictitious Beneficiary

Figure 15: Example of Mapped Medication Order

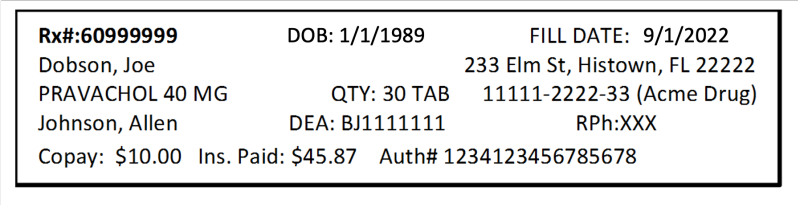


1. Patient Name
2. Drug Dame (Active Ingredient)
3. Drug Strength
4. Dispense As Written (DAW) product selection if applicable
5. Provider with Prescriptive Authority
6. Prescription Date
7. Directions

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



Note: Fictitious Beneficiary

Figure 17: Example of Unacceptable Documentation – Refill List

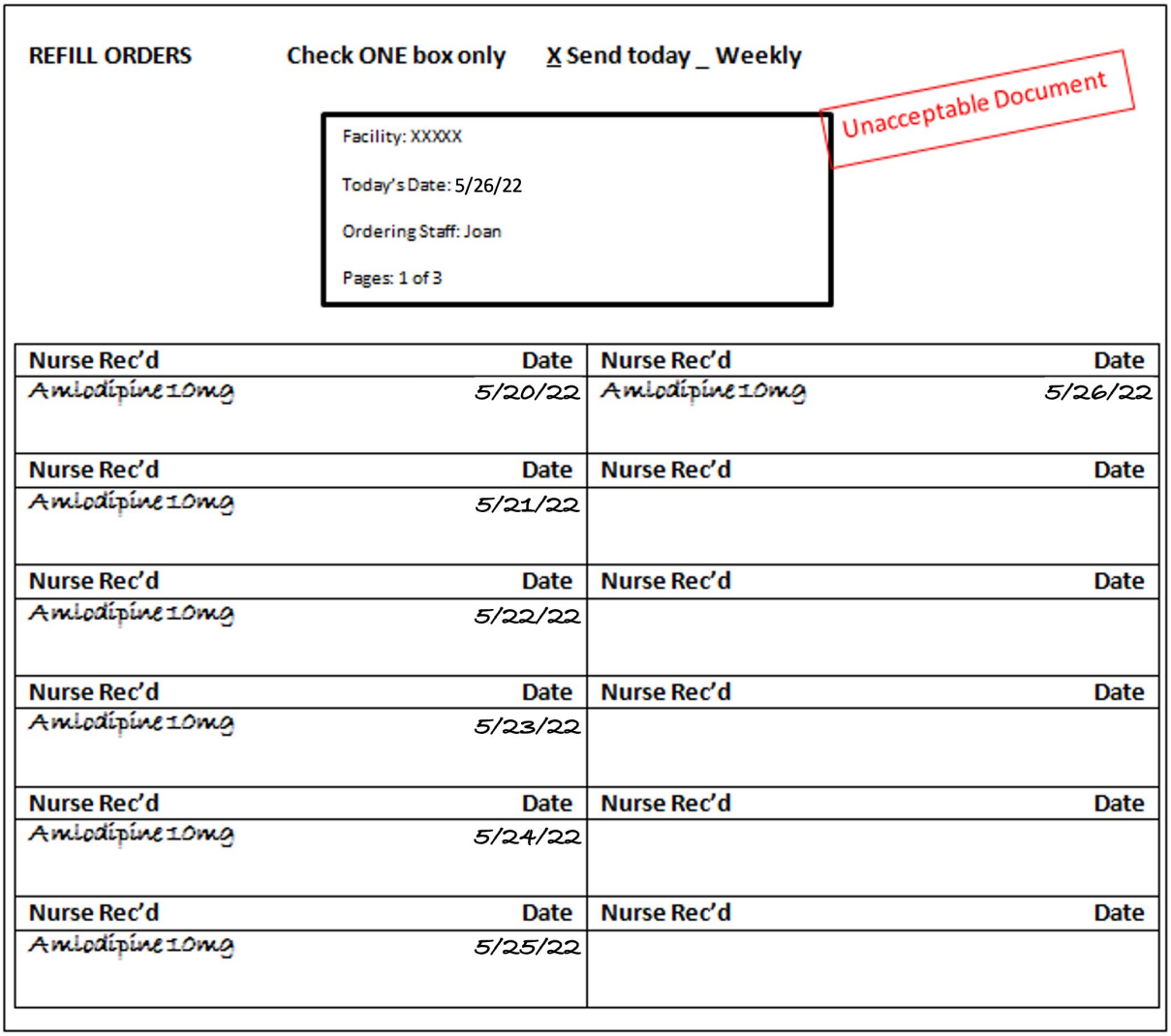
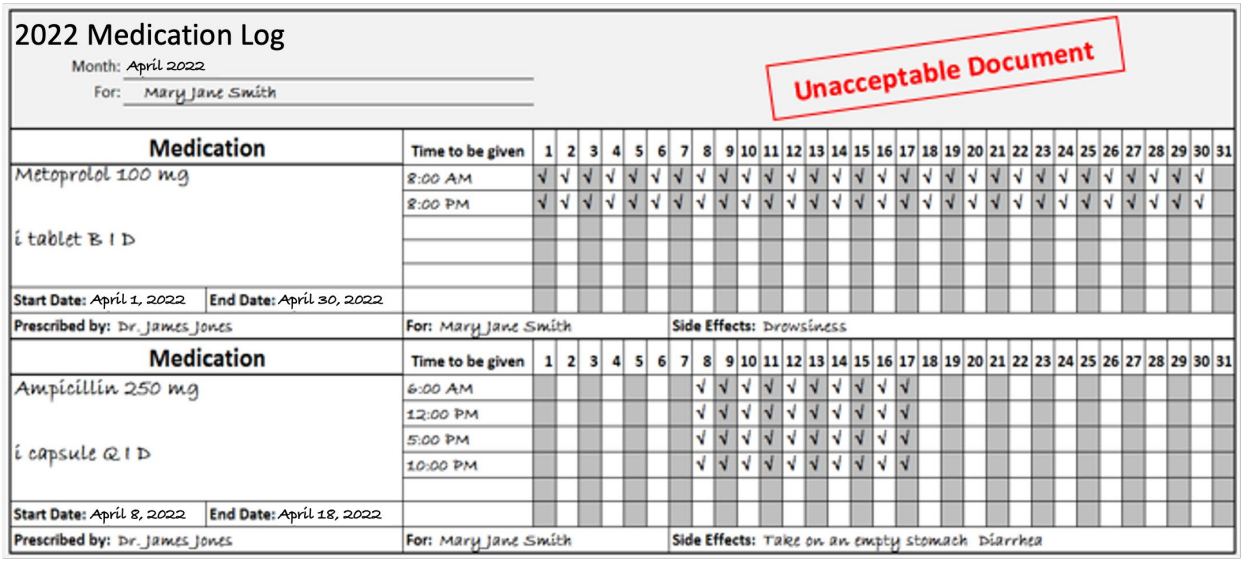


Figure 18. Example of Unacceptable Documentation – MAR Form



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	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	
1 tablet B I D																																
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							√	√	√	√	√	√	√	√	√	√															
	5:00 PM							√	√	√	√	√	√	√	√	√	√															
1 capsule Q I D	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

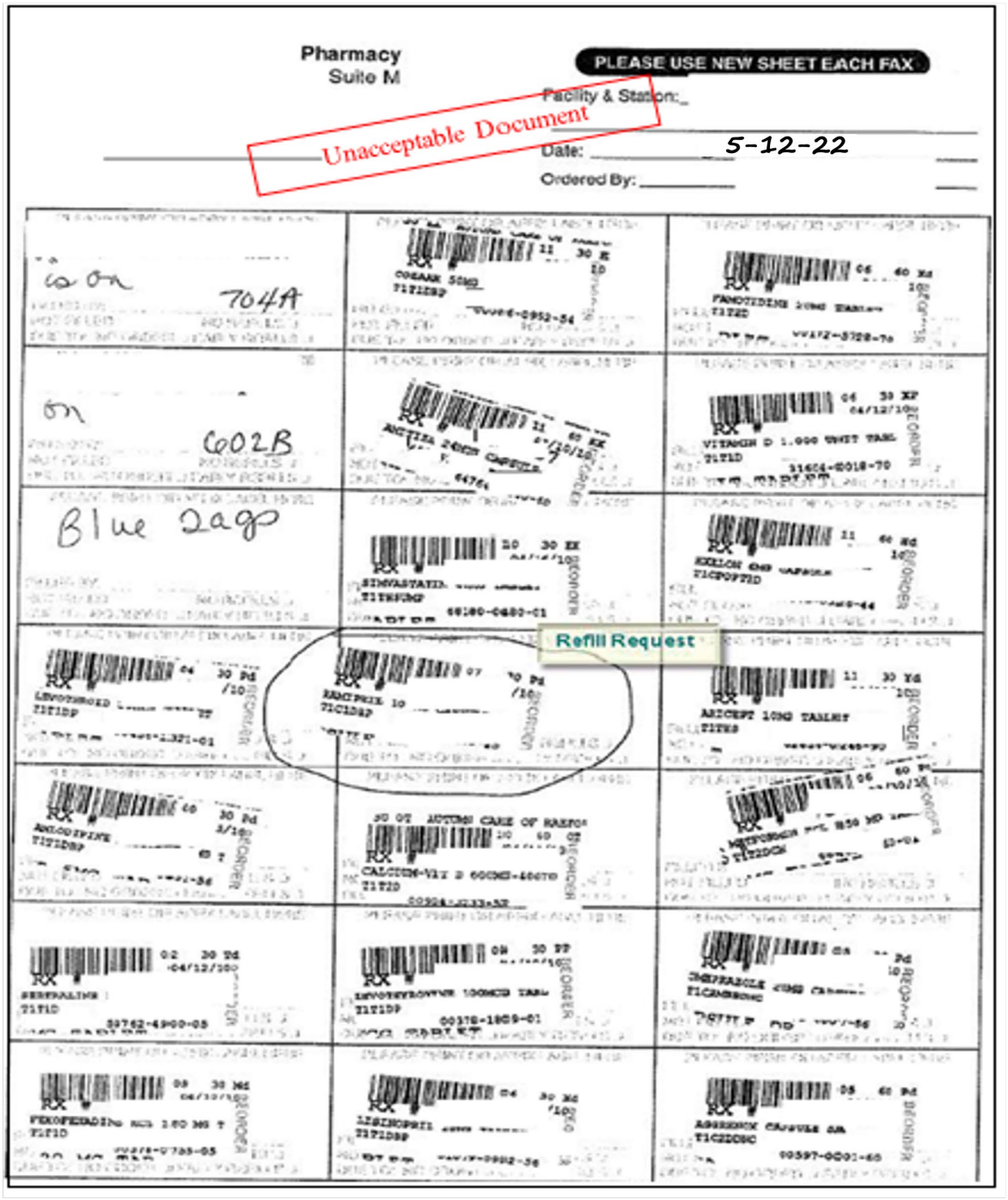
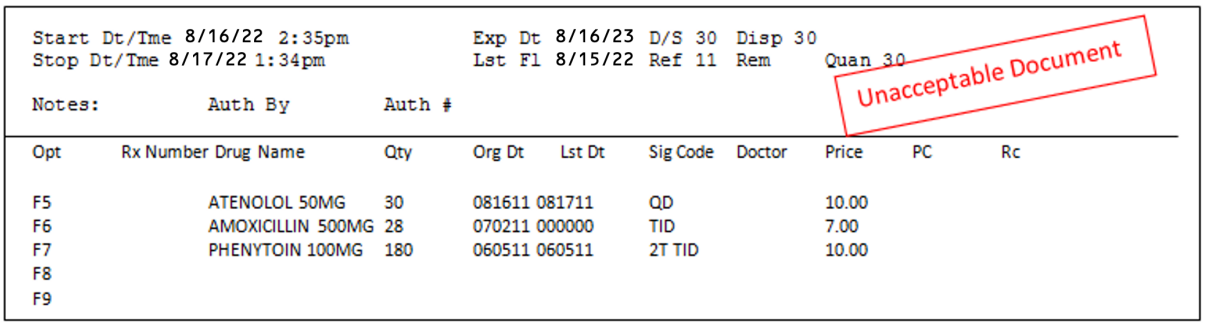


**Figure 20: Example of Unacceptable Documentation –
Screenshot of Electronic Refills and Order Processing File**

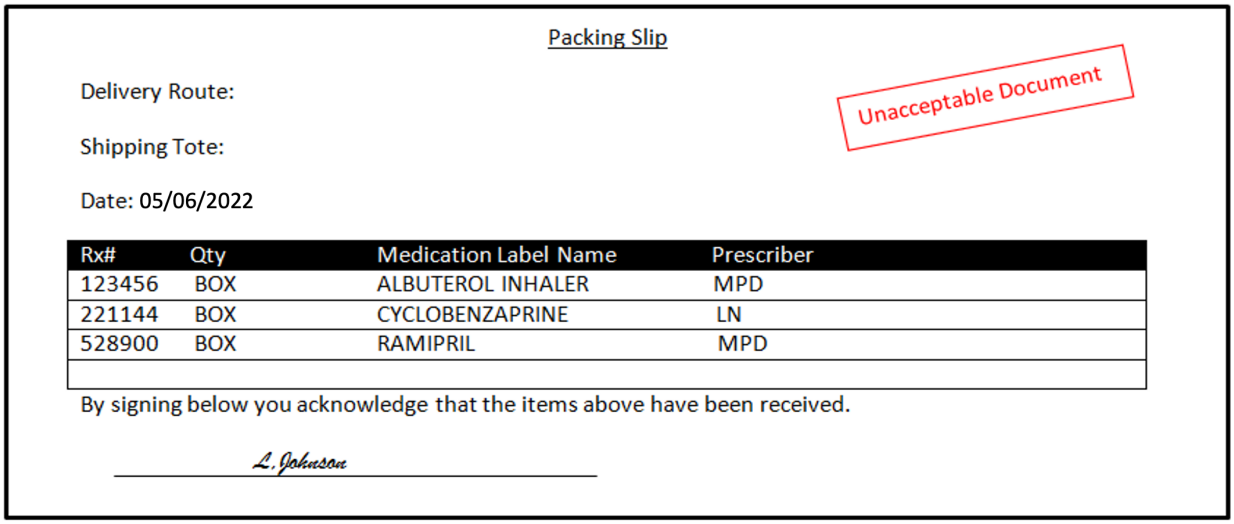


Note: Fictitious Beneficiary

Figure 21: Example of Unacceptable Documentation – Internal Audit Report

Note: Fictitious Beneficiary

Figure 22: Example of Unacceptable Documentation – Packing Lists



Packing Slip

Delivery Route:

Shipping Tote:

Date: 05/06/2022

Unacceptable Document

Rx#	Qty	Medication Label Name	Prescriber
123456	BOX	ALBUTEROL INHALER	MPD
221144	BOX	CYCLOBENZAPRINE	LN
528900	BOX	RAMIPRIL	MPD

By signing below you acknowledge that the items above have been received.

L. Johnson

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 cure a deficient medication order. Supplemental documentation must be copied together along with the medication order into one PDF using the appropriate naming convention for the file.

Examples of supplemental documentation include:

- A completed Physician Attestation 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 NPI
- Date of service
- Quantity
- Days supply
- Ingredient cost paid
- Dispensing fee paid
- Sales tax
- Vaccine administration fee

This supporting documentation must be provided in the following form:

- The CDF must be submitted using the Excel template provided to each Part D sponsor via the HPMS Part D IPM Module, as seen in Figure 23. There is one Excel template for each contract.

- 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	PDE ID Status
100	H0001_2021_0001	A1B2C37868C	Jane	Doe	1234567893	16729021815	1669498515	09/09/2021	30	30	523.45	0.75	0	0	Complete
101	H0001_2021_0002	B2A3C37874C	Jim	Smith	11111111112	60505014102	1992809784	12/13/2021	60	30	198.53	2	0	0	Complete

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 Part D 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 CFR 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 Claim Detail File, and the PDE record.

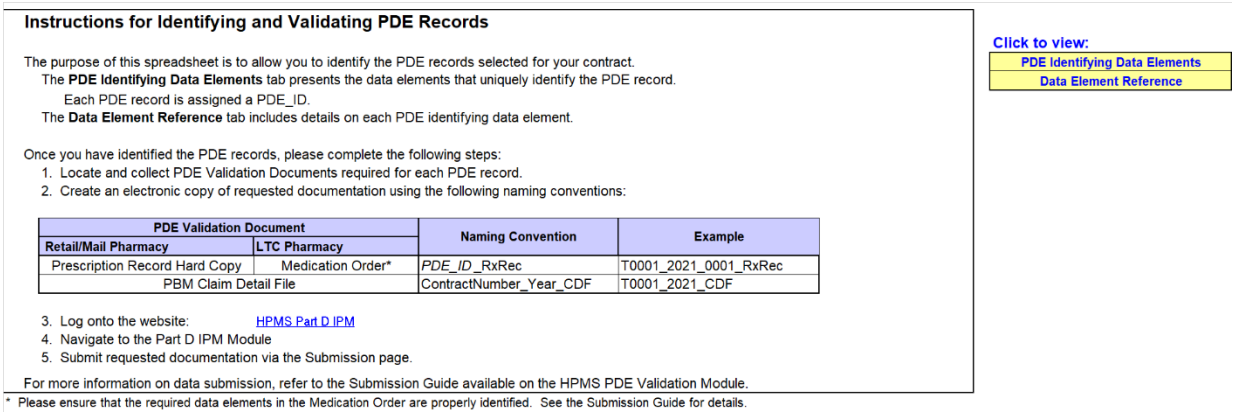
Identifying Your PDE Records in the Sample

The CY 2021 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



Instructions for Identifying and Validating PDE Records

The purpose of this spreadsheet is to allow you to identify the PDE records selected for your contract.
The **PDE Identifying Data Elements** tab presents the data elements that uniquely identify the PDE record.
Each PDE record is assigned a PDE_ID.
The **Data Element Reference** tab includes details on each PDE identifying data element.

Once you have identified the PDE records, please complete the following steps:
1. Locate and collect PDE Validation Documents required for each PDE record.
2. Create an electronic copy of requested documentation using the following naming conventions:

PDE Validation Document		Naming Convention	Example
Retail/Mail Pharmacy	LTC Pharmacy		
Prescription Record Hard Copy	Medication Order*	*PDE_ID*_RxRec	T0001_2021_0001_RxRec
PBM Claim Detail File		ContractNumber_Year_CDF	T0001_2021_CDF

3. Log onto the website: HPMS Part D IPM
4. Navigate to the Part D IPM Module
5. Submit requested documentation via the Submission page.

For more information on data submission, refer to the Submission Guide available on the HPMS PDE Validation Module.

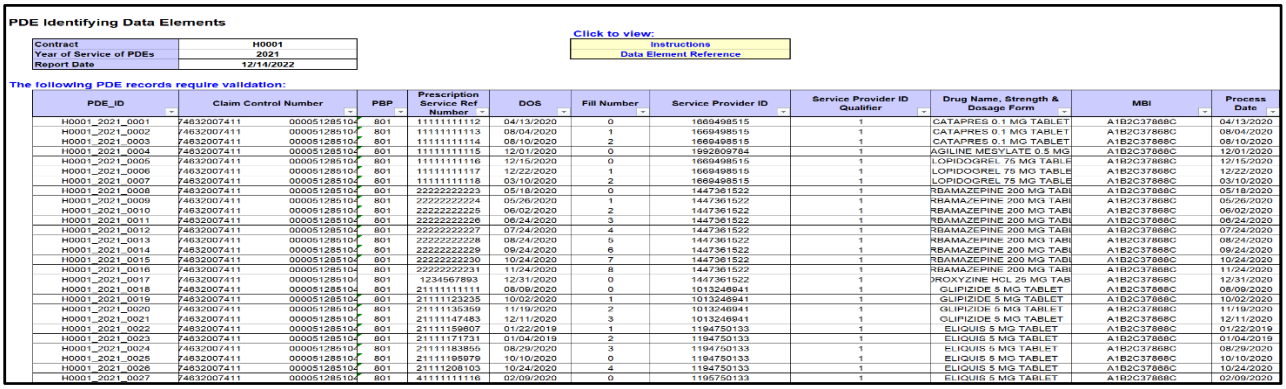
* Please ensure that the required data elements in the Medication Order are properly identified. See the Submission Guide for details.

Click to view:
PDE Identifying Data Elements
Data Element Reference

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 contractors. **Do not use protected health information (PHI) or personally identifiable information (PII) when communicating about a PDE record via email or the Discussion Board. Please use the PDE ID when communicating with CMS regarding this project.**

Figure 25: Tab 2, PDE Identifying Data Elements



PDE Identifying Data Elements

Contract	H0001
Year of Service of PDEs	2021
Report Date	12/14/2022

Click to view:
Instructions
Data Element Reference

The following PDE records require validation:

PDE_ID	Claim Control Number		PBP	Prescription Service Ref Number	DOS	Fill Number	Service Provider ID	Service Provider ID Qualifier	Drug Name, Strength & Dosage Form	MBI	Process Date
H0001_2021_0001	74632007411	00005128510	801	11111111112	04/13/2020	0	1669498515	1	CATAPRES 0.1 MG TABLET	A1B2C37868C	04/13/2020
H0001_2021_0002	74632007411	00005128510	801	11111111113	08/04/2020	1	1669498515	1	CATAPRES 0.1 MG TABLET	A1B2C37868C	08/04/2020
H0001_2021_0003	74632007411	00005128510	801	11111111114	08/10/2020	2	1669498515	1	CATAPRES 0.1 MG TABLET	A1B2C37868C	08/10/2020
H0001_2021_0004	74632007411	00005128510	801	11111111115	12/01/2020	0	1992809784	1	AGILINE MESYLATE 0.5 MG	A1B2C37868C	12/01/2020
H0001_2021_0005	74632007411	00005128510	801	11111111116	12/15/2020	0	1669498515	1	LOPIDOGREL 75 MG TABLE	A1B2C37868C	12/15/2020
H0001_2021_0006	74632007411	00005128510	801	11111111117	12/22/2020	1	1669498515	1	LOPIDOGREL 75 MG TABLE	A1B2C37868C	12/22/2020
H0001_2021_0007	74632007411	00005128510	801	11111111118	03/10/2020	2	1669498515	1	LOPIDOGREL 75 MG TABLE	A1B2C37868C	03/10/2020
H0001_2021_0008	74632007411	00005128510	801	22222222223	05/18/2020	0	1447361522	1	RBAMAZEPINE 200 MG TABL	A1B2C37868C	05/18/2020
H0001_2021_0009	74632007411	00005128510	801	22222222224	05/26/2020	1	1447361522	1	RBAMAZEPINE 200 MG TABL	A1B2C37868C	05/26/2020
H0001_2021_0010	74632007411	00005128510	801	22222222225	06/02/2020	2	1447361522	1	RBAMAZEPINE 200 MG TABL	A1B2C37868C	06/02/2020
H0001_2021_0011	74632007411	00005128510	801	22222222226	06/24/2020	3	1447361522	1	RBAMAZEPINE 200 MG TABL	A1B2C37868C	06/24/2020
H0001_2021_0012	74632007411	00005128510	801	22222222227	07/24/2020	4	1447361522	1	RBAMAZEPINE 200 MG TABL	A1B2C37868C	07/24/2020
H0001_2021_0013	74632007411	00005128510	801	22222222228	08/24/2020	5	1447361522	1	RBAMAZEPINE 200 MG TABL	A1B2C37868C	08/24/2020
H0001_2021_0014	74632007411	00005128510	801	22222222229	09/24/2020	6	1447361522	1	RBAMAZEPINE 200 MG TABL	A1B2C37868C	09/24/2020
H0001_2021_0015	74632007411	00005128510	801	22222222230	10/24/2020	7	1447361522	1	RBAMAZEPINE 200 MG TABL	A1B2C37868C	10/24/2020
H0001_2021_0016	74632007411	00005128510	801	22222222231	11/24/2020	8	1447361522	1	RBAMAZEPINE 200 MG TABL	A1B2C37868C	11/24/2020
H0001_2021_0017	74632007411	00005128510	801	1234567893	12/31/2020	0	1447361522	1	ROXYZINE HCL 25 MG TAB	A1B2C37868C	12/31/2020
H0001_2021_0018	74632007411	00005128510	801	21111111111	08/09/2020	0	1013246941	1	GLIPIZIDE 5 MG TABLET	A1B2C37868C	08/09/2020
H0001_2021_0019	74632007411	00005128510	801	21111123235	10/02/2020	1	1013246941	1	GLIPIZIDE 5 MG TABLET	A1B2C37868C	10/02/2020
H0001_2021_0020	74632007411	00005128510	801	21111135359	11/19/2020	2	1013246941	1	GLIPIZIDE 5 MG TABLET	A1B2C37868C	11/19/2020
H0001_2021_0021	74632007411	00005128510	801	21111147483	12/11/2020	3	1013246941	1	GLIPIZIDE 5 MG TABLET	A1B2C37868C	12/11/2020
H0001_2021_0022	74632007411	00005128510	801	21111159607	01/22/2019	1	1194750133	1	ELIQUIS 5 MG TABLET	A1B2C37868C	01/22/2019
H0001_2021_0023	74632007411	00005128510	801	21111171731	01/04/2019	2	1194750133	1	ELIQUIS 5 MG TABLET	A1B2C37868C	01/04/2019
H0001_2021_0024	74632007411	00005128510	801	21111183855	08/29/2020	3	1194750133	1	ELIQUIS 5 MG TABLET	A1B2C37868C	08/29/2020
H0001_2021_0025	74632007411	00005128510	801	21111195979	10/10/2020	0	1194750133	1	ELIQUIS 5 MG TABLET	A1B2C37868C	10/10/2020
H0001_2021_0026	74632007411	00005128510	801	21111208103	10/24/2020	4	1194750133	1	ELIQUIS 5 MG TABLET	A1B2C37868C	10/24/2020
H0001_2021_0027	74632007411	00005128510	801	41111111116	02/09/2020	0	1195750133	1	ELIQUIS 5 MG TABLET	A1B2C37868C	02/09/2020

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 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 A. PDE Layout for the entire list of 2021 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 *
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 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. 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.
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.

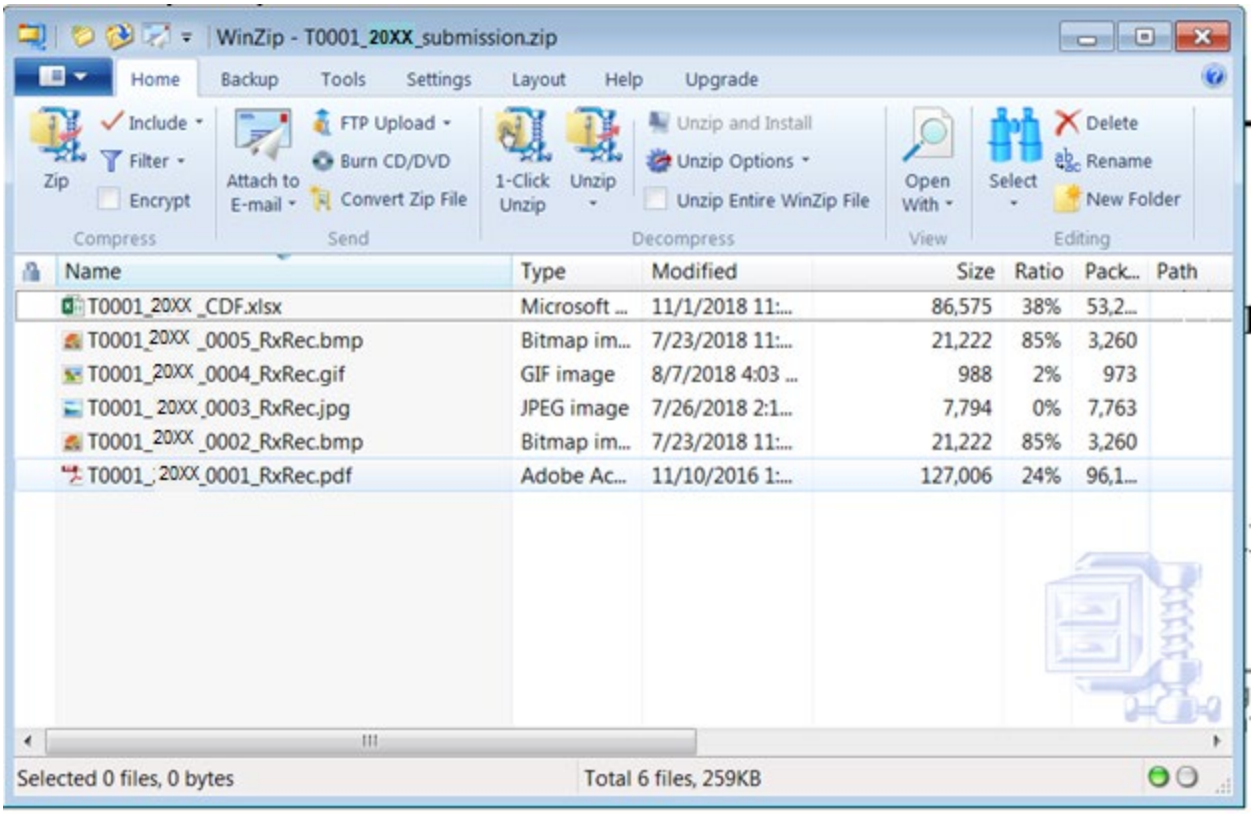
File Consolidation, Upload, and Verification

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

CY 2021 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 each missing document.

You should complete and upload this form only if the **entire** document is missing; do not 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):

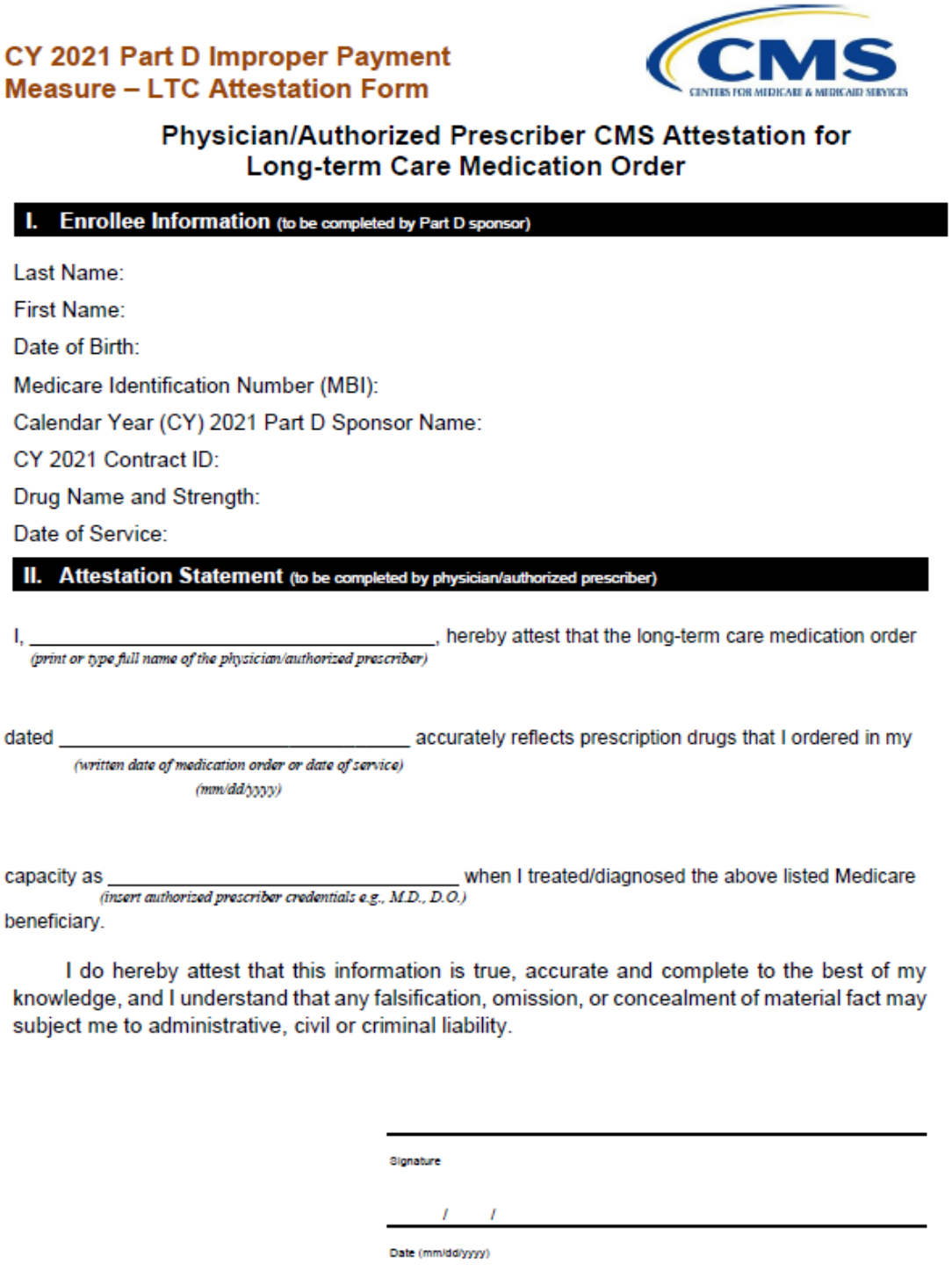
Examples

Prescription Record Hardcopy: Consulted internal pharmacy contracting system, pharmacy is inactive. Spoke with Lori at the Maryland State Board of Pharmacy on February 1, 2023 at 4:00 pm. Confirmed pharmacy was closed on August 1, 2022.
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 will need to submit a separate CMS Physician Attestation 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. CMS Physician Attestation Forms are only to be used for medication orders that are unsigned by a provider with prescriptive authority or improperly signed by someone other than an authorized prescriber. The CMS Physician 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 Physician Attestation Form. The CMS Physician Attestation Form can be found in the Help Documents folder on the HPMS Part D IPM Module.

Figure 30: CMS Physician Attestation Form



CY 2021 Part D Improper Payment Measure – LTC Attestation Form

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

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

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

Last Name:

First Name:

Date of Birth:

Medicare Identification Number (MBI):

Calendar Year (CY) 2021 Part D Sponsor Name:

CY 2021 Contract ID:

Drug Name and Strength:

Date of Service:

II. Attestation Statement (to be completed by physician/authorized prescriber)

I, _____, hereby attest that the long-term care medication order
(print or type full name of the physician/authorized prescriber)

dated _____ accurately reflects prescription drugs that I ordered in my
(written date of medication order or date of service)
(mm/dd/yyyy)

capacity as _____ when I treated/diagnosed the above listed Medicare
(insert authorized prescriber credentials e.g., M.D., D.O.)
beneficiary.

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, the file and its contents will undergo two checks to verify the documents. The Verification Checks include:

- Preliminary checks
- 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 e-mail 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.

Element check results and Interim Finding Reports (IFR) will be provided by March 31, 2023, only for documents submitted on or before the early submission deadline of March 10, 2023. If resubmission of files is desired based on the results of these checks, this can be done before the final submission deadline of April 21, 2023. **Submit files as early as possible within the first 6 weeks of the submission period window to receive the results of element checks, update files with complete and valid documents, and resubmit before the submission deadline.**

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

Refer to the HPMS Plan User Guide, 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 newly requested data elements **and** 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 Discussion Board feature of the HPMS Part D IPM Module. **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. Part D sponsors demonstrated the following best practices in completing the PDE Submission and Validation processes when they:

- Filled in all of the required data elements in the CDF template.
- Reviewed all prescription record hardcopies and/or medication orders subject to PDE submission and confirmed prior to uploading documentation that the documents are signed by licensed providers.
- Submitted medication orders and any additional supplemental documentation (CMS Physician Attestation Form, Medical record, etc.) in a single PDF file.
- Submitted prescription records hardcopies/medication orders in the form of a PDF file and not a Word document, a text document, or jpg.
- Included complete supporting documentation for each beneficiary in the upload file.
- Provided explanatory comments or documents when the beneficiary named on the prescription record hardcopy/medication order was 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 will often refer to the beneficiary's non-given name.
- Submitted an explanation/additional information if a pharmacy sends prescription record hardcopy documentation that fails to support the PDE. Common examples include:

    1. 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 is reflected on the PDE.

    2. 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).

    3. 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 limitations on days' supply available to a beneficiary at retail or by beneficiary request).

Contact Information

HPMS Part D IPM Module: https://hpms.cms.gov

For any questions or concerns regarding the Part D IPM activity, use the email addresses below. Initial responses will be provided within 2 to 3 business days; however, resolution of issues may require additional time.

Policy and Teleconference Questions

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

Please include “Part D IPM 2021” in the subject line.

Questions Regarding the Part D Validation Submission Process

Questions posted on the Discussion Board, available in the HPMS Part D IPM Module 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

Technical questions concerning HPMS, the Part D IPM Module, and the supporting documentation upload process should be sent to hpms@cms.hhs.gov.

Appendix A. PDE Layout

The PDE Inbound Layout File, effective May 31, 2017, can be found on the CMS Customer Service and Support Center (CSSC) website.

Appendix B. CMS Policy Regarding Adjusted Claims

The deadline for submission of PDE data for the CY 2021 Part D Payment Reconciliation was June 29, 2022. The PDE records that CMS sampled for the current CY 2021 Part D IPM process were submitted on or before this date. The CY 2021 Part D IPM process validates the PDE record that the Part D sponsor determined was the final PDE record for purposes of the CY 2021 Part D Payment Reconciliation.

In the situation where the sponsor subsequently adjusted the sampled "recon PDE" (adjustment made **AFTER** June 29, 2022) 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 ancillary documentation indicating that the sampled PDE record was adjusted following reconciliation. Please be sure it is linked to an adjusted PDE *if* it supports the intended field(s) in the "recon PDE." See the earlier section in this Submission Instructions for additional information on submitting ancillary 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 on the 11 fields provided as PDE identifiers (the PDE_ID Number and 10 unique identifiers associated with the PDE being reviewed), as well as the Part D sponsor Contract ID Number.

END OF DOCUMENT