Recommended Use of Quantity Prescribed (460-ET) in NCPDP Telecommunication Standard Version D.0

Version 13

May 2021

The purpose of this paper is to provide information and guidance on the use of the Quantity Prescribed (460-ET) field to address the issues with state requirements related to CII's for dispensing of medication in increments less than the amount prescribed.

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Version13

Published by:
National Council for Prescription Drug Programs, Inc.

Publication History:
Version 10 August 2019
Version 11 December 2019
Version 12 June 2020
Version 12 July 2020 Republication
Version 13 May 2021

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I. PURPOSE

The purpose of this paper is to provide information and guidance on the use of the Quantity Prescribed (460-ET) field for all Schedule II controlled substance claims exchanged between HIPAA covered entities. It is based upon Final Rule CMS-0055-F: Modification of the Requirements for the Use of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) D.0 Standard. The use of the Quantity Prescribed (460-ET) field is intended to address the inability to identify a Schedule II controlled substance claim that is a partial or incremental fill versus a prescription refill. This conflict was recognized in the September 2012 OIG report which identified Schedule II controlled substances that they thought were being billed as refills, and within federal and state requirements related to section 702 of the Comprehensive Addiction and Recovery Act (CARA), in support of dispensing Schedule II medications in increments less than the amount prescribed.

II. BACKGROUND

The following section provides the background of when and by whom the issues originated and were identified.

A. MEDICARE PART D

CMS Medicare Part D 2014 Final Call Letter dated April 1, 2013[1]:

"Incremental Fills of Schedule II Controlled Substances Prescriptions
As part of their compliance plans to detect, prevent, and correct fraud, waste, and abuse, sponsors must have internal controls in place that prevent Part D payment for illegal refills of Schedule II controlled substances prescriptions. In addition, these internal controls must ensure that any PDEs that are submitted for actual illegal refills of Schedule II drugs are promptly adjusted or deleted. The Drug Enforcement Agency (DEA) regulates Schedule II drugs, and the Controlled Substance Act prohibits the refilling of prescriptions for them. (See 21 U.S.C. § 829(a)). Schedule II controlled substances have the highest potential for abuse of any prescription drugs legally available in the United States.

We encourage the industry to promptly address the known limitation of the current HIPAA prescription drug billing standard with respect to distinguishing partial or incremental fills of an original prescription from refills. CMS understands that this limitation may currently result in partial fills of Schedule II controlled substances being billed in a manner that cannot be distinguished from refills, particularly in the LTC setting. Partial fills of Schedule II controlled substances are permissible under Federal law under certain circumstances and occur when a pharmacist does not dispense all doses of the prescribed medication at one time. Partial fills are not considered refills. A September 2012 OIG report found that three-quarters of Part D sponsors inappropriately paid $25 million for Schedule II controlled substances that were billed as refills in 2009. The OIG acknowledged that some of these drugs may have been inaccurately billed, and CMS believes these claims more likely represent legally dispensed partial fills as opposed to illegal refills. (See https://oig.hhs.gov/oei/reports/oei-02-09-00605.asp).

CMS understands from comments received on the draft version of this Call Letter that the industry is actively addressing the limitation in the billing standard through the National Council for Prescription Drug Programs. Nevertheless, the limitation in the billing standard does not obviate the requirement for sponsors to have internal controls in place that prevent Part D payment for illegal refills of Schedule II controlled substances prescriptions. Until a billing solution is implemented by the industry that permits sponsors to compare the amounts billed to the total amount prescribed on the original prescription at the time of claim processing, CMS expects sponsors to ensure compliance through retrospective auditing. We also expect sponsors to ensure that any PDEs that have been erroneously submitted for illegal refills of Schedule II drugs are promptly adjusted or deleted."

B. FEDERAL AND STATE REGULATIONS

In an effort to mitigate the opioid epidemic and to support the Comprehensive Addiction and Recovery Act (CARA) of 2016[2] for partial/incremental fills for Schedule II controlled substances, policy makers have passed or are considering rules that may apply to the original fill or an incremental fill.

[1] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2014.pdf
[2] https://www.congress.gov/bill/114th-congress/senate-bill/524

III. IDENTIFICATION OF THE PROBLEM

A. MEDICARE PART D

As stated in Final Rule CMS-0055-F dated January 24, 2020, there were conflicts in the interpretation of use of the Fill Number (403-D3) field, that led to the problem of assuming Schedule II prescription claims with a Fill Number greater than '00' were invalid.

> *"In September 2012, the HHS Office of the Inspector General (OIG) issued a report titled 'Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills' that analyzed all of the 2009 program year prescription drug event (PDE) records for refills of Schedule II drugs. PDE records are claim summary records that contain data elements from prescription drug claims, submitted by prescription drug plan sponsors to the Centers for Medicare & Medicaid Services (CMS) for every prescription a provider fills for a Medicare Part D beneficiary. One of those data element fields is titled 'Fill Number (403–D3)', which identifies refills. The Version D.0 implementation specifications require that a ''0'' be entered in the Fill Number (403–D3) field for a new prescription and that the number be sequentially increased by ''1'' for each refill. The OIG analyzed 20.1 million records for Schedule II drugs and, focusing on the Fill Number (403–D3) field, identified what it concluded were refills. The OIG concluded that the Medicare Part D program had inappropriately paid $25 million for 397,203 Schedule II drug refills and that LTC facility pharmacies billed for 75 percent of such refills. The OIG stated that the Medicare Part D plan sponsors should not have paid for those drugs because Federal law prohibits Schedule II drug refills, and concluded that '[p]aying for such drugs raises public health concerns and may contribute to the diverting of controlled substances and their being resold on the street'*
>
> *CMS took a different interpretation of the OIG's findings. In its written response to the OIG report, CMS expressed concern that the OIG's strict interpretation of PDE data did not support the OIG's findings. CMS believed the OIG's findings were based, in part, on a misinterpretation of Schedule II drug partial fills dispensed to LTC facility residents as refills."*

B. FEDERAL AND STATE REGULATIONS

Existing and newly enacted controlled substance regulations provide specific conditions under which the incremental dispensing of a Schedule II medication is permitted. The 2007 publication of the Telecommunication vD.0 Standard that was named under HIPAA does not contain the necessary information for the payer to determine the claim to be an incremental fill. The Quantity Prescribed (460-ET) field is needed in order to:

- Identify fills dispensed as shortened days supply (i.e., original or incremental dispensing)
- Prorate patient responsibility/copayment amounts for incremental fills
- Validate total quantity dispensed does not exceed quantity prescribed
- Provide the information necessary to ensure that the prescribed Schedule II medications when dispensed do not exceed regulatory limitations

C. INCREMENTAL VERSUS PARTIAL FILL CLAIM BILLING CONCEPTS

The use of the term partial fill in the CARA Act is defined by NCPDP as an incremental fill. CARA "partial fill" should not be equated to the NCPDP partial fill. Incremental fill and partial fill as applied within NCPDP standards are very different concepts that should not be confused and are not interchangeable.

"Incremental fill" is used to represent the dispensing of incremental quantities of the total amount ordered specifically for Schedule II medications, as allowed under federal and state regulations.

"Partial Fill" is defined by NCPDP to represent an optional claim billing process for when a prescription cannot be filled for the full quantity ordered due to insufficient inventory on-hand at the dispensing pharmacy.

This distinction is available within the definition of the fields used for partial and completion fills. For example, Quantity Intended to be Dispensed (344-HF) represents the "metric decimal quantity that would have been dispensed if adequate inventory were available."

IV. SOLUTION

A. REGULATORY CHANGES

On January 24, 2020, Health and Human Services published the Final Rule: Administrative Simplification: Modification of the Requirements for the Use of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) D.0 Standard: CMS-0055-F. This rule requires a modification to how the Quantity Prescribed (460-ET) field is used in the 2007 publication of the NCPDP Telecommunication Version D.0 Standard.

"This final rule adopts a modification of the requirements for the use of the Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, National Council for Prescription Drug Programs, by requiring covered entities to use the Quantity Prescribed (460–ET) field for retail pharmacy transactions for Schedule II drugs. The modification enables covered entities to distinguish whether a prescription is a ''partial fill,'' where less than the full amount prescribed is dispensed, or a refill, where the full amount prescribed is dispensed, in the HIPAA retail pharmacy transactions. This modification is important to ensure the availability of a greater quantum of data that may help prevent impermissible refills of Schedule II drugs, which will help to address the public health concerns associated with prescription drug abuse in the United States."

"§ 162.1102 Standards for health care claims or equivalent encounter information transaction.
** * * * **
(d) For the period on and after September 21, 2020, the Quantity Prescribed (460–ET) field, as set forth in the Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007 and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs, must be treated as required where the transmission meets both of the following:
(1) Is for a Schedule II drug, as defined in 21 CFR 1308.12.
(2) Uses the standard identified in paragraph (b)(2)(i) of this section."

"§ 162.1302 Standards for referral certification and authorization transaction.
** * * * **
(d) For the period on and after September 21, 2020, the Quantity Prescribed (460–ET) field, as set forth in the Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007 and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs, must be treated as required where the transmission meets both of the following:
(1) Is for a Schedule II drug, as defined in 21 CFR 1308.12.
(2) Uses the standard identified in paragraph (b)(2)(i) of this section."

"§ 162.1802 Standards for coordination of benefits information transaction.
** * * * **
(d) For the period on and after September 21, 2020, the Quantity Prescribed (460–ET) field, as set forth in the Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007 and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs, must be treated as required where the transmission meets both of the following:

(1) Is for a Schedule II drug, as defined in 21 CFR 1308.12.
(2) Uses the standard identified in paragraph (b)(2)(i) of this section."

B. NCPDP GUIDANCE

1. CLAIM REQUEST

NCPDP recommends the use of the following fields in the development of point of service edits for Schedule II controlled substance claims:

Field	Field Name	Definition	Processing Recommendations
460-ET	Quantity Prescribed	Amount expressed in metric decimal units. Editorial Note: This field is intended to communicate the maximum quantity authorized by the prescriber to be dispensed.	• Can be used to identify incremental fills by validating the quantity dispensed is less than the quantity prescribed. • The accumulated quantity dispensed cannot exceed the value contained in the quantity prescribed field for Schedule II prescriptions as refills are not allowed.
442-E7	Quantity Dispensed	Quantity dispensed expressed in metric decimal units.	• The accumulated quantity dispensed cannot exceed the value contained in the quantity prescribed field for Schedule II prescriptions.
403-D3	Fill Number	vD.0: The code indicating whether the prescription is an original or a refill. vEB and higher: The code indicating whether the prescription fill is an original or a subsequent fill as it relates to the Prescription Service Reference Number. Editorial Note: D.0 cannot be changed until the next HIPAA Standard. What is indicated in vEB is consistent with industry practice.	• For incremental fills, the number will increment each time the medication is dispensed. Note: In LTC post-consumption billing and with NCPDP inventory shortage partial fills, the fill number will not increment each time the medication is dispensed. • Payers should not reject solely due to fill number.
402-D2	Prescription/ Service Reference Number	Reference number assigned by the provider for the dispensed drug/product and/or service provided.	• Can be used to match an incremental fill claim by using the Prescription/Service Reference Number and Service Provider ID to a history claim.

Field	Field Name	Definition	Processing Recommendations
201-B1	Service Provider ID	ID assigned to a pharmacy or provider.	• Can be used to match an incremental fill claim by using the Prescription/Service Reference Number and Service Provider ID to a history claim.
415-DF	Number of Refills Authorized	Number of refills authorized by the prescriber.	• If sent, this must always be zero for a Schedule II prescription.

2. CLAIM RESPONSE

Leveraging the fields outlined above, the following Reject Codes (511-FB) may be used to clearly communicate the specific conflict to the pharmacy. Rejections for failure to submit the Quantity Prescribed field (460-ET) are limited to Schedule II controlled substance claims.

Reject Code	Description	Comment
ET	M/I Quantity Prescribed	Recommended use is for when a Quantity Prescribed value is not submitted for a Schedule II controlled substance or if the Quantity Prescribed value submitted is not in the specified format. Note: This reject code should not be used, unless per trading partner agreement, prior to the 09/21/2020 compliance date to CMS-0055-F.
E7	M/I Quantity Dispensed	Recommended use is for when a Quantity Dispensed value is not submitted for a Schedule II controlled substance or if the Quantity Dispensed value submitted is not in the specified format.
648	Quantity Prescribed Does Not Match Quantity Prescribed On Original CII Dispensing	Quantity Prescribed on incremental fill does not match the Quantity Prescribed transmitted on prior claims.
649	Cumulative Quantity For This CII Rx Number Exceeds Quantity Prescribed	Quantity Dispensed for all Prescription/Service Reference Number and Service Provider ID fills exceeds the Quantity Prescribed.
650	Date Of Service Greater Than 60 Days From CII Date Prescription Written For LTC/Terminally Ill Patient	To be used when the Schedule II claim for a patient known to be Long Term Care and/or terminally ill patient is

Reject Code	Description	Comment
		being incrementally filled more than 60 days after the RX was written.
981	Date of Service for Incremental Fill Exceeds Regulatory Timeframe for Dispensing	To be used when RX is being incrementally filled outside of dispensing timeframe allowed by regulation or law (federal or state). Not to be used when Reject Code 650 applies.

Note: Reject Code value 647 Quantity Prescribed Required For CII Prescription was sunset for use as of 01/01/2020. Reject Code ET should be used to designate the required status of this field for Schedule II medications.

The Additional Message Information Qualifier (132-UH) and Additional Message Information (526-FQ) fields may be used to communicate on either a Paid or Rejected claim response the remaining quantity that can be dispensed. This additional detail will allow the pharmacy to prevent a conflict on a future dispensing or better address the current reject by coordinating the necessary patient and prescriber discussions.

Field	Field Name	Value	Value Definition	Processing Recommendations
132-UH	Additional Message Information Qualifier	19	Remaining Quantity: Remaining amount to a maximum quantity limit based on quantity amounts accumulated.	• Determine the Remaining Quantity based on the Prescribed Quantity minus the accumulated Dispensed Quantity values.

V. PROCESSING RECOMMENDATIONS FOR TIME LIMITS ON INCREMENTAL FILLS

Regulations under Title 21 CFR Part 1306.13 (DEA) and Title 21 CSA Section 829 (CARA) allow for Schedule II controlled substances to be dispensed in an amount less than the prescribed quantity. The remaining prescribed quantity can be dispensed within certain time periods, based on the incremental fill reason. Data elements within the NCPDP Telecommunication Standard claim billing transaction allows the receiver of the transaction to determine the incremental fill reason and the associated incremental fill time limit.

The following charts summarize the conditions and time periods for each regulation and provide the associated NCPDP data elements and reject codes that may be used in validation of the time limit in claim billing transactions.

DEA:

Title 21 CFR Part 1306.13

https://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_13.htm

Incremental Fill Condition	Time Allowed Before RX Expires	Time Allowed Start Date	NCPDP Data Elements Used for Time Limit Validation	Processing Recommendations	NCPDP Reject Code (511-FB) Value for Validation Failure
LTCF	60 Days	RX Issue Date	• 384-4X Patient Residence Code • 147-U7 Pharmacy Service Type • 401-D1 Date of Service • 414-DE Date RX Written	Treat as LTCF if Patient Residence Code and Pharmacy Service Type indicate LTC, Diagnosis Code and DUR codes may be Null	650 - Date Of Service Greater Than 60 Days From CII Date Prescription Written For LTC/Terminally Ill Patient
Terminally Ill	60 Days	RX Issue Date	• 424-D0 Diagnosis Code • 441-E6 Result of Service Code • 401-D1 Date of Service • 414-DE Date RX Written	Treat as Terminally Ill if Patient Residence Code and Pharmacy Service Type do not indicate LTC, and Diagnosis Code or DUR codes indicate terminal illness If claim does not contain the applicable terminally ill indicator, incremental fill dates of service beyond 30 days of the RX Written Date would reject due to the date span. Pharmacy may resubmit the claim with the terminally ill	650 - Date Of Service Greater Than 60 Days From CII Date Prescription Written For LTC/Terminally Ill Patient

Incremental Fill Condition	Time Allowed Before RX Expires	Time Allowed Start Date	NCPDP Data Elements Used for Time Limit Validation	Processing Recommendations	NCPDP Reject Code (511-FB) Value for Validation Failure
				value to override the date span reject.	

Note: The conditions of inventory shortage and emergency referenced in the DEA regulation were not included in this chart as they do not meet the NCPDP definition of incremental fill.

CARA:

Title 21 CSA Section 829

https://www.congress.gov/114/plaws/publ198/PLAW-114publ198.pdf

Incremental Fill Condition	Time Allowed Before RX Expires	Time Allowed Start Date	NCPDP Data Elements Used for Time Limit Validation	Processing Recommendations	NCPDP Reject Code (511-FB) Value for Validation Failure
Patient Requested	30 Days	RX Written Date	• 384-4X Patient Residence Code • 147-U7 Pharmacy Service Type • 424-D0 Diagnosis Code • 441-E6 Result of Service Code • 401-D1 Date of Service • 414-DE Date RX Written	Treat as CARA if Patient Residence Code and Pharmacy Service Type do not indicate LTC, and Diagnosis Code or DUR codes do not indicate terminally illness	981 - Date of Service for Incremental Fill Exceeds Regulatory Timeframe for Dispensing
Prescriber Requested	30 Days	RX Written Date	• 384-4X Patient Residence Code • 147-U7 Pharmacy Service Type • 424-D0 Diagnosis Code • 441-E6 Result of Service Code • 401-D1 Date of Service • 414-DE Date RX Written	Treat as CARA if Patient Residence Code and Pharmacy Service Type do not indicate LTC, and Diagnosis Code or DUR codes do not indicate terminally illness	981 - Date of Service for Incremental Fill Exceeds Regulatory Timeframe for Dispensing

Note: The condition of emergency referenced in the CARA regulation was not included in this chart as it does not meet the NCPDP definition of incremental fill.

VI. PRORATION OF COPAYS

With the availability of Quantity Prescribed (460-ET), Submission Clarification Codes (420-DK) are no longer necessary to calculate proration of copays.

Both Quantity Dispensed (442-E7) and the Quantity Prescribed (460-ET) should be used when a predefined month supply is not used to prorate the copay.

If proration is based on a predefined month supply, only the Quantity Dispensed (442-E7) should be used in the copay calculation.

VII. ADDITIONAL CLARIFICATIONS/FREQUENTLY ASKED QUESTIONS

1. **Question:** What happens if the Quantity Prescribed (460-ET) field is submitted for non-Schedule II drugs?

   Response: The NCPDP SNIP Committee strongly recommends for any claim that contains Quantity Prescribed (460-ET) but is not for a Schedule II drug (as defined by state/federal/regulatory agency programs), the field should be ignored for point of service claim adjudication.

2. **Question:** What should happen during the transition period when Schedule II claims history with the same Service Provider ID and Prescription/Service Reference Number were processed prior to the required use of the Quantity Prescribed (460-ET) field and did not contain the Quantity Prescribed?

   Response: It must be assumed that the Quantity Prescribed on the current claim is correct and it applies to all previous claims from the same Service Provider ID and Prescription/Service Reference Number. Therefore, the accumulated Quantity Dispensed from all claims, current and previous, must not exceed the value in Quantity Prescribed. Claims should not be rejected because the prior claims for the same Prescription/Service Reference Number did not have the Quantity Prescribed. For Example:

Date of Service (401-D1)	Service Provider ID (201-B1)	Prescription Service Reference Number (402-D2)	Fill Number (403-D3)	Quantity Dispensed (442-E7)	Quantity Prescribed (460-ET)	Days Supply (405-D5)	Payer Calculated Accumulated Dispensed Quantity
09/01/2020	1234567890	1112223	00	20		10	20
09/10/2020	1234567890	1112223	01	20		10	40
09/21/2020	1234567890	1112223	02	20	60	10	60

3. **Question:** Should Quantity Prescribed be submitted on a compound claim containing one or more Schedule II ingredients?

   Response: If under the most stringent applicable law, the final compounded product is a Schedule II, then the quantity prescribed should be submitted. Also refer to trading partner agreements, as Quantity Prescribed (460-ET) may be required based on the payer's determination that a single compound ingredient is a Schedule II drug. Note, the Quantity Prescribed (460-ET) value submitted represents the prescribed quantity for the final compounded product and not the quantity for the Schedule II ingredient.

4. **Question:** After the compliance date, at which time all Schedule II claims will contain the Quantity Prescribed (460-ET), how does a payer calculate the accumulated dispensed quantity when the payer does not receive all fill numbers for an associated prescription number?

   Response: The payer should base their calculation of accumulated dispensed quantity on the fill data submitted and/or housed within their system for the specific prescription number. Refer to the example below.

Date of Service (401-D1)	Service Provider ID (201-B1)	Payer	Prescription Service Reference Number (402-D2)	Fill Number (403-D3)	Quantity Dispensed (442-E7)	Quantity Prescribed (460-ET)	Days Supply (405-D5)	Payer Calculated Accumulated Dispensed Quantity
10/01/2020	1234567890	ABC	1112223	00	20	60	10	20
10/10/2020	1234567890	XYZ	1112223	01	20	60	10	20
10/20/2020	1234567890	ABC	1112223	02	20	60	10	40

In this scenario, Payer XYZ (such as a cash discount program) has no visibility to the prescription filled on 10/1; therefore, they are not able to include it in their total accumulated calculation. Payer ABC for the 10/20 fill would only have visibility to the 10/1 previously dispensed quantity.

In future versions, the pharmacy would submit the Total Prescribed Quantity Remaining (D02-KW) field. Claims submitted using Version D.0 do not include this field and therefore do not permit a payer to account for any amount dispensed in relation to fill numbers not represented in data submitted to the payer. Until Total Prescribed Quantity Remaining (D02-KW) is available for use, payers cannot assume a dispensed quantity other than zero (0) for any fill numbers not represented in available data.

5. **Question:** Is the partial fill (inventory shortage) scenario mutually exclusive of the incremental fill scenario?

   Response: No, they are not mutually exclusive. Incremental fill could have been requested but the pharmacy also has an inventory shortage. Quantity Prescribed (460-ET) should be submitted as well as the partial fill fields. Please refer to Section 28.1.9.1 Partial Fill of the Telecommunication Standard Version D.0 Implementation Guide for partial fill guidance.

6. **Question:** After the compliance date, if a payer receives multiple claims for a Schedule II drug for the same patient and prescription, are these considered refills?

   Response: No. Provided the Rx number is still the same, these are counted as incremental fills. Refills on Schedule IIs are not allowed.

   To reduce the confusion about the use of the Fill Number (403-D3) field, the definition has been clarified for the next HIPAA named version of the Telecommunication Standard. The updated definition is: The code indicating whether the prescription fill is an original or a subsequent fill as it relates to the Prescription Service Reference Number.

7. **Question:** How many incremental fills are allowed for a Schedule II?

   Response: Neither CARA nor the Quantity Prescribed Final Rule dictate the number of incremental fills allowed. As long as the total of all fills does not exceed the quantity prescribed the fill will be allowed barring any other reason the claim might be rejected (e.g., safety edits, non-formulary etc.).

VIII. BILLING EXAMPLES FOR QUANTITY PRESCRIBED (460-ET)

In order to assist pharmacies, vendors, processors and payers, the use of **Quantity Prescribed** (460-ET) and the supporting Reject Codes is outlined in the example scenarios below. These examples are based upon CARA and DEA limits. Any state limits that may be enacted will not be addressed in this white paper.

#	Source	Drug DEA Class	Time Between Initial / Incremental Fill (s)	Payer Type	Patient Condition / Terminally Ill	Long Term Care (LTC) Facility	QTY dispensed exceeds QTY prescribed	Status	Situation
1	CARA	Schedule II	30 days	All	No	No	No	Paid	Retail
2	CARA	Schedule II	30 days	All	No	No	Yes	Denied	Retail
3	CARA	Schedule II	unknown	All	No	Yes	No	Paid	LTC Post Consumption Billing
4	CARA	Schedule II	unknown	All	No	Yes	Yes	Denied	LTC Post Consumption Billing
5	CARA	Schedule II	30 days	Medicare Part D	No	Yes	No	Paid	LTC Short Cycle Dispensing
6	CARA	Schedule II	30 days	Medicare Part D	No	Yes	Yes	Denied	LTC Short Cycle Dispensing
7	CARA	Schedule II	30 days	All	No	Yes	No	Paid	LTC Split Billing
8	CARA	Schedule II	30 days	All	No	Yes	Yes	Denied	LTC Split Billing
9	CARA	Schedule II	30 days	All	No	Yes	No	Paid	LTC Discharge Fills
10	CARA	Schedule II	30 days	All	No	Yes	Yes	Denied	LTC Discharge Fills
11	DEA	Schedule II	60 days*	All	No	Yes	No	Paid	LTC
12	DEA	Schedule II	60 days*	All	No	Yes	Yes	Denied	LTC
13	CARA	Schedule II	30 days	All	No	No	Missing	Denied	Missing Quantity Prescribed
14	CARA	Schedule II	30 days	All	No	No	Different	Denied	Quantity Different
15	CARA	Schedule II	30 days	All	No	No	Less Than	Denied	Quantity Prescribed is less than what is being dispense

Note:
These examples are highlighted for the purposes of showing how to use the Telecommunication Standard Version D.0 Quantity Prescribed field as well as associated fields and reject codes to streamline the processing of Schedule II incremental fills as allowed under Controlled Substance Act and Comprehensive Addiction Recovery Act (CARA). The fields specified in the examples below are not a comprehensive list of required/optional Telecommunication Standard Version D.0 fields.

LTC is exempt from CARA 30-day restriction and is limited to 60 days. Please refer to the letter from the DEA to the American Society of Consultant Pharmacists (ASCP) on this topic.

Scenario 1 – Retail prescription with an incremental fill, dispensed within fill window and within prescribed quantity

Prescriber / Order Information			
	Attribute	Value	Comments
	RX Written Date	11/1/2019	
	Drug DEA Class	Schedule II	
	Prescribed Quantity	60	
	Directions	One tablet by mouth twice per day	
	Days Supply	30	
	# of authorized refills	0	
Initial Fill Claim Billing			
Field	Field Name	Value	Comments
102-A2	Version Release Number	D0	
401-D1	Date of Service	11/1/2019	
384-4X	Patient Residence	1	Home
402-D2	Prescription/Service Reference Number	1234567	
403-D3	Fill Number	00	
460-ET	Quantity Prescribed	60	
442-E7	Quantity Dispensed	30	
415-DF	Number of Refills Authorized	0	
405-D5	Days Supply	15	
414-DE	Date Prescription Written	11/1/2019	
420-DK	Submission Clarification Code	(blank)	
429-DT	Special Packaging Indicator	(blank)	

Initial Fill Claim Response			
Field	Field Name	Value	Comments
112-AN	Transaction Response Status	P	Paid
132-UH	Additional Message Information Qualifier	19	19 = Remaining Quantity
526-FQ	Additional Message Information	30	CII Quantity Remaining Calculation = Qty Prescribed - Accumulated Qty Dispensed
548-6F	Approved Message Code	(blank)	
Incremental Fill Claim Billing			
Field	Field Name	Value	Comments
102-A2	Version Release Number	D0	
401-D1	Date of Service	11/16/2019	
384-4X	Patient Residence	1	
402-D2	Prescription/Service Reference Number	1234567	
403-D3	Fill Number	01	Incremental Fill
460-ET	Quantity Prescribed	60	
442-E7	Quantity Dispensed	30	
415-DF	Number of Refills Authorized	0	
405-D5	Days Supply	15	
414-DE	Date Prescription Written	11/1/2019	
420-DK	Submission Clarification Code	(blank)	
429-DT	Special Packaging Indicator	(blank)	

Incremental Fill Claim Response			
Field	Field Name	Value	Comments
112-AN	Transaction Response Status	P	Paid
132-UH	Additional Message Information Qualifier	(blank)	
526-FQ	Additional Message Information	(blank)	
548-6F	Approved Message Code	(blank)	

Scenario 2 – Retail prescription with an incremental fill, dispensed within fill window but exceeds prescribed quantity

Conditions			
	Attribute	Value	Comments
	Drug DEA Class	Schedule II	
	Time Between Initial and Incremental Fill	30 days	
	Payer Type	All	
	Patient's Condition	Unknown	
	Patient resides in LTC Facility	No	
Prescriber / Order Information			
	Attribute	Value	Comments
	RX Written Date	11/1/2019	
	Drug DEA Class	Schedule II	
	Prescribed Quantity	60	
	Directions	One tablet by mouth twice per day	
	Days Supply	30	
	# of authorized refills	0	

Initial Fill Claim Billing			
Field	Field Name	Value	Comments
102-A2	Version Release Number	D0	
401-D1	Date of Service	11/1/2019	
384-4X	Patient Residence	1	Home
402-D2	Prescription/Service Reference Number	1234567	
403-D3	Fill Number	00	
460-ET	Quantity Prescribed	60	
442-E7	Quantity Dispensed	30	
415-DF	Number of Refills Authorized	0	
405-D5	Days Supply	15	
414-DE	Date Prescription Written	11/1/2019	
420-DK	Submission Clarification Code	(blank)	
429-DT	Special Packaging Indicator	(blank)	
Initial Fill Claim Response			
Field	Field Name	Value	Comments
112-AN	Transaction Response Status	P	Paid
132-UH	Additional Message Information Qualifier	19	19 = Remaining Quantity
526-FQ	Additional Message Information	30	CII Quantity Remaining Calculation = Qty Prescribed - Accumulated Qty Dispensed
548-6F	Approved Message Code	(blank)	

Incremental Fill Claim Billing			
Field	Field Name	Value	Comments
102-A2	Version Release Number	D0	
401-D1	Date of Service	11/16/2019	
384-4X	Patient Residence	1	
402-D2	Prescription/Service Reference Number	1234567	
403-D3	Fill Number	01	Incremental Fill
460-ET	Quantity Prescribed	60	
442-E7	Quantity Dispensed	45	
415-DF	Number of Refills Authorized	0	
405-D5	Days Supply	15	
414-DE	Date Prescription Written	11/1/2019	
420-DK	Submission Clarification Code	(blank)	
429-DT	Special Packaging Indicator	(blank)	

Incremental Fill Claim Response			
Field	Field Name	Value	Comments
112-AN	Transaction Response Status	R	Rejected
132-UH	Additional Message Information Qualifier	(blank)	
526-FQ	Additional Message Information	(blank)	
511-FB	Reject Code	649	Cumulative Quantity For This CII Rx Number Exceeds Quantity Prescribed

Scenario 3 – LTC Post-Consumption Billing prescription dispensed within prescribed quantity but occurs as a single billing transaction therefore the processor has no visibility into the time between the initial and incremental fills.

Conditions			
	Attribute	Value	Comments
	Drug DEA Class	Schedule II	
	Time Between Initial and Incremental Fill	Unknown	
	Payer Type	All	
	Patient's Condition	Unknown	LTC Post Consumption Billing
	Patient resides in LTC Facility	Yes	
Prescriber / Order Information			
	Attribute	Value	Comments
	RX Written Date	11/1/2019	
	Drug DEA Class	Schedule II	
	Prescribed Quantity	31	
	Directions	One tablet by mouth once per day	
	Days Supply	31	
	# of authorized refills	0	
Fill Claim Billing			
Field	Field Name	Value	Comments
102-A2	Version Release Number	D0	
401-D1	Date of Service	11/1/2019	Earliest date in the billing cycle
384-4X	Patient Residence	3	Nursing Facility
402-D2	Prescription/Service Reference Number	1234567	
403-D3	Fill Number	00	

Fill Claim Billing			
Field	Field Name	Value	Comments
460-ET	Quantity Prescribed	31	
442-E7	Quantity Dispensed	31	
415-DF	Number of Refills Authorized	0	
405-D5	Days Supply	31	
414-DE	Date Prescription Written	11/1/2019	
420-DK	Submission Clarification Code	(blank)	
429-DT	Special Packaging Indicator	(blank)	
Fill Claim Response			
Field	Field Name	Value	Comments
112-AN	Transaction Response Status	P	Paid
132-UH	Additional Message Information Qualifier	(blank)	
526-FQ	Additional Message Information	(blank)	
548-6F	Approved Message Code	(blank)	

Scenario 5 – LTC Short Cycle Dispensing dispensed within fill window and within prescribed quantity.

Conditions			
	Attribute	Value	Comments
	Drug DEA Class	Schedule II	
	Time Between Initial and Incremental Fill	30 days	
	Payer Type	Medicare Part D	
	Patient's Condition	Unknown	
	Patient resides in LTC Facility	Yes	
Prescriber / Order Information			
	Attribute	Value	Comments
	RX Written Date	11/1/2019	
	Drug DEA Class	Schedule II	
	Prescribed Quantity	32	
	Directions	One tablet by mouth twice per day	
	Days Supply	16	
	# of authorized refills	0	
Initial Fill Claim Billing			
Field	Field Name	Value	Comments
102-A2	Version Release Number	D0	
401-D1	Date of Service	11/1/2019	
384-4X	Patient Residence	3	Nursing Facility
402-D2	Prescription/Service Reference Number	1234567	
403-D3	Fill Number	00	
460-ET	Quantity Prescribed	32	
442-E7	Quantity Dispensed	28	

Initial Fill Claim Billing			
Field	Field Name	Value	Comments
415-DF	Number of Refills Authorized	0	
405-D5	Days Supply	14	
414-DE	Date Prescription Written	11/1/2019	
420-DK	Submission Clarification Code	34	LTC dispensing: 14 day or less
429-DT	Special Packaging Indicator	1	Not Unit Dose - Indicates the product is not being dispensed in special unit dose packaging
Initial Fill Claim Response			
Field	Field Name	Value	Comments
112-AN	Transaction Response Status	P	Paid
132-UH	Additional Message Information Qualifier	19	19 = Remaining Quantity
526-FQ	Additional Message Information	4	CII Quantity Remaining Calculation = Qty Prescribed - Accumulated Qty Dispensed
548-6F	Approved Message Code	(blank)	
Incremental Fill Claim Billing			
Field	Field Name	Value	Comments
102-A2	Version Release Number	D0	
401-D1	Date of Service	11/14/2019	
384-4X	Patient Residence	3	
402-D2	Prescription/Service Reference Number	1234567	
403-D3	Fill Number	01	Incremental Fill

Incremental Fill Claim Billing			
Field	Field Name	Value	Comments
460-ET	Quantity Prescribed	32	
442-E7	Quantity Dispensed	4	
415-DF	Number of Refills Authorized	0	
405-D5	Days Supply	2	
414-DE	Date Prescription Written	11/1/2019	
420-DK	Submission Clarification Code	25	LTC dispensing: 2 days
429-DT	Special Packaging Indicator	1	Not Unit Dose - Indicates the product is not being dispensed in special unit dose packaging

Incremental Fill Claim Response			
Field	Field Name	Value	Comments
112-AN	Transaction Response Status	P	Paid
132-UH	Additional Message Information Qualifier	(blank)	
526-FQ	Additional Message Information	(blank)	
548-6F	Approved Message Code	(blank)	

Scenario 6 – LTC Short Cycle Dispensing within fill window time frame but exceeds prescribed quantity.

Conditions			
	Attribute	Value	Comments
	Drug DEA Class	Schedule II	
	Time Between Initial and Incremental Fill	30 days	
	Payer Type	Medicare Part D	
	Patient's Condition	Unknown	
	Patient resides in LTC Facility	Yes	
Prescriber / Order Information			
	Attribute	Value	Comments
	RX Written Date	11/1/2019	
	Drug DEA Class	Schedule II	
	Prescribed Quantity	32	
	Directions	One tablet by mouth twice per day	
	Days Supply	16	
	# of authorized refills	0	
Initial Fill Claim Billing			
Field	Field Name	Value	Comments
102-A2	Version Release Number	D0	
401-D1	Date of Service	11/1/2019	
384-4X	Patient Residence	3	Nursing Facility
402-D2	Prescription/Service Reference Number	1234567	
403-D3	Fill Number	00	
460-ET	Quantity Prescribed	32	

Initial Fill Claim Billing			
Field	Field Name	Value	Comments
442-E7	Quantity Dispensed	28	
415-DF	Number of Refills Authorized	0	
405-D5	Days Supply	14	
414-DE	Date Prescription Written	11/1/2019	
420-DK	Submission Clarification Code	34	LTC dispensing: 14 day or less
429-DT	Special Packaging Indicator	1	Not Unit Dose - Indicates the product is not being dispensed in special unit dose packaging
Initial Fill Claim Response			
Field	Field Name	Value	Comments
112-AN	Transaction Response Status	P	Paid
132-UH	Additional Message Information Qualifier	19	19 = Remaining Quantity
526-FQ	Additional Message Information	4	CII Quantity Remaining Calculation = Qty Prescribed - Accumulated Qty Dispensed
548-6F	Approved Message Code	(blank)	
Incremental Fill Claim Billing			
Field	Field Name	Value	Comments
102-A2	Version Release Number	D0	
401-D1	Date of Service	11/14/2019	
384-4X	Patient Residence	3	Nursing Facility
402-D2	Prescription/Service Reference Number	1234567	

Incremental Fill Claim Billing			
Field	Field Name	Value	Comments
403-D3	Fill Number	01	Incremental Fill
460-ET	Quantity Prescribed	32	
442-E7	Quantity Dispensed	28	
415-DF	Number of Refills Authorized	0	
405-D5	Days Supply	14	
414-DE	Date Prescription Written	11/1/2019	
420-DK	Submission Clarification Code	34	LTC dispensing: 14 day or less
429-DT	Special Packaging Indicator	1	Not Unit Dose - Indicates the product is not being dispensed in special unit dose packaging

Incremental Fill Claim Response			
Field	Field Name	Value	Comments
112-AN	Transaction Response Status	R	Rejected
132-UH	Additional Message Information Qualifier	(blank)	
526-FQ	Additional Message Information	(blank)	
511-FB	Reject Code	649	Cumulative Quantity For This CII Rx Number Exceeds Quantity Prescribed

Scenario 13 – Retail prescription with an incremental fill, dispensed within fill window but missing Quantity Prescribed (460-ET)

Conditions			
	Attribute	Value	Comments
	Drug DEA Class	Schedule II	
	Time Between Initial and Incremental Fill	30 days	
	Payer Type	Medicare Part D	
	Patient's Condition	Unknown	
	Patient resides in LTC Facility	No	
Prescriber / Order Information			
	Attribute	Value	Comments
	RX Written Date	11/1/2019	
	Drug DEA Class	Schedule II	
	Prescribed Quantity	60	
	Directions	Take one tablet by mouth twice a day	
	Days Supply	30	
	# of authorized refills	0	
Initial Fill Claim Billing			
Field	Field Name	Value	Comments
102-A2	Version Release Number	D0	
401-D1	Date of Service	11/1/2019	
384-4X	Patient Residence	1	Home
402-D2	Prescription/Service Reference Number	1234567	
403-D3	Fill Number	00	
460-ET	Quantity Prescribed	(blank)	
442-E7	Quantity Dispensed	30	

Initial Fill Claim Billing			
Field	Field Name	Value	Comments
415-DF	Number of Refills Authorized	0	
405-D5	Days Supply	15	
414-DE	Date Prescription Written	11/1/2019	
420-DK	Submission Clarification Code	(blank)	
429-DT	Special Packaging Indicator	(blank)	

Initial Fill Claim Response			
Field	Field Name	Value	Comments
112-AN	Transaction Response Status	R	Rejected
132-UH	Additional Message Information Qualifier	(blank)	
526-FQ	Additional Message Information	(blank)	
511-FB	Reject Code	ET	M/I Quantity Prescribed

Scenario 14 – Retail prescription with an incremental fill, dispensed within fill window but Quantity Dispensed (442-E7) is different from Quantity Prescribed (460-ET)

Conditions			
	Attribute	Value	Comments
	Drug DEA Class	Schedule II	
	Time Between Initial and Incremental Fill	30 days	
	Payer Type	All	
	Patient's Condition	Unknown	
	Patient resides in LTC Facility	No	
Prescriber / Order Information			
	Attribute	Value	Comments
	RX Written Date	11/1/2019	
	Drug DEA Class	Schedule II	
	Prescribed Quantity	60	
	Directions	Take one tablet by mouth twice a day	
	Days Supply	30	
	# of authorized refills	0	
Initial Fill Claim Billing			
Field	Field Name	Value	Comments
102-A2	Version Release Number	D0	
401-D1	Date of Service	11/1/2019	
384-4X	Patient Residence	1	Home
402-D2	Prescription/Service Reference Number	1234567	
403-D3	Fill Number	00	
460-ET	Quantity Prescribed	60	
442-E7	Quantity Dispensed	30	

Initial Fill Claim Billing			
Field	Field Name	Value	Comments
415-DF	Number of Refills Authorized	0	
405-D5	Days Supply	15	
414-DE	Date Prescription Written	11/1/2019	
420-DK	Submission Clarification Code	(blank)	
429-DT	Special Packaging Indicator	(blank)	
Initial Fill Claim Response			
Field	Field Name	Value	Comments
112-AN	Transaction Response Status	P	Paid
132-UH	Additional Message Information Qualifier	19	19 = Remaining Quantity
526-FQ	Additional Message Information	30	CII Quantity Remaining Calculation = Qty Prescribed - Accumulated Qty Dispensed
548-6F	Approved Message Code	(blank)	
Incremental Fill Claim Billing			
Field	Field Name	Value	Comments
102-A2	Version Release Number	D0	
401-D1	Date of Service	11/16/2019	
384-4X	Patient Residence	1	
402-D2	Prescription/Service Reference Number	1234567	
403-D3	Fill Number	01	Incremental Fill
460-ET	Quantity Prescribed	30	Original Quantity Prescribed 60
442-E7	Quantity Dispensed	30	
415-DF	Number of Refills Authorized	0	

Incremental Fill Claim Billing			
Field	Field Name	Value	Comments
405-D5	Days Supply	15	
414-DE	Date Prescription Written	11/1/2019	
420-DK	Submission Clarification Code	(blank)	
429-DT	Special Packaging Indicator	(blank)	

Incremental Fill Claim Response			
Field	Field Name	Value	Comments
112-AN	Transaction Response Status	R	Rejected
132-UH	Additional Message Information Qualifier	(blank)	
526-FQ	Additional Message Information	(blank)	
511-FB	Reject Code	648	Quantity Prescribed Does Not Match Quantity Prescribed On Original CII Dispensing

Scenario 15 – Retail prescription with an incremental fill dispensed within fill window but Quantity Prescribed (460-ET) is less than Quantity Dispensed (442-E7)

Conditions			
	Attribute	Value	Comments
	Drug DEA Class	Schedule II	
	Time Between Initial and Incremental Fill	30 days	
	Payer Type	All	
	Patient's Condition	Unknown	
	Patient resides in LTC Facility	No	
Prescriber / Order Information			
	Attribute	Value	Comments
	RX Written Date	11/1/2019	
	Drug DEA Class	Schedule II	
	Prescribed Quantity	60	
	Directions	Take one tablet by mouth twice a day	
	Days Supply	30	
	# of authorized refills	0	
Initial Fill Claim Billing			
Field	Field Name	Value	Comments
102-A2	Version Release Number	D0	
401-D1	Date of Service	11/1/2019	
384-4X	Patient Residence	1	Home
402-D2	Prescription/Service Reference Number	1234567	
403-D3	Fill Number	00	
460-ET	Quantity Prescribed	30	
442-E7	Quantity Dispensed	60	

Initial Fill Claim Billing			
Field	Field Name	Value	Comments
415-DF	Number of Refills Authorized	0	
405-D5	Days Supply	15	
414-DE	Date Prescription Written	11/1/2019	
420-DK	Submission Clarification Code	(blank)	
429-DT	Special Packaging Indicator	(blank)	
Initial Fill Claim Response			
Field	Field Name	Value	Comments
112-AN	Transaction Response Status	R	Rejected
132-UH	Additional Message Information Qualifier	(blank)	
526-FQ	Additional Message Information	(blank)	
511-FB	Reject Code	ET E7	M/I Quantity Prescribed M/I Quantity Dispensed

IX. HISTORY OF CHANGES

History of changes for Quantity Prescribed can be found on the NCPDP HIPAA Information page at: https://ncpdp.org/Resources/HIPAA-Information

X. APPENDIX A: DOCUMENT REVISIONS

Version 10

- Original Publication

Version 11

- Updated opening paragraph of IV Solution
- Changed LTCF to LTC throughout document
- VII Billing Examples for Quantity Prescribed
    - Updated chart including removal of Examples 11 and 12; re-ordered remaining example numbers
    - Updated note below chart
    - Examples 15 to 17 were renumbered to be 13 to 15
    - Added Directions and Day Supply to the Prescriber/Order Information for each Scenario
    - Updated the Dates in each Scenario
    - Added a note below Scenario 3

Version 12

- Modified Disclaimer, Purpose, Identification of Problem and Solution sections following the release of the final rule
- Modified NCPDP Guidance in sub-section of the Solution section
- Added two additional reject codes to and removed a reject code from the chart in the Rejection sub-section of the Solution section
- Removed Industry Timeline section
- Added section for Processing Recommendations for Time Limits on Incremental Fills
- Added section for Proration of Copays
- Modified FAQ section
- Modified the Payer Type column in the chart in Billing Examples for Quantity Prescribed
- Removed the Regulatory References to CII Partial/Incremental Fills because content was duplicated in the Processing Recommendations for Time Limits on Incremental Fills section
- Changed CII to Schedule II

Version 12 Republication July 2020

- Updated to clarify the processing recommendation for Number of Refills Authorized (415-DF) in IV. Solution B. NCPDP Guidance 1. Claim Request

Version 13

- Modified response to question 4 in the Additional Clarifications/Frequently Asked Questions section.

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