NCPDP QUANTITY PRESCRIBED (460-ET)
IMPLEMENTATION TIMELINE GUIDANCE

VERSION 11

This paper offers guidance to the pharmacy industry in preparing for the implementation of CMS-0055-F, which requires the Quantity Prescribed (460-ET) field for all Schedule II drugs.

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National Council for Prescription Drug Programs
9240 East Raintree Drive
Scottsdale, AZ 85260

Phone: (480) 477-1000
Fax (480) 767-1042

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Version 11

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1. PURPOSE

The NCPDP Strategic National Implementation Process (SNIP) Committee developed this White Paper as guidance to the pharmacy industry to prepare for the implementation of the use of the Quantity Prescribed (460-ET) field for all Schedule II drug claims exchanged between HIPAA covered entities, as required under CMS-0055-F Quantity Prescribed final rule.

2. SCOPE

The implementation timelines put forth in this document are based on the CMS-0055-F Quantity Prescribed final rule and recommendations of the NCPDP SNIP Committee. The intent of the timeline is to provide early action and sufficient time for the industry to implement a compliant and standardized process.

It is important to note the NCPDP Telecommunication Standard vD.0, published August 2007, has not changed and is still the HIPAA-named version of the standard. While the Quantity Prescribed (460-ET) field is listed as "Not Used" within this publication, per CMS-0055-F the Quantity Prescribed field is now REQUIRED for all Schedule II drugs.

On January 24, 2020, Health and Human Services (HHS) 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 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."

3. QUANTITY PRESCRIBED (460-ET) IMPLEMENTATION TIMELINES

CMS-0055-F was published on January 24, 2020, with a March 24, 2020, effective date and September 21, 2020, compliance date. The following implementation timeline recommendations are intended to provide industry stakeholders sufficient time to coordinate system enhancements, internal and external testing and deployment that will mitigate unnecessary point-of-care rejects and system failures, while meeting the CMS-055-F compliance date.

Event	Dates
CMS-0055-F Effective Date	3/24/2020
Payer Sheet Publication Date	7/01/2020
Payer initial acceptance of Quantity Prescribed (460-ET)	Payer Determination
NCPDP Recommended Required Use of Quantity Prescribed (460-ET)	9/21/2020
CMS-0055-F Compliance Date	9/21/2020

Coordination is required between trading partners to ensure streamlined implementation of the Quantity Prescribed (460-ET) field. The following guidance outlines specific actions that should occur between PBMs/payers and pharmacies.

3/24/2020: CMS-0055-F Effective Date

- Quantity Prescribed field may be sent based on trading partner agreement
- Payer may not reject claims that do not have Quantity Prescribed (460-ET) field for Schedule II prescription claims until 9/21/2020

3/24/2020 – 9/20/2020: Testing

- External testing, validation of field acceptance and required status for Schedule II drugs

7/01/2020: Payer Sheet Publication

- Payer sheets should be updated and published by 7/01/2020, (See NCPDP Payer Sheet Template Update section)
- The Effective Date of the published Payer Sheet may be later than 7/01/2020, where the Effective Date reflects the effective date of the noted changes
- Other applicable trading partner communications or materials, such as provider notifications, should be released with the payer sheet. These notifications could include testing information or other claims processing guidance as outlined within the Recommended Use of Quantity Prescribed (460-ET) in NCPDP Telecommunication Standard Version D.0 White Paper. For example:
  - External testing procedures to allow pharmacy and payers to validate claim adjudication results for various business cases associated to the required status of the field
  - References to specific Reject Codes (511-FB)
  - References to Additional Information Message Qualifier (132-UH) and Additional Information Message (526-FQ) that would be returned for the specific Quantity Prescribed business cases

9/21/2020: CMS-0055-F Compliance Date

- Pharmacy must be able to send Quantity Prescribed (460-ET) field for Schedule II prescription claims

    - Pharmacies may submit Quantity Prescribed (460-ET) field to comply with most restrictive rules, where the drug may be a Schedule II based on state classification rather than federal classification
- Payer must require Quantity Prescribed (460-ET) field for Schedule II prescription claims
- Payer must begin rejecting claims that do not have Quantity Prescribed (460-ET) field for Schedule II prescription claims

4. NCPDP PAYER SHEET TEMPLATE UPDATES

The NCPDP Payer Sheet Template is used as guidance in filling out and creating a NCPDP Telecommunication Standard Implementation-based Version D.0 Payer Sheet, in accordance with the NCPDP Telecommunication Standard Implementation Guide vD.0 (August 2007) and CMS-0055-Final Rule published January 24, 2020.

The Quantity Prescribed (460-ET) field listed within the payer sheet template reflects the use of this field as defined under CMS-0055-F, required for all Schedule II drugs, versus the NCPDP Telecommunication Version D.0 Standard situation of "Not Used."

Payers should publish their updated payer sheets by July 1, 2020, allowing pharmacy providers time to coordinate and schedule updating claim formats prior to the September 21, 2020, compliance date. The payer sheet should include:

- Payer sheet 'Date' represents the publication date, e.g., 7/01/2020
- Payer sheet 'Effective Date' represents the date on which the changes apply
    - If the Quantity Prescribed (460-ET) field is the only change, the Effective Date would represent the date on which the field will be accepted
    - If multiple changes with different effective dates are reflected within the payer sheet, the earliest effective date should be placed in the Payer Sheet Effective Date cell and all other changes with later effective dates should be identified within the 'Payer Requirement' section of the applicable field(s).
    - For example, a single payer sheet could be published to represent the following changes with different effective dates:
        - 7/01/2020: Effective Date for new BIN/PCN 222222/XYZ, for Stay Home Save Lives Health Plan
            - 7/01/2020 is set as the Payer Sheet Effective Date
        - 8/01/2020: Effective Date when the Quantity Prescribed (460-ET) field can be transmitted
            - Payer Requirement for this field would indicate the 8/01/2020 field acceptance date
        - 9/21/2020: Effective Date when the Quantity Prescribed (460-ET) field will be required for Schedule II drug claims
            - Payer Requirement for this field would indicate the 9/21/2020 required date for Schedule II drugs
- Payer Requirement for the Quantity Prescribed (460-ET) field must include the following:
    - The date on which the payer will ACCEPT the Quantity Prescribed (460-ET) field
        - If the field is already accepted by the time the payer sheet is published, this date should reflect the Effective Date as stipulated in the General Information Section of the payer sheet or the 03/24/2020 Effective Date of the rule, whichever applies
    - The date on which the payer will REQUIRE the Quantity Prescribed (460-ET) field for Schedule II drug claims
        - This date must not be any earlier than the CMS compliance date of 9/21/2020
    - Any other information relevant to the Quantity Prescribed field

For example:

Payer Name: PBM USA	Date: Date Payer Sheet is Published 6-15-2020	
Plan Name/Group Name: Stay Home Save Lives	BIN: 222222	PCN: XYZ
Processor: Processor/Fiscal Intermediary		
Effective as of: Date the Plan will begin accepting transactions using this payer sheet 7/01/2020	NCPDP Telecommunication Standard Version/Release #: D.0	
NCPDP Data Dictionary Version Date: August 2007	NCPDP External Code List Version Date: 10/15/2019	
Contact/Information Source: Other references such as Provider Manuals, Payer phone number, web site, etc. (Recommend including Hyperlink/embed Plan Notice Document, that outlines the specific changes)		
Certification Testing Window: Certification Testing Dates		
Certification Contact Information: Certification phone number and information		
Provider Relations Help Desk Info: Phone number and information		
Other versions supported: Other versions of Telecommunication Standard Supported (if applicable) and information		

	Claim Segment Segment Identification (111-AM) = "07"			**Claim Billing/Claim Rebill**
Field #	*NCPDP Field Name*	*Value*	*Payer Usage*	*Payer Situation*
460-ET	QUANTITY PRESCRIBED		RW	***Imp Guide**** **:** Required when the transmission is for a Schedule II drug as defined in 21 CFR 1308.12 and per CMS-0055-F (Compliance Date 9/21/2020. Refer to the Version D.0 Editorial Document). *Payer Requirement: (example only)* • *Effective 08/01/2020, field can be transmitted for Schedule II drugs* • *Effective 09/21/2020, field is required for Schedule II drugs*

* Clarifications that affect the Telecommunication Standard Implementation Guide Version D.0 are cited in the *Telecommunication Version D and Above Questions, Answers and Editorial Updates*.

Also refer to the NCPDP Payer Sheet Template found on the NCPDP website.

5. FREQUENTLY ASKED QUESTIONS

1. Question: Is the Quantity Prescribed (460-ET) field only required for Medicare Part D and Medicaid Schedule II prescription claims?

   Response: The Quantity Prescribed (460-ET) field requirement is not limited to Medicare Part D and Medicaid claims. CMS-0055-F requires the Quantity Prescribed (460-ET) field on all Schedule II prescription claims exchanged between HIPAA-covered entities.

2. Question: What is the earliest date a PBM/payer can reject and require the Quantity Prescribed (460-ET) field for Schedule II drugs?

   Response: PBM/Payer must not require or reject Quantity Prescribed (460-ET) field for Schedule II prescription claims prior to 9/21/2020.

3. Question: What is the earliest date on which the pharmacy provider can submit the Quantity Prescribed (460-ET) field?

   Response: The use of the Quantity Prescribed (460-ET) field was allowed as of the 03/24/2020 effective date of CMS-0055-F. Trading partners should refer to the above Section: Quantity Prescribed Implementation Timeline recommendations to determine when the field can be supported and to adhere to the 9/21/2020 compliance date.

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

   Response: NCPDP SNIP strongly recommends for any claim that contains Quantity Prescribed (460-ET) but is not for a Schedule II drug, the field should be ignored for point-of-service claim adjudication.

5. Question: Where can I find additional NCPDP claim billing transaction guidance on the use of the Quantity Prescribed (460-ET) field for purposes of identifying Schedule II incremental fills?

   Response: Refer to the 'Recommended Use of Quantity Prescribed (460-ET) in NCPDP Telecommunication Standard Version D.0' White Paper.

6. Question: Where can I find additional guidance on how the prescriber would request within the electronic prescription message that the pharmacy dispense the Schedule II prescribed quantity in incremental fills?

   Response: Refer to the SCRIPT Implementation Recommendations document, section titled "General Recommendations for Incremental Fills."

7. Question: What happens if a PMB/Payer is rejecting claims that contain the Quantity Prescribed (460-ET) field because they are not ready to accept the field by the compliance date?

Response: The NCPDP SNIP Committee has the following suggestions when the pharmacy provider determines the claim is being rejected for the presence of Quantity Prescribed (460-ET) field for a Schedule II drug:

1. Refer to your company's internal compliance policies.
2. If no policy exists, the pharmacy provider may report the non-compliant entity through the HIPAA non-compliance process.
3. If it is a Medicare Part D processor, the pharmacy provider may also report the non-compliant entity to PartDPolicy@cms.hhs.gov.

8. Question: Could a pharmacy provider wait until they start receiving claim rejections for the Quantity Prescribed (460-ET) field and then make the system changes to send the field?

   Response: The Final Rule states all pharmacy providers must submit the Quantity Prescribed (460-ET) field for a Schedule II drug by the compliance date of September 21, 2020.

9. Question: Are there any proactive ways for pharmacy providers to identify which PBMs/Payers can accept the Quantity Prescribed (460-ET) field for a Schedule II drug prior to the compliance date?

   Response: The NCPDP SNIP Committee recommends payer sheets be available as of July 1, 2020 to communicate readiness to accept the field. If no payer sheet has been received, providers may contact PBMs/payers to coordinate the submission of the field prior to the compliance date.

6. OTHER RESOURCES

NCPDP recommends the use of the below additional resources to support standardization in the implementation of the Quantity Prescribed (460-ET) final rule CMS-0055-F, allowing for improved electronic communication processes for Schedule II drugs dispensed as incremental fills within current named standards and to prepare for applicable changes within future versions of these standards.

- CMS-0055-F
- Recommended Use of Quantity Prescribed (460-ET) in NCPDP Telecommunication Standard Version D.0
- SCRIPT Implementation Recommendations
- Web-enabled Data Dictionary
- Web-enabled External Code List
- Telecommunication Standard Implementation Guide, versions D.0 and above
- SCRIPT Standard, versions 20170701 and above

7. APPENDIX A – HISTORY OF CHANGES

7.1 VERSION 10

- Original Publication

7.2 VERSION 11

The following new FAQs were added:

- What happens if a PBM/payer is rejecting claims that contain the Quantity Prescribed (460-ET) field because they are not ready to accept the field by the compliance date?
- Could a pharmacy provider wait until they start receiving claim rejections for the Quantity Prescribed (460-ET) field and then make the system changes to send the field?
- Are there any proactive ways for pharmacy providers to identify which PBMS/payers can accept the Quantity Prescribed (460-ET) field for a Schedule II drug prior to the compliance date?