January 16, 2018

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-4182-P
P.O. Box 8013
Baltimore, MD 21244-8013

http://www.regulations.gov

RE: NCPDP Comments to CMS-4182-P Proposed Rule

The National Council for Prescription Drug Programs (NCPDP) is grateful for the opportunity to review and submit comments to CMS-4182-P: *Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program*.

NCPDP is a not-for-profit, ANSI-Accredited Standards Development Organization (SDO) consisting of more than 1,400 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies, and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system.

For over 40 years NCPDP has been committed to furthering the electronic exchange of information between healthcare stakeholders. The NCPDP Telecommunication Standard is the standard used for eligibility, claims processing, reporting, and other functions in the pharmacy services industry as named in HIPAA. The NCPDP SCRIPT Standard, Telecommunication Standard, and the Formulary and Benefit Standard are the standards in use in electronic prescribing as named in MMA.

NCPDP appreciates this opportunity to provide the following comments to the provisions and references outlined in CMS-4182-P as they relate to NCPDP standards, guidance and industry practices used to support the Medicare Part D prescription drug program.

Introduction

56338: Acronyms

NCPDP National Council of Prescription Drug Programs

NCPDP Comment:
The acronym description for NCPDP is incorrect; it is "National Council for Prescription Drug Programs."

56339: I. Executive Summary

…In addition, this rule proposes technical changes related to treatment of Part A and Part B premium adjustments and updates the Script standard used for Part D electronic prescribing…

NCPDP Comment:
All references to the NCPDP SCRIPT Standard should be capitalized (SCRIPT).

Naming of NCPDP SCRIPT Version 2017071

General Comments

- The use of the NCPDP SCRIPT Version 2017071 needs to be reconciled with other government programs requiring the use of SCRIPT Version 10.6 (such as the CMS Electronic Health Record Incentive Program Stage 3 and the 2015 Edition Health IT Certification Criteria) prior to any compliance date if CMS expects successful adoption throughout the industry. Requirements naming different versions of SCRIPT for different programs create confusion and will negatively impact industry adoption of Version 2017071 under this proposed rule.

- The pharmacy industry recommends this rule adopt the NCPDP transactions for electronic prior authorization (ePA) within SCRIPT Version 2017071. The industry acknowledges the Prior Authorization transactions named under HIPAA (ASC X12N 278) is not sufficient for ePrescribing workflows. NCPDP began work to create the NCPDP SCRIPT ePA transactions as a result of an ePrescribing pilot conducted in 2006 that evaluated the efficacy of the ASC X12N 278 and ASC X12N 275 transactions. The pilot found that ASC X12N transactions were sub-optimal for the support of prior authorizations for medications and did not offer improvements in administrative efficiency. It is clear from studies and research that the ASC X12N Prior Authorization transactions named under HIPAA are for medical benefits and is not effective for the exchange of information related to prior authorizations covered under the drug benefit.

- The National Committee on Vital and Health Statistics (NCVHS), in a letter in May of 2014, recommended to the Secretary of Health and Human Services that the prior authorization transactions found in NCPDP SCRIPT be adopted for the exchange of prior authorization information between prescribers and processors for pharmacy benefits. They also recommended the standard be named in the most appropriate regulation and at the earliest possible time.

- Currently, the NCPDP SCRIPT ePA transactions have been adopted by more than 60% of pharmacy benefit managers (https://epascorecard.covermymeds.com/). The use of these

transactions significantly reduces the approval time of prior authorizations to hours instead of days leading to speedier access to therapy for the patient and resulting in improved outcomes.

- Some benefits of adopting the NCPDP SCRIPT Version 2017071 ePA transactions include:
    - Supports the proposed measures for the 2021 Star Ratings.
    - Helps CMS achieve the intent of supporting innovative approaches to improving program quality, accessibility and improvement in the CMS customer experience.
    - Reduces the burden for all participants in the CMS Medicare Part D program.
    - Supports CMS's intent of establishing a framework and addressing the opioid epidemic in which plan sponsors may establish a drug management program for beneficiaries at risk for prescription drug abuse or misuse.
    - Reduces the burden related to printing and mailing and the number of paper documents that plans have to provide, which is a CMS initiative.

- NCPDP respectfully requests the NCPDP SCRIPT Version 2017071 ePA transactions be named in a regulation, as their use is currently part of the pharmacy industry prior authorization process. Adoption of the NCPDP ePA transactions would streamline and standardize the prior authorization process nationwide.

- NCPDP also requests CMS add medication history transactions to the list of named transactions. The use of the RxHistoryRequest and RxHistoryResponse transactions are an effective tool to help combat the opioid crisis. These transactions are named in the 2015 Edition Health Information Technology (Health IT) Certification Criteria (§ 170.315(b)(3) (Electronic prescribing)) and are used in states which allow prescribers and pharmacies to obtain data from Prescription Drug Monitoring Programs (PDMP) to assist in clinical decisions for possible overuse or misuse of controlled substances.

56438: 8. E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards

a. Legislative Background

…There is no requirement that prescribers or dispensers implement eprescribing. However, prescribers and dispensers who electronically transmit prescription and certain other information for covered drugs prescribed for Medicare Part D eligible beneficiaries, directly or through an intermediary, are required to comply with any applicable standards that are in effect.

NCPDP Comment:

NCPDP recommends this rule be inclusive of all entities that electronically exchange the SCRIPT transactions referenced and not limited to prescribers and dispensers. Including all such entities will make it more likely for the industry to meet the objectives of the MMA to improve ''(i) patient safety; (ii) the quality of care provided to patients; and (iii) efficiencies, including cost savings, in the delivery of care."

The business cases supported by NCPDP SCRIPT Version 2017071 reflect participation by multiple entities such as prescribers, dispensers, and payers who offer services throughout the continuum of

care, including long-term care. NCPDP recommends the use of these transactions be determined by the business case and the entities performing the electronic communication. This eliminates the confusion where it appears that all entities are required to support all the transactions. NCPDP recommends any references to the use of transactions be based on the situations documented within the SCRIPT standard and not reference specific types of individuals and entities.

56439: Adoption of NCPDP SCRIPT version 2017071

NCPDP Comment:
NCPDP applauds the decision to move to the NCPDP SCRIPT Version 2017071. There have been many new messages and features added to the NCPDP SCRIPT Standard that are needed by the industry, which will improve patient safety, interoperability and efficiency throughout the health care system.

Throughout the NPRM, the SCRIPT Standard transactions are inconsistently and/or incorrectly referenced, with either an incorrect name, or a single name referencing multiple transactions. NCPDP requests that in the final rule, all transactions are referenced by the name stated in the NCPDP SCRIPT Implementation Guide Version 20170701, section 4.2, as listed in the table below. Definitions for these transactions can be found in the NCPDP SCRIPT Implementation Guide Version 20170701, section 4.2.

Applicable Page # (s)	Name as published in the NPRM	Name as published in the NCPDP Standard	Additional NCPDP Comments
56439; 56440; 56513	Prescription drug administration message	DrugAdministration	
56439; 56440; 56513	New prescription requests	NewRxRequest	
56439; 56440; 56513	New prescription response denials	NewRxResponseDenied	
56439; 56440; 56513	Prescription transfer message	RxTransferRequest; RxTransferResponse; RxTransferConfirm	These are three distinct transactions and should be referenced accordingly.
56439; 56440; 56513	Prescription fill indicator change	RxFill	
56439; 56440; 56513	Prescription recertification	Recertification	
56439; 56440	Risk Evaluation and Mitigation Strategy (REMS)initiation	REMSInitiationRequest	

	request		
56439; 56440	REMS initiation response, REMS request	REMSInitiationResponse; REMSRequest	These are two distinct transactions and should be referenced accordingly.
56439; 56440; 56513	REMS response	REMSResponse	
56440; 56513	Refill/Resupply prescription request transaction	RxRenewalRequest; Resupply	These are two distinct transactions and should be referenced accordingly. RefillRequest has been renamed to RxRenewalRequest.
56440; 56513	Refill/Resupply prescription response transaction	RxRenewalResponse	There is no response for Resupply. RefillResponse has been renamed to RxRenewalResponse.
56440; 56513	Get message transaction	GetMessage	
56440; 56513	Status response transaction	Status	
56440; 56513	Error response transaction	Error	
56440	New prescription request transaction	NewRxRequest	
56440; 56513	Prescription change request transaction	RxChangeRequest	
56440; 56513	Prescription change response transaction	RxChangeResponse	
56440; 56513	Verification transaction	Verify	
56440; 56513	Password change transaction	N/A	As stated in our comments below, this transaction should be removed.
56440; 56513	Cancel prescription request transaction	CancelRx	
56440; 56513	Cancel prescription	CancelRxResponse	

	response transaction		
56440; 56513	Fill status notification	RxFill	
56513	REMS initiation request	REMSInitiationRequest	
56513	REMS initiation response	REMSInitiationResponse	
56513	REMS request	REMSRequest	
56513	New prescription transacton	NewRx	

NCPDP Comment:
NCPDP requests the following transactions be included in the named transactions as previously indicated in our comments:

- RxHistoryRequest
- RxHistoryResponse
- PAInitiationRequest
- PAInitiationResponse
- PARequest
- PAResponse
- PAAppealRequest
- PAAppealResponse
- PACancelRequest
- PACancelResponse

56440: Password change transaction

NCPDP Comment:
Although the Password Change Transaction remains in the 201707 SCRIPT Standard, its use has been replaced with alternative enhanced security authentication measures. To ensure continuation of use of these security measures, we ask that CMS remove the Password Change Transaction within the final rule.

56440: Propose to incorporate NCPDP SCRIPT version 2017071

> *… we propose to incorporate NCPDP SCRIPT version 2017071 by reference in our regulations. We seek comment regarding our proposed retirement of NCPDP SCRIPT version 10.6 on December 31, 2018 and adoption of NCPDP SCRIPT Version 2017071 on January 1, 2019 as the official Part D e-prescribing standard for the e-prescribing functions outlined in our proposed § 423.160(b)(1)(v) and (b)(2)(v), and for medication history as outlined in our proposed § 423.160(b)(4), effective January 1, 2019. We are also soliciting comments regarding the impact of these proposed effective dates on industry and other interested stakeholders.*

NCPDP Comment:

NCPDP requests a transition period be added to the implementation timeline as has been done successfully in the past. We suggest a voluntary use date of the effective date of the Final Rule and the sunset date for SCRIPT Version 10.6 is 24 months from the effective date. Having the transition period will decrease the risk of healthcare delivery delays and interruption. The transition from SCRIPT Version 8.1 to SCRIPT Version 10.6 took approximately three years and provided an opportunity for early adopters to identify any possible issues that may impact implementation and develop remediation plans. Additionally, there are many actions that must happen prior to the mandated use of SCRIPT Version 2017071. These actions by electronic prescribing/EHR vendors, pharmacy software vendors, prescribers, pharmacies, payers and intermediaries who route transactions include:

- Evaluation of changes required by the final rule, those required by the standard and those changes that could optionally be included
- Design
- Development
- Testing
  - Release
  - End user testing
- Implementation
  - Software certification
  - Auditing associated with electronic prescribing of controlled substances (EPCS)
  - Training

In addition, NCPDP recommends the regulatory compliance date for the NCPDP SCRIPT Standard Version 2017071 not occur in January. January 1 is a traditional date for plan year changes. NCPDP believes compliance with the new SCRIPT version deserves its own timeline to minimize the risk of healthcare delivery delays and interruptions associated with the normal processing and administrative changes occurring with a new plan year.

56513*: § 423.160 Standards for electronic prescribing*

(v) On or after January 1, 2019, the standards specified in paragraphs (b)(2)(iii) and (b)(3), (b)(4)(ii),

NCPDP Comment:

It is believed the highlighted reference is incorrect and would allow for the use of the NCPDP SCRIPT Version 10.6 after January 1, 2019 (presumed effective date). The reference should be (b)(2)(iv).

56513: National Council for Prescription Drug Programs SCRIPT standard, Implementation Guide Version 2017071 transactions

(iv) The National Council for Prescription Programs SCRIPT standard, Implementation Guide Version 2017071 approved July 28, 2017 (incorporated by reference in paragraph (c)(1)(i) of this section)…

NCPDP Comment:

The reference for National Council for Prescription Programs is incorrect and should be National Council for Prescription Drug Programs.

It is believed the highlighted reference is incorrect and should be (b)(1)(iv).

56514: Medication history

NCPDP Comment:
NCPDP requests CMS add the medication history transactions to the list of named transactions detailed in this rule. The use of the RxHistoryRequest and RxHistoryResponse transactions are an effective tool to help combat the opioid crisis. These transactions are named in the 2015 Edition Health Information Technology (Health IT) Certification Criteria (§ 170.315(b)(3) (Electronic prescribing)) and are used in states which allow prescribers and pharmacies to obtain data from Prescription Drug Monitoring Programs (PDMP) to assist in clinical decisions for possible overuse or misuse of controlled substances.

Proposed Modifications to Opioid Policy

NCPDP Comment:
NCPDP recommends CMS work with other federal agencies and/ or departments (i.e. FDA, DEA, ONC) to ensure consistent coordinated efforts in defining solutions to combat the opioid crisis.

56346: Exempted Beneficiary

> *Section 1860D–4(c)(5)(C)(ii) of the Act defines an exempted individual as one who receives hospice care, who is a resident of a long-term care facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy, or who the Secretary elects to treat as an exempted individual. Consistent with this, we propose that an exempted beneficiary, with respect to a drug management program, would mean an enrollee who: (1) Has elected to receive hospice care; (2) Is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents…*

NCPDP Comment:
Thank you for clarifying that the MED exemption applies to Long Term Care. NCPDP requests CMS specify if this exemption applies to all beneficiaries serviced by a Long Term Care pharmacy or if the exemption is limited to beneficiaries who live in certain types of residences.

56347: Exempted Beneficiary

> *We have not proposed to exempt these additional categories of beneficiaries but we seek specific comment on whether to do so and our rationale…*

NCPDP Comment:
NCPDP notes that plans are only able to identify exemptions either through the data provided by CMS, i.e. hospice status, or through case management, which could identify beneficiaries who are receiving palliative care.

NCPDP supports CMS in their effort to apply new policies to minimize the effects of the opioid crisis, and asks CMS to continue working with standards development organizations such as NCPDP to leverage

standards for exchanging information between healthcare partners (e.g. prescribers, pharmacies, plans) to ensure beneficiaries have appropriate and timely access to medications.

56351

We intend to develop language for the initial notice. Therefore, the proposed regulatory text states that the notice must use language approved by the Secretary.

(B) Limitation on the Special Enrollment Period for LIS Beneficiaries With an At-Risk Status (§ 423.38)

NCPDP Comment:
In order for the limitation on the special enrollment period for LIS beneficiaries to be effective as envisioned, additional work will need to be done with standards development organizations (SDOs) (i.e. NCPDP and X12) so the information is available to the stakeholders via the existing data exchange mechanisms. It is important for CMS to acknowledge the SDOs will require time to review and modify their standards to ensure the exchange of this information.

56355: (A) Special Requirement To Limit Access to Coverage of Frequently Abused Drugs to Selected Prescriber(s) (§ 423.153(f)(4))

We seek comment on whether this 6-month waiting period would reduce provider burden sufficiently to outweigh the additional case management, clinical contact and prescriber verification that providers may experience if a sponsor believes a beneficiary's access to coverage of frequently abused drugs should be limited to a selected prescriber(s). Comments should include the additional operational considerations for sponsors to implement this proposal.

NCPDP Comment:
NCPDP respectfully requests CMS verify communication to a prescriber through existing mechanisms, such as drug utilization review (DUR) messaging, is not precluded by this rule.

56357: (4) Confirmation of Pharmacy and Prescriber Selection (§ 423.153(f)(13))

NCPDP Comment:
NCPDP requests CMS be mindful of the impact to our standards of any additional messaging requirements. Standards modifications timelines are controlled both by NCPDP's *Standing Operating Procedures* and, for those standards named in other federal legislation (e.g. HIPAA), the associated rule-making process. These timelines need to be taken into consideration during rulemaking to ensure the standards include the desired functionality.

56357: (ix) Drug Management Program Appeals …

NCPDP Comment:
NCPDP requests clarification as to whether the beneficiary Notice of Appeal Rights (reject code 569) should accompany any point-of-sale (POS) claim rejections regarding prescriber or pharmacy lock-in, or any additional beneficiary-specific POS edits recommended by CMS.

56410: Proposed Change in Definition of Retail Pharmacy

Proposed definition of Mail Order and Retail Pharmacy We solicit comment on our proposed definition of mail-order pharmacy and our proposed modification to the definition of retail pharmacy …

NCPDP Comment:
NCPDP respectfully requests CMS be mindful of any changes that may require modifications of our standards such as the proposed changes in definitions. Standards modifications timelines are controlled both by NCPDP's *Standing Operating Procedures* and, for those standards named in other federal legislation (e.g. HIPAA), the associated rule-making process. These timelines need to be taken into consideration during rulemaking to ensure the standards include the desired functionality. The current NCPDP standards named under HIPAA for pharmacy claims (Telecommunication Standard Version D.0, Batch Standard Version 1.2 and the Batch Standard Medicaid Subrogation Standard Version 3.0), allow the pharmacy to indicate the appropriate pharmacy service type. This enables the plan to determine under which network (retail, LTC, mail order) the claim is processed for reimbursement.

Transitional Supply

56413: 14. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes.

NCPDP Comment:
NCPDP requests clarification if a transitional or emergency supply override can be used if a clinical complication has occurred as a result of a generic or formulary substitution.

Manufacturer Rebates

56419 Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale

NCPDP Comment:
The NCPDP Telecommunication Standard Version D.0 does not contain fields on the claim response to report pharmacy price concessions. The Ingredient Cost field is defined as "Ingredient cost of the medication dispensed"; therefore, to be in compliance with HIPAA, the field cannot contain any other pricing information.

The ASC X12N 835 Version 5010 transaction contains fields for payers to report to provider's amounts at the claim level and allows adjustments that reduce the amount paid. Price concessions can be reported on the 835 transaction with the corresponding claim level transaction codes. Some price concessions are only calculated at the pharmacy store level and therefore adjusted at the store level, not at the claim level, on the 835 transaction.

56421: c. Manufacturer Rebates to the Point of Sale

NCPDP Comment:
NCPDP requests clarification on whether or not rebates would be required to be reported to the pharmacy. NCPDP respectfully requests CMS be mindful of any changes that may require modifications of our standards such as new functionality. Standards modifications timelines are controlled both by NCPDP's *Standing Operating Procedures* and, for those standards named in other federal legislation (e.g. HIPAA), the associated rule-making process. These timelines need to be taken into consideration during rulemaking to ensure the standards include the desired functionality.

56424: d. Pharmacy Price Concessions to Point of Sale

NCPDP Comment:
NCPDP requests clarification on whether plans report price concessions to the pharmacy and how that information is reported on the PDE. NCPDP respectfully requests CMS be mindful of any changes that may require modifications of our standards such as new functionality. Standards modifications timelines are controlled both by NCPDP's *Standing Operating Procedures* and, for those standards named in other federal legislation (e.g. HIPAA), the associated rule-making process. These timelines need to be taken into consideration during rulemaking to ensure the standards include the desired functionality.

Precluded Providers

General Comments

NCPDP appreciates and agrees with CMS' revised approach in leveraging a precluded provider process to prevent fraud, waste, and abuse risks and ensure patient safety. There are several factors however, that require CMS' consideration to ensure a smooth implementation and prevent access to care risks.

From a technical perspective, NCPDP requests additional guidance on claims for dual eligible beneficiaries, the proposed comprehensive file layout, and the ability to access and download the file, sufficient file testing period, hierarchy of excluded provider files, PDE changes and beneficiary appeal rights. Timing of changes to the NCPDP standards also has to be considered, as previous code values specific to prescriber enrollment need to be sunsetted and potentially new values created.

From a rule perspective, NCPDP requests CMS consider the numerous risks associated to the proposed provisional coverage period and support an alternate approach that allows CMS to manage patient access to care concerns with the use of post-dated preclusion effective dates.

Finally, NCPDP asks CMS to consider the coordination that is necessary to ensure an effective and efficient implementation of the precluded provider process and request an effective date that is no earlier than January 1, 2020 and a minimum of 18 months after the publication of necessary technical guidance and confirmed file layouts.

56442: Effective Date

The effective date of our proposed provisions in § 423.120(c)(5) would be 60 days after the publication of a final rule. The effective date of our proposed revisions to § 423.120(c)(6) would be January 1, 2019.

NCPDP Comment:

NCPDP applauds CMS for their thoughtful consideration of previous concerns with the prescriber enrollment process and agree the alternative precluded provider process will achieve the fraud waste and abuse objectives to protect beneficiaries and reduce healthcare administrative costs without creating patient access to care risks. However, the January 1, 2019 effective date for the precluded provider provisions under 423.120 (c)(6), is an aggressive timeline that will be a significant challenge for the industry to meet due to the additional technical guidance, updates, development of potential new NCPDP code set values and sufficient testing period that are necessary to ensure an effective and efficient implementation.

NCPDP respectfully requests CMS consider the comments and recommendations outlined in the following sections that support the need for an effective date that is no earlier than January 1, 2020 and a minimum of 18 months after CMS publishes the necessary technical guidance and confirmed file layouts.

56443: Burdens and Un-intended Consequences to NPI Requirement

… seek comment on associated burdens or unintended consequences and alternative approaches.

NCPDP Comment:

NCPDP requests CMS confirm that, with the revisions to the section 423.120 (c)(5) and based on section 507 of MACRA, the 24 hour follow-up for the plan sponsor to work with the pharmacy to identify the prescriber NPI and resubmit the claim is no longer applicable.

56443: Risks to Precluded Provider Identification Process

We are also seeking comment on an alternative by which we would first identify, through PDE data, those providers who are prescribing drugs to Medicare beneficiaries…

NCPDP Comment:

NCPDP supports CMS' recommendation to leverage the PDE data as the initial data source for precluded provider analysis. Any changes to the PDE layout to support these efforts would need to be outlined in technical guidance to ensure efficient and effective data exchanges. NCPDP also requests that all technical guidance related to other authorized prescribers (OAP) be removed.

To ensure standardization of processes, clear communications to the beneficiary, and prevent risks to patient access to care, NCPDP asks CMS to consider the following precluded provider operational processes:

1. CMS clarifies the Precluded Provider criteria will be distinctly different than the OIG Excluded provider criteria. This will eliminate duplication of provider IDs across the files and allow for clear and precise messaging to the beneficiary. If a provider is on both files, the plan sponsor

would have to send two different notices to the beneficiary, but only the OIG exclusion would be communicated at point of sale, based on the hierarchy of prescriber validation rules.

2. CMS supports a consistent Operational Flow of events before the precluded provider edit occurs at point of sale.
    a. Recommended Operational Flow:
        I. CMS conducts analysis and identifies specific prescriber.
        II. CMS notifies prescriber of pending precluded status and outlines appeal process.
        III. Once appeal period has concluded, CMS notifies impacted beneficiaries.
        IV. CMS adds prescriber to precluded provider file with a future effective date, e.g. 90 days after beneficiary notification. CMS to add precluded provider end date based on reenrollment bar criteria.
            **Note: If effective dates are not sufficiently post-dated, it may create additional risks where CMS may need to support point of service override processes due to timing delays associated with monthly file updates.
    b. These steps allow CMS to manage the provisional fill period and any variances across preclusion types or beneficiary risk levels (e.g. opioids), where plan sponsors would reject claims as of the preclusion effective date. The expectation would be that all preclusion dates would be post-dated, eliminating the need to support any variances in the timing of file integration.
    c. Regardless of who notifies the beneficiary, CMS would need procedures in place to address beneficiary questions. If plan sponsors notify the beneficiary, the plan sponsor has no access to the reason for the preclusion to be able to answer beneficiary questions. Additionally, CMS notification to the beneficiary would align with the beneficiary appeal process as outlined in section (4) Appeals (pg. 56446).
    d. These recommendations will also mitigate point of service conflicts and beneficiary confusion with provisional fill rules competing with existing prescriber validation rules (e.g.: DEA, state medical boards, etc.) and transitional fill processes.
3. CMS clarifies whether the Medicare Part D precluded provider list will be shared with state Medicaid programs for inclusion into the state's Medicaid exclusion list. CMS provides additional technical guidance for dual-eligible claims that would eliminate beneficiary confusion. NCPDP recommends the precluded provider rule apply to both the Medicare and Medicaid benefits where coordination occurs between these programs under Medicare/Medicaid Plans (MMP) and Special Needs Plans (SNP).

56445: Timing of File Updates and Point of Service Edits

NCPDP Comment:

As previously noted , NCPDP recommends CMS support a consistent operational flow and timeline for each step within the precluded provider process including the initial provider notification, appeal process, beneficiary notification and adding the future effective date to the precluded provider file. This operational flow would allow files integrated into plan sponsors' claim processing systems to always leverage future effective dates, eliminating the need to define a reasonable time period for file integration. Leveraging the aforementioned operational flow also mitigates risks of a provider being removed from the precluded provider file mid-month, as the appeals process would have been completed.

In order to ensure a smooth implementation, NCPDP requests CMS' support in defining the following technical details:

1. CMS work closely with NCPDP and other industry stakeholders to define the minimum necessary attributes of the file layout.
2. Location of published file.
3. File access for all stakeholders, including plan sponsors, PBMs and pharmacy providers.
4. Availability of sufficient testing period.
5. Clarification as to whether there will be any overlap between precluded providers and the following CMS provider exclusion files:
    - LEIE (List of Excluded Individuals and Entities)
    - MED (Medical Exclusion List)
    - GSA/SAM (General Services Administration/System for Award Management)
6. CMS confirmation that the following hierarchical order of edits is appropriate:
    - LEIE
    - MED
    - GSA/SAM
    - Precluded Provider
7. CMS confirmation that updates will only be made to the file once a month and all records will be post-dated, eliminating conflicts between plan sponsor and CMS information due to a retroactive effective or termination date.

56445 – 56446: Modifications to Provisional Coverage and Time Period

…We are proposing a 90-day provisional coverage period in lieu of a 3-month drug supply/90-day time period established in existing § 423.120(c)(6), which was described on page 6 in the Technical Guidance on Implementation of the Part D Prescriber Enrollment Requirement (Technical Guidance) issued on December 29, 2015 …

NCPDP Comment:

The proposed rule places the responsibility of managing provisional coverage on the industry. NCPDP recommends CMS simplify this process by postdating the effective date of the precluded provider. Industry management of the provisional period carries the following risks and concerns:

1. Industry confusion as to whether remaining days supply would apply to the 90 day provisional coverage period, where prescriptions could require a shortened days supply or the beneficiary could obtain up to 180 days supply of a medication. For example:
    - 01/01/2020: Preclusion effective date
    - 01/02/2020: Beneficiary obtains a 90 day supply of medication
    - 01/02/2020 – 04/01/2020: Provisional Coverage period set at the beneficiary/prescriber level
    - 03/20/2020: Beneficiary requests prescription refill for a 90 day supply. It is unclear which of the following rules would apply:
        - 90 day supply is covered, as the 03/20/2020 claim date of service is within the provisional coverage period; **Or**,
        - 13 day supply is covered, as there are only 13 days remaining (03/20 – 04/01) in the provisional coverage period
2. Unique provisional coverage rules based on the drug class will create beneficiary and prescriber confusion, as well as compromise existing claim adjudication hierarchical rules.

- Placing edits on opioids contradicts CMS' proposal that the definition of a drug is no longer needed.
- The provisions as stated lack clarity on the use of a "preclusion reason" to be able to identify when a different provisional coverage period would apply.

3. It is unclear if the revised provisional coverage period applies across a beneficiary's lifetime (changing plans, changing pharmacies) as was outlined in the prescriber enrollment provisional coverage technical guidance.
4. Claims that meet both transitional fill and provisional coverage criteria will result in the beneficiary receiving two different notices.
5. It is unclear how plan sponsors would coordinate the provisional coverage period and adhere to the following as referenced on pg. 56446:
    a. *In paragraph (c)(6)(iii), we propose to state: ''A Part D plan sponsor may not submit a prescription drug event (PDE) record to CMS unless it includes on the PDE record the active and valid individual NPI of the prescriber of the drug, and the prescriber is not included on the preclusion list, defined in § 423.100, for the date of service.'' This is to help ensure that—*
    (1) the prescriber can be properly identified, and
    (2) prescribers who are on the preclusion list are not included in PDEs

As previously stated, the NCPDP recommended operational flow, which incorporates a 90-day time period managed by CMS, eliminates the need for a point of service provisional coverage period managed by the industry and the associated risks and concerns.

Additionally, to ensure consistency in beneficiary communication, prescriber communication and standard system rules, NCPDP recommends CMS require plan sponsors to treat all precluded provider claims in the same manner regardless of the drug. If the CMS preclusion warrants a discretionary effective date based on the preclusion reason, this should be managed by CMS.

56446: Timing of Appeals Process and Beneficiary Appeal Rights

We propose to revise § 498.3(b) to add a new paragraph (20) stating that a CMS determination to include a prescriber on the preclusion list constitutes an initial determination…
… we propose that if CMS or the prescriber under paragraph (n)(2) is dissatisfied with a hearing decision as described in paragraph (n)(2), CMS or the prescriber may request review by the Departmental Appeals Board (DAB) and the prescriber may seek judicial review of the DAB's decision…

NCPDP Comment:

As noted previously in the NCPDP recommended operational flow, the appeals process would occur prior to the prescriber being added to the preclusion list. This would eliminate point of service confusion if changes to the prescriber's preclusion status occur, as a result of a latent appeal process.

Additionally, we request CMS confirm that similar to the excluded provider guidance, plan sponsors will not return reject code 569 – "Provide Notice: Medicare Prescription Drug Coverage and Your Rights' on claims that reject as a result of a precluded provider.

56446: Clarification of Provisions

In § 423.100, we propose to delete the definition of ''other authorized prescriber'' and add the following:

++ Preclusion List means a CMS compiled list of prescribers who:

(1) Meet all of the following requirements:

(A) The prescriber is currently revoked from the Medicare program under § 424.535.

(B) The prescriber is currently under a reenrollment bar under § 424.535(c).

NCPDP Comment:

Section (3) of § 424.535 - Revocation of enrollment in the Medicare program indicates a felony charge as a reason for conviction. As previously stated, NCPDP recommends CMS define the Precluded Provider criteria to be distinctly different than the OIG Excluded Provider criteria to eliminate duplication of provider IDs across the files and allow for clear and precise messaging to the beneficiary.

56449

We propose to revise this requirement to state than an MA organization shall not make payment for an item or service furnished by an individual or entity that is on the preclusion list (as defined in § 422.2). We also propose to remove the language beginning with ''This requirement applies to all of the following providers and suppliers'' along with the list of applicable providers, suppliers, and FDRs…

NCPDP Comment:

NCPDP requests CMS clarify how "entities" would be identified on the Precluded Provider file and whether the individual providers providing services under that entity would also be precluded. For example, if the individual providers under the entity are also precluded, the affiliated Type 1 NPIs will also be listed on precluded provider file.

Medication Therapy Management (MTM)

56458: (2) Medication Therapy Management (MTM) (§§ 422.2430 and 423.2430)

…We propose to modify our regulations at §§ 422.2430 and 423.2430 by adding new paragraph (a)(4)(i), which specifies that all MTM programs that comply with § 423.153(d) and are offered by Part D sponsors (including MA organizations that offer MA–PD plans (described in § 422.2420(a)(2)) are QIA …

NCPDP Comment:

NCPDP encourages the adoption of the existing electronic standards for pharmacist professional services which enable support of drug management programs, including opioid management, and will assist CMS in achieving the goals outlined for MTM.

NCPDP technical standards support the ability to electronically capture and share pharmacist provided patient clinical care services using the following:

- NCPDP Specialized Implementation Guide
    - MTM Service Request and Response Transactions
    - MTM Service Documentation Transaction
    - Clinical Info Request and Response Transactions

- NCPDP/HL7 harmonized C-CDA documents
    - C-CDA Release 2.1 Clinical Notes: Pharmacist eCare Plan
    - CDA® R2 Implementation Guide: Medication Therapy Management (MTM) Templates, Release 1 (contains the Part D Takeaway Document)

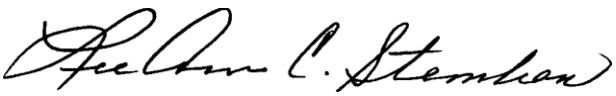
These standards are nationally recognized and have the ability to contain national standardized terminology (i.e. SNOMED CT ®, RxNorm, LOINC®, ICD, HCPCS) in support of standardized clinical quality measures. The Pharmacist eCare Plan includes a use case for sharing management of opioid therapy.

Closing Comments

NCPDP appreciates the opportunity to provide comments to CMS as they relate to NCPDP standards, guidance and industry practices used to support the Medicare Part D prescription drug program. NCPDP thanks CMS for their thoughtful consideration of our extensive comments and respectfully request CMS be mindful of the potential impact to our standards. Standards modifications timelines are controlled both by NCPDP's *Standing Operating Procedures* and, for those standards named in other federal legislation (e.g. HIPAA), the associated rule-making process. These timelines need to be taken into consideration during rulemaking to ensure the standards include the desired functionality.

NCPDP looks forward to working with CMS to ensure a smooth implementation of this rule as we work collaboratively to improve the quality of care of Medicare patients.

Sincerely,



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cc: NCPDP Board of Trustees