101 Jim Wright Freeway South, Suite 200, Fort Worth, TX 76108-2252, Phone: (817) 246-6760

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: PDX Comments to CMS-4182-P

PDX, Inc appreciates 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*.

PDX, Inc. is a technology company built on a foundation of and a commitment to Community Pharmacy. For over 30 years, we have and continue to provide innovative solutions and an integrated comprehensive suite of product and services to meet the needs of pharmacy. The partners that use our systems operate in all 50 states, the District of Columbia, Puerto Rico, US Virgin Islands, and Guam. Our system-partners include individual pharmacies and chain pharmacies with up to and in some cases more than 1,000 sites and for a total of nearly 10,000 pharmacy sites.

We respectfully ask that CMS thoughtfully review the comments on the following pages.

Should CMS have any questions related to these comments, please contact:

Leann Lewis
Director, Industry Relations
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Phone: 817-935-7454

Naming of NCPDP SCRIPT Version 2017071

General Comments

PDX concurs with NCPDP recommendations that this rule or a future rule adopt the NCPDP transactions for electronic prior authorization (ePA) within SCRIPT version 2017071.

- As a result of the an ePrescribing pilot conducted in 2006, and other studies, it was determined that the HIPAA named ACS X12N 278 is not sufficient for ePrescribing workflows and exchanging information related to prior authorizations for drug benefit. Therefore, NCPDP began work to create the NCPDP SCRIPT ePA transactions.
- Currently, the NCPDP SCRIPT ePA transactions have been adopted by more than 60% (https://epascorecard.covermymeds.com/) of pharmacy benefit managers. 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 which results in improved outcomes.

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.

PDX Comment:

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

PDX also concurs with NCPDP comments and recommends that any references to the use of transactions be based on the business cases documented within the SCRIPT standard and the entities performing the electronic communication and should not reference specific types of individuals and entities. The business cases supported by NCPDP SCRIPT Version 2017071 reflect participation by multiple entities such as prescribers, dispensers, facilities, and payers who offer services throughout the continuum of care. This clarifies a misconception that all entities are required to support all the transactions.

56439: Adoption of NCPDP SCRIPT version 2017071

PDX Comment:
PDX agrees with 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.

However, the timelines for the use of the NCPDP SCRIPT Version 2017071 need 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 ONC 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 confuses the industry as to which is the appropriate standard and will negatively impact industry adoption of Version 2017071 under this proposed rule.

56439: Adoption of NCPDP SCRIPT version 2017071

PDX Comment:
PDX echoes the comments from NCPDP that throughout the NPRM, the SCRIPT Standard transactions are incorrectly referenced, either with an incorrect name, or a single name referencing multiple transactions. PDX requests that in the final rule, all transactions are referenced by the names stated in the NCPDP SCRIPT Implementation Guide version 20170701, section 4.2, as listed in the table below. Definitions for these each of these transactions may be referenced 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 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 to 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 request	REMSInitiationRequest	
56439; 56440	REMS initiation response, REMS request	REMSInitiationResponse; REMSRequest	These are two distinct transactions and should to 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 to 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, this transaction should be removed.
56440; 56513	Cancel prescription request transaction	CancelRx	
56440; 56513	Cancel prescription response transaction	CancelRxResponse	
56440; 56513	Fill status notification	RxFill	
56513	REMS initiation request	REMSInitiationRequest	
56513	REMS initiation response	REMSInitiationResponse	
56513	REMS request	REMSRequest	
56513	New prescription transaction	NewRx	

PDX Comment:
We also request that the following ePA transactions be included in the named transactions as previously requested:

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

56440: Password change transaction

PDX Comment:
While the Password Change Transaction is available in the 201707 SCRIPT Standard, the use of this transaction has been replaced with alternative enhanced security authentication measures. To ensure

continuation of use of these documented security measures, PDX asks that CMS remove the reference to 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.*

PDX Comment:
PDX concurs with NCPDP comments which request a transition period be added to the implementation timeline as has been done successfully in the past implementation of the SCRIPT standard. We also add additional reasons as to why we believe the timelines should be extended.

PDX requests voluntary use date of the new standard as of the effective date of the Final Rule. We also request a sunset date for SCRIPT Version 10.6 be 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, PDX does not believe that items listed below can be accomplished by 01-01-2019. These actions by electronic prescribing/EHR vendors, pharmacy software vendors, prescribers, pharmacies, payers, and intermediaries who route transactions include:

- Initial gap analysis between existing and proposed standard adoption.
- Roadmap of timelines and budgeting for changes
- Detailed System Design
- Systems Development
- Quality Assurance Testing in various phases
  - Initial Testing
  - Alpha and Beta Testing
  - End User Pre-Implementation Testing
- Implementation Considerations
  - Software and standards certification with intermediaries
  - End User Procedures documentation and training
  - Software deployment schedules
- DEA Audits associated with electronic prescribing of controlled substances (EPCS) are required every two years. A short implementation period as proposed in the NPRM could require virtually every entity involved in ePrescribing to conduct a costly and time consuming out of cycle audit. Given that many states are requiring or proposing mandatory EPCS due to the nationally declared opioid crisis, it could negatively impact

the ability to use the important tool of EPCS used to combat diversion of opioid and other controlled substance prescriptions.

PDX recommends the regulatory compliance date for the NCPDP SCRIPT Standard Version 2017071 not occur between November 1 and January 31 due to the following reasons.

- January 1 is the traditional date for both Medicare Part D and other plan year changes. We believe that compliance with the new SCRIPT version deserves its own timeline. A unique timeline would minimize the risk of healthcare delivery delays and interruptions by not being coupled with the risks associated with the normal processing and administrative changes occurring with a new plan year.
- Starting mid-November and running through mid-January, many pharmacies initiate what is called "code freeze" whereby software updates are not performed on the systems to limit the possibility of disruptions to health care delivery and patient safety during the potential chaos of the first of the year plan changes.

56514: Medication history

(4) Medication history.

PDX Comment:
PDX concurs with NCPDP comments requesting CMS add medication history transactions to the list of 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 currently being used as Meaningful Use (MU) criteria and in states which allow for 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.

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

General Comments

PDX acknowledges that the use of manufacturer rebates by Plan sponsors or their PBMS, and price concessions for the pharmacies is a complicated issue. We also believe that transparency of these pricing issues between not only Plan sponsors/PBMS and CMS, but also between plans and pharmacies at point of service is critical to providing the lowest cost to Part D beneficiaries and the lowest drug spend for CMS. However, we respectfully request CMS be mindful that many of the programs implemented by the plan sponsors have adversely affected many community pharmacies and their bottom line which could ultimately impact beneficiary access to care, medication adherence, and their needed medications.

First, PDX recommends that CMS should clarify how DIR Fees reported by the Plans/PBMS to CMS to provide a clear distinction between:

- Manufacture Rebates

- Price Concessions or penalties applied to the pharmacy providers

Second, CMS should provide clear categories of reporting the different types of price concessions applied to pharmacies including but not limited to:

- "Pay to Play" fees for network participation
- Price concessions for performance metrics (e.g. medication adherence, medication synchronization, brand/generic dispensing ratios, audit results)
- Discrepancies between the target reimbursement rate in pharmacy agreements and aggregate contracted rate

Third, CMS should require a refinement or replacement of the "reasonably estimated at point of sale" to require the majority of pharmacy price concession to be reported at POS. The table below effectively demonstrates the impact of retroactive DIR fees for 3 reporting periods in 2017. It clearly shows how a pharmacy assumes a net profit on an adjudicated claim and point of service, which quickly becomes a net loss once price concessions are applied. In many cases, these fees impact pharmacy to the point of a prescription which appeared to have a net profit, becomes a net loss.

Plan / PBM	Total Claim Count	Total DIR Fees $	Average DIR Fee per claim	Total Gross Profit $ After DIR	Average Gross Profit Per Claim
Plan 1					
2.5% of Ing Cost	494,701	$1,605,310.75	$3.25	$2,113,336.76	$4.27
Plan 2					
5.5% of Ing Cost	235	$584.95	$2.49	$280.61	$1.19
Plan 3					
11% Ing Cost 34+DS	23,209	$199,265.56	$8.59	($129,573.50)	($5.58)
9% Ing Cost-1-33DS	83,120	$608,723.70	$7.32	($172,342.56)	($2.07)
Plan 4					
$9.25 per claim	17,138	$158,526.50	$9.25	$192,782.01	$11.25
Plan 5					
$5.00 per claim	315,559	$1,577,795.00	$5.00	$5,399,198.63	$17.11
Plan 6					
3% off Ing Cost	6,833	$18,522.93	$2.71	$173,117.82	$25.34
Plan 7					
$6.75/claim	15,727	$106,157.25	$6.75	$20,980.76	$1.33
Plan 8					
$5.50 per claim	27,254	$149,897.00	$5.50	($44,239.99)	($1.62)
Grand Total	**983,776**	**$4,424,783.64**	**$4.50**	**$7,553,540.54**	**$7.68**

56419

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

PDX Comment:
Manufacturers Rebates which are applied per claim and reimbursed to the plan should theoretically have limited if any negative effect on pharmacy reimbursement. Manufacturer Rebates do not impact the price the pharmacy pays for the drug from their supplier. If reported as part of negotiated price at time of adjudication in the response, it could negatively impact pharmacy reimbursement. However, it should be reported per claim to CMS in the PDE and not at end of year DIR reporting.

56426 (1) All Pharmacy Price Concessions

PDX suggests that CMS develop guidance to ensure that ideally, all pharmacy price concessions be reported at point of service. However, this goal may be unrealistic given proposed CMS proposed guidance for "reasonably determined" at point of sale. As cited by NCPA FAQ document (http://www.ncpa.co/pdf/faq-direct-indirect-remuneration-fees.pdf), plans have been reluctant for full transparency, as well "some Plans/PBMs may intentionally structure their programs for 2016 to make it more difficult for their DIRs to be "reasonably determined" at the point of sale in anticipation of the pending CMS guidance" . An example might be some of the "Pay for Play" fees associated with network participation.

56427 (2) Lowest Possible Reimbursement

It is stated by CMS in the NPRM, "that pharmacies rarely receive an incentive payment above the original reimbursement rate for a covered claim. We gather that performance under most arrangements dictates only the magnitude of the amount by which the original reimbursement is reduced, and most pharmacies do not achieve performance scores high enough to qualify for a substantial, if any, reduction in penalties". However, we believe change to Lowest Possible Reimbursement Rate for all pharmacies would negatively impact medium to high performing pharmacies and have limited impact to beneficiary out of pocket expenses. PDX suggests a compromise to where pharmacies are reimbursed based on calculated rates based on previous performance, perhaps the last 1-2 reporting periods.

In terms of the cost to the beneficiary, we agree that is there is" a risk that pricing differential could potentially create a perverse incentive for beneficiaries to choose a lower performing pharmacy for the advantage of a lower price." To mitigate this risk, we recommend that CMS consider alternative coinsurance/copay models, particularly coinsurance models, whereby, coinsurance is not entirely tied to pharmacy reimbursement (e.g. 20% of pharmacy reimbursement), but also include manufacturer rebates received by the plans.

Closing comments

Additionally, PDX respectfully requests that CMS review the appropriateness of the varied performance metrics applied by the plans to pharmacies. An example of one of these metrics is as brand/generic ratio thresholds which are unrealistic for pharmacies to meet especially if brand drugs which are required as DAW (dispense as written) by the prescriber, or for beneficiaries who have gone through step therapy to obtain brand name drugs, are not excluded from the calculations and count against the pharmacies performance. Another example would be in patient adherence metrics which can be

optimized by medication synchronization or other services offered by pharmacies. If declined by the beneficiary due to a beneficiary's inability to pay all copays on the same day of the month or other reasons, this should not count against a pharmacy willing to provide those services.

As stated in the NPRM, there have been comments from the plans/PBMS to as to the complexity in increasing transparency in pricing, DIR fees, and price concessions. Additionally, numerous articles and press releases by many of the plan sponsors or their PBMS cite the difficulties in doing so. We suggest that a definitive statement from CMS that this transparency is critical at point of sale. This benefits not only the beneficiary, but also the pharmacy industry and CMS in general. However, CMS must be mindful that any changes would require changes to standards that would require an adequate period to implement. The standards can be adapted, but given the reluctance by the plans/PBMS, we believe it will require a directive from CMS to force movement in this direction.

Proposed Modifications to Opioid Policy

PDX Comment:
PDX concurs with NCPDP recommendations that CMS work with other federal agencies and/ or departments (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*

PDX Comment:
PDX thanks CMS for clarifying that the MED exemption applies to Long Term Care. PDX 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

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

PDX Comment:
PDX 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.

PDX supports CMS in their effort to apply new policies to minimize the effects of the opioid crisis, and we ask CMS to continue working with standards development organizations such as NCPDP, review legislation and regulation in various states, to leverage and make consistent 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)

PDX Comment:
PDX concurs with NCPDP that there is concern that for this to be effective as envisioned, work needs to be done with standards development organizations (SDOs) (i.e. NCPDP and X12) so that the information is available to the stakeholders via the existing data exchange mechanisms. It is important for CMS to acknowledge the SDOs will need time to review and modify their standards to ensure the exchange of this information. In addition, once new standards are approved, systems developers and users will need time to plan and implement changes as outlined in the comments on the adoption of the new NCPDP SCRIPT standard.

56351

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.

PDX Comment:
PDX respectfully requests CMS verify that 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))

PDX Comment:
Again, PDX echoes NCPDP comments requesting CMS be mindful of the impact to our standards of any additional messaging requirements as well as impact to systems developers and pharmacy users. 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 that the standards include the desired functionality.

Additionally, PDX requests that CMS be mindful of the beneficiary's preference for prescriber and pharmacy preference with dealing with lock-in situations. In many cases, the familiar community pharmacy or prescriber can be critical in managing potential issues where by an unknown mail order of

PBM owned pharmacy may not have the desired relationship to the beneficiary to resolve the issues related to case management.

56357: (ix) Drug Management Program Appeals …

PDX Comment:
PDX echoes NCPDP's request for clarification as to whether the beneficiary Notice of Appeal Rights (reject 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.

56486 12. Any willing pharmacy

PDX Comment:
PDX agrees with CMS in that the changes to this policy would "help maintain beneficiary access to specialty drugs from community pharmacy".

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

PDX Comment:
PDX agrees with CMS that revising the definition of Retail pharmacy and adding a definition of Mail-Order Pharmacy would help to mitigate plan sponsors and PBMS ability to limit a pharmacy's participation in a network based on ambiguity in the present rule definitions.

Precluded Providers

General Comments

PDX concurs with many of the NCPDP comments 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.

PDX concurs with NCPDP's general comments related to the new approach of a Precluded Provider list. This new approach would enable payers to properly prepare for implementation of point of service edits when adjudicating claims to minimize service disruption and affect patient adherence and patient care. These items include requests for clarification and other considerations as listed below:

- A request for additional guidance on claims for dual eligible beneficiaries
- Comprehensive file layout, and ability to access and download the file
- Sufficient file testing period, hierarchy of excluded provider files,

- Timing of changes to the NCPDP standards also must be considered, as previous code values specific to prescriber enrollment need to be sunsetted and new values may need to be created and well as time required for systems developers and pharmacy end users to implement.
- From a rule perspective, PDX 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.
- The request that 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.

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

1. CMS clarifies that 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 to clarify 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. PDX recommends that 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

PDX Comment:
As previously noted, PDX concurs with NCPDP recommendations that 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. Retroactive placement on the precluded provider list could potentially causing plan recoupments from the pharmacies for which pharmacies have no recourse.

In order to ensure a smooth implementation, PDX echoes NCPDP's request for CMS' support in defining the following technical details:

1. We recommend 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 …
We seek specific comment on the modifications we are proposing as to the provisional coverage and time period.

PDX Comment:
The proposed rule places the responsibility of managing provisional coverage on the industry, and specifically timing considerations that could result in the pharmacy becoming the messenger to the patient that the patient's prescriber is no longer a valid prescriber. Point of Sale is not the appropriate time for a patient to discover that their prescriber is no longer value. That communication should come from either CMS or the plan sponsor long before an edit is applied at point of sale to reject a claim to provide beneficiary access and adherence to needed medications. PDX believes that CMS can 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 day's supply would apply to the 90 day provisional coverage period, where prescriptions could require a shortened day's supply, or the beneficiary could obtain up to 180 day's 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 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's 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 PDX endorses the NCPDP recommended Operational Flow, which incorporates a 90-day time period managed by CMS. This eliminates the need for a point of

service provisional coverage period managed by the industry and the associated risks and concerns. It would also minimize the possibility of a patient showing up at the pharmacy to claim their medications would be unable to obtain their needed medication due to a failure of the plan sponsor or CMS to effectively communicate the precluded provider status.

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…

PDX 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 to 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, thereby eliminating the need for the pharmacy to provide the notice 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…

PDX Comment:
PDX 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 <u>all MTM programs that comply with § 423.153(d)</u> and are <u>offered by Part D sponsors</u> (including MA organizations that offer MA–PD plans (described in § 422.2420(a)(2)) <u>are QIA</u> …

PDX Comment:

PDX encourages the adoption of the existing electronic standards for pharmacist professional services which enable support of drug management programs, including opioid management, and adherence programs to accomplish the goals outlined for MTM. However, PDX is also concerned that plan sponsors might impose requirements on pharmacies to perform such services. We also encourage that CMS consider pharmacist and pharmacy payment for such services instead of plan sponsors penalizing pharmacies with retroactive DIR or price concessions for failing to provide such services like medication synchronization and other programs which increase adherence and patient outcomes. For example, a patient's inability to utilize medication synchronization services due to an inability to pay all patient copays at the same day of the month, should not negatively impact a pharmacy's bottom line when the pharmacy is willing to perform services which are declined by the patient.

Closing Comments

Conclusion:

PDX appreciates the opportunity to provide comments to CMS as they relate to standards, guidance and industry practices and implementation used to support the Medicare Part D prescription drug program. We thank CMS for their careful consideration of our comments and respectfully request CMS be mindful of the potential impact to the industry. Many factors and coordination of efforts are involved in successful implementation of programs and regulation including the HIPAA rule making process, standard developments, software development life cycle, and deployment processes. These timelines need to be taken into consideration during rulemaking to ensure that sufficient time it allowed for success.