

DST PHARMACY SOLUTIONS, INC. RESPONSE TO CMS PROPOSED RULE – CMS-4182-P

January 15, 2018

Pharmacy Solutions respectfully submits the following comments and clarifying questions related to CMS proposed legislation, CMS-4182-P.

1. Preclusion List – Part D Provisions

The proposed rule requires the prescription drug plan (PDP) sponsor to reject a pharmacy claim for Part D drugs prescribed by an individual on the preclusion list.

Preclusion List – Part D Provisions (§ 423.120)
CMS Proposed Revision
<p>The effective date of CMS' proposed provisions in § 423.120(c)(5) would be 60 days after the publication of a final rule. The effective date of CMS' proposed revisions to § 423.120(c)(6) would be January 1, 2019.</p> <p>CMS proposes to revise § 423.120(c)(6), as further specified in this proposed rule, to require that a Part D plan sponsor must reject, or must require its PBM to reject, a pharmacy claim (or deny a beneficiary request for reimbursement) for a Part D drug prescribed by an individual on the preclusion list. The preclusion list would be updated on a monthly basis.</p>
Pharmacy Solutions' Comment
<p>Pharmacy Solutions disagrees with the proposed effective date of January 1, 2019. Based on the proposed rule changes, additional Reject Codes and possible Submission Clarification Codes (SCCs) will need to be implemented by the National Council for Prescription Drug Programs (NCPDP). There will not be sufficient time for NCPDP to implement new codes by January 1 2019, after CMS issues the final regulation. We also disagree with the proposed effective date due to the many questions regarding how the proposed rules are to be administered. We recommend an effective date no earlier than January 1, 2020 and a minimum of 18 months after CMS publishes the necessary technical guidance and confirmed file layouts. Pharmacy Solutions also requests that CMS adopt the precluded provider operational process outlined by NCPDP in order to have a consistent industry approach.</p> <p>We have the following questions for CMS:</p> <ul style="list-style-type: none"> • The preclusion list is proposed to be updated monthly. If a prescriber appeals being on the preclusion list, will it require a month for the prescriber to be removed from the list? • Do processors continue to deny claims if provisional fills have been granted? • Will the preclusion list be published on a public site or a restricted site that only plan sponsors can access (e.g., CMS MED files)? • Will the preclusion file include termination dates as well as effective reinstatement dates, or will the prescriber be removed from the file upon reinstatement
CMS Proposed Revision
<p>Part D claim rejections by Part D sponsors and their PBMs under § 423.120(c)(6) would only apply to claims for Part D prescriptions filled or refilled on or after the date he or she was added to the preclusion list.</p>

Pharmacy Solutions' Comment
<p>We have the following questions for CMS:</p> <ul style="list-style-type: none"> • How will this affect a dual-eligible or Medicare-Medicaid Program (MMP)? • Can the drug be covered under Medicaid, or will the rule apply to both lines of business?
CMS Proposed Revision
<p>Provisional Coverage</p> <p>CMS proposes to maintain the provisional coverage requirement consistent with what was finalized in the IFC, but with a modification.</p> <p>Proposing a 90-day provisional coverage period in lieu of a 3-month drug supply/90-day time period.</p> <p>Under CMS' proposal, however, a beneficiary would have one 90-day provisional coverage period with respect to an individual on the preclusion list.</p> <p>Accordingly, a sponsor/PBM would track one 90- day time period from the date the first drug is dispensed to the beneficiary pursuant to a prescription written by the individual on the preclusion list. This dispensing event would trigger a written notice and a 90-day time period for the beneficiary to fill any prescriptions from that particular precluded prescriber and to find another prescriber during that 90-day time period.</p> <p>With respect to beneficiaries who would also be entitled to a transition, CMS is not proposing any change to the current policy.</p>
Pharmacy Solutions' Comment
<p>We have the following questions for CMS:</p> <ul style="list-style-type: none"> • A beneficiary fills a prescription on January 1, starting the 90-day provisional period. On March 15, may the beneficiary obtain a refill or a new fill from the same prescriber for a 90-day supply? • Would a beneficiary only receive drug quantities to extend through March 31, the end of the proposed 90-day provisional coverage period? • Is a letter for provisional coverage only required with the first drug fill and not the first fill of each different drug?
CMS Proposed Revision
<p>In paragraph (c)(6)(i), CMS proposes to state: "Except as provided in paragraph (c)(6)(iv) of this section, a Part D sponsor must reject, or must require its PBM to reject, a pharmacy claim for a Part D drug if the individual who prescribed the drug is included on the preclusion list, defined in § 423.100."</p>
Pharmacy Solutions' Comment
<p>We have the following questions for CMS:</p> <ul style="list-style-type: none"> • What is the hierarchical order of processing: Office of the Inspector General (OIG), Office of Personnel Management (OPM), Preclusion list? • Is it possible that a prescriber could be on more than one list and thereby create overlap between precluded providers and the CMS provider exclusion file? • We recommend that CMS define the technical details outlined by NCPDP and allow an implementation timeline with a minimum of 18 months after CMS publishes the necessary technical guidance and confirmed file layouts.

CMS Proposed Revision
In paragraph (c)(6)(iii), CMS proposes 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."
Pharmacy Solutions' Comment
<p>We have the following questions for CMS:</p> <ul style="list-style-type: none"> • Does the type of fill and prescriber type still need to be included in the PDE as outlined previously? • For PDE editing, will CMS use the creation date of the preclusion file or will it be based on the active preclusion file when the PDE is processed?
CMS Proposed Revision
<p>In paragraph (c)(6)(iv), CMS proposes to address the provisional coverage period and notice provisions as follows:</p> <p>"(iv)(A) A Part D sponsor or its PBM must not reject a pharmacy claim for a Part D drug under paragraph (c)(6)(i) of this section or deny a request for reimbursement under paragraph (c)(6)(ii) of this section unless the sponsor has provided the provisional coverage of the drug and written notice to the beneficiary required by paragraph (c)(6)(iv)(B) of this section.</p> <p>(B) Upon receipt of a pharmacy claim or beneficiary request for reimbursement for a Part D drug that a Part D sponsor would otherwise be required to reject or deny in accordance with paragraphs (c)(6)(i) or (ii) of this section, a Part D sponsor or its PBM must do the following:</p> <p>(1) Provide the beneficiary with the following, subject to all other Part D rules and plan coverage requirements:</p> <p>(i) A 90-day provisional supply coverage period during which the sponsor must cover all drugs dispensed to the beneficiary pursuant to prescriptions written by the individual on the preclusion list. The provisional supply period begins on the date-of-service the first drug is dispensed pursuant to a prescription written by the individual on the preclusion list.</p> <p>(ii) Written notice within 3 business days after adjudication of the first claim or request for the drug in a form and manner specified by CMS.</p> <p>(2) Ensure that reasonable efforts are made to notify the prescriber of a beneficiary who was sent a notice under paragraph (c)(6)(iv)(B)(1)(ii) of this section."</p>
Pharmacy Solutions' Comment
<p>We have the following question for CMS:</p> <p>For claims submitted after the provisional coverage period, would these claims receive NCPDP Reject Code 569 (Provide Notice: Medicare Prescription Drug Coverage and Your Rights) or Reject Code 829 (Pharmacy Must Notify Beneficiary: Claim Not Covered Due To Failure To Meet Medicare Part D Active, Valid Prescriber NPI Requirements)?</p>

2. Compliance Program Training Requirements

The proposed rule modifies training and education requirements by removing first tier, downstream, and related entities (FDRs) from the scope of Medicare Advantage Organizations (MAOs) and PDP sponsors' obligations.

Reducing the Burden of the Compliance Program Training Requirements (§§ 422.503 and 423.504)
CMS Proposed Revision
<p>CMS proposes to delete the provisions from the Part C and Part D regulations that require use of the CMS-developed training.</p> <p>CMS is proposing to delete not just the regulatory provision requiring acceptance of CMS' training as meeting the compliance training requirements, but also the reference to FDRs in the compliance training requirements codified at §§ 422.503(b)(4)(vi)(C) and 423.504(b)(4)(vi)(C). Specifically, CMS proposes to remove the phrases in paragraphs (C)(1) and (C)(2) that refer to first tier, downstream and related entities and remove the paragraphs specific to FDR training at §§ 422.503(b)(4)(vi)(C)(2) and (3) and 423.504(b)(4)(vi)(C)(3) and (4).</p>
Pharmacy Solutions' Comment
<p>We support CMS' proposed removal of the phrases in paragraphs (C)(1) and (C)(2) that refer to first tier, downstream and related entities; removal of the paragraphs specific to FDR training at §§422.503(b)(4)(vi)(C)(2) and (3) and 423.504(b)(4)(vi)(C)(3) and (4).; and, the proposed technical revisions to restructure §422.503(b)(4)(vi)(C)(1) into two paragraphs.</p> <p>In order to ensure consistency in Compliance Program Training, we ask CMS to confirm that any revisions to the proposed language will be reflected in Chapter 9 of the Medicare Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual.</p>

3. Any Willing Pharmacy Standards

The proposed rule is aimed at strengthening the Part D Any Willing Pharmacy requirements. Several proposals clarify the requirement that the Part D plan sponsor permit participation in its plan of "any willing pharmacy" that meets the standard terms and conditions.

Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types (§§ 423.100, 423.505)
CMS Proposed Revision
<p><u>Revised the Definition of Retail Pharmacy:</u></p> <p>CMS proposes to incorporate the concepts of being open to the walk-in general public and retail cost-sharing such that the definition of retail pharmacy would mean "any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy."</p> <p><u>Added a Definition of Mail-Order Pharmacy:</u></p> <p>Defined at §423.100 as a licensed pharmacy that dispenses and delivers extended days' supplies of covered Part D drugs via common carrier at mail-order cost sharing.</p>

Pharmacy Solutions' Comment
<p>We agree with the proposed revision to the definition of retail pharmacy and to the new definition of mail-order pharmacy.</p> <p>The proposed definitions should be objective to allow pharmacy audits by PBMs. For example, if a pharmacy exceeds thresholds that are used to define retail vs. mail-order, the thresholds are objective to be auditable.</p> <p>We suggest the final rule include comment that the revised definition is for the pharmacy's primary mode of operation. Best practice would have pharmacies use a unique NPI/NCPDP ID for each designation. However, we ask CMS to recognize that a pharmacy may operate as multiple types (e.g., retail and home infusion). The current NCPDP Telecommunication standard named under HIPAA for pharmacy claim submission allows the pharmacy to indicate the appropriate pharmacy service type at a claim level. This enables the plan to determine under which network the claim is processed for reimbursement and allows pharmacies to be held accountable at a claim level to the threshold associated with that designation.</p>
CMS Proposed Revision
<p><u>Treatment of Accreditation and Other Similar Any Willing Pharmacy Requirements in Standard Terms and Conditions:</u></p> <p>CMS does not support the use of Part D plan sponsor- or PBM-specific credentialing criteria, in lieu of, or in addition to, accreditation by recognized accrediting organizations, apart from drug-specific limited dispensing criteria such as FDA-mandated REMS or to ensure the appropriate dispensing of Part D drugs that require extraordinary special handling, provider coordination, or patient education when such extraordinary requirements cannot be met by a network pharmacy.</p>
Pharmacy Solutions' Comment
<p>CMS' proposed position would require communication of standard credentialing criteria to be provided to plan sponsors and PBMs. Additional accreditation that supports access needs (e.g., plans that operate in areas with high multiple language requirements or plans with high volume of disabled patients requiring special access support) should be allowed as well.</p>
CMS Proposed Revision
<p><u>Timing of Contracting Requirements:</u></p> <p>CMS proposes to require at § 423.505(b)(18)(i) that Part D plan sponsors have standard terms and conditions readily available for requesting pharmacies no later than September 15 of each year for the succeeding benefit year.</p> <p>CMS proposes to require at § 423.505(b)(18)(ii) that, after that date and throughout the following plan year, Part D plan sponsors must provide the applicable standard terms and conditions document to a requesting pharmacy within two business days of receipt of the request.</p>
Pharmacy Solutions' Comment
<p>We agree the proposed turnaround time for providing standard terms to a requesting pharmacy is reasonable. However, we recommend the proposed annual timing for availability of contract requirements be no later than 30 days prior to the start of the succeeding benefit year.</p> <p>We also recommend that the turnaround time be dependent on the requesting pharmacy providing valid contact information and that the start of the turnaround time period would begin when the plan sponsor has obtained the valid delivery information (e.g., email, fax number, mailing address) from the requesting pharmacy.</p>

4. Manufacturer Rebates & Pharmacy Price Concessions at POS

CMS is soliciting comments on how CMS might most effectively require Part D sponsors to pass through a share of manufacturer rebates at the point of sale and the potential effect of this type of requirement (e.g., a rule that Part D plan sponsors must include a specified minimum percentage of rebates in the negotiated price).

Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale
CMS Proposed Revision
<p>CMS is considering requiring, through future rulemaking, Part D sponsors to include in the negotiated price reported to CMS for a covered Part D drug a specified minimum percentage of the cost-weighted average of rebates provided by drug manufacturers for covered Part D drugs in the same therapeutic category or class. CMS will refer to the rebate amount that CMS would require be included in the negotiated price for a covered Part D drug as the “point-of-sale rebate.” Under such a policy, sponsors could apply as DIR at the end of the coverage year only those manufacturer rebates received in excess of the total point-of-sale rebates. In the unlikely event that total manufacturer rebate dollars received for a drug are less than the total point-of-sale rebates, the difference would be reported at the end of the coverage year as negative DIR.</p>
Pharmacy Solutions’ Comment
<p>CMS’ proposed rule requires that a percentage of rebates and all pharmacy price concessions be applied in real time at point of sale (POS). Rebates (market share influenced) and performance-based pharmacy price concessions require no less than a full year of experience to calculate the actual reimbursement as full reconciliation of rebates submitted to those received typically lag beyond the date of submission to the manufacturer. Plans will need to “project” what they expect these performance based amounts to be and allocate them at a claim level at POS. Sharing rebates and pharmacy arrangements with the beneficiary at POS, as indicated by CMS, would drive up premium for all beneficiaries and other program costs.</p> <p>Also, the plan will need to assume the risk in offering the rebate and pharmacy price concession at POS as these amounts are not available to plans until reconciliation, which takes place many months after the POS event. The projected performance based concessions for both rebates and pharmacy arrangements will have to be reflected in the bid. Should the plan not project the costs for rebates or pharmacy concessions correctly the bid amount could be affected. Even small errors in bid amounts could make a plan less marketable to the Part D population. Loss of market share and cost uncertainty could cause plan withdrawals similar to experiences in the Affordable Care Act (ACA) market. In addition, any failure to correctly identify the rebates and pharmacy price concessions at POS, or change in market or contract conditions that affect projected amounts, could result in the use of incorrect or inaccurate POS amounts which could then have a potentially significant effect on beneficiaries and their cost-sharing, out-of-pocket, and phase of coverage.</p> <p>This proposed arrangement may create disincentives for plans to offer new or extended value-based arrangements because of possible risk reallocations. New arrangements will have no claim experience from which to base a projection and errors in projecting the value of such program through POS and the plans bid could result in membership issues, including a real loss of membership. Plans may be discouraged from continuing or expanding their value based arrangements because of the uncertainty of savings which seems contrary to CMS’s direction of moving plan reimbursement from a “fee for services” to “pay for performance” model. Attempts to implement innovative and new programs with potential benefits to member health and member and government costs may be stymied because the anticipated, yet unproven benefits of such a program would need to be calculated and applied up front, rather than after performance and success are established. As a result, plans would be at risk for the full failure of such</p>

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programs and efforts, rather than having the opportunity to put arrangements in place to prove and establish their value.

Finally, while an allocation at POS may appear on the surface as a straightforward process, this would require substantive changes throughout the industry to business practices and systems. Many, if not most, (claims) processing and financial systems do not currently handle such (whether manufacturer, pharmacy, processor, etc.) and the complexity and cost of doing so would be substantial.

Outside of the potential plan effects, there are also technical challenges to implementing this at POS. The HIPAA-mandated transaction standard for pharmacy claim submission, the NCPDP Telecommunication standard D.0, does not contain fields on the claim response to report pharmacy price concessions.

The X12 835 5010 transaction, the HIPAA-mandated transaction for communicating pharmacy remittance, contains fields to report amounts back 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 adjustment reason 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. Modifications to the NCPDP Telecommunication standard and the X12 835 may be needed to ensure the exchange of rebate and price concessions at POS. As both the NCPDP Telecommunication standard and the X12 835 standard are HIPAA-named transactions, the process and timelines for implementing changes to those standards will prohibit timely implementation of a POS solution for returning rebate and pharmacy price concessions.

5. Comprehensive Addiction and Recovery Act (CARA)

The proposed rule aims at establishing additional methods that Part D plans can use to reduce abuse or misuse of frequently abused drugs.

Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions Confirmation of Pharmacy and Prescriber Selection (§ 423.153(f)(13))

CMS Proposed Revision

Section 1860D-4(c)(5)(D)(v) of the Act requires that, before selecting a prescriber or pharmacy, a Part D plan sponsor must notify the prescriber and/or pharmacy that the at-risk beneficiary has been identified for inclusion in the drug management program which will limit the beneficiary's access to coverage of frequently abused drugs to selected pharmacy(ies) and/or prescriber(s) and that the prescriber and/or pharmacy has been selected as a designated prescriber and/or pharmacy for the at-risk beneficiary.

CMS proposes that plan sponsors can obtain a network provider's confirmation in advance by including a provision in the network agreement specifying that the provider agrees to serve as at-risk beneficiaries' selected prescriber or pharmacy, as applicable. In these cases, the network provider would agree to forgo providing specific confirmation if selected under a drug management program to serve an at-risk beneficiary. However, the contract between the sponsor and the network provider would need to specify how the sponsor will notify the provider of its selection. Absent a provision in the network contract, however, the sponsor would be required to receive confirmation from the prescriber(s) and/or pharmacy(ies) that the selection is accepted before conveying this information to the at-risk beneficiary.

Pharmacy Solutions' Comment

We recommend CMS propose minimum requirements that pharmacies must meet to participate in drug management programs for at-risk beneficiaries.