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Sent: Monday, March 04, 2019 3:38 PM
To: Elise Balden <ebalden@ncdpd.org>
Cc: Cimmino, Michael A. (CMS/CPI) <Michael.Cimmino@cms.hhs.gov>; Annadata, Vani (CMS/CPI) <Vani.Annadata@cms.hhs.gov>
Subject: RE: Preclusion List Requirements Frequently Asked Questions (FAQs) Clarification Request

Hi Elise,

Please see our responses below. We will be revising our FAQs on CMS.gov to incorporate these responses. Thank you

Alisha Sanders

Sent: Wednesday, February 6, 2019 6:35 PM
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Subject: Preclusion List Requirements Frequently Asked Questions (FAQs) Clarification Request
Importance: High

Good Afternoon,

During the recent NCPDP Definition of a Valid Prescriber Task Group Call, a reference was made to the January 24, 2019 call between CMS CPI representatives and several plan sponsors/PBMs. One of the topics of concern was the need for additional clarification as to when the Precluded Provider edits apply to MA plans or claims for Part B covered products. Since the NCPDP Task Group had similar questions that were forwarded to CMS on December 22, 2018, we wanted to take this opportunity to resend that detail so that you had written context to reference. NCPDP appreciates CMS' assistance in supporting the industry with additional guidance in these areas.

FAQ:

33. Are Part C/D plans required to reject claims from pharmacies since pharmacies won't be on the Preclusion List?

Pharmacies will appear on the Preclusion List if they meet the following criteria:

- Is currently revoked from Medicare, are under an active reenrollment bar, and CMS has determined that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program, or
- Have engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the

underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare Program.

The current regulation does not address entities that prescribe or dispense, only individuals. Therefore, **Part D plans should not reject claims if the prescribing or dispensing pharmacy is included on the Preclusion List and has not yet been removed from the plan's network.** This issue will be addressed in future rulemaking. **Part C plans should deny payment if the pharmacy is included on the Preclusion List.**

Clarification Point Needed:

As there is some crossover between Part D and Part C plans (i.e., MAPD and MA plans), how is CMS defining Part C plans as it relates to denying payment to pharmacies on the Preclusion List? For example, if the dispensing pharmacy is on the Preclusion list:

- Should prescription claims submitted to a Part C MAPD or MA plan reject regardless of the product billed?
- Should prescription claims submitted to a Part C MAPD or MA plan reject, only when the product is not covered under the Part D benefit and is covered under the Part C benefit?

Plans should not reject claims for a Part D drug if the prescribing or dispensing pharmacy is included on the Preclusion List and has not yet been removed from the plan's network. Plans should deny payment for a Part B drug (covered under Part C benefit which includes Parts A&B) if the pharmacy is included on the Preclusion List.

FAQ:

34. Should the pharmacy drug claims for Part B follow the same rules as for Part D (e.g. Part B denies immediately, Part D denies after 90 days)?

The Preclusion List only applies to Parts C and D. **Part B claims processing will follow its normal process.**

Clarification Point Needed:

- Based on the FAQ response, is CMS inferring that Part B prescription claims submitted to an MA plan with Part B benefits should not reject? We believe this contradicts the regulation verbiage and potentially FAQ #34, as Part B plans can technically be considered MA organizations.

*CFR 422.224 states "An MA organization may not pay, directly or indirectly, on any basis, for **items or services furnished** to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is included on the preclusion list, defined in § 422.2."*

- Or, is the FAQ response specific to the Medicare FFS program, where Precluded Provider requirements will not apply? **No, these claims will pay in FFS as there is no prescriber edit.**
- If MA and MAPD plans are expected to adhere to the Precluded Provider requirements, we refer back to the concerns outlined in FAQ #33 above. To mitigate beneficiary confusion with Part D and Part B/C products prescribed from the same precluded provider, are MAPD and MA plans expected to reject all claims regardless of which Medicare benefit the coverage would fall under, if the prescriber is on the Preclusion list? **Yes, the plan should reject all claims regardless of the benefit type. The plan shall not reimburse for any prescriptions from a precluded provider.**

FAQ:

35. Should pharmacies be removed from networks? Or should claims just deny?

As stated in the November 2, 2018 HPMS guidance memo, “**Part D plans are also expected to remove any precluded pharmacy from their network as soon as possible.**” MA plans are not required to contract with pharmacies.

Clarification Point Needed:

- If a pharmacy is listed on the Preclusion List and the Part D plan removes the pharmacy from the network, does the patient have the right to appeal the out-of-network rejection? **We would first like to clarify that Part D plans are not required to reject claims from precluded pharmacies (the dispensing entity). For any other precluded prescriber removed from a plan’s network, if the plan rejects the claim due to the prescriber’s preclusion status then no, a point of sale rejection due to preclusion does not trigger appeal rights.**
- Can the Part D plan reimburse the patient for any out-of-pocket payments made as a result of an out-of-network pharmacy point of service reject? **Plan sponsors should review the guidance in Section 60.1 “Out-of-Network” Pharmacy Access of the Medicare Prescription Drug Benefit Manual – Chapter 5. To summarize this guidance , Part D sponsors must ensure that their enrollees have adequate access to covered Part D drugs dispensed at OON pharmacies when those enrollees cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy, and when such access is not routine.**