DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services 7500
Security Boulevard
Baltimore, Maryland 21244-1850

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TO: All Medicare Advantage Organizations, Part D Plan Sponsors, 1876 Cost Plans and Programs of All-Inclusive Care for the Elderly (PACE)

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SUBJECT: Preclusion List Requirements Frequently Asked Questions (FAQs)

Background

On November 2, 2018, the Centers for Medicare & Medicaid Services (CMS) issued a memo (Nov. 2 memo) providing guidance with respect to the final rule CMS-4182-F published on April 16, 2018 that included Preclusion List requirements. The Nov. 2 memo had the subject line, "Preclusion List Requirements."

This memo supplements the Nov. 2 memo with FAQs and a revised sample beneficiary notice. These documents will also be posted on the Preclusion List website at the following link:

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html

Frequently Asked Questions

General

1. Please clarify the interaction/overlap between the 2019 rule and guidance and the 2020 NPRM.

The November 2, 2018 HPMS guidance memo provides guidance for plan year 2019. The proposed rule, CMS-4185-P (RIN 0938-AT59) published on November 1, 2018, if finalized as proposed, would apply to plan years 2020 and beyond. To provide comment on the proposed rule, please follow the instructions in the proposed rule.

2. **Has CMS considered delaying the effective date of the Preclusion List requirements?**

   CMS will not be delaying the Preclusion List requirements.

Beneficiary Notice

3. **May a plan send the beneficiary a notice before the 30-day time period has passed from publication of the most recent Preclusion List? If the plan does, may it wait until the end of the 90 day period to begin rejecting claims?**

   In accordance with the November 2, 2018 HPMS guidance memo, the beneficiary should be notified "as soon as possible but not later than 30 days from the posting of the list" and the beneficiary should have "at least 60 days' advance notice" before a plan denies payment/rejects claims associated with a precluded provider. Thus, a plan may provide a beneficiary with more than 60 days' notice, and if a plan does so, the plan should not deny payments/reject claims earlier than 90 days after publication of the associated Preclusion List. This period will allow the beneficiary at least 60 days to find a new provider and obtain a new prescription.

   For example:
   - The Preclusion List is posted January 1, 2019.
   - The plan sends notifications to impacted beneficiaries on January 15, 2019.
   - On April 1, 2019, the plan begins denying payment/rejecting claims based on the January 1, 2019 Preclusion List with dates-of-service (DOS) of April 1, 2019 and later.

4. **Do Plan sponsors have flexibility to use their own letters containing the CMS information?**

   Yes. The beneficiary notice attached to the November 2, 2018 HPMS guidance memo is a sample notice. Plans are not required to use this version for the required beneficiary notice, however, the letters should include the information specified in the sample notice.

5. **Does the beneficiary letter have to be translated?**

   The Medicare Communications and Marketing Guidelines (MCMG) discuss requirements applicable to all communication activities and materials, as well as additional requirements only applicable to marketing activities and materials. The beneficiary letter is designated as a communication material and as such, this means that all activities and materials are aimed at prospective and current enrollees, and are within the scope of the regulations at 42 C.F.R. Parts 417, 422, and 423.

   As stated in section 30.1 of the MCMG, Plans/Part D sponsors must comply with their obligations under other federal anti-discrimination rules and requirements. Plans/Part D sponsors must be aware of and comply with their other obligations under Federal law that are not specifically addressed in the MCMG. In accordance with 42 C.F.R. Part 423.2268(a)(7), plans/Part D sponsors must translate vital materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

6. **Please clarify what date should be placed in the "Last Updated<Date>" field in the sample beneficiary letter? Is this the date the list was provided?**

   The intent of this field in the sample beneficiary notice attached to the November 2, 2018 HPMS

guidance memo is for plans to include a version-control date, since plans are not required to use the sample notice as the required beneficiary notice. If a plan uses the sample notice as is, CMS suggests the plan use the date 11/02/18 in this field.

7. **What is the date that should be indicated in the "Effective Date Plan Claim Rejections Begin"? Our assumption is that the "EXCLDATE" date should appear in this file.**

   For better clarity, the Preclusion List file has been updated to include a preclusion date and a payment denial/claim rejection date. For example, the initial Preclusion List will contain a preclusion date of January 1, 2019 and a payment denial/claim rejection effective date of April 1, 2019. Plans can refer to the updated Preclusion List file layout and sample file located at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html.

8. **The memo states that "Medicare plans and Part D plans may notify providers included on the Preclusion List by copying the provider on the notice sent to the enrollee or by other means." Then in the beginning of the letter template it states, "The plan must also ensure reasonable efforts are made to notify the beneficiary's provider of a beneficiary who was sent a notice." Which statement is correct? Is this mandatory?**

   Both statements are correct. The regulation states that a sponsor must ensure reasonable efforts are made to notify the prescriber of a beneficiary who was sent a notice. The purpose of this notification is not to alert the provider that they are on the Preclusion List, since CMS would have already notified them, but to emphasize which patients in their practice are impacted by their inclusion on the Preclusion List. MA plans should notify precluded providers that they can no longer treat plan enrollees and also notify all plan enrollees who have received services from the precluded provider over the past 12 months as soon as possible but no later than 30 days after the date the provider has become precluded.

   Reasonable efforts would include copying the precluded provider on the required notice to the beneficiary. Alternatively, a plan could send a separate notice to the provider by mail or email.

9. **Will CMS allow different modes of communication (e.g., email or mail) with the member preference for receiving communication?**

   No.

10. **Shouldn't the letter clearly state that the determination of a provider's preclusion and any subsequent claim denials or rejections are not appealable by the beneficiary?**

    No; we do not believe it would be useful to state that a beneficiary does not have appeal rights under these circumstances. Instead, we have revised the letter (attached) to clearly state that the appropriate action for the enrollee to take is to find another provider in the area to furnish these services and to contact the plan if assistance is needed. In addition, an enrollee always has the right to seek a coverage decision from the plan if there's a question regarding coverage for an item, service or drug.

11. What are the expectations for situations where there is no claim history because the beneficiary is a new patient to the precluded provider, post the release of the preclusion date?

Beneficiary notification is not required if the beneficiary is a new patient of the precluded provider, post the release of the preclusion date. In addition, CMS notifies the provider of their potential inclusion on the Preclusion List and their applicable appeal rights prior to being added to the list. The provider would be aware of their preclusion status prior to taking on any new patients.

The claim rejection date on the Preclusion List applies to all claims based on date-of-service regardless of when or if claim history may have occurred between the beneficiary and the prescriber.

12. Does the Part C plan notification to beneficiaries who have received care in the past 12 months apply to non-contracted providers as well as contracted providers?

Yes.

13. Do health plans need to send letters to providers that have no relationship with a beneficiary (e.g., non-choice providers like emergency room doctors, pathologists)?

No. The regulation states that a sponsor must ensure reasonable efforts are made to notify the prescriber of a beneficiary who was sent a notice. CMS does not view reasonable efforts as including notifying these types of providers.

Preclusion List File

14. Who is able to access the Preclusion List?

Only approved CMS healthcare plans, with a valid Health Plan ID, can gain access to the Preclusion List. For instructions on how to access the Preclusion List visit https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html.

If the healthcare plan delegates their claims adjudication and credentialing activities to a subcontractor, the plan will need to share the Preclusion List with them. CMS will not grant access to the Preclusion List to Pharmacy Benefit Managers (PBMs), delegated claims/credentialing entities or subcontractors.

15. What if I don't know my Health Plan ID?

Plans should contact their compliance officer to obtain their Health Plan ID.

16. How do unlock my Enterprise Identity Management (EIDM) account?

Please contact the EUSSupport@cgi.com. The EUS contact information is listed below:

Chat: https://eus.custhelp.com/app/chat/chat_launch
E-mail: EUSSupport@cgi.com
Phone: 1-866-484-8049/ (TYY: 1-866-523-4759)
Hours of operation: Monday-Friday 6am to 6pm CST

17. How do I change my EIDM account password?

Please use the self-service link or contact the EUSSupport@cgi.com for the CMS Preclusion List application you are attempting to access via the Enterprise Portal.

18. What is the Preclusion List file name?

The latest file will be called PreclusionList.csv and will have the time stamp when it was last uploaded.

19. Will the 30 day period to intake the Preclusion List and distribute the beneficiary notices apply to each monthly file?

Yes. As stated in the November 2, 2018 HPMS guidance memo, "CMS recommends that Medicare plans and Part D plans follow the same process for monthly updates to the Preclusion List as they did for the initial list. The plans will have 30 days to review the Preclusion List for updates and should notify the impacted enrollees as soon as possible, but no later than 30 days from the posting of the updated list." However, since the subsequent Preclusion Lists will be full files, Medicare plans and Part D plans are not required to resend monthly notifies to the same beneficiaries when the same precluded provider appears on the monthly list.

20. Will all plan sponsors apply 60 days post the 30 day beneficiary notice period before activating point of service edits for each monthly file?

Yes. As stated in the November 2, 2018 HPMS guidance memo, "CMS recommends that Medicare plans and Part D plans follow the same process for monthly updates to the Preclusion List as they did for the initial list… Medicare enrollees should be given at least 60 days' advance notice before payment denials and claims rejections begin."

21. Is the first Preclusion List file a full and then subsequent monthly files with changes only or will the subsequent files be full files?

The initial and subsequent Preclusion Lists will be full files.

22. How will precluded provider records appear on the file, when there are multiple records for the same provider with overlapping dates?

A provider with multiple preclusion events will appear as separate line items on the file with separate effective and end dates. The dates will not overlap.

23. Will the Preclusion List include entities in addition to individual prescribers?

Yes. The Preclusion List is comprised of any individual or entity that meets the below 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.

24. How will provider groups be displayed on the list and should claims edit at the TIN or NPI level?

Groups will be added to the list at the TIN level. However, plans should confirm the TIN and/or NPI match before denying or rejecting claims from the particular group.

25. Will dentists be included on the Preclusion List?

If the dentist meets the below criteria, they will be included on the Preclusion List:

- 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.

26. What will be used as the exclusion date for precluded providers being reported solely based on the OIG Exclusion data?

CMS will not base the preclusion date on the OIG exclusion date. The preclusion date is based on the publication date. The Preclusion List and exclusion file overlap in the sense that excluded providers will be 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.

Precluded providers who are not excluded will not be on the exclusion file.

27. When will the actual Preclusion List be available for plan sponsors to evaluate the data content, as the test data lacks the necessary detail for the necessary QA processes to occur?

The first file with actual precluded provider data will be available on January 1, 2019.

28. What is the process for plans to communicate/escalate questionable data records (e.g. missing required fields such as an NPI, missing effective dates, irregularities or concerns with the data content etc.)?

Please refer any inquires related to the file to providerenrollment@cms.hhs.gov.

29. Is there an automated process for retrieving the Preclusion List?

No. Plans must download the file every month.

30. Can the Preclusion List be made public?

Currently the Preclusion List will not be made available publically because it contains Medicare revocation data. Historically, CMS has not made this data public.

Prescription Drug Event (PDE)

31. We need guidance on the relationship between the Preclusion List and PDE edits. For example, for a member for whom there is no history (see example above in question 10), and there is a 90 day wait period before the claim rejects, will CMS pay for the PDE?

PDE guidance is forthcoming.

32. When are the PDE edits expected?

PDE edits are expected to be in place on April 1, 2019.

Pharmacies

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.

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.

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.

Precluded Network Providers

36. If the medical providers is excluded (sanctioned), are plans expected to remove these providers from their plan networks immediately? This implies that medical claims will start to deny immediately upon the provider showing up in the Preclusion List.

Yes, the beneficiary should be notified "as soon as possible but not later than 30 days from the posting of the list" and the beneficiary should have "at least 60 days' advance notice" before a plan denies payment/rejects claims associated with a precluded provider. Thus, a plan may provide a beneficiary with more than 60 days' notice, and if a plan does so, the plan should not deny payments/reject claims earlier than 90 days after publication of the associated Preclusion List. This period will allow the beneficiary at least 60 days to find a new provider and obtain a new prescription.

37. Will Precluded Providers also be precluded from being paid for services to Medicaid members?

No, the preclusion list is not applicable to Medicaid.

Attachment:

Revised Sample Beneficiary Notice

2019 Part C and D Sample Precluded Provider Letter

[Instructions: This sample letter should be used by Medicare plans and Part D plans to alert a member that future medication fills prescribed or health care services furnished by his or her current provider will no longer be covered because the individual or entity has been placed on CMS's preclusion list, as required by 42 CFR § 417.478(e), § 422.224(b), § 460.86(b), and § 423.120(c)(6)(iv)(B)(1). After publication of the preclusion list, the Medicare plans or Part D plans should send a notice to ensure that members who have previously received a prescription or care in the last 12 months from a precluded provider receive a notice as soon as possible but no later than 30 calendar days after the publication of the associated list or update. The plan must also ensure reasonable efforts are made to notify the beneficiary's provider of a beneficiary who was sent a notice.]

<DATE>

<MEMBER NAME>
<ADDRESS>
<CITY, STATE ZIP>

Dear <MEMBER NAME>:

This letter is to inform you that we can no longer cover [*Insert all that apply* <prescription medications> <health care items> <health care services>] for dates of service after [Effective Date Plan Claim Rejections Begin] that are [*Insert one* <prescribed > <ordered>] by <NAME OF PROVIDER>. [*Insert if applies* <This includes new prescriptions, as well as any refills left on the prescription(s) you are currently taking>]. You will need to find another provider in your area to furnish these services.

<PLAN NAME> cannot cover [*Insert as applicable* <health care items>< health care services> <medications>] [*Insert as applicable* <provided> <ordered> <prescribed>] by <NAME OF PROVIDER> as of [Effective Date Plan Claim Rejections Begin] because he/she has been placed on a Medicare "preclusion list" by the Centers for Medicare & Medicaid Services (CMS). Medicare plans are prohibited from making payment for [*Insert as applicable* <health care items and services furnished> < prescriptions prescribed>] by individuals and entities on the preclusion list. For more information about the preclusion list, you may visit CMS's website at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html.

{Plan should insert one of the two sentences below.}
[*Part C plans insert \:* Please call <Customer/Member> Service at <phone number> (TTY/TDD users should call <TTY/TDD number>) if you need assistance finding another provider in your area.] [*Stand-alone Part D plans insert:* Please call 1-800-Medicare (1-800-633-4227) (TTY users should call 1-877-486-2048) if you need assistance finding another provider.] If you have further questions regarding the status of your prescription(s), we are available from <hours of operations>.

Sincerely,

<Plan Representative>

Last Updated <Date>
[Appropriate language, including disclaimers, is expected to appear in this sample document.]

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