Preclusion List Frequently Asked Ouestions (FAOs)

General

1. What is the Preclusion List?

The Preclusion List is comprised of any individual or entity that meets 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,
- 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, or
- Have been convicted of a felony under federal or state law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program.

CMS makes the Preclusion List available to the Medicare Advantage (MA) plans and Part D plans. MA plans will deny payment for a health care item or service furnished by an individual or entity on the Preclusion List. Part D plans will reject a pharmacy claim (or deny a beneficiary request for reimbursement) for a Part D drug that is prescribed by an individual on the Preclusion List.

Note: CMS precludes individuals and entities at the Tax Identification Number (TIN) level. Therefore, individuals and entities will not appear on the preclusion list unless <u>ALL</u>Medicare enrollments under their TIN are revoked or inactive.

2. Are Part D prescribers and providers participating in Medicare Advantage (MA) required by CMS to enroll in Medicare Fee-for-Service?

No. CMS published CMS-4182-F on April 16, 2018, which rescinds the CMS enrollment requirement for:

- Providers who prescribe drugs to patients enrolled in Medicare Part D, and
- Network providers and suppliers that furnish health care items or services to a Medicare beneficiary who receives his or her Medicare benefit through a Medicare Advantage (MA) organization.

Note: MA regulations require MA plans credential providers (see §422.204 - Provider selection and credentialing). Additionally, MA organizations may, as a condition of contracting, require providers to be enrolled in Medicare. Additionally, institutional providers and suppliers must be enrolled in Medicare (see Chapter 6 section 70 of the Medicare Managed Care Manual section, available at

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c06.pdf).

3. How will a provider know if they are on the Preclusion List?

CMS or a Medicare Administrative Contractor (MAC) will follow up with a written notice through mail to the impacted provider in advance of his or her inclusion on the Preclusion List and their applicable appeal rights.

4. Where will the preclusion notification letter be sent?

The letter will be sent to the provider's most recent correspondence address found in the Provider Enrollment Chain and Ownership System (PECOS) if they are currently revoked from Medicare and are under an active reenrollment bar or the most recent mailing address found in the National Plan and Provider Enumeration System (NPPES) if they have engaged in behavior for which CMS could have revoked, to the extent applicable, if they had been enrolled in Medicare.

5. What are my appeal rights if I am listed on the Preclusion List?

Impacted providers who are notified of their inclusion on the Preclusion List are afforded appeal rights in accordance with 42 CFR Part 498. These appeal rights allow a provider to challenge CMS' placement of the provider on the list and not to challenge the underlying reason for the revocation, OIG exclusion, or other adverse action that led to their inclusion on the Preclusion List. If the individual's or entity's inclusion on the preclusion list is based on a Medicare revocation under 424.535 and receives contemporaneous notice of both actions, then a joint reconsideration of these actions can be sought. Any appeal under this provision will be limited strictly to the individual's inclusion on the Preclusion List. Appeal instructions are included in the letter. Appeals are sent to CMS provider enrollment group through regular mail. Individuals and impacted providers with questions regarding the letter may contact CMS via email at providerenrollment@cms.hhs.gov.

6. What is the length of time a provider can expect to be on the Preclusion List?

A provider will be precluded for the length of their re-enrollment bar if they are currently revoked or would have been revoked had they enrolled in the Medicare program. The reenrollment bar becomes effective 30 days from the date of issuance of the initial determination letter and lasts a minimum of 1 year, but not greater than 10 years, depending on the severity of the basis for revocation. In addition, CMS may impose a re-enrollment bar of up to 20 years if the provider or supplier is being revoked from Medicare for the second time.

Note: A provider placed on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter length of time is warranted (Effective 01/01/2020).

7. 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 final rule, CMS-4185-F (RIN 0938-AT59) published on April 16, 2019, applies to plan years 2020 and beyond.

8. Regarding dual members who see a precluded provider, who becomes the primary payer? Is the plan to follow standard coordination of benefits guidance?

Yes, the plan should follow standard coordination of benefits processing. Medicare would be primary with Medicaid wrapping around. In terms of a dual eligible MA enrollee who obtains services from a precluded provider, the MA plan may not pay. However, those denied/rejected claims shall not trigger payment by Medicaid. The state may cover only Medicaid state plan covered services, which would not be covered under Medicare. Therefore, a denial or rejection due to a precluded provider should not trigger crossover to Medicaid for payment.

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

CMS will not be delaying the Preclusion List requirements, which took effect on January 1, 2019.

Beneficiary Notice

10. 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 CMS-4185-F (RIN 0938-AT59) published on April 16, 2019, 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. A plan may provide a beneficiary with more than 60 days' notice, but shall not pay claims after the close of the 90 day period. This period will allow the beneficiary at least 60 days to find a new provider and obtain a new prescription. Thus, CMS has indicated a claim rejection/payment denial date on the file which is consistent with the provider's 91st day in precluded status and the day on which claims must reject/payment must deny, as 90 days have elapsed since the exclusion date (EXCLDATE).

Additionally, plan sponsors or their PBMs should use the later of the below two dates as the start date of the 30-day beneficiary notification period:

- 1. EXCLDATE (the date the provider is added to the file, representing the first of the month); or,
- 2. File Release Date (the 25th day of the month or the last Monday of the month, prior to the EXCLDATE).

Regardless of the option selected, the plan should not begin denying payment/rejecting claims until the claim rejection/payment denial date on the file.

For example:

- The Preclusion List is posted December 25, 2018.
- 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 December 31, 2018 Preclusion List with dates-of-service (DOS) of April 1, 2019 and later.

11. 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.

12. 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.

13. 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.

14. 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 claim reject/payment denial date. For example, the initial Preclusion List contained a preclusion date of January 1, 2019 and a claim reject/payment denial 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.

15. 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 at 42 CFR § 423.120(c)(6)(iv)(B)(2) 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 was added to the preclusion list.

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. The plan shall use available correspondence data in their systems to copy the provider on the notice mailed to the beneficiary. If provider correspondence data is not readily accessible or available to the plan, the plan is not required to notify the provider. We do expect that plans will already have access to contact information for any contracted providers.

It is important to note this requirement will change effective January 1, 2020 per CMS-4185-F. At that time, CMS will only require plans to send a notice to precluded providers upon receiving a claim from a precluded provider after the expiration of the 60-90 day beneficiary notification period or after the payment denial/claim rejection date, and only for those beneficiaries who were not identified and notified during the initial 12-month look back period.

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

No, mail is the surest way of ensuring that the beneficiary receives notice.

17. 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. To further clarify, claim rejection or payment denial due to preclusion is not a coverage determination and therefore does not warrant appeal rights. However, the enrollee has the right to request a grievance if there is dissatisfaction due to a claim being rejected or payment denied because

of a precluded provider.

18. If a coverage request is clinically appropriate and approvable, should an authorization be placed with the claims processor that allows the drug to pay under a provider not on the preclusion list, but reject for a provider on the preclusion list?

The issue of the provider being on the preclusion list is not a coverage request. Therefore, clinical appropriateness should not be reviewed, and, there would not be a reason for an authorization to be put in place for a Part D drug.

19. What are the expectations for situations where there is no claim history, for example, 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. This applies to all of the provider's patients,

regardless whether they are new or not, if there is no claims data within the past 12 months. In addition, CMS notifies the provider of their potential inclusion on the Preclusion 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 and is the latest date a plan may wait to begin claim denials and rejections. To further clarify, if no claims history exists for the previous 12-month period, the plan is not required to notify beneficiaries. If no notification is made, the 60-90 day period is not required, although plans may choose to wait to deny claims until the claim denial/reject date included on the preclusion list file.

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

Yes, effective January 1, 2020, the regulation will formally require application of the preclusion list to non-contracted MA providers. However, CMS stated in the preamble to CMS-4182-F that plans should begin applying these requirements, including beneficiary notification, to non-contracted providers as a best practice.

21. 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.

22. What should beneficiaries do if they have access to care issues due to the Preclusion List?

Impacted beneficiaries that have concerns or need assistance finding a new provider should contact Medicare's toll-free customer care operations at 1-800-MEDICARE (1-800-633-4227).

Preclusion List File

23. Who is able to access the Preclusion List?

Only CMS approved 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 <u>https://www.cms.gov/Medicare/Provider-Enrollment-and-</u> Certification/MedicareProviderSupEnroll/PreclusionList.html.

24. How many users are able to access the Preclusion List per Healthcare Plan?

Healthcare plans may allocate up to 5 users access to the Preclusion List. If the healthcare plan delegates their claims adjudication and credentialing activities to a subcontractor, Pharmacy Benefit Managers (PBMs) or delegated claims/credentialing entity, the plan will need to share the Preclusion List with them or may approve the entity to use some of their allocated slots. The plan's compliance officer will be required to confirm the entity's association to the plan.

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

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

26. How do I unlock my Identity Management (IDM) account?

Please contact the External User Services (EUS) Help Desk: **EUS Help Desk Information** Hours of Operation: Monday - Friday, 7am-7pm EST Website: <u>https://eus.cms.gov</u> Email: <u>EUS_Support@cms.hhs.gov</u> Toll-Free Phone: (866) 484-8049

27. How do I change my IDM account password?

Please use the self-service link at https://portal.cms.gov/portal/forgotpassword or contact the EUS Help Desk above for the CMS Preclusion List application.

28. 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.

29. 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 notices to the same beneficiaries when the same precluded provider appears on the monthly list. CMS will provide the claim rejection and payment denial date for all newly added providers each month.

For new patients, please see question 19.

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

No, as the 30 day data intake period may not be necessary for some plans. However, all plans must reject claims/deny payment as of the claim rejection/payment denial date on the Preclusion List for beneficiaries who have been sent notices. For further convenience and consistency amongst plans, CMS has added a claim rejection/payment denial date to the list, which indicates the 91st day in precluded status and the day on which claims must reject/ payment must deny, as 90 days have elapsed since the exclusion date. Additionally, 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."

We note that pursuant to final regulation CMS-4185-F, beginning January 1, 2020, plans must reject claims/deny payment as of the claim rejection/payment denial date associated with beneficiaries who received a notice.

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

The initial and subsequent Preclusion Lists will be full files.

32. 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.

33. How are providers removed from the Preclusion List?

Impacted providers will not drop off the Preclusion List; however, the list will indicate a reinstatement date that an impacted provider is no longer precluded. Providers are not added to the list until they have exhausted their first level of appeal. If the first level appeal is found favorable, they would not be included on the list. If the first level appeal is unfavorable or the impacted provider fails to submit an appeal at all, they would be added to the list. The reinstatement date will not be published to the list until the provider is reinstated.

Note: There are additional levels of appeal afforded to providers beyond the first level to

include an Administrative Law Judge (ALJ) Hearing, Departmental Appeals Board (DAB) Hearing or Judicial Review.

34. Will there be a circumstance where a provider is retroactively reinstated?

Yes, it is possible, depending on the outcome of the provider's subsequent appeal, they may be reinstated back to the exclusion date on the file. This would remove any period of preclusion for the provider. Providers and beneficiaries may resubmit any claims denied or rejected during the preclusion period once the provider is reinstated.

35. 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,
- 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, or
- Have been convicted of a felony under federal or state law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program.

36. 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.

37. Will dentists be included on the Preclusion List?

If the dentist meets the preclusion list criteria, then the dentist will be included on the Preclusion List.

38. What will be used as the exclusion date for precluded providers being reported solely basedon 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.

39. 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 list with actual precluded provider data was made available on December 31, 2018. Updates to the Preclusion List will be made available approximately every 30 days. In an effort to provide MA and Part D plans more time to process new providers and reinstatements received on the Preclusion List, CMS will publish the Preclusion List by the 25th of each month or the last Monday of the month, whichever is earlier, for the following month. These changes will be implemented with the Preclusion List published in September 2019 (i.e., CMS will publish the September Preclusion List on August 26th as August 25th falls on a weekend).

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

Please refer any inquires related to the file to <u>preclusionlist@cms.hhs.gov</u>. Preclusion list policy questions should be sent to <u>providerenrollment@cms.hhs.gov</u>.

The Preclusion List is cumulative, therefore, CMS does not drop records from the list. If an error has been identified in the list, CMS will add a reinstatement date to the provider's record that is the same as the effective date. This will indicate that there was no period of preclusion for the provider.

41. What action are plans to take if beneficiary notices are issued in error?

CMS would expect plans to issue a rescission or clarification notice to the beneficiary.

Additionally, CMS has revised the Preclusion List file layout to include a new column to capture the last modified date for changed records.

42. The production Preclusion List file contained commas within the business name and address fields that, when uploaded, altered the format of the file and created loading issues. Will this be corrected?

Yes. CMS will remove the commas moving forward.

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

No. Plans must download the file every month.

44. 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.

45. Under what circumstances would the CLMREJECTDATE field on the Preclusion List be blank?

CMS recently identified scenarios where a blank CLMREJECTDATE is warranted because the provider no longer meets the criteria to remain precluded and this action occurred prior to the CLMREJECTDATE. This CLMREJECTDATE field may be blank in the following scenarios:

- The provider is no longer revoked in Medicare and is instead deactivated.
- The provider's revocation was or will be revised and reissued.
- The provider's revocation was rescinded.
- CMS has decided not to implement claim denials or rejections due to access to care concerns.
- The provider's revocation was overturned on appeal (Note: There are multiple appeal levels afforded to a provider, see question 33).

In these scenarios the Preclusion List will display a Reinstatement Date that equals the Exclusion Date and a blank CLMREJECTDATE. Moving forward, the CLMREJECTDATE field will not be populated for cases in which a provider no longer meets the criteria to be precluded prior to the CLMREJECTDATE.

46. What is the *Preclusion_List_Supplemental_Revocation_Authority_File.csv* file and is there any action for the MA and Part D plans?

The revocation authority file is a supplement to the preclusion list. It contains the revocation reason(s) that led to the provider's preclusion in Medicare for each provider identified on the preclusion list. The file will be published each month along with the preclusion list. It is for informational purposes only and there is no action required by the MA and Part D plans in regards to this file.

Prescription Drug Event (PDE)

47. 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 was released on January 9, 2019. The guidance can be found at <u>https://www.cms.gov/Medicare/Provider-Enrollment-and-</u> Certification/MedicareProviderSupEnroll/PreclusionList.html._

48. When are the PDE edits expected?

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

Pharmacies and Part B Drugs

49. Are Medicare Advantage/ and Part D plans required to reject claims from pharmacies on the Preclusion List?

A pharmacy will appear on the Preclusion List if it meets 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,
- 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, or
- Have been convicted of a felony under federal or state law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program.

Therefore, per CMS 4182-F and CMS 4185-F, Part D plans are not required to 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.

Additionally, CMS-4185-F, effective January 1, 2020, requires Medicare Advantage plans to deny payment if the pharmacy is included on the Preclusion List for a Part A or Part B drug covered under Part C, and any other plan-covered item furnished by the pharmacy. While Medicare Advantage plans may begin editing claims in this manner now as discussed in the preamble of CMS-4182-F, plans will be required to edit claims in this manner effective January 1, 2020 per CMS-4185-F.

50. Please clarify the requirements for claims for Part B drugs that were prescribed by precluded providers.

Medicare Advantage plans should deny payment with respect to Part B drugs prescribed by providers on the Preclusion List beginning on the applicable Claim Rejection/Payment denial Date. Additionally, we would like to note that while application to Part B drugs is not a regulatory requirement under CMS-4182-F, it is required per CMS-4185-F, effective January 1, 2020.

The Preclusion List does not apply when stand-alone Part D plans determine a drug is a Part B drug, and original Part B fee-for-service (FFS) claims processing will follow its normal process.

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

It is suggested that Part D plans remove any precluded pharmacy from their network as soon as possible, however, this discretion is left up to the Part D plans. Note this includes MA-PD plans. However, MA only plans are not required to contract with pharmacies.

52. For organizational providers on the Preclusion List, what data elements should plans use when terminating contracts or adjudicating claims?

Please refer to the February 7, 2019 HPMS guidance memo, "Additional Preclusion List Requirements". Medicare Advantage plans should only remove a contracted provider from their network and deny payment for a health care item or service, if they are able to determine an exact match to the organizational provider's Employer Identification Number (EIN). Medicare Advantage plans should not rely on the organizational provider's Type 2 NPI. Similarly, Part D plans should only remove a contracted pharmacy from their networks, if they are able to determine an exact match between the pharmacy's EIN and the EIN on the Preclusion List. Part D plans should not rely on the pharmacy's organizational Type 2 NPI on the Preclusion List.

53. Should claims also be rejected or denied for individual providers who are linked to a precluded organizational provider?

No. Only claims submitted by the precluded organizational provider should be rejected or denied.

Excluded Network Providers

54. If the provider is OIG 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.

Plans should follow their existing processes for OIG excluded providers and entities, which are based on the exclusion effective date.

Applicability to Medicaid

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

No, the preclusion list is not applicable to Medicaid. Additionally, Part C and D claims for dually eligible individuals, which are denied/rejected due to preclusion, will not crossover to Medicaid.

Finally, for plans such as an Medicare-Medicaid Plan (MMP) where the provider may be contracted separately with each program, based on current Medicaid regulation at 42 CFR § 455.416, State Medicaid Agencies (SMAs) are required to deny or terminate enrollment for any provider who is terminated under the Medicare program. Thus, a provider who is added to the preclusion list due to revocation, should not be active in any State Medicaid program.

However, we recognize there may be instances where a state has not yet taken termination action, which would lead to the Medicaid claims being processed while Medicare Part C or D claims will reject/deny. We believe this scenario will be rare.