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



DATE: November 2, 2018

- **TO:** All Medicare Advantage Organizations, Part D Plan Sponsors, 1876 Cost Plans and Programs of All-Inclusive Care for the Elderly (PACE)
- FROM: Zabeen Chong, Director Provider Enrollment and Oversight Group

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SUBJECT: Preclusion List Requirements

Background

The Centers for Medicare & Medicaid Services (CMS) published CMS-4182-F on April 16, 2018, rescinding the Medicare enrollment requirement for contracted providers¹ that receive payment from Medicare Advantage (MA), 1876 Cost Plans, or Programs of All-Inclusive Care for the Elderly (PACE) organizations for health care items and services furnished to Medicare beneficiaries enrolled in MA or MA-PD plans (hereafter referred to as "Medicare plans"), 1876 Cost Plans or PACE organizations. In the same regulation, CMS rescinded a requirement that providers who prescribe drugs enroll in Medicare in order for the prescriptions they write to be covered under Part D.

As an alternative, the April 2018 final rule adopted a requirement that, in order for contracted and noncontracted providers to receive payment from a Medicare plan, 1876 Cost Plan, or PACE organization for health care items and services furnished to beneficiaries enrolled in Medicare plan, 1876 Cost Plans, or PACE organizations, such providers must not be included on the Preclusion List. Likewise, in order for Part D drugs to be covered by a Part D plan, the prescriber must not be included on the Preclusion List.

In this memo providing guidance on how Medicare plans, 1876 Cost Plans and PACE organizations implement and comply with the Preclusion List requirements, we refer to these entities collectively as Medicare plans as their obligations under 42 CFR 422.222 and 422.224, 417.487, and 460.86 are very similar. Where there are different requirements applicable to them, we use the specific term. Please note

¹ For purposes of this memo, providers refers to providers and suppliers who furnish Part A or B or supplemental benefits for Medicare plans, cost plan or PACE enrollees or prescribers of Part D drugs.

that MA-PD plans must also comply with the Part D plan Preclusion List requirements in connection with coverage of Part D drugs.

The Preclusion List

The Preclusion List will consist of providers (individuals and entities) that fall within either of the following categories:

(1) Are currently revoked from Medicare, are under an active reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program; or

(2) 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.

Prior to being added to a Preclusion List, providers will be notified by CMS of their potential inclusion on the Preclusion List and their applicable appeal rights. CMS will add a provider to the Preclusion List only if the provider's appeal is denied at the CMS level or the timeframe for the provider to request a CMS level appeal has been exhausted.

There will be one Preclusion List with subsequent updates. CMS will make the initial Preclusion List available to Medicare plans and Part D plans beginning January 1, 2019 on a secure website. Updates to the Preclusion List will be made available approximately every 30 days, around the first business day of each month. The "Access to CMS Preclusion List Quick Reference Guide" provides step-by-step instructions for accessing the list at: <u>https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/PreclusionList.html</u>. Also found on the website is a Sample Preclusion List and a Preclusion List File Layout/Data Dictionary.

Medicare plans must remove any contracted provider, who is included on the Preclusion List, from their network as soon as possible. Part D plans are also expected to remove any precluded pharmacy from their network as soon as possible. Medicare plans and Part D plans should review the Preclusion List for this purpose as soon as possible beginning January 1, 2019, but no later than January 31, 2019, and on a regular basis going forward.

Medicare plans and Part D plans are required to notify those enrollees who have received care in the last 12 months from a contracted provider or a prescription from a provider who is included on the preclusion list as soon as possible. A sample notice to enrollees is attached.

CMS acknowledges that the relevant enrollee notification and claim adjudication timeframes in CMS-4182-F are not consistent within the preamble and regulation. A recent CMS proposed rule, if finalized, would clarify these timeframes. For 2019, CMS recommends that Medicare plans and Part D plans furnish the Medicare beneficiaries with at least 60 days' advance notice before they begin denying payment for a health care item or service furnished by a provider on the Preclusion List and rejecting a pharmacy claim (or denying a beneficiary request for reimbursement) for a drug that is prescribed by a provider on the Preclusion List. As such, we suggest such payment denials and claims rejections begin on April 1, 2019, for the January 1, 2019 Preclusion List. This would allow 30 days for plans to review the Preclusion List and notify the beneficiaries as soon as possible but no later than 30 days from the posting of the list and an additional 60 days for beneficiaries to prepare. Medicare plans and Part D plans may not reimburse or make payment for claims (i.e., for covered items or services) or prescriptions associated with any providers on the initial Preclusion List for dates of service on or after April 1, 2019, including for emergency or urgent care circumstances.

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. Medicare enrollees should be given at least 60 days' advance notice before payment denials and claims rejections begin.

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. This will notify providers about their patients who are impacted by their preclusion from the Medicare program.

The Preclusion List does not replace regulatory requirements related to provider selection, credentialing, and oversight under the regulations at §§ 422.204 (MA organizations), 417.416 (1876 Cost Plans) and 460.64 through 460.71 (PACE organizations). Use of the Preclusion List does not eliminate or address the responsibility for Medicare plans MA and Part D plans to validate that providers are not included on the Office of Inspector General (OIG) exclusion file. The Preclusion List and exclusion file overlap in the sense that excluded providers will be on the preclusion list but precluded providers who are not excluded will not be on the exclusion file. Therefore, if a plan finds a provider on the OIG exclusion file, the plan is not required to check the Preclusion List.

Attachment:

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>].

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

{*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.] [*Standalone 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.]