June 18, 2018

Frank Whelan
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244
(410) 786–1302
Frank.Whelan@cms.hhs.gov

Re: NCPDP Implementation Questions to CMS 4182-F Section 10. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE

Dear Mr. Whelan,

NCPDP is a not-for-profit ANSI-Accredited Standards Development Organization (SDO) consisting of more than 1,400 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies, and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system.

For over 40 years NCPDP has been committed to furthering the electronic exchange of information between healthcare stakeholders. The NCPDP Telecommunication Standard is the standard used for eligibility, claims processing, reporting, and other functions in the pharmacy services industry as named in HIPAA. The NCPDP SCRIPT Standard, Telecommunication Standard, and the Formulary and Benefit Standard are the standards in use in electronic prescribing as named in MMA.

The NCPDP Definition of a Valid Prescriber Task Group has been working closely with CMS Medicare Part D and Center for Program Integrity (CPI) representatives since the publication of the original prescriber enrollment requirements outlined within CMS 4159-F. We appreciate CMS' recognition of the barriers associated with the prescriber enrollment requirement, including the provisional fill expectations, and the benefits to transitioning to an alternative precluded provider process. NCPDP would like to take this opportunity to request CMS' assistance with the below questions related to the Precluded Provider requirements. CMS' responses to these questions will help facilitate a streamlined implementation without creating patient access to care risks.

NCPDP appreciates CMS' support with these inquiries. Responses and additional direction from CMS would be appreciated either in writing or by participating interactively during the NCPDP Definition of a

Valid Prescriber Task Group meeting. The Task Group Meeting details are copied below. If the Task Group meetings are the most convenient forum for CMS to support, please contact the NCPDP Staff liaison so the meeting agendas can be coordinated.

WG1 Definition of a Valid Prescriber Task Group
Every Monday beginning Monday, May 21, 2018
8:00 a.m. PDT and AZ/9:00 a.m. MDT /10:00 a.m. CDT/11:00 a.m. EDT
Duration: 90 minutes

Join the meeting from your computer, tablet or smartphone.
https://global.gotomeeting.com/join/240121661
You can also dial in using your phone.
United States: +1 (669) 224-3412 Access Code: 240-121-661
NCPDP Staff Liaison: Elise Balden ebalden@ncpdp.org

PRECLUDED PROVIDER IMPLEMENTATION QUESTIONS:

1. Industry stakeholders require a minimum of 12 months for development, testing and deployment of system changes to support the precluded provider process. NCPDP requests CMS delay the compliance date of this provision until 12 months after the availability of the following key technical components and responses to the questions outlined below.
    a. Precluded Provider File Layout
    b. Precluded Provider Test File (with data)
    c. Hierarchical Rules between OIG and Precluded Provider (e.g., beneficiary notices, OIG waivers, Point-of-Service rejects)
    d. Beneficiary Letter Template
    e. PDE Guidance

CLARIFICATION OF FINAL RULE LANGUAGE

2. The below information from the Final Rule appears to imply that only beneficiaries impacted by the initial list of precluded providers will be notified. (Refer to page 16653)

    "Once a provider has exhausted their first level appeal process or has not submitted an appeal within 60 days, an additional 90-day period will lapse prior to their addition to the preclusion list. The 90-day period allows the plans 30-days to intake the preclusion data and a 60-day beneficiary notification period. Subsequent updates to the list will provide any newly added provider with a 60-day appeals window but will not provide a 90-day period as discussed above, thus after implementation beneficiaries may not be notified that they may have received a prescription or services from a provider that is now precluded."

    a. Can CMS please clarify the expected beneficiary notification process upon implementation of the precluded provider process and thereafter?

b. What, if any, notice requirements are necessary when a beneficiary has no previous claim history with a prescriber and presents a new prescription where that prescriber is on the precluded provider file with an effective date that is prior to the claim date of service?

c. What, if any, notice requirements are necessary when a beneficiary has no previous claim history with a prescriber and presents a new prescription where that prescriber is on the precluded provider file with an effective date that is after the claim date of service?

d. The preamble language refers specifically to exhaustion of the "first level appeals process". If a prescriber submits a second level appeal, assuming there is such a process, and it is granted, would CMS notify the member (or require the plan to notify the member) that their prescriber has been removed from the list?

3. There appears to be conflicting language within the Final Rule regarding the appeal and data integration time periods. Can CMS please clarify which of the following applies?

   Refer to Page 16653: *"The 90-day period allows the plans 30-days to intake the preclusion data and a 60-day beneficiary notification period."*

   Refer to Page 16660: *"CMS will only place a prescriber and their applicable preclusion period on the preclusion list after the prescriber has exhausted the appeals process (described in more detail below), plus an additional 90-day period, including a 60-day period for plans to ingest preclusion data and a 30-day beneficiary notice period."*

4. The below information from the Final Rule appears to imply that emergency situations will not be supported by the precluded provider process and will also no longer apply to OIG Excluded providers. Can CMS please provide clarification on the intent to ensure consistency in addressing patient access to care during emergency situations? (Refer to pages 16655, 16667)

   Additionally, we note that urgent and emergency services as defined in § 422.113, are excluded as indicated in the regulatory text at § 460.86(a) for Part C covered services and § 422.224(a) for Part D covered drugs.
   Revise § 422.222(a) to state: ''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''. We note that the language that excluded emergency and urgently needed services from the scope of § 422.222(a) has been removed. § 422.222(a)

5. There also appears to be conflicting language within the Final Rule as to whether the precluded provider process applies only to the prescriber or if it could also apply to the pharmacy as the provider entity that would be represented as the Service Provider ID within the prescription claim. Can CMS provide additional clarification as to how the below references should be interpreted and implemented for Medicare Part D, as it relates to an earlier response from CPI indicating the Service Provider ID field would be subject to the Precluded Provider edits?

- The "preclusion list" is defined differently for Part C and Part D purposes, including "individuals and entities" for Part C purposes, but only "prescribers" for Part D purposes (although the preamble says there is only one list for both).

- In 42 CFR 423.120(c) describing what may not be paid, the Part D language clearly refers only to an "individual" (Refer to Page 16739)
  …. "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."

- Other language in that section also points to the prescriber: (Refer to Page 16739)
  "(v)(A) CMS sends written notice to the prescriber via letter of his or her inclusion on the preclusion list. The notice must contain the reason for the inclusion on the preclusion list and inform the prescriber of his or her appeal rights".

  (B) A prescriber may appeal his or her inclusion on the preclusion list under this section in accordance with 42 CFR part 498.

  (vi) CMS has the discretion not to include a particular individual on (or if warranted, remove the individual from) the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to prescriptions.

- This is in contrast to the language in 42 CFR 422.222, (Refer to Page 16733)
  "(a)(1) An MA organization must not make payment for a health care item or service furnished by an individual or entity that is included on the preclusion list, defined in § 422.2".

  "(2) CMS sends written notice to the individual or entity via letter of their inclusion on the preclusion list. The notice must contain the reason for the inclusion and inform the individual or entity of their appeal rights"

FILE CONTENT & USABILITY

6. Will a precluded provider end date always be applied to a record?

7. Could the precluded provider end date be changed to an earlier date where it would be retroactive?

8. Will the precluded provider effective date always be set to the first of the month, at least 90 days in the future of the first publication of the record (e.g., first publication for 1/1/2019 has an effective date of 4/1/2019)?

9. How will the precluded provider effective date be reflected for OIG excluded providers that will be incorporated into the Precluded Provider File?

10. The Final Rule indicates that OIG excluded providers will be incorporated into the Precluded Provider File. In order to apply hierarchical rules, an exclusion/preclusion source type is necessary. Will the Precluded Provider file include such an indicator to support the necessary identification of OIG excluded providers versus Precluded Providers in order for the hierarchical rules to apply?

11. Will a precluded provider only be added to the file after the Precluded Provider Appeal Process has been exhausted?

12. Will the Precluded Provider file contain the following minimum necessary attributes?
    a. NPI and NPI Type Indicator (Type 1 or Type 2)
        - Note, the NCPDP claim adjudication process does not support EIN, where NPI is the required data element to identify the service provider ID and the prescriber
    b. Provider Name (Type 1 = Individual Name, Type 2 = Entity Name)
    c. DOB
    d. Provider Specialty/Taxonomy
    e. Address (City, State, Zip Code)
    f. Preclusion Start Date
    g. Preclusion End Date
    h. Exclusion/Preclusion Source Type
    i. Record Update Date (needed to identify Adds and Updates to the monthly full file refresh)

        - Note, the above attributes are similar to the data elements within the OIG Excluded Provider File as copied in the following table

FIELD VALUE	FIELD LENGTH
LASTNAME	20
FIRSTNAME	15
MIDNAME	15
BUSNAME	30
GENERAL	20
SPECIALTY	20
UPIN	6
NPI	10
DOB	8
ADDRESS	30
CITY	20
STATE	2
ZIP CODE	5
EXCLTYPE	9
EXCLDATE	8
REINDATE	8
WAIVERDATE	8
WAIVERSTATE	2

13. How will a Precluded Provider 'record' be defined within the file?
    a. Will CMS assign a specific key to a record to allow entities to compare a current file to a previous file and identify record keys that have been removed?
    b. If no record key, how will CMS publish situations where a prescriber has multiple preclusion events?
    c. If a provider has multiple preclusion events, will there be a record for each preclusion source type or will there be a record for each effective and termination date?

14. Should waivers be allowed when a prescriber is on the OIG list with a waiver and is on the preclusion list with a preclusion reason of OIG exclusion?

15. Should waivers be allowed when a prescriber is on the OIG list with a waiver and is on the preclusion list with a preclusion reason not related to an OIG exclusion?

FILE AVAILABILITY & TIMING:

16. When will a precluded provider test file be available for plan sponsors and their PBMs to evaluate and schedule the applicable testing efforts?

17. When will the initial production precluded provider file be available for plan sponsors and their PBMs to access and integrate into their systems?

18. Will the initial precluded provider data be made available to the plan sponsors and their PBMs outside the formal file process to support any necessary beneficiary notification requirements prior to the determined effective date of this provision?

19. Will updates only be made to the file once a month where all records will be post-dated to eliminate conflicts between plan sponsor and CMS precluded provider information as would occur with retroactive effective or termination dates?

20. Will the monthly Precluded Provider file updates align with the OIG, LEIE, MED and GSA/SAM file updates to ensure consistency in data and prevent erroneous point of service rejects?

21. Will the precluded provider file be accessible to all stakeholders (plan sponsors, PBMs/processors, pharmacies, pharmacy software vendors, prescriber data vendors) to ensure effective point of care coordination?

BENEFICIARY AND PROVIDER NOTIFICATIONS

22. Assuming the hierarchy of prescriber validation rules will set OIG exclusions as the priority, is the plan sponsor expected to send two different beneficiary notices if the prescriber is on both the OIG excluded and Precluded Provider files?

23. When will CMS provide the Beneficiary Notice guidance that clarifies whether CMS or the plan sponsor will notify the beneficiary? Please note, this information is needed immediately, so that the appropriate IT development can be coordinated to support the template. (Refer to page 16651)

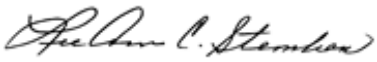
    "Notice will be provided to beneficiaries at least 60 days prior to the prescriber or provider being added to the list. Whether the notice originates from CMS or plans will be addressed in guidance outside of rulemaking."

24. When will CMS update the information on the CMS website, clarifying the enrollment process has been replaced with a Precluded provider process?

https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Prescriber-Enrollment-Information.html

NCPDP appreciates CMS' support with reviewing and responding to these questions in order to ensure a smooth implementation of the Precluded Provider initiative that will protect and ensure beneficiary access to care. As noted above, we encourage CMS to participate in the NCPDP Definition of a Valid Prescriber Task Group meetings, where collaboration with industry stakeholders will expedite the delivery of expected outcomes.

Sincerely,



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