December 3, 2018

Kim Brandt, Principal Deputy Administrator for Policy and Operations
Kimberly.Brandt1@cms.hhs.gov
200 Independence Avenue, SW.
Mail Stop: C5-02-00
Woodland, MD 20201

Re: Medicare Part D Precluded Provider January 01, 2019 Effective Date Concerns and Recommendations

Dear Ms. Brandt,

National Council for Prescription Drug Programs (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 the Health Insurance Portability and Accountability Act (HIPAA). Additionally, the NCPDP SCRIPT Standard, Telecommunication Standard, and the Formulary and Benefit Standard are used in electronic prescribing as named in the Medicare Modernization Act (MMA).

Since the publication of the Precluded Provider requirements outlined within CMS 4182-F, NCPDP has worked closely with Centers for Medicare & Medicaid Services representatives to facilitate a streamlined implementation. While NCPDP appreciates CMS' acknowledgement of specific areas of concern that we have identified, there are several unresolved key factors that will compromise meeting the expected results of the January 1, 2019 effective date and the April 1, 2019 date on which point of service prescription claims are to reject. Our initial concerns were outlined within the Notice of Proposed Rule Making comments and further escalated to CMS on June 18, 2018, August 10, 2018 and August 28, 2018. Understandably, CMS took the necessary time to evaluate and respond to the inquiries. The November 9, 2018 CMS call, intended to address many of these questions, further compounded the confusion due to contradictions in the multiple responses from CMS representatives. These unresolved topics are outlined in the below Critical Factors section. The availability of the beneficiary model notice and the associated guidance are critical factors required by the industry to ensure that correct implementation of claim adjudication requirements are established by April 1, 2019.

While this information was released on November 2, 2018, several areas of concern identified and communicated to CMS remain unresolved.

Unresolved critical factors are listed below. Once these factors are addressed and resolved, appropriate time is needed for plan sponsors, pharmacy benefit managers (PBMs) and pharmacy providers to:

- coordinate system enhancements,
- integrate new files and file layouts,
- identify and distribute letters to impacted beneficiaries, and
- develop and complete pharmacy training.

Without this coordination, Medicare beneficiaries will be confused and access to care will be severely compromised.

NCPDP Recommendations:

NCPDP recognizes the importance of moving forward with the Precluded Provider process; however, the implementation needs to be thoughtfully coordinated to ensure uninterrupted beneficiary access to care and to mitigate unnecessary confusion. As noted above and within the detailed questions outlined below, additional guidance is needed to support a streamlined implementation. As such, NCPDP respectfully offers the following recommendations:

1. Delay the January 1, 2019 beneficiary notification process to start no less than 90 days from the date responses to all identified critical factors have been published, taking into consideration the 30-day file incorporation period. This would in turn delay the effective date of point of service rejections.
2. If a delay is not feasible from a regulatory perspective, as a compromise, NCPDP recommends:
    a. As of January 1, 2019, the CMS Precluded Provider file shall only include Office of Inspector General (OIG) excluded providers, where existing processes will adhere to fraud, waste, and abuse and beneficiary protection expectations
    b. No less than 90 days from the publication of responses to all identified critical factors, providers who are not on the OIG list but determined to be CMS Precluded Providers shall be added to the Precluded Provider file

Outstanding Critical Factors:

1. Will the Precluded Provider file include entities in addition to individual prescribers?
    - If yes, what are these entities?
    - If yes, will the beneficiary notice instructions be updated?
    - If yes, from a point of service perspective, are all plans (MA, MA-PD, PDP) required to reject claims received from that entity?

2. Should Plan sponsors only be using the Precluded Provider beneficiary model notice provided on November 2, 2018?
    - If requested, does the letter have to be translated?
    - If translation is expected, will updates be made to Medicare Communications and Marketing Guidelines section 100.4?

3. Based on the latest sample test file and layout documents that include the CLMREJECTDATE field, will CMS also publish an FAQ that would make industry stakeholders aware of this new field and its intended use?
    - For the initial file and subsequent update files, will the CLMREJECTDATE **always** be 90 days from the exclusion date, as indicated in the file layout document?

4. Can CMS clarify the CLMREJECTDATE applies to all claims regardless of when or if claim history may have occurred between the beneficiary and the prescriber?
    - For example, in a scenario where Dr. Smith, precluded as of 1/1/19, is a new provider for Mrs. Jones, should the CLMREJECTDATE apply regardless if/when the beneficiary receives the letter?
        - 1/01/2019 = EXCLDATE
        - 4/01/2019 = CLMREJECTDATE
        - 4/01/2019 = Beneficiary is seen by the precluded provider for the first time and RX is written. Beneficiary does not receive the Precluded Provider notice as no previous history of the relationship is on file.

5. Since the initial file will not be available until 1/1/19, is there a process in place for plan sponsors to report any irregularities or concerns with the data content? For example, how will correction files be handled?

6. Are plan sponsors required or expected to show reasonable efforts to notify the precluded provider as outlined in the final rule and within recent guidance, even though CMS verbally indicated this was not required?

7. In order to expedite processes, will CMS consider allowing PBMs access to the Precluded Provider file?

8. When there are multiple preclusion occurrences for the same provider with overlapping dates, how will precluded provider records appear on the file?

9. When will PDE guidance be available?

NCPDP appreciates this opportunity to collaborate with CMS in developing an effective and efficient provider validation process to ensure patient safety without compromising access to care and mitigating unnecessary administrative costs.

For direct inquiries or questions related to this letter, please contact:
Elise Balden, Standards Development
National Council for Prescription Drug Programs
Email: ebalden@ncpdp.org

Sincerely,

Lee Ann C. Stember
President & CEO
National Council for Prescription Drug Programs (NCPDP)

9240 E. Raintree Drive
Scottsdale, AZ 85260
(480) 477-1000, ext. 108
(602) 321-6363 cell
lstember@ncpdp.org

CC:
Demetrios Kouzoukas, Principal Deputy Administrator for Medicare & Director, Center for Medicare
Demetrios.Kouzoukas@cms.hhs.gov
Katie Mucklow, Deputy Director, Division of Policy and Regulations, Governance Management Group, Center for Program Integrity
Katie.mucklow@cms.hhs.gov
Michael A. Cimmino, Technical Advisor, Center for Program Integrity
Michael.Cimmino@cms.hhs.gov
Alisha J. Sanders, Director, Division of Enrollment Operations, Center for Program Integrity
Alisha.Sanders@cms.hhs.gov