October 13, 2017

Ms. Seema Verma
Mail Stop: 314G
Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Seema.Verma@cms.hhs.gov

RE: NCPDP Implementation Recommendations for Medicare Part D and Medicaid Provider Enrollment

Dear Ms. Verma,

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit ANSI-Accredited Standards Development Organization (SDO) consisting of more than 1,600 members who are 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.

NCPDP would like to take this opportunity to outline the increasing concerns with the current Medicare Part D and Medicaid provider enrollment requirements and provide an alternate recommendation that will mitigate patient access to care risks, ensure patient safety, streamline processes, lower healthcare administrative costs and meet CMS's fraud, waste and abuse objectives. While the compliance date for Medicare Part D prescriber enrollment has been delayed until January 1, 2019, on-going collaboration between industry stakeholders and government officials has been at a standstill for the past 9 months, preventing the development of necessary system enhancements to be able to meet this date. Additionally, the Affordable Care Act has placed a significant burden on the industry requiring all Medicaid Managed Care programs to implement Medicaid provider enrollment validations as of January 1, 2018, without the necessary tools, standardization of processes and guidance to even begin system development. NCPDP requests Centers for Medicare and Medicaid Services (CMS) to consider the recommendations outlined below and facilitate collaboration between all stakeholders to develop the appropriate solutions that will ensure the protection of Medicare and Medicaid beneficiaries without compromising access to care.

Outlined below are some of the critical issues to the Medicare Part D prescriber and Medicaid provider enrollment requirements. These barriers prevent consistent, timely, effective and efficient implementations that will result in point of service rejections and compromise patient access to care. The current Medicare and Medicaid foundation for provider enrollment will also incur retrospective validations that will significantly increase administrative costs and may place stakeholders at a financial risk. NCPDP has previously provided CMS detailed documentation of the Medicare Part D areas of concern described below. These historical documents can be made available upon request.

Medicare Part D Areas of Concern

1. The Medicare Individual Provider Enrollment File layout is inefficient to ensure standardization and accuracy of real-time claim and Prescription Drug Event (PDE) processing.

- On 01/07/2017, NCPDP submitted the File Layout and Claims Processing Recommendation document constructed to facilitate standardization of processes and eliminate inconsistencies in the results, specifically as it relates to retro-active enrollment. CMS has not yet provided any feedback.

2. Stakeholders are unable to implement system rules to support the provisional fill process based on the current CMS definitions of a "drug" and a "compound drug".
3. It is unclear as to how plan sponsors and CMS will support the calculation of the provisional fill period when claims are processed retro-actively.
4. There are significant operational risks associated to the expected overlap between Transition and Provisional Fills that will ultimately create beneficiary confusion.
5. Validation of the provider enrollment status as it relates to non-Part D drugs creates significant confusion and will require a redesign of system logic to apply coverage determination for the dual-eligible population.
6. There are multiple provider exclusion files that may apply to a Medicare or Medicaid claim, resulting in a lack of clarity on the hierarchy of use, file accessibility and data integrity between files; for example:
    - It is unclear as to what processes may be in place to prevent discrepancy between the Office of Inspector General (OIG) and the System for Award Management (SAM) data (e.g. latency in SAM data).
    - Stakeholders will need to coordinate system enhancements if another exclusion type provider file becomes available that may be in addition to or replace an existing file.

Medicaid Fee For Service (FFS)/Managed Care Areas of Concern

1. While Medicaid FFS programs were expected to comply with the Ordering and Referring Provider Enrollment Requirements as of April 2012, to date there are multiple states not yet able to support this requirement due to the complicated enrollment process and the volume of providers and patients at risk.
2. One Medicaid program has not yet implemented the Type 1 National Provider Identifier (NPI) as the unique provider ID.
3. Inconsistent use of point of service reject codes to identify a non-enrolled provider.
4. Inconsistent use of emergency override procedures to ensure patient access to care.
5. Lack of reporting to identify the number of patients and claims at risk to effectively schedule the effective date of the point of service edit.
6. Conflicting guidance in the identification of the 'prescriber,' specifically in hospital settings where the intern or resident is unable to enroll.
7. Lack of guidance for provider enrollment criteria as it relates to dual eligibles.
    - No connection between Medicare and Medicaid enrollment.
8. Lack of standardized file layout and timely access to Medicaid FFS enrollment data and processes.
9. Medicaid provider enrollment requirements also apply to the dispensing pharmacy, where in a Managed Medicaid setting this creates significant administrative and beneficiary access risks; for example:
    - Current Medicaid FFS enrollment processes take months to process an application and add the pharmacy to its State Medicaid Roster file.
    - The Medicaid pharmacy enrollment process is extremely lengthy and labor intensive where achieving comprehensive enrollment to meet beneficiary access to care needs, specifically across state lines is not practical.

Additional Area of Concern

Recent natural disasters (e.g., Hurricanes Harvey, Irma, Maria and Nate, wildfires in western states) are perfect examples where the beneficiary may require services from an unenrolled provider (prescriber and/or pharmacy) due to typical evacuation or emergency preparedness processes. The following are examples where a patient's access to care will be compromised:

- Medicare Part D patient receives a medication prescription for an acute condition at the evacuation shelter, written by a Medical Student (intern/resident). While the Medicare Part D provisional fill guidance supports an exception process for non-enrolled prescribers, claims will initially reject due to the prescriber's medical student status, resulting in confusion, administrative barriers and significant delays in care.
- Managed Medicaid patient evacuates to another state and attempts to refill a maintenance medication at a local pharmacy. Since Medicaid enrollment is at each individual state level and requires both the pharmacy and prescribing providers to be enrolled, the claim will reject due the pharmacy's non-enrolled status. While this is an existing barrier with Medicaid FFS programs, expanding the enrollment requirement to Managed Medicaid plans will impact a greater population of patients.

NCPDP Recommendations:

NCPDP appreciates CMS' on-going efforts to protect beneficiaries and ensure the appropriate regulations are in place to prevent fraud, waste and abuse. Pharmacy industry stakeholders have been working closely with CMS since the release of the Medicare Part D final rule in 2014, the Medicaid Ordering Referring requirements outlined in the 2011 Affordable Care Act and the 2016 Medicaid and Children's Health Insurance Program (CHIP) Managed Care Final Rule. Within the past three years, additional requirements were enacted that will significantly increase healthcare administrative costs without streamlining the implementation process to achieve the intended goals.

NCPDP offers the following recommendations to create the appropriate balance between ensuring beneficiary protection and maintaining the appropriate fraud, waste and abuse measures with mitigating healthcare administrative costs and facilitating patient access to care.

1. Delay the 01/01/2018 Medicaid Provider Enrollment and 01/01/2019 Medicare Part D Prescriber Enrollment requirements until such time a streamlined provider validation process can be implemented.
2. Support a single, streamlined process to monitor eligible providers and identify exclusions that would apply to claims for Medicare and Medicaid beneficiaries.
3. Replace the provider enrollment requirement with an Eligible to Service status, where unless the provider is identified with an exclusion status, all providers are identified as eligible to service Medicare and Medicaid beneficiaries.
4. Enhance the NPI enumeration process and National Plan and Provider Enumeration System (NPPES) registry to ensure integrity of Type 1 and Type 2 NPIs.
5. Collaborate with state and federal licensing boards to integrate provider Type 1 NPI information and streamline provider identification processes for purposes of CMS prescriber exclusion status.
    - Enforce NPI maintenance through state license renewal processes.
    - Note: not all prescribers have a Drug Enforcement Administration (DEA) license.

6. Distinctly identify prescriber exclusion types and the associated guidance to allow for consistency in implementation across all stakeholders and prevent un-intended consequences for the beneficiary and the providers.
    - Define applicable grace periods and override processes to ensure patient access to care.
7. Replace existing disparate systems e.g. List of Excluded Individuals and Entities (LEIE), SAM, Medicare Exclusion Database (MED), Medicaid State Exclusions with a comprehensive CMS Provider Exclusion file to include the appropriate exclusion types, add and update dates, and other identifiers and guidance to support consistency in implementation.
8. Eliminate the use of retro-active exclusions as this cannot be supported with the real-time environment of prescription claims processing.
9. Eliminate the Medicare Individual Provider Enrollment File.
10. Eliminate the Provisional Fill process.
11. Eliminate the Medicaid Ordering, Referring Provider requirements for Medicaid FFS and Managed Medicaid programs.

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:
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Sincerely,

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