March 6, 2016

AdvanceNotice2016@cms.hhs.gov
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit ANSI-accredited Standards Development Organization (SDO) consisting of more than 1500 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. Our diverse membership develops solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system.

NCPDP submits the following comments in response to the Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter.

For direct inquiries or questions related to this letter, please contact
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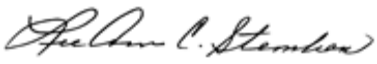
Sincerely,



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Making the Exceptions and Appeals Processes More Accessible for Beneficiaries
Improved Information at the Point of Sale (pg. 78-79)

"Under current requirements at 42 CFR § 423.562(a)(3), Part D plan sponsors must arrange with network pharmacies to provide enrollees with a written copy of the standardized pharmacy notice (Prescription Drug Coverage and Your Rights - Form CMS-10147) when the enrollees' prescriptions cannot be filled under the Part D benefit and the issue cannot be resolved at the point of sale. The notice instructs enrollees on how to contact their plans and explains an enrollee's right to receive, upon request, a coverage determination (including a detailed written decision) from the Part D plan sponsor regarding his or her Part D prescription drug benefits, including information about the exceptions process.

The pharmacy notice, as it exists now, does not include any personalized information. Pharmacies have the discretion to include the enrollee's name and the drug or prescription number, but these fields are not required. We have received feedback from beneficiary advocacy groups that it would be more helpful if the notice provided personalized information, specifically the reason for the POS rejection. This could, in theory, save the enrollee time and effort in reaching out to the plan separately to understand why a prescription could not be filled at POS and help an enrollee determine next steps if s/he wants to request a coverage determination. Alternatively, advocacy groups suggest that a rejection at the pharmacy counter should be treated as an adverse coverage determination and immediately trigger the processing of an appeal by the plan. They suggest that this would eliminate the need for enrollees to request a coverage determination and an appeal for certain POS rejections. CMS intends to work with stakeholders to further explore whether such an approach is feasible for certain types of POS rejections, such as those based on PA criteria, step therapy requirements and quantity limits so long as proper transaction codes are in place.

As CMS has previously stated, collaboration with the National Council of Prescription Drug Programs (NCPDP) would be necessary to develop and standardize codes that would assist Part D sponsors, processors and pharmacies with generating information on certain POS transactions, such as specific reasons for the rejection of a claim. As we explore how best to approach any potential changes, we ask for comments from our partners on the benefits and costs of implementing these potential changes and developing new standardized codes, suggestions about reasonable timeframes for implementing such standards and other considerations that we should keep in mind as we pursue potential refinements to our programs."

NCPDP Comment:
NCPDP appreciates CMS' reference to NCPDP in the development of the necessary standardized codes to assist industry stakeholders in communicating to the beneficiary the specific reason for the Part D claim rejection. NCPDP would like to take this opportunity to provide recommendations in how NCPDP can assist in addressing these business needs and outline any concerns that require consideration in the development of future CMS guidance.

As CMS is aware, NCPDP standards support a codified set of values used to communicate specific rejected transaction response information. There are currently over 1,100 reject codes with standardized descriptions within the NCPDP External Code List (ECL). While updates can be made to the ECL to support new reject codes for NCPDP Telecommunication Standard vD.0, the approval and implementation of these changes adheres to a timeline of two years. As part of the approval process, NCPDP validates the business case to ensure streamlined processes and duplication of

reject code descriptions is eliminated. It is important to note that the reject code descriptions are specifically developed for interpretation by the healthcare professional and system processes. These descriptions have character length limitations and include abbreviations and acronyms specific to healthcare transactional data and are not in terms that may be understood by the patient. Additionally, pharmacy software systems may have limitations as to how often their software is updated. Limitations to print capabilities at point of service further complicate this issue. As a result of these concerns, NCPDP does not recommend the use of reject codes to convey the point of service conflict to the beneficiary. NCPDP needs to further evaluate the business need to determine the appropriate technical solution that drives standardization and supports clear and concise communication to the intended recipient. Depending on the complexities of the solution, NCPDP recognizes it may take up to 7+ years to implement as this may require a new version of the Telecommunication Standard as well as other NCPDP related standards.

Alternatively, CMS proposed that specific rejection scenarios would automatically trigger an adverse coverage determination where the plan sponsor would immediately trigger the appeals process. NCPDP does not believe the proposed approach will meet the intent for the following reasons:

- Existing Medicare Part D regulations found in the Prescription Drug Benefit Manual, Chapter 18, conflict with the above mentioned alternative proposal. For example,
    - Section 10.3.2 Coverage Determination states:
        1. The right to a timely coverage determination;
        2. The right to request an expedited coverage determination as described in this chapter;
        3. The right to receive written information from a network pharmacist regarding the enrollee's ability to obtain a detailed written notice from the Part D plan sponsor regarding the enrollee's Part D benefits;
        4. The right to a detailed written notice of a Part D plan sponsor's decision to deny a benefit in whole or in part, which includes the enrollee's appeal rights; and
        5. The right to receive notice when a coverage determination is forwarded to the IRE.
    - Section 40.1 How to Request a Coverage Determination is in direct conflict with what is being proposed as only the enrollee, an enrollee's representative, or an enrollee's prescribing physician or other prescriber may request a standard coverage determination.
- Plan Sponsors are unable to determine when an immediate appeal would apply as the pharmacy provider may be working with the prescriber to resolve the point of service rejection.
- CMS guidance does not explicitly stipulate when the notice is required and as a result inconsistencies occur.
- This change in process would eliminate the information available to the Plan Sponsor therefore; the existing timing on coverage determination and appeals would need to be re-evaluated.
- A comprehensive review of sub-regulatory guidance, including but not limited to all chapters of the Prescription Drug Benefit Manual would need to be undertaken to determine and address existing conflicts.

NCPDP appreciates the opportunity to provide comments on the draft guidance and is available to discuss any questions you may have related to our response.