CMS received 6 comments on the June 5, 2017 *Federal Register* notice, extending the use of our currently approved collection entitled "Medicare Prescription Drug Coverage and Your Rights." We received comments from Medicare advocacy organizations, a health plan, a pharmacist, and other independent stakeholders.

**Comment 1:** The commenter expressed concern regarding the burden placed on pharmacies, rather than the involvement of the physician to consider the financial cost for their patients before determining their treatment.

CMS Response: The regulation at 42 CFR § 423.562(a)(3) states that Part D plan sponsors must arrange with network pharmacies to distribute a written notice instructing enrollees "how to contact their plan to obtain a coverage determination or request an exception." The existing pharmacy notice satisfies this requirement. A Part D plan enrollee may consult with his/her prescriber at any time regarding the possibility of using a different prescription drug.

Action(s) Taken: CMS does not plan to take action in response to this comment.

**Comment 2:** The commenter expressed concerns regarding the burden placed on pharmacies to provide a beneficiary with their plan's formulary each time a transaction denies, in addition to the burden placed on the plan to send their new formularies to each network pharmacy. This commenter also expressed concern regarding the time burden placed on a beneficiary who must call their treating physician to resubmit a different prescription.

CMS Response: We appreciate this commenter's concern; however, under this requirement it is not our expectation that a network pharmacy would be providing a beneficiary with their plan's formulary. Upon notification that a drug is not covered under Part D or subject to a prior authorization or other utilization management requirement, the network pharmacy is required to distribute a copy of the pharmacy notice instructing the enrollee how to contact their plan and obtain a coverage determination or request an exception. We believe this results in a reduction of burden on the beneficiary and prescriber, if the beneficiary is able to resolve the issue with the plan directly.

Action(s) Taken: CMS does not plan to take action in response to this comment.

**Comment 3:** The commenter was in support of the Pharmacy Star Rating program instituted by CMS, and its role in improving medication adherence and safety.

CMS Response: We appreciate this commenter's support of the program; however, this comment is out of scope for purposes of the Standardized Pharmacy Notice.

Action(s) Taken: CMS does not plan to take action in response to this comment.

**Comment 4:** Two commenters support the requirement that plan sponsors coordinate with their network pharmacies to provide enrollees with the "Medicare Prescription Drug Coverage and Your Rights" notice, but expressed their concern that the notice is not being consistently delivered and about CMS monitoring compliance.

CMS Response: We appreciate the commenter's support of the Standardized Pharmacy Notice. We acknowledge their recommendation for monitoring delivery of the notice. Part D plan sponsors are required to arrange delivery of this notice with their network pharmacies whenever the designated electronic transaction response is returned. Chapter 18, section 40.3.1 outlines CMS' expectations for plan sponsors to ensure consistent delivery of the notice. CMS monitors for compliance with the pharmacy notice requirements during Part D program audits and rejected claims reviews.

Action(s) Taken: CMS does not plan to take action in response to this comment.

**Comment 5:** The commenter requested that CMS consider translation of the notice into the 15 threshold languages, and, in the meantime, instruct plans to ensure that the pharmacy provides a multilanguage insert to beneficiaries.

CMS Response: CMS produces the pharmacy notice in English and Spanish. Although the notice is distributed by the network pharmacy, not the Part D plan sponsor, it directs the enrollee to contact the plan for more information and next steps. Part D plan sponsors are required to offer interpreter and translation services when requested by an enrollee, and we believe these requirements adequately address any need for such services. Part D plan sponsors are also required to provide enrollees with information about nondiscrimination, including their rights under Section 1557, in their general plan materials. The nondiscrimination notice must include taglines in at least the top 15 non-English languages spoken by individuals with limited English proficiency of the relevant State or States.

Action(s) Taken: CMS does not plan to take action in response to this comment.

**Comment 6:** The commenter brought to our attention a discrepancy between the form and form instructions with regards to the instruction of placement of the OMB-control number on the notice.

CMS Response: We appreciate the commenter bringing this to our attention, and have revised the form instructions accordingly.

Action(s) Taken: We revised the language in the form instructions to specify that the OMB control number must be displayed in the lower right corner of the notice.