August 1, 2011

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulatory Development
Attention: CMS-10147
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

[Submitted online at: www.regulations.gov]

Re: Docket No. CMS–10147. CMS Information Collection Request: Standardized Pharmacy Notice – Your Prescription Cannot be Filled

Dear Sir/Madam:

The American Pharmacists Association (APhA) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed information collection request, Your Prescription Cannot be Filled (f/k/a Medicare Prescription Drug Coverage and Your Rights), published May 31, 2011 (76 FR 31338). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services. Our comments reflect the views of pharmacists practicing across the spectrum of health and patient care settings.

APhA appreciates the efforts of CMS to modify the current standardized pharmacy notice (Form Number – CMS 10147) to comply with the recently adopted Final Rule Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes (76 FR 21432). As indicated in the Final Rule, 42 CFR 423.562(a)(3) was amended to remove the option for pharmacies to post notices instructing Medicare Part D enrollees how to contact their plans to obtain a coverage determination or request an exception if the patient disagree with the plan’s coverage denial decision and relayed by the pharmacist. The Final Rule instead requires pharmacists to provide written notices instructing enrollees how to contact their plans to obtain a coverage determination or request an exception.

While we understand that CMS must implement the Final Rule pursuant to pharmacist distribution of the notice, we are concerned with the potential for administrative burden and cost shift to pharmacy to
implement the requirement. Furthermore, given that prescription claims denial information that pharmacists provide to patients is based on real-time, electronic prescription claims adjudication messaging received directly from the Part D plan, we encourage CMS to explore ways to require plans to directly contact their enrollees to provide them with the denial information and instructions for pursuing coverage determination/exceptions. It would be beneficial for Medicare patients to receive information directly from the plan making the initial coverage determination and for what reason in order to have timely information available to address the claim issue.

As CMS finalizes the standardized notice, APhA recommends that CMS consider the following recommendations to improve the document and ensure patients receive the information that is most helpful for them to access needed medications:

- Clarify distribution expectations for the form regarding need to dispense every time any applicable real-time electronic claim denial is issued regardless of efforts to resolve the issue (i.e. dialogue between pharmacists and prescriber to potentially dispense a different medication that is covered), or only when the patient needs to initiate the coverage determination and exceptions process.
- Clarify distribution options for pharmacies that may have the technology to create an electronic, patient-customized, computer-generated print-out of the standardized notice. The distribution options should not be restricted to paper-only as systems move to utilization of electronic health information.
- Clarify if the patient has an option for how they wish to receive the information (paper or electronic message).
- Provide additional guidance on distribution if the patient does not return to or contact the pharmacy, then compliance with the notice distribution should be negated.
- Ensure that a claim denial message clearly indicates that the patient is on a Medicare Part D plan, not a private plan with the same insurer.
- Ensure that improvements continue in claims messaging so that specific information as to why a claim was denied is included in the electronic message facilitated through NCPDP standards in addition to the steps that need to be taken to resolve the claim or what drug would be covered.
- Ensure that Part D patients receive general coverage determination options and information from their plan (i.e. in a yearly welcome packet or something similar) to help increase enrollee awareness of steps to address potential coverage issues.
- Consider ways in which the plan could cover the costs of distribution as the proposal is a cost shift to pharmacy.
- Clarify mail-order pharmacy requirements to distribute the notice.
- Consider revising the title of the document from “Notice: Your Prescription Cannot be Filled” to “Notice: Your Insurance Did Not Pay for Your Prescription” or something similar so as not to suggest that pharmacy/pharmacist made the decision.
- Clarify requirements related to distribution of notices in foreign languages.
- Continue to evaluate the readability and literacy level of the notice.

**Conclusion**

As CMS finalizes provisions requiring pharmacist to distribute the standardized notice, we encourage you to consider the previous recommendations. Pharmacists are committed to the needs of patients but are concerned with the potential administrative burden and cost shift to pharmacy. We also urge CMS to consider ways to ensure that plans are also providing this information to patients.
Thank you for the opportunity to provide comments on the standardized pharmacy notice. We look forward to continuing to work with CMS on this important issue. If you have any questions or require additional information, please contact Marcie Bough, Senior Director of Government Affairs at mbough@aphanet.org or by phone at (202) 429-7538.

Sincerely,

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Executive Vice President and CEO

cc: Brian Gallagher, BSPharm, JD, Senior Vice President, Government Affairs
Marcie Bough, PharmD, Senior Director, Government Affairs