



MEDICARE ENROLLMENT & APPEALS GROUP

DATE: December 27, 2012

TO: Medicare Advantage Organizations
Medicare Prescription Drug Plan Sponsors

FROM: Arrah Tabe-Bedward
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SUBJECT: Revised Guidance for Distribution of Standardized Pharmacy Notice
(CMS-10147)

The purpose of this memorandum is to provide additional, updated guidance about the requirement to distribute the Standardized Pharmacy Notice (CMS-10147, “Medicare Prescription Drug Coverage and Your Rights”) when a prescription cannot be covered (“filled”) under the Medicare Part D benefit at the point-of-sale (POS). This memorandum provides additional information on distribution requirements based on numerous questions that have been raised related to implementation of this requirement, including specific guidance which clarifies requirements for a number of non-retail specialty pharmacy settings, as well as eliminating the requirement to distribute the notice in certain limited scenarios.

Where it conflicts, the guidance in this memorandum supersedes any previously issued CMS guidance related to this requirement. Enforcement action for noncompliance with the revised guidance contained in this memorandum will not be taken until after March 31, 2013.

The current OMB-approved pharmacy notice and instructions can be found at:

<http://cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/PlanNoticesAndDocuments.html>

Requirements Under 42 CFR 423.128(b)(7)(iii) and 423.562(a)(3)

Part D plan sponsors must arrange with network or preferred pharmacies to provide enrollees with a written copy of the standardized pharmacy notice when the enrollees’ prescription cannot be filled under the Part D benefit and the issue cannot be resolved at the POS. Permissible exceptions to this requirement are detailed below. The Part D plan sponsor must use the OMB-approved notice (link provided below). The notice instructs the enrollee on how to contact their plan 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. Plan sponsors

must arrange with their network pharmacies (including mail-order and specialty pharmacies) to distribute the notice to enrollees.

The pharmacy notice must be provided to the enrollee if the pharmacy receives a transaction response indicating the claim is not covered by Part D and the designated National Council for Prescription Drug Programs (NCPDP) response code is returned.

The designated NCPDP response code is NOT returned in the following scenarios:

- The claim rejects only because it does not contain all necessary data elements for adjudication;
- The drug in question is an over the counter (OTC) drug that is not covered by the enrollee's Part D plan sponsor;
- The prescription is written by a sanctioned provider who has been excluded from participation in the Medicare program;
- The drug is not listed on the participating CMS Manufacturer Labeler Code List;
- The drug is not listed on the Food and Drug Administration (FDA) Electronic List—NDC Structured Product Labeling Data Elements File (NSDE);
- The Part D plan rejects the claim for the drug in question only because of a “refill too soon/early refill” edit; or
- The drug in question is not covered by the Part D plan benefit, but is covered by a co-administered insured benefit managed by a single processor. In this scenario, the pharmacy submits a single claim transaction for the drug and the drug is covered by the co-administered insured benefit after being rejected by Part D and processed in accordance with the benefits offered by the supplemental payer. [NOTE: If the drug is not covered by the Part D plan, but the enrollee pays for the cost of the drug pursuant to plan-sponsored negotiated pricing or a discount card program (which may provide a lower price but leaves the enrollee responsible for 100% of the drug cost), a designated NCPDP response code will be returned notifying the pharmacy to provide the enrollee with a copy of the pharmacy notice.]

Printing the pharmacy notice on prescription label stock or an integrated prescription receipt is permitted, so long as the notice is provided in at least 12-point font. Electronic distribution of the notice is permitted if the enrollee or the enrollee's appointed representative has provided an e-mail address or fax number and has indicated a preference for that method of communication. The only permissible customization of the pharmacy notice is population of optional fields for the enrollee's name and the drug/Rx# to be added to the notice.

Failure to distribute the standardized pharmacy notice does not in any way limit an enrollee's right to request a coverage determination from their plan sponsor.

Mail-Order Pharmacies

As stated above, plan sponsors must make arrangements with network mail-order pharmacies to meet these requirements; that is, if a prescription cannot be covered (“filled”) under the Medicare Part D benefit as described above, the mail-order pharmacy must distribute the standardized

pharmacy notice to the enrollee. The mail-order pharmacy has the option of working with the plan and the prescriber to resolve the matter and provide the needed medication or an appropriate substitute. If the matter cannot be resolved and the pharmacy cannot fill the prescription, the notice must be provided to the enrollee via the enrollee's preferred method of communication (fax, electronic, or first class mail) as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the pharmacy's receipt of the original transaction response indicating the claim is not covered by Part D.

Home Infusion Pharmacies

Plan sponsors must make arrangements with network home infusion pharmacies to meet these requirements. If a prescription cannot be covered ("filled") under the Medicare Part D program as described above, the home infusion pharmacy must distribute the standardized pharmacy notice to the enrollee either electronically, by fax, in-person, or by first class mail. The home infusion pharmacy has the option of working with the plan and the prescriber to resolve the matter and provide the needed medication or an appropriate substitute. If the pharmacy cannot fill the prescription, the notice must be provided to the enrollee as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the pharmacy's receipt of the original transaction response indicating the claim is not covered by Part D. For enrollees brought on service by the home infusion pharmacy, the pharmacy can also choose to deliver the notice in person with delivery of home infusion drugs or through an infusion nurse, as long as the next scheduled visit is within 72 hours of the receipt of the transaction code indicating the claim cannot be covered by Part D.

Pharmacies Serving Long-Term-Care Facilities

Given the uniqueness of the long-term-care (LTC) setting, there is typically no point-of-sale encounter between the pharmacy and the enrollee (LTC resident) and, therefore, no practical means for the pharmacy to provide the notice directly to the enrollee. In most instances where there is an issue with the prescription, CMS expects that the pharmacist will contact the prescriber or an appropriate staff person at the LTC facility to resolve the matter and ensure the resident receives the needed medication or an appropriate substitute, obviating the need to deliver the notice. If the pharmacy must fax or otherwise deliver the notice to the enrollee, the enrollee's representative, prescriber or an appropriate staff person at the LTC facility as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the pharmacy's receipt of the original transaction response indicating the claim is not covered by Part D.

NOTE: If the enrollee is a self-pay resident, and the pharmacy cannot fill the prescription under the Part D benefit, the pharmacy must, upon receipt of the transaction response, fax or otherwise deliver the notice to the enrollee, the enrollee's representative, prescriber or an appropriate staff person at the LTC facility. After distribution of the notice, the LTC pharmacy should continue to work with the prescriber or facility to resolve the matter and ensure the resident receives the needed medication or an appropriate substitute.

Indian Health Service (IHS), Tribe and Tribal Organization and Urban Indian Organization (I/T/U) Pharmacies

Because IHS members' prescription drugs, when dispensed through I/T/U pharmacies, are filled and dispensed at no cost to the enrollee regardless of whether the drug is rejected at POS by the Part D plan, I/T/U pharmacies are exempt from the requirement to distribute the pharmacy notice.

NOTE: This exemption applies only to I/T/U pharmacies that dispense prescriptions at no cost to the enrollee. Any network commercial pharmacy providing services to IHS-eligible Part D enrollees must distribute the notice in accordance with the requirements outlined in this memorandum.

Compliance with this Requirement

CMS expects plan sponsors to have internal controls in place to reasonably ensure that network pharmacies are complying with the requirement to distribute the standardized pharmacy notice to enrollees when a prescription cannot be covered ("filled") under the Medicare Part D benefit at the point-of-sale. For example, plan sponsors should be able to demonstrate:

- Periodic communication with network pharmacies (including non-retail pharmacies) regarding the requirement to distribute the pharmacy notice (e.g., reminders on related policies and procedures, training materials for pharmacy staff). An appropriate internal control may also include periodic "secret shopper" or beneficiary survey/outreach calls.
- A means of identifying enrollee complaints about a failure to receive the pharmacy notice that would lead to ad hoc investigations and compliance actions on the part of the plan sponsor.

Questions

For questions concerning the standardized pharmacy notice, please send an email to: PartD_Appeals@cms.hhs.gov.