



CENTER FOR MEDICARE

DATE: October 14, 2011

TO: All Part D Sponsors

FROM: Anthony Culotta, Director
Medicare Enrollment & Appeals Group

SUBJECT: Revised Standardized Pharmacy Notice (CMS-10147)

Overview

Consistent with our April 15, 2011, final rule, beginning with the 2012 plan year, each Part D plan sponsor must have a system in place that transmits codes to network pharmacies to instruct the pharmacies to provide a printed notice to enrollees when a prescription cannot be covered (“filled”) under the Medicare Part D benefit at the point-of-sale (POS). The printed POS notice will tell enrollees how to request a coverage determination by contacting the plan sponsor’s toll free customer service line or by accessing the plan sponsor’s Web site. (See 42 CFR 423.128(b)(7)(iii) and the final rule published on April 15, 2011 (76 FR 21471). This memo provides information on the status of the standardized pharmacy notice, and answers questions that have been raised related to the implementation of this requirement.

Standardized Pharmacy Notice (CMS-10147)

Since the inception of the Part D program in 2006, sponsors have been required under 42 CFR 423.562(a)(3) to arrange with their network pharmacies to post or distribute notices that instruct enrollees to contact their plans for a coverage determination if they disagree with information being provided by the pharmacist. The standardized pharmacy notice (CMS-10147) that has been used for this purpose is now being revised, through the Paperwork Reduction Act (PRA) process, which includes two opportunities for public review and comment. Most recently, the revised notice was published on September 16, 2011, for a final 30-day comment period. The notice can be found at:

<http://www.gpo.gov/fdsys/pkg/FR-2011-09-16/pdf/2011-23801.pdf>.

The revised pharmacy notice and related supporting documents also can be found at:

<https://www.cms.gov/PaperworkReductionActof1995/PRAL/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=2&sortOrder=descending&itemID=CMS1248216&intNumPerPage=10>

We anticipate that the new standardized pharmacy notice will be made final in November, after which it will be posted immediately on the CMS website at:
http://www.cms.gov/MedPrescriptDrugApplGriev/14_PlanNoticesAndDocuments.asp#TopOfPage.

Questions & Answers

Q1. Under what circumstances does the pharmacy have to provide the pharmacy notice to the enrollee?

A1. The pharmacy notice must be provided to the enrollee if the enrollee's prescription cannot be filled under the Medicare Part D benefit at POS. In other words, the notice must be provided if the pharmacy receives a transaction response (rejected or paid) indicating the claim is not covered by Part D.

Q2. Does the pharmacy notice have to be given to an enrollee if the prescription is not covered by the Part D plan, but is covered at POS by a secondary payer?

A2. The pharmacy notice must be provided if the pharmacy receives a transaction response indicating the claim is not covered by Part D, even if the prescription is covered by a secondary payer. The beneficiary has a right to contact the Part D plan sponsor and request a coverage determination.

Q3. Are network pharmacies permitted to print the pharmacy notice on prescription label stock?

A3. In an effort to afford some flexibility in how the notice may be provided, 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.

Q4. Are network pharmacies permitted to provide the notice electronically?

A4. Electronic distribution of the notice is permitted if the enrollee or the enrollee's appointed representative has provided an e-mail address and has indicated a preference for that method of communication. This will afford some flexibility when an alternative pharmacy setting (e.g., mail order) is involved in the transaction.

Q5. Are network pharmacies permitted to provide the notice verbally?

A5. The content of the pharmacy notice cannot be delivered exclusively verbally (e.g., by telephone). The information in the pharmacy notice must also be provided to the enrollee in writing.

Q6. Are long term care (LTC) or mail order pharmacies exempt from the requirement to provide the pharmacy notice?

A6. We recognize that delivery of the notice in the LTC or mail order setting presents unique challenges. For example, because there is no physical encounter between the pharmacy and the long-term care resident (enrollee) at a point-of-sale, there is no practical means for the pharmacy to provide the notice directly to the enrollee. The same circumstances applied with respect to the previous notice. Thus, section 40.3.1 of Chapter 18 of the Medicare Prescription Drug Benefit Manual provides additional guidance on how the notice requirement applies in these situations. In practice, we believe in most instances where there is an issue with a prescription for a LTC resident, the pharmacist will contact the prescriber or an appropriate staff person at the LTC facility to resolve the matter and ensure that the resident receives the needed medication or a substitute, obviating the need to deliver the pharmacy notice.

Q7. Is customization of the pharmacy notice permitted?

A7. We have proposed optional fields for the enrollee's name and the drug/Rx # to be added to the notice. This is the only customization that is permitted at this time.

Q8. Once OMB has approved the pharmacy notice, will it be available on the CMS website?

A8. Yes, the final OMB-approved notice will be posted under "Downloads" at:
http://www.cms.gov/MedPrescriptDrugApplGriev/14_PlanNoticesAndDocuments.asp#TopOfPage

Q9. Will implementation of this requirement be delayed to allow adequate time for plan sponsors to program system changes?

A9. The regulation requires distribution of this written notice as of January 1, 2012. We strongly encourage sponsors to take all available steps to make the new notice available to enrollees by that time. However, given the anticipated timing of the publication of the final notice, we recognize that plan sponsors may need additional time to ensure that operations and systems are in place to fully comply with this requirement. Therefore, any action for noncompliance would be taken no earlier than 90 days after the publication of the final OMB-approved pharmacy notice (CMS-10147).

Q10. Is a network pharmacy required to provide the pharmacy notice when the drug was covered at POS by the Part D plan at a non-preferred price?

A10. The pharmacy notice must be provided only in instances where a Part D drug is not covered by the Part D plan at POS. It should not be provided if the drug is covered, but at a non-preferred price.

Questions

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