Form Instructions for the "Notice of Denial of Medicare Prescription Drug Coverage" CMS-10146

A Part D plan must complete and issue this notice whenever it denies a Part D plan enrollee's request for prescription drugs. This is not model language. This is a standard form. Part D plans may not deviate from the content of the form provided. The notice contains text in curly brackets "{ }" to be inserted as explained in these instructions. Bracketed text shown in *italics* must be inserted in the notice as written **when it is applicable to the situation**. Bracketed text that is not italicized provides instruction on text to be inserted in the notice.

Please note that the OMB number must be displayed in the upper right corner of the notice.

Heading

Logo - A logo is not required. Part D plans may elect to place their logo in this space. The name, address, and telephone number of the Part D plan must be immediately under the logo, if not incorporated within the logo.

Date - Enter the month, day, and year that the notice is issued to the enrollee, the enrollee's prescriber, or the enrollee's representative.

Enrollee's Name - Enter the enrollee's full name.

Member Number- Enter the enrollee's drug plan member identification number. This number should not include or be the enrollee's Social Security Number or Health Insurance Claim (HIC) number.

Section titled: Your request was denied

List the denied prescription drug or drugs requested by the enrollee or prescriber.

Section titled: Why did we deny your request?

The Part D plan must provide a specific and detailed explanation of why the prescription drug is being denied, including a description of any applicable Medicare coverage rule or any other applicable Part D plan policy upon which the denial decision was based. If the plan needs more information in order to approve the request, they must clearly state what information is needed.

Note for B v. D determinations or drugs not covered under Part D:

In addition to the specific denial rationale, if the plan believes that the drug is covered (or may be covered) under a different benefit such as Medicare Part B, the plan must populate the applicable bracketed language.

Example: In the case of an MAPD where the plan has determined that the requested drug is covered under Part B, the plan may insert the text as follows: "Medicare Part D has denied your request, however, **Medicare Part B** has approved coverage/payment for the requested drug(s). **This approval is valid through December 31, 2013.** If you think Medicare Part D should have paid- you may appeal."

Example: In the case of a PDP where the plan has determined that the requested drug is a Part B drug, the plan must explain why the drug is not a Part D covered drug and should also insert the following text: "Your drug may be covered under Medicare Part B. For more information, call 1-800-Medicare."

The plan's explanation must be written in a manner calculated to be understood by the enrollee.

Section Titled: What If I Don't Agree With This Decision?

No information is required to be completed.

Section Titled: Who May Request an Appeal?

In the spaces provided, the Part D plan is required to enter the Part D plan's telephone and TTY numbers that enrollees should use to obtain information or forms on how to name a representative.

Section Titled: There Are Two Kinds of Appeals You Can Request

No information is required to be completed.

Section Titled: What Do I Include with My Appeal?

No information is required to be completed.

Section Titled: How Do I Request an Appeal?

Under the subsection "For an Expedited Appeal" –The Part D plan is required to enter the telephone, TTY or fax number that the enrollee, prescriber, or the enrollee's representative can use to request an expedited (fast) appeal.

Under the subsection "For a Standard Appeal" –The Part D plan must provide the address where the enrollee, prescriber, or the enrollee's representative can mail or hand deliver a standard appeal request. If the Part D plan accepts oral appeal requests, then it must provide the telephone and TTY numbers that the enrollee, prescriber, or the enrollee's representative may use to request a standard appeal.

Section Titled: What Happens Next?

No information is required to be completed.

Section Titled: Get Help & More Information

In the spaces provided, the plan must insert the plan's toll free phone and TTY numbers for the enrollee, physician or representative to call if they need information or help. The plan must also insert the hours of operation for the call center and the plan's appeal website.

This section must always be included in the notice

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection is 0938-0976. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, and gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.