

**Form Instructions for the
“Notice of Denial of Medicare Part D Drug Coverage”
CMS-10146**

A Part D plan sponsor 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. Curly 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.

The Part D Denial Notice is available in English and Spanish. Part D plan sponsors should choose the version of the notice that will be readable and understandable for the beneficiary.

Please note that the OMB number must be displayed in the lower 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 prescribing provider, 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 Medicare Beneficiary Identifier (MBI).

Section titled: Coverage of your drug was denied

List the denied prescription drug or drugs requested by the enrollee or prescribing provider.

Section titled: Why was coverage for this drug denied?

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 (e.g., a Medicare National Coverage Determination, or a section of the plan’s Evidence of Coverage). A specific explanation about what information is needed to approve coverage must be included. If the drug could be approved under the exception rules, this section must explicitly state the need for a prescribing provider’s supporting statement and clearly identify the type of information that should be submitted when requesting a

formulary or tiering exception. Where applicable, the Part D plan sponsor should include excerpts from the plan's CMS-approved formulary, including detailed clinical information related to the plan's coverage criteria for the requested drug.

Additional Instructions for drugs not covered under Part D when the plan has determined that the drug is or may be covered under Medicare Part A or Part B:

In addition to the specific denial rationale described above, if the plan has approved coverage under Medicare Part A or Part B or believes that the drug is covered (or may be covered) under Medicare Part A or Part B, include the applicable bracketed language as described below:

MA-PDs: Where the plan processes a Part D coverage determination but determines that the requested drug is covered under Part A or Part B, insert the following additional text: "This request was denied under your Medicare Part D benefit; however, coverage/payment for the requested drug(s) has been approved under Medicare Part A/B {include an explanation of the conditions of approval in a readable and understandable format}. If you think Medicare Part D should cover this drug for you, you may appeal." If the plan determines that the requested drug is typically covered under Part B and instead processes a Part C organization determination, the plan must send the Integrated Denial Notice (CMS-10003) if coverage is denied under Part B (e.g., Part B drug step therapy requirements have not been met).

Standalone PDPs: Where the plan has determined that the requested drug is covered under Part A or Part B, or does not have sufficient information to make a favorable determination under Part D, insert the following additional text: "This request was denied under your Medicare Part D benefit; however, it may be covered under Medicare Part A or Part B. For more information, talk to your prescribing provider or call 1- 800-MEDICARE."

Section Titled: You have the right to appeal this decision

No information is required to be completed.

Section Titled: Who can ask for 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 2 Kinds of Appeals: standard or expedited (fast)

No information is required to be completed.

Section Titled: How to ask for an appeal?

Under the section titled "How to ask for an appeal?" the subsection titled "For a Standard Appeal" gives two options. If the plan accepts verbal requests for standard appeals, the plan must keep the information after the brackets that states "For plans that accept verbal standard requests". If the plan does not accept verbal standard requests, the plan must only keep the section after the brackets that states "For plans that do not accept verbal standard requests". Plans that accept verbal requests are required to enter the telephone number, TTY number, fax number, plan website and plan mailing address. Plans that do not accept verbal standard requests are required to enter fax number, plan website and physical address that the enrollee, prescribing provider's, or the enrollee's representative can use to mail an appeal request.

Section Titled: What to include with your appeal request

No information is required to be completed.

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, prescribing provider 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 website.

PRA Disclosure Statement 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 information collection is 0938-0976. This information collection is for the notice Medicare drug plans must provide when a request for a drug is denied in whole or in part. The time required to complete this information collection is estimated to average less than 30 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, to review and complete the information collection. This information collection is mandatory under Section 1860D-4(g)(h) of the Act and the regulatory authority set in Subpart M of Part 423 at 42 CFR 423.568 and 423.572. If you have 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, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.