OMB Approval No. 0938-0976

(Expires: 02/29/2020)

Form Instructions for the
"Notice of Denial of Medicare Part D Prescription 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 appropriate version of the notice based on the language the beneficiary best understands. Insertions must be in English when the English language Denial Notice is used. Similarly, when a Spanish language Denial Notice is used, the Part D plan sponsor should make insertions on the notice in Spanish, if applicable.

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 Medicare Beneficiary Identifier.

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 (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 prescriber'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 has determined 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."

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 prescriber or call 1- 800-MEDICARE."

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.