Crosswalk Document for Changes to CMS-10146
Notice of Denial of Medicare Prescription Drug Coverage
Submitted for Collection March 2010

Summary of Changes to CMS-10146:
The form "Notice of Denial of Medicare Prescription Drug Coverage" is used by Part D plans to notify an enrollee when the plan denies coverage for a prescription drug. Based on new regulations that permit a prescribing physician or other prescriber to request a standard redetermination (plan level appeal) on behalf of an enrollee, CMS has revised the denial notice to reflect this regulatory change so that the notice accurately informs Part D enrollees of the appeals process. This package also includes other changes (noted below) to the form and instructions based on formatting considerations (e.g., 508 compliance), the need for additional clarification, or comments received. These changes do not affect the hourly burden estimates associated with issuing the denial notice.

Changes made to the form

The following changes have been made to the form based on regulatory changes:

- Under the section entitled "Who May Request an Appeal?," the first sentence was modified to reflect the regulatory change that permits a prescriber to request a standard appeal on behalf of a Part D plan enrollee. The revised sentence states "You, your prescriber, or your representative may request an expedited (fast) or standard appeal." The revised sentence indicates that an enrollee's prescriber may request a standard appeal in addition to an expedited appeal. The subsequent sentence that is on the currently approved notice ("You or your representative may request a standard appeal") has been deleted because it is redundant with the revised version of the first sentence.
- Under the section entitled "There Are Two Kinds of Appeals You Can Request" on the second page, the section related to standard appeals has been modified to indicate that the enrollee's prescriber can request a standard appeal.
- Under the section entitled "How Do I Request an Appeal?" on the second page, the section related to standard appeals has been modified to indicate that the enrollee's prescriber can request a standard appeal and can do so by mailing or delivering a written appeal request to the address supplied by the plan.

The following changes have been made to the form due to formatting considerations, the need for additional clarification, or based on comments received:

- This package incorporates minor formatting revisions to the form and the instructions to better comply with 508 accessibility requirements. For example, use of all capital letters has been eliminated in the title "Important Information About Your Appeal Rights" on the second page and certain uses of parentheticals have been eliminated; for example, the use of "drug(s)" has been changed to "drug or drugs". Also, the abbreviation ("ID") for "identification" was removed

from the member number field for purposes of 508 compliance. The instructions explain that the field should be populated with the member's plan identification number.

- Language was added before the first free-text field on the first page of the notice to clarify that a denial in coverage includes a decision to deny payment for a drug. Specifically, the sentence has been revised to state "We have denied coverage or payment for the following prescription drug or drugs that you or your prescriber requested."
- Under the section entitled "There Are Two Kinds of Appeals You Can Request" on the second page, the section related to expedited appeals has been modified to clarify that an enrollee can't request an expedited appeal if the enrollee is asking to be reimbursed for a drug the enrollee has already received. CMS believes this language is better placed in the introductory paragraph of this section; accordingly, the last bullet point ("Your appeal will not be expedited if you've already received the drug you are appealing") has been deleted to eliminate redundancy.
- Under the section entitled "Other Resources to Help You," the field for including a TTY number for the Medicare Rights Center has been deleted because this is not information the plan can provide; instead, the plan provides its own TTY number in the previous section under "Contact Information." Moreover, existing instructions in the currently approved package for this collection properly indicate that "No information is required to be completed" by the plan in the "Other Resources to Help You" section.
- Based on a comment received and in an effort to streamline the form, the second line has been removed from the top of the page 2 ("For more information about your appeal rights, call us or see your Evidence of Coverage"). We believe this text is unnecessary given that the 2nd column of page 2 contains a section entitled "Contact Information" where the enrollee is instructed to contact the plan if information or help is needed; the Part D plan is required to enter the plan's telephone and TTY numbers in this section.
- Based on a comment received and in an effort to further clarify regulatory requirements related to expedited appeals, the second sentence of the second bullet point under the Expedited section (1st column, 2nd page) has been revised to state: "We will notify you if we do not give you an expedited appeal and we will decide your appeal within 7 days."

<u>Changes made to the instructions</u>

The following changes have been made to the instructions:

- This package incorporates minor formatting revisions to the form and the instructions to better comply with 508 accessibility requirements.
- The instructions for the "Date" field under the "Heading" section have been modified to reference the enrollee's prescriber. In other words, the instructions

now indicate that the plan should enter the month, day and year that the notice is issued to the enrollee, the enrollee's prescriber, or the enrollee's representative.

- Under the "Heading" section, "Member's Number" has been changed to "Member Number" to be consistent with that corresponding field on the form (this changes was based on a comment received during the 60 day comment period).
- Under the "Heading" section, the instructions clarify that when listing the denied drug or drugs, the plan should include denials related to requests for payment; this comports with the clarification made on the denial notice ("We have denied coverage or payment for the following prescription drug or drugs that you or your prescriber requested.").
- The instructions for the section titled "How Do I Request an Appeal?" have been revised to include references to the prescriber. This change is consistent with the corresponding changes to the denial notice, which indicate that the enrollee's prescriber can request a standard appeal on the enrollee's behalf.
- The instructions for the section titled "How Do I Request an Appeal?" have been revised to eliminate the use of "address(es)" and replaced with "address" for 508 compliance and to establish consistency with the use of "address" in the revised form.