

## Response to Comments for CMS-10147

### OMB Comments:

1. Based on Part A, my understanding is that the key change in this Revision is the elimination of a previously available option for pharmacies to post a general notice; instead, they are now required to hand out a paper copy to every beneficiary when a prescription can't be filled. I didn't see this shift reflected in the burden write-up, though. Can CMS add a discussion of what proportion of pharmacies have been using the general notice approach, and the amount that total burden will increase as a result of those pharmacies now being required to hand out individual notices?

**CMS Response: There is a detailed discussion of the burden of handing out the notice included in the burden estimate. We assumed all pharmacies took the option of posting the notice and therefore assumed the requirement to hand out the notice would be new for all pharmacies. I have pasted our analysis of the burden from our Supporting Statement below.**

“..Based on current prescription drug event data, the projected number of transactions (filled prescriptions) for 2010 is 1,123,860,661. Further, based on anecdotal information provided by pharmacy benefits managers (PBMs), approximately 10% (or 112,386,066) of these transactions do not get automatically processed and require some type of action at point of sale in an attempt to remedy the rejection. For example, a keying or data entry error may need to be corrected in order to process the transaction or the pharmacy may need to contact the plan to obtain an override on a systems edit. We estimate that these types of issues can be resolved at the point of sale for about two-thirds of the 112,386,066 rejected claims. In other words, for one-third (or 37,087,402) of the rejected claims, the pharmacy will not be able to process the transaction (fill the prescription) and will be required to provide the enrollee with the written standardized pharmacy notice. Again, assuming an average time per response of one minute (0.01666 hour), we estimate the total annual hour burden to be 617,876 hours (0.01666 multiplied by 37,087,402 notices). Applying the aforementioned hourly rate of \$13.50 per hour, this results in an estimated annual cost burden of \$8,341,326 (617,876 hours multiplied by \$13.50)..”

2. I thought that MAPRx's suggestion for including a brief checklist of possible reasons for denial sounded like a great idea:

In addition, MAPRx recommends that the form include a brief checklist of possible reasons for denial. The pharmacist would then check the relevant reason so the beneficiary receiving the notice would know exactly why the plan has refused to cover the prescribed drug. This checklist would include as an option a checkbox entitled “Other” along with a space for the pharmacist to indicate the reason for the denial. This list should be simple, brief and in plain language, similar to this example:

Your Medicare Part D prescription drug plan has denied coverage for the  
following reason:

\_\_\_\_\_ Prior Approval Required by Plan

\_\_\_\_\_ Exceeds Quantity Limits

\_\_\_\_\_ Step Therapy Required

\_\_\_\_\_ Other

Reason provided by plan: \_\_\_\_\_

CMS responded that “This type of customization is not supported by current coding. The pharmacist is unlikely to have the information necessary to complete these types of check boxes.” Could CMS please elaborate, either in writing or on a call? It seems logical to assume that a pharmacist would know why they are not able to fill a prescription, and that a simple indication of the reason could appear on the form as an aid to beneficiaries.

**CMS Response:** The NCPDP is the organization that develops the codes that are transmitted between plans and pharmacies. We have been informed by that organization that the claim reject coding is not detailed or explicit enough to help a pharmacist understand why the claim has been denied. While it may seem logical to assume that a pharmacist would know why they are not able to fill a prescription, this is often not the case. And it is certainly not in terms a beneficiary can understand. They really need to be directed back to the plan to get a full explanation of what they need to do to resolve the issue.

Additionally, many pharmacies will not be able to support a print-on-demand function that could be tailored to the specific claim transaction. Many pharmacies will have to pre-print a generic notice and hand that out. Such a pre-printed notice obviously cannot be customized and our requirements must be applicable to all pharmacies and claims.

Med Impact Comment:

Question: Is it required that the pharmacy provide the member with the notice for a drug that has been dispensed as a non-preferred drug? The third bullet on the notice for requesting a coverage determination “exception” states: “You need to take a non-preferred drug and you want the plan to cover the drug at the preferred drug price”.

Recommendation: We would like to recommend that bullet 3: “you need to take a non-preferred drug and you want the plan to cover the drug at the preferred drug price.” in the first section of the notice is removed or re worded as the guidance states the Notice should only be provided when the Part D rejection cannot be resolved at point of sale or the drug was covered by a supplemental payer.

**CMS Response:** Pharmacies are not required to provide the notice if a drug is covered by Part D as a non-preferred drug. However, we have retained the bullet point (“you need to take a non-preferred drug and you want the plan to cover the drug at the preferred drug price”) because enrollees do have a right to request a tiering exception in such a scenario. While it is not required, pharmacies are not prohibited from providing a copy of the notice in this scenario.