

**CENTER FOR MEDICARE ADVOCACY, INC.**  
1025 CONNECTICUT AVENUE NW, SUITE 709  
WASHINGTON, DC 20036  
(202) 293-5760 FAX (202) 293-5764  
www.medicareadvocacy.org

**ATTORNEYS**

Judith A. Stein\*  
Brad S. Plebani\*  
Margaret M. Murphy\*  
Pamela A. Meliso\*  
Gill Deford  
Alfred J. Chiplin, Jr.  
Toby Edelman  
Vicki Gottlich  
Patricia Nemore  
Mary T. Berthelot\*  
Mary A. Ashkar\*  
Abigail G. Sheehan\*  
Tiana V. Hercules\*  
Nancy V. Gifford\*  
David A. Lipschutz\*

**OF COUNSEL**

Sally Hart\*  
Wey-Wey Elaine Kwok\*

\*Admitted in other jurisdictions

**ADMINISTRATOR**  
Carolyn S. Boyle

**DATA PROJECTS COORDINATOR**  
Larry S. Glatz

**DATA MANAGER**  
Shaun Harrington

**CONSULTANTS**  
Ellen L. Lang, R.N., M.P.H.  
Marcus Tilton  
Jocelyne Watrous

July 29, 2011

**Submitted Electronically at regulations.gov**

Centers for Medicare and Medicaid Services  
Office of Strategic Operations and Regulatory Affairs  
Division of Regulations Development  
Attn: Document Identifier/OMB Control Number  
Room C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**Re: Comments to CMS-10147: Standardized Pharmacy Notice  
Document ID CMS-2011-0112-0001**

To Whom It May Concern:

The undersigned organizations are a coalition of consumer advocates with extensive experience assisting beneficiaries who confront pharmacy access problems in both the Medicare and Medicaid programs. We submit these comments to the above-referenced pharmacy notice.

General Comment re: Individualized Notices

We recognize that this notice follows the final regulations set out in CMS-4144-F, issued April 15, 2011, that require pharmacies to give a general notice that Medicare beneficiaries can contact their drug plans if they are told at the pharmacy that coverage will not be provided. Our organizations continue to assert, however, that individually-tailored notices provided at the point of sale that explain why coverage was denied are legally required. Until that requirement is met, though, we

believe that this standardized notice is an important interim step, and that the provision of a generalized notice to each individual is an improvement upon the current requirement that information merely be posted in the pharmacy.

We appreciate the opportunity to provide the following specific comments to the draft notice, organized by section.

#### First Section – Your Medicare Rights

The notice states that a beneficiary has the right to request a coverage determination from his or her “Medicare drug plan.” The phrase “or Medicare health plan” should be added to reflect that some people get their drug coverage through Medicare Advantage-Prescription Drug Plans (MA-PDs).

Among the reasons listed for which a beneficiary can request a coverage determination, the second bullet states that “A coverage rule (such as prior authorization or a quantity limit) should not apply to you for medical reasons.” The phrase “or if you have already met the coverage rule” should be added to this bullet so that it reads “A coverage rule (...) should not apply to you for medical reasons or if you have already met the coverage rule.”

We appreciate that the third bullet addresses a situation in which an individual might request an exception to tiered cost-sharing if they “need a non-preferred drug” and the individual wants “the plan to cover the drug at the preferred drug price.” In order to ensure that a beneficiary is aware of the right to make such a request, we suggest that instructions given to pharmacists about this notice include clear language about tiering exception scenarios. Currently, both the title of the notice “Your Prescription Cannot be Filled” and the accompanying Form Instructions for the notice which states that it must be used “[i]f the pharmacy cannot fill the enrollee’s prescription” do not adequately account for situations in which a beneficiary has a right to request a tiering exception. In other words, a prescription might be able to be filled, but an individual might not be able to afford it, or believe s/he should pay a preferred price. For example, if a beneficiary expresses to the pharmacist that s/he cannot afford a prescribed non-preferred drug, or asks about alternatives, instructions to pharmacists (and corresponding CMS manual provisions governing plan sponsors) should include this situation as one requiring distribution of this notice.

In addition, as proposed by the MAPRx Coalition in separate comments, we recommend that the form include a brief checklist of possible reasons for denial. The pharmacist should then be required to check the applicable reason so that 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. Although such a checklist would not contain all of the information

necessary to properly exercise one's appeal rights or other options under plan rules, such as a list of alternative drugs that are on the plan's formulary, a checklist would certainly aid an individual in understanding why a drug has been denied. As suggested by MAPRx, the list could be 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:

---

### Second Section – What you need to do

Similar to a comment above, the reference to contacting “your Medicare drug plan” should be expanded to include “or Medicare health plan” to account for individuals enrolled in MA-PDs.

We believe that the list of items an individual should have ready when they contact their health plan is helpful. We suggest that item number 2 about requesting exceptions be moved to the end of the list since not all enrollees will be requesting exceptions.

We suggest that a fifth bullet be added to this list to reflect an individual's right to request an expedited coverage determination. For example, language similar to the following could be used: “5. Whether you need the drug plan to make an expedited (faster than usual) decision on your coverage determination or exception request if your health is threatened (you can ask your doctor to support your request for a faster decision).”

In the last paragraph, time frames within which a plan must provide an enrollee with a written decision should be included, both for standard and expedited appeals.

### Language Access

Because the notice is both very important and short, we strongly recommend that CMS provide plans with model translations in 10-15 languages so that pharmacies serving individuals with needs for language services can have appropriate information available. Since the document is only one page in length, we also

recommend printing it in English on one side and Spanish on the other as a simple way to address the needs of the largest group of limited English proficient beneficiaries.

If multiple translations will not be immediately available, we urge that pharmacies be told to also include a one-page insert with tag lines in multiple languages telling recipients that they can get interpreter assistance in understanding the document by calling the plan's customer service number. We understand that CMS is in the process of developing this insert for inclusion with marketing materials and urge that it be used at the pharmacy as well.

We appreciate the opportunity to provide these comments. Thank you for your time and attention.

Sincerely,



David A. Lipschutz  
Center for Medicare Advocacy

On behalf of:

Families USA  
Tennessee Justice Center  
Medicare Rights Center  
National Senior Citizens Law Center  
National Health Law Program