Medicare Rights Center

BOARD OF DIRECTORS

Robert Arnow
Chairman
Weiler Arnow Management Co.

Marilyn Moon
Vice President, Health
American Institutes of Research

Donna Regenstreif
Senior Program Officer
John A. Hartford Foundation

Bruce C. Vladeck
Principal, Health Sciences Advisory
Ernst & Young LLP

Gordon Woodward
Partner
Kohlberg & Company, LLC

William Bernstein
Partner
Manatt, Phelps & Phillips, LLP

Diane Archer
Founder & Special Counsel
Medicare Rights Center

Micki Chen
General Counsel
Verizon Long Distance
Verizon Communications

Daniel A. DeVito
Partner
Skadden, Arps, Slate, Meagher & Flom LLP

Edith Everett
President
Everett Foundation

Salomeh Keyhani, M.D.
Assistant Professor, Departments of Health Policy & Medicine
Mount Sinai School of Medicine

Nina Lesavoy
Managing Partner
Cue Capital

Alan B. Lubin
Executive Vice President
New York State United Teachers

Stephen M. Merkel
Executive Managing Director
Cantor Fitzgerald, Inc.

Joel L. Olah
Executive Director
Aging Resources of Central Iowa

Robert M. Hayes
President
Medicare Rights Center

Washington, D.C. Office:

1030 15th Street, NW, Suite 250
Washington, DC 20005
Tel: 202-589-1316
Fax: 202-589-1310

Baltimore Office:

102 Pilgrim Landing
Baltimore, MD 21230
Tel/Fax: 410-752-3292

March 6, 2006

Centers for Medicare and Medicaid Services

PartDformularies@cms.hhs.gov

Re: Comments on Draft Transition Process Requirements for Part D Sponsors, February 2006 and 2007 Draft Guidelines --- Formularies, CMS Strategy for Affordable Access to Comprehensive Drug Coverage

Dear CMS Colleagues,

The Medicare Rights Center appreciates the opportunity to comment on the Draft Transition Process Requirements for Part D Sponsors, February 2006 and 2007 Draft Guidelines --- Formularies, CMS Strategy for Affordable Access to Comprehensive Drug Coverage. The Medicare Rights Center is the largest independent source of Medicare information and assistance in the United States. Founded in 1989, MRC helps older adults and people with disabilities get good, affordable health care. MRC is non-partisan and accepts no funding from the pharmaceutical industry.

Many of the transition process requirements for Part D sponsors proposed by CMS for 2007 would provide stronger protections for people with Medicare than the transition processes expected of sponsors in 2006.

Among the most significant of these proposals is the requirement that Part D sponsors provide transitional supplies for medicines subject to quantity limits, and that sponsors provide the same transitional protections for enrollees transitioning to a new level of care, and that sponsors provide access in the retail setting to at least one 30- day temporary supply during the first 90 days of enrollment.

The access problems that these proposed requirements address exist now. Consistent with the authority utilized by CMS to strengthen transition policies in the first month of 2006, CMS should require Part D sponsors to provide these and other protections outlined below immediately.

MRC supports CMS's proposal to require that plans include specific protections in their transitional processes, such as the requirement for a minimum 30-day temporary fill in the retail setting for non-formulary drugs and drugs subject to prior authorization or step therapy. The approach taken by CMS in its 2005 transition guidance –outlining expectations and suggesting preferable policies—resulted in grossly uneven implementation of transition processes by plans, and widespread and continuing problems in obtaining coverage for non-formulary drugs and those restricted by utilization management techniques. As a result, CMS has been forced to amend its transition guidance in an effort to shore up protections.

For example, on January 6, CMS belatedly told plans that transitional supplies must also be provided for drugs subject to prior authorization and step therapy. This is now an explicit requirement for 2007 transition policies, because, as CMS recognizes, "a formulary drug whose access is restricted via utilization management requirements is essentially equivalent to a non-formulary Part D drug to the extent that the relevant utilization management requirements are not met for a particular enrollee.[1]" **MRC supports this requirement and asks CMS to ensure that all plans are implementing it in 2006.**

The draft transition process requirements also mandate that plans provide transitional supplies for medicines subject to quantity limits, a requirement that MRC believes is vital. This requirement is not

currently imposed on Part D plan sponsors. As a result, MRC has fielded numerous complaints from people with Medicare who were denied fills for the full amount prescribed by their physician or denied fills for any of the prescribed drug (quantity limit edits can sometimes outright reject pharmacy claims for the drug in question). **We urge CMS to require all Part D sponsors to immediately provide transitional supplies for drugs subject to quantity limits. To the extent, safety concerns require that beneficiaries return to refill prescriptions in excess of the quantity limit, Part D sponsors should not impose additional copayments.**

MRC supports CMS requirement that plans provide temporary supply fills of at least 30 days duration "anytime during the first 90 days of a beneficiary's enrollment in a plan." The rationale for this proposal is even more compelling in 2006, when the mandatory 90 day transitional period expires at the end of March. The exceptions and prior authorization procedures for most plans are functioning poorly, if at all, requiring that plans implement the most robust transitional protections. **We urge CMS to require plans to extend the 90 days of transitional protections from the date of 2006 enrollment of all beneficiaries.**

Similarly, MRC supports the requirement that a change in the level of care, such as a transfer from a nursing home or hospital setting to a community setting, also trigger the same transitional protections as apply to new enrollees. Specifically, Part D sponsors must meet the same temporary supply requirements for non-formulary drugs and drugs restricted by utilization management for both community residents and those residing in long-term care facilities. **These protections should be put in place in 2006; there is no reason to delay their implementation until 2007.**

MRC supports the requirement proposed by CMS that transitional fills be provided at any time during the first 90 days a beneficiary spends in a long term care facility, and that emergency supplies outside the 90 day window last for at least 30 days**. These protections as well should be implemented in 2006.**

For 2007, CMS reiterates requirements, already applicable in 2006, that plans provide public notice of their transition processes, both as an important point of comparison for potential enrollees and as an educational service to advocates. CMS explicitly mentions that information on transition processes be available on plan websites and in enrollment materials. **CMS should clarify that existing public notice requirements for 2006 should be implemented by the prominent display of detailed transition protections on plan websites and in enrollment materials. CMS Prescription Drug Plan Finder should also provide a link to this information on plan web sites.**

MRC also commends CMS for requiring Part D sponsors to submit to CMS detailed descriptions of how transition processes, including the override of edits for nonformulary drugs and drugs restricted by utilization management, are implemented through electronic transactions with pharmacies. This information is crucial for an adequate review of the functioning of these transition processes. **Armed with the experience of 2006, CMS should only approve transition processes that have proven effective in 2006.**

In addition, MRC supports CMS's proposed requirements that plans notify beneficiaries within 72 hours of the provision of a transitional supply. **This notice should provide specific instructions on how to request a formulary exception or prior authorization, including the relevant forms and contact information for these procedures. Beneficiaries should also be provided with specific information on alternative medicines that are covered, including any utilization management restrictions and tiering information, if relevant. CMS should require that plans begin providing such notices immediately.**

MRC also supports the proposed requirement that Part D sponsors provide an edit code to pharmacies signaling that a claim was processed as a transitional supply. This will prompt pharmacists to inform customers that they may need to seek an exception to maintain coverage of the drug or that they may wish to have their prescribing physician switch them to a covered drug, if one is appropriate. This too should not wait until 2007.

2007 Draft Guidelines--Formularies

MRC supports the continuation of coverage mandates in 2007 of the “six classes of clinical concern”—the requirement that Part D plan formularies include all or substantially all drugs in the immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral and antineoplastic classes.

In particular, MRC would like to emphasize its support for the following proposal outlined in the draft guidelines:

“Part D plan sponsors may not implement prior authorization or step therapy requirements that are intended to steer beneficiaries to preferred alternatives with these classes for enrollees who are currently taking a drug. If a plan cannot determine at the point of sale that an enrollee is not currently taking a drug (e.g. new enrollee filling a prescription for the first time), plans shall treat such enrollees as currently taking the drug.”

In effect, this guidance requires that plans lift prior authorization or step therapy requirement if they cannot distinguish through their transaction with the pharmacy between a new prescription and a maintenance medication. In fact, for the overwhelming number of new enrollees, plans do not have the ability to make such distinction because they have no records of medication history and the information is not available through claims processing transactions with pharmacies. It would be unwise to further burden plan call centers and pharmacies with a requirement that pharmacies call plans about each individual case, particularly since pharmacists are unlikely to have definitive information (beneficiaries use multiple pharmacies or have switched pharmacies). **As a result, where plans do not have definitive information that the claim is for a new prescription, Part D sponsors should lift utilization management restrictions for all drugs in the six classes. Formulary guidance in effect for 2006 already outlines CMS’s expectation that utilization management would not force changes for patients already stabilized on drugs in these six classes. CMS should immediately inform Part D sponsors, that when they cannot distinguish between maintenance prescription, utilization management restrictions should be immediately lifted.**

Thank you for the opportunity to comment. Please contact Paul Precht, MRC policy coordinator, at 202-589-1316 with any questions.

Sincerely,

Robert M. Hayes
President
Medicare Rights Center