

March 17, 2009

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4138-IFC4
Mail Stop C4-26-05
7500 Security Boulevard,
Baltimore, MD 21244-1850

To Whom it May Concern:

The National Council for Community Behavioral Healthcare is pleased to offer comments on the Interim Final Rule CMS-4138-IFC4 - Medicare Program: Medicare Advantage and Prescription Drug Programs MIPPA Drug Formulary & Protected Classes Policies.

The National Council for Community Behavioral Healthcare is a non-profit association representing over 1600 community mental health and addiction organizations across the country. The National Council is dedicated to helping its members increase both access to care and the quality of clinical care delivered to persons with mental illnesses and addictions in this country.

The National Council supports the enactment of Section 176 of MIPPA and codification of the sub-regulatory guidance regarding the six classes of clinical concern that have been in place since 2005. The policy of identifying six protected classes was established to ensure that Part D beneficiaries have access to key medications including medications essential for the treatment of mental illness including anti-psychotics, anti-depressants, and anti-convulsants. Research and practice have demonstrated that individuals respond differently to these medications and guaranteeing access is essential for continued recovery. Maintaining an open process is essential to preventing barriers to access now and in the future.

The National Council strongly supports the statements in the Preamble to the Interim Final Rule (P. 2884) clarifying that CMS is retaining its authority under the MMA to continue to enforce the current six protected class's policy. It ensures that CMS will have the requisite legal authority to enforce this "all or substantially all" coverage policy for any of the six classes that do not survive the multi-level review process set forth in the Interim Final Rule. It is important that the protected classes be maintained. The separation of these six drug classes is based on the reality that these medications are not clinically interchangeable and that rigid formulary limits would pose a dangerous risk to the most vulnerable and medically fragile Medicare beneficiaries.

No language in MIPPA directs CMS to abandon its original mandate under the MMA to prevent discrimination and ensure that vulnerable beneficiaries that rely on drugs in these six classes are not substantially discouraged from enrolling in certain Part D plans or

prevented from accessing necessary therapies once enrolled in a plan. CMS remains responsible for protecting vulnerable beneficiaries from discrimination with regard to access, regardless of the process established around the protected classes. It is our hope that CMS will take a proactive role in ensuring that prescription drug plan sponsors are not placing arbitrary barriers to accessing critical medications.

Medically Accepted Indication

The rule states that for all Part D drugs not used in anticancer chemotherapeutic regimens, "medically accepted indication" has the meaning given in section 1927(k)(6) of the Act, except that in applying this provision, the Secretary shall revise the list of compendia described in section 1927(g)(1)(B)(i) of the Act as appropriate for identifying medically accepted indications for drugs, in a manner consistent with the process for revising compendia under section 1861(t)(2)(B) of the Act. The National Council supports the flexibility afforded to the Secretary to revise the list of compendiums used to identify medically accepted off-label indications. We also encourage the inclusion of expertise and professional oversight like those published in peer-reviewed articles.

Access to Covered Part D Drugs

With regard to the multi-level review process that CMS plans to use to identify the classes of medications that meet the criteria in MIPPA for protected status, the National Council is concerned that for the first level of review a contractor would only be tasked with assessing which classes meet the second criterion in MIPPA, i.e., whether there is a significant clinical need for individuals to have access to multiple drugs in a class due to unique chemical actions and pharmacological effects of the drugs in that class. We urge CMS to clarify that the contractor will also assess the drug classes using the first criterion in MIPPA, i.e., that restricted access to drugs in the class would have major or life threatening clinical consequences.

There are several references to major or life threatening clinical consequences associated with the protected classes. We encourage CMS to also insert this language in the first-level review to guide contractors to examine a wide array of evidence that includes observational studies, disease registry data, and expert opinions drawn from clinical guidelines. Given the complexity of weighing symptom relief vs. side effects in determining which medicines to use in the treatment of mental illnesses such as schizophrenia, information gathered during the first level review must take these issues into consideration as well as gaps in knowledge.

The second level review panel, as described in the interim final rule, will include only physicians and pharmacists. We strongly recommend that the panel should be structured in a way that keeps the unique interests of mental health patient populations in mind. The panel should consist of 3-4 actively practicing physicians with documented experience in caring for Medicare patients that fall within the therapeutic areas treated by these classes of drugs and should also include 3-4 individuals representing patient and consumer advocacy groups. In order to add any significant value to the patient and the Medicare program, all interests must be represented.

We support the utilization of the notice and comment process for all exceptions. We hope that this step will dissuade plans from seeking unnecessary exceptions that could curtail treatment choice and undermine recovery for a group of patients with very complex, co-morbid mental and physical health conditions.

Lastly, the National Council is concerned that CMS is misinterpreting the second criterion in MIPPA which requires a showing of a "significant clinical need for such individuals to have access to multiple drugs within a category or class due to unique chemical actions and pharmacological effects of the drugs within the category or class". We believe CMS may be interpreting this criterion to only capture drug classes for which an individual would need to take multiple drugs in that class at the same time. Congressional staff, responsible for drafting this provision in MIPPA, indicated that this interpretation of the second criterion is inconsistent with Congressional intent.

Sincerely,

A handwritten signature in cursive script that reads "Linda Rosenberg".

Linda Rosenberg, MSW
President & CEO