

December 7, 2009

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard,
Baltimore, MD 21244-1850

Re: CMS-4085-P

To Whom it May Concern:

The National Council for Community Behavioral Healthcare is pleased to offer comments on the proposed rule on Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs published on October 22, 2009.

The National Council for Community Behavioral Healthcare is a non-profit association representing nearly 1700 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.

Data on the Medicare program suggest that anywhere between 16%-25% of beneficiaries have a mental disorder;^{1,2} additionally, data on Medicare beneficiaries who are dually-eligible for the Medicaid program shows that an estimated 34% of these beneficiaries have a mental disorder.³ For many individuals with mental illnesses, access to prescription medications is a vital component of a comprehensive treatment plan. Similar to beneficiaries with other chronic conditions, the Medicare Part D program serves the critical function of providing access to needed prescription medications.

Findings from a recent National Council survey of its membership indicates that many community-based mental health providers have seen increased use of utilization management and cost-sharing techniques in Medicare Part D this year, as compared to 2008.⁴ In fact, 84.3% of provider respondents indicated that their Part D clients (includes dual-eligibles) have been subjected to utilization management techniques at an increased rate this year. Similarly, 75% of provider respondents indicated that their clients have experienced an increased financial burden, primarily in the form of higher co-pays, when attempting to fill a needed mental health prescription in 2009.

Just as there is understanding of the importance of providing individuals with mental illness access to prescribed medications, several studies have indicated that the use of utilization management techniques – such as step therapy, utilization review, and prior authorization – have a negative impact on the overall well-being of individuals with mental illnesses. Such ‘spill-over effects’ can be seen in increased rates of emergency department visits, hospitalizations, homelessness, and incarceration.^{5,6}

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 these exceptions is of critical importance for persons with serious mental illness who often respond differently to mental health prescription medications. If a clear prohibition on the application of utilization management restrictions on anti-depressants, anti-convulsants, and anti-psychotics is not possible, the National Council urges CMS to clarify that the “scientific evidence” needed for an exception must clearly indicate that application of plan strategies to restrict access – such as utilization management – 1) supports effective use of these medications, 2) does not increase the risk of premature discontinuation of drug therapy, 3) and produces overall cost-savings.

In addition, as CMS implements the proposed process for establishing protected therapeutic categories and classes pursuant to MIPPA, the National Council respectfully requests that it gives further consideration to the following:

- Relying on the exceptions and appeals process, rather than the protected classes policy places an increased burden on providers and beneficiaries to gain access to needed medications. This process, including submitting appeals, requires providers and beneficiaries to take additional time to receive authorization for medications, thus adding additional barriers to access. Adopting the proposed definition of “significant need for access to multiple drugs” in a manner that incorporates a timeframe for access (as suggested by the proposed rule) is not only unnecessary, it is beyond the policy established in the statute.
- Having a vague time limit within which restricted access must result in major or life threatening clinical consequences to a beneficiary creates unnecessary ambiguity for providers and could place beneficiaries in a situation in which they are inappropriately prevented from accessing needed medications.
- Establishing any exceptions to the statutory requirement that all Part D drugs in the protected categories and classes be included on formulary until the process for establishing such exceptions is finalized will inappropriately allow plans the opportunity to limit access to medications in the protected classes. The process of finalizing the exceptions, as required by MIPPA, was established in a manner to ensure that proper stakeholder input is involved; circumventing this process will only lead to ambiguity that could potentially allow plans to establish exceptions that would not have been put in place had the correct process been observed.
- Limiting the utilization management tools that plan sponsors may impose on drugs and biologics within the protected categories and classes is extremely important to ensure access and fortifies the intention of establishing the protected categories and classes.
- Defining the “widely used treatment guidelines” to include any array of sources, including national guidelines, Part D compendia, and medical journals will appropriately include advances in the field and allow providers the necessary flexibility to effectively treat beneficiaries with mental illnesses.
- Describing – in detail - how Prescription Drug Event data will be used in establishing the protected categories and classes and the inclusion of drugs and biologics within those categories and classes will help provider organizations to ensure that they are appropriately

trained and prepared to meet reporting standards. Additionally, it is important to acknowledge that claims data is inherently limited as a method to forecast future beneficiary needs.

- As an opportunity to provide greater transparency and stakeholder involvement, adopting a formal notice and comment rulemaking process for establishing and revising the protected categories and classes will help to ensure proper and timely adoption of any policy changes.

Thank you for taking our comments into consideration.

Sincerely,



Linda Rosenberg, MSW
President & CEO

¹ Kaiser Family Foundation. "Dual Eligibles and Medicare Part D". May 2006.

² Loftis, C. & Salinsky, E. "Medicare and Mental Health: The Fundamentals". National Health Policy Forum, George Washington University. 2006.

³ Kaiser Family Foundation, "Dual Eligibles and Medicare Part D". May 2006.

⁴ National Council for Community Behavioral Healthcare. "The Medicare Part D Program: Ability of Individuals with Mental Illnesses to Access Needed Prescription Medications". November 2009.

⁵ West, J., Wilk, J, et al. "Medicaid Prescription Drug Policies and Medication Access and Continuity: Findings from Ten States". *Psychiatric Services*. May 2009. Vol. 60(5).

⁶ Huskamp, H., West, J, et al. "Part D and Dually Eligible Patients with Mental Illness: Medication Access Problems and Use of Intensive Services". *Psychiatric Services*. September 2009. Vol. 60(9).