

Thank you for providing the opportunity for the College of Psychiatric and Neurologic Pharmacists (CPNP) to comment on the proposed rule for the 2015 Medicare program published in the Federal Register on January 10, 2014; file code CMS-4159-P.

CPNP is a professional association of specialty pharmacists who work to improve the minds and lives of those affected by psychiatric and neurologic disorders. These professionals apply their clinical knowledge in a variety of healthcare settings and positions ranging from education to research to clinical practice with the goal to apply evidence-based, cost efficient best practices in achieving patient recovery and improving quality of life.

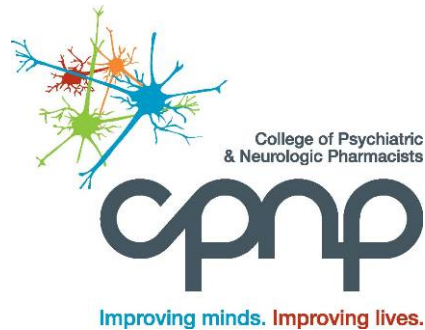
CPNP would like to take this opportunity to comment on 2 issues presented in the proposed changes.

#### **1. Medication Therapy Management Services (§ 423.153(d))**

Overall we applaud CMS for efforts to broaden the eligibility for medication therapy management (MTM) services. We support the use of the comprehensive medication review (CMR) as the most effective way to engage with beneficiaries to identify and solve drug therapy problems.

As pharmacists specializing in medication management for people with mental illnesses, CPNP is especially interested in the efforts to engage the low income subsidy (LIS) population, especially those with disabilities such as mental illnesses. We agree that simplistic one-size-fits-all strategies are unlikely to engage this patient population. But beyond multiple outreach strategies to this population, we believe that it is important to use pharmacists in the community who may have a pre-existing personal relationship with the patient to provide MTM services. Given the impact of some mental illnesses on cognition, communications and the development of interpersonal relationships, such a strategy may be more acceptable to patients and more likely to succeed than a consultation taking place over the phone with an unknown pharmacist.

We believe that these same issues call for the use of pharmacists who have additional education, training, and experience in working with people with mental illnesses, such as board certified psychiatric pharmacists (BCPP). Given their experience and training, BCPPs are the ideal individuals to provide CMR to people with mental illnesses. The use of BCPPs provides an opportunity to improve outcomes and reduce costs associated with common drug therapy problems such as poor adherence, drug interactions, adverse reactions, and an accumulation of duplicate or unnecessary medications. These drug therapy problems often result in both high drug cost and high overall cost of medical care. The high cost of medical care may be as a result of poorly treated psychiatric disorders but also due to higher rates of



resource utilization such as readmission rates for the treatment of medical conditions in patients with mental illnesses.

In summary, we would suggest that MTM programs contract with board certified psychiatric pharmacists in the patients' community who can provide face-to-face medication management services for patients with mental illnesses. Accountable care organizations, patient-centered medical homes, community mental health centers, federally qualified health centers, and psychiatric pharmacist provider networks all present opportunities for such contracts.

## **2. Drug Categories and Classes of Clinical Concern and Exceptions (423.120(b)(2)(v) and (vi))**

CPNP believes that appropriate use of all medications, but particularly antidepressants and antipsychotics results in the best possible outcomes for patients and the best possible use of healthcare resources. We support the ability of plans to be able to negotiate with pharmaceutical companies for the best possible drug costs or supplemental rebates. However, any financial considerations must be tempered by the development of patient friendly procedures that safeguard the clinical needs of patients. Such safeguards could include "grandfathering" of patients already on stable therapy and step therapy options that increase the number of options available to patients who need them without carrying the tiered copayment structure of current programs.

We remain concerned that access to as few as five antipsychotics or nine antidepressants (based on the USP Medicare Model Guidelines Classes) may not recognize the tolerability and individual patient response differences among these agents. As a category, the antipsychotics vary dramatically in rates of movement disorder side effects, sedation, metabolic effects such as diabetes, weight gain, and dyslipidemia, and for other medications, activation or agitation. Although research does not show superior efficacy of antipsychotic over another within a population, there is clear evidence that an individual patient may respond to one agent and not another. This underscores the need for access to a range of antipsychotics to treat the individual patient. Consultation with the patient's mental health care providers is key to providing the best care and most effective outcomes.

Reducing access to necessary medication may reduce drug costs while inadvertently increasing overall healthcare costs. This could result from drug discontinuation due to adverse effects or non-adherence, emergency room visits for adverse effects or relapse, health costs of exacerbated comorbid conditions or even hospitalization. In addition to the financial costs, one must consider the human costs due to loss of control of co-occurring medical conditions, worsening of substance use disorders due to self-treatment, or an increased risk of suicide or violence due to inadequate treatment. We recommend that plans be required to include a psychiatrist or board certified psychiatric pharmacist on their formulary or

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pharmacy and therapeutic committees. We encourage CMS to require plans to offer a range of medications within the established categories and classes, even if limitations are developed. In addition to encouraging provisions for “grandfathering” and copay independent step therapy, we wish to emphasize the need to develop clinically oriented review processes using appropriately trained pharmacists or psychiatrists to consider prescriber requests for non-formulary medications that may be in the individual patient’s best interest. In addition to being clinically based, these reviews must occur in a prompt manner that avoids delays that may result in hospitalization, disability or loss of life. Furthermore, these processes must reflect the different needs of patients with mental illnesses.

We appreciate the efforts of CMS to allow plans to address the inappropriate use of antipsychotics for off-label or unsafe uses. However, patients with serious mental illnesses such as major depression, bipolar disorder, and schizophrenia may be inadvertently harmed by the efforts to target inappropriate use in other conditions. Perhaps CMS should consider allowing open access to psychiatric medications for patients with indicated uses while focusing efforts on reducing inappropriate use.

CPNP applauds CMS for addressing medication therapy management and the expense of mental health drugs. Study after study has proven that direct patient interaction with the patient’s pharmacist improves patient outcomes and saves money. The team approach promoted by the Affordable Care Act provides these same benefits when applied to the treatment of those with psychiatric illnesses. We strongly urge CMS to promote and encourage the use of psychiatric pharmacists in interdisciplinary care of patients.

We thank you again for the opportunity to comment on these proposed changes.

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