Introduction

Chairman Smith and members of the committee, my name is Dr. Carl Clark and I am the Chief Executive Officer of the Mental Health Center of Denver. I have been a practicing psychiatrist for over 20 years, and I am also an Assistant Professor at the Department of Psychiatry at the University of Colorado School of Medicine. The mental health center I administer serves thousands of indigent and uninsured people annually, including a very large number of individuals with severe mental illnesses like schizophrenia and bipolar disorder.

I am proud to say that this testimony reflects the consensus views of the National Council for Community Behavioral Healthcare (NCCBH), American Psychiatric Association (APA), the National Alliance for the Mentally Ill (NAMI), the National Mental Health Association (NMHA), and the Treatment Effectiveness Now Project.

Vulnerable Dual Eligibles: A Patient Example

Although each of these organizations is strongly committed to the successful implementation of the Medicare Prescription Drug Modernization Act (MMA), we are concerned about the required transition of persons eligible for both Medicare and Medicaid to the new Part D drug benefit. Here's why. Medpac recently estimated that almost 40% of the 6.5 million dual eligibles have cognitive impairments or mental illnesses. Additionally, dual eligibles are twice as likely to have Alzheimer's disease as other Medicare beneficiaries. Thus, many of these persons may lack the capacity to

manage the automatic enrollment process and ensure their enrollment in a plan that provides seamless coverage for the medications they need.

Let me take a brief moment to put human face on those statistics. At the Mental Health Center of Denver, I am personally responsible for the mental health care of a man who is dually eligible. Due to patient confidentiality, I can't tell you his real name, so let's call him Peter. Peter is in his late 50's, and he was a homeless man who wandered the streets of Denver for many years due to untreated schizophrenia. Through a combination of intensive services and some of the latest psychotropic medications, we were able to get him off the street; he's now living independently in the community, and he's gone back to school. You should know that in addition to his severe mental illness, Peter also has diabetes and coronary artery disease. Mr. Chairman, I won't go into the detail, but suffice it to say that Peter is taking a wide array of medications to control each of these chronic illnesses. His day-to-day medical management is extremely complicated.

MMA Enrollment Challenges

Because of the special health care needs of dual eligibles, the Center for Medicare and Medicaid Services (CMS) included a provision in the final MMA rule requiring that this population be automatically enrolled in Part D plans. The mental health community applauds Dr. McClellan for taking this critically important step.

However, even with these provisions, we remain deeply concerned about MMA implementation. CMS has stated that dual eligibles with severe mental illnesses who are randomly assigned to plans that don't reflect their current medication regimens can re-enroll into PDPs that do. Based upon my years of clinical experience with this population, I have very serious doubts about this approach.

Let's go back to Peter for just a moment. His schizophrenia severely impairs his cognitive functioning including memory, speech, information-processing and decision-making. The odds aren't very good that he will successfully navigate the plans available in the Denver region to find one that meets all his medication needs. In effect, the overloaded case managers at the Mental Health Center of Denver and Peter's family will have to help him. But Peter's mother is 80 years old and doesn't even live in Colorado. And my case managers are struggling to handle their existing responsibilities, much less help thousands of patients find new PDPs.

Patient Protections

The end result could well be significant coverage gaps for particular medications required by some of the most disabled people in our society for weeks or even months after initial MMA implementation. By contrast, CMS has the regulatory authority to adopt a more practical approach to ensure continuity of care for this vulnerable population.

Specifically, we propose a regulatory strategy that permits beneficiaries – clinically stabilized on antipsychotic medications and other psychotropic medications – to maintain access to those same medications regardless of the PDP they are enrolled in. This exception to a plan's formulary or utilization process would be automatically granted – without prospective review by the PDP – when the attending physician provided written certification that the patient is clinically stable and the medication is medically necessary to maintain the patient's functioning. The physician would also be required to certify that mandatory switching to alternative drugs on the formulary would be medically contraindicated; plans should defer to the physician's medical determination.

Since the final MMA rule requires plans to have "an appropriate transitional process" for dual eligibles during the initial enrollment period, CMS should employ its review authority to ensure that these key continuity of care principles are followed. Let me note that the agency – in its own strategy on formulary review – noted that formularies should contain the majority of antidepressant and antipsychotic medications and further stated: "When medically necessary, beneficiaries should be permitted to continue utilizing a drug that is providing beneficial outcomes." Of course, the level of agency review we are seeking would supplement the formulary exceptions process outlined in the final rule. In addition, CMS or PDPs would have to furnish providers with the resources – technical or otherwise – to verify enrollment.

This regulatory approach should be combined with a robust outreach and education program designed to educate consumers while helping state agencies, patient and family organizations, and community mental health providers furnish the one-one-one counseling that will clearly be required.

Denial of Continuity of Care: The Consequences

I want to close by emphasizing what is at stake here. If CMS fails to adopt the common sense continuity of care approached we've outlined, the clinical consequences for the individual are serious indeed. The medical literature indicates that a very large percentage of patients forced to switch medications will fail. Typically, this means rapid de-compensation into psychiatric crisis – usually in matter of days. To stabilize the patient again requires an emergency room admission followed by a lengthy stay in psychiatric hospital. Of course, there is the ever present threat of suicide during this terrifying downward spiral.

The consequences for state governments are also significant. It is distinctly possible that dual eligibles with severe mental illnesses who fail to successfully navigate the transition to the new Part D benefit could end up destitute, homeless or in state prison. Mr. Chairman, my staff and I worked very hard over many months to get Peter off the streets of Denver. Let's make sure he stays in school and lives in the community where he belongs.