



October 1, 2004

Mark B. McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
PO Box 8014
Baltimore, MD 21244-8014

Dear Dr. McClellan:

Attached are comments on the Centers for Medicare and Medicaid Services proposed rule, "Medicare Program; Medicare Prescription Drug Benefit" prepared by the Pennsylvania Community Providers Association (PCPA). PCPA represents more than 150 community mental health, substance abuse and mental retardation service providers in Pennsylvania.

Access to a wide variety of prescription medications is imperative for the populations that our members serve. Indeed, for persons with mental illnesses, continuity in medication use is critical. For such vulnerable persons, sufficient time must be allocated for outreach and education to allow enrollment choice and to ensure that there are no gaps in service. Also, plans must not be permitted to involuntarily disenroll some of the most severely impaired persons, such as those with mental illnesses and dementia, for "disruptive" and "noncompliant behavior," when it is often their illness and condition that causes such behavior. The processes for grievances and appeals are overly complex and take too much time for persons who are so very ill to navigate. They must be simplified, streamlined, and made more independent of the plans.

Thank you for this opportunity to comment.

Sincerely,

George J. Kimes
Executive Director

Attachment

Comments submitted by the Pennsylvania Community Providers Association on Centers for Medicare and Medicaid Services proposed rules "Medicare Programs; Medicare Prescription Drug Benefit" (CMS-4068-P) on October 1, 2004. Comments reference the affected section of the rule.

§ 423.34 Enrollment process.

The impact of the enrollment process for the Medicare prescription drug benefit on dually eligible individuals, those who currently have drug coverage through the Medicaid Program, is of great concern. As Medicaid drug coverage ends for dual eligible individuals on January 1, 2006, disruptions in service are very likely. CMS must ensure that vulnerable beneficiaries, especially those who have mental illnesses, are enrolled in prescription drug plans (PDPs) before their Medicaid benefit ends so that there can be continuity of service. This can be done, either through automatic enrollment in a plan with the ability to switch to another plan of choice, or by extending the deadline for switching coverage from Medicaid to Medicare. The deadline should be extended for at least six months, while outreach efforts are undertaken to educate and enroll vulnerable beneficiaries.

Also, provisions must be included to ensure continuity of psychiatric medications in the transition from Medicaid to Medicare coverage. Changing medications used to treat mental illness is very difficult and harmful to the individual. Provisions are needed to ensure grandfathering of medications used to treat mental illnesses to minimize harm to individuals resulting from changing medications. PDPs open to enrollment by dually eligible beneficiaries are those that offer "basic prescription drug coverage." Because these programs will likely have very restrictive formularies, an exception process is needed to ensure that persons with mental illnesses have access to a broad variety of medications that may best meet their needs.

§ 423.44 Disenrollment by the PDP.

Allowing PDPs to disenroll individuals for "disruptive behavior" will effectively deny coverage for those who arguably need it most. This provision could be interpreted to permit exclusion of persons with dementia, mental illnesses, or mental retardation whose disruptiveness and lack of compliance arises from their illness or condition. Further, PDPs can use an expedited disenrollment process for disruptive behavior. Also, PDPs can refuse to reenroll an individual for an unspecified period of time. An individual who is involuntarily disenrolled from a PDP may enroll in another, although subject to a late enrollment penalty. These provisions must be removed.

The language in §423.44(b)(2)(v) that an "individual materially misrepresents information, as determined by CMS, to the PDP sponsor that the individual has or expects to receive reimbursement for third-party coverage" is problematic. It is not

clear that mistakes or inadvertent omissions would be excluded as criteria for disenrollment.

§ 423.120 Access to covered Part D drugs.

Use of formularies by PDPs or Medicare Advantage (MA) organizations must not be so restrictive as to preclude inclusion of branded medications for those who require them. Utilization management processes that restrict access to medications for certain conditions, such as mental illnesses, are detrimental to successful treatment. Therapeutic equivalency is imprecise and does not guarantee that one generic medication has the same effect as another or as the original branded product. Because the likelihood of recovery is diminished if the first course of treatment fails, and physicians must take great care in crafting drug therapies for each individual with mental illnesses, a broad spectrum of medications must be available. This is especially true for older adults who often use multiple medications to treat their health conditions. The use of an open formulary for persons with mental illnesses is strongly encouraged.

§ 423.153 Cost and utilization management, quality assurance, medication therapy management programs, and programs to control fraud, abuse, and waste.

PDPs and MA-PD plans must not use utilization management processes that require prior authorization, fail first and step therapy for persons with mental illnesses. These processes are very harmful and must not be permitted.

Subpart M – Grievances, Coverage Determinations, and Appeals

Requirements in this section are overly complex and inaccessible to this vulnerable population. Many levels of internal appeal are required before an appeal can be made to an administrative law judge. Access to an administrative law judge is not always possible. Persons with mental illnesses and others who have severe impairments will have great difficulty navigating these complex and protracted processes. Simpler and quicker processes that require expedited review for immediate needs must be established.

No further comments at this time.