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Statement of the

American Psychiatric Association

for the

Senate Committee on Finance

on

Implementation of the New Medicare Drug Benefit

February 8, 2006

The American Psychiatric Association (APA) thanks Chairman Grassley, Ranking Member Baucus, and members of the Finance Committee for your commitment to ensuring that the Medicare Part D program plays an effective role in the nation's efforts to provide the highest quality medical care to our seniors and disabled adults. The APA represents more than 36,000 psychiatric physicians nationwide who specialize in the diagnosis and treatment of mental and emotional illnesses and substance use disorders. We too are committed to the success of Medicare Part D.

INITIAL IMPLEMENTATION PROBLEMS

Unfortunately, widespread problems persist as the Medicare Part D program is being implemented. Many of these problems concern the transition of Medicare/Medicaid dual eligibles to Part D drug plans, and 27 states have spent millions of dollars covering the medication costs of these beneficiaries on an emergency basis. Common problems include inaccurate enrollment data, excessive charges for deductibles and co-payments, drug plans failing to provide a temporary transition supply to beneficiaries stabilized on drugs, and ineffective use of the fallback drug plan. As a result, thousands of Part D beneficiaries are unable to access their medications.

The APA has received numerous reports of patients forced to go without mental health medications due to these problems. For example, in Alabama, two patients were hospitalized when they were denied medications and experienced a relapse of acute psychiatric symptoms. In Massachusetts, beneficiaries were unable to obtain clozapine, an antipsychotic often employed for the most severe forms of schizophrenia. In Wisconsin, beneficiaries were unable to obtain coverage for dosages of mental health drugs recommended by practice guidelines. Plans would only cover lower doses. In Minnesota and Florida, plans failed to comply with the transition policy of the Centers for Medicare and Medicaid Services (CMS), barring access to vital medications that had been covered under previous drug coverage. In some cases, plans claimed they were unaware of this transition policy. These examples are only a small sample of the experiences of psychiatrists across the country.

ENSURING CONTINUITY OF CARE

The APA is deeply concerned that patients unable to access psychotropic medications will suffer serious consequences. When mental disorders such as schizophrenia, bipolar disorder, or major depression are inadequately treated, the risk for loss of function, hospitalization, co-morbid medical conditions, and mortality is substantially elevated. Elevated risk for negative patient outcomes begins when patients are unable to continue taking their medications. Interrupting a regimen for even a day or two may result in a psychiatric crisis for a patient. CMS recognized the vital importance of psychotropics by including antipsychotics and antidepressants among the six categories of drugs for which plan formularies were required to provide access to "all or substantially all" available medications in order to comply with a June 2005 CMS guidance.

It is urgently important that Part D implementation problems be resolved so that patients can access medications without being told at the pharmacy that they are not covered by the plan in which they enrolled, that they must pay a deductible or co-pay that does not apply to them, or that no information is available about a plan's prior authorization policies.

Other widespread problems may emerge. As the program enters its second month, millions of beneficiaries and their doctors will be faced with decisions about switching medications. Required temporary "transition supplies" of medications will be depleted, and patients whose medications are not covered by the plans they have enrolled in will need prescriptions for covered drugs. Doctors will have to work with patients to weigh a number of factors in deciding which medications should be switched, including the drugs available on plan formularies, the history of treatment with different medications, side effects, drug interactions, and co-morbid conditions. Often, it will be necessary to employ Part D appeals processes to obtain exceptions to plans' coverage determinations for medications.

It is vitally important that the widespread data, customer service, and formulary policy difficulties experienced by drugs plans in January not continue into this "medication switching" stage of implementation. Ensuring continuity of care for beneficiaries requires that Part D processes be transparent, user-friendly, and timely. To avoid further problems, it will be necessary to address a number of issues:

- **Emergency one-time fills.** CMS's transition guidance to drug plans articulated an expectation that Part D beneficiaries experiencing difficulty in having prescription refills covered would be provided with an emergency supply of medications until administrative concerns are resolved. Many plans did not comply with this policy and there are many reports that plans persist in non-compliance even after problems are reported to CMS. It is important that CMS actively enforce the transition policies that have been extended for 60 days.

- **Continuity of care for patients with serious medical conditions.** Guidance issued by CMS in June 2005 requires "all or substantially all" drugs to be covered by the plans in six categories: antidepressants, antipsychotics, anticonvulsants, anticancer drugs, immunosuppressants, and drugs for HIV/AIDS. The guidance was based on the complexity and high cost of the diseases these drugs treat as well as evidence-based practice. CMS also stated that plans must presume that new enrollees submitting refills for drugs in these categories are stabilized on these medications. CMS directed the plans to have transition policies in place to ensure that patients are able to fill these prescriptions without being subject to prior authorization or restrictive formulary policies – and they should be able to continue doing so. Unfortunately, many drug plans do not have effective transition policies in place and complaints to CMS have not improved performance. Improved enforcement is also needed in this area during the extension of transition policies.

- **Ongoing continuity of care issues.** The "all or substantially all" guidance also recommended that flexible formulary policies be maintained after the transition period, since beneficiaries can be expected to experience "unplanned transitions," such as a change of medications after a hospital visit. Further, beneficiaries may need exceptions to formulary policies when required for unique clinical situations. In this regard CMS stated, "In all cases, we make it clear [in our final rule] that a Part D plan sponsor is required to make coverage determinations and redeterminations as expeditiously as the enrollee's health condition requires." This flexibility in formulary policies is crucial to ensuring

continuity of care in drug therapies, and it should be continued as an ongoing policy after the implementation period is over.

- **Coverage explanations.** Reports are emerging that plans are not providing beneficiaries with the coverage explanations CMS requires so they know what drugs each plan covers. This information should be made available to beneficiaries on Web sites, by telephone, and through printed documents.

- **Notification of appeal rights.** There have been complaints that plans are not notifying beneficiaries of their right to appeal coverage determinations and that inadequate directions are communicated to those who wish to file appeals.

- **Administrative burden.** Patients and practitioners face significant resource demands in dealing with the Part D program. They will spend significant amounts of time learning about formulary policies, assessing the clinical factors involved in switching medications, and considering the costs patients are able to bear. Information tools should be developed to assist patients with these activities and physicians should be compensated for clinical decision making.

PART D COVERAGE FOR IMPORTANT MEDICATIONS

In addition to addressing ongoing implementation problems, the Committee is urged to develop legislation that will clarify CMS formulary policies and expand Medicare Part D coverage to ensure that patients have access to the full range medications used in the treatment of mental illnesses and substance use disorders. Unfortunately, for a number of clinically important medications for the treatment of these disorders, the Part D program fails to provide adequate coverage, and for some categories of medications, provides no coverage at all. Access problems exist for a number of addiction treatment medications because they are inappropriately classified in formulary guidelines. Other medications are excluded from statute governing the Part D program. Legislative action should address several issues:

- **Re-classification of addiction treatment medications.** The model formulary guidelines developed by U.S. Pharmacopeia (USP) for Medicare Part D mis-classify medications used to treat substance use disorders. As a result, drug plans may fail to include these medications in their formularies or may apply inappropriate utilization review procedures in making coverage determinations. Specifically, two drugs proven clinically effective in the treatment of opioid dependence, methadone and buprenorphine, are listed as analgesics as opposed to addiction treatment medications. Naltrexone is included in the USP guidelines for the treatment of opioid dependence, but it is also used as an alcohol deterrent, and should be covered for this use as well. Congress should pass legislation to instruct CMS to fix this problem by working with USP to change the model formulary guidelines or by issuing guidance to drug plans.

- **Adding coverage of benzodiazepines.** Benzodiazapines are sedative agents that have significant clinical value in treating a number of medical conditions, including anxiety disorders, panic disorders, seizure disorders, skeletal muscle spasticity, and the nausea and

vomiting associated with cancer chemotherapy. Congress should amend the Part D statute to include coverage of these medications.

- **Adding coverage of barbiturates.** Barbiturates are sedative agents that are clinically effective in treating seizures associated with epilepsy and head injuries. In addition, they effectively treat insomnia. Legislation should require the Part D program to cover this category of medications.

RECOMMENDATIONS

These issues must be addressed to ensure the success of the Medicare Part D program. The APA recommends that the Committee consider the following approaches to improving the program:

- Require CMS to report on drug plans' progress in implementing effective transition policies. It is important that CMS enforce requirements that plans provide emergency prescription fills or waive formulary policies as necessary to ensure that drug therapies are not abruptly interrupted.

- Request that CMS re-state its "all or substantially all" guidance to the plans, directing them to have formulary policies that allow ongoing, flexible access to exceptionally important categories of drugs (such as antipsychotics, antidepressants, anticonvulsants, anticancer drugs, immunosuppressants, and HIV/AIDS drugs) beyond the initial transition period. In addition, CMS should be provided with adequate statutory authority to enforce this policy with plans.

- Ask CMS to monitor the plans' exceptions and appeals processes and report on the number of beneficiaries filing appeals, the timeliness of response, and the final resolution of appeals.

- Pass legislation to address inadequate Part D coverage of important categories of medications, including addiction treatment medications, benzodiazepines, and barbiturates.

- Establish a CMS advisory committee, with wide stakeholder representation, to identify persistent problems and short- and long- term correctives to these problems.

We look forward to working with you to help the Medicare Part D program effectively support high quality medical care.

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