

United States Senate

WASHINGTON, DC 20510

August 1, 2011

Via Electronic Transmission

Honorable Donald Berwick, M.D.
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Berwick:

We are writing to follow-up on our May 6, 2011 letter on the report issued by the U.S. Department of Health and Human Services Office of Inspector General (HHS OIG) titled, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*. In that letter, we requested that the Centers for Medicare and Medicaid Services (CMS) provide answers to a series of questions, to which we are awaiting a timely response.

Upon further review of several of the key findings in the HHS OIG report, we now request that parallel concerns about overutilization of these drugs in connection with pharmaceutical benefit managers (PBMs) also be addressed.

In CMS' response to the aforementioned HHS OIG report, the agency acknowledged that contractual financial incentives with long-term care pharmacies (LTC pharmacies) can drive up the use of antipsychotics among nursing home residents. CMS also stated that it is exploring "alternative methods" within its statutory authority to directly address the financial incentives in contractual agreements between drug manufacturers, LTC pharmacies, facilities, and consultant pharmacists in nursing homes.

Because prescription drug coverage for Medicare beneficiaries residing in nursing homes is generally administered by PBMs -- many of which also have financial rebate incentives in their contractual agreements with drug manufacturers -- we request that CMS expand its examination to examine the potential role of PBMs in unnecessarily increasing the use of antipsychotic drugs, and to subsequently take action to address such practices and to curb excess costs.

For example, we believe that if CMS were to identify antipsychotics as drugs subject to significant overuse, the agency could require Part D sponsors to engage in focused retrospective drug utilization management analysis. CMS could also provide appropriate guidance to Part D sponsors on how to undertake such analyses. Such steps would have the additional benefit of ensuring that PBMs clearly communicate any evidence of fraudulent or abusive utilization patterns back to plan sponsors.¹

¹ Federal regulations implementing MMA at 423.153(c)(3) specifically call on Part D sponsors to have retrospective drug utilization review systems in place that are designed to identify patterns of inappropriate or medically unnecessary care among enrollees, or that are associated with specific drugs or groups of drugs.

CMS also has clear authority under the Medicare Modernization Act of 2003 (MMA) to require medication therapy management and quality assurance programs as a means of addressing and curbing overutilization.² Further, CMS can audit PBM drug claims related to prescribing antipsychotics under its authority at §423.505(i)(2). Finally, we recommend that the agency consider requiring physicians who prescribe medications with “black box” warnings on an off-label basis to certify in writing that the drug being ordered meets the minimum criteria for coverage and reimbursement by virtue of being listed in at least one of the authorized drug compendia used by Medicare.

In sum, we urge CMS to explore and implement these and related policies, which we believe would, if properly implemented, reduce payments made for antipsychotics that lack a medically-accepted indication as required under Section 1860D-2(e)(1)(B) of the Social Security Act. Taking such proactive steps will create disincentives for entities that administer pharmacy benefits to allow these practices to flourish, while also providing CMS with clearer means to recoup erroneous payments. Most important, frail nursing home residents, many of them with dementia but no diagnosis of psychosis, would be at significantly lower risk of being given unnecessary antipsychotic medications. Research has firmly established that antipsychotics in this population increases the risk of death from serious side effects, as summarized by the Food and Drug Administration in warnings issued in 2005 and 2007 for atypical and conventional antipsychotics, respectively.

Sincerely,



Charles E. Grassley
United States Senator



Herb Kohl
United States Senator

² SSA Sec. 1860D-4