United States Senate
WASHINGTON, DC 20510

May 6, 2011

Via Electronic Transmission

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

Dear Dr. Berwick:

This week, the Department of Health and Human Services Office of Inspector General (HHS OIG) issued a report titled, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*. This report examines the extent to which atypical antipsychotic drugs were prescribed off-label to nursing home residents and paid for by Medicare from January 1 through June 30, 2007. Senator Grassley asked HHS OIG to conduct this review in December 2007 after the *Wall Street Journal* reported that nearly 21 percent of nursing home residents received antipsychotic drugs even though they did not have a psychosis diagnosis.[1]

We are concerned that nursing home residents may be receiving powerful medications that were not intended for their underlying conditions, especially in light of the cases involving the promotion of off-label uses by pharmaceutical companies. For example, in January 2009, Eli Lilly and Company agreed to plead guilty and pay $1.415 billion for promoting off-label uses of its drug Zyprexa, an atypical antipsychotic drug. The U.S. government alleged that Eli Lilly targeted its illegal marketing to doctors who treat the elderly in nursing homes and assisted living facilities and primary care physicians, encouraging the doctors to prescribe Zyprexa for dementia and other off-label uses. The Food and Drug Administration (FDA) has not approved atypical antipsychotic drugs for elderly patients with dementia and, in fact, required that these drugs include "black box" warnings in their label because of the increased risk of death in elderly patients with dementia-related psychosis. Yet, HHS OIG found that 83 percent of the atypical antipsychotic drugs prescribed to nursing home residents were for off-label conditions and 88 percent were for patients with dementia.[2]

In agency comments, CMS also expressed concern about the incentives created by contractual agreements involving long-term care (LTC) facilities and pharmacies and pharmaceutical manufacturers and/or distributors to over-prescribe antipsychotic drugs in nursing homes. It remains to be seen whether recent fines and penalties imposed on Eli Lilly and Omnicare, Inc. (a LTC pharmacy) will deter promotion of over-utilization of antipsychotic drugs in nursing homes.

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[1] Lucette Lagnado, "Nursing Homes Struggle To Kick Drug Habit," *The Wall Street Journal*, Dec. 20, 2007.
[2] Although the findings of HHS OIG's report are based on data from 2007, HHS OIG cites other studies, including a 2009 study of Department of Veterans Affairs patients, showing that off-label use of antipsychotic drugs is not uncommon.

Alarmingly, based on its review of Medicare claims from 2007, HHS OIG also estimated that 51 percent of the claims were improperly paid—about $116 million—because they failed to meet the criteria for reimbursement. Medicare covers "medically accepted indications," which is broader than simply FDA-approved conditions. Reimbursement for an off-label condition is considered appropriate if that use is "supported by one or more citations included or approved for inclusion in" any of the authorized drug compendia, such as Thomson Reuters' DRUGDEX System.[3] However, HHS OIG found that 50.2 percent of the claims were associated with antipsychotic drug uses not supported by *any* of the approved literature.

In addition, HHS OIG found that 22 percent of atypical antipsychotic drugs were not administered according to CMS standards for drug therapy in nursing homes. Nursing homes must meet Federal standards for quality and safety as a condition of participation in Medicare, including a standard regarding unnecessary drug use in nursing homes. According to HHS OIG, CMS defines unnecessary drug use as excessive dosage, excessive duration, without adequate monitoring, without adequate indications for use, and/or in the presence of adverse consequences. The psychiatrists hired to conduct the medical record reviews for the HHS OIG study "noted that some nursing homes that failed to comply with CMS standards regarding unnecessary drugs may not adequately ensure nursing home residents' health and safety."

To address the high rate of improper payments, HHS OIG recommends that the Centers for Medicare and Medicaid Services (CMS) facilitate access to information, such as diagnosis codes, to ensure accurate and appropriate Medicare coverage. CMS, however, does not concur with that recommendation, and we are troubled that the agency did not identify specific plans for addressing the problem. HHS OIG also recommends that CMS assess whether its current survey and certification processes provide sufficient safeguards against unnecessary antipsychotic drug use and consider alternative methods for promoting compliance with Federal nursing home standards.

In light of the HHS OIG report, we would appreciate your response to the following questions and requests for information by no later than May 27, 2011:

1. In agency comments, CMS acknowledged that additional efforts are needed to safeguard nursing home residents from unnecessary antipsychotic drug use. Please detail steps CMS will be taking to safeguard nursing home residents from unnecessary antipsychotic drug use. Please also detail efforts, if any, that the agency is taking to give greater emphasis to non-pharmacologic therapies for those nursing home residents who do not have a diagnosis of psychosis, and who may not be candidates for atypical antipsychotic drugs.

2. HHS OIG's finding that more than half of the claims were paid in error raises critical questions about the appropriateness of off-label use of atypical antipsychotic drugs for many

[3] The Social Security Act § 1927(g)(1)(B)(i), 42 U.S.C. § 1396r-8(g)(1)(B)(i).

nursing home residents and the lack of oversight of payment systems in place for Medicare reimbursement of off-label prescriptions. This lack of oversight could be costly for taxpayers. Accordingly, we request that CMS:

a. Specify who, or what entity, is responsible under current law or regulation for ensuring that claims for reimbursement of off-label prescriptions of atypical antipsychotic drugs meet the criteria for Medicare reimbursement.

b. Please explain why the responsible individuals or entities failed to ensure that CMS criteria for reimbursing for medically acceptable indications were met for more than half of the claims submitted.

c. Going forward, what actions will CMS take to require that reimbursements for atypical antipsychotic drug prescriptions, which are made on behalf of nursing home residents, actually meet the "medically accepted indication" standard?

3. What actions is CMS taking or has CMS already taken to recoup the erroneous payments?

4. Please outline any options that CMS could explore to address the serious concerns about unnecessary drug use and erroneous payments that are raised in the HHS OIG report. For example, could CMS consider requiring LTC consultant pharmacies to evaluate and report on the extent of use of atypical antipsychotics in nursing homes with which they contract on a periodic basis, and take further action, as appropriate, based on such findings?

Thank you for your attention to this important matter. If you have any questions regarding this letter, please contact Angela Choy of Senator Grassley's staff at (202) 224-5225 and Anne Montgomery of Senator Kohl's staff at (202) 224-5364.

Sincerely,

Chuck Grassley

Charles E. Grassley
Ranking Member
Committee on the Judiciary

Herb Kohl

Herb Kohl
Chairman
Special Committee on Aging