Testimony before the United States Senate

Special Committee on Aging

"Overprescribed: The Human and Taxpayers' Costs of Antipsychotics in Nursing Homes"

Testimony of:
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Good afternoon, Chairman Kohl, Ranking Member Corker, and other distinguished Members of the Committee. I am Daniel Levinson, Inspector General of the U.S. Department of Health and Human Services (HHS or the Department). Thank you for the opportunity to testify about the HHS Office of Inspector General's (OIG) work relating to the use of antipsychotic drugs in nursing homes.

Two recent OIG reports raise concerns about the use of atypical antipsychotic drugs[1] by elderly nursing home residents, particularly those with dementia.[2] We hired psychiatrists expert in treating elderly patients to review a sample of medical records. Their review revealed the following:

- 14 percent of nursing home residents, or nearly 305,000 patients, had Medicare claims for atypical antipsychotic drugs.
- Half of these drug claims should not have been paid for by Medicare because the drugs were not used for medically accepted indications.
- For one in five drug claims, nursing homes dispensed these drugs in a way that violated the Government's standards for their use. For example, the prescribed dose was too high, or residents were on the medication for too long.
- Part D prescription drug plan (PDP) sponsors lack access to the information necessary to ensure appropriate reimbursement of Part D drugs, including antipsychotics.

These findings indicate that Medicare is paying for drugs that it should not and Part D prescription drug plans are not able to adequately prevent inappropriate payments for drugs, including antipsychotics, for uses that do not meet coverage requirements. In addition, nursing homes often fail to comply with regulations designed to prevent overmedication of these powerful and at times dangerous drugs.

OIG's reports also found that atypical antipsychotics are frequently prescribed "off-label," that is, for uses that are not approved by the Food and Drug Administration (FDA). FDA has imposed a strong safety warning on atypical antipsychotics, emphasizing an increased risk of death when used by elderly patients with dementia. Yet we found that the large majority of claims for atypical antipsychotics were for elderly patients with dementia. These findings are also troubling given that there is ample evidence that some drug manufacturers have illegally marketed these drugs for off-label use.

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[1] "Atypical antipsychotic drugs" refers to second-generation antipsychotic drugs developed to treat psychoses and/or mood disorders.

[2] *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents* (OEI-07-08-00150), issued May 2011. Available online at http://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf.

Taken collectively, our findings raise concerns about whether atypical antipsychotic drugs are being prescribed and monitored appropriately. The Federal Government, health care providers, and families of nursing home residents all have roles to play in addressing these issues.

Half of Medicare Atypical Antipsychotic Drug Claims for Nursing Home Residents Did Not Meet Reimbursement Criteria

Atypical antipsychotic drugs that are provided to Medicare beneficiaries, including residents in nursing homes, are generally covered by the Medicare Part D program. Although physicians can prescribe drugs for any indications, to qualify for Medicare Part D reimbursement, the drugs must be used for medically accepted indications. These indications include both the uses approved by FDA and those uses (including off-label uses) supported by one or more citations in the compendia specified in the Social Security Act or designated by the Secretary.

Claims amounting to almost $116 million did not meet Medicare coverage requirements for medically accepted indications

Based on review of a sample of medical records by expert psychiatrists, OIG determined that almost 723,000 of the 1.4 million atypical antipsychotic drug claims for elderly nursing home residents in the first half of 2007 did not comply with Medicare reimbursement criteria because they were not used for medically accepted indications. This high payment error rate may be partly due to PDP sponsors' lack of access to information necessary for appropriate reimbursement of Part D drugs.

PDP sponsors lack the information necessary to ensure that Part D drugs claims, including those for antipsychotics, meet coverage requirements

The Centers for Medicare & Medicaid Services (CMS) requires PDP sponsors to ensure that Medicare reimbursement for Part D drugs is limited to medically accepted indications. PDP sponsors employ a number of strategies to prevent inappropriate payments for drugs, including prepayment edits, prior authorization, and post-payment review. However, PDP sponsors often cannot determine whether a given drug claim was prescribed for a medically accepted indication, because:

- Prescriptions and claims data lack diagnosis information. Without medical record review, reviewers cannot routinely determine why drugs were prescribed.
- FDA label and compendia listings at the time of the dispensing, not at the time of review, govern eligibility for coverage. Compendia listings can change as frequently as every quarter. For retrospective review, PDP sponsors lack archival information to all compendia to determine what indications were listed at the time a drug was dispensed.

PDP sponsors have reported to OIG that they do not routinely collect diagnosis information because CMS does not require diagnoses as a data element for Part D claims. PDP sponsors do not generally collect diagnoses for Part D claims from pharmacies because it is not standard practice for prescribers to provide them the diagnoses. Without diagnosis information on a Part

D claim, determining whether a drug was provided for a medically accepted indication, and therefore was reimbursable by Medicare, is not possible using claims data alone. Sponsors reported to us that they do collect diagnosis information when using prior authorization, a utilization management tool that requires medical justification for covering a drug claim. The PDP sponsors indicated that prior authorization is the best tool that they currently have to compare the diagnosis provided by the prescriber to the medically accepted indications contained in the compendia. However, because antipsychotics are one of the six protected drug classes under Part D, the PDP sponsors indicated that they use prior authorization for antipsychotics only in limited circumstances.

PDP sponsors also reported using post-payment review as a general safeguard to prevent fraud and abuse. However, these reviews do not commonly focus on medically accepted indications. PDP sponsors reported that they have real-time access to all compendia, but do not have access to historical data. Because one of the compendia is published quarterly, it is possible that information about a particular drug may be updated between the time a drug is provided and the time payment review is conducted.

OIG has recommended that CMS facilitate PDP sponsors' access to information necessary to ensure accurate reimbursement of Part D claims. For example, expansion of the required data elements for Part D claims to include diagnosis codes could help both drug plan sponsors and CMS ensure that a drug is used for an FDA-approved indication or a medically accepted indication supported by the compendia. CMS did not concur with this recommendation, and in its comments on our report noted that Congress did not mandate diagnosis information on Part D claims. CMS has also stated that it does not have statutory authority to require physicians to include diagnosis information on prescriptions, which are generally governed by State law.

Antipsychotics Are Prescribed in Violation of Nursing Home Quality and Safety Standards

As a condition of participation in Medicare, nursing homes must comply with Federal nursing home quality and safety standards. One standard requires that nursing home residents' drug regimes be free from unnecessary drugs, which CMS defines as those that are used: (1) in excessive dose; (2) for excessive duration; (3) without adequate monitoring; (4) without adequate indications for use; or (5) in the presence of adverse consequences that indicate that the dosage should be reduced or discontinued.

Nursing homes' failure to comply with Federal standards regarding unnecessary drugs may affect their participation in Medicare because they would no longer be meeting their conditions of participation. However, nursing homes' noncompliance with these standards does not cause Medicare payments for the individual drug claims to be erroneous.

Twenty-two percent of the atypical antipsychotic drugs claimed were not administered in accordance with CMS standards regarding unnecessary drug use in nursing homes

For the 6-month review period, OIG determined that for more than 1 in 5 claims (or 317,971 of the 1.4 million Medicare claims), atypical antipsychotic drugs were administered in ways that did not meet CMS standards for drug regimens in nursing homes. Forty-two percent of these

claimed drugs did not comply with CMS standards for more than one reason (e.g., the drug was in an excessive dose and for an excessive duration).

Failure to comply with CMS standards regarding unnecessary drugs may indicate that nursing homes are not adequately ensuring residents' health and safety. Our medical experts noted instances where nursing home beneficiaries were given antipsychotics to control symptoms like agitation without first receiving a workup to assess whether the symptom might be a sign of another treatable condition. For example, in one case, a workup of an agitated patient would have detected a urinary tract infection. Instead of properly diagnosing the urinary tract infection and treating it with antibiotics, the patient was given antipsychotic drugs to control the agitation.

The Vast Majority of Antipsychotic Drug Use in Nursing Homes Was Off-Label or Against Black Box Warning

FDA approves drugs based on scientific proof of safety and effectiveness for specific uses. If FDA determines that a drug's health benefits for its intended use outweigh its known risks, then it approves the drug for marketing for that use. After FDA approves a drug to be marketed for a specific use, then physicians are permitted to prescribe the drug for other uses. This practice is not uncommon and is referred to as off-label use. Medicare pays drug claims for off-label use, provided that the use is an accepted medical indication (i.e., supported by one or more citations in a designated compendia). However, although physicians may prescribe off-label, drug manufacturers are not permitted to promote off-label uses of their drugs.

FDA also reviews scientific evidence to determine what warnings a drug must carry. If a drug manufacturer or FDA determines that an approved drug may produce severe or life-threatening risks, then FDA requires that the manufacturer include a boxed warning (also referred to as a black-box warning) on the product's labeling to warn prescribers and consumers of these risks. Nevertheless, physicians are permitted to prescribe a drug for a patient with a condition specified in a boxed warning if such a treatment therapy is warranted in their clinical judgment. Atypical antipsychotic drugs carry a black-box warning emphasizing an increased risk of death when used in elderly people with dementia.

Some manufacturers have illegally marketed antipsychotics for patients with dementia

Despite the fact that elderly dementia patients who are treated with atypical antipsychotics face an increased risk of death, ample evidence exists that some drug companies have illegally marketed their products toward this vulnerable population for off-label uses. For example, with the sales slogan "5 at 5," Eli Lilly promoted its atypical antipsychotic, Zyprexa, for the treatment of elderly patients with sleep problems, behavioral issues, and dementia. The company directed its sales representatives to tell doctors that giving 5 milligrams of the drug at 5 pm would help their patients sleep. In January 2009, Eli Lilly agreed to plead guilty and paid $1.4 billion for the illegal promotion of Zyprexa. Several other pharmaceutical companies have settled Government allegations that they improperly promoted their antipsychotic drugs for unapproved uses and/or have paid kickbacks to influence prescribing. Drug companies have paid more than a billion dollars to resolve civil and criminal liability for illegally marketing these drugs. Even after

government action stops these illegal marketing campaigns, their effect on prescribing patterns may be long-lasting and difficult to undo.

Off-label use and use of atypical antipsychotics for patients with dementia were prevalent among nursing home residents

Based on a review of a sample of medical records by medical experts, OIG determined that 83 percent of Medicare claims for atypical antipsychotic drugs for elderly nursing home residents were prescribed for off-label uses. Eighty-eight percent of atypical antipsychotic drugs claims were for residents with dementia, the condition specified in the boxed warning.

Physicians are permitted to prescribe drugs for off-label conditions or in the presence of the condition(s) specified in the FDA boxed warning. Such prescribing may be medically appropriate despite the risks – in fact, off-label prescribing is common for many classes of drugs.

However, our findings raise concerns. Through our enforcement and compliance monitoring activities, OIG has identified inappropriate use of psychotropic medications for nursing home residents as a risk area in at least two ways—inappropriate uses such as those identified through OIG's work may violate the prohibition against inappropriate use of chemical restraints and the requirement to avoid unnecessary drug usage. OIG has issued guidance to nursing facilities on risks related to psychotropic medications (a category which includes antipsychotics).[3] These risks include:

- use for staff convenience rather than providing appropriate non-pharmacological interventions;
- use without first determining the causal and contributing factors of the behavior;
- lack of specific and individualized care plans;
- lack of continued monitoring of the need for or the amount of the medication; and
- inappropriate admission of residents with mental health diagnoses that the facility is not prepared to treat.

In light of these risks, we recommended that nursing facilities ensure there is an adequate indication for the use of the medication and should carefully monitor, document, and review the use of each resident's psychotropic drugs.

Recommendations to Protect Nursing Home Patients From Unnecessary Drug Use

Medication therapy for nursing home residents is often complex. Many residents have multiple conditions that require management with multiple medications, as well as non-pharmacological interventions. Most physicians and nursing homes dispense antipsychotic drugs with the best interests of patients in mind. Physicians are permitted to prescribe drugs for unapproved indications, even in light of a black-box warning, but should use their best clinical judgment to determine that the benefits outweigh the risks.

[3] OIG's Supplemental Compliance Program Guidance for Nursing Facilities is available online at: http://oig.hhs.gov/compliance/compliance-guidance/docs/complianceguidance/nhg_fr.pdf.

However, OIG has found that all too often, nursing home patients receive antipsychotic drugs in ways that violate Federal standards designed to prevent overmedication and inappropriate use.

To ensure the safety of this vulnerable population, CMS should:

- Consider enhancing claims data to ensure accurate coverage and reimbursement determinations. For example, adding diagnosis codes to drug claims would help determine whether the prescription is for a medically accepted indication and the claim is payable.
- Hold nursing homes accountable for unnecessary drug use through the survey and certification process.
- Explore other options, such as incentive programs and provider education, to promote compliance with quality and safety standards. For example, CMS could require nursing homes to reimburse the Part D program when claimed drugs violate these standards.

The Government must also continue to monitor the marketing of antipsychotics. Some drug manufacturers have promoted these drugs for off-label use by the elderly with dementia. These practices can violate the law and even if the drug company is fined, the pernicious influence of such marketing campaigns can be difficult to undo.

Doctors, pharmacists, and nursing homes must carefully analyze the patient's best interests when prescribing or dispensing antipsychotics. Families, in partnership with these medical professionals, can serve as a crucial support by learning about appropriate use, proper dosages, and possible side effects of these drugs.

My office continues to examine protections and quality of care for patients who are receiving antipsychotic drugs. The extensive prescribing of these drugs and the concerning case examples we have encountered in the course of this work raise serious questions about whether nursing home residents are receiving high-quality, coordinated care. To further explore this issue, we are currently conducting a new review that will determine whether nursing facility patients taking atypical antipsychotic drugs have received the required patient assessments and thorough care planning that Federal standards require.

CONCLUSION

Over the next 18 years, 10,000 Americans will become newly eligible for Medicare each day. As the baby boomer population ages, it is imperative to address the overuse and misuse of antipsychotic drugs among nursing home patients. Thank you for your interest in this issue and for your support of OIG's mission.