

STATEMENT OF

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ON

**THE OVERUTILIZATION OF ATYPICAL ANTIPSYCHOTICS IN LONG-TERM CARE
SETTINGS**

BEFORE THE

UNITED STATES SENATE SPECIAL COMMITTEE ON AGING

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U.S. Senate Special Committee on Aging
Hearing on the Overutilization of Atypical Antipsychotics in Long-Term Care Settings
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Chairman Kohl, Ranking Member Corker, and members of the Committee, thank you for the invitation to discuss the Centers for Medicare & Medicaid Services' (CMS) efforts to improve dementia care and reduce the use of antipsychotic drugs for residents of nursing homes and other long-term care facilities. CMS is committed to ensuring that every Medicare and Medicaid beneficiary receives appropriate and high-quality health care, in every health care setting. I share your concerns about the potential for inappropriate use of these medications, and appreciate the Committee's efforts to bring attention to this important topic.

Background

All beneficiaries, including those with dementia, deserve high quality, patient-centered care. Without question, a dementia diagnosis presents a host of health and safety challenges for a patient and his or her family. Caring for individuals with Alzheimer's disease and related dementias is challenging for families, caregivers and our health care system, with 5.4 million Americans living with Alzheimer's disease today.¹ This number is expected to grow significantly as the Baby Boom generation ages, with estimates suggesting that as many as 16 million Americans will have the disease by 2050.² Nursing homes play an important role in providing care for those with dementia; any discussion of how to best improve the quality of health care for Alzheimer's and dementia patients must necessarily involve this component of the health care delivery system. According to the Alzheimer's Association, 75 percent of people with Alzheimer's will be admitted to a nursing home by age 80.³

While there is still much we do not understand about the causes, diagnosis, and treatment of Alzheimer's disease, there are concerns that the use of certain medications, including atypical antipsychotics, to treat the behavioral symptoms of Alzheimer's or other dementias may not be appropriate. CMS recognizes that a crucial component to improving the quality of care for

¹ http://www.alz.org/documents_custom/2011_Facts_Figures_Fact_Sheet.pdf

² Ibid

³ Ibid

beneficiaries with dementia is eliminating the inappropriate or harmful use of medications. We share the concern of the Committee and others that some residents of nursing homes and other long-term care facilities are receiving antipsychotic medications that may have a detrimental impact on their health and safety. The Food and Drug Administration (FDA) has approved eleven atypical antipsychotic drugs for various indications, including the treatment of schizophrenia and the treatment of certain symptoms associated with bipolar disorder.⁴ The FDA has warned that antipsychotic medications are associated with an increased risk of death when used for the treatment of behavioral disorders in elderly patients with dementia, and requires manufacturers of these drugs to include in the drugs' labeling boxed warnings that discuss this risk.⁵ While these drugs are a critically important treatment for patients with certain mental health conditions, the "off-label" use, or the use of drugs for conditions other than those approved by the FDA, is also widespread.

Despite these warnings, evidence suggests that a significant number of elderly patients are receiving these medications. Recent work by the Department of Health and Human Services (HHS) Office of Inspector General (OIG) found that 14 percent of elderly nursing home residents had Medicare claims for antipsychotic drugs in the first six months of 2007 and 83 percent of these claims were associated with off-label conditions.⁶ CMS has already taken steps to eliminate the inappropriate use of antipsychotic drugs in nursing homes, updating guidance relating to Survey and Certification of nursing homes to better measure and address potentially inappropriate prescribing. While the progress that has been made is encouraging, CMS continues to explore new ways to strengthen enforcement of current rules, eliminate conflicts of interest that may influence prescribing, and better educate providers, prescribers, and patients' families to eliminate inappropriate prescribing in nursing homes.

⁴ Approved atypical antipsychotic drugs are Aripiprazole, Asenapine Maleate, Clozapine, Iloperidone, Lurasidone, Olanzapine, Olanzapine/Fluoxetine, Paliperidone, Quetiapine, Risperidone, and Ziprasidone (<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm094303.htm>)

⁵ Ibid.

⁶ Department of Health and Human Services Inspector General, "Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents," May 2011.

Survey and Certification Improvements

To help ensure that nursing homes meet both Federal and State standards, CMS conducts initial and ongoing inspections of all facilities participating in the Medicare or Medicaid program. This Survey and Certification process is an important tool in CMS' efforts to ensure that beneficiaries receive high quality health care and to monitor nursing home compliance with requirements relating to unnecessary drug use. In September 2006, CMS implemented substantial improvements to onsite surveys to help address these concerns. Specifically, CMS revised interpretive guidelines for unnecessary medications, including clarifying several aspects of medication management and developing a new medication table that includes medications that are problematic for nursing home populations. These Survey and Certification reviews are designed to determine whether residents receive only drugs that are clinically indicated in an appropriate dose and duration, whether non-pharmacological interventions are considered, and whether gradual dose reduction is attempted when clinically appropriate. Examples of noncompliance can include excessive dosing of medication, prolonged use of antipsychotic medications without attempting dose reduction, or failure to implement behavioral interventions to enable attempts to eliminate or reduce antipsychotic medication. This process is carefully balanced with the need to protect the ability of physicians to make a clinical decision on the use of atypical antipsychotics in patients with dementia, based on the needs of the individual patient.

Since the implementation of this guidance in December 2006, the percent of surveys with citations for unnecessary drug use has increased significantly. In the seven years prior to implementation of this change, 12.6 percent to 14.0 percent of facilities were cited for unnecessary drug use; this has grown to 18.2 percent in 2007 and 19.4 percent in 2009.⁷ Accurate detection is the first stage in identifying potential harm and eliminating it. We are in the process of determining how we could use this information to target educational programs and technical assistance to providers in States or regions with high citation rates or target surveys on low performers.

Providing appropriate care to beneficiaries with dementia is also more complex than simply avoiding the inappropriate use of medication. The guidance also requires providers to use non-

⁷ Federal Register, Volume 76, No. 196, October 11, 2011. Pg. 63039.

pharmacological interventions to help manage behavioral or other health issues. Possible interventions may include increasing exercise or time outdoors, monitoring for and managing acute and chronic pain, or planning individualized activities for beneficiaries.

CMS has also worked to ensure that as part of routine onsite reviews, Survey and Certification personnel have the tools and resources necessary to effectively monitor nursing homes' compliance with these policies. For example, offsite preparation in advance of the survey may include review of the rate of antipsychotic drug use for that facility. This enables surveyors to target specific residents, families and staff (including physicians), to interview during the survey.

Eliminating Conflicts of Interest for Long-Term Care Pharmacists

Despite the improvements CMS has initiated in the Survey and Certification process, CMS understands that the overuse of antipsychotics in nursing homes remains a serious problem. CMS is very concerned about the nature of contractual arrangements involving long-term care (LTC) facilities, LTC pharmacies, and LTC consultant pharmacists and the incentives these arrangements may provide for inappropriate prescribing practices. LTC facilities are required to employ or retain the services of a licensed pharmacist to consult on all aspects of pharmacy services, including a monthly review of each resident's drug regimen. This consultant pharmacist can notate a patient's medical record with recommendations for medication changes, and physicians frequently follow these recommendations. As a result, these consultant pharmacists can have significant influence over the drugs that many LTC facility residents receive.

CMS is concerned that various financial relationships and arrangements may provide incentives to these consultant pharmacists to make prescription recommendations with a possible negative impact on residents' health and safety. The practice of LTC pharmacies providing consultant pharmacists to nursing homes below cost or below fair market value is one such type of arrangement. We are concerned that these arrangements may also be used to entice nursing homes to enter into contracts with the LTC pharmacy for pharmacy dispensing services and the purchase of prescription drugs.

Further, we are greatly concerned with any financial arrangement that involves payments from pharmaceutical manufacturers directly or indirectly to LTC pharmacies and LTC consultant pharmacists, which may be designed to increase use of the manufacturer's drugs. For example, the Department of Justice reached a \$98 million settlement with Omnicare, Inc. in November 2009, resolving allegations that it received kickbacks to recommend drugs, including an atypical antipsychotic, in nursing homes.⁸ Financial arrangements or payments from manufacturers have the potential to directly or indirectly influence consultant pharmacist drug regimen recommendations and may create perverse incentives for the LTC consultant pharmacist to make recommendations that are in conflict with the best interests of nursing home residents, as well as with Part D sponsors' formularies and/or drug utilization management programs. As a result, the arrangements bring into question the ability of the LTC consultant pharmacists to provide impartial reviews of the residents' drug regimens, which in turn raises concerns regarding the quality of those reviews and potential impact on resident health and safety.

Taking action to address these concerns, as part of the proposed changes to Medicare Advantage and Medicare Part D programs for contract year (CY) 2013 (CMS-4157-P), CMS is considering changes to the Conditions of Participation for Long-Term Care Facilities that would require LTC consultant pharmacists to be independent from LTC pharmacies, pharmaceutical manufacturers and distributors, or affiliates of these entities. Severing the relationship between consultant pharmacist and other pharmaceutical interests could help to protect LTC residents by assuring that prescription decisions are made free from the possible influence of financial arrangements. Although we outlined a specific approach under consideration and solicited comments on that approach, we are open to alternative solutions that address the conflict of interest we have identified. Consequently, we have requested comments on any alternative approaches that would reduce or eliminate this conflict of interest and potential overprescribing that exist in nursing homes today. CMS will carefully consider all comments that are made on this proposed regulation and evaluate them as plan guidance is developed for CY 2013. The comment period for the proposed rule closes on December 12, 2011.

⁸ Department of Health and Human Services Inspector General, "Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents," May 2011. Page 1.

Ongoing CMS Initiatives to Improve Care for Patients with Alzheimer's or Dementia

Research and Quality Measures

In addition to survey oversight and this potential change in LTC facilities' conditions of participation, CMS recognizes that eliminating improper use of medications and encouraging non-pharmacological approaches to care will require an ongoing, multifaceted approach. First, CMS is interested in a better understanding of the factors that influence prescribing practices in nursing homes, to help identify additional interventions that may be effective. To that end, we have awarded a new contract to conduct a study in 20 to 25 nursing homes that will evaluate nursing home decision-making related to the use of antipsychotic medications in dementia residents. Findings will be used to target and implement interventions to improve the overall management of residents with dementia, including reducing the use of antipsychotic drugs in this population.

CMS is also seeking to encourage the development of quality measures addressing antipsychotic medication use. Beneficiaries and their families should have access to clear information about nursing home performance, and providing this information through the Nursing Home Compare website or other means would help make this information more accessible.

Using Quality Improvement Organizations

Quality Improvement Organizations (QIOs) can also play an important role in ensuring the nursing homes' prescribing practices are medically appropriate. QIOs, under the auspices of the 10th Scope of Work, are working to reduce adverse drug events, including high risk beneficiaries taking short or long acting antipsychotics of any class. The QIO 10th Scope of Work includes a metric for quality improvement of patient care by reducing these adverse events, with a goal of reducing the number of beneficiaries who are taking long or short acting antipsychotic medication and are prescribed a potentially inappropriate medication by 25 percent from baseline at 18 months, with a final target reduction by at least half at the end of the three year period. The QIOs have a history of successfully working in quality improvement with nursing homes in the areas of physical restraints and pressure ulcers.

Improving Training and Education

CMS is also working to improve training for both providers and surveyors to emphasize non-pharmacological interventions for nursing home residents who do not have a diagnosis of psychosis or may not be candidates for atypical antipsychotic drugs. Under provisions in Section 6121 of the Affordable Care Act, CMS added language to the State operations manual to make dementia care and abuse prevention issues a mandatory part of annual training. Additionally, CMS is currently producing educational information DVDs for surveyors and providers regarding the care of residents with dementia that emphasize non-pharmacological interventions and approaches. These will be distributed to all nursing homes and State survey agencies. CMS is also working to improve surveyor skill at detecting unnecessary medication use in nursing homes by improving the curriculum for new surveyor training and strengthening surveyor interpretive guidance. Additionally, CMS is actively collaborating with several Federal partners, including the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Administration on Aging (AoA) to promote non-pharmacological behavioral interventions and staff and facility training to prevent the use of seclusion and restraint.

New Statutory Authorities

CMS is an active participant in the efforts of HHS to implement the National Alzheimer's Project Act (P.L. 111-375). This law requires the creation and maintenance of an integrated plan to overcome Alzheimer's, including coordination of research and service across agencies. As a part of these implementation efforts, the Department has convened a subgroup to examine issues relating to the long-term care supports and service needs for those with Alzheimer's, which will examine gaps in the current system of long-term care services and supports and develop priorities for the National Plan. The Department's work surrounding the National Alzheimer's Project Act will help to identify needs in our health care infrastructure and improve the quality of care that these patients receive.

Partnership with States and Stakeholders

Many of these efforts would not be possible without an ongoing commitment and partnership with stakeholders, including States, provider groups, and patient advocates. State officials and organizations are important partners in efforts to ensure that current rules and regulations are enforced. CMS is also interested in partnering with States that are taking innovative approaches

to this health challenge, to help identify and spread best practices more widely. For example, the State Survey Agency in Massachusetts convened a task force, including nursing homes, physicians, nurses, social workers, researchers, government agencies, advocates and consumers to address antipsychotic drug use and measure outcomes in the next one to two years. CMS is also funding work with the Illinois Survey Agency and Drug Control Program to use enhanced nursing home drug data to detect and monitor issues related to antipsychotic use in dementia residents.

CMS is also engaged in ongoing dialogue with several professional associations and consumer organizations, such as the American Medical Directors Association (AMDA) the American Society of Consultant Pharmacists (ASCP), the American Health Care Association (AHCA), LeadingAge, Consumer Voice and others to deliver educational programs for prescribers on eliminating or reducing the off-label use of antipsychotic drugs for nursing home residents with dementia. We are committed to working collaboratively with organizations such as these to accomplish our shared goal of eliminating inappropriate treatments for dementia.

Conclusion

CMS seeks to function as a major force and trustworthy partner for the continual improvement of health and health care for all Americans. As a practicing physician and son of a Medicare beneficiary, I personally take this commitment to serve and improve our health system very seriously. This commitment includes ensuring that all of our beneficiaries receive high-quality, safe, and appropriate care, at all times. For patients suffering from Alzheimer's or dementia, this involves comprehensive, behavioral health by an interdisciplinary team of geriatric professionals who are knowledgeable in the use of non-pharmacologic interventions and appropriate and judicious use of medication when indicated. While we have made significant strides in addressing over-medication, our commitment to continual improvement means that CMS will seek new approaches and partnerships to improve care for Americans with Alzheimer's and dementia.

I look forward to working with the Committee on this issue and to answering any questions you may have.