

## **Consumer Group Asks HHS for Policies to End Chemical Restraint of Nursing Home Residents**

### **Resolutions Call for Action on Antipsychotic Drugs, Pharmacist Independence**

Member organizations of The National Consumer Voice for Quality Long-Term Care this week approved resolutions calling for the Department of Health and Human Services to curb the widespread misuse of antipsychotic drugs in nursing homes as chemical restraints and ensure that long-term care consultant pharmacists are free from the influence of pharmacies and manufacturers that benefit from increasing drug sales.

Twenty-six percent of nursing home residents receive antipsychotic medications. The HHS Office of Inspector General found that 88 percent of residents who receive antipsychotics are elderly people with dementia—people whom the Food and Drug Administration says are at increased risk of death from their use.

Medicare and Medicaid prohibit physically or chemically restraining residents for staff convenience, but the government alleged that major pharmaceutical companies and the largest long-term care pharmacy illegally marketed antipsychotics to treat symptoms of dementia. Inspector General Daniel Levinson said “government, taxpayers, nursing home residents, as well as their families and caregivers should be outraged—and seek solutions” to the misuse of antipsychotic drugs as restraints.

The Consumer Voice resolutions call on HHS to take specific steps, including:

- (1) Prohibiting the use of psychoactive drugs without written informed consent;
- (2) Publishing facilities’ rate of psychoactive drug use on Nursing Home Compare;
- (3) Strengthening enforcement of regulations on chemical restraints and unnecessary drugs;
- (4) Implementing procedures to prevent Medicare payment for non-therapeutic use of antipsychotics;
- (5) Excluding long-term care pharmacies from Medicare and Medicaid if they illegally promote antipsychotic drugs in long-term care facilities;
- (6) Sponsoring education programs about the dangers of antipsychotic drugs and alternative forms of care; and
- (7) Publishing regulations it is considering to prohibit consultant pharmacists from affiliation with drug manufacturers or long-term care pharmacies.

For more information, contact Janet Wells, Director of Public Policy, 202-332-2275, ext. 205.

## **Resolution Requesting the Department of Health and Human Services to Address the Misuse of Antipsychotic Drugs in Nursing Homes**

WHEREAS the chemical restraint of nursing home residents is a leading form of elder abuse that causes misery, loss of independence, over-sedation, confusion, falls, severe medical side effects and death;

WHEREAS many nursing homes commonly use antipsychotic drugs to chemically restrain elderly residents with dementia and as a substitute for needed care;

WHEREAS 26% of U.S. nursing home residents – more than 350,000 residents – are given antipsychotic drugs;

WHEREAS nearly 40% of U.S. nursing home residents who have cognitive impairments and behavioral symptoms are given antipsychotic drugs despite the absence of psychotic or related conditions;

WHEREAS the Centers for Medicare & Medicaid Services guidelines on unnecessary drugs state that analysis of antipsychotic drug use by 693,000 Medicare nursing home residents found that 28.5% of the doses received were excessive and 32.2% lacked appropriate indications for use;

WHEREAS the United States Food and Drug Administration (FDA) has not approved antipsychotic drugs for the treatment of dementia and has issued advisories and “black box” warnings that antipsychotic drugs greatly increase the risk of death for persons with dementia;

WHEREAS nursing home residents who receive antipsychotic drugs and their representatives are often not properly informed about the dangers of these drugs or of alternative forms of care and treatment;

WHEREAS the HHS Office of Inspector General issued a prominent report in May 2011 revealing that – despite FDA warnings on the greatly increased risk of death – 88 percent of the nursing home residents who are subjected to powerful antipsychotic drugs are elderly persons with dementia; and that Medicare overpaid \$116 million for erroneous nursing home claims for atypical antipsychotic drugs in a six-month period of 2007;

WHEREAS HHS Inspector General Daniel Levinson issued a public statement on May 9, 2011 declaring that “government, taxpayers, nursing home residents, as well as their families and caregivers should be outraged – and seek solutions” concerning the misuse of antipsychotic drugs to chemically restrain nursing home residents;

WHEREAS the U.S. Department of Justice has prosecuted several cases against large drug manufacturers for illegally promoting and selling antipsychotic drugs to nursing homes and doctors as a treatment for dementia; and whereas one large national long-term care pharmacy

has entered into agreements with the Department of Justice and several state governments to settle charges that it accepted kickbacks from a pharmaceutical company to encourage physicians to prescribe an antipsychotic drug it manufactures;

WHEREAS a large national long-term care pharmacy continues to provide drugs to residents of hundreds of long-term care facilities after settling charges with the Department of Justice and several state governments that it accepted kickbacks from a pharmaceutical company to encourage physicians to prescribe an antipsychotic drug that it manufactures;

WHEREAS the Nursing Home Reform Law of 1987 and implementing regulations prohibit the unnecessary use of antipsychotic drugs and chemical restraints;

WHEREAS the Department of Health and Human Services (HHS) published proposed regulations on February 5, 1992 that would significantly strengthen the protections for nursing home residents against chemical restraint and prohibit the use of psychoactive drugs without written informed consent; and whereas, however, the proposed regulations have not been finalized:

WHEREAS federal regulations require each nursing home to employ or obtain the services of a licensed pharmacist to perform a monthly drug regimen review for each resident and provide consultation on all aspects of pharmacy services within the facility; however, this requirement is not serving its purpose of independent analysis of nursing home drug use because most consultant pharmacists work for large long term care pharmacies that are the exclusive provider of drugs to the nursing homes, and the long term care pharmacies often subsidize the cost of consultant pharmacist services;

WHEREAS the Affordable Care Act of 2010 requires the Centers for Medicare & Medicaid Services to review and modify the Nursing Home Compare website to provide clear, timely and comprehensive information of value to consumers;

WHEREAS numerous studies have found that antipsychotic drugs are generally ineffective in treating behavioral symptoms of dementia, and that they are sometimes outperformed by placebos; studies also show that it is often a nursing home's drug use rate, not a resident's medical condition, which determines the likelihood of whether a resident will be given antipsychotic drugs and put at risk of serious harm and premature death;

WHEREAS, a growing number of nursing homes are proving there is a better way of caring for residents with dementia that focuses on ensuring their comfort and on timely assessment and response to the underlying causes of any behavioral symptoms;

THEREFORE BE IT RESOLVED that Congress hold hearings to address the rampant misuse of antipsychotic drugs to sedate and chemically restrain nursing home residents and that Congress enact legislation to ensure that antipsychotic drugs are not given to nursing home residents without medical justification and without the specific informed consent of residents and their representatives.

BE IT FURTHER RESOLVED that the Centers for Medicare & Medicaid Services publish up-to-date information on each nursing home's use of antipsychotic drugs on Nursing Home Compare and that it factor antipsychotic drug use into its Five-Star Rating System for nursing homes.

BE IT FURTHER RESOLVED that HHS adopt the 1992 proposed regulations on chemical restraint, subject to modifications that nursing homes be required to inform residents and their representatives in writing of the known risks of psychoactive drugs, including any black box warnings, and to advise them if the drugs are being prescribed for off-label purposes.

BE IT FURTHER RESOLVED that HHS adopt regulations that ensure the independence of nursing home consultant pharmacists by prohibiting any affiliations with a facility's long term care pharmacy, drug manufacturers and distributors, or any affiliates of these entities.

BE IT FURTHER RESOLVED that HHS adopt regulations that ensure the independence of nursing home consultant pharmacists by prohibiting any affiliations with a facility's long term care pharmacy, drug manufacturers and distributors, or any affiliates of these entities.

BE IT FURTHER RESOLVED that the Centers for Medicare & Medicaid Services and state survey agencies strengthen enforcement of existing chemical restraint and unnecessary drug requirements by carefully examining antipsychotic drug use during surveys and complaint investigations, by consulting with consumer stakeholders on needed modifications to survey and enforcement procedures for this purpose, and by promulgating new regulatory methods to prevent or discourage the prescribing of antipsychotic drugs for residents in the absence of psychotic or related conditions (such as implementing computerized warning systems particularly related to the use of antipsychotic drugs).

BE IT FURTHER RESOLVED that HHS establish and implement effective procedures to prevent Medicare payment for non-therapeutic use of antipsychotic drugs and to recover erroneous payments for these drugs.

BE IT FURTHER RESOLVED that when the HHS Office of Inspector General and the Department of Justice find that a provider of pharmacy services is illegally engaged in marketing and promoting antipsychotic drugs to long-term care facilities, they exclude the long-term care pharmacy from Medicare and Medicaid.

BE IT FURTHER RESOLVED that the Centers for Medicare & Medicaid Services and state survey agencies establish high-profile education campaigns to advise consumers, nursing home employees, and physicians about the dangers associated with the misuse of antipsychotic drugs and to inform them of alternative forms of care and treatment for symptoms of dementia.

## **Resolution Supporting a Federal Requirement for Long-Term Care Pharmacist Independence from Conflict of Interest**

WHEREAS the health and safety of nursing home residents depends upon medication recommendations and reviews being conducted by long term care consulting pharmacists whose independence and clinical judgments are free from conflicts of interest;

WHEREAS federal regulations require each nursing home to employ or obtain the services of a licensed pharmacist to perform drug regimen reviews for each resident at least monthly and to provide consultation on all aspects of pharmacy services within the facility;

WHEREAS CMS guidelines on unnecessary drugs and the findings in the May 2011 OIG Report, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents* (OEI-07-08-00150), indicate that there exists in our nation's nursing homes a serious and ongoing problem of residents being given unnecessary, excessive, inappropriate drugs, and even potentially lethal drugs covered under FDA "Black Box" warnings;

WHEREAS financial arrangements between long term care facilities, long term care pharmacies, pharmaceutical manufacturers, and long term care consultant pharmacists may create misaligned incentives for long term care consulting pharmacists to put other interests ahead of what is the most appropriate medical care for residents;

WHEREAS the Office of Inspector General has raised concerns that pharmacists employed by long term care pharmacies inappropriately influence the drugs that are prescribed to residents in nursing homes, and that drug manufacturer rebates to long term care pharmacies may create undisclosed incentives for pharmacists and consultant pharmacists to recommend certain drugs over others based on financial considerations as opposed to clinical considerations;

WHEREAS many long term care consultant pharmacists work for large long term care pharmacies, a highly concentrated industry in which a few companies enjoy huge percentages of market share for the provision of drugs to nursing home residents, and the long term care pharmacies often provide consultant pharmacist services to nursing homes at a subsidized rate;

WHEREAS the Department of Justice announced in 2009 that the nation's largest nursing home pharmacy and drug manufacturer would pay \$112 million dollars to settle False Claims Act cases, including allegations of kick-backs which involved physicians prescribing antipsychotic medications to nursing home residents, illegal conduct which "can undermine the medical judgments of healthcare professionals, lead to patients being prescribed medications they do not need, and drive up the costs of health care," according to the Department of Justice's Assistant Attorney General;

WHEREAS the U.S. Department of Justice has prosecuted several cases against large drug manufacturers for illegally promoting and selling antipsychotic drugs to nursing homes and doctors for "off-label" use as a treatment for dementia;

WHEREAS a large national long term care pharmacy continues to provide drugs to residents of hundreds of long term care facilities after settling charges with the Department of Justice and several state governments that it accepted kickbacks from a pharmaceutical company to encourage physicians to prescribe an antipsychotic drug that it manufactures;

WHEREAS HHS Inspector General Daniel Levinson issued a public statement on May 9, 2011 declaring that “government, taxpayers, nursing home residents, as well as their families and caregivers should be outraged – and seek solutions” concerning the misuse of antipsychotic drugs to chemically restrain nursing home residents; and

WHEREAS concern over patient safety and quality of care has prompted the Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Services to publish proposed federal regulations CMS-4157-P, Federal Register Vol. 76, No. 196, Oct. 11, 2011, which would:

**Require** LTC consultant pharmacists to be independent of any affiliations with LTC facilities/pharmaceutical manufacturers, distributors or any affiliates of these entities; and

**Require** LTC facilities to use qualified professional pharmacists to conduct drug regimen reviews and make medication recommendations solely on the best interests of the resident; and

**Define** independent pharmacists as those who are not employed, under contract, or otherwise affiliated with the facility’s pharmacy, pharmaceutical manufacturer or distributor, or any affiliate of these entities.

THEREFORE BE IT RESOLVED that The National Consumer Voice for Quality Long-Term Care urges the Department of Health and Human Services to adopt regulations to ensure the independence of long term care consultant pharmacists by prohibiting any affiliations between the long term care consultant pharmacists and the facility’s long term care pharmacy, drug manufacturers, distributors, or any affiliates of these entities; and

BE IT FURTHER RESOLVED that The National Consumer Voice for Quality Long-Term Care urges the Centers for Medicare & Medicaid Services and state survey agencies to create strict enforcement mechanisms to ensure the independence of long term care consultant pharmacists, including imposition of lengthy exclusion from participation in Medicare and Medicaid for any non-compliance, and including CMS consultation with consumer stakeholders about data collection, modifications to survey and enforcement procedures, and other means for ensuring strict compliance with the independent consulting pharmacist requirement.