

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.