

## **Advocates for Long-Term Care Residents Support Regulations to Ensure Independence of LTC Consultant Pharmacists**

December 12, 2011

Marilyn B. Tavenner  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

**RE: File Code CMS-4157-P (RIN0938-AQ86) – Independence of LTC Consultant Pharmacists (Section 483.60) -- Submitted electronically**

Dear Ms. Tavenner:

The undersigned organizations support CMS's proposal to publish regulations to protect the health and safety of long-term care residents by requiring long-term care consultant pharmacists to be independent of conflicts of interest. We concur with CMS that consultant pharmacists should make medication recommendations based solely on the best interests of residents, and that to do so, they must not have conflicting financial interests that can encourage overprescribing, overutilization, and inappropriate use of drugs. Therefore, we urge you to use your authority to promulgate regulations to require long-term care facilities to employ consultant pharmacists who are not employed by, under contract with, or affiliated with the facility's pharmacy, a pharmaceutical manufacturer or distributor, or any of their affiliates.

The signers of this letter are national, state and local organizations that represent and advocate on behalf of the elderly, many of whom receive institutional long-term care. We commend CMS for this proposal and recent actions to curb one of the most critical health care and quality of life problems in long-term care facilities—the widespread, off-label use of powerful and potentially lethal antipsychotic drugs to control residents' behavior. We are alarmed by recent federal data showing that almost one-quarter of nursing home residents receive antipsychotic drugs,<sup>1</sup> and by the HHS Office of Inspector General's finding that 88 percent of residents who receive antipsychotics are elderly persons with dementia—the population that the Food and Drug Administration warns is at increased risk of death from antipsychotic medications.<sup>2</sup> Other data show that almost 40 percent of residents with cognitive impairments and behavioral symptoms are given antipsychotic drugs in the absence of psychotic conditions; that more than 28 percent

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<sup>1</sup> Centers for Medicare & Medicaid Services, *MDS Active Resident Information Report*, Third Quarter, 2010.

<sup>2</sup> Department of Health and Human Services Office of Inspector General, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*, May 2011.

of doses are excessive; and that more than 32 percent of prescriptions lacked appropriate indications for use.<sup>3</sup>

### **Inappropriate Use of Powerful Antipsychotics Is Increasingly Recognized As a Problem**

In an alert on off-label use of antipsychotics, the Center for Medicare Advocacy reported the following problems cited in newspaper investigations in two states:

Reviewing more than 40,000 federal and state inspection reports for Illinois' 742 nursing facilities, the Chicago Tribune, in an article in 2009, identified 1200 violations involving psychotropic medications and affecting 1900 residents, since 2001. The Chicago Tribune identified 12 resident deaths and dozens of incidents where residents broke bones after falling while they were medicated. The reasons for the medication: one resident was "yelling out" and "easily annoyed," another resident "was teasing another resident and generally being 'nasty.'" Earlier this month, the Boston Globe reported that nearly 28% of all Massachusetts nursing home residents were given antipsychotic drugs in 2009 and that 22% of the (2483 residents) did not have a medical condition supporting use of the drug."<sup>4</sup>

The Center also noted that in 2007, FDA official David Graham, MD, testified before a House committee that he estimated that each year, 15,000 elderly nursing home residents were dying from off-label use of antipsychotic medications "for an indication that FDA knows the drug doesn't work."<sup>5</sup>

Recent federal and state lawsuits against large long-term care pharmacies, pharmaceutical manufacturers, and nursing home chains provide evidence that conflicts of interest and misaligned financial incentives in the payment system perpetuate overmedication and inappropriate care. A settlement agreement between the long-term care pharmacy giant Omnicare and the Justice Department in a False Claims Act case in 2009 stipulated that Omnicare submitted claims to Medicare and Medicaid that were fraudulent because they resulted from kickbacks in the form of consultant pharmacist services that Omnicare provided to nursing homes below its cost of providing the services.<sup>6</sup>

Nursing home residents receive altogether, on average, some 8 to 10 prescription drugs of various kinds, many of which may have unproven efficacy or safety or potential for harmful interactions. This also makes it imperative that the LTC consultant pharmacist be independent to fulfill his or her proper regulatory function to ensure that residents receive appropriate medications and drug regimens.

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<sup>3</sup> Briesacher, B.A., et al., "The Quality of Antipsychotic Drug Prescribing in Nursing Homes," *Archives of Internal Medicine*, 165, pp. 1280-1285.

<sup>4</sup> CMA Alert, "Off-Label Drug Use Is Common and Hurts Nursing Home Residents," Center for Medicare Advocacy, March 25, 2010.

<sup>5</sup> See above.

<sup>6</sup> *Settlement Agreement among (A) United States, (B) Omnicare, and (C) Adam Resnick, David Kammerer, Deborah Maguire, and Bernard Lisitza*, 2009.

For many nursing home residents, overmedication appears to be the consequence of inadequate staffing. A 2004 study found that residents in nursing homes with fewer RNs to residents had twice the risk of receiving potentially inappropriate prescriptions.<sup>7</sup> This is unsurprising given the research showing that at the nurse staffing levels in more than 90 percent of our nursing homes, residents are likely to be harmed. Understaffing is not, however, an excuse for overmedicating residents; in fact, overmedicating allows understaffing and substandard care by silencing residents' ability to express their needs. This clearly contradicts long-established Medicare and Medicaid requirements for nursing homes to have sufficient staff, just as they are required to respect and foster resident dignity and provide care that is free from physical and chemical restraint and unnecessary drugs.

The United States is struggling with unsustainable growth in health care costs, and our most vulnerable citizens are living under the threat of deficit reduction with severe, permanent cuts in safety net programs. CMS should address all aspects of a system that the Inspector General says allowed more than 300,000 nursing home residents to receive drugs that were not used for medically approved reasons, may have jeopardized their health or caused their death, and cost Medicare \$116 million in inappropriate payments, in addition to unknown costs of treating any medical problems and loss of functioning caused by the drugs.

### **Government Action to Stop Abuses Is Overdue**

In the 1970s, the Senate Special Committee on Aging held hearings and issued a series of reports under the title *Nursing Home Care in the United States: Failure in Public Policy*. Supporting Paper No. 2 was subtitled "Drugs in Nursing Homes: Misuse, High Costs, and Kickbacks." The paper explored overmedication of residents, promotion of "the social control potential" of drugs that met "management needs and wishes of professionals rather than the therapeutic needs of the elderly," kickbacks from pharmacies to nursing homes for the privilege of providing drugs to their residents, and other practices that were "highly questionable and in most cases clearly illegal."<sup>8</sup>

The report called psychotropic drugs of the day a "chemical straight jacket." By the early 70s, \$30 million a year was already being spent in nursing homes for "the two strongest tranquilizers available, Thorazine and Mellaril."<sup>9</sup> The manufacturer of Mellaril (thioridazine) advertised that it was "especially suited to the nursing-home patient" since staff "find their work load greatly lightened."<sup>10</sup> Similarly, Valium (diazepam) was advertised to reduce symptoms in residents who would become "less complaining," "less dependent," "less troublesome," and require "less nursing care."<sup>11</sup> But as the National Council of Senior Citizens noted in testimony before the committee in 1970, "Excessive use of tranquilizers can quickly reduce an ambulatory patient to a

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<sup>7</sup> Potentially Inappropriate Medication Prescriptions among Elderly Nursing Home Residents: Their Scope and Associated Resident and Facility Characteristics, Denys T. Lau and others, *Health Services Res.* 2004 October; 39(5): 1257-1275.

<sup>8</sup> *Nursing Home Care in the United States: Failure in Public Policy*, Supporting Paper No. 2, *Drugs in Nursing Homes: Misuse, High Costs, and Kickbacks*, Subcommittee on Long-Term Care, Senate Special Committee on Aging, January 1975, p. 284.

<sup>9</sup> See above, p. 268.

<sup>10</sup> See above, p. 277.

<sup>11</sup> See above, pp. 282-283.

zombie, confining the patient to a chair or bed, causing the patient's muscles to atrophy from inaction and causing general health to deteriorate quickly."<sup>12</sup>

In the past several years, the government has charged several major pharmaceutical companies, nursing home chains, and long-term care pharmacies with illegal practices, including kickbacks and off-label marketing of antipsychotic drugs with FDA "black box" warnings that they increased the risk of death in elderly persons with dementia.

- Eli Lilly paid \$1.415 billion to settle federal and state claims that its sales force promoted Zyprexa, an atypical antipsychotic approved for treatment of psychiatric disorders, to help elderly patients with sleep problems, behavioral issues, and dementia. This "illegal off-label marketing campaign raised safety issues and posed potential risk to patients," according to the Justice Department. "Eli Lilly knew that significant weight gain and obesity were adverse side effects of Zyprexa and that weight gain and obesity were factors in causing hyperglycemia and diabetes." In long-term care facilities, the campaign was called "5 at 5," assuring providers that five milligrams of Zyprexa at 5 p.m. would help troublesome patients sleep all night—an adverse side effect, not a therapeutic benefit, according to prosecutors."<sup>13</sup>
- As noted previously, Omnicare paid the government \$98 million in 2009 to settle various charges, including a claim that Omnicare solicited and received kickbacks from Johnson & Johnson to recommend that physicians prescribe Risperdal, which increases the risk of strokes and heart attacks in elderly persons with dementia. In this case, the Justice Department alleged "that Omnicare regularly paid kickbacks to nursing homes by providing consultant pharmacist services at rates below the company's cost and below the fair market value of such services in order to induce the homes to refer their patients to Omnicare for pharmacy services." Moreover, the government alleged, "J&J understood that Omnicare's pharmacists reviewed nursing home patients' charts at least monthly and made recommendations to physicians on what drugs should be prescribed for those patients. The government further alleges that J&J knew that physicians accepted the Omnicare pharmacists' recommendations more than 80 percent of the time, and that J&J viewed such pharmacists as an 'extension of [J&J]'s sales force."<sup>14</sup>

Inspector General Levinson has said, "The drug companies have paid billions to resolve these civil and criminal liabilities under federal health and safety laws. But money can't make up for the years of corporate campaigns that market drugs with questionable benefits and potentially deadly side effects for vulnerable, elderly patients."<sup>15</sup>

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<sup>12</sup> See above, p. 269.

<sup>13</sup> Press Release, "Pharmaceutical Company Eli Lilly to Pay Record \$1.415 Billion for Off-Label Drug Marketing," United States Attorney, Eastern District of Pennsylvania, Jan. 15, 2009.

<sup>14</sup> Press Release, "U.S. Files Suit Against Johnson & Johnson for Paying Kickbacks to Nation's Largest Nursing Home Pharmacy, U.S. Department of Justice, Jan. 15, 2010.

<sup>15</sup> "Overmedication of Nursing Home Patients Troubling," Daniel R. Levinson, Inspector General, Department of Health and Human Services, May 9, 2011.

In 1975, better use of consultant pharmacists was recommended as a remedy to keep check on conflicts of interest and abuses in the system.<sup>16</sup> Since then, the growth of long-term care pharmacies has changed the dynamics in nursing home prescribing but not the fact that conflicts of interest profoundly affect the quality of care and life of many nursing home residents.

### **Recommendations**

The undersigned organizations therefore urge CMS to:

- Require long-term care consultant pharmacists to be independent of any affiliations with long-term facilities or pharmaceutical manufacturers, distributors, or affiliates of these entities.
- Require long-term care facilities to use qualified professional pharmacists to conduct drug regimen reviews and make medication recommendations solely on the best interests of the resident.
- 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.
- Create strict enforcement mechanisms to ensure the independence of long-term care pharmacists, including lengthy exclusion from participation in Medicare and Medicaid for non-compliance.
- Implement modifications to survey and enforcement procedures, including data collection mechanisms, to ensure strict compliance with the requirement.
- Consult with consumer stakeholders, including long-term care ombudsmen, on the effectiveness of steps taken to address the issue.

Attached to this letter are:

- [Proposed regulatory language to amend 42 CFR 483.60 related to pharmacy services.](#)
- [A resolution approved by member organizations of The National Consumer Voice for Quality Long-Term Care calling on CMS to require consultant pharmacists to be free of conflict of interest.](#)

Thank you again for the opportunity to comment on this critically important proposal to eliminate conflict of interests that affect the independent judgment of consultant pharmacists.

Sincerely,

[Signing organizations will be listed here]

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<sup>16</sup> See *Failure in Public Policy*, pp. 295-296.