



“The War on Drugs Meets the War on Pain: Nursing Home Residents Caught in the Crossfire”

**Hearing before the Senate Special Committee on Aging
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Statement of the Center for Medicare Advocacy and California Advocates for Nursing Home Reform

**Toby S. Edelman
Senior Policy Attorney
Center for Medicare Advocacy**

The Center for Medicare Advocacy, a national non-profit organization that represents the rights and interests of Medicare beneficiaries, including nursing home residents, and California Advocates for Nursing Home Reform (CANHR), a statewide advocacy organization for residents, are extremely troubled by the Senate Aging Committee’s hearing today. The hearing is focused on the wrong question and it appears to have pre-judged the answer. The issue is not whether nursing home residents should receive the pain medication that they need. The answer to that question is an obvious yes. (Moreover, nursing homes under-identify and under-treat residents’ pain.) The real question is why nursing facilities are violating not only the Controlled Substances Act but also the Nursing Home Reform Law. Why is medical attention so inadequate in so many nursing homes? Why are physicians not available 24 hours a day, as required by the federal Nursing Home Reform Law, to direct the medical care of residents? Why are physicians rubber-stamping facility recommendations for pain medication and not examining seriously ill residents to determine why facility staff believe pain medication is needed on an emergency basis? The Center and CANHR oppose any actions by Congress that would condone inadequate care practices and further erode the quality of care that nursing home residents receive.

The Center and CANHR urge the Committee to focus on the real medication issue that is literally killing nursing home residents each day – the inappropriate off-label use of antipsychotic medications with residents who do not have a diagnosis of psychosis.

The issue of this hearing

The Drug Enforcement Administration (DEA) has recently begun to enforce long-standing rules and policy regarding controlled substances and nursing home residents. These rules and policy require that physicians write and sign prescriptions for all controlled substances, including many pain medications commonly taken by nursing home residents. The DEA's recent enforcement activity has led to a loud and orchestrated outcry by the nursing home and nursing home pharmacy industries, which argue, individually and collectively, that long-standing practice is being overturned. They contend that under common practice, nursing home nurses who assess a resident's changed condition may contact the physician by phone to describe the resident's symptoms and vital signs. When the physician gives a nurse an order for a new drug or a changed drug or agrees to the nurse's recommendation for a pain medication, the nurse records the prescription in the chart and calls it in to the pharmacy or fills it through the emergency supply of drugs that is kept on hand in the facility. Nursing homes use such so-called "chart orders" for all medications, including controlled substances.

The nursing home and long-term care pharmacy industries argue that if federal law is not amended to allow these practices, nursing home residents will not get the pain medication they need. Congress should not yield to such diversionary arguments, but should ask, instead, where are the physicians?

Where are the physicians? For nearly 20 years, **the Nursing Home Reform Law** has required that the care of each resident be under the supervision of a physician and that each nursing facility "provide for having a physician available to furnish necessary medical care in case of an emergency."¹ Regulations addressing Physician Services reiterate the statutory requirement for emergency physician availability and require that "(1) The medical care of each resident is supervised by a physician; and (2) Another physician supervises the medical care of residents when their attending physician is unavailable."² Federal guidance for surveyors suggests that surveyors ask a question that is directly related to the topic of this hearing, "If the supervising physician was unavailable and could not respond, did the facility have a physician on call? Did this physician respond?"³

The nursing home and long-term care pharmacies' arguments in support of continuing their "chart order" practices completely ignore the existing requirements of the Nursing Home Reform Law. Instead of discussing nursing homes' obligation to have physicians available 24 hours a day to attend to residents who are seriously ill, they contend that residents' physicians are unavailable – physicians are present in nursing homes only intermittently, they do not have offices, they work out of their cars.⁴

¹ 42 U.S.C. §§139i-3(b)(6)(A), (B), 1396r(b)(6)(A), (B), Medicare and Medicaid, respectively. The requirements of the Reform Law became effective for nursing homes on October 1, 1990.

² 42 C.F.R. §483.40(a)(1), (2).

³ CMS, State Operations Manual, Appendix PP, §483.40(a) probes, at 505, http://cms.hhs.gov/manuals/Downloads/som107ap_pp_guidelines_ltcf.pdf

⁴ See, e.g., AAHSA, "Issue Brief: Nursing Home Chart Orders and the Controlled substances Act" (Oct. 1, 2009). <http://www.aahsa.org/article.aspx?id=10080>; American Health Care Association/American Medical Directors Association, "Physician Order Sheet & Verbal Orders White Paper" (Nov. 17, 2009).

The Department of Justice has correctly rejected the industries' specious arguments. In December 2, 2009 letters to Senators Herb Kohl and Sheldon Whitehouse, Assistant Attorney General Ronald Weich reported that pharmacists' complaints to the DEA had promoted the recent investigations. While sharing the Senators' concerns that residents' health and welfare be assured, he argued that business practices like chart orders "trivialize the doctor patient relationship and weaken the quality of care for the frail and infirm," while increasing the risk of diversion of controlled drugs.⁵ The Center and CANHR strongly agree.

Drug diversion in nursing homes and assisted living facilities

Drug diversion is indeed a problem in nursing homes, as it is in many other health care settings where drugs are readily available. Among the many recent convictions, guilty pleas, arrests, and investigations of drug diversion and drug misuse in nursing homes and assisted living facilities are the following:⁶

- The North Carolina State Bureau of Investigation is investigating how nine of 29 residents of the Alzheimer's unit of a Chapel Hill nursing home, including one resident who died, tested positive for opiate pain control medication that was not prescribed for them.⁷
- A registered nurse in Iowa is charged with stealing prescription drugs from the nursing home where she worked and with falsifying names on prescriptions in order to receive the medications or to cover up her repeated thefts.⁸
- A Pennsylvania nurse pleaded guilty to stealing painkillers meant for patients at the nursing home where she worked.⁹
- The former director of a Georgia assisted living facility was sentenced to one year in prison for stealing a resident's prescription medications. A federal investigation linked her to the theft of nearly 4000 prescription painkillers prescribed for the facility's residents.¹⁰

⁵ http://www.ascp.com/advocacy/qccpp/upload/120209%20DEA%20Response%20Kohl_Whitehouse.pdf.

⁶ The Center and CANHR thank Barbara Becker, an Indiana nursing home advocate, for her assistance in identifying these cases.

⁷ Chris Lavender, "SBI investigates Britthaven of Chapel Hill," *Kinston.com* (March 12, 2010), <http://www.kinston.com/news/investigation-62673-britthaven-operated.html>; Sarah Avery and Thomas Goldsmith, "Positive tests for opiates alarm Chapel Hill nursing home staff," *News-Observer* (Feb.18, 2010), <http://www.newsobserver.com/2010/02/18/344567/positive-tests-for-opiates-alarm.html>.

⁸ "Nurse faces felony charges," *Muscatine Journal* (Dec. 4, 2009), http://muscatinejournal.com/news/local/article_50e6e624-19f9-51bf-8ad2-0cc224350167.html.

⁹ Matt Miller, "Nurse pleads guilty in West Shore drug theft case," *The Patriot-News* (Sep. 17, 2009), http://www.pennlive.com/midstate/index.ssf/2009/09/nurse_pleads_guilty_in_west_sh.html.

¹⁰ Teresa Stepzinski, "Georgia ex-care director gets year for stealing patient drugs," *The Florida Times-Union* (Dec. 4, 2009), http://jacksonville.com/news/georgia/2009-12-04/story/georgia_ex_care_director_gets_year_for_stealing_patient_drugs.

The real medication issue that this Committee and Congress should address – the inappropriate off-label use of antipsychotic medications with nursing home residents

In April 2005, the Food and Drug Administration (FDA) issued “black box” warnings against prescribing atypical antipsychotic drugs for patients with dementia, cautioning that the drugs increased dementia patients’ mortality.¹¹ In June 2008, extending its “black box” warning to conventional antipsychotic drugs, the FDA directly and unequivocally advised health care professionals, “Antipsychotics are not indicated for the treatment of dementia-related psychosis.”¹²

In the fourth quarter of 2009, the federal government reports that 26.1% of the nation’s 1,359,787 nursing home residents – 354,904 people – received antipsychotic drugs.¹³ Studies confirm that 25-30% of nursing home residents nationwide are given conventional and atypical antipsychotic drugs, most often, for off-label reasons not approved by the FDA.¹⁴ Many residents are dying, as a result. In February 2007, David Graham, M.D., MPH, Associate Director, Science and Medicine, FDA Office of Surveillance and Epidemiology, testified in the

¹¹ FDA, “Information for Healthcare Professionals: Conventional Antipsychotics,” FDA Alert (June 16, 2008), <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforHealthcareProfessionals/ucm084149.htm>.

¹² FDA, “Information for Healthcare Professionals: Conventional Antipsychotics,” FDA Alert (June 16, 2008), <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforHealthcareProfessionals/ucm084149.htm>.

¹³ Centers for Medicare & Medicaid Services, *MDS Active Resident Information Report: Fourth Quarter 2009*, O4a: Medications - Days Received the Following Medication – Antipsychotic, http://www.cms.hhs.gov/MDSPubQIandResRep/04_activeresreport.asp?isSubmitted=res3&var=O4a&date=29.

¹⁴ A retrospective analysis of the use of anti-psychotic drugs by Medicare beneficiaries in nursing homes in 2000-2001 found the highest rate of antipsychotic drug use in more than a decade. The analysis reported that 27.6% of residents received at least one prescription for antipsychotic drugs, that nearly one-quarter (23.4%) had no appropriate indication, and that more than half (58.2%) “took doses exceeding maximum levels, received duplicative therapy, or had inappropriate indications according to guideline requirements.” Becky A. Briesacher, Rhona Limcangco, Linda Simoni-Wastila, Jalpa A. Doshi, Suzi R. Levens, Dennis G. Shea, Bruce Stuart, “The Quality of Antipsychotic Drug Prescribing in Nursing Homes,” *Arch Intern Med.*, Vol. 165 (June 13, 2005), <http://archinte.ama-assn.org/cgi/reprint/165/11/1280?maxtoshow=&hits=10&RESULTFORMAT=&fulltext=Briesacher&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT>. Using data from the 2004 National Nursing Home Survey, a later study found that 23.5% of residents received at least one second-generation antipsychotic drug, that 86.3% of the drug use was off-label, and that 43% of the use “was without strong scientific support.” Pravin Kamble, Jeff Sherer, Hua Chen, Rajender Aparasu, “Off-Label Use of Second-Generation Antipsychotic Agents Among Elderly Nursing Home Residents,” *Psychiatric Services*, Vol. 61, No. 2, p. 130 (Feb. 2010). Abstract available at <http://ps.psychiatryonline.org/cgi/content/abstract/61/2/130?maxtoshow=&hits=10&RESULTFORMAT=&fulltext=Kamble&searchid=1&FIRSTINDEX=0&sortspec=relevance&resourcetype=HWCIT>. Even after the FDA issued a black-box warning against prescribing the atypical antipsychotic drugs for patients with dementia in April 2005, cautioning that the drugs increased dementia patients’ mortality (FDA, “Information for Healthcare Professionals: Conventional Antipsychotics,” FDA Alert (June 16, 2008), <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforHealthcareProfessionals/ucm084149.htm>), a study of nursing home residents admitted to nursing homes in 2006 – after the black box warning was issued – found that more than 29% of newly-admitted residents received at least one antipsychotic medication in 2006 and that 32% of the residents “had no identified clinical indication for this therapy.” Yong Chen, Becky A. Briesacher, Terry S. Field, Jennifer Tjia, Denys T. Lau, Jerry H. Gurwitz, “Unexplained Variation Across US Nursing Homes in Antipsychotic Prescribing Rates,” *Arch Internal Medicine*, Vol. 170, No. 1 (Jan. 11, 2010), <http://archinte.ama-assn.org/cgi/content/abstract/170/1/89>.

House of Representatives that, by his estimate, “15,000 elderly people in nursing homes [are] dying each year from the off-label use of antipsychotic medications for an indication that FDA knows the drug doesn’t work.”¹⁵

Conclusion

Residents who are experiencing pain need to be seen by physicians, who can evaluate the causes of the pain and prescribe appropriate treatments, including medications. For 20 years, federal law has required that physicians be available 24 hours per day to attend to the emergency medical needs of nursing home residents. The Centers for Medicare & Medicaid Services and states need to assure that long-standing requirements of the 1987 Nursing Home Reform Law are fully implemented; the DEA needs to enforce the requirements of the Controlled Substances Act.

Implementation of both laws will assure that residents receive the care, services, and medications they need, that residents are not in pain, and that controlled substances are not diverted.

The Center for Medicare Advocacy is a private, non-profit organization founded in 1986, that provides education, analytical research, advocacy, and legal assistance to help elders and people with disabilities obtain necessary healthcare. The Center focuses on the needs of Medicare beneficiaries, people with chronic conditions, and those in need of long-term care. The Center provides training regarding Medicare and healthcare rights throughout the country and serves as legal counsel in litigation of importance to Medicare beneficiaries nationwide.

California Advocates for Nursing Home Reform is a statewide non-profit 501(c)(3) advocacy organization that is dedicated to improving the choices, care, and quality of life for California’s long-term care consumers. Through direct advocacy, community education, legislation, and litigation, CANHR works to educate and support long-term care consumers and advocates regarding the rights and remedies under the law and to create a united voice for long term-care reform and humane alternatives to institutionalization.

¹⁵ Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, “The Adequacy of FDA to Assure the Safety of the Nation’s Drug Supply,” 110th Cong., First Sess. (March 13, 2007), Serial No. 110-5, page 66, http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_house_hearings&docid=f:35502.pdf.