Working Together to Curb Misuse of Powerful Antipsychotic Drugs in Nursing Homes || CMA

On May 31, 2012, the Centers for Medicare & Medicaid Services (CMS) announced an initiative to reduce the rampant misuse and overuse of antipsychotic drugs in nursing facilities. The Center for Medicare Advocacy has been working to educate policy makers, advocates, and the public about the misuse of antipsychotic drugs for many years, and is part of an ad hoc coalition of advocates working with CMS and Congress to address the problem that both harms residents and costs the Medicare program billions of dollars.[1]

CMS's press release announcing the "Partnership to Improve Dementia Care"[2] describes several steps that CMS is taking:

- **Enhanced training**: CMS has developed "Hand in Hand," a training series for nursing homes that emphasizes person-centered care, prevention of abuse, and high-quality care for residents. CMS is also providing training focused on behavioral health to state and federal surveyors;
- **Increased transparency**: CMS is making data on each nursing home's antipsychotic drug use available on Nursing Home Compare starting in July of this year, and will update the data;
- **Alternatives to antipsychotic medication**: CMS is emphasizing non-pharmacological alternatives for nursing home residents, including potential approaches such as consistent staff assignments, increased exercise or time outdoors, monitoring and managing acute and chronic pain, and planning individualized activities.

At the May 31, 2012 press briefing announcing the initiative, Shari M. Ling, M.D., CMS's Deputy Chief Medical Officer, identified additional CMS strategies – raising public awareness, strengthening regulatory oversight, and research. Dr. Ling said that residents' advocates working on the issue of antipsychotic drugs for many years had brought the issue to the forefront of public attention. She said, "We would not be here today without them."[3]

**Antipsychotic Drug Deficiencies Are Cited, But Enforcement Is Timid**

Speaking earlier this month at a symposium on dementia care without drugs, sponsored by California Advocates for Nursing Home Reform (CANHR), Jonathan Evans, M.D., a geriatrician and president-elect of the American Medical Directors Association, described the CMS plan as reasonable but primarily “‘an effort to try to educate people rather than to regulate.’”[4] CANHR attorney Tony Chicotel agreed with the need for increased enforcement. The Center for Medicare Advocacy agrees with their concerns.

Since the Nursing Home Reform Law (enacted in 1987) was implemented in October 1990, federal law and its implementing regulations and guidance have contained strong restrictions on the use of antipsychotic drugs.[5] Two survey and enforcement issues, however, undercut the law's effectiveness.

1. "Level of Harm" Coding Assigns a Value to Deficiencies that is Too Low Either to Provide a Meaningful Sanction for Poor Care or to Lead to Better Facility Practices.
Although some drug deficiencies are cited each year, their significance is understated and undercoded. The federal enforcement system assigns a scope and severity level to each deficiency that is cited, using a federal scope and severity grid. The grid was published in 1994 as part of the final enforcement regulations.[6] There are four levels of severity. Two levels indicate no harm (substantial compliance and no harm) and two indicate harm (harm and immediate jeopardy). Generally, when states cite deficiencies at a no-harm level, no financial penalty is imposed.

State survey agencies typically cite antipsychotic drug deficiencies at the no-harm level. In fiscal year 2012, 1,213 unnecessary drug deficiencies, 42 C.F.R. §483.25(l), (F329), were cited nationwide. (F329 is the tag where antipsychotic drugs are cited.) However,

- 1185 (98%) nationwide were cited at a no-harm level;
- Only 13 deficiencies nationwide (0.01%) were cited at a harm level; and
- Only 12 deficiencies nationwide (0.01%) were cited at the highest level of harm, immediate jeopardy.

As a consequence of the no-harm, no-penalty practice, FY2012 data show that most facilities cited with unnecessary drug deficiencies are unlikely to have had any financial penalty imposed.


At present, even when an unnecessary drug deficiency is cited and even when a remedy is imposed, the drug deficiency does not result in a meaningful financial penalty. Under the federal enforcement system, facilities that have remedies imposed against them may request an administrative appeal before an Administrative Law Judge (ALJ). They may not request a hearing if a deficiency is cited, but no remedy is imposed.

Since 2006, there have been only six ALJ decisions nationwide addressing unnecessary drug deficiencies, 42 C.F.R. §483.25(l), and only two of these decisions involved deficiencies for antipsychotic drugs. Both decisions were from Illinois and were decided by ALJ Carolyn Cozad Hughes.

- Manor Care at Palos Heights – West v. CMS, Civil Remedies Division (CR) 1847 (Sep. 24, 2008),[7] sustained three jeopardy-level deficiencies for excessive doses of Risperdal, that were given to a resident because of transcription errors from the hospital. The resident, who was given 10 times the amount actually prescribed during her entire 12-day stay at the nursing facility, who did not have any diagnosis justifying use of the antipsychotic drug, and who was given three different psychotropic medications, died. The ALJ rejected as "frivolous" the facility's argument that the 68-year old resident was not elderly and therefore not covered by the Food and Drug Administration's Black Box warning that antipsychotic drugs increase the risk of death in older people with dementia.[8] Sustaining immediate jeopardy, the ALJ wrote, "On multiple occasions, facility nurses administered to a vulnerable resident massively excessive doses of a potentially dangerous medication. The warning of potentially dire consequences went unheeded. The consulting pharmacist posed no questions about it, even though she had no idea why the drug had been prescribed." The civil money penalties were $3050 for one day of jeopardy, $50 per day for 27 days of non-jeopardy (the minimum daily amounts authorized by federal law), and totaled $4400.

- Washington Christian Village v. CMS, CR2403 (July 2, 2011),[9] sustained an unnecessary drug deficiency, based on multiple antipsychotic drugs given to two residents, neither of whom had a diagnosis justifying use of the drugs. Tracking the requirements of the regulations, ALJ Hughes sustained the deficiency, finding that the physician provided inadequate justification for the
drug use, the residents were given duplicate therapy (multiple drugs for the same purpose), dosages were high (in violation of federal guidance), and the facility did not monitor residents for side effects. The civil money penalties were $300 per day for 47 days and $100 per day for 27 days and totaled $16,800.

Although a third decision by ALJ Hughes discussed antipsychotic drugs, the 24-year old resident died because of an excessive dose of a different category of drugs. Embassy Health Care v. CMS, CR2464 (Nov. 8, 2011)[10]. (The resident was given a total of 22 different drugs, including four antipsychotic drugs, three antidepressants, and one pain reliever.) The civil money penalties ($300 per day) totaled $3900.

The civil money penalties imposed in each of these cases were too small to be meaningful sanctions against facilities that so seriously harmed residents and violated federal law or to bring about change in the facilities' practices.

The Misuse of Antipsychotic Drugs in Nursing Facilities Has Long Been Known

In February 1992, in the preamble to proposed regulations that would have given residents new protections from chemical restraints, the Health Care Financing Administration (HCFA) (predecessor agency to CMS) described the long-standing and "significant public health problem in many, but not all of this nation's long-term care facilities."[11] The problem of misuse of psychoactive drugs by nursing homes that HCFA described was, even then, more than 15 years old:

For many years, there have been allegations of misuse of psychoactive drugs in these facilities. In 1975, the Special Committee on Aging of the U.S. Senate held hearings on this public health problem and made reference to "chemical straight jackets" in nursing homes. In 1980, the House Select Committee on Aging held hearings on the same subject. They entitled their report, "Drug Abuse in Nursing Homes." Most recently, articles that deal with the subject have appeared in a number of medical journals. These papers generally question the extent of the use of psychopharmacologic drugs in nursing homes and question whether adequate monitoring of the use of these drugs exists.[12]

The misuse of antipsychotic drugs was most recently brought to public attention by The Wall Street Journal in 2007, when Lucette Lagnado reported that:

- Most nursing home residents given atypical antipsychotic drugs had no diagnosis justifying use of the drugs;
- Most use was off-label and conflicted with Black Box warnings from FDA; and
- There was little benefit to residents from the drugs, in light of the risks.[13]

Senator Charles Grassley (R, IA) asked the HHS Office of Inspector General (OIG) to investigate the charges. OIG issued a May 2011 report documenting the excessive use of atypical antipsychotic drugs.[14] This report led to a hearing before the Senate Special Committee on Aging in November 2011 entitled Overprescribed: The Human And Taxpayers' Costs Of Antipsychotics In Nursing Homes, at which the Center's Senior Policy Attorney Toby S. Edelman testified.[15]

Conclusion

The CMS initiative is an important step in the effort to reduce antipsychotic drugs, but it focuses primarily on education and public information. The Center and the advocates with whom it works are hopeful that an expanded CMS initiative, including a strong enforcement response, will reverse the epidemic use of antipsychotic drugs in nursing facilities, a problem particularly relevant this week as we honor Elder Abuse Awareness Day (Friday, June 15th) and work towards solutions to ensure older
Americans are not harmed in any care setting.

[1] The ad hoc coalition of advocates, including California Advocates for Nursing Home Reform, the National Consumer Voice for Quality Long-Term Care, the (New York) Long Term Care Community Coalition, and the Legal Aid Justice Center of Charlottesville, Virginia, has focused on the misuse of antipsychotic drugs for several years. Last fall, the group met with then-CMS Administrator Donald Berwick about the pervasive problem of antipsychotic drug use.


[3] The Center for Medicare Advocacy is part of the ad hoc coalition of advocates (California Advocates for Nursing Home Reform, the National Consumer Voice for Quality Long-Term Care, the (New York) Long Term Care Community Coalition, and the Legal Aid Justice Center of Charlottesville, Virginia) that has focused on the misuse of antipsychotic drugs for several years. Last fall, the group met with then-CMS Administrator Donald Berwick about the pervasive problem of antipsychotic drug use, which both harms residents and costs the Medicare program billions of dollars.


[12] Id.


[14] Office of Inspector General, Department of Health and Human Services, Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents, OEI-07-08-00150 (May