

# LONG TERM CARE COMMUNITY COALITION

*Advancing Quality, Dignity & Justice*

## Issue Alert: Antipsychotic Drugs

### I. What are Antipsychotic Drugs?

Antipsychotic medications are highly potent drugs that are indicated to treat specific conditions and diagnoses, such as schizophrenia. They include drugs such as Haldol, Abilify, and Seroquel (see <http://nursinghome411.org/antipsychotics-by-class/> for a list of antipsychotic drugs).

### II. Why are Antipsychotic Drugs a Concern to the Elderly?

The inappropriate antipsychotic drugging of nursing home residents, particularly those with dementia, is a widespread, national problem. Despite the Food and Drug Administration's 'black box' warnings against using powerful and dangerous antipsychotics on elderly patients with dementia, they are frequently used to treat the so-called behavioral and psychological symptoms of dementia.<sup>1</sup> These and other psychotropic drugs are often used as a form of chemical restraint, sedating residents so that not only their behaviors but also the underlying causes for those behaviors do not have to be addressed by staff. In addition to destroying social and emotional well-being, these drugs greatly increase risks of stroke, heart attack, diabetes, Parkinsonism, and falls. They are **not** clinically indicated for dementia-related psychosis. They **are** associated with a significant increase in death when given to elderly people with dementia.

While nursing home residents with dementia have been the focus of the federal campaign to reduce inappropriate antipsychotic drugging, these drugs can be a problem for elderly people with dementia no matter where they live. Although this Issue Alert focuses on the federal requirements for nursing homes, they are predicated on care standards that, we believe, apply to individuals no matter where they live.

### III. What are the Standards of Care?

Under the federal Nursing Home Reform Law, **each resident has the right to be treated with dignity and to be free from abuse and neglect.** Federal standards require that residents be given the necessary care they need to reach their highest practicable physical, emotional, and psychological well-being. For residents with dementia, this means that nursing homes must provide care, personal assistance and social services that are tailored to, and appropriate for,

#### Note to Readers:

LTCCC Issue Alerts provide basic information about an issue of concern to nursing home residents.

For further information, please see the Resources and references at the end of the Alert, as well as our website, [www.nursinghome411.org](http://www.nursinghome411.org).

the individual. The standards explicitly include protections against inappropriate antipsychotic drug use and the use of chemical restraints.

Federal minimum standards include:

- **Avoid Antipsychotic Drugs.** Nursing homes must ensure that residents are not given antipsychotic drugs unless such drugs are necessary to address a specific condition that has been diagnosed and documented.
- **Informed Consent.** Nursing homes must inform the resident, or the resident's representative, of any proposed treatment, in language that the individual can understand. Residents (or their representatives) have the right to refuse treatment.
- **Gradual Dose Reduction.** If a resident is given antipsychotic drugs, nursing homes must gradually reduce the resident's dose unless it is clinically inadvisable.<sup>2</sup>

#### IV. Is This Really a Big Problem?

According to the federal Centers for Medicare & Medicaid Services (CMS), about 20% of nursing home residents are being given antipsychotic drugs.<sup>3</sup> That is over a quarter of a million nursing home residents. Yet, less than two percent of the population will ever have a diagnosis for a clinical condition identified by CMS when it risk-adjusts for potential appropriate uses of these drugs.<sup>4</sup>

When citing nursing homes for inappropriate antipsychotic drug use, state surveyors currently cite to the general category of "Unnecessary Drug Use."<sup>5</sup> As of November 2017, state surveyors have cited nursing homes for 10,758 deficiencies over the course of the last three inspection cycles. While not all deficiencies in this category specifically relate to antipsychotics, reports indicate that about one-third to one-half of deficiencies may be for the inappropriate use of antipsychotic drugs.<sup>6</sup>

As noted earlier, this problem extends beyond nursing homes. A recent study found that two-thirds of assisted living residents have been diagnosed with dementia and 37% of those individuals have received an antipsychotic drug.<sup>7</sup>

For more information on the relevant standards, including advocacy tips, visit LTCCC's Learning Center at <http://nursinghome411.org/learning-center/>. The Learning Center has many free, easy-to-use resources, including the Dementia Care Advocacy Toolkit.

#### V. How Can I Find Out About Antipsychotic Drug Rates – and Deficiencies – in My Nursing Home or Those in My State?

Rates of antipsychotic drug use can vary greatly nursing home to nursing home. [Nursing Home Compare](http://www.medicare.gov/nursinghomecompare) (<http://www.medicare.gov/nursinghomecompare>) provides information on individual licensed nursing homes across the country. For each nursing home, antipsychotic drug rates are provided for both short-term and long-term stay residents under "Quality of resident care."

In order to provide the public with relevant information on antipsychotic drug use, LTCCC's [Nursing Home Information & Data Page](http://www.nursinghome411.org) (on our [www.nursinghome411.org](http://www.nursinghome411.org) website) has searchable and downloadable files on every licensed nursing home in the country, including:

### **US Nursing Home Antipsychotic Medications Rates for Long-Stay Residents**

This page provides individual files for every state and Washington, DC. Each file has information on the antipsychotic drugging rates for every licensed facility in the state. This list is searchable by facility name, city, and zip code. It can also be sorted to see which facilities have the highest – and lowest – antipsychotic drug rates in the state.

### **US Nursing Home Citations for Unnecessary Drug Use**

This page also provides individual files for every state and Washington, DC. Each file contains the names of each facility in the state that have been cited for unnecessary drug use in the last three years (as of the processing date indicated). It is searchable by facility name, address, city, and zip code.

All of the data are from the federal Medicare website. They have been formatted to make it easy to access relevant information on nursing homes in your state or community.

#### **VI. Case Study of a Resident Who Suffered From Antipsychotic Drugging**

When a state surveyor identifies substandard care, those findings are described in what is called a Statement of Deficiencies (SoD). All nursing home SoDs are published on [Nursing Home Compare](#). A June 2017 inspection of the Penn Yan Manor Nursing Home in Penn Yan, New York, illustrates one such instance where surveyors cited a nursing facility for substandard care because of unnecessary drug use.

State surveyors found that, for two of the five residents reviewed, the facility was deficient in “mak[ing] sure that each resident’s drug regimen is free from unnecessary drugs and that each resident’s entire drug/medication is managed and monitored to achieve highest well-being.”<sup>8</sup>

One resident was prescribed 50mg of an antipsychotic drug for dementia with hallucinations and paranoia in April 2016. By June of that year, the physician noted that the resident’s hallucination had stopped; by September, the pharmacist recommended that the resident’s dose be gradually reduced and that non-pharmacological interventions be used instead. The nurse practitioner documented that she disagreed and that the antipsychotic drug would still be given at the original dose.

A second pharmacy consult in February 2017 resulted in the same recommendations as before. The pharmacist recommended that the resident’s dose be lowered and even noted that certain medical symptoms the resident was experiencing may have been linked to his current dose. The nurse practitioner decided to have a psychiatric consult before reducing the resident’s dose, which a social worker was responsible for scheduling.

The social worker noted in April 2017 that the resident needed to see a psychologist. When state surveyors interviewed the social worker in June, the social worker stated that she made a mistake in scheduling a psychologist because that was not the same as a psychiatrist. The

***Too many of these institutions fail to comply with federal regulations designed to prevent overmedication, giving nursing home patients antipsychotic drugs in ways that violate federal standards for unnecessary drug use . . . Government, taxpayers, nursing home residents, as well as their families and caregivers should be outraged - and seek solutions.***

-Daniel R. Levinson, Inspector General, HHS (May 2011).

surveyors then intervened and scheduled a psychiatric consult for the resident. The Acting Director of Nursing acknowledged that the pharmacist's recommendations should have been addressed within a week and that there was no reason why a gradual dose reduction should not have been attempted.

### VII. A Note on Nursing Home Oversight & Accountability

Although the resident was given an antipsychotic drug for over a year despite recommendations for a gradual dose reduction and medical symptoms stemming from that dosage, state surveyors cited this deficiency as causing "no harm."

The accurate identification of substandard nursing home care is a longstanding issue of public concern. Too often, even when resident abuse or neglect are identified, the problems are not identified by surveyors as having caused harm to the nursing home's residents. Recent studies by LTCCC have indicated that states only identify resident harm about 5 percent of the time that they cite a facility for substandard care, abuse, or neglect.

Under the new survey requirements for psychotropic drugs, state surveyors cannot cite inappropriate antipsychotic drug use as simply "no harm."<sup>9</sup> CMS guidance states that "the failure of the facility to provide appropriate care and services to manage the resident . . . places residents at risk of more than minimal harm."<sup>10</sup> **Unfortunately, state surveyors will still be allowed to cite deficiencies as "no actual harm," but only by acknowledging that there is potential for more than minimal harm.** This categorization still allows federal fines to be optional.

### VIII. References for More Information & Help

- [LTCCC](http://nursinghome411.org/learning-center/dementia-care-advocacy-toolkit/) developed a dementia care toolkit which contains fact sheets on a range of issues related to dementia care, including antipsychotic drug use. See <http://nursinghome411.org/learning-center/dementia-care-advocacy-toolkit/>.
- The National Consumer Voice for Quality Long-Term Care's website contains a fact sheet with useful tips for residents, families, and advocates. See <http://theconsumervoice.org/uploads/files/issues/postcard.pdf>.
- Unnecessary drug use among nursing home residents is not limited to antipsychotics. A recent CNN report highlighted the inappropriate use of Nuedexta, which is indicated to treat pseudobulbar affect (involuntary laughing or crying). The report highlights that Nuedexta is only meant to treat less than one percent of the population; however, fourteen million pills were sent to long-term care facilities in 2016. See <http://www.cnn.com/2017/10/12/health/nuedexta-nursing-homes-invs/index.html>.
- The implementation date for the Phase II Requirements of Participation is November 28, 2017. CMS has issued a revised State Operations Manual with the new regulations and interpretative guidance. See <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Advance-Appendix-PP-Including-Phase-2-.pdf>

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<sup>1</sup> The FDA has addressed the dangers of antipsychotic drug use on the elderly with dementia. *Public Health Advisory: Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances*, FDA (April 11, 2005), <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm053171.htm>.

<sup>2</sup> 42 C.F.R. § 483.45(e)(1)-(2).

<sup>3</sup> This percentage is based on third quarter 2017 figures for the “number of residents who have received the medications during the last 7 days or since admission/entry or reentry if less than 7 days.” *MDS 3.0 Frequency Report- Third Quarter 2017, NO410A: Medications- Medications Received- Antipsychotic*, CMS, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Minimum-Data-Set-3-0-Public-Reports/Minimum-Data-Set-3-0-Frequency-Report.html> (last visited on Oct. 19, 2017).

<sup>4</sup> Richard A. Friedman, M.D., *A Call for Caution on Antipsychotic Drugs*, N.Y. Times (Sept. 24, 2012), <http://www.nytimes.com/2012/09/25/health/a-call-for-caution-in-the-use-of-antipsychotic-drugs.html>.

<sup>5</sup> Note: Effective November 28, 2017, new national survey protocols and F-tags will be in place.

As of that date, state surveyors will be required to cite inappropriate antipsychotic use under “Psychotropic Drugs” (F-Tag 758).

<sup>6</sup> Toby Edelman, *Examining Inappropriate Use of Antipsychotic Drugs, Part One: How Seven States Cite Antipsychotic Drug Deficiencies*, Center for Medicare Advocacy, <http://www.medicareadvocacy.org/examining-inappropriate-use-of-antipsychotic-drugs-part-one-how-seven-states-cite-antipsychotic-drug-deficiencies/> (noting that the study was based on data on seven states that CMS selected for review—“Georgia, Illinois, Massachusetts, Missouri, Oregon, Pennsylvania, and Texas – reflecting states that use the traditional survey process and states that use the new Quality Indicator Survey process”).

<sup>7</sup> Alan Kronhaus, et. al, *Prevalence and Medication Management of Dementia by a Medical Practice Providing Onsite Care in Assisted Living*, 17 JAMDA 673 (2016), [http://www.jamda.com/article/S1525-8610\(16\)30122-0/pdf](http://www.jamda.com/article/S1525-8610(16)30122-0/pdf).

<sup>8</sup> *Statement of Deficiency for The Willows at Ramapo Rehab & Nursing Center* (June 6, 2017), CMS, <https://www.medicare.gov/nursinghomecompare/InspectionReportDetail.aspx?ID=335148&SURVEYDATE=07/07/2017&INSPTYPE=STD&profTab=1&state=NY&lat=0&lng=0&name=THE%2520WILLOWS%2520AT%2520RAMAPO%2520REHAB%2520AND%2520NURSING%2520CENTER&Distn=0.0>.

<sup>9</sup> “No Harm” in this case refers to “no actual harm with potential for minimal harm.” This categorization applies to scope and severity levels A-C.

<sup>10</sup> *State Operations Manual*, Pub. No. 100-07, Appendix PP, (“Revision to State Operations Manual (SOM) Appendix PP for Phase 2, F-Tag Revisions, and Related Issue”), <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Advance-Appendix-PP-Including-Phase-2-.pdf>.