

# LONG TERM CARE COMMUNITY COALITION

*Advancing Quality, Dignity & Justice*

## **Mid-Term Report: The Inappropriate Use of Antipsychotic Drugs among Nursing Home Residents Continues to be Widespread and Immediate Action is Still Needed to Protect Residents from Chemical Restraints**

Submission to the United Nations Universal Periodic Review of  
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Submitted by:  
The Long Term Care Community Coalition  
One Penn Plaza, Suite 6252  
New York, NY 10119  
Contact Name: Richard Mollot  
Contact Phone/Email: 1-212-385-0355/richard@ltccc.org  
[www.nursinghome411.org](http://www.nursinghome411.org)

The Long Term Care Community Coalition (LTCCC) is a U.S. nonprofit organization dedicated to improving the quality of life and quality of care for people who use and/or reside in nursing homes and other types of long term care (LTC) facilities in New York and nationally. The Coalition is comprised of a range of professional, civic, aging, and disability organizations. It uses the perspectives gained from its members to identify the major issues affecting quality of care and quality of life for elderly and disabled LTC consumers and undertakes studies and in-depth analyses of those issues in order to gain insights and develop meaningful recommendations for both policymakers and stakeholders. Nursing home resident rights and other legal, policy and regulatory issues related to nursing home care have been the focal point of LTCCC's work since the organization was incorporated in 1989.

## I. Summary

1. In 2015, the Long Term Care Community Coalition (LTCCC) submitted a report<sup>1</sup> to the United Nations Universal Periodic Review of the United States concerning the inappropriate use of antipsychotic drugs in nursing homes as a means of chemically restraining nursing home residents. The 2015 report provided a discussion of the 1987 U.S. Nursing Home Reform Law and the Reform Law's implementing regulations and enforcement system. The report used this legal framework for a guided discussion on the widespread and inappropriate use of antipsychotic drugs in U.S. nursing homes, despite the known, serious dangers associated with these drugs and federal prohibitions against both unnecessary antipsychotic drug use and the use of chemical restraints. The report concluded that "the U.S. government's failure to protect nursing home residents from chemical restraints violates the requirements of the Reform Law as well as several international conventions and covenants."<sup>2</sup>
2. This mid-term report is an update to our 2015 submission. LTCCC has continued to monitor the use of antipsychotic drugs over the last three years. Data indicate that there has been only a very modest change in the prevalence of inappropriate antipsychotic drugging since our organization submitted the initial report to this body. In addition, recent studies have indicated that reported progress in reducing inappropriate antipsychotic drug use may, in fact, be overstated by both the U.S. government and nursing home industry.<sup>3</sup> As a result, unnecessary antipsychotic drugging of U.S. nursing home residents, particularly those with dementia, continues to be a widespread problem with, too often, a catastrophic impact on individuals and their families. Thus, LTCCC maintains our original conclusion that the U.S. government is violating its own requirements as well as international conventions and covenants on torture and cruel, inhuman, or degrading treatment or punishment.

## II. Background

3. Antipsychotic drugs are indicated to treat specific clinical conditions, such as schizophrenia. Importantly, less than two percent of the population will ever have a diagnosis for a clinical condition identified by the U.S. Centers for Medicare and Medicaid Services (CMS) when it risk-adjusts for potentially appropriate uses of these

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<sup>1</sup> *Protecting Nursing Home Residents From Chemical Restraints: Action is Needed to Reduce & Eliminate Widespread Inappropriate Antipsychotic Drugging*, LTCCC (Apr. 2015), <http://nursinghome411.org/ltccc-submission-to-the-united-nations-human-rights-review-of-the-united-states/>.

<sup>2</sup> *Id.*

<sup>3</sup> See, e.g., *Increased Reporting of Exclusionary Diagnoses Inflate Apparent Reductions in Long-Stay Antipsychotic Prescribing*, *Clinical Gerontologist* (Dec. 2017), <https://www.tandfonline.com/doi/abs/10.1080/07317115.2017.1395378>; *Winning at All Costs: An Analysis of Inflation in Nursing Homes' Rating System*, Production and Operations Management (Feb. 2018), <https://onlinelibrary.wiley.com/doi/abs/10.1111/poms.12804>.

drugs.<sup>4</sup> Nevertheless, when we submitted our initial report in 2015, 22.42% of U.S. nursing home residents were administered an antipsychotic drug.<sup>5</sup> These and other psychotropic drugs are, too 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 nursing home staff. In light of such inappropriate use, the U.S. Food and Drug Administration (FDA) issued a “black box” warning against using antipsychotics to treat elderly patients with dementia.<sup>6</sup> The FDA warning provides that the use of antipsychotics on elderly patients with dementia is associated with a significantly increased risk of death.<sup>7</sup> Antipsychotic drugs are also associated with Parkinsonism, falls, and increased risks of heart attacks and strokes. In addition to the risk of serious clinical side effects, their considerable sedative effects are widely acknowledged to have a substantial, often catastrophic, impact on an elderly individual’s quality of life.

4. The U.S. government has long acknowledged the seriousness of the crisis surrounding the inappropriate antipsychotic drugging of nursing home residents. The U.S. Department of Health and Human Services’ Inspector General (IG) stated in 2011 that “[t]oo many [nursing homes] 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 . . . [g]overnment, taxpayers, nursing home residents, as well as their families and caregivers should be outraged—and seek solutions.”<sup>8</sup> The IG’s statement came in the wake of a report from his office which found that 83 percent of antipsychotic drug use in nursing homes was off-label and that 88 percent of antipsychotic drug use was associated with the condition specified in the FDA’s “black box” warning.<sup>9</sup>
5. In response to the IG’s report and pressure from resident advocates, CMS launched the National Partnership to Improve Dementia Care in Nursing Homes in 2012.<sup>10</sup> The initial goal of the campaign was to reduce the rate of inappropriate antipsychotic drugging by

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<sup>4</sup> *Issue Alert: Antipsychotic Drugs*, LTCCC (Nov. 2017), <http://nursinghome411.org/issue-alert-antipsychotic-drugs/>. In addition to schizophrenia, CMS risk-adjusts for individuals with a diagnosis of Tourette’s syndrome and Huntington’s disease.

<sup>5</sup> See *Nursing Home Antipsychotic Drugging Rates & Drugging Citations: January 2015*, LTCCC, <http://nursinghome411.org/nursing-home-antipsychotic-drugging-rates-drugging-citations/> (providing state and national data on average, non-risk-adjusted, antipsychotic drugging rates).

<sup>6</sup> See *Atypical Antipsychotic Medications: Use in Adults*, CMS, <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Pharmacy-Education-Materials/Downloads/atyp-antipsych-adult-factsheet11-14.pdf>, (last visited on 04/5/2018) (providing readers with the black box warning).

<sup>7</sup> *Id.*

<sup>8</sup> Daniel R. Levinson, *Overmedication of Nursing Home Patients Troubling*, HHS OIG (May 2011), [https://oig.hhs.gov/newsroom/testimony-and-speeches/levinson\\_051011.asp](https://oig.hhs.gov/newsroom/testimony-and-speeches/levinson_051011.asp).

<sup>9</sup> Daniel R. Levinson, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*, HHS OIG (May 2011), <https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf>.

<sup>10</sup> *Data show National Partnership to Improve Dementia Care achieves goals to reduce unnecessary antipsychotic medications in nursing homes*, CMS (Oct. 2, 2017), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-02.html?DLPage=2&DLEntries=10&DLSort=0&DLSortDir=descending>.

15 percent in nine months (by the end of the 2012 calendar year).<sup>11</sup> Unfortunately, U.S. nursing homes failed to meet this goal. In fact, that initial goal was not achieved for an additional 12 months.<sup>12</sup> As a result, as of that year (2014) we estimated that 80,000 additional U.S. nursing home residents were being given antipsychotic drugs, at great personal and financial cost, simply because CMS and the nursing home industry failed to achieve and sustain their initial, modest goal.<sup>13</sup> Furthermore, an analysis we conducted of national data in 2015 indicated that neither the states nor CMS effectively enforced longstanding resident protections prohibiting unnecessary antipsychotic drugging.<sup>14</sup> At that time we found that the average state citation rate for inappropriate drugging was 0.31%. Of those citations, harm to residents was only identified two percent (2%) of the time. This is particularly important because, in the absence of a finding of harm in a citation, a nursing home is unlikely to face any penalty for the violation of the standard of care.

6. Given these poor results in the first years of the Partnership, one might expect that the federal government would have taken a different approach to address this burgeoning problem. Instead, CMS simply continued its education and outreach activities to the nursing home industry, essentially flouting its mandate to enforce federal standards and safeguard nursing home residents.<sup>15</sup> Subsequently, it added new, lower goals of a five percent reduction in 2015 and 2016.<sup>16</sup> In October 2017, CMS announced that it had reduced antipsychotic drug use by 30 percent over the years of its Partnership.<sup>17</sup> Despite the persistent failure of nursing homes to meet its modest goals in the announced time frame, CMS, state agencies, and the nursing home industry itself continue to mischaracterize the Partnership as a “success” and mislead residents and their families about the quality of U.S. nursing homes.

### III. Federal Data & Recent Reports Indicate Insufficient Reduction, Continued Widespread Use of Antipsychotic Drugs

7. LTCCC regularly monitors and provides to the public updated data on nursing home antipsychotic drugging rates and citations for inappropriate drugging. In December

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<sup>11</sup> *Left Behind: The Impact Of The Failure To Fulfill The Promise Of The National Campaign To Improve Dementia Care*, LTCCC (2014), <http://nursinghome411.org/left-behind-the-impact-of-the-failure-to-fulfill-the-promise-of-the-national-campaign-to-improve-dementia-care/>.

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Safeguarding Nursing Home Residents & Program Integrity: A National Review of State Survey Agency Performance*, LTCCC (2015), <http://nursinghome411.org/national-report-safeguarding-nursing-home-residents-program-integrity/>.

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> *Data show National Partnership to Improve Dementia Care achieves goals to reduce unnecessary antipsychotic medications in nursing homes*, CMS (Oct. 2, 2017), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-02.html?DLPage=2&DLEntries=10&DLSort=0&DLSortDir=descending>.

2017, we published an Issue Alert which reported that approximately 20% of U.S. nursing home residents are still being administered antipsychotic drugs.<sup>18</sup> This is based on quarterly federal reports (known as MDS frequency reports), which indicated that 20.26 percent of U.S. nursing home residents were being administered at least one antipsychotic drug in the third quarter of 2017. This is only about two percentage points less than the 2014 drugging rate we reported in 2015.<sup>19</sup>

8. In February 2018, Human Rights Watch published “‘They Want Docile’: How Nursing Homes in the United States Overmedicate People with Dementia,” which found that over 179,000 nursing home residents are being given antipsychotic drugs for off-label purposes every week.<sup>20</sup> The report noted that most of the residents on antipsychotic drugs have Alzheimer’s disease or other forms of dementia, which fall under the FDA’s black box warning against such use.<sup>21</sup> Human Rights Watch called on CMS, as well as federal and state governments, to stop the inappropriate use of antipsychotic drugs, to establish the right to informed consent prior to the administration of any antipsychotic drug, to ensure nursing staff numbers and education are adequate, and to strengthen the enforcement of the nursing home standards of care.<sup>22</sup>
9. In “Increased Reporting of Exclusionary Diagnoses Inflate Apparent Reduction in Long-Stay Antipsychotic Prescribing,” a report published in December 2017, researchers concluded that the reduction in antipsychotic drug use is correlated to an increase diagnoses of the three excluded conditions.<sup>23</sup> Specifically, the study found that, since the launch of the CMS Partnership, “nationally reported rates of these diagnoses increased by 12 percent in nursing homes.”<sup>24</sup> The study added that “as much as 20 percent of the reduction . . . could be explained by increased reporting of exclusionary diagnoses rather than a true reduction in medication use.”<sup>25</sup> Ultimately, the study found that the “[a]pparent reductions in inappropriate long-stay antipsychotic use since the National Partnership may be exaggerated.”<sup>26</sup>

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<sup>18</sup> *Issue Alert: Antipsychotic Drugs*, LTCCC (Nov. 2017), <http://nursinghome411.org/issue-alert-antipsychotic-drugs/>.

<sup>19</sup> The drugging rate reported in the MDS for 2014 Q4 was 22.42% of residents. MDS frequency data are available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Minimum-Data-Set-3-0-Public-Reports/index.html>.

<sup>20</sup> Hannah Flamm et al., “*They Want Docile’: How Nursing Homes in the United States Overmedicate People with Dementia*,” Human Rights Watch (Feb. 2018), <https://www.hrw.org/report/2018/02/05/they-want-docile/how-nursing-homes-united-states-overmedicate-people-dementia>.

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> Jonathan D. Winter et al., *Increased Reporting of Exclusionary Diagnoses Inflate Apparent Reduction in Long-Stay Antipsychotic Prescribing*, *Clinical Gerontologist* (Oct. 24, 2017), <http://www.tandfonline.com/doi/abs/10.1080/07317115.2017.1395378>.

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

10. The number of U.S. nursing home residents has also decreased since 2015, making it likely that a portion of the decrease in the number of residents drugged is due, simply, to attrition. Based on the MDS report for the third quarter of 2015, there were 1,305,618 nursing home residents in the U.S. (including U.S. territories).<sup>27</sup> By the third quarter of 2017, the total number of nursing home residents declined to 1,273,099 residents—a difference of 32,519.<sup>28</sup> Based on the system-wide antipsychotic drugging rate of 20.26%, this means that about 6,600 people fewer nursing home residents are receiving these drugs simply because they are not nursing home residents (rather than as a result of improvements in care or enforcement of minimum standards).

#### **IV. The U.S. is in Violation of Domestic Laws, as well as International Conventions and Covenants**

11. The U.S. ratified the UN International Covenant on Civil and Political Rights in 1992. Article Seven of that Covenant prohibits torture and cruel, inhuman, or degrading treatment or punishment. In 1994, the U.S. ratified the UN Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment.

12. The Universal Declaration on Human Rights states that “no one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment.”<sup>29</sup> Similarly, the U.S. Nursing Home Reform Law requires nursing homes to “provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident . . . .”<sup>30</sup> The U.S. government’s continuing failure to protect nursing home residents from the inappropriate use of antipsychotic drugs, often as a form of chemical restraint and despite known clinical and psychosocial hazards, is in violation of these domestic and international mandates.

#### **V. Current Recommendations**

13. As recommended in our 2015 report, CMS should implement its core mandate and ensure that nursing homes are held accountable for meeting relevant and longstanding standards of care. State Survey Agencies should be monitored more closely and held accountable for enforcing regulatory standards. To effectuate this, CMS should establish stronger guidelines with concrete citation levels. For instance, when an individual is given antipsychotic drugs under circumstances that conflict with professional standards,

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<sup>27</sup> See N0410A: Medications - Medications Received - Antipsychotic, <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 04/05/2018) (accessing the data requires selecting and submitting “Third Quarter 2015,” then selecting the variable mentioned).

<sup>28</sup> See *id.* (accessing the data requires selecting and submitting “Third Quarter 2017,” then selecting the variable mentioned above).

<sup>29</sup> Universal Declaration of Human Rights, Article 5, [http://www.ohchr.org/EN/UDHR/Documents/UDHR\\_Translations/eng.pdf](http://www.ohchr.org/EN/UDHR/Documents/UDHR_Translations/eng.pdf).

<sup>30</sup> 42 U.S.C § 1395i–3(b)(2).

this should be identified as harmful and a penalty should be imposed. In addition, agencies should be expected to assess for compliance with all relevant regulations when a drugging violation is uncovered. CMS should monitor and audit, on an ongoing basis, state agency performance in relation to facility and state level antipsychotic drugging rates and use the results to address performance issues.

14. CMS should also reverse its 18-month moratorium on the full enforcement of eight standards of care, including one that relates to restricting the use of antipsychotic drugs. These standards were promulgated in 2016 and were set to be implemented nationwide on November 28, 2017. However, CMS issued a memorandum on November 24th (four days before their implementation), indicating that it will not be enforcing these standards of care with the use of financial penalties for the next 18 months.<sup>31</sup> This sends a dangerous message to the nursing home industry and is likely to further undermine efforts to ensure that U.S. nursing home residents are free from chemical restraints.

## VI. Conclusion

15. The inappropriate use of antipsychotic drugs as a means of chemically restraining nursing home residents continues to be rampant in the United States, despite the known risks such drugs pose to residents. The government's failure to meaningfully address the prevalent and inappropriate use of antipsychotic drugs is in direct violation of the 1987 Nursing Home Reform Law, as well as the United Nations' conventions and covenants on torture and cruel, inhuman, or degrading treatment or punishment. LTCCC reiterates our recommendations from the 2015 report and urges the U.S. to take immediate, substantive action to ensure that current and future nursing home residents are free from chemical restraints.

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<sup>31</sup> *Temporary Enforcement Delays for Certain Phase 2 F-Tags and Changes to Nursing Home Compare*, CMS (Nov. 24, 2017), <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-18-04.pdf>.