

**Protecting Nursing Home Residents From Chemical Restraints: Action is Needed
to Reduce & Eliminate Widespread Inappropriate Antipsychotic Drugging**

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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. The 1987 U.S. Nursing Home Reform Lawⁱ and its implementing regulations set forth strong standards for the care of nursing home residents in the United States. Under the law, each resident must be provided the care he or she needs, as an individual, to attain and maintain his or her highest practicable physical, emotional and psychosocial well being. There are explicit safeguards to prevent physical and chemical restraint use and unnecessary drugging of nursing home residents. However, despite these longstanding requirements, and a US Food and Drug Administration (FDA)ⁱⁱ “black box warning” against use of antipsychotic drugs on the elderly, approximately one in five U.S. nursing home residents are administered antipsychotic drugs every day. These drugs are essentially used as a form of chemical restraint, stupefying residents so that they are more easy to care for. In addition to destroying social and emotional well-being, these drugs greatly increase risks of stroke, heart attack, Parkinsonism & falls. There is a strong correlation between antipsychotic drugging and mortality for the elderly. This correlation increases the longer an individual is drugged.

2. This submission raises concerns relating to cruel, inhuman and degrading treatment; abuse and neglect of vulnerable populations (both nursing home residents in general and elderly individuals with Alzheimer’s Disease or other dementia in particular); and denial of the rights to be informed of and consent to treatment.

3. Our findings and concerns are based on the results of numerous studies, including many conducted over the years by (or for) the United States government, as well as our own studies on inappropriate antipsychotic drugging rates and the widespread and persistent failures of the government to prevent this drugging and uphold longstanding standards for nursing home resident care. In addition, our concerns are informed by numerous cases (both legal cases and anecdotal reports from families and the grassroots organizations with which we work) from across the country that substantiate the pervasiveness of this problem and the significant harm it causes to thousands of nursing home residents and their families every year.

4. Our recommendations are fundamentally simple: the United State government should enforce longstanding standards of care and treatment of nursing home residents and, particularly, of the numerous residents suffering from Alzheimer’s Disease or other forms of dementia.

II. LEGAL FRAMEWORK

5. As noted above, the 1987 Nursing Home Reform Law provides substantial protections to ensure that U.S. nursing home residents receive adequate and appropriate care and are free from chemical and physical restraints. Virtually all nursing homes participate in either the Medicaid or Medicare programs (or both), and, as a result, the U.S. government is the primary payer of nursing home care. Thus, in terms of both the legal Requirements for Participationⁱⁱⁱ and the contractual requirements that facilities agree to when admitting and retaining residents, nursing homes are required to meet the standards set forth in the Reform Law and implementing regulation and, importantly, the U.S. has both the right and the obligation to ensure that these standards are met. To that end, it is also worthwhile to note that the Reform

Law's standards of care, quality of life and dignity are applicable to each nursing home resident. In other words, the standards are not general requirements (such as to have a set number of staff or purchase a specific amount of food per facility). Rather, and critically, the Reform Law requires that sufficient care and services are provided to meet each resident's individual needs. Thus, as regards staffing and food, nursing homes are required – and paid – to have sufficient staff to ensure that every resident is able to attain, and maintain, his or her highest practicable functioning and well-being, and sufficient and appropriate foods to meet the nutritional and preferential needs of each resident.

6. The Reform Law's standards are set forth in the Code of Federal Regulations^{iv} and operationalized via a system of "F-tags" in which, roughly, each provision of the Code has a corresponding F-tag which surveyors (inspectors) use to cite nursing homes for "deficiencies" (i.e., failure(s) to meet minimum standards). F-Tags, in turn, are cited in the "Statements of Deficiencies" that are the written record of a surveyor's findings. While the federal agency, CMS, has ultimate responsibility for enforcing these standards, it contracts with the states to conduct oversight of the nursing homes within each state. There exists an extensive system by which CMS monitors state performance to ensure that residents are safe and receive care that meets or exceeds standards. Both the state and federal agencies have a range of penalties that can be imposed on nursing homes when a failure to meet standards is identified, ranging from fines and mandatory trainings to removal from the Medicaid/Medicare payment systems. In turn, CMS can impose penalties on state agencies that fail to sufficiently protect residents.

7. In 2013, we conducted a study to identify the federal regulations relevant to chemical restraint use and inappropriate drugging. The resulting report^v identified 26 F-tags (and their related CFR provisions). These include three principal standards: residents must be kept free from unnecessary drugs (F-329),^{vi} residents must receive necessary care for their highest practicable well being (F-309)^{vii} and residents must be free from chemical restraints (F-222).^{viii} The remaining 23 standards either directly or strongly relate to the chemical restraint context. These include F-154 ("The resident has the right to be fully informed in advance about care and treatment..."),^{ix} F-223 ("The resident has the right to be free from verbal, sexual, physical, and mental abuse..."),^x and F-240 ("A facility must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life.").^{xi}

8. While the Reform Law and the various provisions of the CFR provide for strong protections against chemical restraints and the use of antipsychotic drugs on nursing home residents, the U.S. government has failed to adequately enforce these protections. As a result of this persistent failure, approximately 20% of U.S. nursing home residents are given antipsychotic drugs inappropriately every day.

9. The U.S. government itself has recognized the seriousness and pervasiveness of this problem. In 2011, U.S. Inspector General Daniel Levinson noted "'Too 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.'" The Inspector General concluded, "Government, taxpayers, nursing home residents, as well as their families and caregivers should be outraged – and seek solutions."^{xii} This statement related

to the findings of a study conducted by his office which found, *inter alia*, (1) “Eighty-three percent of Medicare claims for atypical antipsychotic drugs for elderly nursing home residents were associated with off-label conditions; 88 percent were associated with the condition specified in the FDA boxed warning.,” (2) Fifty-one percent of Medicare atypical antipsychotic drug claims for elderly nursing home residents were erroneous....; and (3) “Twenty-two percent of the atypical antipsychotic drugs claimed were not administered in accordance with CMS standards regarding unnecessary drug use in nursing homes.”^{xiii}

10. Following this report and the statement by the Inspector General, LTCCC’s executive director^{xiv} and five other nursing home resident representatives^{xv} met with CMS’s then Acting Administrator Donald Berwick to advocate for a reduction in chemical restraint use and inappropriate antipsychotic drugging. Following that meeting, CMS launched a national campaign to reduce antipsychotic drugging and improve dementia care in U.S. nursing homes. This campaign was launched in March 2012, with an initial goal of a 15% reduction in U.S. nursing home antipsychotic drugging by December 31, 2012 with further, more ambitious, goals expected to follow. In the two years (plus) since its launch, CMS has conducted a range of educational programs and initiatives to both improve the nursing home industry’s understanding and practice and to improve enforcement of those standards by state and federal survey agency staff.

11. The results of this initiative have, unfortunately, been lackluster and (as noted earlier) the rate of inappropriate and dangerous antipsychotic drugging remains unacceptably high. The federal campaign failed to come close to achieving its initial goal and, in fact, did not achieve the 15% reduction for an additional full year. Importantly, from our perspective, despite the Inspector General’s report, the FDA’s “black-box” warning and numerous studies showing the significant harm associated with antipsychotic drug use, the U.S. government has failed to take meaningful steps to enforce longstanding laws and regulatory standards. In short, regardless of whether or not the educational component of the federal campaign has been successful, the U.S. government has continued in its failure to take substantive steps, within its authority and mandate, to protect the tens (if not hundreds) of thousands of nursing home residents who continue to receive antipsychotic drugs inappropriately and illegally.

12. Two recent studies demonstrate this failure to protect residents from inappropriate drugging and chemical restraint. Last year, one of our partners in advocacy on this issue, the Center for Medicare Advocacy, undertook a study with Dean Lerner Consulting which assessed federal deficiencies cited against nursing facilities for antipsychotic drugging. That study “reviewed all antipsychotic drug deficiencies cited in seven states over a two-year period. [It] found that 95% of the deficiencies were described as “no harm,” meaning... that the facilities were unlikely to be sanctioned, regardless of actual effects on residents.”^{xvi}

13. Earlier this year (2014), we conducted a study that assessed enforcement trends, nationally and for New York State, for the three principal antipsychotic drugging/chemical restraint F-tags^{xvii} Our study found, “**Many nursing homes are using antipsychotics at very high rates, up to (and sometimes even beyond) 50% of their residents.** This is especially surprising given that the data are risk-adjusted, meaning that these figures do not include drugs given to residents

who have one of several antipsychotic conditions identified by CMS. Presumably, **few if any of the incidents of drugging reported on Nursing Home Compare should be happening at all, no matter at the rates we are seeing across the state and the country.**^{xviii} Among the state and national findings in this study, perhaps most relevant to this submission are our findings regarding citations for inflicting chemical restraints on nursing home residents. For the three year period of 2011 through 2013 (2011 being the baseline year for the federal campaign and 2013 being the last complete calendar year), there were only 124 citations in the entire U.S. for F-222 (out of a population of over 1.3 million nursing home residents, and a risk-adjusted antipsychotic drugging rate of over 20% of that population over those years).^{xix} In addition, we found that roughly half the states had no F-222 citations whatsoever, in any of those three years, for chemical restraint of residents.

III. U.S. COMPLIANCE WITH ITS INTERNATIONAL HUMAN RIGHTS OBLIGATIONS

14. In addition to federal law and numerous regulations, the U.S. government's failure to protect nursing home residents from chemical restraints violates several international conventions and covenants. 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.^{xx} In 1994, The US ratified the UN Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment.^{xxi} In addition, The Universal Declaration on Human Rights states, in Article 5, that "no one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment."

IV. RECOMMENDATIONS

15. The United States should take immediate and robust action to significantly reduce inappropriate antipsychotic drugging of current nursing home residents and ensure that future residents are adequately protected from chemical restraints. To accomplish this, 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, this should be identified as harmful. 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. Rather than dedicating agency resources to industry trainings and collaborations, CMS should dedicate resources to identifying and implementing additional ways to ensure that standards are achieved. CMS should also take concrete steps to improve the quality of data available on Nursing Home Compare, the country's principal resource for nursing home quality information, so that the public is better positioned to make informed choices about the quality of care in the nursing homes in their communities.

III. CONCLUSION

16. Despite significant, known risks to physical health and mental well being, the illegal and inappropriate use of antipsychotic drugs on nursing home residents persists at high rates across the United States. This is the result of the failure by the U.S. government, and its state agents, to ensure that tens of thousands of residents, most of whom have Alzheimer’s Disease or other forms of dementia, are protected from inappropriate drugging and chemical restraint. In the face of this widespread and persistent pernicious problem, we recommend that the U.S. government agency, CMS, take immediate and robust action to fulfill its quality assurance mandate by enforcing the provisions of the 1987 Nursing Home Reform Law.

ⁱ Nursing Home Reform Law, 42 U.S.C. §§1395i-3(a)-(h), 1396r(a)-(h) (Medicare and Medicaid, respectively) (December 1987). The Reform Law’s text is available at:

<http://law.justia.com/cfr/title42/42-3.0.1.5.22.html#42:3..15.22.2>.

ⁱⁱ The FDA Alert on atypical antipsychotic was issued in April 2005. In June 2008 the FDA included conventional antipsychotics, “notifying healthcare professionals that both conventional and atypical antipsychotics are associated with an increased risk of mortality in elderly patients treated for dementia-related psychosis. ... Antipsychotics are not indicated for the treatment of dementia-related psychosis.” (Accessed on September 14, 2014 at <http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm124830.htm>.)

ⁱⁱⁱ Requirements for Long Term Care Facilities, 42 CFR 483. Published February 2, 1989; effective August 1, 1989. According to the description on the U.S. Centers for Medicare and Medicaid Services website, “The provisions of this part contain the requirements that an institution must meet in order to qualify to participate as a SNF in the Medicare program, and as a nursing facility in the Medicaid program. They serve as the basis for survey activities for the purpose of determining whether a facility meets the requirements for participation in Medicare and Medicaid.” Available at <http://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/LTC.html>.

^{iv} *Id.*

^v Mollot, Richard J. and Butler, Daniel, Federal Requirements & Regulatory Provisions Relevant to Dementia Care & The Use Of Antipsychotic Drugs (November 2013). Available at <http://www.nursinghome411.org/?articleid=10066>.

^{vi} 42 CFR 483.25(l)(2)(i, ii).

^{vii} 42 CFR 483.25.

^{viii} 42 CFR 483.13(a).

^{ix} 42 CFR 483.10(d)(2).

^x 42 CFR 483.13(b).

^{xi} 42 CFR 483.15.

^{xii} Daniel R. Levinson, “Overmedication of Nursing Home Patients Troubling” (Statement, May 9, 2011). Available at http://www.oig.hhs.gov/testimony/levinson_051011.asp.

^{xiii} U.S. Department of Health and Human Services, Office of the Inspector General, Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents, OEI-07-08-00150 (May 2011).

^{xiv} Richard J. Mollot, the author of this submission.

^{xv} Janet Wells (National Consumer Voice for Quality Long Term Care), Toby Edelman (Center for Medicare Advocacy), Anthony Chicotel and Michael Connors (California Advocates for Nursing Home Reform) and Claire Curry (Legal Aid Justice Center).

^{xvi} Edelman, Toby and Lerner, Dean, "Examining Inappropriate Use of Antipsychotic Drugs in Nursing Facilities" (December 12, 2013). Available at <http://www.medicareadvocacy.org/cma-report-examining-inappropriate-use-of-antipsychotic-drugs-in-nursing-facilities/>.

^{xvii} Mollot, Richard J., "Antipsychotic Drug Use in NY State Nursing Homes: An Assessment of New York's Progress in the National Campaign to Reduce Drugs and Improve Dementia Care" (March 2014). Available at <http://www.nursinghome411.org/?articleid=10082>. Approximately eight percent of U.S. nursing home residents are in New York State facilities.

^{xviii} *Id.* at page 6. [Emphases in original.]

^{xix} *Id.* at page 20.

^{xx} <http://www.ohchr.org/en/professionalinterest/pages/ccpr.aspx>.

^{xxi} <http://www.hrweb.org/legal/cat.html>. It defines torture as "any act by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person for such purposes as obtaining from him or a third person information or a confession, punishing him for an act he or a third person has committed or is suspected of having committed, or intimidating or coercing him or a third person, or for any reason based on discrimination of any kind, when such pain or suffering is inflicted by or at the instigation of or with the consent or acquiescence of a public official or other person acting in an official capacity. It does not include pain or suffering arising only from, inherent in or incidental to lawful sanctions."