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**In Memoriam (1935–2019)*

September 13, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3347-P
P.O. Box 8010
Baltimore, Maryland 21244

**Re: Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities
CMS-3347-P**

Submitted electronically: <http://www.regulations.gov>

Dear Administrator Verma:

Human Rights Watch is an independent, nongovernmental human rights organization that conducts research and advocacy in over 90 countries on a range of human rights issues, including the [rights of older people](#). We use our research to draw attention to important human rights matters and offer concrete recommendations to improve human rights protections.

We are writing to express our concerns with the proposed changes to the Requirements for Long-Term Care Facilities, CMS-3347-P. We appreciated the reference to our 2018 report, “[‘They Want Docile.’ How Nursing Homes in the United States Overmedicate People with Dementia](#)” in your explanatory comments for the proposed changes. The proposed changes contradict the report’s recommendations and would, in our view, decrease protections for the rights of older people living in nursing facilities across the United States. In particular, they risk perpetuating the serious problem of overmedication of people with dementia in nursing homes in the United States.

As the Centers for Medicare & Medicaid Services (CMS) will be aware, facilities’ use of antipsychotic drugs to control older people with dementia risks the health of these persons and violates their right to be free from chemical restraint. The use of antipsychotic drugs on older people with dementia is associated [with a nearly doubled risk of death](#).

Below is a detailed explanation of our concerns regarding four of the proposed changes to the regulations: staffing data, antipsychotic drug use, facility assessments, and civil money penalties. Any revisions to the regulations should only be made if they improve resident protections, not reduce them. We also include detailed recommendations from our 2018 report for CMS to proactively improve protections from chemical restraint, a practice prohibited in US law and regulation.

The proposed changes would roll back critical resident rights and protections. We are concerned that CMS’s apparent justification for most of the proposed changes is to

reduce the regulatory burden on nursing homes rather than to protect residents. This justification, without an effort to address the existing harms we have identified, flies in the face CMS's long-standing statutory duty to protect residents and ensure appropriate federal spending for Medicare and Medicaid Services. We urge CMS to cease efforts to reduce protections for older people in nursing homes. Thank you for your consideration.

Sincerely,

Bethany Brown
Older People's Rights Researcher
Human Rights Watch

NURSE STAFFING DATA (§ 483.35)

We support retaining the current requirement that facilities maintain daily nurse staffing data for at least 18 months.

Currently, nursing facilities must retain daily nurse staffing data for at least 18 months, but in the proposed changes to the regulations, CMS proposes to reduce this minimum time to 15 months. Data on daily nurse staffing is important because it shows the level of available support for the people living in nursing facilities. It also helps regulators with insight into whether residents are receiving adequate care. Human Rights Watch's research, documented in our 2018 report "'They Want Docile,' How Nursing Homes in the United States Overmedicate People with Dementia," identified government failures to ensure minimum staffing levels necessary for residents to attain their highest practicable wellbeing as a key gap in existing regulations to prevent the inappropriate use of antipsychotic medications.

According to a 2015 study by the US Government Accountability Office, staffing is an important determinant of the quality of support in nursing facilities. That study found that so-called setting-specific factors — such as staff leadership, training and education levels, and quantity of staff — were the principal determinants of the prevalence of antipsychotic drug use, rather than patient-specific factors such as medical conditions or behaviors.¹

We recommend that CMS retain the current 18-month minimum for retaining nurse staffing data. CMS allows surveys of facilities to measure compliance with its regulations to take place as much as 15 months apart. Maintaining 18 months of records provides helpful information if a survey is late. We are not aware of any evidence that nursing facilities face any significant difficulty in retaining information for an additional three months, particularly since the information likely is stored electronically.

PSYCHOTROPIC DRUGS (§ 483.45(e))

We recommend retaining current limitations on as-needed administration of antipsychotic drugs and recommend the addition of a requirement that all psychotropic medications only be administered with informed consent.

Current regulations limit PRN (standing for *pro re nata*, meaning "as needed") prescriptions for antipsychotic drugs to 14 days.² The regulation only allows the extension of PRN orders for antipsychotic drugs if "the attending physician or prescribing practitioner evaluates the resident for the appropriateness

¹ US Government Accountability Office, "Antipsychotic Drug Use; HHS Has Initiative to Reduce Use among Older Adults in Nursing homes, but Should Expand Efforts to Other Settings," 2015, <http://www.gao.gov/assets/670/668221.pdf>, p. 10.

² 42 CFR § 483.45(e)(4).

of that medication.”³ According to CMS’s Interpretive Guidelines, which give guidance on these regulations, evaluation “entails the attending physician or prescribing practitioner directly examining the resident and assessing the resident’s current condition and progress to determine if the PRN antipsychotic medication is still needed.”⁴

In the proposed changes, CMS claims that this requirement is “overly burdensome” for prescribers and facilities. CMS proposes to allow for an examination of people on PRN antipsychotics at a maximum of every 70 days for most residents if the physician documents justification for prolonged use and it is in keeping with the facility’s policies.

CMS indicates in its explanation of the proposed changes that extending the length of time between doctors’ exams would respond to concerns raised by some nursing facilities in rural areas and smaller nursing facilities about accessing physicians frequently enough to conduct evaluations every 14 days. We urge CMS to respond to such concerns by taking steps to improve access to physicians, rather than decreasing resident protections.

We also urge CMS not to remove the 14-day time period for evaluations for antipsychotic medication on a PRN basis. In many nursing facilities, prescribers and individuals receiving treatment may already have minimal interaction. Clinical research has found that frequency of interaction between the prescriber and individual receiving treatment has an important bearing on the quality and individual approach to treatment.⁵ Without routine personal evaluations by a physician prior to medication decisions, these decisions may rely more on an individual facility’s existing “beliefs and assumptions” about treatment. The decisions also may be less specific to the individual and circumstances at hand, leading to a facility’s increased inappropriate use of antipsychotic drugs.

CMS should ensure the enforcement of US regulations prohibiting the use of any unnecessary drugs, including antipsychotic drugs.⁶ In its discussion of the existing rule requiring examinations every 14 days of residents receiving antipsychotic drugs PRN, CMS identifies the potential risk that, as a result of the protections on PRN use, prescribers may resort to increased regular use of antipsychotic drugs. It noted the potential that “prescribers would write routine orders that would result in residents receiving more of the drug more often than if it were given PRN or only as needed.” CMS acknowledges that it has received concerns that this practice may be occurring and should respond with better enforcement of existing rules, rather weakening them.

³ *Id.* at § 483.45(e)(5).

⁴ State Operations Manual – Appendix PP – Guidance to Surveyors for Long Term Care Facilities, CMS, Rev. 173, 11-22-17, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf.

⁵ Yong Chen et al., “Unexplained Variation across U.S. Nursing Homes in Antipsychotic Prescribing Rates,” *Archives of Internal Medicine*, Vol. 170 (2010), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2897009/pdf/nihms173699.pdf>/ p. 5.

⁶ Pharmacy Services, Unnecessary Drugs – General, Code of Federal Regulations, Title 42, <https://www.law.cornell.edu/cfr/text/42/483.45> sec. 483.45(d); CMS, “Revision to State Operations Manual (SOM) Appendix PP – Incorporate Revised Requirements of Participation for Medicare and Medicaid Certified Nursing Facilities,” <https://www.cms.gov/Regulations-and-Guidance/Transmittals/2017Downloads/R168SOMA.pdf> sec. 483.45.

Human Rights Watch's Research on Antipsychotic Drug Use in Nursing Homes

Weakening protections regarding antipsychotic drug use risks harming older people. As we documented in our 2018 report, the use of these drugs continues to be widespread and can have serious consequences. Antipsychotic medications have been shown to be dangerous for older people with dementia. The US Food and Drug Administration requires manufacturers to include a warning on antipsychotic drug labels, stating that older patients with “dementia-related psychosis” treated with antipsychotic drugs are at an increased risk of death.⁷

In 2016 and 2017, Human Rights Watch interviewed people living in nursing facilities who had dementia and were currently on antipsychotic medications or had been on them previously, as well as family members. We spoke with 74 residents and 36 family members in six states, and documented the consequences of inappropriate antipsychotic drug administration.

Human Rights Watch found that the drugs' sedative effect, rather than any anticipated medical benefit, too often drives the high prevalence of use in people with dementia. Residents described the trauma of losing their ability to communicate, to think, and to remain awake. Family described the pain of witnessing these losses in a loved one.

Informed Consent

The antipsychotic drugs section of the existing and proposed regulation is missing the explicit requirement that all antipsychotic medications only be administered with informed consent. In its 2018 report, Human Rights Watch also documented that nursing facilities often fail to obtain consent or even make any effort to do so. While all medical interventions should follow from informed consent, it is particularly egregious to administer a drug posing such severe risks and little chance of benefit without it. International human rights standards require that any medical intervention be provided only with free and informed consent, as part of the right to the highest obtainable standard of physical and mental health.⁸ At its foundation, this right arises from an individual's right to decide what is done with their own body.⁹ Free and informed consent—written or oral permission, however it is obtained and whatever its basis—requires a full understanding of the purpose, risks, benefits, and alternatives to the medical intervention, and the absence of pressure or coercion in making the decision.¹⁰ Permission granted under coercion, or based on misleading explanations, does not constitute consent.

⁷ Food and Drug Administration (FDA), “Information for Healthcare Professionals: Conventional Antipsychotics,” June 16, 2008, <https://www.fda.gov/Drugs/DrugSafety/ucm124830.htm> (accessed September 23, 2017); FDA, “Public Health Advisory: Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances,” April 11, 2005, <https://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm053171> (accessed September 23, 2017).

⁸ Please see Section V, “International Human Rights and US Law,” at p. 93. “‘Dignity Must Prevail’ – An Appeal to Do Away with Non-consensual Psychiatric Treatment World Mental Health Day,” press release, UN Office of the High Commissioner for Human Rights, October 10, 2015, <http://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=16583> (accessed September 11, 2017); Human Rights Council, Report of the special rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, Juan E. Méndez, February 1, 2013, A/HRC/22/53, http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session22/A.HRC.22.53_English.pdf para. 28 (“Guaranteeing informed consent is a fundamental feature of respecting an individual's autonomy, self-determination and human dignity in an appropriate continuum of voluntary health-care services.”).

⁹ *Schloendorff v. Society of New York Hospital*, Court of Appeals of New York, No. 105 NE 92, 211 NY 125, Judgment, April 14, 1914, para. 4. (“Every human being of adult years and sound mind has a right to determine what shall be done with his body, and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages.”)

¹⁰ See, e.g., Improving Dementia Care Treatment for Older Adults Act of 2012, US Congress, S. 3604, introduced to Senate September 20, 2012, <https://www.congress.gov/bill/112th-congress/senate-bill/3604/text>.

As noted above, studies have found that on average, antipsychotic drugs almost double the risk of death in older people with dementia. When the drugs are administered without informed consent, people are not making the choice to take such a risk.

FACILITY ASSESSMENTS (§ 483.70(e))

We recommend that CMS continue to require annual facility assessments.

CMS proposes to reduce facilities' own assessment frequency from annually to every other year. The facility assessment is critically important. In its assessment, the facility follows a formal process to determine its staffing needs.

As outlined above, Human Rights Watch and others have found staffing to be crucial to protecting residents' rights to be free from chemical restraint. Reviewing and updating the facility assessment at least annually is crucial. Otherwise, too much time will elapse between reviews and the staffing levels may not reflect a change in the acuity level, types of diseases, conditions, and physical and cognitive disabilities of a facility's residents.

CIVIL MONEY PENALTIES: Waiver of Hearing, Reduction of Penalty Amount (§ 488.436)

CMS should not reduce the penalties for nursing homes found in violation of the minimum standards of care, including for resident abuse and neglect, with an automatic 35 percent discount in the amount of a civil money penalty if they do not ask for a hearing.

Under current rules, CMS has the power to issue fines, or civil money penalties (CMPs), for violations of the minimum standards of care; the agency also has the power to waive or reduce CMPs in certain circumstances, such as when the facility waives its right to an administrative hearing about a violation identified by CMS.

CMPs are the main sanction at the CMS's disposal to incentivize nursing facilities to comply with the law. The proposed regulations would allow facilities to benefit from reduced penalties without requiring them to formally waive their right to an administrative hearing. A constructive waiver process would mean that the facility would not have to request the waiver in writing; instead, it would happen automatically. Facilities that constructively waive their hearing rights in this manner would retain a 35 percent CMP reduction.

CMS offers no rationale for the proposed change, other than saying that "the constructive waiver process would meet the needs of most facilities facing CMPs."¹¹ CMS anticipates annual savings of \$1,108,226 for facilities and annual savings of \$125,886 to CMS.¹²

CMS should not automatically reduce penalties for facilities when they have been found to have violated the minimum standards of care. State surveyors already classify the majority of nursing home violations (more than 95 percent) as having no civil money penalties. As a result, typically less than 5 percent of identified violations have even the potential of resulting in a fine. In the absence of a meaningful financial penalty, nursing homes may have little incentive to correct the underlying causes of resident abuse, neglect, and other harm. The proposed fine reduction risks further decreasing already weak enforcement of the standards of care and undermine residents' health, safety, and well-being.

¹¹ 84 Fed. Reg. at 34,737, 34,751.

¹² *Id.* at 34737, 34761-34762.

Annex

Human Rights Watch's Recommendations to the Centers for Medicare & Medicaid Services from the 2018 report "They Want Docile": How Nursing Homes in the United States Overmedicate People with Dementia"

For Free and Informed Consent:

- To the greatest extent of its authority, require free and informed consent from the individual whose care is concerned, including with support as needed in the decision, or their appointed representative, as long as this representative is chosen freely and is tasked with reflecting the individual's will and preferences.
- Develop and implement models of supported decision-making that enable people living in nursing facilities to make their own decisions about treatment and care.
- Strengthen enforcement of existing regulatory requirements related to informed consent, appropriate medication administration, and care planning regulatory provisions, including the rights to refuse treatment; to be involved in care planning; to be free from unnecessary drugs; to be free from chemical restraints, and to receive necessary care to achieve the highest practicable wellbeing.

For Adequate Minimum Staffing:

- Revise the final rule for Requirements for Long-Term Care Facilities for Participation in the Medicare and Medicaid Programs to require a 24/7 registered nurse presence, and to establish stronger minimum nurse staffing levels or ratios or other stronger and more enforceable minimum requirements to provide care compliant with the law.
- Publish payroll-based staffing data, as required by the Affordable Care Act, without delay and audit the Payroll-Based Journal submission system.
- Consider automatic penalties to facilities that do not meet minimum quantitative and qualitative staffing requirements, such as imposing a temporary ban on the entrance of new residents until staffing numbers are in compliance with the law.

For Enforcement Efforts Specific to Antipsychotic Medications:

- Strengthen enforcement of existing requirements around unnecessary drugs, chemical restraints, and all other relevant resident rights.
- Amend deficiency categorization guidance for antipsychotic medication-related deficiencies. Inappropriate uses of antipsychotic medications should automatically be considered a Level 3 or 4 severity level unless there is a basis to lower it.
- Amend the Psychosocial Outcome Severity Guide and Investigative Protocol to take into account the particular risks of antipsychotic medications in people with dementia. The Investigative Protocol should provide concrete examples of the occasions when the inappropriate use of antipsychotic drugs would *not* amount to a Level 3 or 4 severity level.
- Create a discrete f-tag, the identifier for each health or safety issue within the federal regulations for which facilities may be cited for noncompliance, for inappropriate uses of antipsychotic medications. Currently, the deficiency citations for chemical restraints, unnecessary drugs, right to refuse treatment, and other relevant citations do not distinguish between any types of treatment or drugs.

- Consider creating a new survey protocol for any facility with a high antipsychotic medication rate that takes into account potential problems of lack of medical necessity and lack of free and informed choice in accepting the medication.

For General Enforcement to Protect Residents' Rights and Wellbeing:

- Ensure greater compliance with reporting abuse and neglect allegations. Per US Department of Health and Human Services Office of Inspector General recommendations, improve mechanisms to reduce underreporting of abuse and neglect.
- Retract the July 7, 2017, sub-regulatory guidance to state survey agency directors revising the Civil Money Penalty Tool, which reduces potential dollar amounts of penalties assessed for many instances of substantial noncompliance, and the November 24, 2017, 18-month moratorium on enforcement of critical regulatory requirements.
- Collect, analyze, make publicly available, and conduct enforcement based on ownership-level data to the greatest degree of its authority. Disseminate ownership-level data for oversight and enforcement purposes among federal and state governmental agencies.