



HUMAN
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WATCH

“They Want Docile”

How Nursing Homes in the United States Overmedicate
People with Dementia

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Summary

Too many times I'm given too many pills.... [Until they wear off], I can't even talk. I have a thick tongue when they do that. I ask them not to [give me the antipsychotic drugs]. When I say that, they threaten to remove me from the [nursing] home. They get me so I can't think. I don't want anything to make me change the person I am.

—Walter L., an 81-year-old man given antipsychotic drugs in a Texas nursing facility, December 2016.

It used to be like a death prison here. We cut our antipsychotics in half in six months. Half our residents were on antipsychotics. Only 10 percent of our residents have a mental illness.

—A director of nursing at a facility in Kansas that succeeded in reducing its rate of antipsychotic drug use, January 2017.

In an average week, nursing facilities in the United States administer antipsychotic drugs to over 179,000 people who do not have diagnoses for which the drugs are approved. The drugs are often given without free and informed consent, which requires a decision based on a discussion of the purpose, risks, benefits, and alternatives to the medical intervention as well as the absence of pressure or coercion in making the decision. Most of these individuals—like most people in nursing homes—have Alzheimer's disease or another form of dementia. According to US Government Accountability Office (GAO) analysis, facilities often use the drugs to control common symptoms of the disease.

While these symptoms can be distressing for the people who experience them, their families, and nursing facility staff, evidence from clinical trials of the benefits of treating these symptoms with antipsychotic drugs is weak. The US Food and Drug Administration (FDA) never approved them for this use and has warned against its use for these symptoms. Studies find 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.

The drugs' sedative effect, rather than any anticipated medical benefit, too often drives the high prevalence of use in people with dementia. Antipsychotic drugs alter consciousness

and can adversely affect an individual's ability to interact with others. They can also make it easier for understaffed facilities, with direct care workers inadequately trained in dementia care, to manage the people who live there. In many facilities, inadequate staff numbers and training make it nearly impossible to take an individualized, comprehensive approach to care. Many nursing facilities have staffing levels well below what experts consider the minimum needed to provide appropriate care.

Federal regulations require individuals to be fully informed about their treatment and provide the right to refuse treatment. Some state laws require informed consent prior to the administration of antipsychotic drugs to nursing home residents. Yet nursing facilities often fail to obtain consent or even to 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.

Such nonconsensual use and use without an appropriate medical indication are inconsistent with human rights norms. The drugs' use as a chemical restraint—for staff convenience or to discipline or punish a resident—could constitute abuse under domestic law and cruel, inhuman, and degrading treatment under international law.

The US has domestic and international legal obligations to protect people who live in nursing facilities from the inappropriate use of antipsychotic drugs, among other violations of their rights. These obligations are particularly important as people in nursing facilities are often at heightened risk of neglect and abuse. Many individuals in nursing facilities are physically frail, have cognitive disabilities, and are isolated from their communities. Often, they are unable or not permitted to leave the facility alone. Many depend entirely on the institution's good faith and have no realistic avenues to help or safety when that good faith is violated.

US authorities, in particular the Centers for Medicare & Medicaid Services (CMS) within the US Department of Health and Human Services, are failing in their duty to protect some of the nation's most at-risk older people. On paper, nursing home residents have strong legal protections of their rights, but in practice, enforcement is often lacking. Although the federal government has initiated programs to reduce nursing homes' use of antipsychotic medications, and the prevalence of antipsychotic drug use has decreased in recent years, the ongoing forced and medically inappropriate use of antipsychotic drugs continues to

violate the rights of vast numbers of residents of nursing facilities. The US government should use its full authority to enforce longstanding laws, including by penalizing noncompliance to a degree sufficient to act as an effective deterrent, to end this practice.

This report documents nursing facilities' inappropriate use of antipsychotic drugs in older people as well as the administration of the drugs without informed consent, both of which arise primarily from inadequate enforcement of existing laws and regulations. The report is based on visits by Human Rights Watch researchers to 109 nursing facilities, mostly with above-average rates of antipsychotic medication use, between October 2016 and March 2017 in California, Florida, Illinois, Kansas, New York, and Texas; 323 interviews with people living in nursing facilities, their families, nursing facility staff, long-term care and disability experts, officials, advocacy organizations, long-term care ombudsmen, and others; analysis of publicly available data; and a review of regulatory standards, government reports, and academic studies.

This report is especially relevant at this time because the US is aging rapidly. Most of the people in the nursing facilities Human Rights Watch visited are over the age of 65. Older people now account for one in seven Americans, almost 50 million people. The number of older Americans is expected to double by 2060. The number of Americans with Alzheimer's disease, the most common form of dementia, is expected to increase from 5 million today to 15 million in 2050. The system of long-term care services and supports will have to meet the needs—and respect the rights—of this growing population in coming years.

Social Harm and Health Risks Caused by Antipsychotic Drugs Used Unnecessarily or as Chemical Restraints

The *American Psychiatric Association (APA) Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia* states that, after eliminating or addressing underlying medical, physical, social, or environmental factors giving rise to manifestations of distress associated with dementia, antipsychotic drugs “can be appropriate” as a means to “minimize the risk of violence, reduce patient distress, improve the patient’s quality of life, and reduce caregiver burden.” However, given the “at best small” potential benefits and the “consistent evidence that antipsychotics are

associated with clinically significant adverse effects, including mortality,” it is essential that the drug treatment is only attempted when appropriate.

Nursing facility staff, individuals living in facilities, their families, long-term care advocates, and others told Human Rights Watch that the drugs are not used only as a last resort, after all factors potentially giving rise to a person’s distress have been ruled out, and after nonpharmacologic interventions have been attempted unsuccessfully. Instead, antipsychotic drugs are used sometimes almost by default for the convenience of the facility, including to control people who are difficult to manage.

One facility social worker said that one of the most common “behaviors” leading to antipsychotic drug prescriptions was someone constantly crying out “help me, help me, help me.” An 87-year-old woman reflected that at her prior facility, which gave her antipsychotic drugs against her will, “they just wanted you to do things just the way they wanted.” A social worker who used to work in a nursing facility said the underlying issue is that “the nursing homes don’t want behaviors. They want docile.” A state surveyor said: “I see way too many people overmedicated.... [Facilities] see it as a cost-effective way to control behaviors.”

Human Rights Watch interviewed people who live in nursing homes and their family members who described the harmful cognitive, social, and emotional consequences of the medications that all too often should never have been administered in the first place: sedation, cognitive decline, fear, and frustration at not being able to communicate. Most or all antipsychotic drugs are associated with sedation and fatigue in people with dementia.

A 62-year-old woman in a nursing facility in Texas who said she was given Seroquel, a common antipsychotic drug, without her knowledge or consent said: “[It] knocks you out. It’s a powerful, powerful drug. I sleep all the time. I have to ask people what the day is.” The daughter of a 75-year-old woman in Kansas said that when the nursing facility began giving her mother an antipsychotic drug, her mother “would just sit there like this. No personality. Just a zombie.... The fight is gone.”

Nursing staff, social workers, long-term care ombudsmen, and state surveyors echoed this perception. One director of nursing said: “You actually see them decline when they’re on an antipsychotic. I think it’s sadder than watching someone with dementia decline.”

Lack of Informed Consent Prior to Antipsychotic Medication Administration

The use of antipsychotic drugs to control people without their knowledge or against their will in nonemergency situations violates international human rights. The practicalities of obtaining consent from an older person with dementia can be fraught. However, in many of the cases Human Rights Watch documented, nursing facilities made no effort to obtain meaningful, informed consent from the individual or a health proxy before administering the medications in cases where it clearly would have been possible to do so.

Our research suggests that in many other cases, facilities that purport to seek consent fail to provide sufficient information for consent to be informed; pressure individuals to give consent; or fail to have a free and informed consent procedure and documentation system in place. Under international human rights law, in the absence of free and informed consent, a nonemergency medical intervention that is not necessary to address a life-threatening condition is forced treatment.

One former nursing facility administrator explained:

The facility usually gets informed consent like this: they call you up. They say, “X, Y, and Z is happening with your mom. This is going to help her.” Black box warning (the government’s strongest warning to draw attention to serious or life-threatening risks of a prescription drug)? “It’s best just not to read that.” The risks? They gloss over them. They say, “That only happens once in a while, and we’ll look for problems.” We sell it. And, by the way, we already started them on it.

A current director of nursing admitted, “We are supposed to be doing informed consent. It’s on the agenda. But really antipsychotics are a go-to thing. ‘Give ‘em some Risperdal and Seroquel.’ We tell the family as we’re processing the order. The family is notified.” The daughter of a woman in a nursing facility described having consented to antipsychotic drugs for her mother without understanding the risks: “I had no idea, not at all, that the drugs were dangerous. I had *no* idea.... I’m guessing most people have no idea.”

A detailed examination of the question of legal capacity—the right to exercise one’s own rights and to make decisions on one’s own behalf—is outside the scope of this report.

Because many people living in nursing facilities have dementia and other progressive conditions that affect their cognitive ability, it is a highly complex question how medical and other decisions concerning their care should be made in a rights-respecting manner. In US nursing facilities, substituted decision-making—where a family member or other third party, whether voluntarily designated in advance or not, makes decisions on an individual’s behalf—is common.

Government Obligations

In 2012, CMS created the National Partnership to Improve Dementia Care in Nursing Homes, in recognition of the unacceptably high prevalence of antipsychotic drug use. While the initiative—which set targets for the industry to reduce antipsychotic drug rates—may have contributed to the reduction of the use of antipsychotic medications over the last six years, it cannot substitute for the effective regulation of nursing homes, including by ensuring that facilities face meaningful sanctions for noncompliance with mandatory standards. Our research found that CMS is not using its full authority to address this issue. Recently, CMS is in fact moving in the opposite direction, limiting the severity of financial penalties and the regulatory standards with which facilities must comply.

CMS and the state agencies with which it contracts to enforce federal regulations are not meeting their obligation to protect people from the nonconsensual, inappropriate use of antipsychotic drugs. Human Rights Watch identified several key areas of concern:

- Failure to adequately enforce the right to be fully informed and to refuse treatment or to require free and informed consent requirement. The Nursing Home Reform Act of 1987 grants residents the right “to be fully informed in advance about care and treatment,” to participate in care planning, and to refuse treatment without penalty. If it were enforced fully, these protections would not differ substantially from the right to free and informed consent. However, without adequate enforcement, current practice falls far short of this protection.
- Lack of minimum staffing regulations. Adequate numbers of sufficiently competent staff are at the crux of nursing facility care. Yet government regulations do not set a minimum staffing requirement for nursing facilities, instead requiring that facilities determine for themselves what amounts to “sufficient” and “competent” staff for

their residents. While experts put minimum adequate nursing staffing time at 4.1 to 4.8 hours per resident per day, most facilities self-reported to the government providing less than that; almost one thousand facilities self-reported providing less than three hours of staff time per day.

- Weak enforcement of federal regulations specifically banning chemical restraints and unnecessary drugs. Federal regulations prohibit chemical restraints—drugs used for the convenience of staff or to discipline residents without a medical purpose—and unnecessary drugs: a technical term meaning drugs used without adequate clinical indication, monitoring, or tapering. The regulations also provide for the right to refuse treatment. However, federal and state enforcement of these regulations is so weak that the drugs are routinely misused without significant penalty. Almost all antipsychotic drug-related deficiency citations in recent years have been determined to be at the level of causing “no actual harm,” curtailing the applicability and severity of financial sanctions.

With such vast numbers of nursing facility residents still getting antipsychotic drugs that many do not need, do not want, and that put their lives and quality of life at risk, federal and state governments need to do more to ensure that the rights of residents are adequately protected. An industry entrusted to provide care—and paid billions of public and private dollars to do so—cannot justify compounding the vulnerabilities, challenges, and loss that people often experience with dementia and institutionalization.

Key Recommendations

Federal and state government agencies should take steps to end the inappropriate and nonconsensual use of antipsychotic medications in nursing facilities. In particular, the Centers for Medicare & Medicaid Services (CMS) and other government agencies should:

- End the inappropriate use of antipsychotic drugs in older people with dementia in nursing facilities, including many instances where they are administered without free and informed consent; used as chemical restraints; or where their use qualifies as an “unnecessary drug.” CMS and state agencies should use the regulatory and enforcement tools at their disposal to ensure that routine violations of regulations that help to safeguard individuals’ human rights cease.
- Require nursing facilities and residents’ physicians to seek free and informed consent prior to the administration of antipsychotic medications to nursing facility residents. Federal regulations providing for the right to be fully informed and to refuse treatment—as well as state laws that provide for informed consent—should be enforced more effectively. The establishment in the federal regulations of a right to informed consent may improve protection in practice by clarifying the right’s content and underscoring its significance. Congress and CMS should require that consent be documented and revisited as appropriate.
- Ensure nurse staffing numbers and training levels are adequate. CMS should establish minimum nurse staffing levels for facilities or undertake other effective measures to address understaffing, inadequate training, and high turnover rates in many nursing facilities. Implementation of the payroll-based staffing data collection system, as required by the Affordable Care Act, should be completed, particularly with regard to nursing staff who provide direct resident care. This includes public reporting of staff-to-resident hours of care per day and turnover and retention rates in each nursing home certified by Medicare and Medicaid.
- Strengthen enforcement on particular subjects linked to the inappropriate use of antipsychotic drugs, including care planning requirements and transfer and discharge rights. CMS should improve inspection and penalty guidance and enforcement practices related to antipsychotic drugs. Surveyors should follow CMS

guidance indicating that many inappropriate uses of antipsychotic drugs amount to Level 3 or 4—actual harm and immediate jeopardy—severity of violations.

Methodology

This report focuses on the inappropriate use of antipsychotic drugs among older people, primarily with dementia, in nursing facilities across the US. Many older people who live in nursing facilities or reside there temporarily are at risk of suffering from this abuse. They rely on the government's enforcement of federal regulations to protect their rights, including to be free from unnecessary drugs, drug treatment to which they object, and sedating drugs administered for the convenience of facility staff. Human Rights Watch found that enforcement is inadequate to deter the misuse of antipsychotic drugs.

This topic was chosen because of the paradox that misuse of the drugs has been well-documented for decades, prohibited by law, and yet persists as a pervasive, serious problem. The amount of publicly available data on nursing homes and antipsychotic drugs specifically made it feasible to conduct the research. The project was also chosen to attempt to amplify the voice and highlight the circumstances of some of the most isolated individuals: not only by living in nursing homes or having dementia, but also by being under the influence of the psychotropic medication.

The report is based on interviews with 323 people in New York, Texas, Kansas, Illinois, California, and Florida between October 2016 and March 2017. Additional interviews were conducted over the phone from September 2016 to April 2017. In addition, Human Rights Watch consulted secondary sources, conducted significant background research, and analyzed copious amounts of data.

These six states were selected for multiple reasons. California and Texas have the highest number of nursing facilities, with 1,219 and 1,212 respectively in 2014. California, Florida, Illinois, New York, and Texas have among the highest numbers of nursing facility residents of any state. Excluding facilities where less than half of the residents are over age 65, Texas and New York lead all states in terms of the number of nursing home residents taking antipsychotic drugs without an exclusionary diagnosis of schizophrenia, Huntington's disease, or Tourette syndrome. Kansas, Texas, and Illinois have some of the highest proportions of residents on antipsychotic drugs. More detailed data on these states and their rankings nationally can be found in Appendix 3. Most of these states were

also chosen based on their strong citizen advocacy organizations working on nursing facility reform and resident rights protection and their long-term care ombudsman programs.

In the six states, Human Rights Watch interviewed 74 people between the ages of 37 and 93 who live in nursing facilities, including 15 under the age of 65. All of the individuals in nursing facilities had cognitive, psychosocial, and/or physical disabilities. Almost all of the individuals were in facilities with high rates of antipsychotic drug use; in many cases, they or someone who knows them told Human Rights Watch that they currently or previously took antipsychotic drugs. However, not all interviewees claimed to take antipsychotic drugs, and it was not possible to view the medical records of the majority of interviewees.

We interviewed 36 family members of residents, 20 long-term care ombudsmen, 18 advocates including attorneys, 10 state and federal government officials, 90 facility administrators, nursing, and social services staff, and six medical professionals such as pharmacists, psychologists, psychiatrists, and doctors. We have omitted people's names or used pseudonyms where names or other identifying information may compromise the privacy of individuals or invite possible reprisals.

Human Rights Watch also interviewed 69 experts, including lawyers, academic researchers, professors, journalists, doctors (in addition to those interviewed associated with nursing facilities or nursing facility residents mentioned above), government officials, and advocates. Human Rights Watch sent letters to CMS, the American Health Care Association (AHCA), and LeadingAge—the government agency that oversees the nursing facility industry, the for-profit trade association, and the nonprofit trade association, respectively—with questions regarding this report's findings. We received responses from AHCA and LeadingAge (see Appendices 6 and 7). We did not receive a response from CMS at time of writing.

Human Rights Watch visited 109 facilities. In 17 of the 109 facilities, we were not allowed to conduct research. Of the remaining 92, sometimes our entry was with explicit permission of the facility, sometimes with permission of the person we were visiting, and sometimes without permission of the facility but without objection. In some cases, we talked to staff only and not residents.

Two of the 109 facilities were in New York, 25 in Texas, 20 in Kansas, 16 in Illinois, 23 in California, and 23 in Florida. One of the 109 has since closed. All facilities were skilled nursing facilities or nursing facilities rather than assisted living facilities, and all received some combination of payment through Medicare, Medicaid, private insurance, and private pay. The US Department of Veterans Affairs operates community living centers, nursing homes, and state veterans' homes across the country as well, as part of the Veterans Health Administration; they are regulated differently and outside the scope of this project. Facilities were selected based on publicly available data on the average percentage of residents without an exclusionary diagnosis given at least one antipsychotic medication in the last quarter.

We primarily visited facilities with a majority population over the age of 65. As of 2010, 16 percent of the nation's nursing home population was between the ages of 31 and 64. Younger people live in nursing facilities for a variety of reasons. However, nursing homes with majorities of younger people and high rates of antipsychotic drug use tend to have greater concentrations of people with psychosocial disabilities. While the administration of antipsychotic drugs may be inappropriate despite psychiatric diagnoses for which the drugs are approved, the root of the rights violations may be distinct, and this report was limited to the demographic of older people, often with dementia.

Of the 109 facilities visited, 79 facilities (72 percent) were for-profit and corporate owned; five (5 percent) were for-profit and individually owned; five (5 percent) were for-profit and part of a partnership government hospital district; 16 facilities (15 percent) were nonprofit and corporate owned; and one facility (1 percent) was nonprofit and church related.

Researchers were refused admission or asked to leave shortly after arriving in 24 facilities. In some cases, administrators had notice of our interest in visiting and refused to meet or allow us to speak with residents who might wish to speak with us. In other cases, facilities did not have notice and requested that we return at another time.

Whenever possible, Human Rights Watch spoke directly with people who live in nursing facilities. In some cases, nursing facility administrators, directors of nursing, directors of social services, or business or admissions officers refused our request to speak with residents. Some facilities claimed that no resident was their own "responsible party" and that they thus could not consent to an interview.

Where access to residents was not blocked, Human Rights Watch sought to interview residents and staff in private so that they could speak openly without fear of potential retaliation. In some facilities, finding locations that afforded sufficient privacy was difficult. As a result, in some cases, with the interviewee's permission, we conducted interviews in rooms where the interviewee's roommate was asleep or watching television. In other cases, we conducted interviews in an activity room or at the end of a hallway that was out of ear shot of other people, but not fully secluded.

Human Rights Watch asked interviewees questions on a wide range of issues, including use of antipsychotic medicines; quality of care; quality of life; demographics of the facility residents; access to health care and rehabilitative services; respect for free and informed consent; autonomy; privacy; visitation; and discharge rights.

Interviews were conducted in English or Spanish. Human Rights Watch obtained the consent of each interviewee; explained the aim of the research; how information collected would be used; and informed them that they could discontinue the interview at any time and could decline to answer questions without consequence. Human Rights Watch provided no personal service or benefit and informed interviewees that their participation was voluntary and confidential.

Finding and interviewing people on antipsychotic drugs is difficult for a number of reasons. First, many are unaware because they were never informed, or are unable to recall, that they are on these medications. Facility staff sometimes do not inform the individuals concerned—or their relatives, the legal representative in some cases—that they are being given antipsychotic drugs.

Second, the effect of the medications can make it difficult to respond to interview questions, and the drugs often make people drowsy.

Third, most people in nursing homes have dementia or other cognitive disability. Additionally, most people given antipsychotic drugs without an “exclusionary diagnosis”—schizophrenia, Huntington's disease, or Tourette syndrome, common conditions for which antipsychotic drugs are approved—have dementia, which affects memory and the ability to express oneself understandably.

Fourth, privacy concerns make determining who is receiving the medications difficult.

Fifth, nursing facility staff often do not consider residents to be their own “responsible party”—a term of art frequently used in an overly broad manner to indicate who can exercise a person’s rights. In many cases, facility staff decided on behalf of all residents that Human Rights Watch could not interact with them, often justifying that decision by invoking the need to protect residents.

Informed consent and legal capacity—the right to exercise one’s rights and to make decisions—are critical human rights linked inextricably with the question of appropriate antipsychotic drug use. The administration of psychoactive medication may violate a person’s rights if it is not administered with informed consent. Legal capacity controls *whose* consent is necessary and valid. However, a comprehensive analysis of consent and legal capacity is beyond the scope of this report. The report focuses on violations of the right to informed consent in cases where it was clearly possible for the facility to seek it, either because a person lacked any severe cognitive disability or because the person had voluntarily designated a proxy to act on their behalf.

Because of significant practical challenges, the residents interviewed do not reflect the most isolated and at-risk people in nursing facilities: people who are on their own, without family or friend visiting or communicating with the facility staff, and who have significant cognitive disabilities that impair their ability to communicate or advocate on their own behalf. Compounding the aforementioned challenges in interviewing residents, for these “unbefriended” or “unrepresented” individuals, there is the additional barrier of not having any intermediary person to identify and connect Human Rights Watch researchers to the person living in the nursing facility.

It is these individuals with severe cognitive disabilities and without someone to assist their communication or decision-making whose rights to legal capacity and informed consent are at the greatest risk of violation. However, they are also the individuals whom it is hardest to access to inquire about an interview and hardest to interview. As a result, the rights violations documented in this report reflect those experienced by people in nursing homes either able to more easily communicate with Human Rights Watch researchers or those experienced by people with family or friends involved in their care.

This report does not analyze nonconsensual use of antipsychotics in nursing facilities on persons who have a diagnosis for which antipsychotics have been approved. Rather, it focuses on the use of these drugs on people with dementia. This report also does not address the process in which people are placed in nursing homes. These issues are complex and go beyond the scope of this report.

Human Rights Watch relied upon several data sets for the quantitative analysis involved in this report, including one provided by Nursing Home Compare. This website, maintained by CMS, provides facility- and state-level data based on the Minimum Data Set (MDS), a federally mandated national database of periodic, individual, clinical, comprehensive assessments of all residents in Medicare and Medicaid certified nursing homes. Nursing facilities submit electronically the MDS information. Nursing Home Compare includes other self-reported and governmental surveyor-reported data for all facilities in the country certified to receive payment from Medicare and Medicaid, which is almost all facilities nationwide.

Despite the volume of publicly available data on the use of antipsychotic drugs in nursing facilities, a number of significant challenges arose in conducting quantitative analyses. First, it is not possible to determine from a single publicly available data set the proportion of all individuals with dementia in nursing facilities without a psychiatric or neurological diagnosis for which an antipsychotic drug is clinically indicated that takes antipsychotic medication. Second, a significant amount of the data on nursing homes is self-reported by those facilities, some of which could be inaccurate and as such may influence the results of statistical tests that Human Rights Watch ran.

Nonetheless, through quantitative data analysis, Human Rights Watch was able to estimate the total numbers of people who receive antipsychotic drugs, live in nursing facilities with a majority population over the age of 65, and do not have an exclusionary diagnosis. (Age 65 is a rough cut-off point to exclude people who are younger and given antipsychotic drugs, appropriately or not, since this research was focused on older people.) We also analyzed antipsychotic drug-related deficiency citations, which are federal and state government inspectors' findings of facilities' noncompliance with the federal regulations that establish minimum health and safety standards for the industry. A detailed description of the methodology used can be found in Appendix 4.

I. Background

Long-Term Care in the US

The population of the US is growing older. Between 2005 and 2015, the country's population aged 65 and over increased by 30 percent. Older people now account for one in seven Americans: almost 50 million people, over 26 million women and over 21 million men.¹ By 2060, the number of older Americans (age 65 and older) is expected to double to almost 100 million, or one in four Americans.² The population aged 85 and over is growing particularly rapidly and is expected to triple by 2050.³ The US population will include so many older people in the coming decades because the baby boom generation is aging while fertility rates continue to decline and life expectancy rates have increased.⁴

As the older population increases, more people will experience age-related disabilities, and dementia in particular.⁵ Today, over 5 million Americans have Alzheimer's disease or

¹ US Department of Health and Human Services, Administration on Aging and Administration for Community Living, "A Profile of Older Americans: 2016," 2016, <https://www.acl.gov/sites/default/files/Aging%20and%20Disability%20in%20America/2016-Profile.pdf> (accessed September 8, 2017); "Projected Future Growth of Older Population," Administration for Community Living, U.S. Department of Health and Human Services, last modified April 26, 2017, <https://www.acl.gov/node/579> (accessed October 10, 2017).

² US Census Bureau, "Projections of the Size and Composition of the U.S. Population: 2014 to 2060," March 2015, <https://www.census.gov/content/dam/Census/library/publications/2015/demo/p25-1143.pdf> (accessed September 8, 2017) p. 4; The number of Americans aged 85 and older is expected to triple between 2015 and 2040, reaching almost 15 million people. One in five older adults are people of color; by 2030, the proportion is expected to exceed one in four older adults.

³ Erica L. Reaves and MaryBeth Musumeci, "Medicaid and Long-Term Services and Supports: A Primer," *Kaiser Family Foundation*, December 15, 2015, <http://www.kff.org/medicaid/report/medicaid-and-long-term-services-and-supports-a-primer/> (accessed September 8, 2017).

⁴ US Census Bureau, "Projections of the Size and Composition of the U.S. Population: 2014 to 2060," March 2015, <https://www.census.gov/content/dam/Census/library/publications/2015/demo/p25-1143.pdf> (accessed September 8, 2017) pp. 5-6, 12; US Census Bureau, "An Aging Nation: The Older Population in the United States," May 2014, <https://www.census.gov/prod/2014pubs/p25-1140.pdf> (accessed September 24, 2017) p. 3.

⁵ David E. Bloom et al., "Macroeconomic Implications of Population Ageing and Selected Policy Responses," *The Lancet*, vol. 385: 9968 (2015), <http://www.sciencedirect.com/science/article/pii/S0140673614614641> (accessed September 24, 2017); Claudia H. Kawas and Maria M. Corrada, "Alzheimer's and Dementia in the Oldest-Old: A Century of Challenges," *Current Alzheimer Research*, vol. 3(5) (2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3373256/> (accessed September 24, 2017).

another form of dementia, involving the loss of cognitive abilities, memory, and language.⁶ By 2050, as many as 16 million Americans could have Alzheimer’s disease; currently, one person in the United States develops the condition almost every minute of every day.⁷

With the growth in older populations and the increases in debilitating conditions such as dementia, the need for long-term care and support services will grow rapidly. Although some forms of dementia have earlier onset, the disease is associated with older age: increasing age is the “greatest known risk factor” for Alzheimer’s disease.⁸ Experts estimate that approximately 70 percent of people aged 65 and over will require long-term services and support, ranging from limited support in their own homes and communities to around-the-clock care in institutional settings.⁹

In the US, older people receive long-term care in a variety of settings: at home, in institutional facilities, and in in-between settings like retirement communities, senior housing, assisted living facilities, and board and care homes. Skilled nursing facilities (which provides short-term rehabilitation) and nursing facilities (for long-term care) provide certified and regulated services to people with significant healthcare and assistance needs.

Of the 6 million older people receiving long-term care, about 4 million receive care from a home health agency at home.¹⁰ About 1.2 million people aged 65 and over lived in 15,600

⁶ US Department of Health and Human Services, “National Plan to Address Alzheimer’s Disease: 2016 Update,” 2016, <https://aspe.hhs.gov/system/files/pdf/205581/NatlPlan2016.pdf> (accessed September 8, 2017); US Congress, Office of Technology Assessment, “Special Care Units for People with Alzheimer’s and Other Dementias: Consumer Education, Research, Regulatory, and Reimbursement Issues,” August 1992, <http://ota.fas.org/reports/9234.pdf> (accessed September 8, 2017); see, e.g., Kevin R. Scott and Anna M. Barrett, “Dementia Syndromes: Evaluation and Treatment,” *Expert Review of Neurotherapeutics*, vol. 7(4) (2007), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2536654/pdf/nihms43078.pdf> (accessed September 8, 2017).

⁷ “2017 Alzheimer’s Disease Facts and Figures: Quick Facts,” Alzheimer’s Association, <http://www.alz.org/facts/> (accessed September 8, 2017).

⁸ “What Is Alzheimer’s?” Alzheimer’s Association, https://www.alz.org/alzheimers_disease_what_is_alzheimers.asp (accessed September 24, 2017).

⁹ Reaves and Musumeci, “Medicaid and Long-Term Services and Supports: A Primer,” *Kaiser Family Foundation*, <http://www.kff.org/medicaid/report/medicaid-and-long-term-services-and-supports-a-primer>.

¹⁰ Federal Interagency Forum on Aging-Related Statistics, “Older Americans: Key Indicators of Well-Being, 2016,” August 2016, <https://agingstats.gov/docs/LatestReport/Older-Americans-2016-Key-Indicators-of-WellBeing.pdf> (accessed September 8, 2017).

nursing facilities in 2014, and almost 780,000 people lived in other residential care communities.¹¹ The proportion of people living in institutional settings increases with age because care needs become more intensive.¹²

Other institutional care settings like assisted living are non-medical and provide minimal supervision. Medicare and Medicaid do not pay for assisted living in most cases.¹³ Medicare is the primary provider of health insurance to people aged 65 and older in the United States. It includes four parts: Parts A, B, C, and D, covering hospital insurance (including the first 100, rehabilitative days in a skilled nursing facility); medical insurance (such as doctors, outpatient care, medical equipment, and preventive services); private companies' health plans (Medicare Advantage); and prescription drugs (including long-stay nursing facility residents' drug prescriptions), respectively.¹⁴

Medicaid, which is the primary public health insurance program for people with low income in the US and is jointly administered by the federal government and the states, is the primary payer for long-term care, accounting for 51 percent of the nursing home industry's

¹¹ Just under 20 percent of residents are ages 65 to 74, over a quarter are ages 75 to 84, and over 30 percent are ages 85 to 95. "MDS 3.0 Frequency Report: First Quarter 2017 Report," Centers for Medicare & Medicaid Services (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> (accessed September 8, 2017); "Nursing Home Care," Centers for Disease Control and Prevention, last modified May 3, 2017, <https://www.cdc.gov/nchs/fastats/nursing-home-care.htm>.

¹² US Census Bureau, "65+ in the United States: 2010," June 2014, <https://www.census.gov/content/dam/Census/library/publications/2014/demo/p23-212.pdf> (accessed September 24, 2017) p. 43.

¹³ Medicare Payment Advisory Committee (MedPAC), "Skilled Nursing Facility Services," in *Report to Congress, Medicare Payment Policy*, (Washington, DC: MedPAC, 2017), http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch8.pdf?sfvrsn=0 (accessed September 8, 2017); Barbara S. Klees, Christian J. Wolfe, and Catherine A. Curtis, "Brief Summaries of Medicare & Medicaid," CMS, Office of the Actuary, November 2016, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/Downloads/MedicareMedicaidSummaries2016.pdf> (accessed September 8, 2017).

¹⁴ "What Medicare Covers," CMS, <https://www.medicare.gov/what-medicare-covers/index.html> (accessed September 24, 2017).

expenditures.¹⁵ Consequently, to receive institutional long-term care outside of a nursing facility requires significant private resources, estimated at over US\$3,000 per month.¹⁶

The total cost of long-term care varies by context. In 2015, the median annual cost of living in a nursing facility was over \$90,000, roughly twice the cost of having a home health aide and five times the cost of an adult day health care program (almost \$18,000).¹⁷ Long-term care costs vary significantly by state. For example, a semi-private skilled nursing home room in the most expensive states (Alaska, Connecticut, and Massachusetts) costs almost three times as much as in the least expensive states (Texas, Missouri, and Louisiana), \$143,000–\$168,000 compared to \$56,000–\$61,000 annually. Moreover, home health aides in the most expensive states (Massachusetts, Alaska, and New Jersey) cost almost twice as much as in the least expensive states (Alabama, Louisiana, and West Virginia), \$28–\$31 versus \$17–\$19 hourly.¹⁸ In 2013, approximately half of Medicare beneficiaries, which include older people and younger people with disabilities, earned less than \$23,500 per year.¹⁹

¹⁵ The federal government matches state Medicaid spending. Robin Rudowitz, “Medicaid Financing: The Basics,” *Kaiser Family Foundation*, December 22, 2016, <http://www.kff.org/medicaid/issue-brief/medicaid-financing-the-basics/> (accessed September 8, 2017); MaryBeth Musumeci and Katherine Young, “State Variation in Medicaid Per Enrollee Spending for Seniors and People with Disabilities,” *Kaiser Family Foundation*, May 1, 2017, <http://www.kff.org/medicaid/issue-brief/state-variation-in-medicaid-per-enrollee-spending-for-seniors-and-people-with-disabilities/> (accessed September 8, 2017). See also, “Medicaid’s Role in Nursing Home Care,” *Kaiser Family Foundation*, June 20, 2017, <http://www.kff.org/infographic/medicaids-role-in-nursing-home-care/> (accessed September 24, 2017).

¹⁶ “Compare Long Term Care Costs Across the United States,” Genworth Financial Inc., last updated June 22, 2016, <https://www.genworth.com/about-us/industry-expertise/cost-of-care.html>.

¹⁷ Reaves and Musumeci, “Medicaid and Long-Term Services and Supports: A Primer,” *Kaiser Family Foundation*, <http://www.kff.org/medicaid/report/medicaid-and-long-term-services-and-supports-a-primer>; Matthew Craft, “Cost of Long-Term Care Beyond Reach for Middle-Class Elderly,” *Press Herald*, July 21, 2015, <http://www.pressherald.com/2015/07/21/cost-of-long-term-care-beyond-reach-for-middle-class-elderly/> (accessed September 8, 2017).

¹⁸ Lincoln Financial Group, “Lincoln Financial Group Annual ‘What Care Costs’ Study Indicates Continued Rise in Long-Term Care Costs in State-by-State Comparison,” February 15, 2017, <http://www.businesswire.com/news/home/20170215005783/en/> (accessed September 24, 2017).

¹⁹ Reaves and Musumeci, “Medicaid and Long-Term Services and Supports: A Primer,” *Kaiser Family Foundation*, <http://www.kff.org/medicaid/report/medicaid-and-long-term-services-and-supports-a-primer>; Gretchen Jacobson et al., “Income and Assets of Medicare Beneficiaries, 2016-2035,” *Kaiser Family Foundation*, April 21, 2017, <http://www.kff.org/medicare/issue-brief/income-and-assets-of-medicare-beneficiaries-2016-2035/> (accessed September 24, 2017).

Despite the common perception that Medicare is for older people and Medicaid is for the poor, many people in the middle class in nursing facilities depend on Medicaid. Many people who saved for assisted living or other non-nursing facility care spend down their savings rapidly. In 2012, paying privately for the median cost of a nursing home (\$81,030) would cost 252 percent of the median household income (\$34,381) for people aged 65 and up.²⁰ One in three people turning 65 may require care from a nursing facility at some point in their life, and three-quarters of long-term nursing facility residents will be covered by Medicaid at some point.²¹

The US Nursing Facility Industry

Seventy percent of nursing facilities in the US—about 11,000—are owned by for-profit companies, and almost 25 percent are nonprofit.²² About 6 percent are publicly owned, most of which (46 percent) are owned by counties, followed by hospital districts (21 percent), states (14 percent), city-county (9 percent), city (8 percent), and the federal government (1 percent).²³ In 2014, almost three in five nursing facilities were part of a chain, meaning they were owned by an entity that owns multiple facilities.²⁴ Private equity firms own about 12

²⁰ AARP Public Policy Institute, “A New Way of Looking at Private Pay Affordability of Long-Term Services and Supports,” October 2012, http://www.aarp.org/content/dam/aarp/research/public_policy_institute/ltc/2012/private-pay-affordability-ltss-insight-AARP-ppi-ltc.pdf (accessed September 8, 2017) p. 19.

²¹ Jacob Liebenluft and Aviva Aron-Dine, “Middle-Class Families Would Face Higher Costs, Worse Coverage Under Senate Health Bill,” *Center on Budget and Policy Priorities*, June 27, 2017, <http://www.cbpp.org/research/health/middle-class-families-would-face-higher-costs-worse-coverage-under-senate-health> (accessed September 8, 2017); David Grabowski, Jonathan Gruber, and Vincent Mor, “You’re Probably Going to Need Medicaid,” *New York Times*, June 13, 2017, <https://www.nytimes.com/2017/06/13/opinion/youre-probably-going-to-need-medicaid.html> (accessed September 8, 2017); Musumeci and Young, “State Variation in Medicaid Per Enrollee Spending for Seniors and People with Disabilities,” *Kaiser Family Foundation*, <http://www.kff.org/medicaid/issue-brief/state-variation-in-medicaid-per-enrollee-spending-for-seniors-and-people-with-disabilities/>; Jordan Rau, “Medicaid Cuts May Force Retirees Out of Nursing Homes,” *New York Times*, June 24, 2017, <https://www.nytimes.com/2017/06/24/science/medicaid-cutbacks-elderly-nursing-homes.html>.

²² US Government Accountability Office, “Skilled Nursing Facilities: CMS Should Improve Accessibility and Reliability of Expenditure Data,” September 2016, <https://www.gao.gov/assets/680/679569.pdf> (accessed September 8, 2017). See also, “Provider Info,” Nursing Home Compare, <https://data.medicare.gov/Nursing-Home-Compare/Provider-Info/4pq5-n9py#column-menu>.

²³ Ibid.

²⁴ MedPAC, *Report to the Congress: Medicare Payment Policy*, p. 202.

percent of all nursing facilities (18 percent of for-profit ones).²⁵ Ten chains own the facilities in which 14 percent of the nation’s residents live, the largest concentration.²⁶

In 2015, the nursing facility industry, assisted living, and other types of long-term care recorded annual revenues of \$156.8 billion, 41 percent of which came from Medicaid and 21 percent from Medicare.²⁷ Medicare and Medicaid have provided the financial foundation of the nursing facility industry since their creation.²⁸

The federal government regulates the nursing facility industry through the Nursing Home Reform Act of 1987, requiring facilities to meet certain standards to be certified and paid by Medicare and Medicaid.²⁹ CMS contracts with state agencies to certify facilities and to ensure “substantial compliance” with minimum health and safety requirements.³⁰

In subsequent sections, this report describes the inappropriate use of antipsychotic drugs in older people with dementia in US nursing facilities—including use without valid medical reason; for the convenience of staff; inconsistent with federal regulatory requirements;

²⁵ US Government Accountability Office, “Nursing Homes: Complexity of Private Investment Purchases Demonstrates Need for CMS to Improve the Usability and Completeness of Ownership Data,” September 2010, <http://www.gao.gov/assets/320/310562.pdf> (accessed September 8, 2017).

²⁶ Charlene Harrington, et al., “Nurse Staffing and Deficiencies in the Largest For-Profit Nursing Home Chains and Chains Owned by Private Equity Companies,” *Health Services Research*, vol. 47(1) (2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3447240/pdf/hesr0047-0106.pdf> (accessed September 8, 2017).

²⁷ CMS, “National Health Expenditures 2015 Highlights,” <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf> (accessed September 8, 2017). The nursing facility industry alone had an estimated \$129 billion in revenue. IBIS World, “Nursing Care Facilities in the US: Market Research Report,” August 2017, <https://www.ibisworld.com/industry-trends/market-research-reports/healthcare-social-assistance/nursing-residential-care-facilities/nursing-care-facilities.html> (accessed September 8, 2017); MedPAC, *Report to the Congress: Medicare Payment Policy*, p. 201; Charlene Harrington, et al., “Comparison of Nursing Home Financial Transparency and Accountability in Four Locations,” *Ageing International*, vol. 41(1) (2016), <http://theconsumerveoice.org/uploads/files/general/Harrington-NH-Financial-Accountability-2015.pdf> (accessed September 8, 2017) p. 21.

²⁸ Edward Berkowitz, “Medicare and Medicaid: The Past as Prologue,” *Health Care Finance Review*, vol. 27(2) (2005), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4194925/> (accessed September 8, 2017).

²⁹ “Basis and Scope,” US Code of Federal Regulations, Title 42, sec. 483.1, referring to the Social Security Act of 1935, secs. 1819 and 1919, <https://www.law.cornell.edu/cfr/text/42/483.1> (accessed September 8, 2017); See also “Nursing Homes,” Certification and Compliance, Survey and Certification, CMS, <https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcompliance/nhs.html> (accessed September 8, 2017).

³⁰ Definitions, US Code of Federal Regulations, Title 42, sec. 488.301; “Nursing Homes,” CMS, <https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcompliance/nhs.html>.

and without informed consent. The report discusses the inadequacy of federal regulations, enforcement, and access to private remedies for harm.

This background section describing the long-term care system provides the context to understand—and highlights the salience of—facilities’ abuses and governmental shortcomings. The population is aging, and long-term care services and supports, including nursing homes, are more likely to be necessary as age-related disabilities rise. It is not only the poor who end up in nursing facilities but many people in the middle class: people who never had and never anticipated relying on Medicaid. Dementia—a risk factor for being given antipsychotic drugs in nursing homes inappropriately, until the government enforces protections against such abuse more effectively—affects people across income, gender, and race.

The industry’s reliance on Medicare and Medicaid described in this section, as well as the breakdown in the industry by ownership status, with the prevalence of chain ownership, relate to regulatory and enforcement concerns. As noted, facilities are required to comply with certain standards of care to receive certification and payment from Medicare and Medicaid: these health insurance programs are the government’s basis for regulating facilities.

II. The Risks and Harms of Antipsychotic Medications on People with Dementia in Nursing Facilities

I would just shut off and not say anything. [It] was a very traumatic time.
—Madeline C., an 86-year-old woman at a nursing facility in Illinois describing being on antipsychotic medications, February 2017.³¹

Antipsychotic drugs were originally developed to treat schizophrenia. The first generation—so-called “conventional” antipsychotics, such as Haldol (haloperidol)—was developed in the 1950s, and a second generation—called “atypical” antipsychotics, such as Seroquel (quetiapine)—was developed in the 1980s.³² The US Food and Drug Administration (FDA) has approved some of these medicines for treatment of other conditions since then, such as Tourette syndrome and bipolar disorder.³³ The FDA has not approved antipsychotic drugs for treating symptoms of dementia.

Antipsychotic medications are one of several classes of psychotropic drugs affecting the central nervous system. Psychotropic drugs include anti-anxiety medications, anti-depressants, hypnotics, anxiolytics and sedatives like benzodiazepines (e.g., Xanax, Ativan, Valium, Klonopin), anticonvulsants, and mood stabilizers (e.g., Depakote or lithium, often used for bipolar disorder), some of which have comparable effects to antipsychotic drugs and all of which are used prevalently in nursing facilities.³⁴ (CMS has expressed concern that, as the use of antipsychotic drugs in people with dementia is

³¹ Human Rights Watch interview with Madeline C., 86-year-old resident of NFIL#9 in Illinois, February 5, 2017.

³² J.C. Seida et al., “First- and Second- Generation Antipsychotics for Children and Young Adults,” *Comparative Effectiveness Review*, no. 39 (2012), US Agency for Healthcare Research and Quality, https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0040940/pdf/PubMedHealth_PMH0040940.pdf (accessed September 8, 2017).

³³ Christian R et al., “Appendix A: Tables of FDA-Approved Indications for First- and Second-Generation Antipsychotics,” in “Future Research Needs for First- and Second-Generation Antipsychotics for Children and Young Adults,” *Future Research Needs Papers*, no. 13 (2012), US Agency for Healthcare Research and Quality, <https://www.ncbi.nlm.nih.gov/books/NBK84656/> (accessed September 8, 2017); Office of Inspector General, US Department of Health and Human Services, “Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents,” May 2011, <http://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf> (accessed September 8, 2017).

³⁴ CMS, “National Partnership to Improve Dementia Care in Nursing Homes: Antipsychotic Medication Use Data Report (March 2017),” March 2017, https://www.nhqualitycampaign.org/files/AP_package_20170413.pdf (accessed September 8, 2017).

discouraged as inappropriate, these other classes of medications should not replace them.³⁵) Other types of psychotropic drugs, such as anti-anxiety drugs, can have similar sedating properties and cause adverse effects if used inappropriately. In revising federal regulations in 2016, CMS wrote:

Expanding the requirements for antipsychotic drugs to psychotropic drugs will expand protections for residents prescribed drugs that have an increased potential for being prescribed inappropriately or for reasons other than the resident's benefit, such as for the purpose of a chemical restraint.³⁶

Antipsychotic medicines are widely used off-label, that is, for indications or purposes for which the FDA has not approved them. Off-label use of medication is both common and legal. However, the problem with the use of antipsychotic drug in older people with dementia is beyond the issue of legality. As the FDA states in the boxed warning manufacturers must include on conventional and atypical antipsychotic drug labels, elderly patients with "dementia-related psychosis" treated with antipsychotic drugs are at an increased risk of death.³⁷ It is uncommon for the FDA to require a boxed warning

³⁵ "Use of psychotropic medications, other than antipsychotics, should not increase when efforts to decrease antipsychotic medications are being implemented, unless the other types of psychotropic medications are clinically indicated. Other medications which may affect brain activity such as central nervous system agents, mood stabilizers, anticonvulsants, muscle relaxants, anticholinergic medications, antihistamines, NMDA receptor modulators, and over the counter natural or herbal products must also only be given with a documented clinical indication consistent with accepted clinical standards of practice.... If the record shows evidence of adding other psychotropic medications or switching from one type of psychotropic medication to another category of psychotropic medication, surveyors must review the medical record to determine whether the prescribing practitioner provided a rationale." See "Psychotropic Medications and Antipsychotic Medications (F758 Only Guidance)" in CMS, "Revision to State Operations Manual (SOM) Appendix PP for Phase 2, F-Tag Revisions, and Related Issues," effective November 28, 2017, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Advance-Appendix-PP-Including-Phase-2-.pdf> (accessed September 8, 2017).

³⁶ "Pharmacy Services" in CMS, "Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities," *Federal Register*, vol. 81(192) (2016), <https://www.gpo.gov/fdsys/pkg/FR-2016-10-04/pdf/2016-23503.pdf> (accessed September 10, 2017) p. 68766.

³⁷ 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/postmarketdrugssafetyinformationforpatientsandproviders/ucm053171> (accessed September 23, 2017).

Quetiapine Fumarate (SEROQUEL XR®)
Extended-release tablets
200mg*, once daily

**WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH
DEMENTIA-RELATED PSYCHOSIS**

Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of seventeen placebo-controlled trials . . . in these patients revealed a risk of death in the drug-treated patients of between 1.6 and 1.7 times that seen in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5%, compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. [This drug] is not approved for the treatment of patients with dementia-related psychosis [see *Warnings and Precautions* (5.1)].⁴⁰

A mock-up of the boxed warning on antipsychotic drugs. © 2018/Human Rights Watch

regarding a never-approved use of a drug. Neither off-label use nor the use warned against in boxed warnings affects Medicare coverage of the drug.³⁸

The boxed warning on antipsychotic drugs for use in older people with dementia is based on findings that the drugs increase the risk of death in older people with dementia.³⁹

³⁸ Office of Inspector General, “Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents,” <https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf> pp. 7, 15.

³⁹ See, e.g., LS Schneider et al., “Effectiveness of Atypical Antipsychotic Drugs in Patients with Alzheimer’s Disease,” *New England Journal of Medicine*, vol. 355(15) (2006), <https://www.ncbi.nlm.nih.gov/pubmed/17035647> (accessed September 8, 2017); Philip S. Wang et al., “Risk of Death in Elderly Users of Conventional vs. Atypical Antipsychotic Medications,” *New England Journal of Medicine*, vol. 353 (2005), <http://www.nejm.org/doi/full/10.1056/NEJMoa052827#t=article> (accessed September 8, 2017); “Public Health Advisory: Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances,” US Food and Drug Administration, April 11, 2005, <https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm053171.htm> (accessed September 8, 2017); Office of Inspector General, “Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents,” <https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf> p. 3; “Information for Healthcare Professionals: Conventional Antipsychotics,” U.S. Food and Drug Administration, June 16, 2008, <https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124830.htm> (accessed September 8, 2017).

⁴⁰ “Public Health Advisory: Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances,” FDA, <https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm053171.htm> (accessed October 10, 2017).

Aside from raising the risk of death, the drugs' side effects include severe nervous system problems; neuroleptic malignant syndrome (a life-threatening reaction associated with severe muscular rigidity, fever, and altered mental status); tardive dyskinesia (characterized by stiff, jerking movements that may be permanent once they start and whose likelihood of onset increases the longer antipsychotic drugs are taken); high blood sugar and diabetes; and low blood pressure, which causes dizziness and fainting.⁴¹ Other side effects include increased mortality, cerebrovascular events (stroke), cardiovascular effects, blood clots, central and autonomic nervous system problems, visual disturbances, metabolic effects, extrapyramidal symptoms, fall risk and hip fracture, irreversible cognitive decompensation, and pneumonia.⁴²

In the context of nursing facilities, the most common use of these medications is in older people with dementia for the “behavioral and psychological symptoms of dementia.”⁴³ A 2012 Office of Inspector General investigation found that Medicare processed 1.4 million claims for atypical antipsychotic drugs from nursing facilities in 2007. Older people with dementia accounted for 88 percent of the 1.4 million claims.⁴⁴ Only 4.7 percent of these claims were for medications that were not used in older people with dementia and were not used for an off-label use. In other words, they were used for someone with schizophrenia or another psychiatric or neurological condition for which the drugs are approved.⁴⁵

⁴¹ Office of Inspector General, “Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents,” <https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf> p. 3.

⁴² Martin Steinberg and Constantine G. Lyketsos, “Atypical Antipsychotic Use in Patients with Dementia: Managing Safety Concerns,” *American Journal of Psychiatry*, vol. 169(9) (2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3516138/pdf/nihms421959.pdf> (accessed October 10, 2017); American Psychiatric Association (APA), *The American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia*, (Arlington, Virginia: APA, 2016), <http://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890426807> (accessed September 8, 2017).

⁴³ Office of Inspector General, “Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents,” <https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf>; J. Cerejeira et al., “Behavioral and Psychological Symptoms of Dementia,” *Frontiers in Neurology*, vol. 3 (2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3345875/> (accessed September 23, 2017).

⁴⁴ Office of Inspector General, “Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents,” <https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf> p. ii; 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,” January 2015, <http://www.gao.gov/assets/670/668221.pdf> (accessed September 8, 2017) p. 7.

⁴⁵ Ibid.

The medical reason for prescribing antipsychotic drugs to people with dementia, usually as a last resort, is that dementia is often accompanied by irritability, agitation, aggression, hallucinations, delusions, wandering, disinhibition, anxiety, and depression—what some medical professionals call “behavioral and psychological symptoms of dementia.”⁴⁶

Some studies find that a majority of people with dementia will develop at least one of these symptoms and that individuals in nursing facilities tend to have more severe symptoms than people in other care settings.⁴⁷ These symptoms can be distressing and dangerous to the individuals experiencing them and to those around them, including family and caregivers.⁴⁸ Nursing facility staff that administer antipsychotic drugs to older people inappropriately but who are not administering them intentionally for staff convenience often appear to believe that the drugs are the best or only treatment option for someone seemingly in distress.

Dementia-related symptoms may result from “underlying neurochemical changes,” changes in the body’s nervous system, associated with dementia or from an external or underlying situation such as pain or personal needs.⁴⁹ Pain is often underreported in people with dementia.⁵⁰ Unlike schizophrenia and other psychiatric conditions, the

⁴⁶ Joseph E. Gaugler et al., “Direct Care Worker Training to Respond to the Behavior of Individuals With Dementia: The CARES Dementia-Related Behavior Online Program,” *Gerontology & Geriatric Medicine*, vol. 2 (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4755277/> (accessed September 8, 2017); Laura N. Gitlin et al., “Managing Behavioral Symptoms in Dementia Using Nonpharmacologic Approaches: An Overview,” *Journal of the American Medical Association (JAMA)*, vol. 308(19) (2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3711645/> (accessed September 8, 2017); Alice F. Bonner et al., “Rationales that Providers and Family Members Cited for the Use of Antipsychotic Medications in Nursing Home Residents with Dementia,” *Journal of the American Geriatrics Society*, vol. 63(2) (2015), <http://onlinelibrary.wiley.com/doi/10.1111/jgs.13230/full> (accessed September 8, 2017).

⁴⁷ Ibid.; APA, *The American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia*, <http://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890426807.p.5>.

⁴⁸ APA, *The American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia*, <http://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890426807.p.5>.

⁴⁹ Abhilash K. Desai and George T. Grossberg, “Recognition and Management of Behavioral Disturbances in Dementia,” *Primary Care Companion Journal of Clinical Psychiatry*, vol. 3(3) (2001), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC181170/> (accessed September 8, 2017).

⁵⁰ Studies have documented that people with dementia do not experience pain less than others, but are treated with less pain medication and more antipsychotic medication because of a lack of understanding of why someone with dementia is behaving in a certain way. See, e.g., Wilco P. Achterberg, et al., “Pain Management in Patients with Dementia,” *Clinical Interventions in Aging*, vol. 8 (2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3817007/> (accessed September 8, 2017) (“In addition to the discomfort and distress caused by pain, it is frequently the underlying cause of behavioral symptoms, which can lead to inappropriate treatment with antipsychotic medications.”); S. Kuske et al., “Drug-based Pain

“behaviors” of people with dementia often arise from feelings of loneliness, boredom, depression, anxiety, sun-downing (increased agitation or distress in early evening), apathy, distrust of new caregivers, hunger, dehydration, impairment of the brain’s executive function, grief, noise stress, and delirium.⁵¹

In addition to unmet physical needs, symptoms may be a “response to environmental triggers,” such as being ignored unless a person screams (which inadvertently reinforces the “behavior” of screaming); alternatively, symptoms may be “consequences of a mismatch between the environment and patients’ abilities to process and act upon cues, expectations and demands.”⁵² An example of such a distressing mismatch is “resisting care” when expected to be showered if it frightens a person by association with a prior fall. In its revised guidance that intended to go into effect in November 2017, CMS states:

Behavioral or psychological expressions are occasionally related to the brain disease in dementia; however, they may also be caused or exacerbated by environmental triggers. Such expressions or indications of distress often represent a person’s attempt to communicate an unmet need, discomfort, or thoughts that they can no longer articulate.⁵³

Experts agree on the importance of attempting nonpharmacologic interventions with individuals with dementia-related symptoms; federal regulations also require such interventions unless clinically contraindicated (when the intervention should not be used

Management in People with Dementia After Hip or Pelvic Fractures: A Systematic Review Protocol,” *Systematic Reviews*, vol. 5(113) (2016), <https://systematicreviewsjournal.biomedcentral.com/articles/10.1186/s13643-016-0296-3> (accessed September 8, 2017).

⁵¹ Desai and Grossberg, “Recognition and Management of Behavioral Disturbances in Dementia,” *Primary Care Companion Journal of Clinical Psychiatry*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC181170/>; “F329, Unnecessary Drugs,” in CMS, “Revision to State Operations Manual (SOM) Appendix PP – Incorporate Revised Requirements of Participation for Medicare and Medicaid Certified Nursing Facilities,” March 8, 2017, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R168SOMA.pdf>.

⁵² Gitlin et al., “Managing Behavioral Symptoms in Dementia Using Nonpharmacologic Approaches: An Overview,” *JAMA*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3711645/>.

⁵³ “Section 483.40(b)(3), Behavioral Health Services,” in CMS, “Revision to State Operations Manual (SOM) Appendix PP for Phase 2, F-Tag Revisions, and Related Issues,” <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Advance-Appendix-PP-Including-Phase-2-.pdf>

due to adverse effects).⁵⁴ These interventions follow these steps: evaluating and understanding the origin of the “behavior”; ruling out underlying physical illness, infection, or needs; addressing any underlying dementia-related or environmental issue; and re-evaluating the care plan based on its effectiveness.⁵⁵

Examples of nonpharmacologic interventions include:

- Reducing boredom, pain, loneliness, and similar experiences by changing a person’s activities, surroundings, opportunities, and access to relationships;
- Creating individualized sleep, hygiene, bathroom, and other daily routines that the person prefers;
- Ensuring staff are consistent and familiar to the individual;
- Physical and cognitive exercises; and
- Many types of therapy (music, aroma, reminiscence, behavioral, pet, light, etc.).⁵⁶

Fundamentally, many of these interventions are ways of making an institutional environment conform to an individual’s needs; it is the converse that can give rise to distress, discomfort, and disorientation. Older people and people with dementia should be included and consulted on non-pharmacologic alternatives and other matters that affect their lives and well-being. Including residents shows that their opinions and perspectives about their own care are respected and valued. Even when people with

⁵⁴ “Section 483.45(d), Unnecessary Drugs,” “Use of Psychotropic Medications in Specific Circumstances,” and “Section 483.45, Pharmacy Services,” in CMS, “Revision to State Operations Manual (SOM) Appendix PP for Phase 2, F-Tag Revisions, and Related Issues,” <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Advance-Appendix-PP-Including-Phase-2-.pdf> (facility must ensure expressions or distress are not due to medical condition, environmental stressors, psychological stressors, and are persistent). See also 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf>.

⁵⁵ Gitlin et al., “Managing Behavioral Symptoms in Dementia Using Nonpharmacologic Approaches: An Overview,” *JAMA*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3711645/>; C Salzman et al., “Elderly Patients with Dementia-Related Symptoms of Severe Agitation and Aggression: Consensus Statement on Treatment Options, Clinical Trials Methodology, and Policy,” *Journal of Clinical Psychiatry*, vol. 69(6) (2008), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2674239/> (accessed September 8, 2017).

⁵⁶ Kevin R. Scott and Anna M. Barrett, “Dementia Syndromes: Evaluation and Treatment,” *Expert Review of Neurotherapeutics*, vol. 7(4) (2007), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2536654/pdf/nihms43078.pdf> (accessed September 8, 2017); Desai and Grossberg, “Recognition and Management of Behavioral Disturbances in Dementia,” *Primary Care Companion Journal of Clinical Psychiatry*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC181170/>.

cognitive disabilities have difficulties expressing themselves verbally, they can often indicate some preferences otherwise.

Some medical experts believe and CMS endorses that if it is not possible to address underlying medical, physical, social, or environmental factors in some people, an antipsychotic drug “can minimize the risk of violence, reduce patient distress, improve the patient’s quality of life, and reduce caregiver burden.”⁵⁷ The evidence of the effectiveness of nonpharmacologic intervention is mixed.⁵⁸ According to the American Psychiatric Association, which issued practice guidelines on the use of antipsychotic drugs in people with dementia, the “expert consensus suggests that use of an antipsychotic medication in individuals with dementia can be appropriate.”⁵⁹

Yet the guidelines conclude, “in clinical trials, the benefits of antipsychotic medications are at best small.”⁶⁰ Meanwhile, countering these meager potential benefits is the “consistent evidence that antipsychotics are associated with clinically significant adverse effects, including mortality.”⁶¹ The risks vary depending on the type and stage of dementia,

⁵⁷ Ibid., p. 6.

⁵⁸ See, e.g., Maya E. O’Neil, et al., *A Systematic Evidence Review of Non-Pharmacological Interventions for Behavioral Symptoms of Dementia*, (Washington, D.C.: US Department of Veterans Affairs, 2011), <https://www.ncbi.nlm.nih.gov/books/NBK54971/> (accessed September 8, 2017).

⁵⁹ APA, *The American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia*, <http://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890426807> p. 5. The APA’s recommendations were endorsed by the APA Council on Geriatric Psychiatry, the APA Council on Psychosomatic Medicine, the Academy of Psychosomatic Medicine, the Alzheimer’s Association, the American Academy of Family Physicians, the American College of Physicians, the American Geriatrics Society, the American Medical Directors Association—The Society for Post-Acute and Long-Term Care Medicine, the American Psychiatric Nurses Association, the American Psychological Association, and the World Psychiatric Association.

⁶⁰ Ibid., p. 7.

⁶¹ Ibid., p. 8. See also, Christine M. Campanelli, “American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults,” *Journal of the American Geriatric Society*, vol. 60(4) (2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3571677/pdf/nihms-439055.pdf> (accessed September 8, 2017); Steinberg and Lyketsos, “Atypical Antipsychotic Use in Patients with Dementia: Managing Safety Concerns,” *American Journal of Psychiatry*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3516138/pdf/nihms421959.pdf>; Gitlin et al., “Managing Behavioral Symptoms in Dementia Using Nonpharmacologic Approaches: An Overview,” *JAMA*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3711645/>; 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,” <http://www.gao.gov/assets/670/668221.pdf> p. 8; Tyler R. Reese et al., “Behavioral Disorders in Dementia: Appropriate Nondrug Interventions and Antipsychotic Use,” *American Family Physician*, vol. 94(4) (2016), <http://www.aafp.org/afp/2016/0815/p276.html> (accessed September 8, 2017).

other conditions the person has; other drugs the person takes; the dosing and duration of the antipsychotic drug; and the particular antipsychotic drug.⁶²

Similarly, CMS has warned against inappropriate use of antipsychotic drugs, given the risks that are unwarranted when the drugs do not serve a medical purpose:

It has been a common practice to use various types of psychopharmacological medications in nursing homes to try to address behavioral or psychological symptoms of dementia (BPSD) without first determining whether there is an underlying medical, physical, functional, psychosocial, emotional, psychiatric, or environmental cause of the behaviors.... When antipsychotic medications are used without an adequate rationale, or for the sole purpose of limiting or controlling behavior of an unidentified cause, there is little chance that they will be effective, and they commonly cause complications.⁶³

Human Rights Watch uses the term “inappropriate” to describe use of the drug in older people with dementia that is: inconsistent with recommendations of medical experts and authorities, such as the American Psychiatric Association and FDA; inconsistent with federal regulations governing nursing homes, which overlap significantly with medical experts’ recommendations; and administered without free and informed consent except in cases of emergency. Concretely, “inappropriate use” in people with dementia often entails use that is not a last resort, use excessive in dose or duration, use without appropriate monitoring of side effects, or use not based on an informed choice about treatment options.

Massive Use of Antipsychotic Medications

It is essential that antipsychotic drugs be used cautiously in people with dementia, only where medically appropriate, and only with informed consent because of the propensity for nursing facilities to use the drugs for non-medical purposes and because of the high

⁶² Ibid.

⁶³ “Section 483.25, Quality of Care,” in 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf>.

risk and low likelihood of benefit even when used for medical reasons. However, Human Rights Watch’s analysis of data on the prevalence of use in people without “exclusionary diagnoses” and interviews with this category of people strongly suggest that such limited use is not what occurs in practice.

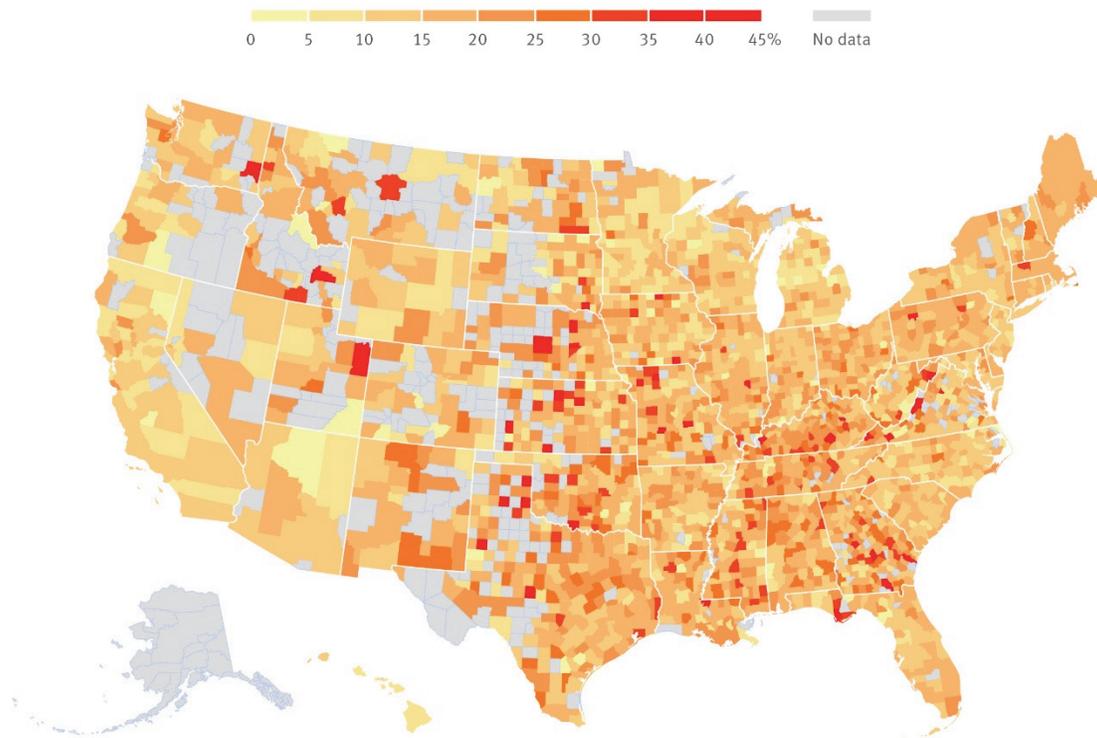
Nursing facilities in the US use antipsychotic medications on a massive scale. Every week, facilities administer antipsychotic drugs to over 179,000 long-stay residents (residing in the facility for more than 100 days) who do not have an exclusionary diagnosis—of schizophrenia, Huntington’s disease, or Tourette syndrome, psychiatric and neurological diseases for which the drugs are approved—and most of whom have dementia.⁶⁴ At the end of 2016, CMS’s official measure was that 16 percent of long-stay nursing home residents were receiving an antipsychotic medication without one of these three exclusionary diagnoses.⁶⁵

While the national average rate of use of antipsychotic medications among older people in nursing facilities without an appropriate diagnosis has declined in recent years, current prescription rates vary significantly across the country (see Map 1).

⁶⁴ CMS, “New Quality Measures on Nursing Home Compare,” April 27, 2016, <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-04-27.html> (accessed September 8, 2017). See also, CMS “MDS 3.0 Quality Measures User’s Manual,” effective April 1, 2017, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/MDS-30-QM-Users-Manual-V11-Final.pdf> (accessed September 8, 2017) p. 34.

⁶⁵ National Partnership to Improve Dementia Care in Nursing Homes, “National Partnership to Improve Dementia Care in Nursing Homes: Antipsychotic Medication Use Data Report (March 2017),” https://www.nhqualitycampaign.org/files/AP_package_20170413.pdf.

Average Proportion of Nursing Home Residents on Antipsychotic Drugs



Map 1. Proportion of Residents on Antipsychotic Drugs in Nursing Facilities with Majority Population over 65 Years Old by County. © 2018/Human Rights Watch

Antipsychotic medications not only have adverse medical consequences, but also have social and emotional effects on nursing facility residents and their families. To capture these consequences of forced and inappropriate antipsychotic drug administration, 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 their family members. We spoke with 74 residents and 36 family members in all six states. 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.

Of course, dementia itself causes significant losses, affecting cognition, communication, memory, and other functions. It is impossible without a comprehensive medical evaluation, if then, to determine the direct cause of any individual changes in residents

described here. However, most or all antipsychotic drugs in people with dementia are associated with sedation and fatigue.⁶⁶ (The type, dose, duration, drug-drug interaction, and other characteristics of antipsychotic drug treatment, as well as a person’s health condition aside from dementia, influence the effects the medications have.⁶⁷) Family members described cognitive and energetic improvements once antipsychotic drugs were stopped—even if the underlying dementia persisted.

Many of the following cases illustrate the psychosocial harm associated with sedation.⁶⁸ While they are not testimonies from medical experts who could authoritatively conclude that the antipsychotic drugs caused the sedation described, these descriptions by residents and family members are representative of what antipsychotic drugs in older people with dementia often induce.⁶⁹ Moreover, in each of the following cases (except one where the individual took the drugs until she was receiving hospice care and died), the sedative effect ceased when they stopped taking antipsychotic drugs.

⁶⁶ Helen C. Kales, et al., “Trends in Antipsychotic Use in Dementia 1999-2007,” *Archives of General Psychiatry*, vol. 68(2) (2011), <http://jamanetwork.com/journals/jamapsychiatry/fullarticle/211061> (accessed September 8, 2017) (“Quetiapine may have also been continued to be prescribed in low doses by providers for sedation and hypnotic purposes.”); Alicia Ruelaz Maher, et al., “Efficacy and Comparative Effectiveness of Atypical Antipsychotic Medications for Off-Label Uses in Adults: A Systematic Review and Meta-analysis,” *JAMA*, vol. 306(12) (2011), <http://jamanetwork.com/journals/jama/fullarticle/1104423> (“Other cardiovascular symptoms, sedation, fatigue, extrapyramidal symptoms, and urinary tract symptoms are also associated with some or all of the studied atypical antipsychotic medications.”); Dilip V. Jeste et al., “ACNP White Paper: Update on Use of Antipsychotic Drugs in Elderly Persons with Dementia,” *Neuropsychopharmacology*, vol. 33(5) (2007), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2553721/> accessed September 8, 2017) (“On the other hand, most of these drugs have other acute and subacute side effects in elderly persons such as sedation, postural hypotension, and falls, especially at higher doses.”); PN Tariot et al., “Efficacy of Atypical Antipsychotics in Elderly Patients with Dementia,” *The Journal of Clinical Psychiatry*, vol. 65 (2004), <http://europepmc.org/abstract/med/15264966> (accessed September 8, 2017); Philip E. Lee, et al., “Atypical Antipsychotic Drugs in the Treatment of Behavioural and Psychological Symptoms of Dementia: Systematic Review,” *The British Medical Journal (BMJ)*, vol. 329 (2004), <http://www.bmj.com/content/329/7457/75> (accessed September 8, 2017) (“The results of blocking these receptors include anticholinergic effects, orthostatic hypotension, and sedation.”); APA, *The American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia*, p. 5.

⁶⁷ “[C]ase reports and observational data suggest a substantial increase in the likelihood of adverse effects when individuals with Lewy body dementia or Parkinson’s disease dementia receive antipsychotic treatment.” See APA, *The American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia*, p. 9.

⁶⁸ *Ibid.*

⁶⁹ *Ibid.*

Ruth D., a 62-year-old woman who said she was given Seroquel (an antipsychotic medication) without her knowledge or consent in a nursing facility in Texas said: “[It] knocks you out. It’s a powerful, powerful drug. I sleep all the time. I have to ask people what the day is.”⁷⁰ The woman described being given the medication against her will, including in her food: “They crush it so you don’t know what you’re getting fed.” When asked to take Seroquel, she would tell nursing staff that she did not want to take it, and that she did not want to eat the food if she suspected the drug was in it. Ms. D continued to object as well as she could to being administered antipsychotic drugs until her discharge from the nursing facility the day after Human Rights Watch interviewed her.

Walter L., an 81-year-old man told Human Rights Watch that antipsychotic medicines “get me so I can’t think.”⁷¹ According to his wife, Anna L., who is his healthcare proxy, he was given them without his or her knowledge or consent. Mr. L told Human Rights Watch that he never again wanted to take something that made him “change the person that I am.” Ms. L. described that when her husband was on the medications he was just “staring straight ahead,” not knowing she was even there. “I leaned him up against the wall, I came back three hours later, and he had not moved,” she said.⁷² Ms. L. learned of the drug after a nurse privately alerted her. After changing facilities, the antipsychotic drug was discontinued.

Madeline C., an 87-year-old woman in a facility in Illinois, described the effect of antipsychotic medications administered in a prior nursing facility. She had been placed in a dementia unit. The woman said that when she “just about went crazy” from being in a locked unit with no activities, she “started speaking out, saying things were not right.” After that, she said, “suddenly I was very sleepy,” adding, “you feel like you’re going to die there.” She said she later learned that the facility had given her an antipsychotic drug. At the time of the interview, the woman was in a different facility that had discontinued the

⁷⁰ Human Rights Watch interview with Ruth D., 62-year-old resident of NHTX#5 in Texas, December 14, 2016. Upon review of Ms. D.’s medical chart, no informed consent sheets were documented for Seroquel although she was prescribed 200mg Quetiapine (Seroquel).

⁷¹ Human Rights Watch interview with Walter L., 81-year-old resident of NFTX#18 in Texas, December 21, 2016.

⁷² Human Rights Watch interview with Anna L., wife of Walter L., 81-year-old resident of NFTX#18 in Texas, December 21, 2016.

drug. “The fog lifted.... There’s the old Madeline again.”⁷³ Being at the prior facility was “a very traumatic time.”⁷⁴

Alma G., the sister and power of attorney of Mariela O., an 84-year-old woman with dementia who died in 2017, said that her sister’s nursing facility gave her an antipsychotic drug to ease the burden of bathing her.⁷⁵ She said, “They give my sister medication to sedate her on the days of her shower: Monday, Wednesday, Friday—an antipsychotic. They give her so much she sleeps through the lunch hour and supper.”⁷⁶

Kirsten D., the daughter and power of attorney of Joan D., a 75-year-old woman in Kansas, said that when the nursing facility began giving her mother antipsychotic and other psychotropic medications, “she would be asleep when I visited. She slept a lot. They’d say she’s adjusting to the meds. I went back weeks later. She would just sit there like this.”⁷⁷

Joan D. said that she tried to avoid taking the antipsychotic drugs—including by hiding them in her dinner roll—because of their effect on her. “I didn’t want to take it so I didn’t. I didn’t want to feel that way.”⁷⁸ She explained further that “I try not to take it. Sometimes I have to.”

Kirsten D. described her mother on the antipsychotic medication as “no personality. Just a zombie.... The fight is gone. It’s gone. That’s what worries me the most.... I think she’s learned to keep it contained. She was vibrant, full of life.... She’s still in there.”⁷⁹ After

⁷³ Human Rights Watch interview with Madeline C., 87-year-old resident of NFIL#9 in Illinois, February 5, 2017.

⁷⁴ Ibid.

⁷⁵ A “power of attorney” is a voluntary legal designation to authorize another person to act on one’s behalf, a form of “prospective autonomy.” A durable power of attorney for health care is a document that enables assigning the right to make healthcare decisions to another person (an agent) with instructions on one’s preferences for medical treatment. Other comparable legal devices under state law are advance directives, health proxy, healthcare representative, attorney-in-fact, legal appointee, or surrogate. This report uses health proxy and power of attorney interchangeably.

⁷⁶ Human Rights Watch interview with Alma G., sister and power of attorney of 84-year-old Mariela O., resident of NFTX#12 in Texas, December 19, 2016.

⁷⁷ Human Rights Watch interview with Kirsten D., daughter of Joan D., 75-year-old resident of NFKS#11 in Kansas, January 10, 2017.

⁷⁸ Human Rights Watch interview with Joan D., 75-year-old resident of NFKS#11 in Kansas, January 16, 2017.

⁷⁹ Human Rights Watch interview with Kirsten D., daughter of Joan D., 75-year-old resident of NFKS#11 in Kansas, January 10, 2017.

significant effort to find another facility with an opening that would accept her mother, Ms. D. moved her mother to another nursing home that ceased the medication. Ms. D said that her mother became lively, talkative, friendly, and mobile again without the medication.

In New York, Dorothy R., the daughter and power of attorney of a woman in a nursing facility, told Human Rights Watch that a nurse informed her that the sudden decline in her mother's health and cognition was due to her mother "getting older." After an advocate's lecture on antipsychotic drugs alerted her to the impact of antipsychotic drugs, Ms. R. requested a list of all the medications her mother was taking. She succeeded in having the facility discontinue the administration of an antipsychotic drug after discovering that the facility had put her on one without her or her mother's knowledge or consent.⁸⁰

In several cases, we documented how people with dementia seemed to improve dramatically once the antipsychotic drugs were discontinued. Laura F., the daughter of a resident in California, initially saw her mother's decline as an irreversible, progressive result of her age: "You know, she's 90. Yesterday, she's alert. Now she's not. That's what happens."⁸¹ But when the nursing facility took her mother, Selina C., off Risperdal, the antipsychotic medication she had been on for over two years at that point, Ms. F. said the mother she had known returned:

Lo and behold, she can talk again. She can read again ... she's conversing ... it's not just that she can walk now ... it's her personality. She came back. She had been sleeping all the time. She was totally incoherent. She had no memory at all. She recognized no one. On the meds, she couldn't remember if you were there while you were there.... She was drugged!⁸²

In this case, the antipsychotic medication had been initiated in a board and care home (similar to assisted living but smaller, with only six or fewer residents). Ms. F., her mother's power of attorney, had consented to their use but had not been given full information about their side effects and risks. Upon Ms. C.'s admission to a nursing home, staff

⁸⁰ Human Rights Watch interview with Dorothy R., daughter of resident of NFNY#2 in New York, October 20, 2017.

⁸¹ Human Rights Watch interview with Laura F., daughter of Selina C., 92-year old resident of NFCA#25 in California, February 13, 2017.

⁸² Ibid.

continued the antipsychotic drug. Once Ms. F. learned of its potential harm and insisted that the facility stop giving it to her mother, staff complied.

Human Rights Watch also visited some facilities that significantly reduced levels of antipsychotic drug use in the last year as a result of federal and state educational and training efforts, or due to governmental or corporate owners' pressure. Interviews with nursing home administrators, directors of nursing, and other nursing staff provided another angle of insight into the extent to which antipsychotic drugs are used inappropriately. In many cases, staff of nursing homes that had reduced the use of antipsychotic drugs now felt very strongly that the drugs not be used inappropriately.

The director of nursing at one facility in Kansas who led an effort to reduce the rate of antipsychotic drug use in people with dementia reflected on the experience to Human Rights Watch: "It used to be like a death prison here. We cut our antipsychotics in half in six months. Half our residents were on antipsychotics. Only 10 percent of our residents have a mental illness."⁸³ She continued:

Some doctors are misinformed. When we said we wanted to reduce the antipsychotics, we had to fight with the doctor. He said: 'You understand if I do this they're all going to go crazy?'

But they don't have behaviors because they need an antipsychotic. You actually see them decline when they're on an antipsychotic. It's just an adjustment when they're first admitted.

There was a woman who would stand at the nurse's station sobbing. We should have done a root cause analysis. But instead we shipped her off to psych. She was gone within a year: stiff muscles, couldn't walk or talk. I think it's sadder than watching someone with dementia decline.

You can reduce antipsychotics.... Residents have behaviors because their needs are not met. Not because of a lack of staff. We reduced the rate

⁸³ Human Rights Watch interview with the director of nursing at NFKS#13 in Kansas, January 17, 2017.

drastically and haven't had to change staffing levels one bit. We did increase staff for activities, but not CNAs [certified nurse aides].

Taking off antipsychotics affects people differently: some are more verbal, more disruptive, louder, but not violent. Some sleep more, some sleep less. We had to educate the staff: don't put them back on immediately. All antipsychotic prescriptions go through me. I do not allow PRN [prescription to take as needed] antipsychotics. Giving someone a Haldol one time has never been effective. It has to build up in the system.⁸⁴

At another facility in Kansas, a nurse told Human Rights Watch about their experience reducing use, echoing many of the same themes:

We were at 55 percent antipsychotic drug rate before. Now we're down to only people with a diagnosis [for which the FDA has approved the medications] on the drugs. They have a better quality of life because they're not sedated. We're not controlling their emotions or their dementia.

At first everyone was like, 'This is going to be awful. What do they want us to do?' But we started with a resident with fewer behaviors and just did one or two a week. It was amazing. It's helpful: it actually minimizes behaviors.

Before, when we slapped them with antipsychotics, they had to be in a wheelchair because they were so drugged up. But now that we're meeting their needs, it's easier on staff.... Their ADLs [activities of daily living] are better, their functioning.

If a resident comes in on an antipsychotic, we go over the info. We say, 'We don't usually use those here.' The family usually agrees. If we start the reduction and it doesn't work, we tell a geriatric psychiatrist to see them

⁸⁴ Ibid.

once a week. We have not had to change our staffing numbers. Without the antipsychotics, the residents take less time.⁸⁵

In Illinois, the director of nursing at a facility explained a similar course of action:

This is our biggest, biggest issue: taking people off. You have to make an attempt to reduce. If someone is taking two antipsychotics, you try to lower the dose and you try taking them off one. We attempt reductions quarterly. We have not had problems with behaviors after slow reductions.... The pharmacist sends a report monthly, giving recommendations [to reduce] every month....

We used to have a big antipsychotics problem. In 2011 more than half of the residents took them. Now everyone on an antipsychotic has a diagnosis. Usually they're a totally different person, they're back to life.⁸⁶

An administrator in California described procedures his nursing facility has put in place to reduce reliance on antipsychotic medicines:

Our psychotropic committee meets monthly. We review all the patients on psychotropics. In 2010, more than 30 percent of the residents were on antipsychotics. Now it is just over 10 percent.... If someone is admitted with an antipsychotic, we monitor them for 72 hours. We notify the doctor. We observe the behavior. [Our consultant psychiatrist] comes in to assess if it's necessary. We gather the baseline to have a point of comparison. We look at the diagnosis. If we get someone from geri-psych, they're often agitated in the unit. Their behavior is not consistent. We put psychotropic medication on hold. We don't restart it. We give them a chance to adjust.⁸⁷

⁸⁵ Human Rights Watch interview with a nurse at NFKS#16 in Kansas, January 18, 2017.

⁸⁶ Human Rights Watch interview with the director of nursing at NFL#11 in Illinois, February 6, 2017.

⁸⁷ Human Rights Watch interview with the administrator at NFCA#12 in California, February 20, 2017.

Inside Nursing Facilities with High Rates of Off-Label Antipsychotic Drug Use

The conditions in about 20 of the 109 facilities visited, across all six states, were disturbingly grim. It was not uncommon for facilities to have stench of urine, in particular on locked dementia units. Many facilities visited on weekends appeared to be severely understaffed. Many facilities were located in old buildings, sometimes former hospitals. The bare, cinderblock rooms—with uniform, old furniture and no privacy except a curtain with a runner on the ceiling—feel like “wards,” though use of the word is discouraged. People were often heard screaming or calling for help. Call light alarms—buttons residents can press that produces sound and light up at a nursing station to alert staff—would often make noise unceasingly. Human Rights Watch researchers encountered residents who desperately needed an aide to help them use the bathroom. In one case, we observed a nurse aide walk past a resident lying on the floor exposed, proceeding to carry a food tray. In several cases, residents had bruised faces or eyes that staff seemed unable to explain.

Researchers observed individuals apparently trapped in “geri-chairs,” a geriatric recliner chair positioned in such a way that they could not get out. Positioning someone in this way constitutes a physical restraint.⁸⁸ Many people’s heads rested on tables or on their chests. Residents slept on couches in the lobby. It was unusual to visit a facility in which people were not sitting in wheelchairs arranged around a nursing station. Human Rights Watch staff observed very few activities aside from meals and television.

Many facilities evinced a startling lack of privacy. Nursing staff enter residents’ rooms unannounced. We often saw staff who failed to close residents’ doors before engaging in tasks that exposed them, such as continence care and some types of therapy. Human Rights Watch observed residents being pushed in wheelchairs to shower rooms with only a sheet draped across their front. We observed residents moving about the facility with catheter bags exposed.

⁸⁸ A restraint is “any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident’s body that the individual cannot remove easily which restricts freedom of movement or normal access to one’s body.” See 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf>.

III. Inappropriate and Non-Consensual Use of Antipsychotic Medications

The inappropriate use of antipsychotic drugs on people with dementia in nursing facilities raises two principal human rights concerns. First, antipsychotic drugs are often administered without a medical purpose—as a last resort to treat psychosis in dementia, although they have not been found to be effective to this end—and for the convenience of facility staff. Such medically unnecessary use of medication may amount to torture or ill-treatment under international law. It may also amount to a prohibited “unnecessary drug” or a chemical restraint—a form of abuse—under US law. Second, these medications are frequently administered without free and informed consent. This practice constitutes forced medication under international law.

Chemical Restraints and Unnecessary Drugs: Use of Antipsychotic Medications for Reasons Other than Medical Need

Antipsychotic drugs are frequently administered to older people with dementia without clinical indication (a valid medical reason). This practice may in some cases rise to the level of torture or cruel, inhuman and degrading treatment. As noted by the UN special rapporteur on torture and other cruel, inhuman or degrading treatment or punishment in a 2013 report: “medical treatments of an intrusive and irreversible nature, when lacking a therapeutic purpose, may constitute torture or ill-treatment when enforced or administered without the free and informed consent of the person concerned.”⁸⁹ In June 2017, the UN special rapporteur on the right to health noted that informed consent is “a core element of the right to health, both as a freedom and an integral part of its enjoyment.”⁹⁰

⁸⁹ UN Human Rights Council, Report of the special rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, Juan E. Méndez, A/HRC/22/53, February 1, 2013, http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session22/A.HRC.22.53_English.pdf (accessed September 8, 2017) para. 32.

⁹⁰ UN Human Rights Council, Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Dainius Puras, A/HRC/35/21, March 28, 2017, http://ap.ohchr.org/documents/dpage_e.aspx?si=A/HRC/35/21 (accessed September 8, 2017) para. 63.

US regulations establish that antipsychotic drugs cannot be administered to nursing facility residents without a medical need based on a comprehensive assessment.⁹¹ However, in some facilities, medical need is often not the primary reason antipsychotic drugs are prescribed and comprehensive assessments are not routinely conducted to determine whether a medical basis exists. CMS recognized facilities' improper use of the drugs:

It has been a common practice to use various types of psycho-pharmacological medications in nursing homes to try to address behavioral or psychological symptoms of dementia (BPSD) without first determining whether there is an underlying medical, physical, functional, psychosocial, emotional, psychiatric, or environmental cause of the behaviors.⁹²

Interviews with residents, family members, and facility staff provide numerous examples that residents are administered antipsychotic drugs without meaningful assessment of their medical necessity—an important consideration, though not one that, alone, justifies administering the medication.

A Culture of Antipsychotic Medication Use

Government reports and academic literature identify a “culture” of antipsychotic drug use as one of the potential explanations for their widespread use. In this context, the “culture” of a nursing facility, meaning the “shared values, beliefs and assumptions” of staff, “may exhibit itself as a facility-level preference for certain therapeutic modalities.”⁹³ When the prescriber and individual receiving treatment interact infrequently, which is often the case in nursing homes, the general treatment approaches may take on heightened significance: without routine personal evaluations by a physician prior to medication decisions, these decisions may follow even more heavily from the existing “beliefs and assumptions” about

⁹¹ 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf>.

⁹² “Section 483.25, Quality of Care,” in 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf>.

⁹³ 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.

treatment, and may be less specific to the individual and circumstances at hand.⁹⁴ A 2015 study by the US Government Accountability Office (GAO) 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.⁹⁵ Academic studies have found that facility characteristics—not just a resident’s behavioral or neuro-psychiatric symptoms—are a strong predictor of the prevalence of psychotropic medication use.⁹⁶ One study found that “new nursing home residents admitted to facilities with high antipsychotic drug prescribing rates were 1.4 times more likely to receive antipsychotics, even after controlling for patient-specific factors.”⁹⁷

In facilities with such a culture of the widespread use of these medicines, the off-label drug use is generally accepted as typical and unproblematic—even the best course of action for the resident. The GAO study found that in such facilities, nursing staff are more likely to believe the medications are truly helpful to residents, and are more likely to have lower levels of education and training around dementia and appropriate use of antipsychotic medicines. Studies have shown that low education among staff about antipsychotic use among people with dementia results in higher rates of use.⁹⁸ The GAO report also found that insufficient staff to engage residents in activities and to provide

⁹⁴ Ibid.

⁹⁵ 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,” <http://www.gao.gov/assets/670/668221.pdf> p. 10.

⁹⁶ H. Kim and AL. Whall, “Factors Associated with Psychotropic Drug Usage Among Nursing Home Residents with Dementia,” *Nursing Research*, vol. 55(4) (2006), <https://www.ncbi.nlm.nih.gov/pubmed/16849977> (accessed September 8, 2017); Chen et al., “Unexplained Variation across U.S. Nursing Homes in Antipsychotic Prescribing Rates,” *Archives of Internal Medicine*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2897009/pdf/nihms173699.pdf/>.

⁹⁷ Chen et al., “Unexplained Variation across U.S. Nursing Homes in Antipsychotic Prescribing Rates,” *Archives of Internal Medicine*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2897009/pdf/nihms173699.pdf/>.

⁹⁸ Celeste A. Lemay, “Knowledge of and Perceived Need for Evidence-Based Education About Antipsychotic Medications Among Nursing Home Leadership and Staff,” *Journal of the American Medical Directors Association*, vol. 14(2) (2013), <http://www.sciencedirect.com/science/article/pii/S1525861013004672>; Katrina Pehudoff et al., “The Psychotropic Education and Knowledge Test for Nurses in Nursing Homes: Striving for PEAK Performance,” *Aging and Mental Health*, vol. 20(11) (2015), <http://www.tandfonline.com/doi/abs/10.1080/13607863.2015.1068738> (accessed September 8, 2017). (“These results suggest that nurses have limited knowledge of psychotropic use in nursing homes and are aware of their knowledge deficits.”).

oversight of them may “make the nursing home residents susceptible to higher antipsychotic drug use.”⁹⁹

In a letter to Human Rights Watch, the American Health Care Association (AHCA), the for-profit nursing home trade association, wrote:

[The] biggest challenge we have found is the mindset that clinicians, nurses and family all have that ‘behaviors’ in dementia are abnormal, resulting from dementia and that medications are an effective treatment. Difficulty in changing this belief is the greatest challenge.¹⁰⁰

To this end, the AHCA has produced a fact sheet on antipsychotic drugs and people with dementia to inform families about the dangers and ineffectiveness of their use.¹⁰¹

Human Rights Watch obtained testimony from staff suggesting a culture in some facilities of excessive antipsychotic drug use in residents. In Texas, a facility’s admissions director seemed to believe that residents should be given the medication: “It’s a red alert if they don’t take them. We try to get them to.”¹⁰² A nurse at a facility elsewhere in Texas, said: “If they’re agitated or having a moment and they don’t have a prescription, we call the doctor or psychiatrist.... If we still can’t handle them, we send them to behavioral [a psychiatric hospital].”¹⁰³

Lena D., the daughter and power of attorney of Lucinda D., an 88-year-old woman in a California nursing facility, said she felt that the facility only attempted to silence with antipsychotic medication the symptoms that disturbed staff. To Ms. D, it was obvious that

⁹⁹ 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,” <http://www.gao.gov/assets/670/668221.pdf> p. 24.

¹⁰⁰ Letter from David R. Gifford, MD, MPH, senior vice president for quality & regulatory affairs, American Health Care Association, to Human Rights Watch, July 6, 2017. See Appendix 7.

¹⁰¹ American Health Care Association, “Fast Facts: What You Need to Know About Antipsychotic Drugs for Persons Living with Dementia,” 2017, https://www.ahcancal.org/quality_improvement/qualityinitiative/Documents/Antipsychotics%20Consumer%20Fact%20Sheet%20-%20English.pdf (accessed September 10, 2017).

¹⁰² Human Rights Watch interview with the admissions director of NFTX#2 in Texas, December 13, 2016.

¹⁰³ Human Rights Watch interview with nurse at NFTX#20 in Texas, December 22, 2016.

her mother had physiological conditions, such as an infection causing smell and fever, requiring medical attention instead of antipsychotic drugs to dull the expression of distress. “Every little thing, they want to put you on psych meds,” she said.¹⁰⁴ Ms. D. said that her mother was screaming from pain. “She would be sitting there, slumped over, mucus everywhere. I would go over and say, ‘She’s sick.’ UTI [urinary tract infection], pneumonia, pulmonary embolism—I’d scream too,” Ms. D. said, listing a number of the infections and harms she says that her mother has endured.¹⁰⁵

In many instances, people living in nursing facility and their relatives—like most people—are inclined to defer to the recommendations of the healthcare provider unless they have a reason not to do so. As one long-time expert in Kansas put it: “The family rarely objects. They think, ‘They’re the doctor. They’re not going to hurt my mom.’”¹⁰⁶ A nurse in Texas explained: “If the medication is on the psychoactive list, we need consent.¹⁰⁷ We call the guardian, get verbal consent. Or not, if it’s declined. Then we’d call the doctor and start over. But we’ve never had to deal with a decline. Families want the best, and they trust the physician to do that.”¹⁰⁸

This trust can backfire in some nursing facilities. Contrary to other contexts, doctors and nurses associated with nursing facilities may favor the easier step of a prescribed medication than more time-consuming interventions. In some cases, medical and nursing staff may truly believe in the utility of the medications in situations where their use is inappropriate. Lastly, the tendency to trust doctors may be problematic in the context of nursing facilities where physicians interact with their patients very rarely even when they are prescribing antipsychotic drugs.

¹⁰⁴ Human Rights Watch interview with Lena D., daughter of Lucinda D., 88-year-old resident of NFCA#15 in California, February 21, 2017.

¹⁰⁵ Ibid.

¹⁰⁶ Human Rights Watch interview with long-term care consultant in Kansas, January 10, 2017.

¹⁰⁷ Texas, like other states, require nursing homes to obtain consent prior to the administration of any psychoactive medications, including antipsychotic drugs and other classes of psychotropic drugs, such as sedatives, anti-anxiety medications, hypnotics, antidepressants, etc. Therefore, many facilities keep a list of these medications to know when consent is necessary. Texas Health and Safety Code, *Texas State Legislature*, Title 4, subtitle B, cap. 242, <http://www.statutes.legis.state.tx.us/Docs/HS/htm/HS.242.htm> secs. 242.501 and 242.505.

¹⁰⁸ Human Rights Watch interview with weekend charge nurse at NFTA#27 in Texas, December 18, 2016.

Antipsychotic Medication Use for the Convenience of Staff

In line with international human rights law, US law and regulation prohibit the use of antipsychotic medicines as a chemical restraint on residents—i.e., when drugs are “used for purposes of discipline or convenience, and not required to treat medical symptoms.”¹⁰⁹ Interpretive guidelines of federal regulations define “convenience” as “any action taken by the facility to control a resident’s behavior or manage a resident’s behavior with a lesser amount of effort by the facility and not in the resident’s best interest.”¹¹⁰

While most staff we interviewed were adamant that they do not use antipsychotic or other medications for their own convenience, a few admitted to exactly that. A social worker at a facility in Texas, for example, said: “You have got to get through incontinent care and the shower. We give meds before their showers.... We give them something they’re taking already. We just want to make sure it’s in their system when we’re showering them.”¹¹¹

While nursing staff may face real challenges providing such direct care to some people, turning to antipsychotic medications is not appropriate. As the CMS State Operations Manual explains, to comply with federal regulations, facilities must find ways to accommodate individuals’ preferences:

If the resident refuses a bath because he or she prefers a shower or a different bathing method such as in-bed bathing, prefers it at a different time of day or on a different day, does not feel well that day, is uneasy about the aide assigned to help or is worried about falling, the staff member should make the necessary adjustments realizing the resident is not refusing to be clean but refusing the bath under the circumstance provided.¹¹²

¹⁰⁹ Respect and Dignity, Resident Rights, Code of Federal Regulations, Title 42, <https://www.law.cornell.edu/cfr/text/42/483.10> sec. 483.10(e).

¹¹⁰ 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf>.

¹¹¹ Human Rights Watch interview with a social worker at NFTX#14 in Texas, December 20, 2016.

¹¹² “Section 483.10(f), Self-determination (F242),” in 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf>.

Generally, as the revised CMS State Operations Manual states:

In some cases, resident with dementia may resist the manner in which care is being provided, or attempted, which can be misinterpreted as declination of care. In some cases, the resident with dementia does not understand what is happening, or may be fearful of unfamiliar staff, or may be anxious or frustrated due to inability to communicate.¹¹³

It is a responsibility of facility staff to “attempt to identify the underlying cause of the ‘refusal/declination’ of care.”¹¹⁴

Many outside observers, such as long-term care ombudsmen, academics, and state inspectors, told Human Rights Watch that antipsychotic medications were being used for the convenience of staff. A social worker at a behavioral hospital in Texas explained their perspective on nursing facilities’ use of antipsychotic medications for staff convenience, as chemical restraints:

People come in here [a hospital] for behaviors, but then we don’t see the behaviors when they’re here. Sometimes we change their meds. But they don’t usually exhibit horrible behaviors. Maybe they just need attention. But the nursing homes don’t want behaviors. They want docile. They want people with no cognitive deficits who can take care of themselves. I’ve worked in nursing homes. They’d say, ‘Send them to [the psychiatric hospital] to get medicated and let them come back.’¹¹⁵

A state inspector with a long career in long-term care said: “I see way too many people overmedicated. The doctor signs off and the nurse fills the prescription. They see it as a

¹¹³ CMS, “Revision to State Operations Manual (SOM) Appendix PP for Phase 2, F-Tag Revisions, and Related Issues,” effective November 28, 2017, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Advance-Appendix-PP-Including-Phase-2-.pdf> (accessed September 8, 2017).

¹¹⁴ Ibid.

¹¹⁵ Human Rights Watch interview with social worker at HOTX#17 in Texas, December 21, 2016.

cost-effective way to control behaviors.”¹¹⁶ Seventeen of 18 ombudsmen we interviewed echoed this view, including at least one from every state visited.¹¹⁷

Madeline C., an 87-year-old woman in Illinois, reflected on her time at a prior facility, which gave her antipsychotic medications against her will, leaving her in a stupor. She said: “When I was in that other place [the prior nursing facility], they just wanted you to do things just the way they wanted.”¹¹⁸ An expert and advocate in Illinois explained: “Antipsychotics are often about the nursing staff, not the residents.” In requesting the medication from a doctor, nursing staff often say: “I need a restraint.’ It’s not just a figure of speech.”¹¹⁹ In other words, it’s the staff who “need” the resident to be taking it.

Failure to Initiate, Monitor, and Discontinue Antipsychotic Medications

US law and regulations require nursing facilities and healthcare providers to have an adequate medical basis for initiating antipsychotic medications and for continuing use. Regulations prohibit the use of any “unnecessary drugs,” defined as:

- In excessive dose, which can be determined based on a manufacturer’s label;
- For excessive duration, meaning beyond the manufacturer’s or clinical studies’ recommended period of use; and/or without evidence of additional therapeutic benefit;
- Without adequate monitoring;
- Without adequate indications for use: “the identified, documented clinical rationale for administering a medication that is based upon an assessment of the resident’s condition and therapeutic goals”;
- In the presence of adverse consequences indicating the medication should be reduced or discontinued. Adverse consequences include “unpleasant” symptoms

¹¹⁶ Human Rights Watch telephone interview with a highly experienced state surveyor in Texas, December 20, 2016.

¹¹⁷ Human Rights Watch interviews in person and by phone with long-term care ombudsmen at all levels: three in California on December 9, 2016, February 16, 2017, and March 14, 2017; one in Florida on February 28, 2017; three in Illinois on November 18, 2016, December 7, 2016, and February 3, 2017; four in Kansas on January 9, 11, and 16, 2017; one in New York on October 7, 2016; and five in Texas on December 12, 14, and 20 2016.

¹¹⁸ Human Rights Watch Interview with Madeline C., 87-year-old resident of NFL#9 in Illinois, February 5, 2017.

¹¹⁹ Human Rights Watch Interview with the director of a long-term care advocacy organization in Illinois, November 17, 2017.

or events, including “impairment or decline in an individual’s mental or physical condition or functional or psychosocial status.”¹²⁰

Federal regulations particular to psychotropic drugs mandate that any prescription for someone not already taking such medication must be “necessary to treat a specific condition as diagnosed and documented in the clinical record.”¹²¹ Anyone given psychotropic medications must “receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.”¹²² Gradual dose reduction must be attempted annually, except twice in the first year of use.¹²³

These regulations represent an attempt to limit and regulate the use of antipsychotic drugs in ways that would help protect the human rights of nursing home residents if facilities adhered to the regulations. One of the most recent government studies on resident assessments and care planning—the foundation for determining what antipsychotic drug use could be appropriate—found that few facilities comply with relevant regulations. The 2012 Office of Inspector General of the US Department of Health and Human Services report found that 99 percent of the records reviewed of older nursing facility residents (aged 65 and older) receiving antipsychotic drugs in 2007 failed to meet at least one federal requirement for resident assessments and care planning.¹²⁴ Human Rights Watch’s research and a review

¹²⁰ 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf> sec. 483.45.

¹²¹ 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf> sec 483.45(e).

¹²² Ibid.

¹²³ “Tapering of a Medication Dose/Gradual Dose Reduction (GDR): Considerations Specific to Antipsychotics,” in 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf> sec 483.45.

¹²⁴ Office of Inspector General, “Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs,” July 2012, <https://oig.hhs.gov/oei/reports/oei-07-08-00151.pdf> (accessed September 8, 2017). This study used a subset of the records from another study, “Medicare Claims for Atypical Antipsychotic Drugs in Nursing Homes,” which limited the scope of its study to Medicare claims and payments for “elderly (i.e., aged 65 and older) nursing home residents.” Office of Inspector General, “Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents,” May 2011, <https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf> (accessed September 23, 2017).

of governmental surveyors' narrative deficiency reports found that these procedures and limitations required for appropriate psychotropic drug use are often ignored.

Many of our interviews tend to bolster the contention that antipsychotic medications are often prescribed to nursing home residents for no valid medical reason. Some nursing staff described to Human Rights Watch the primary “behaviors” for which antipsychotic medications are frequently used. A nurse at a facility in Kansas said that “calling names, screaming, scaring people” justified antipsychotic medication.¹²⁵

In Texas, a social worker said that the most common “behaviors” leading to antipsychotic medication use were: “‘Son of a bitch.’ ‘Help me, help me, help me.’ It’s not having a filter.”¹²⁶ A long-term care pharmacist in Kansas said he routinely sees medication requests without an appropriate diagnosis. “This is a sore spot,” he said. “I write letters to the nursing homes and prescribers because there’s no supporting diagnosis for an antipsychotic at all. It just says ‘Seroquel for dementia,’ or ‘Seroquel for anxiety,’ or ‘Seroquel for behavior dysfunction.’”¹²⁷

A 2005 study found that about one in three nursing facility residents covered by Medicare took medication in excessive doses and lacking appropriate indications.¹²⁸ The US Department of Health and Human Services Office of Inspector General report from 2011 found that 51 percent of Medicare atypical antipsychotic drug claims—the second generation of antipsychotic drugs, commonly used for their perceived lesser side effects—for older people in nursing facilities “were either not used for medically accepted indications as supported by the [medical] compendia or not documented as having been administered to the elderly nursing home residents.”¹²⁹ The Office of Inspector General review of 1.4 million antipsychotic drug claims for older residents found that 22 percent

¹²⁵ Human Rights Watch interview with the director of nursing at NFKS#13 in Kansas, January 17, 2017.

¹²⁶ Human Rights Watch interview with a social worker at NFTX#14 in Texas, December 20, 2016.

¹²⁷ Human Rights Watch interview with a long-term care pharmacist in Kansas, January 12, 2017.

¹²⁸ B.A. Briesacher et al., “The Quality of Antipsychotic Drug Prescribing in Nursing Homes,” *Archives of Internal Medicine*, vol. 165 (2005), pp. 1280-1285.

¹²⁹ Office of Inspector General, “Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents,” May 2011, <https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf> (accessed September 8, 2017) pp. ii-iii.

“were not administered in accordance with CMS standards regarding unnecessary drug use in nursing homes.”¹³⁰

A review of surveyors’ narrative deficiency reports provides examples of facilities’ failure to comply with requirements to monitor, taper, and discontinue antipsychotic drugs. For example, in New York, in 2016, government surveyors issued a deficiency citation for unnecessary drugs because a nursing facility prescribed a “standing dose” of an antipsychotic drug for “wandering, noncompliance, and aggressive behaviors” to a man who had no history of taking antipsychotic drugs. The dose was increased from twice a day to three times a day within one week and surveyors concluded it contributed to the man’s death within 10 days.¹³¹

In Illinois, in 2015, an inspector issued a deficiency citation for unnecessary drugs for a facility’s “failing to have indications for use, assessing, identifying/monitoring targeted behaviors, clinical rationale for the medication dosage use above the recommended level, and completing a Gradual Dose Reduction (GDR)” for an antipsychotic drug.¹³² The excessive dose of an antipsychotic without an appropriate diagnosis in a person with dementia led to the person’s “being continuously somnolent” and falling repeatedly, according to the government surveyor. The individual’s records show that, in less than five months, the individual fell eight times, the last time leading to an irreparable condition and the person’s admission to hospice.

In Texas, in 2015, government surveyors issued a deficiency citation for unnecessary drugs based on a facility’s giving a woman “excessive doses” of an antipsychotic drug, not adequately monitoring her, and giving the drug without an appropriate diagnosis.¹³³ As a

¹³⁰ Ibid.

¹³¹ CMS Region 2, Grace Plaza Nursing and Rehabilitation Center, ID 335483, from 2016 in CMS, “Full Text of Statements of Deficiencies – August 2017” in “Five-Star Quality Rating System,” <https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcompliance/fsqrs.html> (accessed October 10, 2017).

¹³² CMS Region 5, Gardenvue Manor, ID 145926, from 2015 in CMS, “Full Text of Statements of Deficiencies – August 2017” in “Five-Star Quality Rating System,” <https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcompliance/fsqrs.html> (accessed October 10, 2017).

¹³³ CMS Region 6, Edgewood Manor, ID 676069, from 2015 in CMS, “Full Text of Statements of Deficiencies – August 2017” in “Five-Star Quality Rating System,” <https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcompliance/fsqrs.html> (accessed October 10, 2017).

result of the facility’s failure to comply with unnecessary drug regulatory requirements, the woman was hospitalized for septic shock. Nursing staff described the woman’s decline to government regulators: she was “alert, oriented..., could feed herself, and could carry on conversations” when she was admitted. After the excessive medication, the woman could not bear her own weight or “stay awake to eat or drink.” Staff corroborated that no nonpharmacologic interventions were attempted and no behavioral monitoring occurred.

Interviews and a review of national nursing home data also suggest that some facilities are circumventing pressure to reduce inappropriate use of antipsychotic drugs by inappropriately seeking a diagnosis from a physician of a medical condition, such as schizophrenia, for which these medicines are approved in order to not raise red flags when prescribing someone antipsychotic medication inappropriately. The onset of bipolar disorder and schizophrenia rarely occurs in people over the age of 30.¹³⁴ Thus, experts are concerned that the uptick in schizophrenia diagnoses in older people in nursing facilities—from 6.53 percent in the fourth quarter of 2011 to 8.49 percent in the second quarter of 2017, a 30 percent increase in less than six years—is indicative of facilities adding a diagnosis to justify the use of these medicines.¹³⁵

In a joint statement, numerous organizations, including the American Association for Geriatric Psychiatry, American Association of Nurse Practitioners, American Geriatrics Society, American Health Care Association, American Medical Directors Association, Society for Post-Acute and Long-Term Care Medicine, American Psychiatric Association, and LeadingAge, responded to this uptick.

While there is a national need for better and more approved treatments for behavioral and psychiatric symptoms in dementia, clinicians need to be

¹³⁴ “Schizophrenia,” National Institute of Mental Health, last updated February 2016, <https://www.nimh.nih.gov/health/topics/schizophrenia/index.shtml>; “Bipolar Disorder,” National Institute of Mental Health, <https://www.nimh.nih.gov/health/publications/bipolar-disorder/index.shtml>.

¹³⁵ “MDS 3.0 Frequency Report,” 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>.

mindful of and avoid labeling patients with other diagnoses to justify the use of medications or other treatments.¹³⁶

In Kansas, the daughter and power of attorney of a 75-year-old woman learned that the facility had begun “giving her meds for bipolar”—a diagnosis she first received at age 74. In California, a nurse stated:

If they’re coming from an acute hospital (a hospital providing care to individuals experiencing or recovering from acute episodes of illness, injury, surgery, or trauma), they have a diagnosis. We can’t admit them otherwise. Sometimes we go around with the hospital to get us a psych diagnosis.¹³⁷

In Texas, a social worker at a nursing facility said: “Since you’re taking that medicine, then you get a diagnosis. That’s how you get a diagnosis. If we’re treating the symptoms, then you have the disease.”¹³⁸

¹³⁶ “Joint Summary Statement – Diagnosing Schizophrenia in Skilled Nursing Centers,” press release, The Society for Post-Acute and Long-Term Care Medicine, February 21, 2017, <http://www.paltc.org/newsroom/joint-summary-statement-diagnosing-schizophrenia-skilled-nursing-centers> (accessed September 10, 2017).

¹³⁷ Human Rights Watch interview with the director of nursing at NFCA#4 in California, February 15, 2017.

¹³⁸ Human Rights Watch interview with a social worker at NFTX#14 in Texas, December 19, 2016.

Other Discriminatory Ways Nursing Facilities Treat “Difficult” Residents

Administering antipsychotic drugs inappropriately is not the only way nursing facilities mistreat people they consider to be “difficult.” Human Rights Watch’s research found numerous instances where facilities sought to avoid admitting or to discharge such people pretextually in apparent violation of federal regulations which require facilities to “provide equal access to quality care regardless of diagnosis, severity of condition, or payment source.”¹³⁹

Expressing a sentiment we heard in many interviews with nursing facility staff, the director of nursing at a facility in Texas said: “Nursing homes do not want patients with behaviors.”¹⁴⁰ In the words of a long-term care ombudsman in Kansas, “a ‘behavior’ is not being quiet.”¹⁴¹ In Texas, another long-term care ombudsman explained:

A resident is ‘disruptive’ if she’s outspoken: if she’s not happy with what they’re doing. Even if the family is outspoken, that’s a problem.... I get complaints all the time from facilities: residents refusing to get up, not wanting to go to an appointment. They’ll say she’s not cooperating, refusing care. Basically, ‘disruptive’ means a person knows her rights.¹⁴²

Administrators, nurses, and social workers said that they review a potential resident’s “behaviors” prior to admitting them. A director of nursing in Kansas said: “If they’re cognitively impaired, controlling, manipulative, we try to not take them in the first place.”¹⁴³ A director of social services at another facility in the state said: “If we can identify someone’s behaviors before admission, we won’t touch them. The best time to ‘discharge’ though is before we even admit them.”¹⁴⁴ An administrator in California summed it up: “Once you admit them, they’re your liability.”¹⁴⁵

¹³⁹ Requirements for, and Assuring Quality of Care in, Skilled Nursing Facilities: Transfer and Discharge Rights, Code of Federal Regulations, Title 42 <https://www.law.cornell.edu/uscode/text/42/1395i-3> sec. 1395i-3(c) and 1396r(c)(2). See also, Admission, transfer, and discharge rights, Code of Federal Regulations, Title 42, <https://www.gpo.gov/fdsys/pkg/FR-2016-10-04/pdf/2016-23503.pdf> sec. 483.15.

¹⁴⁰ Human Rights Watch interview with the director of nursing at NFTX#2 in Texas, December 14, 2016.

¹⁴¹ Human Rights Watch interview with a former long-term care ombudsman in Kansas, January 9, 2017.

¹⁴² Human Rights Watch phone interview with a long-term care ombudsman in Texas, January 5, 2017.

¹⁴³ Human Rights Watch interview with the director of nursing at NFKS#12 in Kansas, January 16, 2017.

¹⁴⁴ Human Rights Watch interview with the social services director of NFKS#4 in Kansas, January 11, 2017.

¹⁴⁵ Human Rights Watch interview with the administrator of NFCA#20 in California, February 21, 2017.

Facilities sometimes also try to transfer or evict people contrary to their rights. A retired long-term care ombudsman in Kansas said that facilities weigh costs and benefits of wrongful discharges and the possibility of being penalized for them. “Some nursing homes will say, ‘I’ll take the deficiency just to get rid of them.’ They’ll discharge people to homeless shelters.”¹⁴⁶ Since 2010, involuntary discharges have been the top category of complaint that long-term care ombudsmen receive.¹⁴⁷

The great-grandson of a 92-year-old woman in Texas described how his great-grandmother was “dumped three times” from nursing homes, with two psychiatric hospitals in between, before going to two additional nursing homes, the last of which threatened to send her to another hospital.

When I picked her up from the last facility, she had the biggest knot on her head.... She has fallen so many times. She has never been hurt badly. But she always has knots. They never sent her to a hospital for that. Every right she has, has been violated. To me, it’s wrong. She is 92 years old.¹⁴⁸

His great-grandmother was living with him, instead of a nursing home, at the time of the interview.

Failure to Obtain Free and Informed Consent

I don’t take Seroquel. I take Clonidine for cholesterol, something for my heart and blood. But I don’t take Seroquel. It is nowhere in my record.

—Ruth D., a 62-year-old woman in a nursing facility in Texas, December 2016¹⁴⁹

¹⁴⁶ Human Rights Watch interview with a former long-term care ombudsman in Kansas, January 9, 2017.

¹⁴⁷ “Nursing Homes Turn to Eviction to Drop Difficult Patients,” Associated Press, May 5, 2016, <http://www.modernhealthcare.com/article/20160505/NEWS/160509940> (accessed October 10, 2017). See also, “Data-at-a-Glance (NORS),” Aging Integrated Database, Administration for Community Living, <https://agid.acl.gov/DataGlance/NORS/>; “Long-Term Care Ombudsman Program,” US Administration for Community Living, <https://www.acl.gov/programs/protecting-rights-and-preventing-abuse/long-term-care-ombudsman-program> (accessed September 8, 2017).

¹⁴⁸ Human Rights Watch interview with Dayvon G., great grandson of Nora G., 92, former resident of multiple nursing facilities in Texas, December 23, 2016, in Mr. G’s home, where Ms. G. now lives. Human Rights Watch observed bottles of Olanzapine (5m, prescribed 1 at bedtime); Donepezil HCL (10mg, 1 per day); Citaplopram Hbr (1 per day); Haloperidol (1-2mg per day); Trazodone (50mg at bedtime) prescribed to Ms. G.

¹⁴⁹ Human Rights Watch interview with Ruth D., 62, resident of NFTX#5 in Texas, December 14, 2016. Upon review of Ms. D’s medical chart, no informed consent sheets were documented for Seroquel although she was prescribed 200mg Quetiapine (Seroquel).

I don't think antipsychotic drugs are presented well to the family in informed consent conversations. Because if it were, they'd all reject it. And when they [staff] don't inform them beforehand, then the family is not having a real choice.

—A long-term care pharmacist in Kansas, January 2017¹⁵⁰

International human rights standards require that any medical intervention be provided only with free and informed consent.¹⁵¹ At its foundation, this right arises from an individual's right to decide what is done with his or her own body.¹⁵² Free and informed consent—contrary to mere 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.¹⁵³

US federal regulations, including revised regulations that intended to go into effect on November 28, 2017, state that nursing home residents have the right to be fully informed in advance of their treatment and have the right to refuse treatment.¹⁵⁴ Combining the right

¹⁵⁰ Human Rights Watch interview with a long-term care pharmacist in Kansas, January 12, 2017.

¹⁵¹ 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.").

¹⁵² *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.")

¹⁵³ 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>.

¹⁵⁴ Resident Rights: Planning and Implementing Care, Code of Federal Regulations, Title 42 <https://www.law.cornell.edu/cfr/text/42/483.10> sec. 483.10(c)(6). "A resident and/or representative(s) has the right to be informed about the resident's condition; treatment options, relative risks and benefits of treatment, required monitoring, expected outcomes of the treatment; and has the right to refuse care and treatment. If a resident refuses treatment, the facility staff and physician should inform the resident about the risks related to the refusal, and discuss appropriate alternatives such as offering the medication at another time or in another dosage form, or offer an alternative medication or non-pharmacological approach, if available." "Medication Management," in CMS, "Revision to State Operations Manual

to be informed with the right to refuse treatment, individuals should have protection that is substantially similar and potentially equal to informed consent if enforced effectively.

Obtaining free and informed consent for medical interventions can pose significant challenges for doctors and nurses whose patients are in nursing homes. A large percentage of people who live in these institutions experience dementia or other conditions that affect their cognitive abilities. Many people in nursing facilities do not make their own decisions about their treatment.

In some cases, people are formally stripped of legal capacity, meaning the authority under law to exercise one's rights and to make decisions for oneself, and another person acts as a surrogate decision-maker.¹⁵⁵ (Under US regulations, the rights to be fully informed in advance about treatment and to refuse treatment apply only to residents that have not been formally "adjudged incompetent" and who do not have a surrogate authorized to stand in on these subjects.¹⁵⁶) More commonly, doctors either informally determine that people are not competent to make decisions about their care, or doctors and staff discuss care issue with relatives or health proxies by default, regardless of the resident's cognitive abilities and the scope and activation of the proxy.

(SOM) Appendix PP – Incorporate Revised Requirements of Participation for Medicare and Medicaid Certified Nursing Facilities," <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R168SOMA.pdf>.

¹⁵⁵ Legal capacity is a critical element of autonomy: It is the authority to make decisions or otherwise act on one's own behalf. Capacity is presumed in adults; it is lost as to particular subjects, such as contracting, driving a car, consenting to medical care, or signing a will, for example. Normally, outside of temporary emergencies, one or two physicians must establish that a person lacks the ability to understand, to reason, or to communicate as a basis of a capacity determination; loss of legal capacity is not based on a status, such as having dementia. Thaddeus Mason Pope, "Unbefriended and Unrepresented: Better Medical Decision Making for Incapacitated Patients Without Healthcare Surrogates," *Georgia State University Law Review*, vol. 33(4) (2017), http://thaddeuspoppe.com/images/Unbefriended_And_Unrepresented-_Better_Medical_Decision_Making_For_Incapacitated_Patients_Without_Healthcare_Surrogates.pdf (accessed on September 23, 2017); Raphael J. Leo, "Competency and the Capacity to Make Treatment Decisions: A Primer for Primary Care Physicians," *Primary Care Companion Journal of Clinical Psychiatry*, vol. 1(5) (1999), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC181079/> (accessed on September 23, 2017). See also, American Bar Association Commission on Law and Aging and American Psychological Association, "Assessment of Older Adults with Diminished Capacity: A Handbook for Psychologists," 2008, <https://www.apa.org/pi/aging/programs/assessment/capacity-psychologist-handbook.pdf> p. 53.

¹⁵⁶ Resident Rights: Planning and Implementing Care, Code of Federal Regulations, Title 42 sec. 483.10(c)(6).

Proxies are legal devices to protect “prospective autonomy.”¹⁵⁷ Instead of being formally adjudicated to lack capacity, many people voluntarily designate in advance, under state law, another person—termed a proxy, agent, healthcare representative, advanced directive, attorney-in-fact, legal appointee, or durable power of attorney for health care—to support them in decision-making or to act in their stead and carry out their wishes upon a certain stage of cognitive disability.¹⁵⁸ However, these legal representatives are limited in scope and time. The proxy authority is activated only during the period of lost capacity and only on the specified subjects or decisions: “Any decision-making power that is not legally granted to a representative under state law is retained by the resident.”¹⁵⁹

The formal loss of legal capacity and excessive or premature use of proxies can completely exclude people from decisions that have major implications for their health. In some cases, this deprivation happens even when the person concerned does not have significant cognitive disabilities. For example, a former Kansas long-term care ombudsman said: “The nursing home sometimes goes straight to the POA [power of attorney] when the resident still has capacity. I often had to remind the nursing home that the POA is not all-encompassing.”¹⁶⁰ As the revised federal regulations state: “Determinations of capacity to consent depend on the context of the issue and one determination does not necessarily apply to all decisions made by the resident.”¹⁶¹

¹⁵⁷ Thaddeus Mason Pope, “Unbefriended and Unrepresented: Better Medical Decision Making for Incapacitated Patients Without Healthcare Surrogates,” *Georgia State University Law Review*, p. 936.

¹⁵⁸ “Section 483.5, Definitions” in CMS, “Revision to State Operations Manual (SOM) Appendix PP – Incorporate Revised Requirements of Participation for Medicare and Medicaid Certified Nursing Facilities,” March 8, 2017, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R168SOMA.pdf>.

¹⁵⁹ Thaddeus Mason Pope, “Unbefriended and Unrepresented: Better Medical Decision Making for Incapacitated Patients Without Healthcare Surrogates,” *Georgia State University Law Review*, p. 936.

¹⁶⁰ Human Rights Watch interview with a former long-term care ombudsman in Kansas, January 9, 2017.

¹⁶¹ “Section 483.12, Freedom from Abuse, Neglect, and Exploitation,” in CMS, “Revision to State Operations Manual (SOM) Appendix PP for Phase 2, F-Tag Revisions, and Related Issues,” <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Advance-Appendix-PP-Including-Phase-2-.pdf>.

Legal Capacity, Informed Consent, and the Convention on the Rights of Persons with Disabilities

The Convention on the Rights of Persons with Disabilities (CRPD), which the US has signed but not ratified, seeks the abolition of substituted decision-making in favor of supported decision-making and rejects the concept that any person can be deprived of legal capacity because of a disability.¹⁶² Unlike substituted decision-making—in which a second person supplants the individual whose decision is concerned—in supported decision-making, a second person provides whatever assistance is necessary to enable the individual to continue to make all his or her own decisions, except in situations of emergency. Thus, under this new CRPD paradigm, the role of healthcare providers and family members should in all cases be to assist people in making their own decisions, rather than to make decisions on their behalf.

While the US has not ratified the CRPD, it can and should take steps to expand and better protect the rights of people with disabilities, and the Convention is an important source of authoritative guidance.¹⁶³ Though current federal nursing home regulations fall short of what the CRPD envisions, even under current federal nursing home regulations, individuals with cognitive disabilities generally can and should be centrally involved in care planning and medical decision-making. As this report shows, far too many nursing homes fall woefully short in this regard.

In many cases, facilities can also do far more to avoid any question of a resort to substitute decision-making by anticipating the progression of a condition like dementia and engaging in advanced care planning. Individuals who may struggle in the future to participate meaningfully in decisions about their own care can be helped to develop plans laying out their wishes in the event of different possible future scenarios. Informed consent should occur within the person-centered, care planning process that begins, per regulations, upon a person's admission to a facility.¹⁶⁴

A small percentage of people in nursing facilities make up the most complex cases: they have a cognitive disability that compromises their ability to provide informed consent and

¹⁶² Convention on the Rights of Persons with Disabilities (CRPD), adopted December 13, 2006, G.A. Res. 61/106, Annex I, U.N. GAOR, 61st Sess., Supp. (No. 49) at 65, U.N. Doc. A/61/49 (2006), art. 12(4).

¹⁶³ For example, the American Bar Association recently adopted a resolution to urge all state legislatures to amend their guardianship statutes to require that supported decision-making be identified and fully considered as a less restrictive alternative before guardianship is imposed. See, American Bar Association, Resolution 113, adopted August 14, 2017, https://www.americanbar.org/news/reporter_resources/annual-meeting-2017/house-of-delegates-resolutions/113.html (accessed October 10, 2017).

¹⁶⁴ Resident Rights, Code of Federal Regulations, Title 42, <https://www.law.cornell.edu/cfr/text/42/483.10> sec. 483.10(c).

do not have any family members or other support persons, designated or otherwise, to assist them in making medical and other decisions.¹⁶⁵

Most of the cases documented in this report do not fall into the category of highly complex ones. The nursing facility residents whose testimonies on the use of antipsychotic drugs appear in this report did not have significant cognitive disabilities. In our conversations with them, they seemed to understand their situation and to express their preferences regarding—and objections to—antipsychotic drugs. In other cases, the residents had designated a relative as their health proxy.

Yet we found that even in these cases where it clearly would have been possible for nursing facility staff and attending physicians to seek informed consent, doctors and facility staff failed to seek it from the individual or their proxy. In some cases where a health proxy was heavily involved in the individual’s care, the facility or practitioner sought consent but never provided sufficient information for consent to be informed.

In Texas, for example, Human Rights Watch interviewed a woman, Ruth D., 62, in a nursing facility who was given antipsychotic drugs without her or anyone’s consent, despite Ms. D.’s ability to give or withhold consent and objection to the medication.¹⁶⁶ Ms. D. was transferred to a nursing facility for rehabilitation after a minor stroke. After a month, the facility had not discussed care plans with her. Instead, she said, staff administered an antipsychotic medication, without informing her or seeking her informed consent.

Initially, Ms. D. said, she did not realize she was taking new medications. Once she realized, she refused to take them. She told Human Rights Watch: “They crush it so you

¹⁶⁵ The number of “unbefriended” who are not covered by state default surrogate consent statutes is estimated to be 3.5 percent of all long-term care residents, or 45,400 people. “Unbefriend” is a term used along with “unrepresented” to describe individuals who lack capacity to authorize treatment and lack a proxy to make decisions on their behalf. Thaddeus Mason Pope, “Unbefriended and Unrepresented: Better Medical Decision Making for Incapacitated Patients Without Healthcare Surrogates,” *Georgia State University Law Review*, http://thaddeuspope.com/images/Unbefriended_And_Unrepresented_-_Better_Medical_Decision_Making_For_Incapacitated_Patients_Without_Healthcare_Surrogates.pdf, p. 16, fn. 137.

¹⁶⁶ Human Rights Watch interview with Ruth D., 62, resident of NFTX#5 in Texas, December 14, 2016.

don't know what you're getting fed. Put it in baby food. You know, [they put it in the] apple sauce." As a result, Ms. D. said, "I don't want to eat the food."¹⁶⁷

Ms. D. reported that the antipsychotic drug had had a major impact on her state of mind:

I do not mess with no Seroquel [an antipsychotic drug]. I don't know what the drug does. But I know it's dangerous. I was seeing monkeys on the wall... It knocks you out. It's a powerful, powerful drug. I sleep all the time. I have to ask people what the day is... That Seroquel: that's gonna kill me.¹⁶⁸

Over the course of the interview with Human Rights Watch, nursing staff twice knocked, entered, and attempted to administer an antipsychotic drug in gel form to Ms. D. "Can I give you your medicine?" the aide said, "It's your Seroquel." Ms. D. replied, "I don't take Seroquel. I take Clonidine for cholesterol, something for my heart and blood. But I don't take Seroquel. It is nowhere in my record."

With Ms. D.'s permission, the long-term care ombudsman, a registered nurse, and Human Rights Watch staff examined her medical chart at the nurse's station. It did not contain any documentation that Ms. D had ever consented to taking Seroquel.

Throughout our interview, Ms. D. repeatedly stated her desire to leave the facility as she did not trust the staff and wanted to go home. "I will pay for the cab," she kept saying.¹⁶⁹ The long-term care ombudsman helped facilitate her release from the facility the next morning.

In Illinois, Madeline C., 87, told Human Rights Watch that her nursing facility gave her antipsychotic medication without her knowledge or consent, or that of any family member or power of attorney. She said she never signed providing her informed consent. "I just did not know I was taking the medications. But I felt different."¹⁷⁰ The woman's family could

¹⁶⁷ Ibid.

¹⁶⁸ Ibid.

¹⁶⁹ Ibid.

¹⁷⁰ Human Rights Watch interview with Madeline C., 87-year-old resident of NFIL#9 in Illinois, February 5, 2017.

not persuade the facility to cease the medications; instead the family eventually moved her elsewhere.

Informed consent practice varies by state and facility. Consent does not have to be obtained in writing or signed by the person providing it as opposed to nursing staff, but many facilities have informed consent sheets for residents or proxies to sign.¹⁷¹

In Texas, Dayvon G., the great-grandson and power of attorney of Nora G., said his great-grandmother's facility had informed him they were putting her on two antipsychotic medicines. He had not objected. But the facility had failed to give him any information on the potential risks of the medications. Speaking with Human Rights Watch, he asked: "What is a black box warning? No one has mentioned it."¹⁷²

Rosanne J., the wife and power of attorney of Marc J., a 79-year-old man in a Texas nursing facility, said that, although she knew the medicines had a sedative effect, she was "not real familiar with anything else, if they do anything to the mind."¹⁷³ In conversations with Human Rights Watch, she evinced an understanding that antipsychotic medication simply calmed her husband to the point of his appearing to be asleep.

Laura F., the daughter and power of attorney of Selina C., a 92-year-old woman in a California nursing facility, described having consented to antipsychotic drugs for her mother without understanding the risks: "I had no idea, not at all, that the drugs were dangerous. I had no idea. It's on me because I didn't know when I had agreed [to their prescription]. I'm guessing most people have no idea."¹⁷⁴ When her mother was later transferred to another facility, staff there continued administering the drugs without seeking informed consent from Ms. F.

¹⁷¹ See Appendix 8.

¹⁷² Human Rights Watch interview with Dayvon G., great grandson of Nora G., 92, former resident of multiple nursing facilities in Texas, December 23, 2016, in Mr. G's home, where Ms. G. now lives.

¹⁷³ Human Rights Watch interview with Rosanne J., wife of Marc J., 79-year-old resident of NFTX14 in Texas, December 20, 2016.

¹⁷⁴ Human Rights Watch interview with Laura F., daughter of Selina C., in California, February 13, 2017.

In Kansas, a long-term care ombudsman gave an example of what she said was a typical situation in a care plan meeting where facility staff wanted to put a resident on Haldol:

It's not explained to the family. I wanted them [the facility staff] to explain the side effects. They weren't going to tell the family that. The nursing home just said, "the resident could get aggressive, could get hurt" [if they were not put on Haldol]. So, the family agreed to put them on it.¹⁷⁵

Our research suggests that in other cases, facilities that purport to seek informed consent put pressure on individuals to give consent. It is not known how common it is for facilities or doctors to use pressure to obtain consent. It is a serious abuse of the right to informed consent and of several federal regulatory requirements for those affected by the practice.

For example, Ruth D. told Human Rights Watch researchers that she feared retaliation after refusing to take the antipsychotic medication and speaking to long-term care ombudsmen about her objection to the facility's coerced treatment. She said to the ombudsman and Human Rights Watch staff: "Once you leave I'll be in trouble. I'm sweating."¹⁷⁶

In Illinois, a long-time advocate said: "Informed consent is telling people risks and benefits and giving them a choice. In practice, the conversation is, 'take it or we will discharge.'"¹⁷⁷ For many residents, the threat of being evicted—involuntarily discharged—is real, even if federal regulations prohibit it in many circumstances.

Lena D., the daughter and designated health proxy of a resident in California explained: "If I object to the Risperdal, Seroquel, Haldol, they say, 'okay, we are moving her.'"¹⁷⁸ Although the facility did not follow through on that threat, it caused Ms. D significant anxiety and made it more difficult for her to refuse the medications.

¹⁷⁵ Human Rights Watch interview with a long-term care ombudsman in Kansas, January 11, 2017.

¹⁷⁶ Human Rights Watch interview with Ruth D., 62-year-old resident of NFTX#5 in Texas, December 14, 2016.

¹⁷⁷ Human Rights Watch interview with the director of a long-term care advocacy organization in Illinois, November 17, 2017.

¹⁷⁸ Human Rights Watch interview with Lena D., daughter of Lucinda D., in California, February 21, 2017.

In some cases, facilities appear to play on family members' guilt to convince them to approve the medications' use. Christina F., the daughter of a former resident in Kansas, recounted:

The nursing home called a meeting once and said he needs meds. They didn't present alternatives. We said, "no." My father said he trusted my judgment. The physician's assistant told me: "You know you're hurting him. You're making it worse for him."¹⁷⁹

The legitimate challenges in seeking informed consent from some nursing home residents do not excuse facilities' failure to have an adequate standard practice of seeking informed consent. Staff from 15 nursing facilities in Texas, Kansas, California, and Florida, including administrators, directors of nursing, nurses, social workers, and social services directors, said their facilities do not seek consent generally; have no protocol for obtaining informed consent; or do not have regular discussions about these medications with residents or their relatives.¹⁸⁰

Accounts of some of the residents Human Rights Watch interviewed also demonstrated a severely inadequate understanding of the meaning of informed consent among staff at nursing facilities. Ombudsmen and nursing staff explained that many facilities do no more than notify the family after the fact, with no communication with the individual concerned. One ombudsman said: "They routinely do not tell either the resident or the family [about antipsychotic medication initiation]. Or they'll have a meeting [after the fact] and say, 'Well, we tried to call you.'"¹⁸¹ One facility's director of nursing, the most senior medical

¹⁷⁹ Human Rights Watch interview with Christina F., daughter of former resident of multiple nursing homes who died in 2013 at the age of 85, in Kansas, January 12, 2017.

¹⁸⁰ Human Rights Watch interviews with the admissions director at NFTX#2 in Texas, December 13, 2016; a social worker at NFTX#14 in Texas, December 20, 2016; a nurse at NFTX#20 in Texas, December 21, 2016; a hospice social worker with clients in multiple nursing facilities in Kansas, January 10, 2017; the social services director at NFKS#1 in Kansas, January 11, 2017; the social services director at NFKS#2 in Kansas, January 11, 2017; the director of nursing at NFKS#3 in Kansas, January 11, 2017; the director of nursing at NFKS#4 in Kansas, January 12, 2017; the administrator of NFKS#4; a social worker and Minimum Data Set coordinator at NFKS#6 in Kansas, January 13, 2017; the administrator and director of nursing at NFKS#14 in Kansas, January 17, 2017; a nurse at NFKS#16 in Kansas, January 18, 2017; the administrator of NFKS#19 in Kansas, January 19, 2017; the director of nursing of NFCA#4 in California, February 15, 2017; the director of social services at NFCA#10 in California, February 17, 2017; a nurse supervisor at NFFL#11 in Florida, February 26, 2017.

¹⁸¹ Human Rights Watch interview with a former long-term care ombudsman in Kansas, January 9, 2017.

professional in the building at most times and responsible for the administration of medications and interaction with prescribing physicians, admitted to Human Rights Watch:

We are supposed to be doing informed consent. It's on the agenda. But really antipsychotics are a go-to thing. "Give 'em some Risperdal and Seroquel."
We tell the family as we're processing the order. The family is notified.¹⁸²

In Kansas, a director of nursing, admitted: "We don't tell someone with dementia what drug we're giving them. That would be very good practice to do that, but in practice it's only if they ask [that we would tell them]."¹⁸³

A former nursing facility administrator in Kansas said:

The facility usually gets informed consent like this. They call you up. They say, "X, Y, and Z is happening with your mom. This is going to help her."
Black box warning? "It's best just not to read that." The risks? They gloss over them. They say, "That only happens once in a while, and we'll look for problems." We sell it. And, by the way, we already started them on it.¹⁸⁴

A Texas state regulator told Human Rights Watch: "There is very rarely informed consent. Nurse calls [the relatives], says resident is doing this [behavior], is highly agitated. The medication is explained as 'he really needs it.' They [the relatives] don't understand."¹⁸⁵ A social worker at a facility in Kansas said: "There is no informed consent for antipsychotic drugs specifically. The only consent is to see a psychiatrist and to be treated. They can sign that consent at admission."¹⁸⁶ While social workers are not part of the medical or nursing staff, they are liaisons between the facility staff and residents' families and thus would be familiar with these kinds of procedures.¹⁸⁷

¹⁸² Human Rights Watch interview with the director of nursing at NFKS#4 in Kansas, January 11, 2017.

¹⁸³ Ibid.

¹⁸⁴ Human Rights Watch interview with a former nursing facility administrator in Kansas, January 9, 2017.

¹⁸⁵ Human Rights Watch phone interview with a highly experienced state surveyor in Texas, December 20, 2016.

¹⁸⁶ Human Rights Watch interview with a social worker at NFKS#6 in Kansas, January 13, 2017.

¹⁸⁷ Administration, Code of Federal Regulations, Title 42, <https://www.law.cornell.edu/cfr/text/42/483.70> sec. 483.70(p).

In response to an inquiry into the facility’s informed consent procedure, one nurse at a facility in Texas told Human Rights Watch: “For informed consent, we just call to let them [the family] know. It’s verbal consent. They’ll sign it when they next come in.”¹⁸⁸ At another facility in the state, the social services director explained:

The doctor writes the order. The nurse calls the responsible party and says, “The doctor made a medication change. This is what the new medication is.” The [durable power of attorney] or guardian says yes or no. That’s informed consent.¹⁸⁹

While the social services director would not be directly involved in this process, she appeared to explain it based on her personal knowledge of how it is done. In yet another facility, a director of nursing said, inexplicably: “Seroquel is not necessarily an antipsychotic drug. It could be an anti-convulsant. You don’t have to have consent if you’re not using it for psychotropics.”¹⁹⁰

One administrator in Kansas told Human Rights Watch: “I don’t know the answer, whether we have an informed consent procedure.”¹⁹¹ While facility administrators do not have to be medical professionals, they are responsible for the facility’s compliance with federal regulations, which include residents’ right to be fully informed in advance about their treatment options. They are also responsible for facilities’ compliance with state law.¹⁹²

A director of nursing at another facility in Kansas gave her best guess on what informed consent might entail. “How do you do informed consent? I have no idea on that. Maybe call

¹⁸⁸ Human Rights Watch interview with a nurse at NFTX#20 in Texas, December 22, 2016.

¹⁸⁹ Human Rights Watch interview with the social services director at NFKS#1 in Kansas, January 11, 2017.

¹⁹⁰ Human Rights Watch interview with the director of nursing at NFTX#2 in Texas, December 15, 2016.

¹⁹¹ Human Rights Watch interview with executive director of NFKS#19 in Kansas, January 19, 2017.

¹⁹² “Section 483.30, Physician Services,” in CMS, “Revision to State Operations Manual (SOM) Appendix PP for Phase 2, F-Tag Revisions, and Related Issues,” effective November 28, 2017, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Advance-Appendix-PP-Including-Phase-2-.pdf> (accessed September 8, 2017).

the physician, get it prescribed, give it, call and tell the family what we did.”¹⁹³ But, she clarified, “No, we don’t do that.”

The fact that a director of nursing would make this statement is particularly problematic because the job of seeking informed consent is often delegated, legally, nursing staff.¹⁹⁴ As CMS explained in response to comments on its proposed revisions to federal regulations, although only the physician or prescribing practitioner prescribes medication, “[n]urses also bear the responsibility for the medications they administer to residents.”¹⁹⁵ Staff at several facilities that have achieved significant reductions in off-label antipsychotic drug use told Human Rights Watch that they require all requests for antipsychotic drug orders to go through the director of nursing.

¹⁹³ Human Rights Watch interview with the director of nursing at NFKS#3 in Kansas, January 11, 2017.

¹⁹⁴ Physician Supervision and Clinical Records, US Code of Federal Regulations, Title 42 <https://www.law.cornell.edu/uscode/text/42/1396r> sec. 1396r(b)(6)(A), cross-referenced as sec. 1919(b)(6)(A) in Social Security Act, https://www.ssa.gov/OP_Home/ssact/title19/1919.htm.

¹⁹⁵ “Pharmacy Services” in CMS, “Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities,” *Federal Register*, vol. 81(192) (2016), <https://www.gpo.gov/fdsys/pkg/FR-2016-10-04/pdf/2016-23503.pdf> (accessed September 10, 2017) p. 68766.

IV. Inadequate Government Regulation and Enforcement

The US government has a duty to effectively regulate the nursing home industry with a view to protecting the human rights of residents. This responsibility is particularly important because nursing facilities are institutions with almost complete control over all aspects of the lives of residents. Effective regulation and oversight require not only the establishment of an appropriate regulatory framework to protect people from harm, but also effective enforcement of regulatory standards. Voluntary initiatives like the National Partnership to Improve Dementia Care in Nursing Homes are no substitute for the core CMS functions of regulation and enforcement.¹⁹⁶ Our research found that CMS has failed to use the tools at its disposal to ensure adequate protection for residents' rights.

Inadequate Regulation

Nursing industry officials frequently claim that nursing homes are the second most regulated sector in the US after the nuclear industry.¹⁹⁷ In a letter to the then-US Department of Health and Human Services Secretary Thomas Price, AHCA wrote: "We are already the most regulated profession in the country."¹⁹⁸ Following the adoption of the

¹⁹⁶ The National Partnership to Improve Dementia Care in Nursing Homes is a partnership between CMS and federal and state agencies, nursing homes, advocates, and others to "implement practices that enhance quality of life for people with dementia" in nursing homes. Between 2012 when it was established and 2016, it focused on setting targets for the industry to reduce the use of antipsychotic drugs in long-stay nursing home residents. CMS, "National Partnership to Improve Dementia Care in Nursing Homes," July 27, 2017, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/National-Partnership-to-Improve-Dementia-Care-in-Nursing-Homes.html> (accessed September 23, 2017).

¹⁹⁷ The claim also appears widely on the Internet. See, e.g., CMS, "Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities," *Federal Register*, vol. 81(192) (2016), <https://www.gpo.gov/fdsys/pkg/FR-2016-10-04/pdf/2016-23503.pdf> (accessed September 10, 2017) p. 68695; Brendan Williams, "Costly New Medicaid Regs Will Cripple Nursing Homes," *the Hill*, September 10, 2015, <http://thehill.com/blogs/congress-blog/healthcare/253100-costly-new-medicare-regs-will-cripple-nursing-homes> (accessed September 10, 2017); "PHCACALM Respond to Dept. of Health Nursing Home Quality Improvement Task Force," press release, Pennsylvania Health Care Association, August 5, 2015, <https://www.phca.org/news/press-releases/phcacalm-responds-to-dept-of-health-nursing-home-quality-improvement-task-force> (accessed September 10, 2017).

¹⁹⁸ Letter from Mark Parkinson, President and CEO, American Health Care Association, to Secretary Thomas E. Price, MD, March 9, 2017, <http://www.ihca.com/Files/Comm-Pub/AHCA-Final-Price-Ltr-3.9.17.pdf> (accessed September 22, 2017). The American Health Care Association is the largest association of long-term care and post-acute care providers in the United States. It represents the for-profit nursing home providers; LeadingAge is the nonprofit trade association. See "Who We Are," American Health Care Association, https://www.ahcancal.org/about_ahca/Pages/Who-We-Are.aspx (accessed September 23, 2017).

Nursing Home Reform Act of 1987, the federal government has established extensive regulations of the nursing facility sector and requires detailed reporting on numerous aspects of facilities' operations. Nursing facilities' participation in the Medicare and Medicaid programs—whose payments make up over half of the average facility's budget—is contingent upon certification and compliance with these regulations.¹⁹⁹

Despite the depth and breadth of the regulations, which range from emergency preparedness and infection control to prevention of abuse and neglect, crucial shortcomings remain. Our research on the inappropriate use of antipsychotic medications identified the failure to ensure minimum staffing levels necessary for residents to attain their highest practicable wellbeing and the lack of explicit requirements around informed consent (or functionally equivalent legal requirements that are framed in different terms) as key gaps in existing regulations.

Failure to Set Effective Standard to Address Gross Understaffing

The right to health requires governments to ensure that health services are of adequate quality. Gross understaffing and under-training of staff may contribute to the inappropriate use of anti-psychotics. According to one state long-term care ombudsman: “Insufficient CNAs [certified nurse aides] is the crux of the antipsychotics problem.”²⁰⁰ The federal government has not taken effective steps to tackle this problem.

Instead of requiring facilities to ensure every resident has a minimum number of nursing staff hours per day or staff per number of residents, CMS imposes a more general requirement that staffing be “sufficient” and “competent,” based on the facility's own annual assessment of residents' acuity, diagnoses, and care plans.²⁰¹ This self-regulation is inadequate, given the continuing prevalence of staff shortages at many facilities.

¹⁹⁹ Requirements for Long Term Care, Code of Federal Regulations, Title 42, part 483, subpart B, <https://www.law.cornell.edu/cfr/text/42/part-483/subpart-B> (accessed September 10, 2017); US Government Accountability Office, “Skilled Nursing Facilities: CMS Should Improve Accessibility and Reliability of Expenditure Data,” September 2016, <http://www.gao.gov/assets/680/679569.pdf>; MedPAC, *Report to the Congress: Medicare Payment Policy*, http://medpac.gov/docs/default-source/reports/mar17_entirereport.pdf p. 201.

²⁰⁰ Human Rights Watch interview with a state long-term care ombudsman, February 16, 2017.

²⁰¹ Federal law requires “sufficient nursing staff with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.” See “Section 483.35, Nursing Services” in CMS, “Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities,” *Federal Register*, <https://www.gpo.gov/fdsys/pkg/FR-2016-10-04/pdf/2016->

CMS has recognized the importance of staffing, saying that staff competency and numbers are “critical to quality of care and resident safety,” and that there is “no question that staffing and quality are associated.”²⁰² Likewise, numerous studies have shown that adequate staffing—sufficient quantity, training, and consistency of staff—is critically important to the quality of care nursing facility residents receive and that inadequate staffing leads to substandard care.²⁰³ Some studies have found that staffing is the best predictor of deficiencies—findings by government inspectors of substantial non-compliance with the law—and of hospitalization rates of residents, which in turn are associated with neglect.²⁰⁴

Interviewees with distinct vantage points on nursing home challenges—residents, ombudsmen, nursing staff, and administrators—agreed that adequate staffing was essential. In Illinois, Barbara Jo V. described her experiences with and concerns about inadequate staff in her nursing home, where she has lived for ten years: “I need help to get to the bathroom. I can’t go by myself. That’s the problem with me. There’s no nurses at night at the station. Think if we had a fire.”²⁰⁵ Joyce M., another resident of the same facility, where she has lived for five years, said: “You should never wait ten minutes when we have the call light on. I’ve waited an hour for it to be answered. They’re always short of

23503.pdf pp. 68861, 68740; Requirements for, and Assuring Quality of Care in, Skilled Nursing Facilities, US Code of Federal Regulations, Title 42 <https://www.law.cornell.edu/uscode/text/42/1395i-3> (accessed September 10, 2017) sec. 1395i-3(b)(4)(C); Requirements for Nursing Facilities: Requirements Relating to Residents’ Rights, US Code of Federal Regulations, Title 42, <https://www.law.cornell.edu/uscode/text/42/1396r> sec. 1396r(b)(4)(C).

²⁰² “Section 483.35, Nursing Services,” in CMS, “Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities,” *Federal Register*, <https://www.gpo.gov/fdsys/pkg/FR-2016-10-04/pdf/2016-23503.pdf> pp. 68753-59.

²⁰³ John R. Bowblis, “Staffing Ratios and Quality: An Analysis of Minimum Direct Care Staffing Requirements for Nursing Homes,” *Health Research Services Research*, vol. 46(5) (2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3207189/pdf/hes0046-1495.pdf> (accessed September 10, 2017); NB Lerner et al., “Are Nursing Home Survey Deficiencies Higher in Facilities with Greater Staff Turnover,” *Journal of the American Medical Directors Association*, vol. 15(2) (2014), <https://www.ncbi.nlm.nih.gov/pubmed/24139163> (accessed September 10, 2017); HY Lee et al., “The Effects of RN Staffing Hours on Nursing Home Quality: A two-stage model,” *International Journal of Nursing Studies*, vol. 51(3) (2014), <https://www.ncbi.nlm.nih.gov/pubmed/24182619> (accessed September 10, 2017).

²⁰⁴ Charlene Harrington, John Schnelle, Margaret McGregor, and Sandra Simmons, “The Need for Higher Minimum Staffing Standards in U.S. Nursing Homes,” *Health Services Insights*, vol. 9 (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4833431/pdf/hsi-9-2016-013.pdf> (accessed September 10, 2017); Office of Inspector General, “Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries,” February 2014, <https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf> (accessed September 10, 2017) pp. 17-24; Office of Inspector General, “Medicare Nursing Home Resident Hospitalization Rates Merit Additional Monitoring,” November 2013, <https://oig.hhs.gov/oei/reports/oei-06-11-00040.pdf> (accessed September 10, 2017).

²⁰⁵ Human Rights Watch interview with Barbara Jo V., resident of NFLI #3 in Illinois, February 3, 2017.

help.”²⁰⁶ In Kansas, Marisa N., who has lived in several nursing facilities since falling in 2014, said:

I don't think there's enough staff. Many of the residents are two-person transfers. I tell you, it's been very frustrating to me to sit here [in the bathroom] waiting. On weekends it has been horrendous. If they know State [inspectors] is coming, they'll get six or seven more [staff] than usual to come in. Otherwise it's just kitchen, waiter, two or three CNAs [certified nurse aides] on the floor, and a nurse.²⁰⁷

One former ombudsman in Kansas said: “What distinguishes facilities most of all is their staffing. Especially with dementia, you need consistent staffing.”²⁰⁸ An ombudsman in Florida said:

I wish they could get quality staff who stay. Poor CNAs make a pittance. A nursing home might meet the minimum staffing requirement but still not meet residents' needs. AHCA [Florida's regulatory agency, the Agency for Health Care Administration] has okay'ed one CNA for 20 residents. Some residents need a two-person lift!²⁰⁹

A nurse in Texas who has worked in nursing homes since 1992 said: “It's very stressful. The hardest is when there's not enough help. You can't do your job the way you know you need to do it. You just do the most basic needs.”²¹⁰ A nurse elsewhere in Texas said, “Staffing is the biggest problem across the nation. Here, we don't have many staff on weekends. So there are no showers on Sundays. Then the workload is less.”²¹¹ An

²⁰⁶ Human Rights Watch interview with Joyce M., resident of NFL#3 in Illinois, February 3, 2017.

²⁰⁷ Human Rights Watch interview with Marisa N., resident of NFKS#14 in Kansas, January 17, 2017.

²⁰⁸ Human Rights Watch interview with a former long-term care ombudsman in Kansas, January 9, 2017.

²⁰⁹ Human Rights Watch interview with a long-term care ombudsman in Florida, February 28, 2017.

²¹⁰ Human Rights Watch interview with a nurse at NFTX#20 in Texas, December 22, 2016.

²¹¹ Human Rights Watch interview with a nurse at NFTX#27 in Texas, December 18, 2016.

administrator in Texas said: “CNAs are the most important.... They’re the heart of the nursing home and nobody cares. The thinking is, ‘we’ll just get another one.’”²¹²

Various studies have found that staffing levels and staff training affect the use of antipsychotic medicines, although some did not find a robust association.²¹³ Studies that examined efforts to reduce antipsychotic drug use found that staffing and staff training were associated with the success of those efforts. One study found that a full-time advanced practice registered nurse at the nursing home led to a drop from almost one in three to one in ten long-stay residents taking the drugs and “achieved no use of antipsychotic medications for residents with a diagnosis of dementia.”²¹⁴ Another study concluded that “[n]urses working longer on the ward, with lower education, presented higher barriers to discontinuation of antipsychotics.”²¹⁵

Governmental studies have underscored the importance of minimum staffing standards, too.²¹⁶ In 2001, a CMS-funded study concluded that to avoid compromising quality of care, long-stay residents should have 4.85 nursing staff hours per day, and that short-stay residents should have 4.1 hours.²¹⁷ A subsequent report in 2004 by the Institute of

²¹² Human Rights Watch interview with administrator of NFTX#13 in Texas, December 19, 2016.

²¹³ H. Kim, AL Whall, “Factors Associated with Psychotropic Drug Usage Among Nursing Home Residents with Dementia,” *Nursing Research*, vol. 55(4) (2006), <https://www.ncbi.nlm.nih.gov/pubmed/16849977> (accessed September 10, 2017); Bart C. Kleijer et al., “Variability Between Nursing Homes in Prevalence of Antipsychotic Use in Patients with Dementia,” *International Psychogeriatrics*, vol. 26(3) (2014), <https://www.cambridge.org/core/journals/international-psychogeriatrics/article/variability-between-nursing-homes-in-prevalence-of-antipsychotic-use-in-patients-with-dementia/985BBAE0D33F742D29D76C984F124131> (accessed September 10, 2017).

²¹⁴ Marilyn J. Rantz et al., “Better Care, Better Quality: Reducing Avoidable Hospitalizations of Nursing Home Residents,” *Journal of Nursing Care Quality*, vol. 30(4) (2015), http://journals.lww.com/jncqjournal/Fulltext/2015/10000/Better_Care,_Better_Quality__Reducing_Avoidable.2.aspx (accessed September 10, 2017).

²¹⁵ Majda Zermaj, et al., “Barriers to Antipsychotic Discontinuation in Nursing Homes: An Exploratory Study,” *Aging and Mental Health*, vol. 18(3) (2014), <http://www.tandfonline.com/doi/abs/10.1080/13607863.2013.832732> (accessed September 10, 2017).

²¹⁶ “Committee on the Work Environment for Nurses and Patient Safety, *Keeping Patients Safe: Transforming the Work Environment of Nurses*, (Washington, DC: National Academies Press, 2004), <https://www.ncbi.nlm.nih.gov/pubmed/25009849> (accessed September 10, 2017); CMS, “Appropriateness of Minimum Nurse Staffing, Phase II Final Report, Vol. I,” December 2001, <https://phinational.org/sites/default/files/clearinghouse/PhaseIIVolumeofIII.pdf>, pp. 3-19.

²¹⁷ Specifically, it recommended 2.8 hours of nurse aides, 1.3 of licensed staff, and 0.75 of registered nurses for long-stay residents and 2.4 hours of nurse aides, 1.15 of licensed staff, and 0.55 of registered nurses for short-stay residents. CMS, “Appropriateness of Minimum Nurse Staffing, Phase II Final Report, Vol. I,”

Medicine, recommended following these same standards and updating minimum requirements to require at least one registered nurse on duty at all times (not just eight hours a day); staffing levels to increase based on resident numbers, consistent with the 2001 CMS report; and setting staffing levels for nurse aides, recognizing that aides “provide the majority of patient care.”²¹⁸

More than a decade later, staffing at many facilities still falls far short of these recommendations. A review of the data in 2017 shows that almost a thousand nursing facilities reported that they were providing less than three hours of staff time to residents per day—almost 40 percent below the recommended level.²¹⁹ Human Rights Watch analysis found that state-level averages of total reported nurse staffing hours vary: Illinois and Texas have two of the lowest levels, at 3.80 and 3.83 hours respectively; California and Florida have two of the highest, at 4.63 and 4.59 respectively.

Moreover, CMS has stated that those numbers are likely inflated because nursing facilities tend to over-report their staffing levels.²²⁰ CMS expects the payroll-based staffing data collection, mandated by the Affordable Care Act, to “greatly assist us in re-evaluating” current staffing short-comings because they expect their “understanding of how facilities are staffed ... to improve with the collection of payroll-based staffing data.”²²¹ One study

<https://phinational.org/sites/default/files/clearinghouse/PhaseIIVolumeofIII.pdf> pp. 3-17. The CMS-funded study defined the minimum threshold as that beyond which there is no further benefit of additional staffing for quality outcomes. CMS rejected the report’s recommendations, claiming the evidence was insufficient.

²¹⁸ The Institute of Medicine is now called the Health and Medicine Division, a program of the National Academies of Sciences, Engineering, and Medicine that was established by congressional charter in 1863, and is run as an independent, nonprofit institution to inform public policy. Committee on the Work Environment for Nurses and Patient Safety, *Keeping Patients Safe: Transforming the Work Environment of Nurses*, <https://www.ncbi.nlm.nih.gov/pubmed/25009849>; Harrington, Schnelle, McGregor, and Simmons, “The Need for Higher Minimum Staffing Standards in U.S. Nursing Homes,” *Health Services Insights*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4833431/pdf/hsi-9-2016-013.pdf>. For principles of adequate staffing, see, American Nurses Association, *Principles for Nurse Staffing*, Second Edition, (Silver Spring, MD: American Nurses Association, 2012), http://www.nursesbooks.org/ebooks/download/ANA_Principles_Staffing.pdf (accessed September 10, 2017).

²¹⁹ “Quality Measures – Long Stay,” Nursing Home Compare, processing date June 1, 2017, <https://data.medicare.gov/Nursing-Home-Compare/Quality-Measures-Long-Stay/iqd3-nsf3>.

²²⁰ “Section 483.35, Nursing Services,” in CMS, “Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities,” *Federal Register*, <https://www.gpo.gov/fdsys/pkg/FR-2016-10-04/pdf/2016-23503.pdf> pp. 68755-59. Under the Affordable Care Act, facilities will soon be reporting their staffing information based on payroll, which is expected to reflect more accurate numbers. *Ibid.*, p. 68723.

²²¹ *Ibid.*, pp. 68753-59. “Particularly given existing concern that current self-reported staffing data may be inflated, we believe that payroll based staffing data will help us better estimate the [financial] burden [of the proposed federal rule].” See

examining the mix of residents in nursing facilities found that actual staffing levels were lower than predicted, given residents' needs.²²²

Studies also show the importance of having sufficient registered nurses on staff.²²³ Yet federal regulations only require one registered nurse to be on duty for eight consecutive hours per day.²²⁴

In 2016, CMS rejected a minimum staffing level or ratio.²²⁵ First, it stated that facilities are too different for a one-size-fits-all approach—contrary to the position of the 2001 report that holds that the inability to stratify staffing thresholds by case-mix “would in no way invalidate the thresholds that were identified.”²²⁶ Second, it argued that a minimum staffing requirement could have unintended consequences like “staffing to the minimum” or “stifling innovation,” or could “not result in the improved quality and person-centered

also, “Staffing Data Submission PBJ,” CMS, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Staffing-Data-Submission-PBJ.html> (accessed October 10, 2017).

²²² JF Schnelle et al., “Determining Nurse Aide Staffing Requirements to Provide Care Based on Resident Workload: A Discrete Event Simulation Model,” *Journal of American Medical Directors Association*, vol. 17(11) (2016), <https://www.ncbi.nlm.nih.gov/pubmed/27780572> (accessed September 10, 2017).

²²³ Harrington, Schnelle, McGregor, and Simmons, “The Need for Higher Minimum Staffing Standards in U.S. Nursing Homes,” *Health Services Insights*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4833431/pdf/hsi-9-2016-013.pdf>; Haizhen Lin, “Revisiting the Relationship between Nurse Staffing and Quality of Care in Nursing Homes: An Instrumental Variables Approach,” *Journal of Health Economics*, vol. 37 (2014), <http://www.sciencedirect.com/science/article/pii/S0167629614000629> (accessed September 10, 2017); Hongsoo Kim, et al., “A Panel Data Analysis of the Relationships of Nursing Home Staffing Levels and Standards to Regulatory Deficiencies,” *The Journals of Gerontology*, vol. 64B (2009), <https://academic.oup.com/psychsocgerontology/article/64B/2/269/550902/A-Panel-Data-Analysis-of-the-Relationships-of> (accessed September 10, 2017).

²²⁴ “Sec. 483.35(b), Registered Nurse” in 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf> sec. 483.35(b).

²²⁵ CMS, “Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities,” *Federal Register*, <https://www.gpo.gov/fdsys/pkg/FR-2016-10-04/pdf/2016-23503.pdf> p. 68753-59.

²²⁶ “Sec. 483.35(b), Registered Nurse” in 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf> (“This is because the multivariate models used to identify the thresholds adjusted for facility casemix and other facility characteristics that were predictive of the quality measures.”).

care [sought].”²²⁷ Third, CMS concluded that it lacked sufficient data for “determining if and what such [staffing] ratios should be.”²²⁸

Similarly, AHCA wrote to Human Rights Watch regarding its opposition to stronger staffing requirements:

We feel that requiring staffing levels or ratios does not recognize the difference in types and acuity and care needs different individuals and facilities have. A one shoe [sic] fits all approach would not be helpful to assuring high quality care. Also focusing on just staffing levels is misguided. We believe the focus should be on resident outcomes.²²⁹

LeadingAge, the nonprofit nursing home trade association, reiterated this perspective in response to a letter from Human Rights Watch:

LeadingAge has not supported minimum staffing ratios because they become just that – minimum standards to which many providers focus on. We believe that staffing should be based on the needs and acuity of the residents served and the skills/competency of the staff that care for them. Of particular note, non-profit providers typically have higher staffing ratios than the for-profit nursing homes in a given geographic area.²³⁰

Yet the bottom line is that the current standard has not succeeded in pushing nursing facilities to raise staffing levels to the desired levels. A new and more robust approach, which may or may not include minimum staffing levels, is needed. If CMS does not want to establish a specific minimum staffing requirement, it should introduce another approach that is more effective at getting nursing facilities and their owners to address understaffing.

²²⁷ “Section 483.35, Nursing Services,” in CMS, “Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities,” *Federal Register*, <https://www.gpo.gov/fdsys/pkg/FR-2016-10-04/pdf/2016-23503.pdf> p. 68753-59.

²²⁸ *Ibid.*, p. 68755.

²²⁹ Letter from David R. Gifford, MD, MPH, senior vice president for quality & regulatory affairs, American Health Care Association, to Human Rights Watch, July 6, 2017. See Appendix 7.

²³⁰ Letter from Katie Smith Sloan, president and CEO, LeadingAge letter to Human Rights Watch, July 13, 2017. See Appendix 6.

However, based on information gleaned from data from some of the states that have introduced minimum staffing levels, there is no clear evidence that stronger staffing levels mandated by law has led to higher quality of care.²³¹ Human Rights Watch does not take a position on the means that the government employs to ensure sufficient staff to provide the quality of care required by domestic law and human rights standards. However, the current federal regulations are not doing the job.

Inadequate Free and Informed Consent Laws and Regulation

Federal regulations governing nursing facilities certified by Medicare and Medicaid provide for the right “to be fully informed in advance about care and treatment, to be fully informed in advance of any changes in care or treatment that may affect the resident’s well-being, and (except with respect to a resident adjudged incompetent) to participate in planning care and treatment or changes in care and treatment,” as well as the right to refuse treatment.²³²

The regulations do not require nursing facilities to obtain free and informed consent, written or otherwise, from any residents prior to administering antipsychotic or other psychotropic medications. At least half of states also do not require written, informed consent from individuals living in nursing facilities prior to the administration of antipsychotic drugs.²³³

CMS has an obligation to protect the right of people in nursing facilities to informed consent. In practical terms, meeting that obligation should not require a significant legislative or regulatory shift if existing regulations are enforced rigorously. However, given obstacles to doing so, informed consent remains in effect a gap in the regulations.

²³¹ See, e.g., Christine Mueller et al., “Nursing Home Staffing Standards: Their Relationship to Nurse Staffing Levels,” *The Gerontologist*, vol. 46(1) (2006), <https://academic.oup.com/gerontologist/article/46/1/74/566768/Nursing-Home-Staffing-Standards-Their-Relationship> (accessed September 10, 2017); Harrington, Schnelle, McGregor, and Simmons, “The Need for Higher Minimum Staffing Standards in U.S. Nursing Homes,” *Health Services Insights*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4833431/pdf/hsi-9-2016-013.pdf>.

²³² Requirements for, and Assuring Quality of Care in, Skilled Nursing Facilities, US Code, Title 42, <https://www.law.cornell.edu/uscode/text/42/1395i-3> sec. 1395i-3(c)(1)(A)(i).

²³³ Richard J. Mollot, et al., “Informed Consent Rights in U.S. Nursing Homes: An Overview of State & Federal Requirements,” 2013, http://www.ltccc.org/publications/documents/ltccc-rpt-informed-consent-laws-sept2013_001.pdf.

Current guidance states that:

[Federal regulations require facilities to involve residents, families, and representatives] in discussions about potential approaches to address behaviors and about the potential risks and benefits of a psychopharmacological medication (e.g., FDA black box warnings), the proposed course of treatment, expected duration of use of the medication, use of individualized approaches, plans to evaluate the effects of the treatment, and pertinent alternatives.²³⁴

CMS guidance states explicitly that “[r]esidents have the right to be informed about their medical condition, care and treatment; they have the right to refuse treatment and the right to participate in the care plan process.”²³⁵ Individuals in nursing facilities also already have a right to “request, refuse, and/or discontinue treatment.”²³⁶

Substantively, these requirements would amount to informed consent if the provisions were enforced in practice. However, it is difficult to be sure that adequate information was conveyed in an intelligible fashion and that the person receiving care had the opportunity to make an informed decision about their treatment options.

Existing nursing home regulations already require residents be present for and included as much as possible in discussions and decisions. As dementia is a progressive, degenerative disease, nursing facilities should plan ahead for future situations when a resident may increasingly struggle to make informed decisions about their care. Residents

²³⁴ “Medication Use in Dementia,” in 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf>.

²³⁵ *Ibid.*

²³⁶ Resident Rights: Planning and Implementing Care, Code of Federal Regulations, Title 42, sec. 483.10(c)(6). “A resident and/or representative(s) has the right to be informed about the resident’s condition; treatment options, relative risks and benefits of treatment, required monitoring, expected outcomes of the treatment; and has the right to refuse care and treatment. If a resident refuses treatment, the facility staff and physician should inform the resident about the risks related to the refusal, and discuss appropriate alternatives such as offering the medication at another time or in another dosage form, or offer an alternative medication or non-pharmacological approach, if available.” “Medication Management,” in 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf>.

should be proactively engaged to determine their wishes regarding future care in a range of possible scenarios in case it becomes impossible for them to engage in those discussions in the future. It is essential that this planning starts at the point of admission to the facility.

In California, a treating physician may determine that an individual lacks the ability to consent to medical treatment. If there is no legal representative to make the decision on the person's behalf, California law mandates that the person's nursing facility convene an interdisciplinary team to make decisions.²³⁷ Many states have no established procedures for a nursing home to follow to make a determination for individuals in these circumstances.

For example, the two informed consent statutes in Texas relating to antipsychotic drugs and nursing home residents make no provision for individuals deemed to lack capacity without a proxy.²³⁸ Otherwise, the law provides that no resident may be administered a psychoactive medication without the resident's consent unless it is an emergency or "the person authorized by law to consent on behalf of the resident has consented."²³⁹ The law then enumerates when the resident's or proxy's consent is valid, such as when it is voluntary; adequate information was provided on which the person could make the decision; the person giving consent was aware the consent could be revoked; and the consent is documented in the clinical record.²⁴⁰

US procedural safeguards in the determination of incapacity are much stronger in the context of civil commitment and mental or intellectual disability law.²⁴¹ It is worth exploring

²³⁷ Quality of Long-Term Health Facilities, California Health and Safety Code, California State Legislature, cap. 2.4, http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC§ionNum=1418.8 (accessed September 10, 2017) sec. 1418.8. This statute is being challenged in court on constitutional grounds, although it provides a greater involvement of others on paper than other state statutes. *California Advocates for Nursing Home Reform (CANHR) and Gloria A. v. Ronald Chapman, MD, Director of the California Department of Public Health*, Verified Petition for Writ of Mandate, Declaratory Relief and Injunction, Superior Court of California, County of Alameda, http://thaddeuspope.com/images/1418.8_CANHR_complaint.pdf.

²³⁸ Texas Health and Safety Code, Texas State Legislature, Title 4, Subtitle B, cap. 242, <http://www.statutes.legis.state.tx.us/Docs/HS/htm/HS.242.htm> secs. 242.501 and 242.505.

²³⁹ Ibid.

²⁴⁰ Ibid., sec. 242.505(b)-(d).

²⁴¹ See, e.g., Mental Hygiene Law, Surrogate Decision-Making Committees and Panels; Organization, New York Consolidated Laws, New York State Legislature, <http://codes.findlaw.com/ny/mental-hygiene-law/mhy-sect-80-05.html> (accessed

whether nursing facility residents' human rights would be better protected if these protections were to apply to them as well, despite the absence of direct state intervention in their institutional placement.

Ineffective Enforcement

Regulatory standards are only as effective as their enforcement. Our research found several significant shortcomings in enforcement of federal regulations, from the underestimation of harm cited to the inadequate deterrent effect of financial sanctions assessed. Despite widespread failure by nursing facilities to comply fully with regulations put in place to protect people living in these institutions, CMS is not using its full authority to force them to improve their performance.

In November 2017, CMS reduced enforcement requirements further, including placing a moratorium on the issuance of financial sanctions for noncompliance with Obama-era regulatory requirements.²⁴² Previously, industry groups had critiqued even the government's inadequate enforcement efforts. For example, LeadingAge, the nonprofit trade association, wrote to Human Rights Watch saying:

We [believe] that the current Survey and Certification system is NOT driving quality and excellence, but is one that is focused entirely on enforcement, that it is inconsistent, that it is punitive in nature and creates a defensive environment—not one that supports innovation and excellence.²⁴³

In a letter to then-US Department of Health and Human Services Secretary Thomas Price, AHCA pointed out that “a punitive approach by survey teams across the country has

September 10, 2017) sec. 80.05 and <http://codes.findlaw.com/ny/mental-hygiene-law/mhy-sect-80-07.html> (accessed September 10, 2017) sec. 80.07.

²⁴² CMS, “Temporary Enforcement Delays for Certain Phase 2 F-Tags and Changes to *Nursing Home Compare*,” November 24, 2017, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-18-04.pdf> (accessed December 31, 2017); Jordan Rau, “Trump Administration Eases Nursing Home Fines in Victory for Industry,” *New York Times*, December 24, 2017, <https://www.nytimes.com/2017/12/24/business/trump-administration-nursing-home-penalties.html> (accessed December 31, 2017).

²⁴³ Letter from Katie Smith Sloan, president and CEO, LeadingAge letter to Human Rights Watch, July 13, 2017. See Appendix 6.

threatened to shut down even the best operators in our profession.”²⁴⁴ As the following analysis demonstrates, it is not accurate that typical penalties are at all onerous.

The trade associations do not argue that the government assesses sanctions when noncompliance has not in fact occurred. Instead, their view is that progress toward compliance with non-negotiable, federal, legal requirements (“we have so dramatically improved quality”) merits being “rewarded for our efforts.”²⁴⁵

Moreover, most facilities are part of a chain, where the owner has at least two and sometimes hundreds of nursing facilities.²⁴⁶ But the government does not sufficiently collect and analyze nursing facility data based on ownership or conduct standard enforcement taking ownership into account.²⁴⁷ The facility is the only “locus of accountability” in the current enforcement system: a notable shortcoming because in many cases, fundamental decisions—about management, operations, revenue allocation, compliance with state and federal quality of care standards, staffing levels, and government reporting—are not made by the administrators of individual facilities but by upper level managers in the corporate structure that owns them.²⁴⁸ The main enforcement process authorized by law discussed in the following sections—assessing financial, licensing, and other penalties for failure to substantially comply with regulatory requirements—is exclusively focused on individual facilities.²⁴⁹

²⁴⁴ Letter from Mark Parkinson, president and CEO, American Health Care Association, to Secretary Thomas E. Price, MD, March 9, 2017, <http://www.ihca.com/Files/Comm-Pub/AHCA-Final-Price-Ltr-3.9.17.pdf> (accessed September 22, 2017).

²⁴⁵ *Ibid.*

²⁴⁶ The Office of Inspector General of the US Department of Health and Human Services is able to enter Corporate Integrity Agreements with nursing facility owners, but this is not a systematic enforcement mechanism. The Agreements are used as an intermediary step before the government sues a nursing facility owner, which is rare. US Government Accountability Office, “Nursing Homes: Complexity of Private Investment Purchases Demonstrates Need for CMS to Improve the Usability and Completeness of Ownership Data,” September 2010, <http://www.gao.gov/assets/320/310562.pdf> (accessed September 10, 2017).

²⁴⁷ *Ibid.*

²⁴⁸ *Ibid.* See also, Rohit Pradhan et al., “Private Equity Ownership of Nursing Homes: Implications for Quality,” *Journal of Health Care Finance*, vol. 42(2) (2014), <http://healthfinancejournal.com/index.php/johcf/article/view/12/15> (accessed September 24, 2017). Human Rights Watch recognizes that some corporate officials are principally or exclusively concerned with real estate matters or strategic decisions rather than quality of care and daily matters of facilities.

²⁴⁹ Enforcement Process, Requirements for, and Assuring Quality of Care in, Skilled Nursing Facilities, US Code, Title 42, <https://www.law.cornell.edu/uscode/text/42/1395i-3> sec. 1395i-3(h); Requirements for Nursing Facilities, US Code, Title 42, <https://www.law.cornell.edu/uscode/text/42/1396r> sec. 1396r; Pradhan et al., “Private Equity Ownership of Nursing Homes: Implications for Quality,” *Journal of Health Care Finance*, <http://healthfinancejournal.com/index.php/johcf/article/>

CMS is the main agency to regulate nursing facilities. However, other government agencies have overarching enforcement authority across sectors, such as the US Department of Justice (DOJ).²⁵⁰ In 2016, the DOJ created Elder Justice Task Forces to penalize nursing facilities for grossly substandard care.²⁵¹

Underestimation of Severity of Harm Caused by Inappropriate Use of Antipsychotic Drugs

Federal regulations provide for regular inspections of all licensed nursing facilities. CMS contracts with state agencies to conduct enforcement of federal and state laws and regulations.²⁵² Every 15 months at most, state surveyors conduct unannounced inspections to evaluate facilities' compliance with health and safety regulations.²⁵³ Surveyors use a detailed protocol—the State Operations Manual produced by CMS, which includes detailed investigative protocols on particular subjects—to conduct surveys and determine the scope and severity of a deficiency.²⁵⁴ Deficiencies are determinations of noncompliance with more than 150 federal regulatory quality of care, quality of life, safety, fire, and other

view/12/15; David G. Stevenson, Jeffrey S. Bramson, and David C. Grabowski, "Nursing Home Ownership Trends and Their Impact on Quality of Care: A Study Using Detailed Ownership Data from Texas," *Journal of Aging & Social Policy*, vol. 25(1) (2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4825679/> (accessed September 10, 2017).

²⁵⁰ "Elder Justice Task Forces," US Department of Justice, <https://www.justice.gov/elderjustice/task-forces>.

²⁵¹ US Department of Justice, "Department of Justice Launches 10 Regional Elder Justice Task Forces," March 30, 2016, <https://www.justice.gov/opa/pr/departments-justice-launches-10-regional-elder-justice-task-forces>.

²⁵² Pursuant to Section 1864 of the Social Security Act, "each State shall be responsible for certifying, in accordance with surveys conducted under paragraph (2), the compliance of skilled nursing facilities (other than facilities of the State) with the requirements of subsections (b), (c), and (d). "Use of State Agencies to Determine Compliance by Providers of Services with Conditions of Participation," in Section 1864 of the Social Security Act, Code of Federal Regulations, https://www.ssa.gov/OP_Home/ssact/title18/1864.htm (accessed September 10, 2017)

²⁵³ "Survey and Certification Process" in Requirements For, and Assuring Quality of Care In, Skilled Nursing Facilities, Social Security Act, Code of Federal Regulations, https://www.ssa.gov/OP_Home/ssact/title18/1819.htm (accessed October 10, 2017) sec. 1819(g)(2)(A)(iii) and Requirements for Nursing Homes, Social Security Act, Code of Federal Regulations, https://www.ssa.gov/OP_Home/ssact/title19/1919.htm (accessed October 10, 2017) sec. 1919(g)(1)(A). State surveyors conduct enforcement of state standards in ways established by each state. Only their enforcement of federal regulations is standardized across states.

²⁵⁴ 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf>. The new manual, effective November 28, 2017, is available here: CMS, "Revision to State Operations Manual (SOM) Appendix PP for Phase 2, F-Tag Revisions, and Related Issues," <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Advance-Appendix-PP-Including-Phase-2-.pdf>.

Deficiency Severity	Deficiency Scope		
	Isolated	Pattern	Widespread
<i>Level 4 -- Actual or potential for death or serious injury (immediate jeopardy)</i>	J	K	L
<i>Level 3 -- Actual harm that is not immediate jeopardy</i>	G	H	I
<i>Level 2 -- No actual harm with potential for more than minimal harm</i>	D	E	F
<i>Level 1 -- No actual harm with potential for minimal harm</i>	A	B	C

Table 1. Scope and Severity Grid for Deficiency Citations

standards, from freedom from abuse, neglect, and exploitation to the physical environment, emergency preparedness, infection control, food services, and more.²⁵⁵

Surveyors identify and substantiate any deficiencies, and then determine the scope and severity of harm. Inspectors determine whether the deficiency is isolated, part of a pattern, or widespread and its consequence: the potential for or actual occurrence of minimal harm, actual harm, or immediate jeopardy (likelihood or occurrence of “serious injury, harm, impairment, or death to a resident”).²⁵⁶ Table 1 shows the scope/severity grid that surveyors use.

Guidance to surveyors has made clear that an immediate jeopardy citation may be appropriate without any actual harm having yet occurred, that serious harm can result from neglect, and that psychological harm is just as serious as physical harm.²⁵⁷ Triggers for immediate jeopardy citations include adverse medication consequences and use of chemical restraints without adequate monitoring.²⁵⁸ Human Rights Watch analysis found that 12 percent of facilities were cited for at least one immediate jeopardy citation between

²⁵⁵ Ibid.; CMS, “State Operations Manual Appendix P – Survey Protocol for Long Term Care Facilities Part I,” https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_p_ltcf.pdf.

²⁵⁶ “Immediate Jeopardy,” in Definitions, Code of Federal Regulations, Title 42, part 489.3; CMS, “State Operations Manual Appendix Q – Guidelines for Determining Immediate Jeopardy,” February 2014, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_q_immedjeopardy.pdf (accessed September 10, 2017).

²⁵⁷ Ibid.

²⁵⁸ Ibid.

2014 and 2016; 40 percent of facilities were cited for at least one “actual harm” level deficiency. Every facility was cited for at least one deficiency of some severity level.

CMS guidance for surveyors suggests that many cases of inappropriate use of antipsychotic medications should be tagged as Level 3 or 4 severity. For example, the manual defines a Level 3 deficiency as “clinical compromise, decline, or the resident’s inability to maintain and/or reach his/her highest practicable well-being.”²⁵⁹ It cites, among others, the following example:

Facility failure to implement a GDR [gradual dose reduction] that was not contraindicated in a resident receiving prolonged, continuous antipsychotic therapy resulting in functional decline, somnolence, lethargy, tremors, increased falling, or impaired ambulation.²⁶⁰

Level 4 deficiencies are defined as regulatory noncompliance that:

[H]as allowed, caused, or resulted in, or is likely to allow, cause, or result in serious injury, harm, impairment, or death to a resident; and requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.²⁶¹

The guidance includes the following examples related to antipsychotic drugs: “Failure to recognize that continuation of an antipsychotic..., has caused significant changes in the resident’s behavior”; “continuation of the antipsychotic without indication resulted in significant psychosocial harm”; and “failure to re-evaluate continuation of an antipsychotic originally prescribed for acute delirium which resulted in significant side effects from the medication.”

²⁵⁹ 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf>.

²⁶⁰ Ibid. Another example of actual harm is “Failure to evaluate the medication regimen as a possible cause of resident’s decline in functioning evidenced by withdrawal, crying, loss of interest in activities, and social isolation.”

²⁶¹ Ibid.

Deficiency Severity	Scope	Number	Percent	Cumulative Percent
Level 1	B	5	0%	0%
Level 2	D	4,516	64%	64%
	E	2,326	33%	97%
	F	36	1%	98%
Level 3	G	82	1%	99%
	H	11	0%	99%
Level 4	J	24	0%	99%
	K	25	0%	99%
	L	14	0%	99%
Total		7,039		

Table 2. Scope and Severity of Drug-Related Deficiency Citations with Antipsychotic Drug-Related Key Terms²⁶²

Yet Human Rights Watch’s data analysis suggests that deficiencies related to antipsychotic drugs are almost exclusively assessed as “no actual harm.” Our review of more than 7,000 deficiency reports related to antipsychotic drugs between January 1, 2014, and June 30, 2017, found that 97 percent of these deficiencies were tagged as Level 2 (D, E, and F categories), or “no actual harm.” Only 93 deficiencies (1 percent) were tagged as Level 3 (G and H) and 63 deficiencies (less than 1 percent) as Level 4 (J, K, and L). See Table 2 for the distribution of assessed scope and severity. A detailed description of the data analysis performed can be found in Appendix 4.

A study by the Center for Medicare Advocacy, a national nonprofit, nonpartisan law organization focused on protecting older people’s and people with disabilities’ fair access to Medicare and quality health care, and Dean Lerner Consulting, an attorney consultant with expertise in the long-term care industry, of all deficiency citations for unnecessary drugs (f-tag 329) in 2010 and 2011 from seven states (Georgia, Illinois, Massachusetts, Oregon, Pennsylvania, and Texas) reached a similar conclusion. Of 602 citations, 292 concerned antipsychotic drugs. Almost all—95 percent—were cited at the “no actual harm”

²⁶² Human Rights Watch analysis of Nursing Home Compare data from <https://data.medicare.gov>.

level.²⁶³ Examples of what surveyors considered to be “no actual harm” included: a person falling 20 times; becoming more agitated with the drugs; being given more than the “daily recommended dosage;” being prescribed antipsychotic drugs without appropriate evaluation; declining to the point of needing total care; requiring hospitalization for undiagnosed underlying infections; and “spending all her time in bed.”²⁶⁴

This apparently systematic underestimation of the severity of harm caused by inappropriate uses of antipsychotic drugs (among other drugs and medical interventions) not only appears to point to woefully inadequate enforcement and protection of nursing home residents’ rights, but also leads to inappropriately light penalties. Without a finding of more severe harm, financial penalties are minimal, optional, or do not attach.²⁶⁵ A concerted effort from CMS to address this problem is urgently required.

The revised CMS State Operations Manual, which was meant to go into effect on November 28, 2017, before a moratorium on enforcement of significant portions of it was established on November 24, 2017, may go some way toward addressing this routine underestimation of the harm of deficiencies related to antipsychotic drugs if it were enforced.²⁶⁶ The manual states explicitly that Level 1 deficiencies—for no harm with potential for minimal harm—“does not apply for this regulatory requirement [regarding psychotropic drugs] because the failure of the facility to provide appropriate care and services to manage the resident’s

²⁶³ Toby Edelman, “CMA Report: Examining Inappropriate Use of Antipsychotic Drugs in Nursing Facilities,” *Center for Medicare Advocacy*, June 27, 2013. <http://www.medicareadvocacy.org/examining-inappropriate-use-of-antipsychotic-drugs-part-one-how-seven-states-cite-antipsychotic-drug-deficiencies/> (accessed September 10, 2017).

²⁶⁴ *Ibid.*

²⁶⁵ CMS, “Mandatory Immediate Imposition of Federal Remedies and Assessment Factors Used to Determine the Seriousness of Deficiencies for Nursing Homes,” July 29, 2016, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-31.pdf> (accessed September 10, 2017); CMS, “State Operations Manual Appendix Q – Guidelines for Determining Immediate Jeopardy,” February 2014, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_q_immedjeopardy.pdf. Prior government studies have found that the lower end of penalties is often assessed. For example, the Office of Inspector General concluded in 2005, “CMS does not utilize the full dollar range allowed for CMPs; impositions tend toward the lower ends of ranges.” Office of the Inspector General, “Nursing Home Enforcement: The Use of Civil Money Penalties,” April 2005, <https://oig.hhs.gov/oei/reports/oei-06-02-00720.pdf> (accessed September 10, 2017).

²⁶⁶ CMS, “Temporary Enforcement Delays for Certain Phase 2 F-Tags and Changes to *Nursing Home Compare*,” November 24, 2017, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-18-04.pdf> (accessed December 31, 2017).

medication regimen to avoid unnecessary medications and minimize negative outcome places residents at risk for more than minimal harm.”²⁶⁷

It also provides as an example of a Level 4 deficiency:

Failure to recognize that use of an antipsychotic medication, originally prescribed for agitation, has caused significant changes in the resident’s quality of life. The resident no longer participates in activities that they previously enjoyed, has difficulty concentrating and carrying on conversations, and spends most of the day isolated in his or her room, sleeping in a recliner or in bed. Use of the antipsychotic medication without an adequate clinical indication, GDR attempts, and non-pharmacological approaches resulted in psychosocial harm.²⁶⁸

Weak Deterrent Effect of Citations and Penalties in a Remedial Enforcement System

Until they get a tag that bites them, nothing will change. In this industry, there is a real cost-benefit analysis. If the fine will be \$100,000, then they’ll hire the three nurse aides who will cost them about the same amount.

—Long-term care consultant in Kansas, January 2017²⁶⁹

Appropriate financial sanctions and other penalties for violations of regulatory standards are a critical element of a robust enforcement mechanism. Penalties should be commensurate to the seriousness and nature of the infraction and should seek to bring about enduring changes in practice. While the framework for a meaningful enforcement system exists, our research found that CMS and its state counterparts often impose

²⁶⁷ “Deficiency Categorization – Section 483.45(d) Unnecessary Drugs and Sections 483.45(c)(3) and (e) Psychotropic Drugs” in CMS, “Revision to State Operations Manual (SOM) Appendix PP for Phase 2, F-Tag Revisions, and Related Issues,” effective November 28, 2017, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Advance-Appendix-PP-Including-Phase-2-.pdf> (accessed September 8, 2017).

²⁶⁸ Ibid.

²⁶⁹ Human Rights Watch interview with long-term care consultant in Kansas, January 10, 2017.

penalties for serious infractions that are so low, automatically reduced, or negotiable that they do not generate meaningful pressure to address the root causes of violations.²⁷⁰

The scope and severity of harm determines the range of potential fines or civil money penalties. Consequences for facilities' noncompliance with the law fall into three categories. The first category of lightest penalties includes: directed plan of correction; state monitoring; and directed in-service training.²⁷¹ In other words, facilities suffer no financial sanction. The only consequence for noncompliance for the lowest scope and severity deficiencies is making a plan to correct the problem.

The second category of penalties includes: denial of payment for all Medicare and/or Medicaid residents; denial of payment for all new admissions; and the lower range of civil money penalties (CMPs), financial sanctions.²⁷² These penalties, if imposed, may generate financial pressure that incentivizes facilities to take seriously the problem and correct it in a lasting way.

The third category of heaviest penalties includes: termination of the provider agreement; temporary management; and the upper range of CMPs.²⁷³ This category of remedies may include transfer of residents or transfer of residents and closure of facility, at states' or CMS' discretion.²⁷⁴ Historically, government studies of CMS and state level enforcement

²⁷⁰ The most recent Office of Inspector General analysis is from many years ago, but it found that less than half of the civil money penalties imposed at that time were paid and that seventy percent of penalties received a reduction. Office of Inspector General, "Nursing Home Enforcement: The Use of Civil Money Penalties," April 2005, <https://oig.hhs.gov/oei/reports/oei-06-02-00720.pdf>. Facilities automatically obtain a 35 percent reduction in the civil money penalty imposed if it waives its right to a hearing. The opportunities to challenge a citation and its attached penalty are numerous as well. CMS, "Mandatory Immediate Imposition of Federal Remedies and Assessment Factors Used to Determine the Seriousness of Deficiencies for Nursing Homes," July 29, 2016, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-31.pdf>.

²⁷¹ CMS, "Mandatory Immediate Imposition of Federal Remedies and Assessment Factors Used to Determine the Seriousness of Deficiencies for Nursing Homes," July 29, 2016, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-31.pdf>.

²⁷² Ibid.

²⁷³ Ibid.

²⁷⁴ Ibid.; CMS, "State Operations Manual Appendix Q – Guidelines for Determining Immediate Jeopardy," February 2014, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_q_immedjeopardy.pdf; US Code, Title 42, secs. 1395i-3(h)(2)(B)(ii)(I) and 1396r(h)(2)(A)(ii); Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, US Congress, Public Law No. 114-74, <https://www.congress.gov/bill/114th-congress/house-bill/1314/text?overview=closed> sec. 701.

have found that lower levels of all types of penalties are used much more frequently than higher levels.²⁷⁵

Human Rights Watch quantitative analysis of fines assessed in all states between 2014 and 2016 found that 80 percent were less than \$10,000 and 20 percent between \$10,000 and \$100,000. As of July 2017, a citation that is “no actual harm” with potential for more than minimal harm that is widespread can garner a fine of \$405 per day or a per instance fine of \$5,000.²⁷⁶ “Actual harm” citations (Levels G, H, and I, depending on scope) can garner a fine between \$505 and \$2,055 per day and between \$10,000 and \$15,000 per instance, depending on scope. “Immediate jeopardy” level citations (Levels J, K, and L, depending on scope) can garner a fine between \$6,394 and \$10,494 per day or between \$10,000 and \$20,000 per instance, depending on scope. Only the highest level deficiency is now eligible for the top civil money penalties.²⁷⁷

Until July 2017, when CMS revised its Civil Money Penalty Tool through sub-regulatory guidance that had no public notice and comment period, CMS Regional Offices were in most cases instructed to impose a per day (that the noncompliance persisted) penalty.²⁷⁸ Generally, per day penalties are more significant.²⁷⁹ The Bipartisan Budget Act of 2015 amended the Federal Civil Penalties Inflation Adjustment Act of 1990 to allow the civil money penalty amounts set in 1987 to be adjusted for inflation for the first time.²⁸⁰

²⁷⁵ The Office of Inspector General concluded in 2005, “CMS does not utilize the full dollar range allowed for CMPs; impositions tend toward the lower ends of ranges.” Office of the Inspector General, “Nursing Home Enforcement: The Use of Civil Money Penalties,” April 2005, <https://oig.hhs.gov/oei/reports/oei-06-02-00720.pdf> (accessed September 10, 2017).

²⁷⁶ CMS, “CMP Analytic Tool: User’s Guide: Version 1.3,” appearing in CMS, “Revision of Civil Money Penalty (CMP) Policies and CMP Analytic Tool,” July 7, 2017, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-37.pdf> (accessed September 10, 2017).

²⁷⁷ Ibid.

²⁷⁸ CMS, “Civil Money Penalty (CMP) Analytic Tool and Submission of CMP Tool Cases,” December 19, 2014, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-16.pdf> (accessed September 10, 2017).

²⁷⁹ “CMA Alert – SNF Update: Comments on Reimbursement; Civil Money Penalties Weakened,” *Center for Medicare Advocacy*, <http://www.medicareadvocacy.org/cma-alert-snf-update-comments-on-reimbursement-civil-money-penalties-weakened/> (accessed September 10, 2017).

²⁸⁰ US Congress, Public Law 114-74, November 2, 2015, <https://www.congress.gov/114/plaws/publ74/PLAW-114publ74.pdf>; Annual Civil Monetary Penalties Inflation Adjustment, Code of Federal Regulations, Title 45, Part 102, effective February 3, 2017, <https://www.gpo.gov/fdsys/pkg/FR-2017-02-03/pdf/2017-02300.pdf>.

AHCA pushed for such reductions in March 2017.

Any violation in the SNF [skilled nursing facility] setting, no matter how small, is treated as a violation of the requirements of participation in Medicare and Medicaid and puts the SNF on a termination track from these programs. These violations can also result in large Civil Monetary Penalties (CMPs)... The use of CMP's is out of control.... We have seen a dramatic increase in CMPs being retroactively issued and used as a punishment.²⁸¹

The sub-regulatory guidance appears to respond to some of AHCA's specific requests.

Analysis of data on deficiencies related to antipsychotic drugs and rates of use of these medicines by nursing facilities, however, suggests that the issuance of deficiency citations without financial sanctions attached—the current situation given routine practice of assessing antipsychotic drug-related deficiencies as Level 2, with corresponding lighter penalties—has little impact on the off-label use of these medications, raising concerns about the deterrent effect of current enforcement.

To assess the impact of antipsychotic drug-related deficiency citations, we compared rates of antipsychotic drug use in people without an exclusionary diagnosis for the 4,221 unique facilities that received a cumulative 5,880 antipsychotic related deficiencies.²⁸² In the year following an antipsychotic drug-related deficiency citation, facilities reduced their antipsychotic drug use rate in people without an exclusionary diagnosis by 1.5 percentage points (see Table 3).

²⁸¹ Letter from Mark Parkinson, president and CEO, American Health Care Association, to Secretary Thomas E. Price, MD, March 9, 2017, <http://www.ihca.com/Files/Comm-Pub/AHCA-Final-Price-Ltr-3.9.17.pdf>.

²⁸² This sample was drawn from the 7,039 antipsychotic drug-related deficiencies that were assessed between January 1, 2014 and June 30, 2017. We excluded deficiencies assessed after the first quarter of 2016 as our analysis required data on antipsychotic drug use by facilities for four consecutive quarters after receiving an antipsychotic drug-related deficiency.

Citation year	Number of citations	Average percentage point change
2014	1,118	-0.55
2015	1,749	-2.43
Q1 2016	493	-1.02

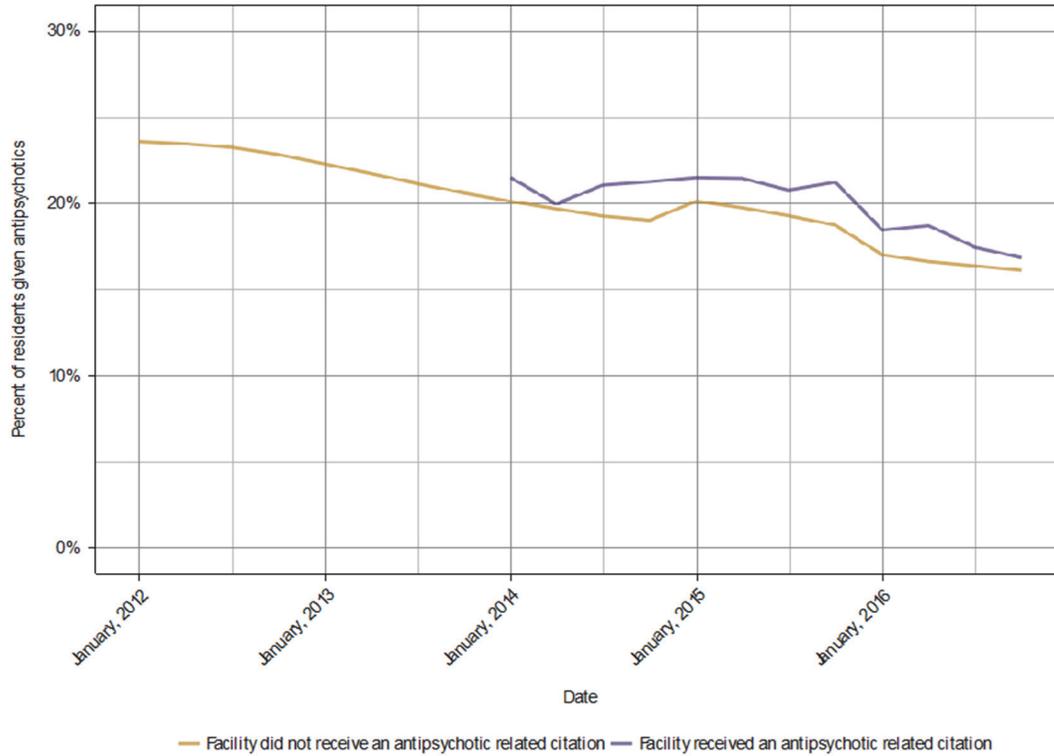
Table 3. Change in Antipsychotic Drug Use in People without an Exclusionary Diagnosis in the Year Following an Antipsychotic Drug-Related Citation

However, there was no statistically significant difference in the rate of change in antipsychotic drug use between facilities that received an antipsychotic deficiency citation and those that did not.²⁸³ Facilities reduced their antipsychotic drug use by 1.57 percentage points on average in the year following a citation, but those same facilities were already reducing their rates by 1.60 percentage points during periods where they were not cited, and facilities that were not cited at all were reducing their rates by 1.29 percentage points. Between 2014 and the first quarter of 2016, the average reduction in antipsychotic use rates was only 0.031 percentage points greater in facilities that received an antipsychotic related citation compared with those that were not cited. For detail on the statistical analysis performed, see Appendix 4.

²⁸³ ANOVA test, F value = 0.412, Pr(>F) = 0.521. We applied an Analysis of Variance (ANOVA) test to the differences between the mean rates of change in antipsychotic drug use which found that that they were not statistically significant. For more detail, see Appendix 3.

Antipsychotic related citations have minimal effect on antipsychotic use rates

Rolling 4-month average of proportion of residents given antipsychotics



Source: Human Rights Watch analysis of Nursing Home Compare data from <https://data.medicare.gov>

Graph 1. Antipsychotic Related Citations Have Minimal Effect on Antipsychotic Use Rates

Efforts to Reduce Inappropriate Use of Antipsychotic Medicines

Since 2012, the national antipsychotic drug rate among people in nursing facilities who do not have schizophrenia, Huntington’s disease, or Tourette syndrome, and most of whom have dementia, has declined from 24 percent in 2011 to 16 percent at the end of 2016.²⁸⁴ (Appendix 3 provides a graph of state reductions between 2011 and 2016.) This decline corresponds to the period since CMS established the National Partnership to Improve Dementia Care in Nursing Homes, in response to significant public and Congressional pressure to address the pervasive and dangerous excessive use of antipsychotic drugs.²⁸⁵ As no thorough evaluations have been conducted of the Partnership, it is not clear to what extent or through what mechanisms the Partnership contributed to this decline.

The Partnership sought to reduce the rate of antipsychotic drug use in nursing facilities as one way to “enhance the quality of life for people with dementia [and] protect them from substandard care and promote goal-directed, person-centered care for every nursing home resident.”²⁸⁶

The initiative primarily set voluntary targets for the industry to attempt to reduce the number of people given antipsychotic medications in violation of their rights and of federal and state regulatory requirements. Since 2016, CMS has not set any new targets for reduction. It provided educational and training materials and opportunities to help the industry attain such reduction. The initiative did not focus on informed consent.²⁸⁷

Human Rights Watch visited a number of facilities that significantly reduced levels of antipsychotic drug use in the last year. In each case, the facility had either experienced corporate pressure to reduce the percent of residents on the drug or had an administrator or director of nursing who had taken it upon him or herself to insist on the reduction—including if that meant challenging a doctor or family member. The increased industry-wide attention to the issue and having a central figure within a facility manage the reduction appeared to be critical elements of the reductions.

²⁸⁴ National Partnership to Improve Dementia Care in Nursing Homes, “National Partnership to Improve Dementia Care in Nursing Homes: Antipsychotic Medication Use Data Report (March 2017),” March 2017, https://www.nhqualitycampaign.org/files/AP_package_20170413.pdf.

²⁸⁵ CMS, “Update Report on the *National Partnership to Improve Dementia Care in Nursing Homes*,” June 3, 2016, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SC-Letter-16-28-Partnership-Update-Report.pdf> (accessed September 10, 2017); CMS, “Interim Report on the CMS National Partnership to Improve Dementia Care in Nursing Homes: Q4 2011 – Q1 2014,” April 11, 2014, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SC-Letter-14-19-Partnership-Interim-Report.pdf> (accessed September 10, 2017).

²⁸⁶ “National Partnership to Improve Dementia Care in Nursing Homes,” CMS, last updated July 27, 2017, <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/National-Partnership-to-Improve-Dementia-Care-in-Nursing-Homes.html>.

²⁸⁷ *Ibid.*

Binding Arbitration Agreements

In many contexts, individuals use civil tort lawsuits to secure accountability and redress for abuses the law does not otherwise prevent or punish. Approximately half of the country's nursing facilities ask residents (or their proxies) to sign binding arbitration agreements upon admission; some make it a condition of admission.²⁸⁸ Under these contract clauses, disputes between the facility and resident must be resolved outside of the court system. In other words, the resident “waiv[es] his or her right to judicial relief for any potential cause of action covered by the agreement.”²⁸⁹ Instead, disputes that may arise are resolved through arbitration proceedings. As is true in many other contexts, these agreements raise concerns about whether arbitration offers a fair and impartial hearing and a realistic chance at remedy.

In 2016, CMS banned the use of pre-dispute arbitration clauses, describing them as “fundamentally unfair” because “it is almost impossible for residents or their decision-makers to give fully informed and voluntary consent to arbitration before a dispute has arisen.”²⁹⁰ Instead of limiting avenues for relief in cases of violations “residents should have a right to access the court system if a dispute with a facility arises.”²⁹¹

CMS noted that “there is significant evidence that pre-dispute arbitration agreements have a deleterious impact on the quality of care for Medicare and Medicaid patients” in nursing facilities.²⁹² It also emphasized that while arbitration proceedings are widespread in the

²⁸⁸ Stephanie Francis Ward, “Judge Blocks Federal Rule that Would Ban Arbitration in Nursing Home Disputes,” *ABA Journal*, November 7, 2016, http://www.abajournal.com/news/article/judge_blocks_federal_rule_which_would_ban_arbitration_in_nursing_home_disputes. “[Attorney Joseph L. Bianculli] estimates that 50 percent of nursing homes have pre-dispute arbitration agreements with residents.”

²⁸⁹ “Section 483.70(n), Binding Arbitration Agreements,” in CMS, “Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities,” *Federal Register*, <https://www.gpo.gov/fdsys/pkg/FR-2016-10-04/pdf/2016-23503.pdf> p. 68790.

²⁹⁰ *Ibid.*, p. 68792.

²⁹¹ *Ibid.* [list from p. 68793]. See also, Tripp, Lisa, “A Senior Moment: The Executive Branch Solution to the Problem of Binding Arbitration Agreements in LTC facilities Admission Contracts”, *Campbell Law Review Symposium*, vol. 31(2) (2009); Tripp, Lisa, “Arbitration Agreements Used by LTC facilities: An Empirical Study and Critique of *AT&T Mobility v. Concepcion*”, *American Journal of Trial Advocacy*, vol. 35(87) (2011); and Bagby, K. and Souza, S., “Ending Unfair Arbitration: Fighting Against the Enforcement of Arbitration Agreements in Long-Term Care Contracts”, *Journal of Contemporary Health Law & Policy*, vol. 29 (2013).

²⁹² *Ibid.*

healthcare industry, the “significant differential in bargaining power” between residents and nursing facilities—the former depends on the latter for almost all their needs—make it “unconscionable” for such facilities to demand, as a condition of admission, that residents sign a pre-dispute agreement for binding arbitration.

In June 2017, CMS did a complete about-face, issuing a new proposed rule that not only would eliminate provisions prohibiting pre-dispute arbitration, but also would allow facilities to deny admission to a resident who refuses to sign the arbitration agreement.²⁹³

In justifying its reversal, CMS stated that the binding contracts are “advantageous to both providers and beneficiaries because they allow for the expeditious resolution of claims without the costs and expense of litigation,” adding that “this proposal is consistent with our approach to eliminating unnecessary burden on providers, and supports the resident’s right to make informed choices about important aspects of his or her healthcare.”²⁹⁴

Proposed federal tort reform legislation could pose additional obstacles to obtaining a remedy for harm. At time of writing, the House of Representatives had passed and the Senate had received H.R. 1215, the Protecting Access to Care Act of 2017, which would impose a three-year statute of limitations for individuals to sue nursing homes for harm, a \$250,000 cap on damages, and a limit on attorney contingency fees.²⁹⁵

These measures would likely not only reduce the compensation an individual might receive for serious harm or wrongful death, but also deter lawyers from taking the cases in the first place. Other proposals would limit class action lawsuits and the number of years after a harm occurs that a plaintiff could sue, whatever occurred—abuse, neglect, sexual assault—by a number of providers of medical care, including nursing facilities.²⁹⁶

²⁹³ CMS, “Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities: Arbitration Agreements,” *Federal Register*, vol. 82(109) (2017), <https://www.gpo.gov/fdsys/pkg/FR-2017-06-08/pdf/2017-11883.pdf> (accessed September 10, 2017).

²⁹⁴ *Ibid.* pp. 26650-51, 26653.

²⁹⁵ Protecting Access to Care Act of 2017, US Congress, H.R. 1215, introduced February 24, 2017 <https://www.congress.gov/bill/115th-congress/house-bill/1215/text> (accessed September 10, 2017).

²⁹⁶ Kimberly Kindy, “House Republicans Quietly Advance Changes to Tort Law,” *Chicago Tribune*, March 9, 2017, <http://www.chicagotribune.com/news/nationworld/politics/ct-house-republicans-tort-law-changes-20170309-story.html> (accessed September 10, 2017).

V. International Human Rights and US Law

Key Obligations Arising from International Human Rights Law

Torture and Other Cruel, Inhuman, and Degrading Treatment

The Convention on the Rights of People with Disabilities (CRPD), which the US has signed but not ratified, requires governments to “take all effective legislative, administrative, judicial or other measures to prevent persons with disabilities, on an equal basis with others, from being subjected to torture or cruel, inhuman or degrading treatment or punishment.”²⁹⁷ The US is not legally bound by the CRPD, but the Convention does represent an important authority on the measures the government should take to protect and improve respect for the rights of people with disabilities.²⁹⁸

In 2013, Juan Mendez, then the UN special rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, warned of the danger of human rights violations in the healthcare setting where the perception persists that “certain practices in health-care may be defended by the authorities on grounds of administrative efficiency, behaviour modification or medical necessity.”²⁹⁹

Mendez also noted that “medical treatments of an intrusive and irreversible nature, when lacking a therapeutic purpose, may constitute torture or ill-treatment when enforced or administered without the free and informed consent of the person concerned.” He also emphasized that an act may constitute ill-treatment, even if it is “intended to benefit the ‘patient’” and may “exist alongside ostensibly therapeutic aims.”

²⁹⁷ Convention on the Rights of Persons with Disabilities (CRPD), adopted December 13, 2006, G.A. Res. 61/106, Annex I, U.N. GAOR, 61st Sess., Supp. (No. 49) at 65, U.N. Doc. A/61/49 (2006), art. 15.

²⁹⁸ As a signatory of the Convention, the US is also obliged to refrain actions that would defeat the “object and purpose” of the treaty. Vienna Convention on the Law of Treaties, adopted May 23, 1969, United Nations, Treaty Series, vol. 1155, p. 331, entered into force January 27, 1980, art. 18.

²⁹⁹ Human Rights Council, Report of the special rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, Juan E. Méndez, A/HRC/22/53, February 1, 2013, http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session22/A.HRC.22.53_English.pdf para. 28.

Mendez stated that this rights violation is particularly likely to occur when the “treatments are performed on patients from marginalized groups, such as persons with disabilities, notwithstanding claims of good intentions or medical necessity.”³⁰⁰ The use of a “prolonged restraint” may constitute torture and ill-treatment; when used against people with mental disabilities, “even a short period of time may constitute torture and ill-treatment.”³⁰¹

The Right to Health and Informed Consent

The highest attainable standard of physical and mental health is a fundamental human right enshrined in numerous international human rights instruments, including the Universal Declaration of Human Rights, the International Covenant on Economic, Social, and Cultural Rights, and the CRPD. The special rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health has expressed that informed consent “is a core element of the right to health, both as a freedom and an integral safeguard to its enjoyment.”³⁰²

In the words of the special rapporteur on the right to health:

Informed consent is not mere acceptance of a medical intervention, but a voluntary and sufficiently informed decision, protecting the right of the patient to be involved in medical decision-making, and assigning associated duties and obligations to health-care providers. Its ethical and legal normative justifications stem from its promotion of patient autonomy, self-determination, bodily integrity and well-being.³⁰³

³⁰⁰ Ibid., para. 32.

³⁰¹ Ibid.

³⁰² Human Rights Council, Report of the special rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Dainius Puras, A/HRC/35/21, March 28, 2017, <https://documents-dds-ny.un.org/doc/UNDOC/GEN/G17/076/04/PDF/G1707604.pdf?OpenElement> (accessed September 10, 2017), para. 63.

³⁰³ United Nations General Assembly, Report of the special rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/64/272, August 10, 2009, <http://www.refworld.org/docid/4aa762e30.html> (accessed September 10, 2017), para. 9; 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, http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session22/A.HRC.22.53_English.pdf para. 28.

Informed consent is fundamental to “respecting an individual’s autonomy, self-determination and human dignity.”³⁰⁴

The special rapporteur on the right to health called on States to:

[R]adically reduce medical coercion..., [and] not to permit substitute decision-makers to provide consent on behalf of persons with disabilities on decisions that concern their physical or mental integrity; instead, support should be provided at all times for them to make decisions, including in emergency and crisis situations.³⁰⁵

However, the special rapporteur acknowledged that such change “is a challenging process that will take time” and emphasized the importance of taking intermediary steps:

- (a) Mainstream alternatives to coercion in policy with a view to legal reform;
- (b) Develop a well-stocked basket of non-coercive alternatives in practice;
- (c) Develop a road map to radically reduce coercive medical practices, with a view to their elimination, with the participation of diverse stakeholders, including rights holders;
- (d) Establish an exchange of good practices between and within countries;
- (e) Scale up research investment and quantitative and qualitative data collection to monitor progress towards these goals.³⁰⁶

Key Domestic Legal Protections

US federal and state laws protect against abuse and neglect in skilled nursing facilities, primarily through the Nursing Home Reform Act of 1987 and associated regulations.³⁰⁷

³⁰⁴ 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, http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session22/A.HRC.22.53_English.pdf para. 28.

³⁰⁵ Human Rights Council, Report of the special rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Dainius Puras, March 28, 2-17, <https://reliefweb.int/sites/reliefweb.int/files/resources/G1707604.pdf> para. 65.

³⁰⁶ *Ibid.*

³⁰⁷ “7000 – Introduction” in CMS, “State Operations Manual: Chapter 7 – Survey and Enforcement Process for Skilled Nursing Facilities and Nursing Facilities,” September 2016, <https://www.cms.gov/Regulations-and->

Some of these protections on the quality of care and quality of life a person is entitled to receive while living in a nursing facility are listed explicitly as “resident rights.”³⁰⁸ Many enumerated rights pertain to antipsychotic medications, discussed below; they also provide for the context of broader care planning based on every individual’s goals and preferences.

These latter rights include: the facility’s promotion of residents’ dignity; the provision of activities to meet individual needs; the provision of medically-related social services; resident assessments as the foundation for all care comprehensive care planning that involves the resident; professional quality services; availability of psychosocial services; sufficient nursing staff; care supervised by a physician; pharmacist reviews of drug regimens; effective administration of facilities; competence of nursing staff; and facilities’ supervision by a medical director.³⁰⁹

Other federal and state laws address the protection of people’s rights when living in a nursing facility. Federal laws include the Americans with Disabilities Act, since anyone eligible to live in a nursing facility meets the definition of having a disability, and the Civil Rights of Institutionalized Persons Act, though only for the minority of individuals living in publicly-owned nursing facilities.³¹⁰ State laws concerning nursing facilities’ regulation and residents’ rights generally emulate the federal law while setting out distinct provisions on some issues that nonetheless comply with federal minimum standards.

Guidance/Guidance/Manuals/Downloads/som107co7.pdf (accessed September 10, 2017); CMS, “State Operations Manual: Appendix P – Survey Protocol for Long Term Care Facilities – Part I,” June 2016, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_p_ltcf.pdf (accessed September 10, 2017); 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf>; CMS, “State Operations Manual: Appendix Q – Guidelines for Determining Immediate Jeopardy,” February 2014, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_q_immedjeopardy.pdf (September 10, 2017).

³⁰⁸ Resident Rights, Code of Federal Regulations, Title 42, <https://www.law.cornell.edu/cfr/text/42/483.10> sec. 483.10.

³⁰⁹ Requirements for, and Assuring Quality of Care in, Skilled Nursing Facilities, Code of Federal Regulations, Title 42, <https://www.law.cornell.edu/uscode/text/42/1395i-3> sec. 1395i-3; 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf>.

³¹⁰ Civil Rights of Institutionalized Persons Act, Code of Federal Regulations, Title 42, <https://www.justice.gov/crt/civil-rights-institutionalized-persons> sec. 1997 et seq.

Freedom from Chemical Restraints, a Form of Abuse, and Unnecessary Drugs

Federal and state laws protect individuals in nursing facilities from chemical restraints and other forms of abuse. US regulations also prohibit the use of any unnecessary drugs, including antipsychotic drugs, in nursing facilities even if they do not amount to chemical restraints.³¹¹

Regulations particular to psychotropic drugs mandate that any prescription for someone not already taking such medication must be “necessary to treat a specific condition as diagnosed and documented in the clinical record”; and anyone given psychotropic medications must “receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.”³¹² For antipsychotic drugs, gradual dose reduction must be attempted twice in the first year of administration and annually thereafter.³¹³

Informed Consent and Right to Refuse Treatment

The Nursing Home Reform Act does not provide for express, written informed consent. However, it provides for the right to be fully informed of one’s health status; the right to participate in treatment planning; the “right to be informed in advance, by the physician or other practitioner or professional, of the risks and benefits of proposed care, of treatment and treatment alternatives or treatment options and to choose the alternative or option he or she prefers”; and the right to refuse treatment.³¹⁴

³¹¹ 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf> sec. 483.45.

³¹² 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf> sec. 483.45(e).

³¹³ “Medication Management: Tapering of a Medication Dose/Gradual Dose Reduction (GDR): Considerations Specific to Antipsychotics,” in 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/Guidance/Transmittals/2017Downloads/R168SOMA.pdf> sec. 483.45.

³¹⁴ Resident Rights, Code of Federal Regulations, Title 42, <https://www.law.cornell.edu/cfr/text/42/483.10> sec. 483.10(c).

Most state laws do not expressly require written informed consent prior to the administration of antipsychotic drugs to individuals in nursing facilities.³¹⁵ However, some state laws do, and in all states, this right should be protected by a combination of nursing home laws and state civil tort statutes. Texas, California, and Illinois are examples of states that require informed consent explicitly, although without a private right of action as a basis to sue if this right is violated. The Texas Health & Safety Code provides for the right to “refuse to consent to the prescription of psychoactive medications;” sets out the requirements for informed consent, including its voluntary and revocable nature and the information that must be provided, and its documentation; and establishes the limited circumstances where it is not required.³¹⁶

California’s Patients’ Rights article states: “Patients shall have the right ... to consent to or to refuse any treatment or procedure,” including to receive all relevant information for making the decision.³¹⁷ For psychotherapeutic drugs specifically, the informed consent discussion must include the reason for the treatment, nature of the intervention including the duration, likely benefit with and without treatment, side effects and risks, reasonable alternatives, and the patient’s right to accept, refuse, and revoke consent.³¹⁸

Illinois’s Nursing Home Reform Law provides that psychotropic medication, including antipsychotic drugs, “shall not be prescribed without the informed consent of the resident, the resident’s guardian, or other authorized representative.”³¹⁹ Informed consent requires

³¹⁵ See generally, Richard J. Mollot, et al., “Informed Consent Rights in U.S. Nursing Homes: An Overview of State & Federal Requirements,” 2013, http://www.ltccc.org/publications/documents/lccc-rpt-informed-consent-laws-sept2013_001.pdf.

³¹⁶ Texas Health & Safety Code, Texas State Legislature, <http://www.statutes.legis.state.tx.us/Docs/HS/htm/HS.242.htm> (accessed September 10, 2017) secs. 242.501(a)(23) and 242.505.

³¹⁷ Patients’ Rights, California Code of Regulations, Title 22, sec. 72527, [https://govt.westlaw.com/calregs/Document/l71F6A1A0A39811E08822C131FF5E2170?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=\(sc.Default\)](https://govt.westlaw.com/calregs/Document/l71F6A1A0A39811E08822C131FF5E2170?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=(sc.Default)), and Informed Consent Requirements, sec. 72528, [https://govt.westlaw.com/calregs/Document/l4C2C6C005F7B11DFBF84F211BF18441D?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=\(sc.Default\)](https://govt.westlaw.com/calregs/Document/l4C2C6C005F7B11DFBF84F211BF18441D?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=(sc.Default)). See also, “Licensing & Certification: Frequently Asked Questions (FAQ) – Informed Consent,” California Department of Public Health, <https://archive.cdph.ca.gov/programs/LnC/Pages/FAQ-InformedConsent.aspx> (accessed September 10, 2017).

³¹⁸ Ibid.

³¹⁹ Nursing Home Care Act, Illinois General Assembly, <http://www.ilga.gov/legislation/ilcs/ilcs4.asp?DocName=021000450HArt%2E+II+Pt%2E+1&ActID=1225&ChapterID=21&SeqStart=4200000&SeqEnd=6350000> (accessed September 10, 2017) secs. 2-104 and 2-106.1(b).

a discussion between the individual concerned or his or her representative and the physician, pharmacist, or nurse regarding the “possible risks and benefits of a recommended medication,” documented in a standard fashion.³²⁰

New York and Florida are examples of states with laws that expressly mimic the federal law. New York’s statute provides that individuals in nursing facilities have the right to “be fully informed of his or her medical condition and proposed treatment..., and to refuse medication and treatment after being fully informed of and understanding the consequences of such actions.”³²¹

Florida’s statute provides for nursing home residents’ right to “be adequately informed of his or her medical condition and proposed treatment,” the right to “be fully informed in advance of any nonemergency changes in care or treatment,” and the right to “participate in the planning of all medical treatment, including the right to refuse medication and treatment.”³²²

Kansas is an example of a state that does not require informed consent. Its administrative regulations for all adult care homes, including nursing facilities, provide for the right to “refuse treatment” only.³²³ Kansas and states like it are bound by federal requirements.

³²⁰ Ibid.

³²¹ Rights of Patients in Certain Medical Facilities, New York Public Health Law, New York State Legislature, <http://codes.findlaw.com/ny/public-health-law/pbh-sect-2803-c.html> (accessed September 10, 2017) sec. 2803(c)(3)(e). New York State Assemblyman Richard Gottfried has introduced a bill to require express, written informed consent: “This bill would require that before such drugs are ordered for a patient residing in a nursing home or an adult care facility, the patient or their lawful surrogate be fully informed of the nature and seriousness of his or her condition, the anticipated benefit from the medication, the dosage and duration of the prescription, the probability, nature and degree of side effects, the reasonable alternatives to the drug and why the health care professional prefers the drug in this instance, and that the patient has the right to refuse consent for the drug, or later to revoke their consent. The consent would be written.” See, Gottfried, “Memorandum in Support of Legislation, Bill A5332,” New York State Assembly, http://assembly.state.ny.us/leg/?default_fld=&bn=A5332&term=2017&Memo=Y.

³²² Nursing Homes and Related Health Care Facilities, Florida Statutes, Florida State Legislature, Title 29, cap. 400, http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&URL=0400-0499/0400/0400.html (accessed September 10, 2017) secs. 400.022(j)-(k).

³²³ Resident Rights in Adult Care Homes, Kansas Statutes Annotated, Kansas State Legislature, <https://www.kdads.ks.gov/docs/default-source/General-Provider-Pages/provider-statutes-and-regulations/ksa-and-kar-for-adult-care-homes/nursing-facilities-2015.pdf?sfvrsn=2> (accessed September 10, 2017) sec. 26-39-103(f)(3).

Americans with Disabilities Act

Based on the admission criteria for skilled nursing facilities and nursing facilities, almost all nursing facility residents are protected by the Americans with Disabilities Act (ADA) of 1990.³²⁴ The ADA defines disability as: “a physical or mental impairment that substantially limits one or more major life activities” or “a record of such an impairment.”³²⁵ A disability under this law could also be merely “being regarded as having such an impairment ... whether or not the impairment limits or is perceived to limit a major life activity,” so long as the impairment is not “transitory” (lasting six months maximum) or “minor.”³²⁶

The US Attorney General has jurisdiction to enforce the ADA: to prosecute the violation of the rights of people with disabilities articulated under it. However, it does not have exclusive jurisdiction; private individuals may sue as well. Anyone who has been “subjected to discrimination on the basis of disability ... may institute a civil action for preventive relief, including an application for a permanent or temporary injunction, restraining order, or other order.”³²⁷ The ADA has not been employed frequently to protect the rights of older people in nursing facilities. However, it is a relevant legal protection for people with dementia.

³²⁴ Americans with Disabilities Act of 1990, as Amended, US Congress, Title 42, cap. 126, <https://www.ada.gov/pubs/adastatuteo8.htm> (accessed September 10, 2017).

³²⁵ *Ibid.*

³²⁶ *Ibid.*, sec. 12102.

³²⁷ Private Suits, Code of Federal Regulations, Title 28, part 36, <https://www.ada.gov/reachingout/t3regl9.html> (accessed September 10, 2017) sec. 36.501.

Recommendations

To the Centers for Medicare & Medicaid Services

- Strengthen enforcement of existing regulatory requirements in conjunction with contracted state agencies to end all inappropriate use of antipsychotic medication in nursing facilities, including when the medication would be an “unnecessary drug;” when it would amount to a chemical restraint; when it would be inconsistent with other regulatory requirements; and when it is not based on free and informed consent (or functionally equivalent legal requirements that are framed in different terms).

To the United States Congress

- Reintroduce and pass S. 3604, “Improving Dementia Care Treatment for Older Adults Act of 2012,” to amend Title XVIII and Title XIX of the Social Security Act to require standardized protocol for obtaining written, free, and informed consent from an older person with dementia prior to prescribing an antipsychotic drug or from the person’s representative as appropriate.
- Reintroduce and pass H.R. 952, “Put a Registered Nurse in the Nursing Home Act of 2015,” to amend Title XVIII and Title XIX of the Social Security Act to require nursing facilities to use the services of at least one registered professional nurse 24 hours a day, seven days a week, to provide assessment, surveillance, and direct care to residents.

Until the inappropriate use of antipsychotic medications in older people with dementia in nursing facilities ceases completely, the following entities should take interim steps to contribute to the drastic and immediate reduction in inappropriate, sometimes coercive, and irreversibly harmful, uses of the medications:

To the Federal Government

To the Centers for Medicare & Medicaid Services

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.

To the US Department of Justice

For Enforcement Efforts Specific to Antipsychotic Medications, and for General Enforcement to Protect Residents' Rights and Wellbeing:

- Increase investigation and enforcement of nursing facilities, nursing facility chains, pharmaceutical companies, and individual pharmacists and providers under the Americans with Disabilities Act; Civil Rights of Institutionalized Persons Act; False Claims Act; and Food, Drug, and Cosmetic Act, among other legal bases of authority.
- Increase attention to inappropriate and nonconsensual uses of antipsychotic drugs within the Elder Justice Initiative efforts to combat the delivery of grossly substandard care.
- Expand efforts of the Elder Justice Task Forces beyond the first 10 regions to improve cooperation among more states' US attorneys' offices, state Medicaid fraud control units, state and local prosecutors' offices, the US Department of Health and Human Services, state adult protective services agencies, state long-term care ombudsman programs, and law enforcement to protect the rights of all individuals in nursing facilities.

To State Governments

To State Legislatures

For Free and Informed Consent:

- Pass legislation to require written, free, and informed consent prior to the administration of antipsychotic medications to individuals in state-licensed nursing facilities, ensuring that the violation of this right is actionable under state law by providing a private right of action and that individuals in need of support for decision-making are afforded it.
- Expand supported decision-making measures and amend relevant statutes to require that supported decision-making processes and supports be available and used as appropriate for people who need support to exercise their right to free and informed consent.
- Take steps to minimize and ultimately reduce to zero the number of individuals in nursing facilities who are deprived of their legal capacity, formally or informally, requiring outreach where appropriate to those who know the individual and can assist, formally or informally, with decision-making.

- Pass legislation to ensure that an individual’s treating physician is not the same person authorized to make a capacity determination and determine subsequent treatment.

For Adequate Minimum Staffing:

- Pass legislation establishing stronger minimum nurse staffing levels and qualifications. Alternatively, pursue other measures to ensure staffing is adequate to provide all residents with necessary care to achieve their *highest* practicable wellbeing.

For Enforcement Specific to Antipsychotic Medications:

- Eliminate statutory provisions that curtail enforcement for lower level citations.
- Pass legislation to require nursing facilities to adopt, implement, and enforce a policy requiring any employee providing direct care to an individual with Alzheimer’s disease or other forms of dementia to complete a training on providing care to meet their needs.

For General Enforcement to Protect Residents’ Rights and Wellbeing:

- Pass legislation to require more significant state civil money penalties and fines instead of adhering to the federal minimum ranges, with a focus on abuse and neglect.

To State Attorneys General Offices, State Departments on Aging, Disability, Elder Affairs, and Public Health, and Other State Agencies

For Free and Informed Consent:

- Provide resources to assist nursing facilities to connect residents with supported decision-making resources, and require nursing facilities to post this information inside facilities, as it does with long-term care ombudsman services posters.
- Take measures to maximize the use of advanced directives, living wills, and, as appropriate, proxies or surrogates.
- Conduct public service message campaigns to ensure that individuals know that they have the right to informed consent, including with regard to the administration of antipsychotic drugs and other nonemergency medical interventions.

For Enforcement Specific to Antipsychotic Medications

- Keep track of facilities and chains using antipsychotic drugs at higher than average rates or struggling to reduce their rate of use to provide additional oversight, or take other appropriate action to protect the rights of residents at heightened risk of nonconsensual and inappropriate uses of antipsychotic drugs.

For General Enforcement to Protect Residents' Rights and Wellbeing:

- Require Medicaid fraud control units to investigate and prosecute abuse, including the use of chemical restraints, and neglect in nursing facilities.

To State Long-Term Care Ombudsman Programs

For Enforcement Specific to Antipsychotic Medications:

- Ensure that in facilities with significant percentages of residents receiving antipsychotic drugs without an exclusionary diagnosis and in facilities where individuals appear at risk of being given antipsychotic drugs without their consent or as chemical restraints, volunteer and staff ombudsmen provide general information to *all* residents, families, and staff regarding the right to be fully informed about treatment; the right to refuse treatment; and the right to informed consent in states that provide for it. Consider disseminating publicity information produced by CMS, advocacy organizations, AHCA, and others on antipsychotic drugs in people with dementia.

For General Enforcement to Protect Residents' Rights and Wellbeing:

- Fulfill obligation under Older Americans Act to “analyze, comment on, and monitor the development and implementation” of all local, state, and federal law, regulation, policy and actions pertaining to residents’ rights; recommend appropriate changes; facilitate public comment; and “provide leadership to statewide systems advocacy efforts ... on behalf of long-term care facility residents.”
- Ensure regional, staff, and volunteer ombudsmen understand that their mandate and responsibility under the Older Americans Act is not to mediate disputes between residents and nursing facilities but to “*represent the interests of residents before governmental agencies*” and ensure residents’ access to “administrative, legal, and other remedies *to protect the health, safety, welfare, and rights of residents.*”

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Appendix I: Glossary

Health Conditions

Dementia	A progressive, degenerative brain disease associated with loss of memory and other cognitive abilities that tends to occur in older age.
Alzheimer’s disease	The most common form of dementia.
Behavioral and psychological symptoms of dementia (BPSD)	Neuropsychiatric symptoms that appear in most people with dementia such as agitation, movement disorders, anxiety, elation, irritability, depression, apathy, disinhibition, and psychosis. They can be triggered by environmental, social, psychological, and biological factors and are often treated with drug-based and non-drug interventions.
Exclusionary diagnosis	The term used by federal government agencies, including the Centers for Medicare & Medicaid Services and US Government Accountability Office, to identify neurological and psychiatric diagnoses—schizophrenia, Huntington’s disease, Tourette syndrome, and initially but not currently bipolar disorder—for which antipsychotic drugs are approved in order to exclude them from calculations of the scope of potentially inappropriate antipsychotic drug use in nursing homes.
Schizophrenia	A chronic mental disorder with onset typically between the ages of 16 and 30 that is associated with hallucinations, delusions, dysfunctional thinking, movement disorders, and/or a “flat” affect, possibly caused by imbalances in the neurotransmitters dopamine and glutamate.
Bipolar disorder	A chronic brain disorder, also called manic-depressive illness, that causes unusual changes in mood, energy, and

activity levels, affecting sleep and the ability to perform daily activities, and that can be accompanied by psychotic symptoms like hallucinations and delusions.

Huntington's disease A rare genetic disorder causing progressive nerve cell breakdown in the brain with typical onset between the ages of 30 and 50. It is associated with personality changes, impaired judgment, memory loss, movement disorders, and slurred speech.

Tourette syndrome A rare neurological disorder associated with involuntary movements and vocalizations with typical onset between the ages of three and nine.

Medications

Nonpharmacologic interventions for BPSD Treatment that excludes the use of medications. Instead, treatment is based on ruling out underlying or environmental causes of pain, distress, or unusual behavior. For symptoms of dementia, nonpharmacologic interventions often include behavioral and mood therapy, exercise, creating sleep and other daily routines, reducing boredom or loneliness, and ensuring consistent caregiver interactions.

Psychotropic drugs Also called psychopharmacological medications or psychoactive or psychodynamic drugs, a class of medications affecting the brain, including antipsychotic drugs, anti-depressants, anti-anxiety drugs, and hypnotics.

Antipsychotic drugs A class of psychotropic medications that blocks dopamine receptors, a neurotransmitter, in the brain. The first generation of these drugs, termed conventional antipsychotics, was developed in the 1950s and originally used to treat schizophrenia. Examples include Haldol (haloperidol), Loxitane (loxapine), Mellaril (thioridazine),

and Thorazine (chlorpromazine). The second generation, termed atypical antipsychotics, were developed in the 1980s and in some cases are thought to have lesser side effects than conventional antipsychotics. Examples include Abilify (aripiprazole), Zyprexa (olanzapine), Seroquel (quetiapine), and Risperdal (risperidone). Antipsychotic drugs are approved to treat or manage symptoms of various forms of schizophrenia, bipolar disorder, agitation, psychotic disorders, Tourette syndrome, anxiety, autism, and depression. Though unapproved for the purpose, antipsychotic drugs are often used in people with dementia. Side effects include neuroleptic malignant syndrome, a life-threatening reaction associated with severe muscular rigidity, fever, and altered mental status; tardive dyskinesia, characterized by stiff, jerking movements that may be permanent once they start; high blood sugar; low blood pressure; stroke; heart failure; blood clots; movement disorders; and visual disturbances, among others. Antipsychotic drugs carry boxed warnings for use in older people with dementia due to an increased risk of mortality.

Off-label use

The common and legal practice of prescribers writing prescriptions for approved drugs not approved for the particular use, condition, age group, dose, or form in which it is being prescribed. Antipsychotic drugs prescribed to treat symptoms of dementia is an off-label use.

**Black box warning;
Boxed warning**

The strongest warning that the Food and Drug Administration can require drug manufacturers to include on product labels to call attention to severe or life-threatening risks or adverse drug reactions associated with the drug for particular uses or in particular demographics.

Long-Term Care Industry

Skilled nursing facility A nursing home or part of a nursing home usually certified by Medicare and/or Medicaid to provide skilled, often rehabilitative, short-term care after a minimum three-day hospital stay. By law, the quality of care and services must be sufficient for recipients to attain or maintain their highest practicable physical, mental, and psychosocial wellbeing.

Nursing facility Used in the report to designate any nursing home (including skilled nursing facilities). Technically, it is a nursing home or part of a nursing home that meets certain health and safety requirements to be certified by Medicaid and that provides long-term care, including health care and assistance with daily living, that cannot be provided in the community, and that is sufficient for recipients to attain or maintain their highest practicable physical, mental, and psychosocial wellbeing. Nursing facilities provide nursing services, specialized rehabilitative services, medically-related social services, pharmaceutical services, dietary services, emergency dental services, and others. States must make nursing facilities available to people aged 21 and older, although they predominantly serve older people.

Assisted living facility A form of institutional long-term care regulated only at the state level that does not provide medical services or as intensive support for activities of daily living compared to those provided by nursing homes.

Medicare The primary provider of health insurance to people aged 65 and older in the US. It includes four parts: Parts A, B, C, and D, covering hospital insurance (including the first 100 days in a skilled nursing facility), medical insurance (such as doctors, outpatient care, medical equipment, and preventive services), private companies' health plans (Medicare

Advantage), and prescription drugs (including long-stay nursing facility residents' drug prescriptions), respectively.

Medicaid The primary public health insurance program in the US for people with low incomes, jointly administered by the federal government and the states. It is the primary payer for long-term care.

Private insurance In this context, payment for a nursing facility stay not based on Medicare, Medicaid, or other source of public insurance.

Private pay In this context, payment for a nursing facility stay not based on insurance.

Long-term care: The provision of supports and services for individuals with disabilities or older people who require health care-related assistance or assistance with activities of daily living. Long-term care may be provided in the home, in the community or in institutional settings, such as board and care homes (usually six-bed maximum), residential care facilities like assisted living, and senior housing or retirement communities. None of these long-term care options is regulated in the same manner as skilled nursing facilities and nursing facilities, and none provides the same level of medical care as skilled nursing facilities.

Nursing Home Enforcement

Nursing Home Reform Act of 1987 A part of the 1987 Omnibus Budget Reconciliation Act, the federal law that amended the Social Security Act to regulate skilled nursing facilities and nursing facilities and established a residents' bill of rights. Associated federal regulations promulgated by the US Department of Health and Human Services, revised in 2016, set out comprehensive and detailed minimum health and safety standards as well as the

parameters of federal and state enforcement of the federal regulations.

Centers for Medicare & Medicaid Services (CMS)

The agency within the US Department of Health and Human Services responsible for, among other things, regulating and conducting enforcement, usually through state counterparts, of the skilled nursing facility and nursing facility industry.

Food and Drug Administration (FDA)

The agency within the US Department of Health and Human Services responsible for, among other things, approving drugs based on evaluations of safety and effectiveness, and for requiring drug manufacturers to include certain information and warnings on product labels. The FDA does not regulate providers' prescription practices once a drug is approved for marketing.

F-tag

The term used to identify each of more than 150 criteria that federal and state inspectors evaluate in their annual and complaint-based surveys of nursing facilities certified by Medicare and Medicaid: the primary means of conducting enforcement. F-tags are related to the rights to be from abuse, neglect, and exploitation; admission, transfer, and discharge rights; resident assessment procedures and care planning; quality of life standards; quality of care standards; physician, nursing, behavioral health, pharmacy, laboratory, dental, food, and rehabilitative services; nursing home administration; emergency preparedness; quality assurance; infection control; physical environment; and other subjects.

Deficiency citation

Federal and state inspectors' indication of noncompliance with federal regulations; the main method of conducting enforcement of the industry. Deficiency citations may be issued for any F-tag at one of three "scopes"—isolated, pattern, or widespread—and one of four "severity" levels: "no actual harm with only potential for minimal harm"; "no

actual harm with potential for more than minimal harm” (“results in no more than minimal physical, mental and/or psychosocial discomfort to the resident and/or has the potential (not yet realized) to compromise the resident’s ability to maintain and/or reach his/her highest practicable physical, mental and/or psychosocial well-being”); “actual harm” (“results in a negative outcome that has compromised the resident’s ability to maintain and/or reach his/her highest practicable physical, mental and psychosocial well-being”); and “immediate jeopardy”.

Immediate jeopardy

The most serious type of deficiency citation for noncompliance with federal regulations that “has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.” Immediate jeopardy deficiency citations may be triggered by neglect and by psychological harm, which, according to regulatory guidance, is treated just as seriously as physical harm. Immediate jeopardy deficiency citations merit the most severe penalties or “remedies,” including the termination of the provider agreement or temporary management of the facility within 23 calendar days if the immediate jeopardy finding is not removed.

Unnecessary drugs

Any drug when used in excessive dose, including as a duplicative drug therapy; for excessive duration; without adequate monitoring; without adequate indications for use; or in the presence of adverse consequences indicating dose should be reduced or discontinued.

Chemical restraint

Any drug used for discipline or staff convenience and not required to treat medical symptoms, where convenience means the result of any action that has the effect of altering a resident’s behavior such that the resident requires a lesser amount of effort or care and that is not in the resident’s best

interest. Discipline means any action by facility staff for the purpose of punishing or penalizing residents.

**Civil money penalty;
Civil monetary penalty
(CMP)** A monetary penalty that the Centers for Medicare & Medicaid Services may impose against skilled nursing facilities and nursing facilities for every day or every instance (of any duration) of substantial noncompliance with federal regulations (specifically, the Medicare and Medicaid requirements of participation for long-term care facilities). A portion of CMPs collected are returned to the state to reinvest in the industry, according to established parameters. They are the main sanction at the government's disposal to incentivize the industry to comply with the law.

Staff

Administrator The person licensed to be responsible for skilled nursing facilities' and nursing facilities' compliance with federal regulatory standards; not necessarily a person with any medical or nursing knowledge.

Medical director A physician responsible for overseeing and coordinating the medical care provided in a nursing facility, consistent with professional standards of practice. Medical directors may serve as attending physicians for individuals in their nursing facilities as well.

**Director of Nursing
(DON)** A registered nurse who is required to work at least 35 hours per week unless the facility receives a waiver of this requirement for skilled nursing facilities and nursing facilities to oversee all nursing services.

**Certified Nursing
Assistant;
Certified Nurse Aide
(CNA)** A person who has been deemed competent after successfully completing a nurse aide training or a competency evaluation program (or who is contemporaneously enrolled in such a program and is a

permanent employee of a nursing home in his or her first four months of employment in the facility). CNAs provide the vast majority of nursing services and assistance with daily care needs to residents of nursing homes: feeding residents; turning, positioning, and transferring residents; bathing and toileting residents; and administering other medical treatments under nurse supervision and physician orders, as appropriate.

Appendix 2: Key Data on States and Facilities Visited

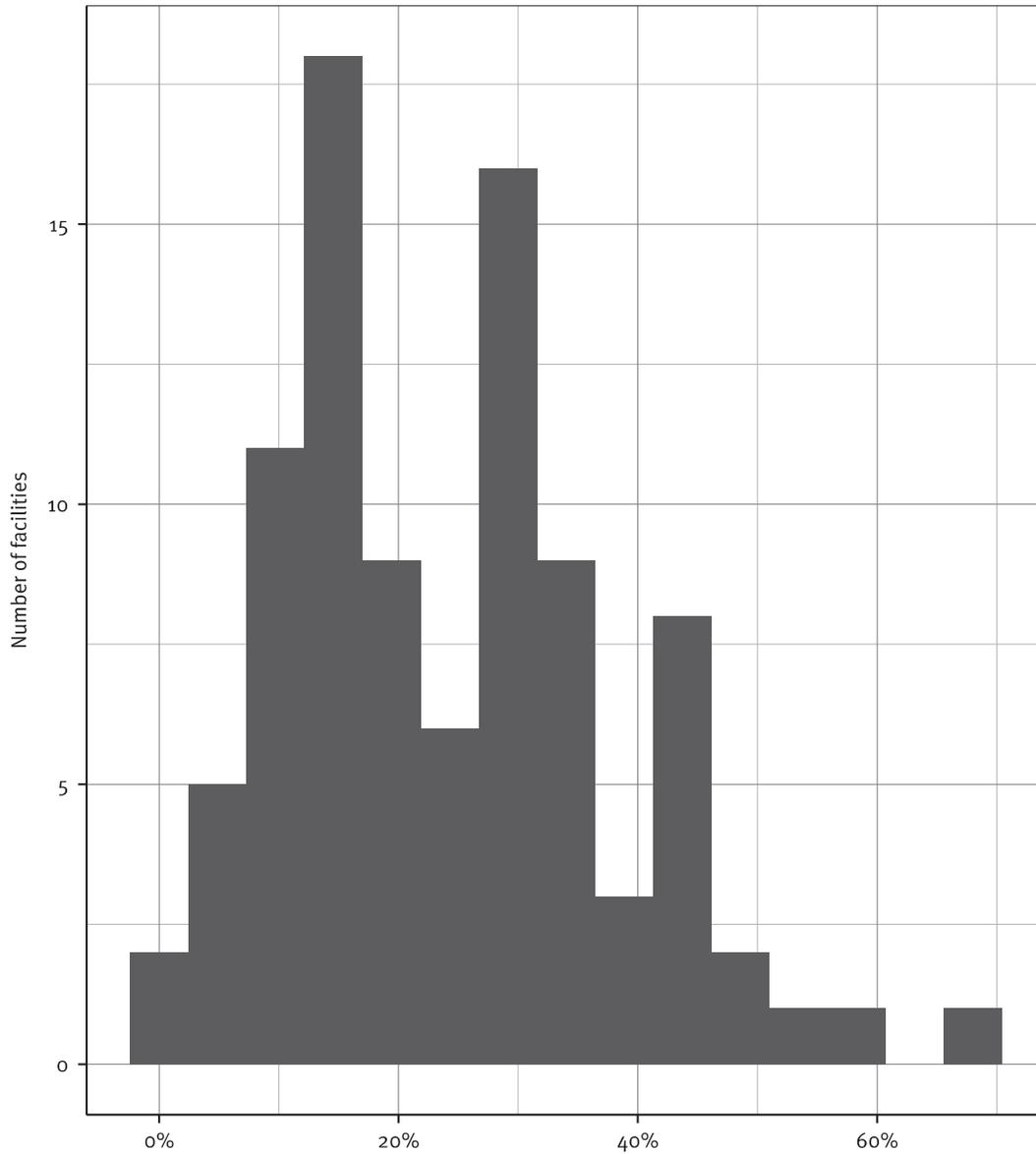
State	Total # of nursing facilities in 2014	Total # of nursing facility residents in 2014	# of long-stay residents in nursing facilities with a majority population >65 taking antipsychotic drugs without an exclusionary diagnosis	National ranking in terms of # of residents in nursing facilities with majority population >65 taking antipsychotic drugs without an exclusionary diagnosis	Percentage of total population in nursing facilities with majority population >65 taking antipsychotic drugs without an exclusionary diagnosis
California	1,219	106,523	8,948	5	11%
Florida	689	76,985	10,623	4	17%
Illinois	762	74,576	8,788	6	17%
Kansas	344	18,424	2,550	27	18%
New York	629	108,291	11,999	2	14%
Texas	1,212	98,413	13,867	1	18%

Table 4. Key Data on Nursing Facilities, Residents of Nursing Facilities, and Antipsychotic Drug Use in States Visited by Human Rights Watch³²⁸

³²⁸ Data from Centers for Medicare & Medicaid Services (CMS), “Nursing Home Data Compendium 2015 Edition,” 2015, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Downloads/nursinghomedatacompendium_508-2015.pdf (accessed September 11, 2017) pp. 22, 199.

Facilities Visited by Human Rights Watch

Proportion of residents given antipsychotics



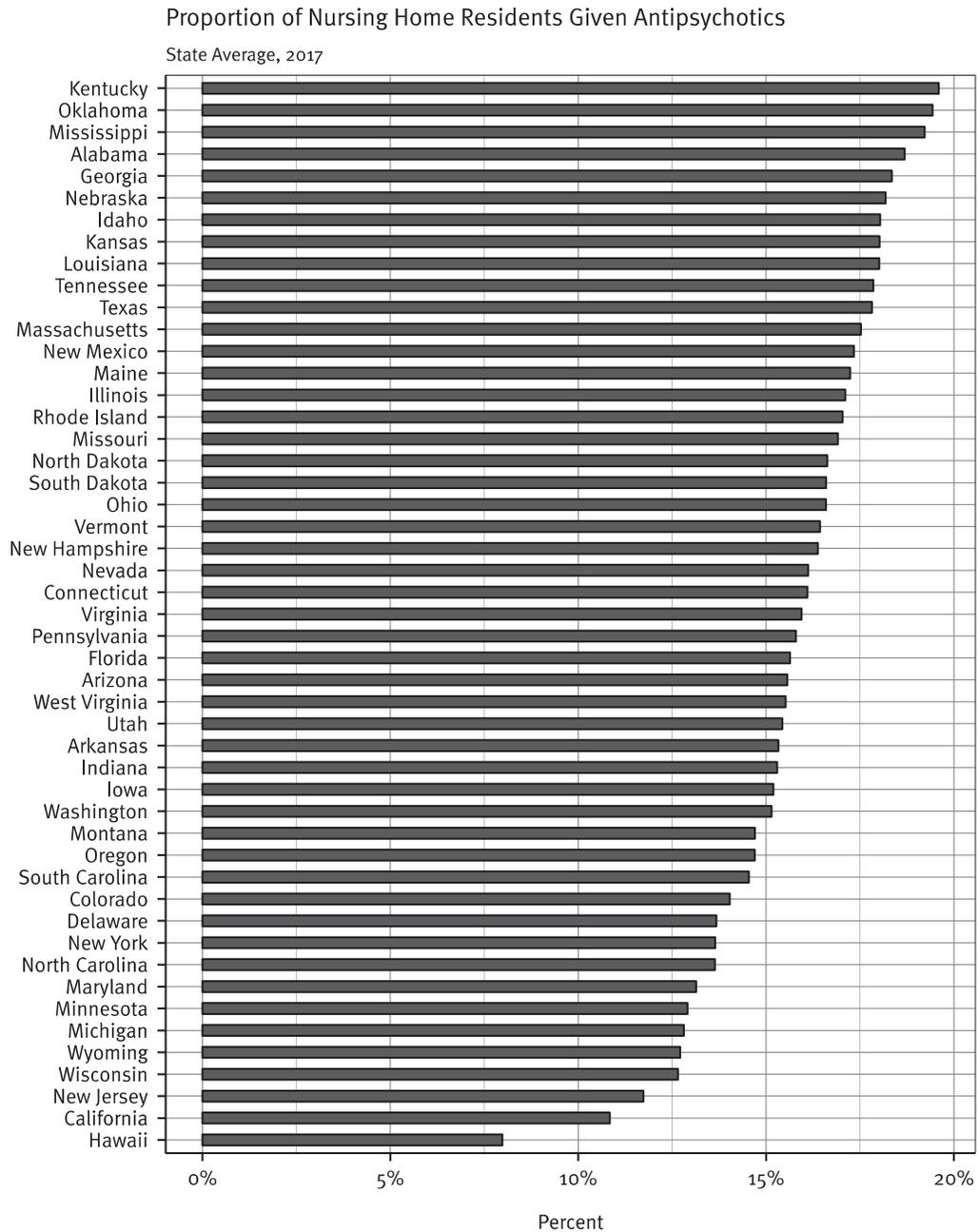
Proportion of residents given antipsychotics

Source: Human Rights Watch analysis of Nursing Home Compare data from <https://data.medicare.gov>

Note: Excludes patients with diagnoses of Schizophrenia, Tourettes syndrome or Huntingtons disease and nursing facilities where fewer than 50 percent of patients are over age 65.

Graph 2. Proportion of Residents Given Antipsychotic Drugs without an Exclusionary Diagnosis in the Facilities Visited by Human Rights Watch

Appendix 3: State-level Data on Antipsychotic Drugs in US Nursing Facilities



Source: Human Rights Watch analysis of Nursing Home Compare data from <https://data.medicare.gov>
 Note: Excludes patients with diagnoses of Schizophrenia, Tourettes syndrome or Huntingtons disease and nursing facilities where fewer than 50 percent of patients are over age 65.

Graph 3: Proportion of Nursing Home Residents Given Antipsychotic Drugs, by State (2017)

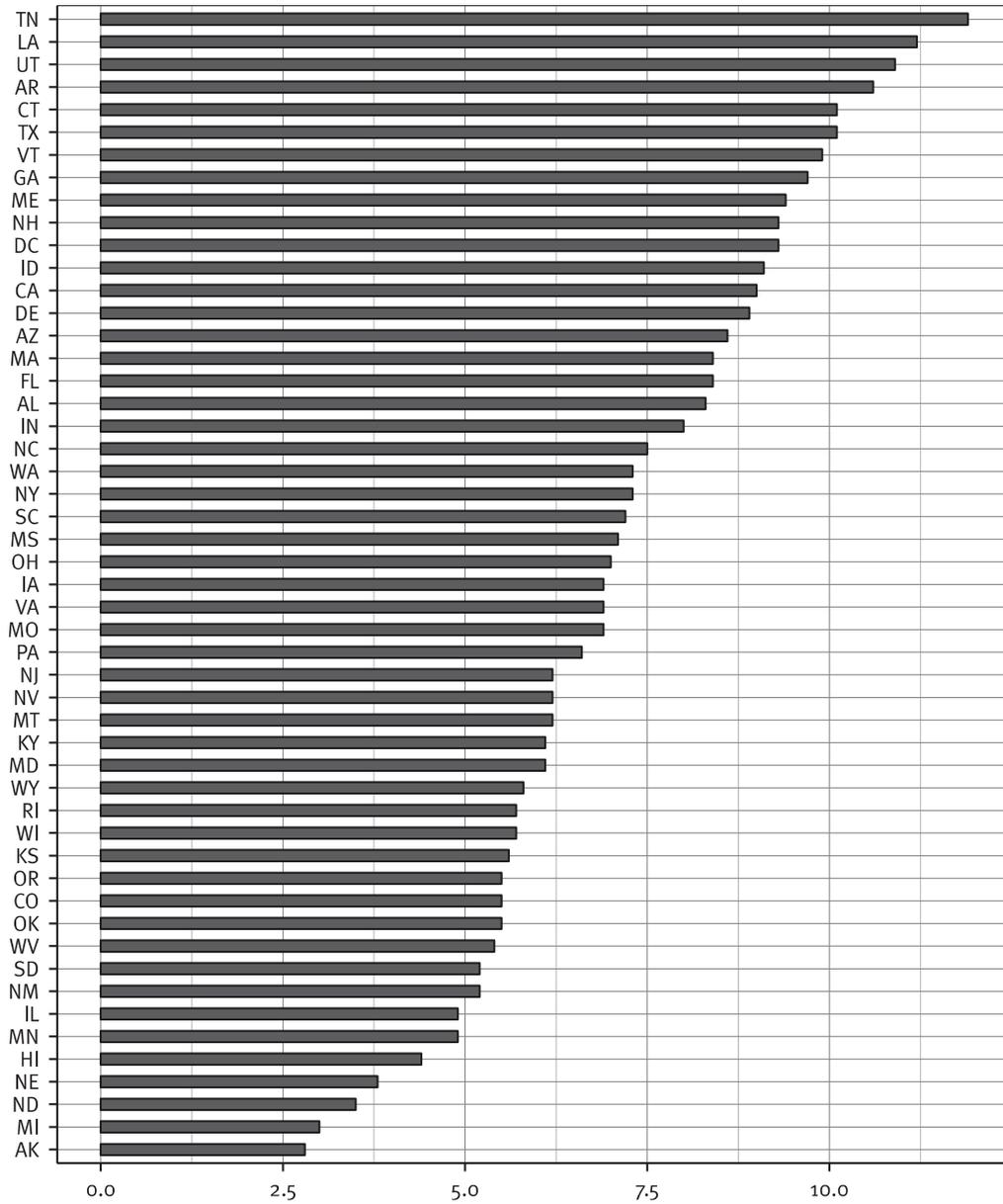
State	2011	2016	Percentage Point	
	Rate	Rate	Difference	Percent Change
LA	30.0%	18.8%	11.2%	-37.3%
TN	30.4%	18.5%	11.9%	-39.1%
GA	28.9%	19.2%	9.7%	-33.6%
TX	28.7%	18.6%	10.1%	-35.2%
AL	27.3%	19.0%	8.3%	-30.4%
AR	26.0%	15.4%	10.6%	-40.8%
MS	26.9%	19.8%	7.1%	-26.4%
UT	26.9%	16.0%	10.9%	-40.5%
ME	26.7%	17.3%	9.4%	-35.2%
VT	26.6%	16.7%	9.9%	-37.2%
CT	26.3%	16.2%	10.1%	-38.4%
MA	26.3%	17.9%	8.4%	-31.9%
NH	26.3%	17.0%	9.3%	-35.4%
KY	26.1%	20.0%	6.1%	-23.4%
ID	25.6%	16.5%	9.1%	-35.5%
MO	25.5%	18.6%	6.9%	-27.1%
OK	25.3%	19.8%	5.5%	-21.7%
AZ	24.7%	16.1%	8.6%	-34.8%
OH	24.6%	17.6%	7.0%	-28.5%
FL	24.5%	16.1%	8.4%	-34.3%
IL	24.1%	19.2%	4.9%	-20.3%
WA	23.0%	15.7%	7.3%	-31.7%
KS	23.8%	18.2%	5.6%	-23.5%
IN	23.5%	15.5%	8.0%	-34.0%
RI	23.1%	17.4%	5.7%	-24.7%
VA	22.8%	15.9%	6.9%	-30.3%
PA	22.5%	15.9%	6.6%	-29.3%
NV	22.4%	16.2%	6.2%	-27.7%
DE	22.3%	13.4%	8.9%	-39.9%
NM	22.3%	17.1%	5.2%	-23.3%

NE	22.2%	18.4%	3.8%	-17.1%
MT	21.0%	14.8%	6.2%	-29.5%
WV	21.0%	15.6%	5.4%	-25.7%
DC	21.9%	12.6%	9.3%	-42.5%
SC	21.8%	14.6%	7.2%	-33.0%
IA	21.6%	14.7%	6.9%	-31.9%
NY	21.6%	14.3%	7.3%	-33.8%
NC	21.3%	13.8%	7.5%	-35.2%
SD	21.2%	16.0%	5.2%	-24.5%
CA	20.0%	11.0%	9.0%	-45.0%
CO	20.6%	15.1%	5.5%	-26.7%
ND	20.3%	16.8%	3.5%	-17.2%
OR	20.1%	14.6%	5.5%	-27.4%
MD	19.9%	13.8%	6.1%	-30.7%
WY	19.1%	13.3%	5.8%	-30.4%
WI	18.4%	12.7%	5.7%	-31.0%
NJ	18.3%	12.1%	6.2%	-33.9%
MN	18.2%	13.3%	4.9%	-26.9%
MI	16.1%	13.1%	3.0%	-18.6%
AK	12.0%	9.2%	2.8%	-23.3%
HI	11.2%	6.8%	4.4%	-39.3%

Table 5. Change in Average Proportion of Residents Given Antipsychotic Drugs, by State (2011 - 2016)

State reductions in antipsychotic use (2011 – 2016)

Change in percentage points in proportion of resident population receiving antipsychotics, state averages

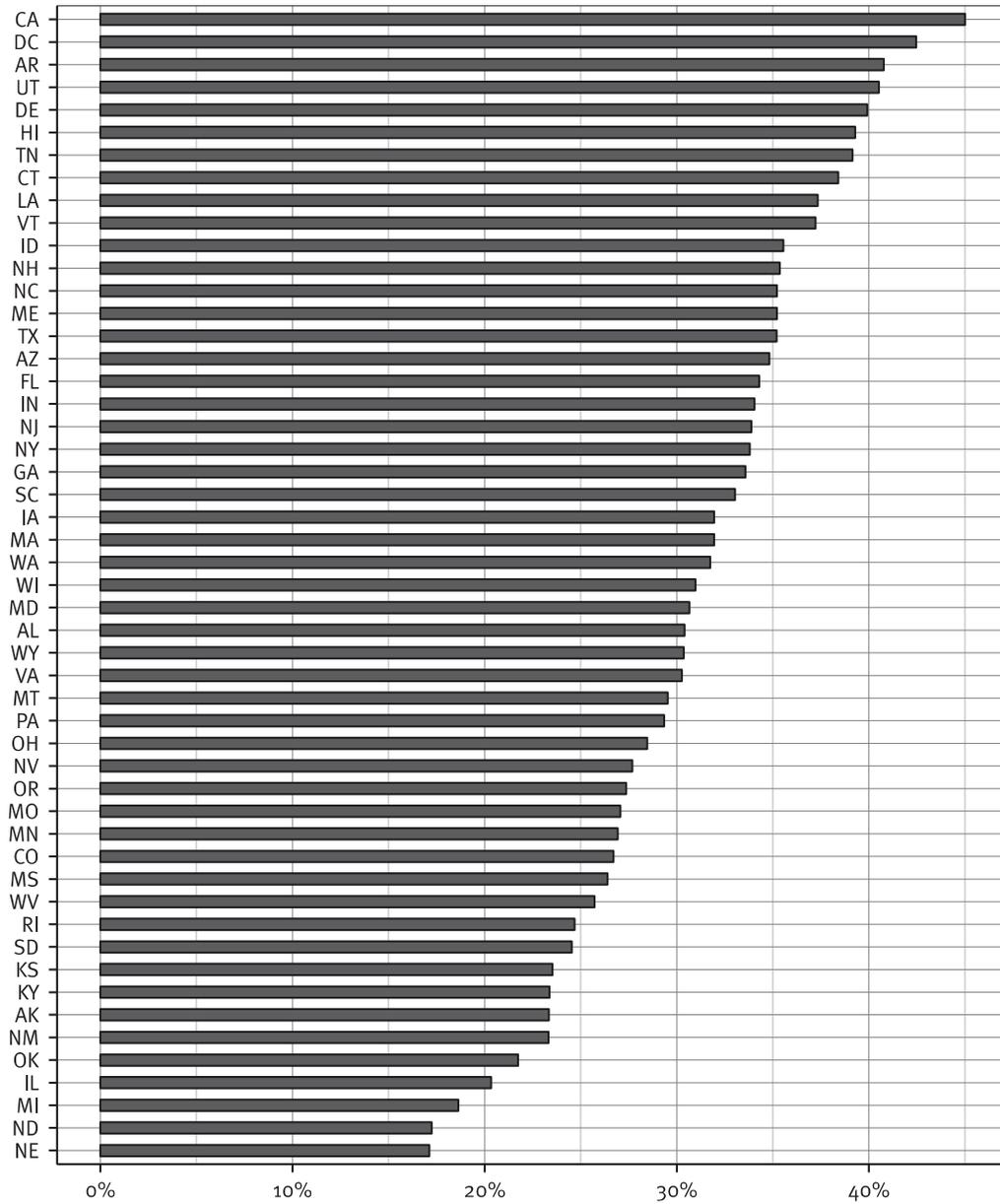


Percentage point reduction
 Source: Human Rights Watch analysis of Nursing Home Compare data from <https://data.medicare.gov>

Graph 4. State Reductions in Antipsychotic Drug Use, by State (2011-2016)

State reductions in antipsychotic use, percent change (2011 – 2016)

Percent reduction in proportion of resident population receiving antipsychotics, state averages



Source: Human Rights Watch analysis of Nursing Home Compare data from <https://data.medicare.gov>

Graph 5. State Reductions in Antipsychotic Drug Use, Percent Change (2011-2016)

Appendix 4: Methodological Note on Data Analysis

All quantitative analyses Human Rights Watch developed in this report used data from the Minimum Data Set, a federally mandated national database at the Centers for Medicare and Medicaid Services which contains periodic, individual, clinical, comprehensive assessments of all residents in Medicare and Medicaid certified nursing homes transmitted electronically by nursing homes, as well as other self-reported and governmental surveyor-reported data for all facilities in the country certified to receive payment from Medicare and Medicaid.³²⁹

Despite the volume of publicly available data regarding nursing homes and antipsychotic drugs specifically, a number of significant challenges arose in conducting quantitative analyses. First, it is not possible to determine from a single publicly available data set what proportion of all individuals in nursing facilities and without a diagnosis for which an antipsychotic drug is approved by the Food and Drug Administration take such drugs.

Second, a significant amount of the data on nursing homes is self-reported by those facilities. Numerous governmental and academic experts have recognized the inadequacy and inaccuracy of this self-reported data—for example, data related to staffing levels. It is possible that the distortions of self-reported data influenced the results of statistical tests that Human Rights Watch ran.

Nonetheless, Human Rights Watch was able to produce several quantitative analyses for this report, including to estimate the total numbers of people who receive antipsychotic drugs, live in nursing facilities with a majority population over the age of 65, and do not have an exclusionary diagnosis; and to analyze antipsychotic drug-related deficiency citations.

³²⁹ “Minimum Data Set 3.0 Public Reports,” CMS, last updated November 14, 2012, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Minimum-Data-Set-3-0-Public-Reports/index.html> (accessed September 11, 2017); “Nursing Home Compare Datasets,” CMS, <https://data.medicare.gov/data/nursing-home-compare> (accessed September 9, 2017).

Estimating the Number of Long-Stay Residents on Antipsychotic Drugs

The antipsychotic drug-related data on Nursing Home Compare is “risk adjusted”: any resident with a diagnosis of schizophrenia, Huntington’s disease, or Tourette syndrome is excluded from the numerator and denominator in calculating the proportion of residents on antipsychotic drugs. The rationale is that these are conditions for which antipsychotic drugs have been approved by the Food and Drug Administration. However, the data on the number of residents within each nursing home is not risk-adjusted and includes those with one of the aforementioned diagnoses. Therefore, a methodology was required to estimate the number of people without one of these diagnoses who were given an antipsychotic in each nursing home.

Human Rights Watch used the following methodology to calculate an estimate for the number of long-stay residents who receive antipsychotic drugs every week without an exclusionary diagnosis and applied the methodology to every facility that had a majority of residents over the age of 65:

Quarterly facility-level data in Nursing Home Compare provide the total number of residents in each facility, including those with schizophrenia, Huntington’s disease, and Tourette syndrome. The proportion of residents with these diagnoses is not available at the facility-level and is only available aggregated at the state level. The state level averages of the proportion of residents with these diagnoses were applied to the facilities within each state to estimate the facility population that does not have one of the three diagnoses. Using the average of the most recent four quarters of reporting, the facility level rate of antipsychotic use in the previous seven days was applied to the estimated facility resident population without the three diagnoses.

Estimating the Change in Antipsychotic Use Rates in Relation to Antipsychotic-related Deficiency Citations

Human Rights Watch identified the narrative descriptions of 28,129 drug related deficiencies handed out by government inspectors to nursing facilities across the country between January 1, 2014 and June 30, 2017.³³⁰ The actual inspection text was then analyzed

³³⁰ CMS, “Full Text of Statements of Deficiencies – August 2017” in “Five-Star Quality Rating System,” <https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcompliance/fsqrs.html>.

to determine the presence of words related to antipsychotics. Search terms included the term “antipsychotic” as well as a list of commonly prescribed antipsychotics, as well as misspellings of these words found in the data (see Table 6 on the next page). Of the over 28,000 drug related deficiency narratives, 25 percent contained at least one of the search terms. (In a minority of cases, an antipsychotic-drug related term appears in the narrative without being the basis for the citation.) Rates of antipsychotic use were then compared for a subset of 4,221 unique facilities that received a cumulative 5,880 antipsychotic related deficiencies.³³¹ In the year following an antipsychotic related deficiency citation, facilities reduced their antipsychotic use rate by 1.5 percentage points.³³² Facilities reduced their rates of use at the greatest rate during the last half of 2015.

³³¹ Analysis required facilities to have four consecutive quarters of antipsychotic use data both before and after receiving an antipsychotic related deficiency.

³³² Mean = -1.57 percentage points; median = -1.02 percentage points.

abilfy	antipsychoyic	clozaril	procholoperazine	risperodone
abilifyi	antipsycotic	clozapam	prolixen	seroquel
abilify	antipsyhchotic	closzepine	prolixin	seroquel
Abilily	antipsyhotic	compazine	quetapine	seroqeul
abilitfy	antipsypsychotic	fluphenazine	quetialine	seroqued
anipsychotic	antipsychotic	geoden	quetiapine	seroquel
anitipsychotic	antipsyshotic	geodon	quetiapene	seroquelå
anitipsychotics	antipychotic	geodone	quetiapin	seroquesl
anitphychotic	antipychotics	haldol	quetiapine	seroquil
anitpsychotic	antipsychotic	haldol1mg	quetiapine100	seroquul
anitpsychotics	antipsychotics	haldoperidol	quetiapine125	stelazine
anitpsycotic	antipsyhctic	haloperidal	quetiapinefumarate	thioridazaine
antipsychotic	antipsychotic	haloperidol	quetiapine	thioridazine
antiphychotic	antipsychotics	haloperidol	quetipiane	thioridine
antiphyschotic	antispychotic	halperidol	quetipine	thiothixene
antipschotic	antisphychotic	loxapin	rispderal	thorough
antipsychotic	antispsychotic	loxapine	rispderdal	trifluoperazine
antipsychotic	antispsychotic	loxipine	rispedal	trifuridine
antipsychotic	antispsychotropic	loxitane	rispeidone	trilafon
antipsychotic	antispsychotic	loxopine	risperadal	trilafon
antipsyc	antopsychotic	navane	risperadol	ziprasadone
antipsych	antpsychotic	olananzapine	risperadone	ziprasidone
antipsychotic	antrpsychotic	olanazapine	risperal	ziprasidone
antipsychiatic	antypsychotic	olansapine	risperdal	ziprosidone
antipsychiatric	antypsycotic	olanzaoine	risperdalconsta	zyprexa
antipsychiatic	aripazole	olanzapin	risperdalå	zyprexa
antipsychoactive	aripiprazole	olanzapine	risperdione	zyprexa
antipsychoic	aripiprozole	olanzepine	risperdol	zyprex
antipsychoitc	aripirazole	olanzipine	risperdone	zyprexa
antipsycholic	aripprazole	olazapine	risperedal	zyprexia
antipsychotic	ariprazole	perphanazine	risperidal	zyprexis
antipsychoticd	aripriprazole	perphenazine	risperidione	zypreza
antipsychoticon	ariprirazole	perphenzine	risperido	zyprezia
antipsychotics	chlorpromazine	pimozide	risperidol	zyxprea
antipsychotive	clozapin	prochlorperazine	risperidone	
antipsychotropic	clozapine	prochlorperazine	risperidone	

Table 6. Search Terms Used to Filter Narrative Deficiency Reports for Antipsychotic Drug-related Deficiency Citations

Appendix 5: Correspondence with CMS

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Marie Warburg

June 20, 2017

Kate Goodrich, M.D.
Director and CMS Chief Medical Officer
Center for Clinical Standards and Quality
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244



HRW.org

Re: Human Rights Watch Research on Nursing Facilities

Dear Dr. Goodrich:

I am a fellow with Human Rights Watch (HRW), the largest U.S.-based human rights research and advocacy organization. HRW operates in over 80 countries around the world, including the United States. Our work is grounded in objective, well-documented research on human rights problems. We use that research to draw attention to important human rights issues and to offer concrete, credible recommendations to improve the protection of people's rights. More information about HRW and examples of our work can be found here: www.hrw.org.

We are currently conducting research on human rights concerns linked to skilled nursing facilities (SNF) and nursing facilities (NF) around the United States. Our primary focus is on the potentially inappropriate use of antipsychotic and other psychotropic medications among older residents and residents with dementia. We are examining broader obstacles to effective regulation and the enforcement of residents' rights under domestic and international law as well. Our key areas of concern include staffing requirements, the government's and public's access to accurate ownership information, and the adequacy of remedies in the facility-level enforcement system.

We have visited a range of facilities in a handful of states across the country, although we do not anticipate identifying any specific facilities in our report. Our preliminary findings include:

1
AMSTERDAM · BEIRUT · BERLIN · BRUSSELS · CHICAGO · GENEVA · GOMA · JOHANNESBURG · KIEV · KINSHASA · LONDON · LOS ANGELES · MOSCOW · NAIROBI ·
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- Some older, long-stay residents would prefer to live in the community, and limited national data describe the extent to which they have a meaningful opportunity to do so;
- Some facilities' institutional nature impinges on some residents' autonomy in ways that are excessive or otherwise unjustifiable;
- Some residents with particular traits, such as disruptive behavior, may experience multiple transfers, discharges, or denials of admission despite facilities' ability to meet their care needs and to protect residents from harm;
- Under-staffing and under-training of staff often result in inferior care for residents;
- Some facilities use antipsychotic medications excessively, and some facilities, residents, and families alike lack knowledge about the medications' risks and about alternatives to their use; and
- Government regulatory and enforcement systems are neither preventing all residents from experiencing substandard care nor providing adequate accountability when facilities cause harm or fail to substantially comply with the law.

As part of our ongoing research and to ensure thorough and objective reporting, we are contacting you with some questions related to our work. In addition to responses to our questions, we would welcome your broader perspectives on the complex issues surrounding the provision of high quality care that respects people's rights.

National Partnership to Improve Dementia Care in Nursing Homes and antipsychotic drug use reduction

1. How did you set the National Partnership's annual and final targets for antipsychotic drug reduction? Is there a target for 2017 or future years?
2. How, if at all, have you measured any correlation between the reduced prevalence of antipsychotic medication use and changes in quality of care and in quality of life of residents since 2012?
3. Have you analyzed the prevalence of antipsychotic drug use by facility owner?
4. What role, if any, do you believe that hospitals play in antipsychotic drug use in nursing facilities? How, if at all, did the Partnership evaluate whether to include or exclude hospitals from the Partnership's efforts?
5. What do you believe has accounted for the failure of some facilities and states to reduce significantly the prevalence of inappropriate antipsychotic drug use?
6. Why do you believe the rates of antipsychotic drug use were as high as they were until the National Partnership led the successful reduction effort?
 - a. What role, if any, do you believe staffing levels play in facilities' rate and purpose of use of antipsychotic medications?

2

- b. What role, if any, do you believe that informed consent policies and procedures have on antipsychotic medication use rates, in particular among residents with dementia?
7. Are you concerned about any potential unintended consequences of the pressure to reduce the inappropriate use of antipsychotic medications in nursing facilities? How do you explain the uptick in the numbers of diagnoses of schizophrenia in nursing facilities according to MDS 3.0 quarterly data between the Fourth Quarter of 2011 and First Quarter of 2017?

Enforcement

1. What evidence, if any, do you have about the effects of the current levels of enforcement on the quality of care delivered at individual SNF/NFs?
2. What evidence, if any, do you have about the relative effectiveness of various enforcement remedies (e.g., denial of payment versus civil money penalties) in deterring future substantial noncompliance?
3. What effect, if any, do you believe the inclusion of a private right of action in the Nursing Home Reform Act would have on quality of care and accountability in the industry?
4. How frequently are facilities decertified? When decertification occurs, how frequently are residents relocated to another building versus a new owner or operator taking over without having to physically relocate residents?
5. How do you formulate your annual nursing home action plans?
6. What, if anything, do you expect the consequences to be of the increasing bifurcation in the industry between Medicare- and Medicaid-only facilities, given the role of cross-subsidization?

Chain ownership

1. What, if anything, is the consequence of conducting enforcement at the facility level despite the prevalence of chain ownership across the industry?
2. Has the Centers for Medicare and Medicaid Services (CMS) ever considered conducting enforcement at an ownership level or taking ownership into account in facility-level enforcement? What regulatory or legislative procedures would be required to amend the existing enforcement system to take facilities' ownership into account?
3. Which entities within the Department of Health and Human Services (HHS) have access to facility ownership and hierarchy of ownership information? Why is this the case? What would it take to expand access to this information within CMS and HHS and for the public?

Residents' rights

1. Does CMS keep track of discharges by facility and appeals of discharges by facility? Why? What does the frequency of resident and others' complaints regarding discharges signify to CMS?
2. Do you have any evidence that residents who are perceived as "difficult" or "disruptive" and whose care needs do not have RUG payment rates get transferred, discharged, or denied admission more frequently than other residents? Do you have any evidence that such residents end up concentrated in facilities of substandard quality?
3. Do you believe older (age 60+), long-stay, nursing facility residents' access to resources and services to transition to the community are adequate? Other than in setting care planning goals upon admission to a facility and in revisiting these goals at certain intervals thereafter, what data does CMS possess, if any, to analyze the extent to which the right of people with disabilities to live in the community under *Olmstead* is protected?
4. Has CMS ever considered measures to afford residents greater due process-type protections in legal capacity determinations within facilities (e.g., neutral or independent decision-makers, opportunities to challenge determinations)?
5. What do you believe would be the implications of establishing the right to informed consent for SNF and NF residents as it is written in the Improving Dementia Care Treatment for Older Adults Act of 2012?

Staffing

1. To what extent will you audit the Payroll Based Journal (PBJ) submission system for facilities' reporting staffing hours?
2. What evidence, if any, do you have that the potential unintended consequences to minimum staffing levels, ratios, or 24/7 RN presence mentioned in the response to comments in the Federal Register from your October 4, 2016, Final Rule would occur (e.g., staffing to the minimum, input substitution, or task diversion)? Please include any relevant documents.
3. How, if at all, would investigation and enforcement actions in response to those unintended consequences differ from investigation and enforcement actions in response to facilities distorting the assessments required to provide sufficient and competent staffing under the current Rule?
4. Do you believe that quality of care with minimum staffing levels, ratio, or 24/7 RN presence would be superior to current quality of care, assuming none of the unintended consequences of setting minimum requirements occurred?
5. What would additional data need to demonstrate for CMS to establish minimum staffing levels, ratios, or a 24/7 RN presence?
6. What evidence, if any, does CMS have that facilities will not make decisions solely or in part on fiscal concerns as a result of CMS adding, in the October

2016 Final Rule, specificity to the approach to determining staffing needs? How, if at all, has CMS analyzed the relative effectiveness of adding this specificity versus adding auditing and sanctions for making decisions on improper factors in deterring this practice?

Appendix 6: Correspondence with LeadingAge

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Dorota Slaughter

Siri Stoll-Nieben
Darian W. Swig

Maikoto Takano
Marie Warburg

June 20, 2017

Katie Smith Sloan
President and CEO
LeadingAge
2519 Connecticut Ave NW
Washington, D.C. 20008



HRW.org

CC: Dr. Cheryl Phillips, Senior Vice President, Public Policy and Health Services

Re: Human Rights Watch Research on Nursing Facilities

Dear Ms. Sloan:

I am a fellow with Human Rights Watch (HRW), the largest U.S.-based human rights research and advocacy organization. HRW operates in over 80 countries around the world, including the United States. Our work is grounded in objective, well-documented research on human rights problems. We use that research to draw attention to important human rights issues and to offer concrete, credible recommendations to improve the protection of people's rights. More information about HRW and examples of our work can be found here: www.hrw.org.

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- Some older, long-stay residents would prefer to live in the community, and limited national data describe the extent to which they have a meaningful opportunity to do so;
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- Government regulatory and enforcement systems are neither preventing all residents from experiencing substandard care nor providing adequate accountability when facilities cause harm or fail to substantially comply with the law.

As part of our ongoing research and to ensure thorough and objective reporting, we are contacting you with some questions related to our work. In addition to responses to our questions, we would welcome your broader perspectives on the complex issues surrounding the provision of high quality care that respects people's rights.

1. What is your response to the concern expressed by the Centers for Medicare and Medicaid Services, in the October 4, 2016, Final Rule on reform of requirements for long-term care facilities to participate in the Medicare and Medicaid programs, that if it were to require minimum staffing levels, standards, or ratios, then facilities would staff to the minimum requirement only?
2. Do you believe that some older (age 60+), long-stay residents of facilities affiliated with your association could be living in the community with appropriate services and supports? What information do you or facilities affiliated with your association collect related to this issue?
3. To what do you attribute any change in the prevalence of use of antipsychotic medications in facilities affiliated with your association since the efforts of the National Partnership to Improve Dementia Care in Nursing Homes started in 2012?
4. To what do you attribute the difference in prevalence of psychotropic drug use across the facilities affiliated with your association, aside from

2

differences in the composition of residents, in terms of diagnoses and medical care needs?

5. Do you believe that there is a problem in the SNF/NF industry generally that some facilities inappropriately or pretextually deny admission or transfer, discharge, or refuse to take residents back from a hospital, based on financial or other improper considerations? How would your association know if these patterns were happening?
6. What effect, if any, do you believe greater facility ownership and expenditure transparency would have on members of your association and quality of care in facilities?
7. How engaged is your association on policy or legislative measures affecting your members at the federal and state levels? How do you engage on those matters?
8. What evidence, if any, suggests that pre-dispute arbitration clauses improve accountability and deter wrongdoing more than the standard court system? Other than state court holdings that arbitration agreements may be unconscionable if admission is predicated on signing them, why has LeadingAge opposed arbitration agreements as conditions of admission to a nursing facility?

We ask that you respond to these queries by July 7, 2017, so we can incorporate your response into our report and into any other public comments HRW issues on this topic. We will be certain to acknowledge publicly full and transparent responses to these queries if they are provided.

Finally, I would like to extend an offer to meet with LeadingAge officials to discuss issues of mutual concern. Please feel free to be in touch with any questions as well. I can be reached by phone at (212) 216-1836 or by email at flammh@hrw.org.

Sincerely,

Hannah Flamm
Fellow
Health and Human Rights Program
Human Rights Watch



July 13, 2017

Hannah Flamm
Fellow
Health and Human Rights Program
Human Rights Watch
350 Fifth Avenue, 34th Floor
New York, NY 10118-3299

Re: Response to June 20th research letter request

Thank you for giving LeadingAge the opportunity to respond and comment on the research questions the Human Rights Watch, is conducting.

The members of LeadingAge and affiliates touch the lives of 4 million individuals, families, employees and volunteers every day. The LeadingAge community (www.LeadingAge.org) includes 6,000 not-for-profit organizations in the United States, 39 state partners, hundreds of businesses, research partners, consumer organizations, foundations and a broad global network of aging services organizations that reach over 30 countries. The work of LeadingAge is focused on advocacy, education, and applied research. LeadingAge promotes home health, hospice, community-based services, adult day service, PACE, senior housing, assisted living residences, continuing care communities, nursing homes as well as technology solutions and person-centered practices that support the overall health and wellbeing of seniors, children, and those with special needs.

Question #1: What is your response to the concern expressed by the Centers for Medicare and Medicaid Services, in the October 4, 2016, Final Rule on reform of requirements for long-term care facilities to participate in the Medicare and Medicaid programs, that if it were to require minimum staffing levels, standards, or ratios, then facilities would staff to the minimum requirement only?

Response: LeadingAge has not supported minimum staffing ratios because they become just that – minimum standards to which many providers focus on. We believe that staffing should be based on the needs and acuity of the residents served and the skills/competency of the staff that care for them. Of particularly note, non-profit providers typically have higher staffing ratios than the for-profit nursing homes in a given geographic area.

Question #2: Do you believe that some older (age 60+), long-stay residents of facilities affiliated with your association could be living in the community with appropriate services and supports? What information do you or facilities affiliated with your association collect related to this issue?

Response: Although LeadingAge members do work to support community-living options, for those who are Medicaid beneficiaries many states have limited home and community based options for Medicaid individuals. And if they need supportive housing – nursing homes often become the default setting of care – not because the providers push for that, but because there are few, if any options in the community to support the individuals under Medicaid. With looming Medicaid cuts, that is likely to take a downward spiral.

LeadingAge is also a national leader in helping to integrate low income senior housing with supportive services - which has shown to reduce the likelihood, or delay nursing home placement.

Question #3: To what do you attribute any change in the prevalence of use of antipsychotic medications in facilities affiliated with your association since the efforts of the National Partnership to Improve Dementia Care in Nursing Homes started in 2012?

Response: LeadingAge was an active supporter of the National Partnership to Improve Dementia Care in Nursing Homes. In part through our leadership work at Advancing Excellence, through member education, and by sharing best practices across the country we collaborated in the partnership. Several of our LeadingAge provider members were recognized as exemplars in the practice of non-med management of dementia.

Question #4: To what do you attribute the difference in prevalence of psychotropic drug use across the facilities affiliated with your association, aside from differences in the composition of residents, in terms of diagnoses and medical care needs?

Response: LeadingAge member providers tend to have a) higher staffing levels and b) a deep focus and priority on person-centered care that translates to the higher quality of care for dementia residents.

Question #5: Do you believe that there is a problem in the SNF/NF industry generally that some facilities inappropriately or perpetually deny admission or transfer, discharge, or refuse to take residents back from a hospital, based on financial or other improper considerations? How would your association know if these patterns were happening?

Response: There are pockets and isolated cases where we know this happens, but there is also another side to this dilemma. We do have examples of providers who told hospitals that they were unable to provide safe care for an individual with significant behavioral health issues – that put residents and staff at risk, but were told by the state “they had to take them back”, only then to have a high level citation for resident-resident abuse situation that followed.

The real core to the problem is inadequate access to meaningful mental and behavioral health services and the dollars to fund. Medicaid funding is grossly inadequate, and there are few providers available – regardless of payor source.

There is also the growing problem of co-mingling medically frail adults, with those who have dementia, with those that have serious mental illness. The assumption then becomes, that the nursing home, with no behavioral health resources, is able to care for all these individuals.

Question #6: What effect, if any, do you believe greater facility ownership and expenditure transparency would have on members of your association and quality of care in facilities?

Response: LeadingAge is supportive of ownership transparency, and because our members are non-profits, ownership disclosure is a requirement.

Question #7: How engaged is your association on policy or legislative measures affecting your members at the federal and state levels? How do you engage on those matters?

Response: LeadingAge is very engaged in public policy and regulatory issues. We believe first and foremost that quality of life and care for the people we serve is a priority. We also believe that the current Survey and Certification system is NOT driving quality and excellence, but is one that is focused entirely on enforcement, that it is inconsistent, that it is punitive in nature and creates a defensive environment – not one that supports innovation and excellence.

Question #8: What evidence, if any, suggests that pre-dispute arbitration clauses improve accountability and deter wrongdoing more than the standard court system? Other than state court holdings that arbitration agreements may be unconscionable if admission is predicated on signing them, why has LeadingAge opposed arbitration agreements as conditions of admission to a nursing facility?

Response: We believe that arbitration agreements should NOT be mandated, but be an option. We do believe in the rights of residents to find relief and remedy, but we are also aware that a current tort system does not drive quality, that by its very nature is contentious and often lengthy and drawn out – resulting in little benefit to the individual, but more often their heirs

LeadingAge would again like to thank you for the opportunity to respond and help comment on the research questions. If there are any questions, please contact Janine Finck-Boyle, Director, Health Regulations and Policy, jfinck-boyle@leadingage.org or at 202.508.9476.

Thank you,



Katie Smith Sloan
President and CEO

Appendix 7: Correspondence with American Health Care Association

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June 20, 2017

The Honorable Mark Parkinson
President and CEO
American Health Care Association
1201 L Street NW
Washington, D.C. 20005



HRW.org

CC: David Gifford, Senior Vice President, Quality & Regulatory Affairs

Re: Human Rights Watch Research on Nursing Facilities

Dear Hon. Parkinson:

I am a fellow with Human Rights Watch (HRW), the largest U.S.-based human rights research and advocacy organization. HRW operates in over 80 countries around the world, including the United States. Our work is grounded in objective, well-documented research on human rights problems. We use that research to draw attention to important human rights issues and to offer concrete, credible recommendations to improve the protection of people's rights. More information about HRW and examples of our work can be found here: www.hrw.org.

We are currently conducting research on human rights concerns linked to skilled nursing facilities (SNF) and nursing facilities (NF) around the United States. Our primary focus is on the potentially inappropriate use of antipsychotic and other psychotropic medications among older residents and residents with dementia. We are examining broader obstacles to effective regulation and the enforcement of residents' rights under domestic and international law as well. Our key areas of concern include staffing requirements; the government's and public's access to accurate ownership information; and the adequacy of remedies in the facility-level enforcement system.

We have visited a range of facilities in a handful of states across the country, although we do not anticipate identifying any specific facilities in our report. Our preliminary findings include:

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AMSTERDAM · BEIRUT · BERLIN · BRUSSELS · CHICAGO · GENEVA · GOMA · JOHANNESBURG · KIEV · KINSHASA · LONDON · LOS ANGELES · MOSCOW · NAIROBI · NEW YORK · PARIS · SAN FRANCISCO · SÃO PAULO · SILICON VALLEY · STOCKHOLM · SYDNEY · TOKYO · TORONTO · WASHINGTON · ZÜRICH

- Some older, long-stay residents would prefer to live in the community, and limited national data describe the extent to which they have a meaningful opportunity to do so;
- Some facilities' institutional nature impinges on some residents' autonomy in ways that are excessive or otherwise unjustifiable;
- Some residents with particular traits, such as disruptive behavior, may experience multiple transfers, discharges, or denials of admission despite facilities' ability to meet their care needs and to protect residents from harm;
- Under-staffing and under-training of staff often result in inferior care for residents;
- Some facilities use antipsychotic medications excessively, and some facilities, residents, and families alike lack knowledge about the medications' risks and about alternatives to their use; and
- Government regulatory and enforcement systems are neither preventing all residents from experiencing substandard care nor providing adequate accountability when facilities cause harm or fail to substantially comply with the law.

As part of our ongoing research and to ensure thorough and objective reporting, we are contacting you with some questions related to our work. In addition to responses to our questions, we would welcome your broader perspectives on the complex issues surrounding the provision of high quality care that respects people's rights.

1. What is your response to the concern expressed by the Centers for Medicare and Medicaid Services, in the October 4, 2016, Final Rule on reform of requirements for long-term care facilities to participate in the Medicare and Medicaid programs, that if it were to require minimum staffing levels, standards, or ratios, then facilities would staff to the minimum requirement only?
2. Do you believe that some older (age 60+), long-stay residents of facilities affiliated with your association could be living in the community with appropriate services and supports? What information do you or facilities affiliated with your association collect related to this issue?
3. To what do you attribute any change in the prevalence of use of antipsychotic medications in facilities affiliated with your association since the efforts of the National Partnership to Improve Dementia Care in Nursing Homes started in 2012?
4. To what do you attribute the difference in prevalence of psychotropic drug use across the facilities affiliated with your association, aside from

2

differences in the composition of residents, in terms of their diagnoses and medical care needs?

5. Do you believe that there is a problem in the SNF/NF industry generally that some facilities inappropriately or pretextually deny admission or transfer, discharge, or refuse to take residents back from a hospital, based on financial or other improper considerations? How would your association know if these patterns were happening?
6. What effect, if any, do you believe greater facility ownership and expenditure transparency would have on members of your association and quality of care in facilities?
7. How engaged is your association on policy or legislative measures affecting your members at the federal and state levels? How do you engage on those matters?
8. What evidence, if any, suggests that mandatory pre-dispute arbitration clauses improve accountability and deter wrongdoing more than the standard court system?

We ask that you respond to these queries by July 7, 2017, so we can incorporate your response into our report and into any other public comments HRW issues on this topic. We will be certain to acknowledge publicly full and transparent responses to these queries if they are provided.

Finally, I would like to extend an offer to meet with American Health Care Association officials to discuss issues of mutual concern. Please feel free to be in touch with any questions as well. I can be reached by phone at (212) 216-1836 or by email at flammh@hrw.org.

Sincerely,

Hannah Flamm
Fellow
Health and Human Rights Program
Human Rights Watch



1201 L Street, NW, Washington, DC 20005
T: 202-842-4444
F: 202-842-5880
www.ahcanal.org

July 6, 2017

Hannah Flamm
Fellow
Health and Human Rights Program
Human Rights Watch
350 Fifth Avenue, 34th Floor
New York, New York, 10118-3299

Dear Ms. Flamm:

Thank you for the opportunity to respond to your questions. I have addressed them in the attached document.

Sincerely,

A handwritten signature in black ink, appearing to read "D. Gifford".

David R. Gifford, MD, MPH
Senior Vice President for Quality & Regulatory Affairs

The American Health Care Association and National Center for Assisted Living (AHCA/NCAL) represent more than 12,000 non-profit and proprietary skilled nursing centers, assisted living communities, sub-acute centers and homes for individuals with medical and developmental disabilities. By delivering solutions for quality care, AHCA/NCAL aims to improve the lives of the millions of frail, elderly and individuals with disabilities who receive long term or post-acute care in our member facilities each day.

We appreciate you reaching out to us for comment on these important issues. However, it is somewhat hard to provide specific comments without seeing a draft of your report and the findings. Would it be possible to share a draft with us? Given that limitation, we have tried to answer the questions you posed.

1. What is your response to the concern expressed by the Centers for Medicare and Medicaid Services, in the October 4, 2016, Final Rule on reform of requirements for long-term care facilities to participate in the Medicare and Medicaid programs, that if it were to require minimum staffing levels, standards, or ratios, then facilities would staff to the minimum requirement only?

We feel that requiring staffing levels or ratios does not recognize the difference in types and acuity and care needs different individuals and facilities have. A one shoe fits all approach would not be helpful to assuring high quality care. Also, focusing on just staffing levels is misguided. We believe the focus should be on resident outcomes.

2. Do you believe that some older (age 60+), long-stay residents of facilities affiliated with your association could be living in the community with appropriate services and supports? What information do you or facilities affiliated with your association collect related to this issue?

First, it would be helpful to know how you define "older residents." Your question indicates you are classifying anyone as over age 60 as "older."

In our experience most individuals, regardless of their age, would rather be living in their home or with their family. However, the decision to move into a long term care facility is a difficult decision often precipitated by an acute hospitalization. Over 90% of all admissions are precipitated by an acute care hospitalization. We work with all individuals who are admitted to determine if they are able to return safely to the community. Unfortunately, not all people admitted from the hospital to long term care facilities are able to go home. In some cases, the family does not want the individual to return home given their concerns for their safety. The family members often feel it is no longer safe for the individual to reside at home despite available resources.

We have made discharging patients back to the community one of our Quality Initiative goals that we measure and work on with all of our members. We supported CMS adding a similar measure to Nursing Home Compare and Five Star rating system. We are pleased to see that the proportion of individuals admitted from a hospital to a skilled nursing facility who are discharged home in the next 100 days has steadily been increasing. As of the most recent data available, 65.1% of all admissions nationally, regardless of payor status, are discharged back to the community, with AHCA members achieving a slightly higher rate than non-members (65.2% vs 64.9% respectively).

3. To what do you attribute any change in the prevalence of use of antipsychotic medications in facilities affiliated with your association since the efforts of the National Partnership to Improve Dementia Care in Nursing Homes started in 2012?

The broad public-private partnership focus on reducing antipsychotics, along with data available for each center to see how they are doing compared to others, has been a big reason for the national reduction in antipsychotic usage. AHCA made reducing the use of antipsychotics one of its four Quality Initiative goals. We have focused on helping our members understand the reasons for the behaviors of residents with dementia and education on alternatives to medications in treating those residents.

We are pleased with the dramatic reductions in the use of antipsychotics across the country from 25.3% in 2011 to 16.0% in 2016. Over half of our members (53.6%) have achieved the joint goal to reduce antipsychotics by over 30% from their 2011 rates of use, with many achieving much larger reductions. Our members have achieved larger reductions in usage of antipsychotics compared to non-members, despite our members starting at higher rates of usage in 2011. AHCA members reduced their rates from 23.6% in 2011 to 15.6% in 2016, while non-members reduced from 23.3% in 2011 to 16.7% in 2016.

4. To what do you attribute the difference in prevalence of psychotropic drug use across the facilities affiliated with your association, aside from differences in the composition of residents, in terms of their diagnoses and medical care needs?

The biggest challenge we have found is the mindset that clinicians, nurses and family all have that "behaviors" in dementia are abnormal, resulting from dementia and that medications are an effective treatment. Difficulty in changing this belief is the greatest challenge. This is reflected by analysis showing that almost two-thirds of all long stay residents (those in the center for at least 100 days) were receiving antipsychotics prior to admission to the skilled nursing facility. Our challenge is getting the family and physicians to feel comfortable discontinuing the medications. We have developed consumer fact sheets in both English and Spanish to help family members feel more comfortable with the decision to discontinue the medications. We would appreciate any help in getting these out for greater use. They can be found at https://www.ahcancal.org/quality_improvement/qualityinitiative/Documents/Antipsychotics%20Consumer%20Fact%20Sheet%20-%20English.pdf

5. Do you believe that there is a problem in the SNF/NF industry generally that some facilities inappropriately or pretextually deny admission or transfer, discharge, or refuse to take residents back from a hospital, based on financial or other improper considerations? How would your association know if these patterns were happening?

We have not seen or heard that is a problem. There are sometimes situations where individuals have unique or high care needs and skilled nursing facilities do not have the resources or staff to care for such individuals. For example, hospitals may look for a skilled nursing facility to care for an individual who needs long term ventilator support. However, most nursing facilities do not have the resources to care for individuals requiring a ventilator. The inability to provide proper care has also been raised with regard to some severely morbidly obese individuals.

6. What effect, if any, do you believe greater facility ownership and expenditure transparency would have on members of your association and quality of care in facilities?

We do not see that as impacting quality of care. CMS already posts ownership status and expenditure status on Nursing Home Compare. Clinical outcome data does drive quality improvement and provides consumers with information needed to make decisions. This is why we have invested heavily in new measures, which we submitted for public review and certification by the National Quality Forum, an independent quasi-public entity that validates quality measures for CMS and others for all health care settings. We have developed measures around rehospitalization rates for new admissions, hospitalization rates for long stay residents, discharge back to the community, consumer satisfaction, family satisfaction and improved mobility and improvements in self-care.

7. How engaged is your association on policy or legislative measures affecting your members at the federal and state levels? How do you engage on those matters?

Our mission is improving lives by delivering solutions for quality care. We devote our energy to providing resources and tools to members to improve their quality of care, as well as working with both the legislative and executive branches of government on regulatory, reimbursement and reporting issues. Like most national associations, we follow proposed rules, technical expert panels, and sub-regulatory guidance as well as meet with members of congress on regular basis to hear their issues and to provide information on our issues as well.

8. What evidence, if any, suggests that mandatory pre-dispute arbitration clauses improve accountability and deter wrongdoing more than the standard court system?

Dispute resolution systems generally have two purposes—to provide compensation for past injuries and to deter future wrongdoing. Arbitration serves both of these purposes better than our overcrowded, expensive court system. Arbitrations are conducted much more quickly than proceedings in court, and claimants and their families can often seek redress without a lawyer—enabling them to keep more of their recoveries and to obtain redress for claims too small to support a lawyer’s fee. Indeed, an Aon study of nursing home-related claims found that arbitrated claims are, on average, resolved three months sooner than lawsuits in court. And claimants recover similar amounts in both systems: the Aon study found that the average payment to claimants under arbitration

was slightly less than the average without arbitration—with the variation accounted for by the greater proportion of extremely large claims in the non-arbitration sample. Finally, parties report high levels of satisfaction with arbitration: a 2016 independent review of the Kaiser Foundation Health Plan’s arbitration system found that 93% of parties found the system to be better or the same as litigation in court. By providing quicker, less expensive dispute resolution, arbitration increases accountability and deters future wrongdoing, because patients more easily obtain redress. And the belief of some that the court system is more effective at identifying wrongdoing is incorrect: studies consistently show that more than 95% of lawsuits are resolved without such a finding, because they are either settled or dismissed. Finally, when an arbitration proceeding results in a finding of liability, that fact becomes public—because the laws of California and other states require arbitration providers to report publicly on consumer arbitration resolutions. (It also is worth noting that in this heavily-regulated field, by far the principal source of deterrence comes from inspections and enforcement action by state and federal regulators, regardless of whether private claims are resolved through arbitration or in court.) For all of these reasons, arbitration does a better job of imposing accountability and deterring wrongdoing than the court system, while providing a better experience and more relief to claimants

Appendix 8: Informed Consent Documents

FACILITY VERIFICATION OF INFORMED CONSENT

1. Consent for: Psychoactive Medication: _____ Dose: _____

Diagnosis: _____

2. I have obtained informed consent from the:

____ Resident: _____

____ Responsible Party (Name/Relationship): _____

I have reviewed with the resident/responsible party all requirements of California Code of Regulations, Title 22, Section 72528 (a) and (b)

Signature of physician who obtained informed consent Date

3. Verification of informed consent obtained from –

Via: _____ Telephone _____ Facsimile _____ In person (see above)

Signature of Facility Representative Date

Resident Name

Room #

Physician's Name

- RESIDENT CARE PLAN

Date _____ Resident _____ Room _____ MR # _____

Physician _____ Nurse _____

Problems/Nursing Diagnosis: CHANGE/NEW PSYCHOTROPIC MEDICATION, POTENTIAL FOR ADVERSE REACTIONS/ SIDE EFFECTS

Goal: 1. No adverse reaction/side effect from new medication
 2. Decreased signs/symptoms of: (circle all that apply) behaviors, depression, insomnia, other: _____

APPROACHES/INTERVENTIONS: Please CIRCLE the appropriate interventions for this resident, mark through what does not apply. Add any additional interventions as needed.

Charge Nurse Responsibilities:

1. Obtain informed consent from the responsible party or the resident (if own responsible party)
2. Inform the responsible party or the resident (if own responsible party) of potential side effects of this class of psychoactive meds.
 Verbal consent received from: _____ Date: _____
 Nurse #1: _____ Nurse #2: _____ Time: _____
3. If refused give reason, _____
4. If refused consequences of refusal explained, _____
5. Proposed course/Duration of Drug Therapy, _____
6. Diagnosis for medication: _____

Potential Side Effects of Psychotropic Medications

() Antipsychotics	() Antidepressants	() Anti-anxiety	() Hypnotic	() Anti-manic / Mood Stabilizers
Neck Stiffness	Dry Mouth	Hypotension	Syncope	Confusion
Confusion	Blurred Vision	Sedation	Dizziness	Drowsiness
Muscle Rigidity	Constipation	Dizziness	Confusion	Hypotension
Anxiety	Urinary Retention	Dry Mouth	Nightmares	Sedation
Drumming	Euphoric	Blurred Vision	Daytime	Nephrotic Syndrome
Blurred Vision	Appetite Changes	Urinary Retention	Hallucinations	Seizures
Tremors	Headache	Drowsiness	Mania	Impaired Cognition
Restlessness	Insomnia	Slurred Speech	Fatigue	Tremors
Sleep Disturbances	Dyspepsia	Confusion	Headache	Impaired Vision
Dry Mouth	Weight Changes	Fatigue	Sedation	Low Heart Rate
Constipation		Nightmares		
Sedation		Appetite Changes		
Involuntary Movements				

Black Box Warning read to responsible party- Not approved for dementia-related psychosis; increased mortality risk in elderly dementia patients on conventional or atypical antipsychotics; most deaths due to cardiovascular or infection events; extent to which antipsychotics contributed to this increase is not certain.

7. Give medication as ordered _____
 (Write medication name here)
8. Monitor resident for adverse reactions/side effects, skin rash, wheals, anaphylaxis etc...
9. Monitor resident for cognitive and behavior changes. Report changes to physician
10. Monitor for effectiveness of treatment
11. Initial dose new medication, write medication on behavior monitoring sheets
12. Other: _____

C.N.A. Responsibilities:

1. Monitor for & report cognitive and behavior changes to Charge Nurse
2. Report resident complaints to Charge Nurse
3. Monitor for adverse reactions/side effects, skin rash, wheals, anaphylaxis, etc...
4. Orient/Cue resident as needed
5. Other: _____

Care Plan Resolved 3 days from the date initiated if no adverse reactions noted.

INFORMED CONSENT FOR THE USE OF PSYCHOACTIVE MEDICATION THERAPY

RESIDENT NAME: _____ ROOM NUMBER: _____

MEDICATION: _____ MEDICATION DOSE: _____ MEDICATION FREQUENCY: _____

DIAGNOSIS FOR MEDICATION: _____

Target Behavior: 1) _____ 2) _____ 3) _____

THE CLINICALLY SIGNIFICANT SIDE EFFECTS POSSIBLY ASSOCIATED WITH THIS MEDICAL INTERVENTION INCLUDE BUT ARE NOT LIMITED TO:

ANTIPSYCHOTIC	ANTI ANXIETY	HYPNOTIC	ANTIDEPRESSANT	ANTIMANIC	PSYHOMOTOR STIMULANT
CONFUSION	BLURRED VISION	CONFUSION	BLURRED VISION	CONFUSION	DRY MOUTH
CONSTIPATION	CONFUSION	ANXIETY	CONSTIPATION	DROWSINESS	IMPAIRED TASTE
DROOLING	HYPOTENSION	FATIGUE	WEIGHT CHANGES	HYPOTENSION	INSOMNIA
DRY MOUTH	SEDATION	MANIA	URINARY RETENTION	IMPAIRED VISION	NERVOUSNESS
SEDATION	NIGHTMARES	HEADACHES	DYSPEPSIA	IMPAIRED COGNITION	ANOREXIA
MUSCLE RIGID	DRY MOUTH	LIGHTHEADED	HEADACHE	NEPHRITIC SYNDROME	
RESTLESSNESS	SLURRED SPEECH	NIGHTMARES	INSOMNIA	SEIZURES	
SLEEP DISTURBANCE	URINARY RETENTION	DIZZINESS	DRY MOUTH	TREMORS	
BLURRED VISION	APPETITE CHANGE	SYNCOPE	APPETITE CHANGE	BRAHYCARDIA	
STIFFNESS OF THE NECK	DIZZINESS	HALLUCINATIONS		NAUSEA	
INVOLUNTARY MOVEMENTS					

IS THIS MEDICATION AN A-TYPICAL MEDICATION WITH A BLACK BOX WARNING? [] YES [] NO

IF YES READ TO RESPONSIBLE PARTY: BLACK BOX WARNING: ELDERLY PATIENTS WITH DEMENTIA RELATED

PSYCHOSIS TREATED WITH A-TYPICAL ANTIPSYCHOTIC ARE AT AN INCREASED RISK OF DEATH COMPARED TO

PLACEBO DURING CLINICAL TRIALS.

THIS MEDICATION WILL BE REVIEWED BY PSYCHIATRIST OR DESIGNATED AGENT FOR PSYCHIATRIST DURING ROUTINE FACILITY ROUNDS AND ATTEMPT GRADUAL DOSE REDUCTION IF APPROPRIATE. AFTER INITIAL EVALUATION THIS WILL BE REVIEWED AS PER FACILITY PROTOCOL.

DATE OF ADMISSION: _____ DATE 1ST GDR REVIEWED: _____

I _____ HAVE BEEN ADVISED OF POTENTIAL SIDE EFFECTS ASSOCIATED WITH THE PRESCRIBED MEDICATION INCLUDING THE BLACK BOX WARNING IF APPLICABLE. I UNDERSTAND THIS IS NOT AN ALL INCLUSIVE LIST OF EVERY POTENTIAL SIDE EFFECT

OF THE PRESCRIBED MEDICATION. CHHC HAVE ADVISED ME OF THE POTENTIAL RISK AND I UNDERSTAND THOSE RISKS. [] YES [] NO

IF NO CHHC HAS PROVIDED OPPORTUNITY TO SPEAK WITH PRESCRIBING PHYSICIAN ANSWER ANY POTENTIAL QUESTIONS. [] YES [] NO

PRESCRIBING PHYSICIAN: _____ DATE PHYSICIAN SPOKE WITH FAMILY: _____

I _____ DO CONSENT to the use of _____
I understand my physician has prescribed the above medication as part of a treatment plan to address specific targeted behaviors as listed on the front of this form. I give this consent voluntarily and without any undue influence or coercion. I understand that this consent may be revoked at anytime by responsible party. I understand this consent is valid until consent is revoked or physician discontinues this medication.

DATE OF REVOCATION IF APPLICABLE: _____

I _____ DO NOT CONSENT to the use of _____
I understand that the medication has been prescribed by a physician as part of a treatment plan. I understand there may be a negative effect by not following the physician prescribed plan and release from liability and responsibility for anything that may happen to the named resident as a result of this refusal. My refusal to consent may also make it necessary to transfer named resident to another healthcare facility as a result of my psychiatric condition.

IN PERSON CONSENT

Nurse Signature Completing Form: _____ Date: _____

Residents Name (Print): _____ Resident Signature: _____ Date: _____

OR

> _____ > _____ > _____

Authorized Persons Name & Relationship

Signature

Date

TELEPHONE CONSENT

Name of Resident: _____

Name of Person Giving Consent: _____ Date: _____

Nurse's Signature: _____ Date: _____

Nurse's Signature: _____ Date: _____

PROPOSED TREATMENT PHYSICAL RESTRAINT: _____

PROPOSED PSYCHOTROPIC MEDICATION TREATMENT: _____

Resident: _____

Responsible Party: _____

**FACILITY VERIFICATION OF INFORMED CONSENT FOR THE USE OF PHYSICAL RESTRAINTS,
PSYCHOTHERAPEUTIC DRUGS OR "PROLONGED USE OF A DEVICE"**

IN ACCORDANCE WITH THE REQUIREMENT OF CALIFORNIA CODE OF REGULATION, TITLE 22, SECTION 72628 (a) & (b),
I HAVE REVIEWED THE FOLLOWING WITH THE RESIDENT OR SURROGATE DECISION MAKER,

1. THE REASON FOR THE TREATMENT, AS WELL AS THE NATURE AND SERIOUSNESS OF THE RESIDENT'S CONDITION.
2. THE NATURE OF THE PROCEDURES TO BE USED IN THE PROPOSED TREATMENT, INCLUDING THEIR PROBABLE FREQUENCY AND DURATION.
3. THE PROBABLE DEGREE AND DURATION (TEMPORARY OR PERMANENT) OF EITHER IMPROVEMENT OR REMISSION EXPECTED WITH OR WITHOUT SUCH TREATMENT.
4. THE NATURE, DEGREE, DURATION AND PROBABILITY OF POTENTIAL SIDE EFFECTS AND/OR SIGNIFICANT RISKS, AS WELL AS EXPECTED BENEFITS TO SUCH TREATMENT.
5. ANY REASONABLE ALTERNATIVE TREATMENTS AND THEIR RISKS AND BENEFITS.
6. THAT THE RESIDENT AND/OR RESPONSIBLE PARTY HAS THE RIGHT TO ACCEPT OR DECLINE THE PROPOSED TREATMENT, AND IF HE OR SHE CONSENTS, HAS THE RIGHT TO REVOKE CONSENT AT ANY TIME.

_____, I HAVE NOT DISCLOSED THE RISKS RELATED TO THE RESTRAINT, PSYCHOTHERAPEUTIC DRUG, OR PROLONGED USE OF A DEVICE TO THE RESIDENT'S REPRESENTATIVE BASED ON SECTION 72628 (a) and (b), BUT I HAVE STILL PROVIDED OTHER MATERIAL INFORMATION AS LISTED ABOVE:

_____, I HAVE OBTAINED INFORMED CONSENT FROM RESPONSIBLE PARTY / FAMILY PRIOR TO ADMISSION

SIGNATURE OF PHYSICIAN WHO
OBTAINED INFORMED CONSENT

DATE

RESIDENT NAME	PHYSICIAN	ROOM#	MR#

**FACILITY VERIFICATION OF RESIDENT INFORMED CONSENT
TO PHYSICAL RESTRAINTS, PSYCHOTHERAPEUTIC DRUGS**

Section I – MAY BE USED BY ATTENDING PHYSICIAN

I have obtained informed consent from _____
for the use of _____
for _____.

In accordance with the requirements of California Code of Regulations, Title 22, Section 72528 (a) and (b), I have reviewed with the resident the following material information:

1. The reason for the treatment and the nature and seriousness of the resident's illness;
2. The nature of the procedures to be used in the proposed treatment, including their probably frequency and duration;
3. The probable degree and duration (temporary or permanent) of improvement or remission expected, with or without such treatment.
4. The nature, degree, duration and probability of the side effects and significant risks, commonly known by the health professions;
5. The reasonable alternative treatments and risks, and why the health professional is recommending this particular treatment; and;
6. That the resident has the right to accept or refuse the proposed treatment, and if he or she consents, has the right to revoke his or her consent for any reason at any time.

_____ I have not disclosed the risks related to the restraint, or the psychotherapeutic drug, to the resident or the resident's representative based on Section 72528 (f), but I have still provided other material information as listed above.

Physician's Signature

Date

SECTION II – TO BE USED BY LICENSED NURSE unless Section I has MD signature.

I have verified that informed consent has been obtained from

_____ to the use of _____

_____ for _____

by _____

Dr. _____

Facility Licensed Nurse Signature

Date

Patient's Name

CONSENT FOR USE OF PSYCHOACTIVE MEDICATIONS

BENEFITS

The use of psychoactive medication(s):

- can be therapeutic and enabling for a resident suffering from mental illnesses.
- can help maintain or improve a resident's functional status.
- can protect a resident from harming self or others.

POTENTIAL NEGATIVE OUTCOMES

As with any medication, there are potential side effects associated with the use of psychoactive medications that may include, but are not limited to: hypotension or hypertension, cardiac arrhythmias, muscular rigidity, parkinsonian symptoms, akinesia, dystonia, akathisia, tardive dyskinesia, gait disturbances, confusion/delirium, depression, hallucinations/delusions, decline in cognition/communication, agitation, changes in vision, dehydration, constipation, urinary retention, dry mouth, increase in total cholesterol, nausea, vomiting. For more information on specific medication side effects and risks, refer to manufacturer's package insert.*

This facility would initiate psychoactive medication intervention only:

- after less restrictive non-drug interventions were attempted and found to be ineffective; and
- when there are appropriate indications for its use.

The facility will monitor the resident's status and adjust care, as necessary. In the presence of adverse consequences (reactions/side effects), the medication will be reduced or discontinued per physician orders.

The following non-drug interventions have been attempted and proven to be ineffective:

Continued on Side Two

* Many antipsychotic medications contain additional warnings such as: Increased Mortality in Elderly Patients with Dementia-Related Psychosis.

Resident Name	ID #	Room #	Physician

CONSENT FOR USE OF PSYCHOACTIVE MEDICATIONS

RECOMMENDATIONS

I understand my physician has recommended and ordered the following medication(s) for the targeted behavior(s)/diagnosis listed.

1 Recommended Drug, Dosage, Frequency: _____
 Targeted Behaviors/Symptom: _____
 Potential Side Effects: _____
 Resident provided with a list of side effects specific to their psychoactive medication.

2 Recommended Drug, Dosage, Frequency: _____
 Targeted Behaviors/Symptom: _____
 Potential Side Effects: _____
 Resident provided with a list of side effects specific to their psychoactive medication.

I have read or it has been explained to me and I understand the benefits, potential negative outcomes and side effects specific to the use of the psychoactive medication(s) listed above. Understanding the benefits, potential negative outcomes and side effects specific to the use of the psychoactive medication(s):

Initial appropriate response

I DO consent to the use of the psychoactive medications listed above in 1/ 2. I understand that once the target behavior/symptom is controlled, the dose will be gradually reduced to the lowest possible dosage and frequency, or discontinued unless contraindicated by my physician/prescriber.

I understand that I have the right to refuse a dose of psychoactive medication at anytime. Additionally, I understand that this consent may be revoked at anytime by me. I understand that this consent is valid until the consent is withdrawn or the physician/prescriber has discontinued any of the above medication(s).

I DO NOT consent to the use of psychoactive medication(s) as recommended above in 1/ 2. I acknowledge that my care planning team has advised me that by not accepting, I may be at additional medical or psychosocial risks including:

Resident Signature		Date
Resident Representative or Durable Power of Attorney Signature/Relationship	<input type="checkbox"/> Consent - In Person <input type="checkbox"/> Consent - By Phone <i>(per facility policy)</i>	Date
Facility Representative Signature/Title		Date

ADDITIONAL COMMENTS:

 Physician order has been obtained.

Resident Name	ID #	Room #	Physician
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“They Want Docile”

How Nursing Homes in the United States Overmedicate People with Dementia

Each week, US nursing facilities administer antipsychotic drugs to over 179,000 people who lack diagnoses for which the drugs are approved, often without their informed consent. Most of these individuals are older and have Alzheimer’s disease or another form of dementia. Too often, the sedative effect of these drugs drives the high prevalence of their use. The drugs can alter consciousness, sever one’s ability to interact with others, and can make it easier for understaffed facilities to control residents. They also increase the risk of death within ten weeks around 1.6 times in older people with dementia.

Based on quantitative analysis and interviews with over 300 people living in facilities in six states, their families, staff, long-term care and disability experts, government officials, and advocates, *“They Want Docile”* demonstrates that inappropriate use of antipsychotic drugs in older people with dementia persists as a pervasive problem despite some recent government efforts to reduce it. The report documents the harm to individuals, the frequent administration of the drugs without informed consent, and the weak deterrent effect of current enforcement efforts.

Human Rights Watch calls on the Centers for Medicare & Medicaid Services to employ the significant regulatory and enforcement tools at its disposal to end the inappropriate use of antipsychotic drugs in older people with dementia in nursing homes. The federal agency and its state counterparts should assess meaningful sanctions against nursing facilities that violate the rights of residents.



Lenora Cline, 88, has lived in a nursing home for years. She has Alzheimer’s disease. Laurel Cline, her daughter, visits her twice a day and assists staff with the care-taking, fearing that otherwise, with the shortage of staff, her mother will not be turned, fed, or changed. She had to persuade the facility to discontinue antipsychotic medications. Before successfully objecting to their use, Ms. Cline said, “Every little thing, they want to put you on psych meds.” Los Angeles, California, August 2017.

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