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

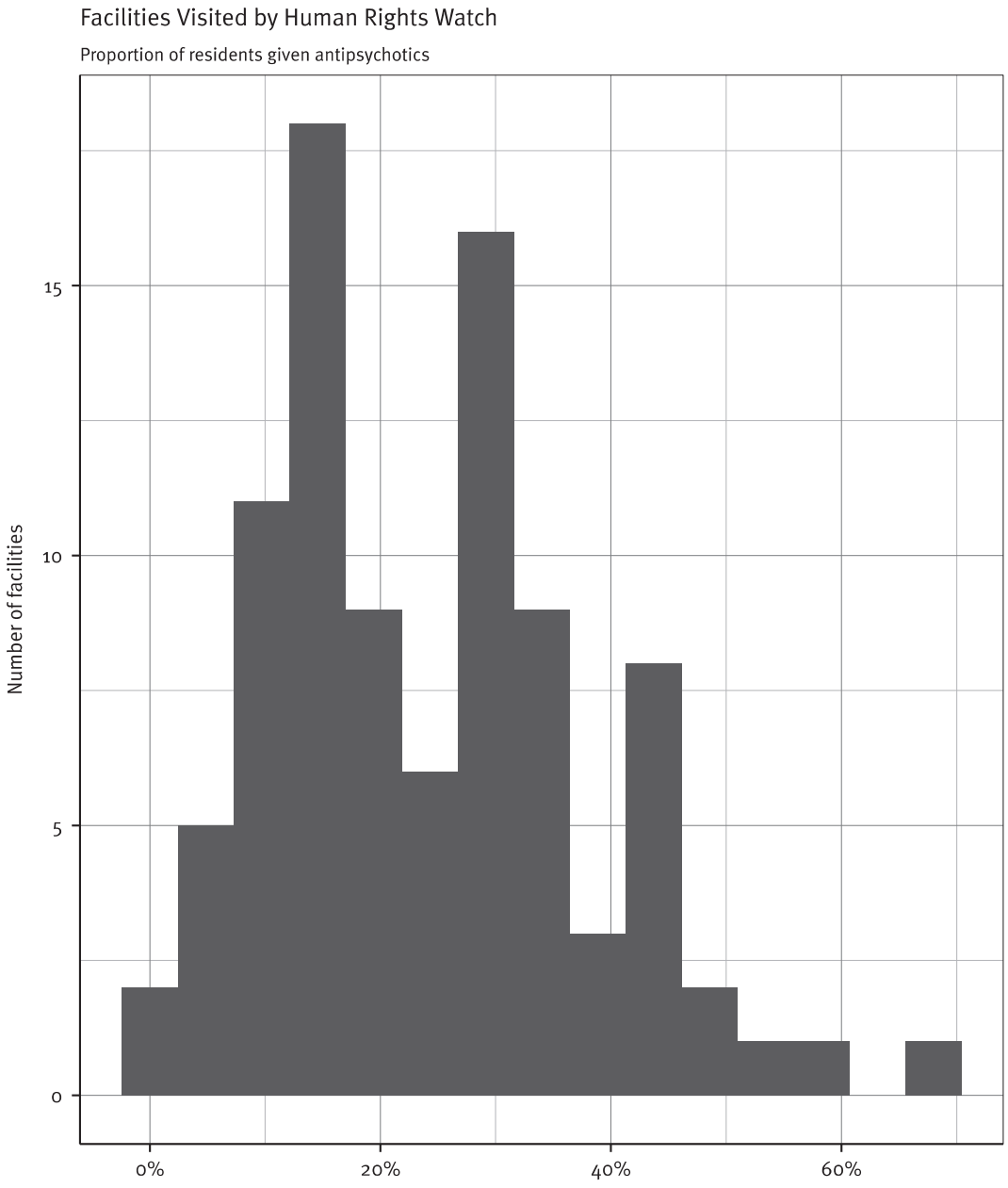
permanent employee of a nursing home in his or her first four months of employment in the facility). CNAs provide the vast majority of nursing services and assistance with daily care needs to residents of nursing homes: feeding residents; turning, positioning, and transferring residents; bathing and 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%

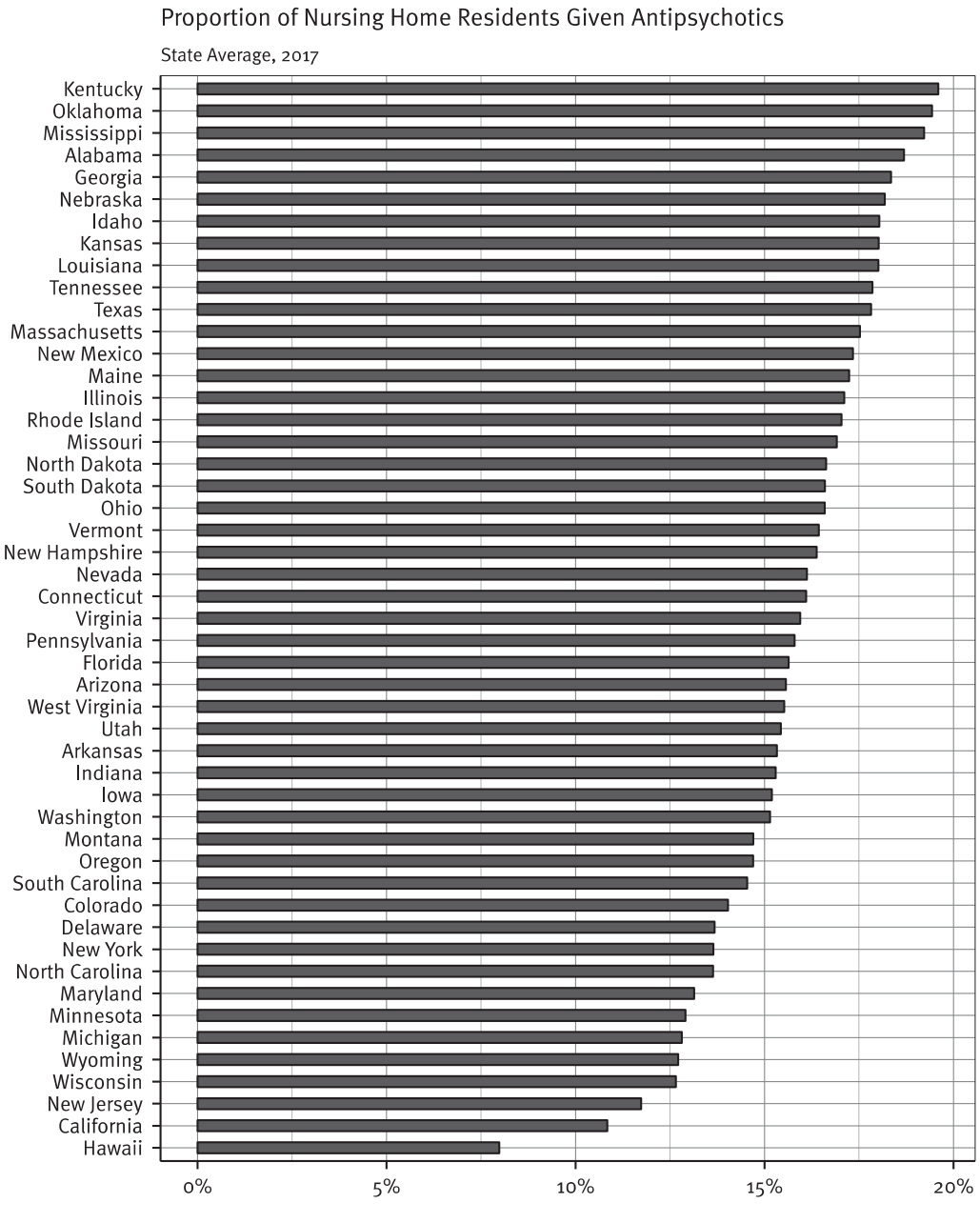
Table 4. Key Data on Nursing Facilities, Residents of Nursing Facilities, and Antipsychotic Drug Use in States Visited by Human Rights Watch[328]

[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/CertificationandComplianc/Downloads/nursinghomedatacompendium_508-2015.pdf (accessed September 11, 2017) pp. 22, 199.



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



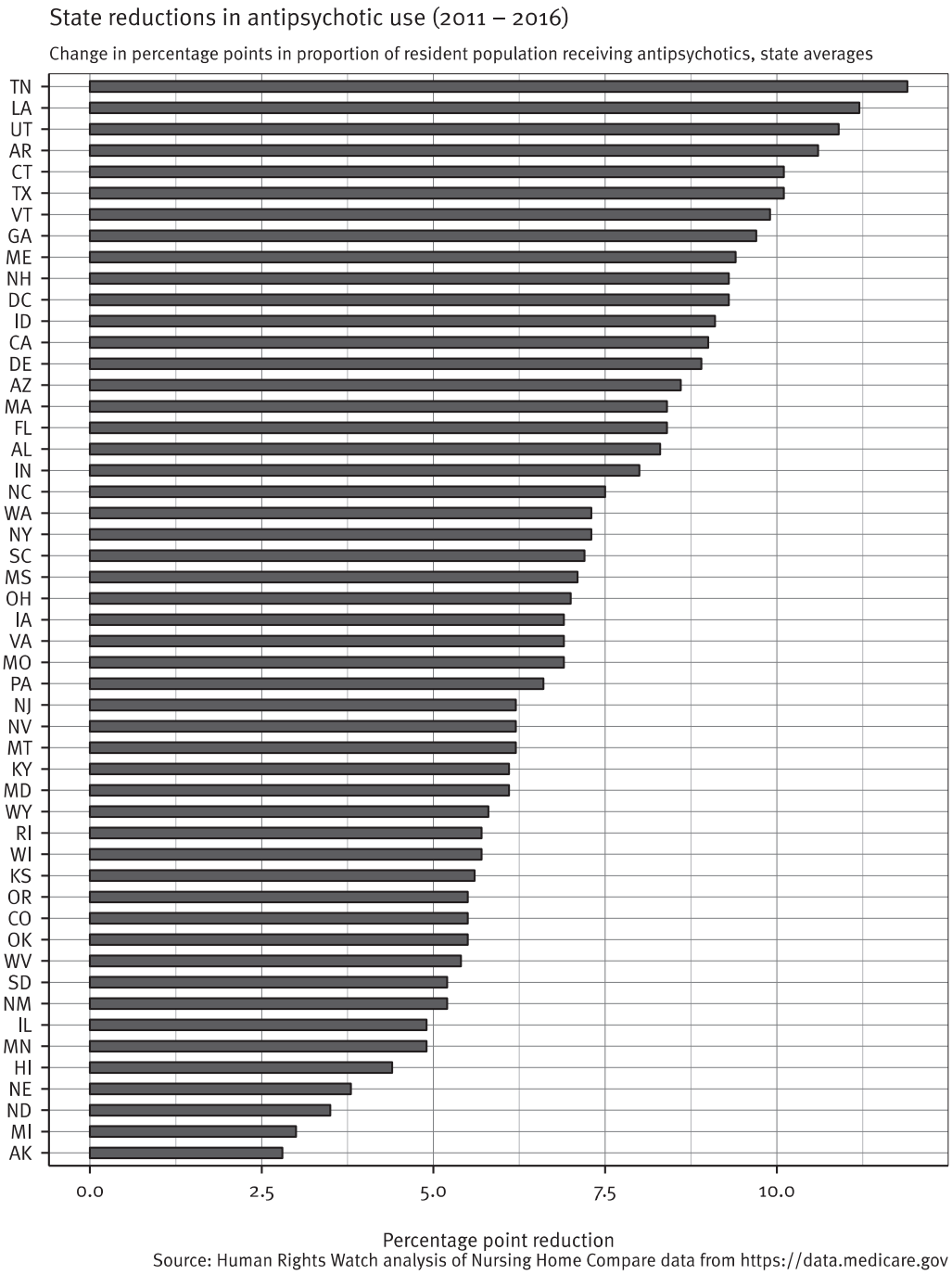
Source: Human Rights Watch analysis of Nursing Home Compare data from https://data.medicare.gov
Note: Excludes patients with diagnoses of Schizophrenia, Tourettes syndrome or Huntingtons disease and nursing facilities where fewer than 50 percent of patients are over age 65.

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

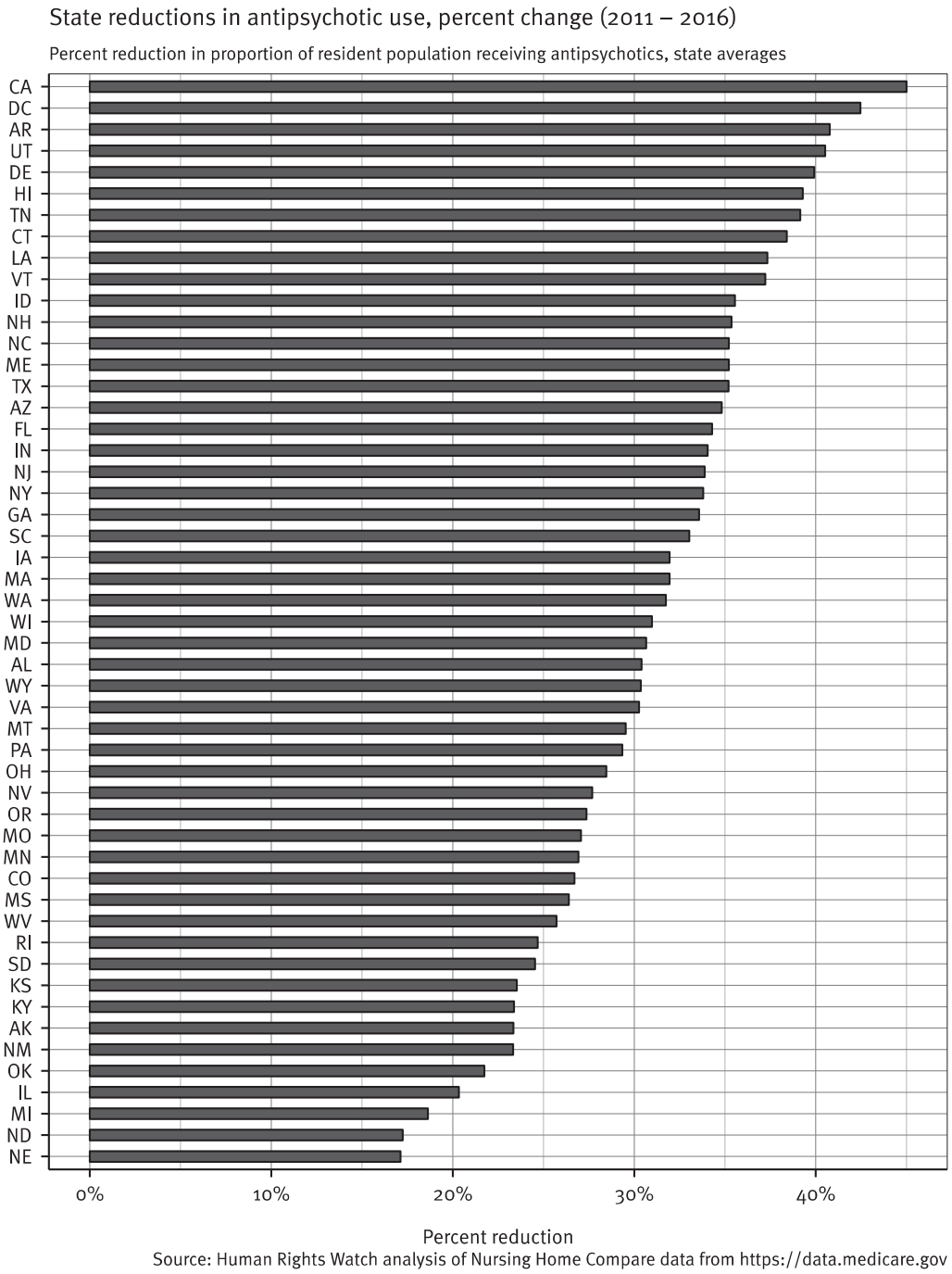
State	2011 Rate	2016 Rate	Percentage Point Difference	Percent Change
LA	30.0%	18.8%	11.2%	-37.3%
TN	30.4%	18.5%	11.9%	-39.1%
GA	28.9%	19.2%	9.7%	-33.6%
TX	28.7%	18.6%	10.1%	-35.2%
AL	27.3%	19.0%	8.3%	-30.4%
AR	26.0%	15.4%	10.6%	-40.8%
MS	26.9%	19.8%	7.1%	-26.4%
UT	26.9%	16.0%	10.9%	-40.5%
ME	26.7%	17.3%	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)



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



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/certificationandcomplianc/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
abilifiy	antipsycotic	clozepam	prolixen	seroguel
abilify	antipsyhchotic	closzepine	prolixin	seroqel
Abilily	antipsyhotic	compazine	quetapine	seroqeul
abilitfy	antipsypsychotic	fluphenazine	quetialine	seroqued
anipsychotic	antipsyschotic	geoden	quetianpine	seroquel
anitipsychotic	antipsyshotic	geodon	quetiapene	seroquelå
anitipsychotics	antipychotic	geodone	quetiapin	seroquesl
anitphychotic	antipychotics	haldol	quetiapine	seroquil
anitpsychotic	antipyschotic	haldol1mg	quetiapine100	seroqul
anitpsychotics	antipyschotics	haldoperidol	quetiapine125	stelazine
anitpsycotic	antipyshcotic	haloperidal	quetiapinefumarate	thioridazaine
antiphsychotic	antipysychotic	haloperidol	quetiiapine	thioridazine
antiphychotic	antipysychotics	haloperiodol	quetipiane	thioridine
antiphyschotic	antispcyhotic	halperidol	quetipine	thiothixene
antipschotic	antisphychotic	loxapin	rispderal	thorough
antipscychotic	antispsychotic	loxapine	rispderdal	trifluoperazine
antipscyhotic	antispychotic	loxipine	rispedal	trifuridine
antipshchotic	antispychotropic	loxitane	rispeidone	trilafon
antipshychotic	antisychotic	loxopine	risperadal	trilafor
antipsyc	antopsychotic	navane	risperadol	ziprasadone
antipsych	antpsychotic	olananzapine	risperadone	ziprasiadone
antipsychcotic	antrpsychotic	olanazapine	risperal	ziprasidone
antipsychiatic	antypsychotic	olansapine	risperdal	ziprosidone
antipsychiatric	antypsycotic	olanzaoine	risperdalconsta	zxprexa
antipsychiotic	aripazole	olanzapin	risperdalå¨	zyperexa
antipsychoactive	aripiprazole	olanzapine	risperdione	zypexa
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	aripririzole	perphenzine	risperido	zyprezia
antipsychotics	chlorpromazine	pimozide	risperidol	zyxprea
antipsychotive	clozapin	prochloperazine	risperidone	
antipsychotropic	clozapine	prochlorperazine	risperiodone	

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

Appendix 5: Correspondence with CMS

350 Fifth Avenue, 34th Floor
New York, NY 10118-3299
Tel: +1-212-290-4700
Fax: +1-212-736-1300; 917-591-3452

HUMAN RIGHTS WATCH

HRW.org

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

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:

- 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?

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?

We ask that you respond to these queries by July 7, 2017, so that we can incorporate your response into our report and into any other public comments HRW issues on

Appendix 6: Correspondence with LeadingAge

350 Fifth Avenue, 34th Floor
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June 20, 2017

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

HUMAN RIGHTS WATCH
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.

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:

- 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

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

LeadingAge

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?

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The Trusted Voice for Aging

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 torte 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

350 Fifth Avenue, 34th Floor
New York, NY 10118-3299
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Fax: +1-212-736-1300; 917-591-3452

June 20, 2017

The Honorable Mark Parkinson
President and CEO
American Health Care Association
1201 L Street NW
Washington, D.C. 20005

HUMAN RIGHTS WATCH
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:

- 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

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

AHCA AMERICAN HEALTH CARE ASSOCIATION
NCAL NATIONAL CENTER FOR ASSISTED LIVING

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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,

David R. Gifford, MD, MPH
Senior Vice President for Quality & Regulatory Affairs

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

4

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:**_____ **Time:**_____
   Nurse #1:_____ **Nurse #2:**_____
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

( ) Anti-psychotics	( ) Antidepressants	( ) Anti-anxiety	( ) Hypnotic	( ) Anti-manic / Mood Stabilizers	
Neck Stiffness	Dry Mouth	Hypotension	Syncope	Confusion	Dizziness
Confusion	Blurred Vision	Sedation	Dizziness	Drowsiness	Rash
Muscle Rigidity	Constipation	Dizziness	Confusion	Hypotension	Headache
Anxiety	Urinary Retention	Dry Mouth	Nightmares	Sedation	Ataxia / Paresthesia
Drooling	Hypotension	Blurred Vision	Daytime	Nephrotic Syndrome	Visual Disturbance
Blurred Vision	Appetite Changes	Urinary Retention	Hallucinations	Seizures	Hepatotoxicity
Tremors	Headache	Drowsiness	Mania	Impaired Cognition	Indigestion/ Nausea/Vomiting
Restlessness	Insomnia	Slurred Speech	Fatigue	Tremors	Drooling
Sleep Disturbances	Dyspepsia	Confusion	Headache	Impaired Vision	Anorexia/Increased Appetite
Dry Mouth	Weight Changes	Fatigue	Sedation	Low Heart Rate	Constipation/Diarrhea
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, whelps, 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, whelps, 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: _____ MEICATION DOSE: _____ MEDICATION FEQUENCY: _____

DIAGNOSIS FOR MEDICATION: _____

Target Behavior: 1) _____ 2) _____ 3) _____

THE CLINICALLY SIGNIFICANT SIDE EFFECTS POSSIBLY ASSOCIATED WITH THIS MEDICAL INERVENTION INCLUDE BUT ARE NOT LIMITED TO:

ANTIPSYCHOTIC	ANTI ANXIETY	HYPNOTIC	ANTIDPRESSANT	ANTIMANIC	PSYHOMOTOR STIMULANT
CONFUSION	BLURRED VISION	CONFUSION	BLURRED VISION	CONFUSION	DRY MOUTH
CONSTIPATION	CONFUSION	ANXIETY	CONSTIPATION	DROWSSINESS	IMPAIRED TASTE
DROOLING	HYPOTENTION	FATIGUE	WEIGHT CHANGES	HYPOTENTION	INSOMNIA
DRY MOUTH	SEDATION	MANIA	URINARY RETENTION	IMPAIRED VISION	NERVOUSNESS
SEDATION	NIGHTMARES	HEADACHES	DYSPEPSIA	IMPAIRED COGNITION	ANOREXIA
MUSCLE RAGID	DRY MOUTH	LIGHTHEADED	HEADACHE	NEPHRITIC SYNDROME	
RESTLESSNESS	SLURRED SPEECH	NIGHTMARES	INSOMIÑA	SEIZURES	
SLEEP DISTURBANCE	URINARY RETENTION	DIZZINESS	DRY MOUTH	TREMORS	
BLURRED VISION	APPETITE CHANGE	SYNCODE	APPETITE CHANGE	BRADYCARDIA	
STIFFNESS OF THE NECK	DIZZINESS	HALLUCINATIONS		NAUSE	
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 DEMENTIS RELATED PSYCHOSIS TREATED WITH A-TYPICAL ANTISYCHOTIC ARE AT AN INCREASED RISK OF DEATH COMPARED TO PLACEBO DURING CLINICAL TRIALS.

THIS MEDICATION WILL BE REVIEWED BY PSYCHAITRIST OR DESIGNATED AGENT FOR PSYCHAITRIST DURING ROUTINE FACILITY ROUNDS AND ATTEMPT GRADUAL DOSE REDUCTION IF APPROPRIATE. AFTER INTIAL EVALUATION THIS WILL BE REVIEWED AS PER FACILITY PROTOCOL.

DATE OF ADMISSION. _____ DATE 1ST GDR REVIEWED: _____

I _____ HAVE BEEEN ADVISED OD POTENTIAL SIDE AFFECTS ASSOCIATED WITH THE PROSCRIBED MEDICATION INCLUDING THE BLACK BOX WARNING IF APPLICABLE. I UNDERSTAND THIS IS NOT AN ALL INCLUSIVE LIST OF EVERY POTENTIAL SIDE AFFECT 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 72528 (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 72528 (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 ot 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 form

_____to the use of _____

_____for_____by

Dr. _____.

_____ _____
Facility Licensed Nurse Signature Date

_____
Patient's Name

SIDE ONE

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

SIDE TWO

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	☐ Consent - In Person ☐ Consent - By Phone *(per facility policy)*	Date
Facility Representative Signature/Title		Date

ADDITIONAL COMMENTS:

☐ *Physician order has been obtained.*

Resident Name	ID #	Room #	Physician