



**Under-Enforced and Over-  
Prescribed: The Antipsychotic  
Drug Epidemic Ravaging  
America's Nursing Homes**

*Report of the Committee on Ways and Means Majority  
U.S. House of Representatives*

July 2020

*“The implicit goal of the regulatory system is to ensure that any person requiring nursing home care be able to enter any certified nursing home and receive appropriate care, be treated with courtesy, and enjoy continued civil and legal rights. This happens in many nursing homes in all parts of the country. But in many other government-certified nursing homes, individuals who are admitted receive very inadequate – sometimes shockingly deficient – care that is likely to hasten the deterioration of their physical, mental, and emotional health.”*

*—Institute of Medicine, 1986*

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## FOREWORD

In 2018 and 2019, the Committee on Ways and Means began investigating the overuse of antipsychotics in nursing homes across the country. This was long before COVID-19 came to American shores – before it descended upon Life Care Center of Kirkland, Washington, and before the novel virus claimed the lives of thousands of our nation’s long-term care facility residents and staff. The virus has largely targeted the most vulnerable among us with individuals over the age of 65 representing almost a third of all COVID-19 cases, nearly half of all hospitalizations, and 80 percent of all deaths.<sup>1</sup> As of mid-July 2020, the number of known COVID-19 cases in long-term care facilities reached 316,000 across nearly 14,000 facilities. Deaths of long-term care residents and staff have likely exceeded 57,000, accounting for more than 40 percent of COVID-19 deaths nationwide and more than 60 percent in many states.<sup>2</sup> Alarming, these numbers are likely an underestimation due to still inadequate testing.

The rampant spread of the virus within and across nursing homes in the United States is unfortunately not surprising. It reflects persistent challenges known to have plagued nursing home settings for decades – some attributable to limited state budgets and the low Medicaid payment rates associated with them, others attributable to low-paying jobs with low retention rates, or to the lack of alignment between financial decision-making and patient needs.<sup>3</sup> Some challenges, too, may reflect cultural attitudes toward aging and the stigma Americans have for years applied to institutional elder care.

Although the story of antipsychotic overuse that the Committee offers in this report is not specific to current concerns – that of preparedness and infection control in nursing homes across the country – it is emblematic of the challenges that have been quietly plaguing nursing homes across the country for years, if not decades. Even in normal times, nursing homes have been hotspots for infection and disease. In the United States, one to three million serious infections occur in nursing homes each year, and more than 60 percent of facilities have been cited for deficiencies related to infection control since the beginning of 2017.<sup>4,5</sup> In addition, sedation, a common side effect of antipsychotics, could result in nursing home residents being less able to communicate symptoms, leading to delayed detection of infections.<sup>6</sup>

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<sup>1</sup> Severe Outcomes Among Patients with Coronavirus Disease 2019 (COVID-19) – United States, February 12–March 16, 2020, *Center for Disease Control and Prevention*, (2020). Available at: [https://www.cdc.gov/mmwr/volumes/69/wr/mm6912e2.htm?s\\_cid=mm6912e2\\_w](https://www.cdc.gov/mmwr/volumes/69/wr/mm6912e2.htm?s_cid=mm6912e2_w)

<sup>2</sup> More Than 40% of U.S. Coronavirus Deaths Are Linked to Nursing Homes, *The New York Times*, (2020). Available at: <https://www.nytimes.com/interactive/2020/us/coronavirus-nursing-homes.html>

<sup>3</sup> Walker, Chas, Poverty Wages in Nursing Homes Have Accelerated the Coronavirus Outbreak, *Boston Globe*, (2020). Available at: <https://www.bostonglobe.com/2020/04/25/opinion/poverty-wages-nursing-homes-have-accelerated-coronavirus-outbreak/>

<sup>4</sup> Nursing Homes and Assisted Living, *Center for Disease Control and Prevention*, (2019). Available at: <https://www.cdc.gov/longtermcare/index.html>

<sup>5</sup> Coronavirus Stress Test: Many 5-Star Nursing Homes Have Infection Control Lapses, *Kaiser Family Foundation*, (2020). Available at: <https://khn.org/news/COVID-19-preparedness-infection-control-lapses-at-top-rated-nursing-homes/>

<sup>6</sup> Adverse Effects of Antipsychotic Medications, *American Family Physician*, (2010). Available at: <https://www.aafp.org/afp/2010/0301/p617.html>

The story of antipsychotics overuse in nursing homes is similar to infection control lapses. It is one of patient harm, inadequate oversight, and insufficient staffing. And it is one of often avoidable heartbreak. Addressing the issues in nursing homes begins with considering the immense vulnerability of our nursing home population and committing to tackling the multitude of interrelated challenges that persist. The scourge of COVID-19 in nursing facilities demonstrates the tragic consequences of turning a blind eye to our nation's seniors and individuals with disabilities, and it underscores the need for robust emergency preparedness and oversight of the nursing home industry.

— *Ways and Means Committee Majority Staff, July 2020*

## EXECUTIVE SUMMARY

In the fourth quarter of 2019, approximately 20 percent of all skilled nursing facility (SNF) residents in the United States (U.S.) – about 298,650 people every week – received some form of antipsychotic medication, most without any psychosis diagnosis for which the drugs are indicated.<sup>7, 8, 9</sup> Nursing homes continue to give these powerful drugs to residents despite the Food and Drug Administration’s (FDA) issuing a black box warning specifically stating that the use of off-label antipsychotics among seniors with dementia can result in injuries, hospitalizations, and even death.<sup>10</sup> In fact, individuals over 70 are 3.5 times more likely than younger individuals to be admitted to the hospital due to adverse drug reactions associated with psychotropic medications.<sup>11</sup> One recent study found that the inappropriate use of antipsychotic medication was associated with a 50 percent increased risk of a serious fall-related bone fracture.<sup>12</sup>

A 2011 Department of Health and Human Services (HHS) Office of Inspector General (OIG) report found that 14 percent of elderly nursing home residents had Medicare claims for atypical antipsychotic use, shining a national spotlight on this issue. In response, the Obama Administration took steps to crack down on the high rates of antipsychotics prescribing in SNFs. In 2016, the Centers for Medicare & Medicaid Services (CMS) published a Final Rule that strengthened the public enforcement system for SNFs violating federal standards of care, called Requirements of Participation (RoPs).<sup>13</sup> This Final Rule increased requirements for pharmacists to report irregularities in antipsychotic overuse, established a 14-day PRN (*pro re nata* or “as needed”) limitation on psychotropic drugs, and implemented behavioral health measures targeted to enhance person-centered care.<sup>14</sup> Finally, CMS directed civil money penalties (CMPs) be imposed against nursing homes for all deficiencies, including the misuse and overuse of antipsychotic drugs, on a per-day basis for each day an individual SNF violated these federal RoPs. By 2016, two-thirds of all CMPs for facility deficiencies were per-day penalties.

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<sup>7</sup> Committee calculations of MDS Frequency Report: Fourth Quarter 2019 Antipsychotic Medications Received, *Centers for Medicare and Medicaid Services*, (2019). Available at: [https://www.cms.gov/apps/mds/mds\\_notemp/mds30FreqStart.asp?isSubmitted=mds30Freq3&var=N0410A&date=33](https://www.cms.gov/apps/mds/mds_notemp/mds30FreqStart.asp?isSubmitted=mds30Freq3&var=N0410A&date=33)

<sup>8</sup> Mollot, Richard, Despite Promised Crackdown, Citations for Inappropriate Drugging Remain Rare, *Long Term Care Community Coalition*, (2018). Available at: <https://nursinghome411.org/wp-content/uploads/2018/11/LTCCC-Advisory-Nursing-Home-Drugging-Citations-November-2018.pdf>

<sup>9</sup> Report to the Congress: Medicare Payment Policy, *Medicare Payment Advisory Commission*, (2020). Available at: [http://medpac.gov/docs/default-source/reports/mar20\\_entirereport\\_sec.pdf](http://medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf)

<sup>10</sup> Atypical Antipsychotic Medications: Use in Adults, *Centers for Medicare and Medicaid Services*, (2015). Available at: <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Pharmacy-Education-Materials/Downloads/atyp-antipsych-adult-factsheet11-14.pdf>

<sup>11</sup> Brooks, Hoblyn, Neurocognitive costs and benefits of psychotropic medications in older adults, *Journal of Geriatric Psychiatry and Neurology*, (2007); 20:199–214.

<sup>12</sup> Fraser, Lisa-Ann, Falls and Fractures With Atypical Antipsychotic Medication Use, *JAMA Network*, (2015). Available at: <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2089230>

<sup>13</sup> Medicare and Medicaid Programs; Reform of Requirements for Long Term Care Facilities, *Centers for Medicare and Medicaid Services*, (2016). Available at: <https://www.govinfo.gov/content/pkg/FR-2016-10-04/pdf/2016-23503.pdf>

<sup>14</sup> *Id.*

As part of the Trump Administration’s broader de-regulation campaign, in 2017 and 2018, the Administration reversed course and rolled back a number of Obama-era regulations and practices. The Trump Administration granted facilities an 18-month moratorium on the 2016 Obama-era safety regulations, including those that established the 14-day PRN limitation and CMPs for citations related to inappropriate antipsychotic use.<sup>15</sup>

This report provides an overview of antipsychotic citation trends in SNFs from 2015 to 2018. Using data from CMS and the Kaiser Family Foundation (KFF), the Committee conducted five state-level descriptive analyses.

## KEY FINDINGS

### *Inappropriate Antipsychotic Drug Use Remains High in Skilled Nursing Facilities*

- Approximately 20 percent of all skilled nursing facility residents in the U.S. – about 298,650 people every week – received some form of antipsychotic medication in the fourth quarter of 2019, while only about two percent had qualifying conditions for such drugs.
- Citations for antipsychotic misuse in SNFs increased by 200 percent between 2015 and 2017 but declined by 22 percent from 2017 to 2018, as the Trump Administration rolled back Obama-era protections.
- Rates of antipsychotic citations remain high, particularly in the Northwest and Midwest.
- Ten percent of citations associated with Actual Harm or Immediate Jeopardy to a resident’s health or safety resulted in no fine from 2017-2018.

**Citations for antipsychotic misuse in SNFs increased by 200 percent between 2015 and 2017 but were followed by a 22 percent decline from 2017 to 2018.** Nationally, between 2015 and 2018, there was a 124 percent increase in the number of citations SNFs received, from 1116 citations (2015) to 2,497 citations (2018). Data showed a 200 percent increase in the rate of citations for unnecessary antipsychotic use from 2015 to 2016 under the Obama Administration (when Obama-era nursing home regulations went into full effect). From 2016 to 2017, the average national citation rate remained relative stable, decreasing by 3.9 percent (about 130 total citations) nationwide. This period was followed by a 22 percent decline in citations from 2017 to 2018 under the Trump Administration, which coincided with a period of SNF deregulation.

<sup>15</sup> Rau, Jordan, Trump Administration Cuts the Size of Fines for Health Violations in Nursing Homes. *National Public Radio*, (2019). Available at: <https://www.npr.org/sections/health-shots/2019/03/15/702645465/trump-administration-cuts-the-size-of-fines-for-health-violations-in-nursing-hom>

Some research suggests this national reduction may also be the result of SNFs increasingly falsifying psychosis diagnoses to avoid inappropriate antipsychotic citations.<sup>16, 17</sup>

**Overall, rates of antipsychotic citations remain high, particularly in the Northwest and Midwest.** In 2018, state surveyors issued an average of 49 citations for unnecessary antipsychotic medications in SNFs. About 15 percent of SNFs nationwide (2,327), received at least one antipsychotic citation that year. States in the Pacific Northwest and Midwest had relatively higher antipsychotic citation rates.

**Ten percent of citations associated with “Actual Harm” or “Immediate Jeopardy” to a resident’s health or safety resulted in no fine.** In 2017-2018, surveyors issued 70 citations for “Actual Harm” or “Immediate Jeopardy to Resident Health or Safety” across the country. Only 0.02 percent of all antipsychotic citations (41 of the total 5,704 antipsychotic citations) within the 2017-2018 dataset documented “Actual Harm” or “Immediate Jeopardy.” Nearly one-fourth of these citations were associated with a fine of less than \$20,000, and almost 10 percent of these citations resulted in *no penalty* whatsoever, despite each of these citations being associated with actual harm to a resident.

The analysis presented in this report illustrates that, across the nation, antipsychotic citation rates have decreased dramatically since 2017. Nevertheless, use of antipsychotics remains high, particularly in the Northwest and Midwest, and the extent to which nursing home management may have falsified diagnoses to justify the inappropriate use of these drugs as a chemical restraint is relatively unknown. Regulatory roll-back and a lack of meaningful federal enforcement may have also played a significant role in permitting the use of antipsychotics to continue.

The high rate of antipsychotics use across our nation’s nursing homes shows that many facilities continue to resort to the use of these potentially dangerous drugs as a chemical restraint – in lieu of proper staffing – which has the potential to harm hundreds of thousands of patients. As the population continues to age and more Baby Boomers increasingly rely on institutional care provided in SNFs, it is critical that meaningful steps are taken to reduce the overuse of antipsychotics and ensure the nation adequately and appropriately addresses the needs of these vulnerable patient groups.

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<sup>16</sup> Flamm, Hannah, Why are nursing homes drugging dementia patients without their consent? *The Washington Post*, (2018). Available at: [https://www.washingtonpost.com/outlook/2018/08/10/8baff64a-9a63-11e8-8d5e-c6c594024954\\_story.html](https://www.washingtonpost.com/outlook/2018/08/10/8baff64a-9a63-11e8-8d5e-c6c594024954_story.html)

<sup>17</sup> Urick, Kaskie, Carnahan,. Improving antipsychotic prescribing practices in nursing facilities: The role of surveyor methods and surveying agencies in upholding the Nursing Home Reform Act. *Res Social Admin Pharm* ,(2016). Jan-Feb;12(1):91-103.

## INTRODCUTION

*“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.”*

— 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

Quotes provided to Committee from *Human Rights Watch analysis*; US: Nursing Homes Misuse Drugs to Control Residents, Human Rights Watch, (2018). Available at: <https://www.hrw.org/news/2018/02/05/us-nursing-homes-misuse-drugs-control-residents>

When the U.S. Congress passed the Omnibus Reconciliation Act (OBRA) of 1987, it included the Nursing Home Reform Act (NHRA), which outlawed the inhumane use of chemical and physical restraints for residents of skilled nursing facilities (SNFs), except in cases where such restraints were necessary to protect a patient from doing physical harm to himself/herself/themselves or to others.<sup>18, 19</sup> Instead of eliminating restraints altogether, passage of the NHRA shifted focus to another kind of restraint: those induced by medications, often called “chemical restraints.”<sup>20</sup> For the purposes of this report, the Committee defines “chemical restraint” as the use of a drug indicated for a psychiatric disorder that is inappropriately prescribed to a resident to modify behavior or for the purposes of discipline or convenience.<sup>21</sup>

Scientists first developed antipsychotic drugs in the 1950s as psychotropic drugs that could alter the central nervous system.<sup>22</sup> They were originally developed to treat schizophrenia, but some were later approved to treat other conditions, including Tourette’s Syndrome and bipolar disorder.<sup>23</sup> Although not clinically indicated for dementia, many patients being treated for dementia have received these drugs, leading the Food and Drug Administration (FDA) to issue a black box warning specifically stating that the use of off-label antipsychotics among seniors without a qualifying diagnosis described on the drug’s label can result in injuries, hospitalizations, and even death (see Figure 1).<sup>24, 25</sup>

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<sup>18</sup> Klauber, Martin and Wright, Bernadette, The 1987 Nursing Home Reform Act, *American Association of Retired Persons*, (2001). Available at: [https://www.aarp.org/home-garden/livable-communities/info-2001/the\\_1987\\_nursing\\_home\\_reform\\_act.html](https://www.aarp.org/home-garden/livable-communities/info-2001/the_1987_nursing_home_reform_act.html)

<sup>19</sup> Subtitle C of the Omnibus Reconciliation Act (OBRA) of 1987, Pub. L. No. 100-203.

<sup>20</sup> US: Nursing Homes Misuse Drugs to Control Residents, *Human Rights Watch*, (2018). Available at: <https://www.hrw.org/news/2018/02/05/us-nursing-homes-misuse-drugs-control-residents>

<sup>21</sup> Flamm, Hannah, Why are nursing homes drugging dementia patients without their consent? *The Washington Post*, (2018). Available at: [https://www.washingtonpost.com/outlook/2018/08/10/8baff64a-9a63-11e8-8d5e-c6c594024954\\_story.html](https://www.washingtonpost.com/outlook/2018/08/10/8baff64a-9a63-11e8-8d5e-c6c594024954_story.html)

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

<sup>23</sup> *Id.*

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

<sup>25</sup> Atypical Antipsychotic Medications: Use in Adults, *Centers for Medicare and Medicaid Services*, (2015). Available at: <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Pharmacy-Education-Materials/Downloads/atyp-antipsych-adult-factsheet11-14.pdf>

**Figure 1. Example of FDA Black Box Warning Label for Antipsychotic, Risperdal<sup>26</sup>**

**WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS  
WITH DEMENTIA-RELATED PSYCHOSIS**  
*See full prescribing information for complete boxed warning.*  
**Elderly patients with dementia-related psychosis treated with antipsychotic  
drugs are at an increased risk of death. RISPERDAL® is not approved for  
use in patients with dementia-related psychosis. (5.1)**

Although off-label prescribing of medications is legal and typically used for specific patient populations in select scenarios, the extensive off-label use of antipsychotic medications in nursing homes does not fall within scenarios of typical off-label medication use and can be dangerous to patients. One study found that the inappropriate use of antipsychotic medication was associated with a 50 percent increased risk patients experiencing a serious fall-related bone fracture.<sup>27</sup> Furthermore, the Centers for Medicare & Medicaid Services (CMS) requires that nursing facility staff employ non-pharmacological approaches, prior to dispensing antipsychotic medications for off-label use, and implement a gradual dose reduction regimen as part of the CMS Developing a Restful Environment Action Manual (DREAM) Toolkit.<sup>28</sup>

The use of antipsychotics in SNFs has increased dramatically since passage of NHRA in 1987. In 2007, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) found that 14 percent of Medicare nursing home residents had claims for an antipsychotic drug, and 83 percent of these claims were for off-label use.<sup>29</sup> CMS reported that in 2010, nearly 40 percent of nursing home residents who did not have a psychosis diagnosis were receiving antipsychotic medications – a pattern that, research shows, persists.<sup>30, 31</sup>

In response to the dramatic increase in antipsychotic misuse in SNFs, CMS started a voluntary program in 2012 to reduce the use of antipsychotics and educate nursing home staff about using behavioral interventions instead of medication.<sup>32</sup> During the same time period, consumer advocacy organizations and federal agencies, such as the American Psychiatric Association (APA) and the Substance Abuse and Mental Health Services Administration

<sup>26</sup> Risperdal Black Box Warning, *Seeger Weiss, LLP* (2020). Available at: <https://www.drugdangers.com/risperdal/black-box-warning/>

<sup>27</sup> Fraser, Lisa-Ann, Falls and Fractures With Atypical Antipsychotic Medication Use, *JAMA Network*, (2015). Available at: <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2089230>

<sup>28</sup> Civil Money Penalty Reinvestment Program, *Centers for Medicare and Medicaid Services*, (2020). Available at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/LTC-CMP-Reinvestment>

<sup>29</sup> Introcaso, David, The Never-Ending Misuse of Antipsychotics in Nursing Homes, *Health Affairs*, (2018). Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20180424.962541/full/>

<sup>30</sup> *Id.*

<sup>31</sup> Improving antipsychotic prescribing practices in nursing facilities: The role of surveyor methods and surveying agencies in upholding the Nursing Home Reform Act, *Research in Social and Administrative Pharmacy* (2016); 12:91–103.

<sup>32</sup> Introcaso, David, The Never-Ending Misuse of Antipsychotics in Nursing Homes, *Health Affairs*, (2018). Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20180424.962541/full/>

(SAMHSA) also released guidelines aimed at reducing inappropriate use of antipsychotics in SNFs.<sup>33, 34</sup>

*The onset of bipolar disorder and schizophrenia rarely occur in people over the age of 30, but data show a 30 percent increase in schizophrenia diagnoses from 2011 to 2017 in the elderly population.*

Between 2011 and 2016, CMS reported that the rate of antipsychotics prescribed in SNFs decreased from 24 percent of residents in 2011 to 16 percent in 2016. That rate is still abnormally high, given that only about two percent of the general population will ever have a diagnosis of psychosis or other medical condition for which the FDA has approved the use of antipsychotic drugs.<sup>35, 36</sup>

Moreover, evidence shows that some SNFs may be falsifying psychosis diagnoses to avoid inappropriate antipsychotic citations.<sup>37</sup> According to a 2016 study, almost 40 percent of state surveyors said they had identified a new but incorrect diagnosis of psychosis in a nursing home to justify an inappropriate antipsychotic prescription.<sup>38</sup> The onset of bipolar disorder and schizophrenia rarely occur in people over the age of 30, but data show a 30 percent increase in schizophrenia diagnoses from 2011 to 2017 in the elderly population.<sup>39</sup>

While the Obama Administration took steps to crack down on the high rates of prescribing in SNFs in 2016, the Trump Administration subsequently rolled back those protections.<sup>40</sup> By 2018, approximately 20 percent of all nursing home residents in the U.S., including 40 percent of those with dementia, were prescribed some form of antipsychotic

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<sup>33</sup> APA Releases New Practice Guidelines on the Use of Antipsychotics in Patients with Dementia, *American Psychiatric Association*, (2016). Available at: <https://www.psychiatry.org/newsroom/news-releases/apa-releases-new-practice-guidelines-on-the-use-of-antipsychotics-in-patients-with-dementia>

<sup>34</sup> Guidance on Strategies to Promote Best Practice in Antipsychotic Prescribing for Children and Adolescents, *Substance Abuse and Mental Health Services Administration*, (2018). Available at: <https://store.samhsa.gov/system/files/pep19-antipsychotic-bp.pdf>

<sup>35</sup> Flamm, Hannah, They Want Docile, *Human Rights Watch*, (2018). Available at: <https://www.hrw.org/report/2018/02/05/they-want-docile/how-nursing-homes-united-states-overmedicate-people-dementia>

<sup>36</sup> How Common is Psychosis, *National Institute of Health, National Institute of Mental Health*, (2019). Available at: <https://www.nimh.nih.gov/health/topics/schizophrenia/raise/raise-questions-and-answers.shtml#3>

<sup>37</sup> Flamm, Hannah, Why are nursing homes drugging dementia patients without their consent? *The Washington Post*, (2018). Available at: [https://www.washingtonpost.com/outlook/2018/08/10/8baff64a-9a63-11e8-8d5e-c6c594024954\\_story.html](https://www.washingtonpost.com/outlook/2018/08/10/8baff64a-9a63-11e8-8d5e-c6c594024954_story.html)

<sup>38</sup> Urick, Kaskie, Carnahan, Improving antipsychotic prescribing practices in nursing facilities: The role of surveyor methods and surveying agencies in upholding the Nursing Home Reform Act. *Res Social Admin Pharm*, (2016). Jan-Feb;12(1):91-103.

<sup>39</sup> Jonathan D. Winter et al., Increased Reporting of Exclusionary Diagnoses Inflate Apparent Reductions in Long-Stay Antipsychotic Prescribing, 42:3, 297-301, *Clinical Gerontologist*, (2019). Available at: <https://www.tandfonline.com/doi/abs/10.1080/07317115.2017.1395378>; Johns Hopkins Medicine, Study suggests overdiagnosis of schizophrenia: Reported symptoms of anxiety and hearing voices most common reasons for misdiagnosis by non-specialty physicians, *ScienceDaily*, (2019). Available at: <https://www.sciencedaily.com/releases/2019/04/190422090842.htm>

<sup>40</sup> Rau, Jordan, Trump Administration Cuts the Size of Fines for Health Violations in Nursing Homes, *National Public Radio*, (2019). Available at: <https://www.npr.org/sections/health-shots/2019/03/15/702645465/trump-administration-cuts-the-size-of-fines-for-health-violations-in-nursing-hom>

medication, most without any diagnosis of psychosis.<sup>41, 42</sup> Accordingly, this report provides an overview of the changes in oversight and regulation of antipsychotic use from 2015 to 2018 and documenting associated trends in antipsychotic use in SNFs during those years.

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<sup>41</sup> Flamm, Hannah, They Want Docile, *Human Rights Watch*, (2018). Available at: <https://www.hrw.org/report/2018/02/05/they-want-docile/how-nursing-homes-united-states-overmedicate-people-dementia>

<sup>42</sup> Molloy, Richard, Despite Promised Crackdown, Citations for Inappropriate Drugging Remain Rare, *Long Term Community Coalition*, (2018). Available at: <https://nursinghome411.org/wp-content/uploads/2018/11/LTCCC-Advisory-Nursing-Home-Drugging-Citations-November-2018.pdf>

## BACKGROUND

In response to the Health Care Financing Administration's (later renamed CMS) 1982 proposal to ease the annual inspection and certification requirement for SNFs, the Institute of Medicine (IOM; later renamed the National Academy of Medicine) conducted a comprehensive two-year study of nursing home regulations, ultimately publishing *Improving the Quality of Care in Nursing Homes* in 1986. The report catalogued inadequacies in the nursing home regulatory system and issued a number of conclusions and recommendations (see Figure 2 below).<sup>43</sup>

### Figure 2. 1986 IOM Nursing Home Conclusions

- 1) Quality of care and quality of life in many nursing homes are not satisfactory.
- 2) More effective government regulation can substantially improve quality in nursing homes. A stronger federal role is essential.
- 3) Specific improvements are needed in the regulatory system.
- 4) There are opportunities to improve quality of care in nursing homes that are independent of changes in Medicaid payment policy or bed supply.
- 5) Regulation is necessary but not sufficient for high-quality care.
- 6) A system to obtain standardized data on residents is essential.
- 7) The regulatory system should be dynamic and evolutionary in outlook.

These conclusions served as the basis for the NHRA, included in OBRA of 1987, which established standards of care that facilities had to meet to receive reimbursement under the Medicare and Medicaid programs.<sup>44</sup> The NHRA also strengthened the survey process to determine nursing home compliance with federal care standards and implemented an enforcement system that could respond with meaningful penalties to the noncompliance that surveyors identified and cited.<sup>45</sup> The law included a lengthy "Residents' Bill of Rights" and effectively banned the use of physical and chemical restraints "imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms."<sup>46</sup>

Although the NHRA was successful in reducing physical restraints – which declined from 21.1 percent in 1991 to less than five percent in 2007 – the decline in physical restraints gave way to the unintended rise in the use of chemical restraints.<sup>47</sup>

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<sup>43</sup> *Improving the Quality of Care in Nursing Homes*, National Academies of Sciences Engineering Medicine, Institute of Medicine, (1986). Available at: <https://www.nap.edu/read/646/chapter/2>

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> Nursing Home Reform Act, Nursing Home Abuse Guide, *Paul and Perkins PA*, (2019). Available at: <https://nursinghomeabuseguide.com/resources/nursing-home-reform-act/>

<sup>47</sup> A letter to state survey agency directors, Freedom from Unnecessary Physical Restraints: Two Decades of National Progress in Nursing Home Care, *Centers for Medicare and Medicaid Services*, (2008). Available at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter09-11.pdf>

## ***Current State of Affairs: Antipsychotic Overuse is a National Problem***

**Antipsychotic misuse.** Although the 2011 HHS OIG report shined a national spotlight on antipsychotic overuse in nursing homes, inappropriate use of these medications remains a major national issue today. In 2018, approximately 20 percent of all nursing home residents continued to receive antipsychotics, while only about two percent had qualifying conditions that medically indicate such drugs were appropriate.<sup>48, 49, 50</sup> In the fourth quarter of 2019, approximately 20 percent of all skilled nursing facility (SNF) residents in the U.S. – about 298,650 people every week – received some form of antipsychotic medication, most without any diagnosis of psychosis.<sup>51, 52</sup> A 2018 Human Rights Watch (HRW) report found similar antipsychotic drugging rates and concluded that CMS may be under-enforcing its own guidance, as less than one percent of all antipsychotic citations also identified resident harm.<sup>53</sup>

*The Human Rights Watch found that in 2018, antipsychotic drugs were administered weekly to more than 179,000 nursing home residents who do not have diagnoses for which the drugs are approved.*

**Resident harm.** The off-label use of antipsychotics can be particularly harmful for frail, elderly patients, leading to injuries, hospitalizations, and even death.<sup>54</sup> A 2015 literature review of clinical outcomes related to antipsychotic use showed that antipsychotic medication use in nursing homes resulted in increased risk of many adverse events for nursing home residents, including hip fractures, thrombotic events, cardiovascular events, hospitalizations, and death.<sup>55</sup> These drugs carry severe potential side effects, including blood clots, diabetes, dyskinesia, fall risk, irreversible cognitive decompensation, pneumonia, severe nervous system problems, stroke, and visual disturbances.<sup>56</sup> One study found that elderly individuals with dementia using

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<sup>48</sup> Levinson, Daniel, Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents, *Department of Health and Human Services*, (2011). Available at: <https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf>

<sup>49</sup> Phillips, et al., An observational study of antipsychotic medication use among long-stay nursing home residents without qualifying diagnoses, *Psychiatric and Mental Health Nursing*, (2018). 1-12.

<sup>50</sup> MDS 3.0 Frequency Report, *Centers for Medicare and Medicaid Services*, (2019). Available at: <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>

<sup>51</sup> Committee calculations of MDS Frequency Report: Fourth Quarter 2019 Antipsychotic Medications Received, *Centers for Medicare and Medicaid Services*, (2019). Available at: [https://www.cms.gov/apps/mds/mds\\_notemp/mds30FreqStart.asp?isSubmitted=mds30Freq3&var=N0410A&date=33](https://www.cms.gov/apps/mds/mds_notemp/mds30FreqStart.asp?isSubmitted=mds30Freq3&var=N0410A&date=33)

<sup>52</sup> Molloy, Richard, Despite Promised Crackdown, Citations for Inappropriate Drugging Remain Rare, *Long Term Care Community Coalition*, (2018). Available at: <https://nursinghome411.org/wp-content/uploads/2018/11/LTCCC-Advisory-Nursing-Home-Drugging-Citations-November-2018.pdf>

<sup>53</sup> *Id.*

<sup>54</sup> Atypical Antipsychotic Medications: Use in Adults, *Centers for Medicare and Medicaid Services*, (2015). Available at: <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Pharmacy-Education-Materials/Downloads/atyp-antipsych-adult-factsheet11-14.pdf>

<sup>55</sup> Chiu, Yunwen et al., A literature review of clinical outcomes associated with antipsychotic medication use in North American nursing home residents. *Science Direct*, (2015). Available at: <http://dx.doi.org/10.1016/j.healthpol.2015.02.014>

<sup>56</sup> Introcaso, David, The Never-Ending Misuse of Antipsychotics in Nursing Homes, *Health Affairs*, (2018). Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20180424.962541/full/>

antipsychotics were in the hospital nearly 1.5 times as long per year relative to those who were not using antipsychotic drugs (i.e., 52 days compared to 35 days per year).<sup>57</sup> Another study found that antipsychotic use increased the mortality risk among elderly individuals with dementia by as much as 3.8 percent.<sup>58</sup> Furthermore, persons over 70 are 3.5 times more likely than younger individuals to be admitted to the hospital due to adverse drug reactions associated with psychotropic medications.<sup>59</sup>

“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.”

— Texas nursing home social worker

Quotes provided to Committee from *Human Rights Watch analysis*; US: Nursing Homes Misuse Drugs to Control Residents, Human Rights Watch, (2018). Available at: <https://www.hrw.org/news/2018/02/05/us-nursing-homes-misuse-drugs-control-residents>

The American Geriatrics Society Beers criteria, a widely respected reference for safe prescribing for the elderly, lists antipsychotic medications in the category of “strongly recommended against use” because of these potential harms.<sup>60</sup> In fact, the 2018 HRW study reported that many nursing home residents and their family members reported sedation,

cognitive decline, fear, and the inability to communicate from the overuse of these medications.

<sup>61</sup> The report also found that many nursing facilities often fail to obtain informed consent from patients or their families, a recommendation provided by the Substance Abuse and Mental Health Services Administration (SAMHSA) – and some facilities reportedly pressured individuals to give consent, despite federal law barring these practices and many state laws requiring informed consent as a predicate to off-label prescribing.<sup>62, 63</sup>

**Relationship with staffing levels.** Research shows that inappropriate use of antipsychotics is linked to lower registered nurse (RN) staffing levels: For residents with and without dementia, one additional RN hour per resident-day could reduce the odds of antipsychotic use by 52 percent and 56 percent, respectively.<sup>64</sup> Another study found that a staff training intervention focusing on alternatives to drugs for agitation led to a 19.1 percent

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<sup>57</sup> Bushak, Lecia, Antipsychotic Drugs Linked to More Hospitalizations Among Dementia Patients, *Being Patient*, (2019). Available at: <https://www.beingpatient.com/antipsychotics-dementia/>

<sup>58</sup> Maust, Donovan et al., Antipsychotics, other Psychotropics and the Risk of Death in Patients With Dementia, *JAMA Network*, (2015). Available at: <https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2203833>

<sup>59</sup> Brooks, Hoblyn, Neurocognitive costs and benefits of psychotropic medications in older adults, *Journal of Geriatric Psychiatry and Neurology*, (2007); 20:199–214.

<sup>60</sup> American Geriatrics Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults, *American Geriatrics Society*, (2019). Available at: [https://qioprogram.org/sites/default/files/2019BeersCriteria\\_JAGS.pdf](https://qioprogram.org/sites/default/files/2019BeersCriteria_JAGS.pdf)

<sup>61</sup> Flamm, Hannah, They Want Docile, *Human Rights Watch*, (2018). Available at: <https://www.hrw.org/report/2018/02/05/they-want-docile/how-nursing-homes-united-states-overmedicate-people-dementia>

<sup>62</sup> *Id.*

<sup>63</sup> Guidance on Inappropriate Use of Antipsychotics, *Substance Abuse and Mental Health Services Administration*, (2019). Available at: [https://store.samhsa.gov/system/files/pep19-inappuse-br\\_0.pdf](https://store.samhsa.gov/system/files/pep19-inappuse-br_0.pdf)

<sup>64</sup> Phillips, et al., An observational study of antipsychotic medication use among long-stay nursing home residents without qualifying diagnoses, *Psychiatric and Mental Health Nursing*, (2018).

reduction in neuroleptic prescribing.<sup>65</sup> According to the HRW report, experts interviewed agreed that many nursing facilities exhibited staffing levels well below what is needed to provide appropriate care, further confirming the link between staffing levels and the overuse of antipsychotics as a chemical restraint.<sup>66</sup>

**Medicare costs.** In addition to the harm antipsychotic overuse inflicts on patients and families, it also carries a high public cost. About one-third of older adult Medicare Part D enrollees with dementia who spent more than 100 days in a nursing home were prescribed an antipsychotic in 2012, constituting roughly \$363 million in Part D plan payments that year.<sup>67</sup> Furthermore, falls – a type of adverse event associated with inappropriate use of antipsychotics in senior populations – are particularly expensive, annually costing \$50 billion (non-fatal) and \$754 million (fatal) for the 65 and older population, according to the Centers for Disease Control and Prevention.<sup>68</sup> Not only does the public bear the cost of overprescribing, but inappropriate prescribing also increases Medicare spending due to increased hospitalizations.<sup>69</sup>

*For residents with and without dementia, one additional RN hour per resident-day could reduce the odds of antipsychotic use by 52 percent and 56 percent, respectively.*

### ***Recommendations to Reduce Antipsychotic Use in Skilled Nursing Facilities***

Due to the ubiquity of antipsychotic use in nursing homes, federal and private sector organizations have developed clinical guidelines for their use. The 2016 APA guidance recommended that patients with dementia be assessed for pain and other potentially modifiable contributors to symptoms prior to providers prescribing antipsychotics.<sup>70</sup> The organization also recommended creating a treatment plan that includes nonpharmacological interventions, a benefit assessment of antipsychotic use, and medication tapering or withdrawal if no clinically significant response is found after a four-week trial.<sup>71</sup>

In 2019, SAMHSA also released guidance, recommending informed consent, side-effect profiling of antipsychotics that align with patient risk, and employment of nonpharmacological

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<sup>65</sup> Mattingly, Joseph, A Review Exploring the Relationship Between Nursing Home Staffing and Antipsychotic Medication Use, *National Center for Biotechnology Information*, (2015). Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4685870/>

<sup>66</sup> *Id.*

<sup>67</sup> Antipsychotic Drug Use: HHS has Initiatives to Reduce Use among Older Adults in Nursing Homes but Should Expand Efforts to Other Settings, *Government Accountability Office*, (2015). Available at: <https://www.gao.gov/assets/670/668221.pdf>

<sup>68</sup> Falls Data: Cost of Older Adults Falls, *Centers for Disease Control and Prevention*, (2019). Available at: <https://www.cdc.gov/homeandrecreationalafety/falls/fallcost.html>

<sup>69</sup> Lund, Brian et. al., Effect of Hospitalization on Inappropriate Prescribing in Elderly Medicare Beneficiaries, *Journal of the American Geriatrics Society*, (2018). Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5844260/>

<sup>70</sup> American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia, *American Psychiatric Association*, (2016). Available at: <https://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890426807>

<sup>71</sup> *Id.*

approaches prior to antipsychotic use.<sup>72</sup> In the event of antipsychotic use, staff should monitor the patient’s vital signs in the determination for reassessment, SAMHSA said.<sup>73</sup> These nonpharmaceutical approaches and gradual dose reductions have been required as the standard of care for decades, since the passage of the NHRA in 1987.<sup>74</sup>

### ***Administrative Efforts to Reduce Antipsychotic Use in Skilled Nursing Facilities***

In 2011, then-CMS Administrator Donald Berwick met with nursing home advocates from several organizations, who expressed concerns over the high rate of antipsychotic medications in nursing homes.<sup>75</sup> The meeting resulted in CMS establishing a 2012 voluntary program under the Obama Administration, the “National Partnership to Improve Dementia Care in Nursing Homes,” to reduce antipsychotic overuse with behavioral techniques.<sup>76</sup> The National Partnership is a public-private coalition that includes CMS, consumers, advocacy organizations, providers, professional associations, and dementia care leaders in every state with the goal of encouraging nursing homes to implement non-pharmacologic approaches and person-centered dementia care practices.<sup>77</sup>

Beginning in July of 2012, CMS began publicly reporting data on the prescribing of antipsychotics to nursing home residents.<sup>78</sup> Additionally, CMS updated its survey process to improve surveyors’ ability to detect deficient practices related to dementia care and unnecessary antipsychotic medication use.<sup>79</sup> This process included updating the unnecessary medication citation to specifically include the unnecessary use of psychopharmacological medications, such as antipsychotics.<sup>80</sup> CMS began nationwide training programs on this updated guidance for all of its state surveyors. By 2015, all CMS state surveyors had completed the nationwide training.<sup>81</sup>

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<sup>72</sup> Guidance on Inappropriate Use of Antipsychotics, *Substance Abuse and Mental Health Services Administration*, (2019). Available at: [https://store.samhsa.gov/system/files/pep19-inappuse-br\\_0.pdf](https://store.samhsa.gov/system/files/pep19-inappuse-br_0.pdf)

<sup>73</sup> *Id.*

<sup>74</sup> Klauber, Martin and Wright, Bernadette, The 1987 Nursing Home Reform Act, *American Association of Retired Persons*, (2001). Available at: [https://www.aarp.org/home-garden/livable-communities/info-2001/the\\_1987\\_nursing\\_home\\_reform\\_act.html](https://www.aarp.org/home-garden/livable-communities/info-2001/the_1987_nursing_home_reform_act.html)

<sup>75</sup> Interim report on the CMS National Partnership to Improve Dementia Care in Nursing Homes: Q4 2011 – Q1 2014, *Centers for Medicare and Medicaid Services*, (2014). Available at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-19.pdf>

<sup>76</sup> Introcaso, David, The Never-Ending Misuse of Antipsychotics in Nursing Homes, *Health Affairs*, (2018). Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20180424.962541/full/>

<sup>77</sup> National Partnership to Improve Dementia Care exceeds goal to reduce use of antipsychotic medications in nursing homes: CMS announces new goal. *Centers for Medicare and Medicaid Services*, (2014). Available at: <https://www.cms.gov/newsroom/press-releases/national-partnership-improve-dementia-care-exceeds-goal-reduce-use-antipsychotic-medications-nursing>

<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

Surveyors rank citations on a 1 to 4 scale, in which a Level 1 deficiency corresponds to No Actual Harm with Potential for Minimal Harm to the resident and a Level 4 deficiency corresponds to Immediate Jeopardy to Resident Health or Safety (see Table 1). According to CMS, a Level 3 deficiency (Actual Harm that is Not Immediate Jeopardy) represents “noncompliance with the requirements that results in actual harm to residents that is not Immediate Jeopardy,” while a Level 4 deficiency (Immediate Jeopardy to resident health or safety) represents “a situation in which entity noncompliance has placed the health and safety of recipients in its care at risk for serious injury, serious harm, serious impairment, or death.”<sup>82, 83</sup>

**Table 1. Interpretation of Scope and Severity of Unnecessary Medication Citations**

Severity Level	Description of Level	Scope is Isolated	Scope is Pattern	Scope is Widespread
1	<i>No Actual Harm with Potential for Minimal Harm</i>	A	B	C
2	<i>No Actual Harm with Potential for more than Minimal Harm that is not Immediate Jeopardy</i>	D	E	F
3	<i>Actual Harm that is Not Immediate Jeopardy</i>	G	H	I
4	<i>Immediate Jeopardy to Resident Health or Safety</i>	J	K	L

*Source:* Table 1. was reproduced from the California Department of Public Health Consumer Guide table on interpreting the severity of a deficient practice that is cited in a federal recertification survey.

Beyond documenting antipsychotic use, CMS enacted other relevant regulatory measures from 2012 and 2016. In 2014, CMS started fining nursing homes on a per-day basis, for each day they were inappropriately prescribing antipsychotic medications. In 2016, CMS published a Final Rule, “Medicare and Medicaid Programs, Reform of Requirements for Long-Term Care Facilities” (CMS-3260-F), which strengthened the public enforcement system for SNFs cited with violating federal standards of care, called Requirements of Participation (RoPs).<sup>84</sup> This

<sup>82</sup> State Operations Manual: Appendix Q – Core Guidelines for Determining Immediate Jeopardy, *Centers for Medicare and Medicaid Services*, (2019). Available at: [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_q\\_immedjeopardy.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_q_immedjeopardy.pdf)

<sup>83</sup> Nursing Home Enforcement – Frequently Asked Questions, *Centers for Medicare and Medicaid Services*, Available at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationEnforcement/Downloads/NH-Enforcement-FAQ.pdf>

<sup>84</sup> Medicare and Medicaid Programs; Reform of Requirements for Long Term Care Facilities, *Centers for Medicare and Medicaid Services*, (2016). Available at: <https://www.govinfo.gov/content/pkg/FR-2016-10-04/pdf/2016-23503.pdf>

change was part of a five-year initiative to revise the federal RoPs, which included strengthening the protections against the inappropriate use of antipsychotics in SNFs.<sup>85</sup> This Final Rule increased requirements for pharmacists to report irregularities in antipsychotic overuse, established a 14-day PRN (*pro re nata* or “as needed”) limitation on psychotropic drugs, and implemented behavioral health measures that were targeted to enhance person-centered care.<sup>86</sup> Finally, CMS directed that civil money penalties (CMPs) be imposed against nursing homes for all deficiencies, including the misuse and overuse of antipsychotic drugs, on a per-day basis – for each day an individual SNF violated these federal RoPs. By 2016, two-thirds of all CMPs for facility deficiencies were per-day penalties. Ultimately, the Obama Administration aimed to strengthen nursing home regulations, some of which had not been updated since 1991.<sup>87</sup>

CMS reported that its efforts reduced antipsychotic use in nursing facilities from 24 percent of residents in 2011 to 16 percent in 2016.<sup>88</sup> Still, the national reduction in antipsychotics use may be misleading because data showed a spike in schizophrenia diagnoses during this time period, suggesting that some SNFs may have falsified psychosis diagnoses to avoid inappropriate antipsychotic citations.<sup>89</sup> One study found that almost 40 percent of state surveyors reported a new but incorrect diagnosis of psychosis to justify an inappropriate antipsychotic prescription in a nursing home.<sup>90</sup> There is also some concern among advocates and researchers that nursing homes are replacing these highly regulated antipsychotics with alternative sedating drugs, which pose similar health risks.<sup>91</sup>

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.'”

— Texas behavioral hospital social worker

Quotes provided to Committee from *Human Rights Watch analysis: US: Nursing Homes Misuse Drugs to Control Residents*, Human Rights Watch, (2018). Available at: <https://www.hrw.org/news/2018/02/05/us-nursing-homes-misuse-drugs-control-residents>

<sup>85</sup> Edelman, Toby, Deregulating Nursing Homes, *American Bar Association*, (2018). Available at: [https://www.americanbar.org/groups/law\\_aging/publications/bifocal/vol--39/issue-3--february-2018-/DeregulatingNursingHomes/](https://www.americanbar.org/groups/law_aging/publications/bifocal/vol--39/issue-3--february-2018-/DeregulatingNursingHomes/)

<sup>86</sup> *Id.*

<sup>87</sup> US: Nursing Homes Misuse Drugs to Control Residents, *Human Rights Watch*, (2018). Available at: <https://www.hrw.org/news/2018/02/05/us-nursing-homes-misuse-drugs-control-residents>

<sup>88</sup> Introcaso, David, The Never-Ending Misuse of Antipsychotics in Nursing Homes, *Health Affairs*, (2018). Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20180424.962541/full/>

<sup>89</sup> Flamm, Hannah, Why are nursing homes drugging dementia patients without their consent? *The Washington Post*, (2018). Available at: [https://www.washingtonpost.com/outlook/2018/08/10/8baff64a-9a63-11e8-8d5e-c6c594024954\\_story.html](https://www.washingtonpost.com/outlook/2018/08/10/8baff64a-9a63-11e8-8d5e-c6c594024954_story.html)

<sup>90</sup> Urick, Kaskie, Carnahan., Improving antipsychotic prescribing practices in nursing facilities: The role of surveyor methods and surveying agencies in upholding the Nursing Home Reform Act. *Res Social Admin Pharm*, (2016). Jan-Feb;12(1):91-103.

<sup>91</sup> Flamm, Hannah, Why are nursing homes drugging dementia patients without their consent? *The Washington Post*, (2018). Available at: [https://www.washingtonpost.com/outlook/2018/08/10/8baff64a-9a63-11e8-8d5e-c6c594024954\\_story.html](https://www.washingtonpost.com/outlook/2018/08/10/8baff64a-9a63-11e8-8d5e-c6c594024954_story.html)

On the state level, efforts to reduce antipsychotic use have been relatively stagnant.<sup>92</sup> Most state policies that go beyond the federal requirements focus on physical rather than chemical restraints.<sup>93</sup> Still, a number of states, such as Kansas, Oklahoma, and Ohio, have broadened the definitions of key terms – SNF, licensed bed, agent, antipsychotic drug, and/or continuing care retirement facilities – to expand the scope of antipsychotic misuse enforcement. California, Oklahoma, and Illinois have extended regulations to require that physicians obtain informed consent from either the resident or resident’s interested family members.<sup>94</sup> Finally, other states, including Oklahoma, Ohio, and Tennessee, have developed financial incentive programs that include specific target thresholds for antipsychotic use among SNF long-stay residents.<sup>95</sup>

### ***Trump Administration Reduction in Skilled Nursing Facility Oversight***

Despite efforts at both the state and federal levels to reduce the inappropriate use of antipsychotics, the HRW report found inadequate enforcement of federal nursing home regulations because surveyors only categorized two percent of all 2017 antipsychotic deficiency citations as “Actual Harm” (Level Three) or “Immediate Jeopardy” (Level Four); see Table 1.<sup>96, 97</sup> As explained in the HRW report, the Trump Administration’s “Patients over Paperwork” initiative undid much of the progress made under the Obama Administration by prioritizing reductions in provider burden over a number of consumer protections, including a reduction in fines for the overuse of antipsychotics – even when the result was the death of a nursing home resident.<sup>98</sup> In November 2018, CMS imposed an 18-month moratorium on eight new Obama-era safety regulations, including the 14-day PRN limitation on psychotropic drugs and CMPs associated with antipsychotic citations under the updated survey process.<sup>99</sup>

*Rather than implementing a five-year initiative to reduce antipsychotic use, CMS imposed an 18-month moratorium on these Obama-era regulations.*

More specifically, the Trump Administration eliminated the Obama-era per-day fining practices in July of 2017, which resulted in CMS issuing a single fine for two-thirds of all inappropriate antipsychotic citations that would have previously resulted in a per-day fine.<sup>100</sup>

<sup>92</sup> Congressional Research Service, e-mail message to authors, August 23, 2019.

<sup>93</sup> *Id.*

<sup>94</sup> *Id.*

<sup>95</sup> *Id.*

<sup>96</sup> The severity of a deficiency is based on a level of 1 to 4, where a Level 1 deficiency implies no actual harm with the potential for minimal harm and a Level 4 deficiency implies Immediate Jeopardy to resident health or safety.

<sup>97</sup> US: Nursing Homes Misuse Drugs to Control Residents, *Human Rights Watch*, (2018). Available at: <https://www.hrw.org/news/2018/02/05/us-nursing-homes-misuse-drugs-control-residents>

<sup>98</sup> Rau, Jordan, Trump Administration Eases Nursing Home Fines in Victory for Industry, (2017). Available at: <https://www.nytimes.com/2017/12/24/business/trump-administration-nursing-home-penalties.html>

<sup>99</sup> Temporary Enforcement Delays for Certain Phase 2 F-Tags and Changes to *Nursing Home Repair, Centers for Medicare and Medicaid Services*, (2017). Available at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-18-04.pdf>

<sup>100</sup> Rau, Jordan, Trump Administration Cuts the Size of Fines for Health Violations in Nursing Homes, *National Public Radio*, (2019). Available at: <https://www.npr.org/sections/health-shots/2019/03/15/702645465/trump-administration-cuts-the-size-of-fines-for-health-violations-in-nursing-hom>

According to a Kaiser Health News (KHN) report, average aggregate fines on nursing homes found to have endangered or injured residents dropped from \$41,260 during President Obama’s last year in office (2016) to \$28,405 in the period between April 2017 and March 2018.<sup>101</sup> KHN also found that CMS issued financial penalties for Immediate Jeopardy citations in fewer cases under the new Trump-era rules compared to the prior administration, and fines were 18 percent lower than they were in 2016.<sup>102</sup> Critics of the earlier approach have suggested the Obama-era regulations led to fines that were based on random timing of an inspection as opposed to the severity of the infraction.<sup>103</sup> For instance, under the Obama Administration approach, if surveyors discovered a deficient practice had been occurring for two months, as opposed to one month, the overall fine would be double, even if the infraction was the same.<sup>104</sup> For a Table cataloguing major CMS policies and actions related to reducing or eliminating nursing home protections from May 2017-March 2020, please see Table 5 in Appendix C.

### ***Ways and Means Committee Responses to Trump-Era Deregulation in SNF Setting***

In July 2018, House Ways and Means Committee then-Ranking Member Richard E. Neal (D-MA) wrote a letter to CMS Administrator Seema Verma expressing concern about the continued overuse of antipsychotics in nursing homes.<sup>105</sup> CMS responded on November 20, 2018, by highlighting the agency’s administrative actions to reduce antipsychotic misuse. On January 22, 2019, now-Chairman Neal wrote a follow-up letter to CMS, noting that progress had slowed in reducing inappropriate use of antipsychotics and raising questions about potential patterns of falsified psychosis diagnoses.<sup>106</sup>

*“Unfortunately, CMS’s data are still extremely disappointing, showing that progress reducing inappropriate use of antipsychotic drugs in nursing homes has slowed. Moreover, I am concerned that the ‘improvement’ is not the result of changed prescribing behavior but, instead, stems from some nursing homes falsifying psychosis diagnoses, making incidence of this contra-indicated prescribing appear improved when it is, in fact, not.”*

*— Chairman Richard E. Neal  
Letter to CMS, January 22, 2019*

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<sup>101</sup> Rau, Jordan, Nursing Home Fines Drop as Trump Administration Heed Industry Complaints, *Kaiser Health News*, (2019). Available at: <https://khn.org/news/nursing-home-fines-drop-as-trump-administration-heeds-industry-complaints/>

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> Neal, Richard, Antipsychotics in individuals with dementia-related psychosis, *Ways and Means Committee*, (2018). Available at: <https://theconsumervoice.org/uploads/files/general/neal-letter-CMS.pdf>

<sup>106</sup> Neal, Richard, Continued concern with overuse of antipsychotics in nursing homes, *Ways and Means Committee*, (2019). Available at:

[https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/SNF\\_Antipsychotics%20letter%20to%20CMS\\_January%202019.pdf](https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/SNF_Antipsychotics%20letter%20to%20CMS_January%202019.pdf)

Chairman Neal’s letter concluded with a request for information about CMS’s efforts to mitigate these issues as well as specific nursing home antipsychotic citation data.<sup>107</sup> While CMS never provided the Ways and Means Committee with a detailed written plan to reduce inappropriate antipsychotic use or to reduce falsified antipsychotic diagnoses, the agency provided the Committee with SNF survey data from 2015 to 2018. This report details the analysis the Committee conducted using these CMS-provided data to identify changes in antipsychotic misuse over time and geographic variation (see Methodology section in Appendix A for more information on the data source and analytic approach used in this report).

On November 14, 2019, the Committee on Ways and Means held a hearing entitled, “Caring for Aging Americans.” In addition to other elderly caregiving issues, witnesses discussed many of the unique challenges of caring for individuals with Alzheimer’s disease and other related dementias, including the misuse of antipsychotics in SNFs. During the hearing, witness Richard Mollot, a nursing home expert representing The Long Term Care Community Coalition (LTCCC), discussed antipsychotic misuse and provided some recommendations to alleviate it:

*The overuse and inappropriate use of antipsychotic drugs on residents and nursing homes and in assisted living and in other settings is really disgraceful, frankly, and it harms hundreds of thousands of people every day. I would say, first of all, a lot of families that we talk to, they do not even know that their loved one is receiving these drugs, or they are explicitly told by caregivers not to look up the drug online. It is really important that we have informed consent, and as part of that, what Congress could do is to pass an informed consent bill that included written informed consent and that provided for the resident and the family to periodically review and, again, give informed consent as necessary if those drugs are to continue because really there are very, very, very limited circumstances under which someone should be receiving an antipsychotic drug for any extended period of time unless they have a condition of schizophrenia or another specific illness.<sup>108</sup>*

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<sup>107</sup> *Id.*

<sup>108</sup> Richard Mollot. Quote from: U.S. Congress. Hearing of the Committee on Ways and Means. “Caring for Aging Americans.” (2019). Available at: <https://waysandmeans.house.gov/legislation/hearings/caring-aging-americans>

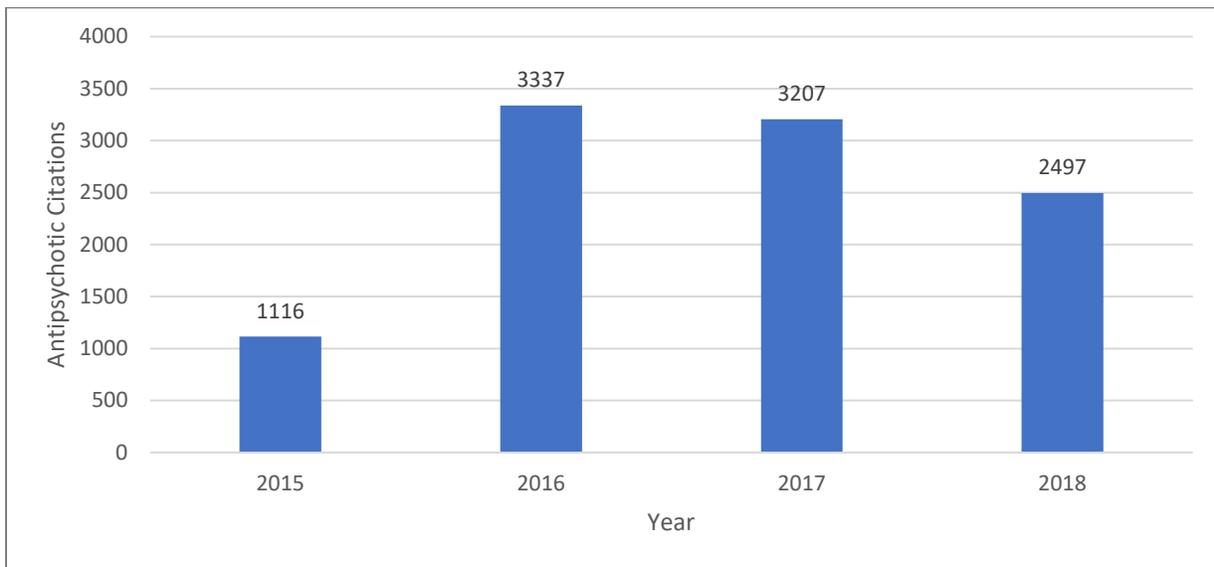
## RESULTS

The following section describes the results from a four-part analysis the Committee conducted to examine trends in antipsychotic use in SNFs across states, using CMS-provided data.<sup>109</sup> A description of the methodology used to conduct this analysis is included in Appendix A.

### *Analysis of Skilled Nursing Facilities' Antipsychotic Citations, 2015-2018*

From 2015 to 2018, the number of antipsychotic citations in SNFs more than doubled. Nationally, there was a 124 percent increase in the number of citations (1,381 more citations) between 2015 and 2018. Despite this marked increase, a year-by-year analysis provides more insight into the trends (see Figure 3): The number of citations peaked in 2016 (3,337 citations) and then decreased to 2,497 by 2018. For a state-level breakdown of these data, see Table 3 and Table 4 in Appendix B.

**Figure 3. Nursing Home Antipsychotic Citations, 2015-2018**



*Source:* All data provided by CMS.

*Notes:* The annual number of unnecessary antipsychotic citations by SNFs in the U.S. from 2015 to 2018 includes all levels of deficiencies cited. Data include all SNFs cited for tags F0222, F0605 (Free from Chemical Restraints), F0329, and F0758 (Free from Unnecessary Drugs). F0605 and F0758 replaced F0222 and F0329 beginning on November 28, 2017.

Figure 3 shows the number of antipsychotic citations nearly tripled from 2015 to 2016 – a 199 percent increase in citation rates (2,221 more citations) with nearly every state experiencing large increases. The largest of these increases was in California, where SNFs received 280 more citations across all facilities in 2016 than in 2015 – an increase of 191 percent. Ohio, Texas, New

<sup>109</sup> Data includes all nursing facilities cited for tags F0605 (Free from Chemical Restraints) and F0758 (Free from Unnecessary Psychotropic Drugs). F0605 and F0758 replaced F0222 and F0329 beginning on November 28, 2017.

York, Pennsylvania, and Indiana SNFs, on average, received at least 100 more citations in 2016 than in 2015.

From 2016 to 2017, the average national citation rate was relatively stable, decreasing by 3.9 percent (about 130 total citations) nationwide. Over this time, many states experienced similar citation rate reductions. For instance, Texas SNFs on average received 71 – about 33 percent fewer – citations in 2017 compared to 2016. Kansas, Iowa, and New York SNFs on average all received fewer citations as well.

*In 2018, the number of citations plummeted, with SNFs receiving 710 – about 22.1 percent fewer – in 2018 compared to 2017.*

In 2018, the number of citations plummeted, with SNFs receiving 710 – about 22.1 percent fewer – in 2018 compared to 2017. The largest of these reductions occurred in California (189 fewer citations), Ohio (90 fewer citations), Indiana (78 fewer citations), and New York (54 fewer citations).

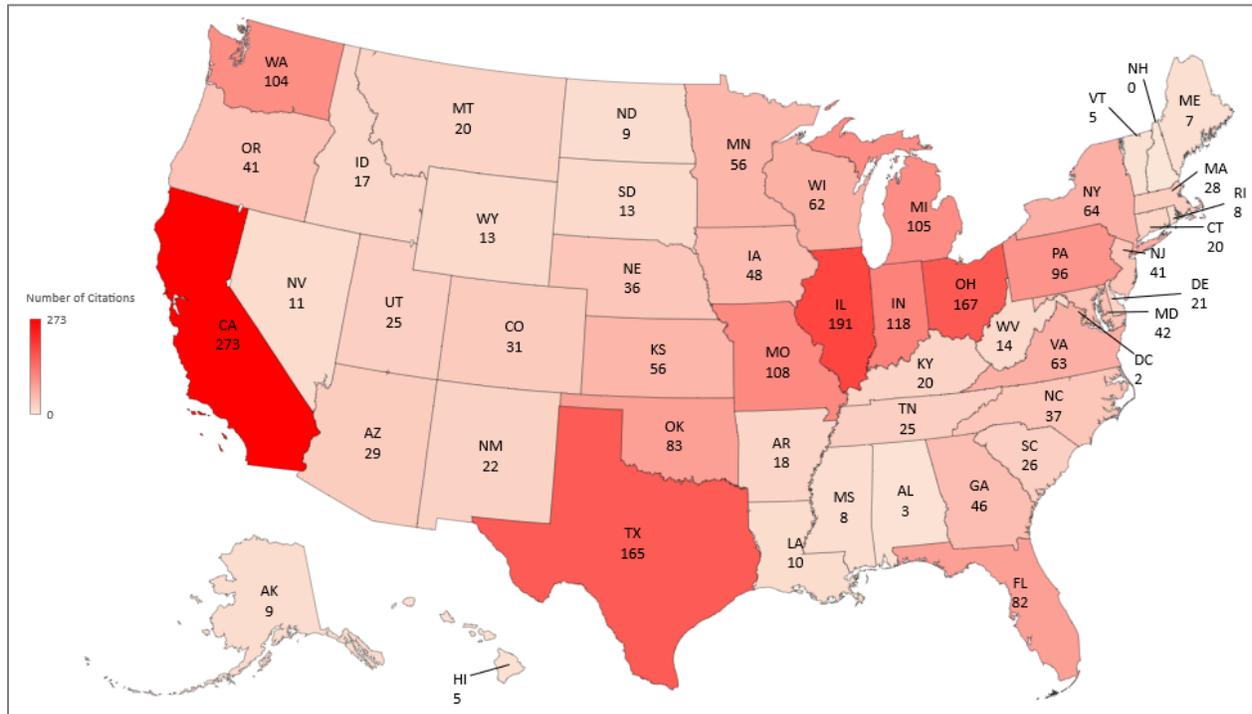
These are also some of the states with the most nursing facilities; to account for such difference, the analysis below adjusts for the number of facilities in a given state.

While most states saw large decreases in the number of citations in 2018, some saw increases, particularly those with relatively lower initial citation rates. For example, Kentucky SNFs received 17 more citations in 2018 than 2017 and Mississippi SNFs received six more citations in 2018 compared to 2017.

### ***Analysis of Skilled Nursing Facilities' Antipsychotic Citations, 2018***

In 2018, on average, state surveyors issued 49 citations for unnecessary medications to SNFs in their respective states. California (273 citations), Illinois (191 citations), Texas (165 citations), and Ohio (167 citations) nursing homes received the most citations – three to six times more than the national average. On the other hand, 11 states' nursing facilities (including Washington, D.C.) received between zero and 10 citations for unnecessary medications (i.e., Washington, D.C., Vermont, Rhode Island, North Dakota, New Hampshire, Mississippi, Maine, Hawaii, Arkansas, Alabama, and Louisiana). Notably, the four states that issued the most citations were also some of the states with the largest populations of seniors in nursing facilities. These findings are presented in Figure 4.

**Figure 4. Skilled Nursing Facility Antipsychotic Citations, 2018**



*Source:* All data provided by CMS.

*Notes:* The total number unnecessary antipsychotic citations by SNFs across all 50 states in 2018 in the U.S. includes all levels of deficiencies cited. Data include all SNFs cited for tags F0222, F0605 (Free from Chemical Restraints), F0329, and F0758 (Free from Unnecessary Drugs). F0605 and F0758 replaced F0222 and F0329 beginning on November 28, 2017.

Due to variations in results by the size of the state nursing home population, the Committee conducted an additional analysis that accounted for population and facility size, using state-level certified nursing facility data from the Kaiser Family Foundation (see Appendix A for description of data sources and methodology).<sup>110, 111</sup> Figure 5 shows the number of antipsychotic citations each state issued for every 10,000 nursing home residents in 2018. That year, states issued an average of 25.1 citations per 10,000 residents in their nursing facilities, equating to about one citation for every 400 SNF residents. After accounting for nursing home resident population size, Texas, California, New York, Illinois, and Ohio had relatively lower citation rates compared to many areas in the Northwest, Southwest, and Mountain regions. Alaska issued the most citations per population – 148 antipsychotic citations per 10,000 SNF residents in 2018. Alaska was followed by the Northwest states of Washington, Oregon, and Wyoming, which issued 65, 56, and 53.5 citations per 10,000 SNF residents, respectively.

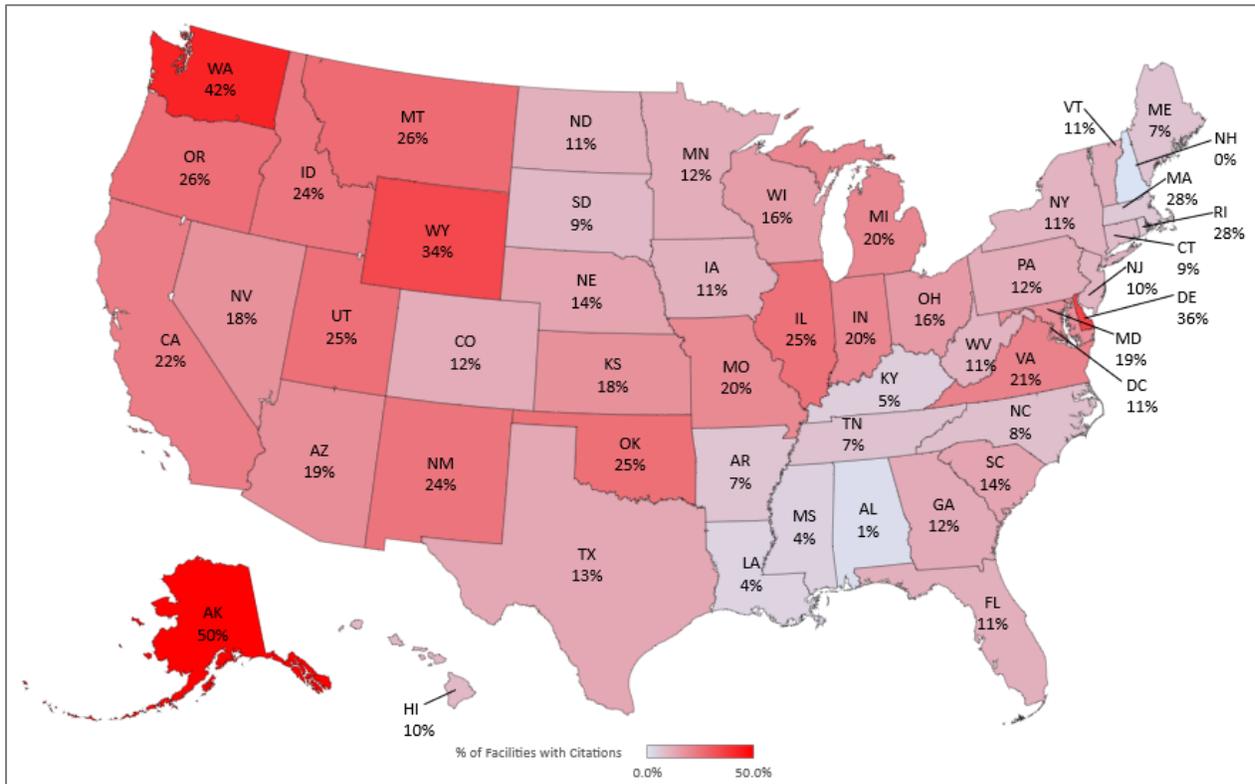
<sup>110</sup> Total Number of Residents in Certified Nursing Facilities, *Kaiser Family Foundation*, (2019). Available at: <https://www.kff.org/other/state-indicator/number-of-nursing-facility-residents/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>

<sup>111</sup> *Id.*



Figure 6 shows the percentage of facilities that received at least one citation in 2018. In 2018, 2,327 SNFs, or about 15 percent of nursing facilities, received at least one antipsychotic citation. Alaska had the highest citation rate, as half of the state’s 18 nursing facilities received at least one antipsychotic citation. Washington and Wyoming followed with 42.4 percent and 34.2 percent of nursing facilities receiving citations, respectively.

**Figure 6. Percent of Skilled Nursing Facilities that Received One or More Antipsychotic Citations, 2018**



*Sources:* All data provided by CMS. data on total number of certified nursing facilities by state retrieved from Kaiser Family Foundation, available at: <https://www.kff.org/other/state-indicator/number-of-nursing-facilities/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>

*Notes:* The percent of SNFs that received one or more unnecessary antipsychotic citations of all deficiency levels across all 50 states in the U.S. in 2018. Data include all SNFs cited for tags F0222, F0605 (Free from Chemical Restraints), F0329, and F0758 (Free from Unnecessary Drugs). F0605 and F0758 replaced F0222 and F0329 beginning on November 28, 2017.

The Northwest still had a relatively high number of facilities that received at least one citation, while the rate was lower in Midwestern states. More than 18 percent of facilities in Kansas and more than 13 percent of facilities in Nebraska received at least one antipsychotic citation in 2018.

*Analysis of Skilled Nursing Facilities Cited for Unnecessary Medications and Resident Harm (G or Higher Deficiency Level Citation), 2017-2018*

Surveyors rank citations on a 1 to 4 scale, in which a Level 1 deficiency corresponds to no actual harm with potential for minimal harm to the resident and a Level 4 deficiency corresponds to Immediate Jeopardy to resident health or safety (see Table 1).

Figure 7 shows the number of SNFs in each state that were cited for Level 3 (Actual Harm that is Not Immediate Jeopardy) or Level 4 (Immediate Jeopardy to Resident Health or Safety) deficiencies in 2017 and 2018. In 2017-2018, SNFs across the country received 70 Level 3 or 4 citations for unnecessary medications. Of these Level 3 and 4 unnecessary medication citations, 41 citations were for the inappropriate use of antipsychotics. In other words, nearly 60 percent of all deficiencies that culminated in Actual Harm or Immediate Jeopardy to a Resident's Health or Safety were the result of inappropriate antipsychotic usage.<sup>112</sup>

*In 2018, a SNF resident in Florida was rushed to the hospital with signs of brain damage after the staff accidentally gave the resident 80 times the ordered amount of the antipsychotic Haldol.*

Source: CMS data; see Table 6 in Appendix D.

*Nearly 60 percent of all deficiencies that culminated in Actual Harm or Immediate Jeopardy to a Resident's Health or Safety were the result of inappropriate antipsychotic usage in 2017-2018.*

Only 0.02 percent of all antipsychotic citations (5,704 antipsychotic citations) within the 2017-2018 dataset documented Actual Harm or Immediate Jeopardy. While the average fine for all 70 Level 3 or 4 citations was \$77,625 over this time period, 23 percent of these citations were associated with a fine of less than \$20,000. Twenty-five percent of these Level 3 or 4 fines were delivered on a per-instance basis (as opposed to a per-day basis), and these fines averaged \$12,600 per citation. For context, these fines are relatively small compared to average annual Medicare payments to SNFs. In 2017, Medicare paid each SNF an average of \$1.7 million for their Medicare beneficiaries.<sup>113</sup> Almost 10 percent of all Level 3 or 4 citations did not result in a fine.

<sup>112</sup> Nursing Home Enforcement – Frequently Asked Questions, *Centers for Medicare and Medicaid Services*, Available at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationEnforcement/Downloads/NH-Enforcement-FAQ.pdf>

<sup>113</sup> Skilled Nursing Facility Services, *Medicare Payment Advisory Commission*, (2019). Available at: [http://www.medpac.gov/docs/default-source/reports/mar19\\_medpac\\_ch8\\_sec.pdf](http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch8_sec.pdf)



SNFs in Michigan, which has an above-average nursing home population size, received seven resident harm citations. With some exceptions, SNFs in Northwest and Midwest states again tended to receive more high-level deficiency citations.

*Analysis of Skilled Nursing Facilities Cited for Antipsychotic Citations, 2016-2018*<sup>114</sup>

According to a Kaiser Health News report, average fines on nursing homes found to have endangered or injured residents significantly decreased between 2016 and the time period between April 2017 to March 2018.<sup>115</sup> Building on this Kaiser Health News study, the Committee investigated how the total number of antipsychotic citations issued changed from Obama's final year in office (2016) to Trump's second full year in office (2018).

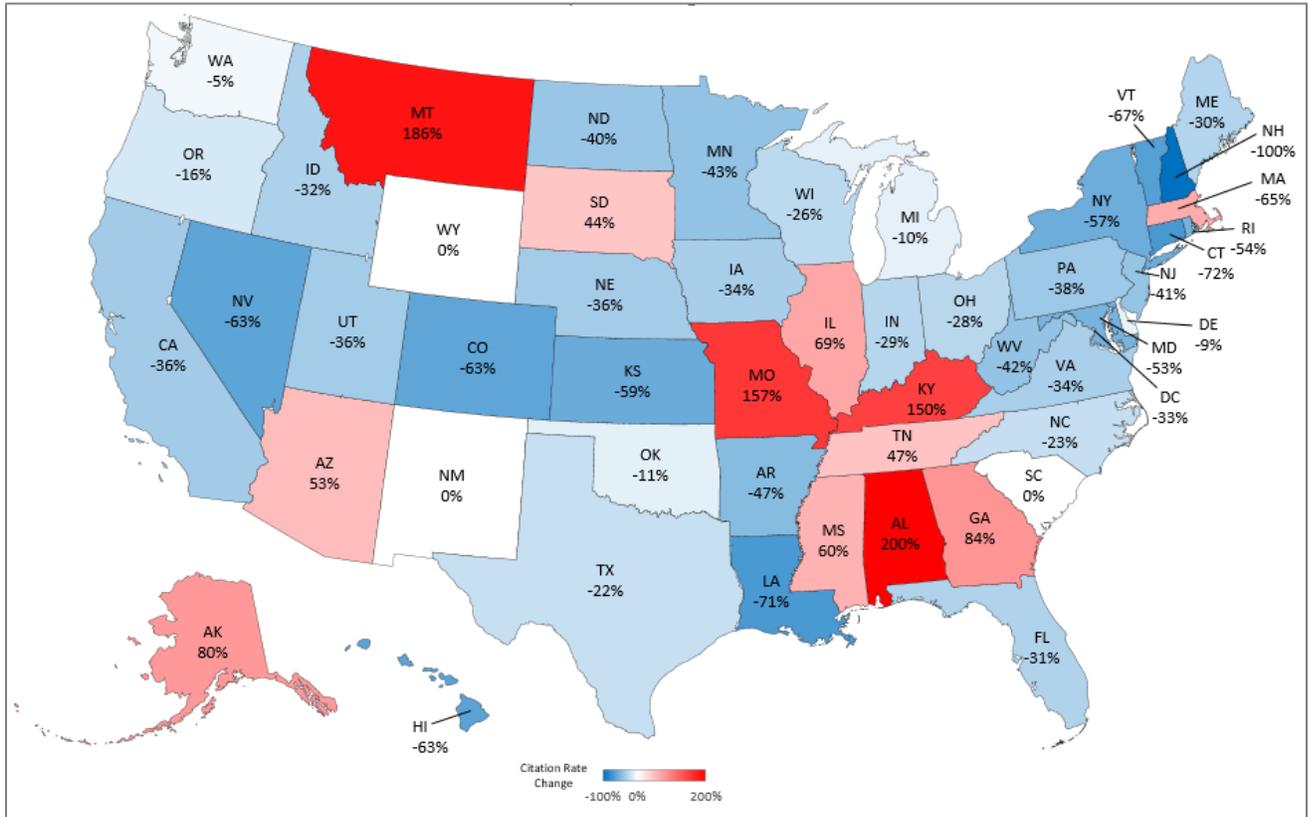
As depicted in Figure 8, state surveyors nationally issued 840 fewer citations in 2018 compared to 2016 – a decrease of 25.2 percent. Only surveyors in 12 states documented more citations in 2018 than in 2016. Four states had relatively large percent increases in the citation rates. Alabama had the largest percent increase – receiving 200 percent more citations in 2018 compared to 2016 – followed by Montana and Missouri, whose nursing homes received 185.7 percent and 157.1 percent more citations, respectively, in 2018 compared to 2016. Still, these 12 states that witnessed an uptick in citation rates were historically lower antipsychotic citation-rate states.

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<sup>114</sup> Data include all SNFs cited for tags F0222, F0605 (Free from Chemical Restraints), F0329, and F0758 (Free from Unnecessary Drugs). F0605 and F0758 replaced F0222 and F0329 beginning on November 28, 2017.

<sup>115</sup> Rau, Jordan, Nursing Home Fines Drop as Trump Administration Heed Industry Complaints, *Kaiser Health News*, (2019). Available at: <https://khn.org/news/nursing-home-fines-drop-as-trump-administration-heeds-industry-complaints/>

**Figure 8. Percent Change in Antipsychotic Citations at Skilled Nursing Facilities, 2016- 2018**



*Source:* All data provided by CMS.

*Notes:* Map shows the percent change from 2016 to 2018 in the total number of unnecessary antipsychotic citations by all SNFs across all 50 states in the U.S. in 2018. This analysis includes all level of deficiencies cited.

State surveyors in 36 states issued fewer antipsychotic citations to SNFs in 2018 compared to 2016. At the top of this list was California, where SNFs received 154 fewer citations in 2018 compared to 2016. New York followed with 86 fewer citations; Kansas SNFs, which received 79 fewer citations; and Ohio SNFs, which received 65 fewer citations. Typically, states with large SNF populations received fewer citations in 2018 compared to 2016. Overall, SNFs in 11 states had a 50 percent or greater reduction in the number of citations they received in 2018 compared to 2016.

## DISCUSSION

This analysis shows an increase in the rates of antipsychotics citations for SNFs across the nation from 2015-2018, with generally higher rates in the Northwest and Midwest. Examining the data in year-over-year changes is more instructive than looking across the entire four-year time frame, however. As the results of this study point to two distinct time periods – one from 2015-2017 and another from 2017 to 2018 – the trends may reflect the external policy environment rather than internal industry prescribing changes. Antipsychotic citation rates increased dramatically – by 187 percent – across the nation during 2015-2017, from 1116 citations in 2015 to 3207 citations in 2017. This period was followed by a sharp 22 percent reduction in citation rates from 2017 to 2018. This citation reduction occurred during the change in administrations – which also corresponded with policy changes from per-day fines under the Obama Administration to single fines for two-thirds of antipsychotics infractions under the Trump Administration. It also corresponded with an 18-month moratorium on eight new Obama-era safety regulations.<sup>116, 117</sup>

“Every little thing, they [the nursing home staff] want to put you on psych meds... She [my mother] would be sitting there, slumped over, mucus everywhere. I would go over and say, ‘She’s sick.’”

— Lena D, daughter and power of attorney of Lucinda D., an 88-year-old woman in a California nursing facility

Quotes provided to Committee from *Human Rights Watch analysis; US: Nursing Homes Misuse Drugs to Control Residents*, Human Rights Watch, (2018). Available at: <https://www.hrw.org/news/2018/02/05/us-nursing-homes-misuse-drugs-control-residents>

Given the descriptive nature of this analysis, it is impossible to determine the extent to which these trends in citation rates reflect internal changes within the SNF industry with respect to antipsychotic prescribing patterns or the external policy shifts that occurred between 2015 and 2018. Examined in isolation, such time trends might reflect an industry responding to external pressures to curb inappropriate antipsychotic use.

In other words, it is possible that the 22 percent reduction in citations from 2017-2018 reflects a true decrease in the proportion of SNF patients inappropriately administered antipsychotics without any behavioral responses to the loosening of administration regulations. More likely though, antipsychotic use remained more-or-less constant and such trends in citation rates reflect the underlying policies of two distinct administrations. On the one hand, the Obama Administration cracked down on antipsychotic overuse by implementing per-day fines, strengthening federal RoPs, and updating surveyor guidance. On the other, the Trump

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<sup>116</sup> Rau, Jordan, Nursing Home Fines Drop as Trump Administration Heed Industry Complaints, *Kaiser Health News*, (2019). Available at: <https://khn.org/news/nursing-home-fines-drop-as-trump-administration-heeds-industry-complaints/>

<sup>117</sup> Temporary Enforcement Delays for Certain Phase 2 F-Tags and Changes to *Nursing Home Repair, Centers for Medicare and Medicaid Services*, (2017). Available at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-18-04.pdf>

Administration was focused on industry-wide de-regulation, weakening federal RoPs and eliminating per-day fining practices.

The findings in this report show an association between federal oversight and antipsychotic citation rates during the final year of the Obama Administration. Between 2015 and 2016, when Obama-era nursing home regulations issued between 2012-2015 went into full effect, there was a 199 percent increase in citation rates (2,221 more citations), as nationwide rates nearly tripled. These rates remained relatively constant from 2016-2017, as these Obama-era regulations remained in place in 2017. The Trump Administration’s “Patients over Paperwork” deregulatory program, which went into effect in late 2017, coincided with a reduction in antipsychotic citation rates compared to President Obama’s final years in office. Between 2016 and 2018, state surveyors issued 840 fewer citations – a drop of 25.2 percent – with 36 states experiencing fewer antipsychotic citations in 2018 compared to 2016.

Following the implementation of the Obama-era nursing home oversight regulations, SNFs across the nation may have taken strides to reduce antipsychotic use. In fact, in April of 2019, CMS reported a 39 percent reduction in antipsychotic misuse in SNFs since 2011.<sup>118</sup> Still, some evidence shows that this national reduction was associated with SNFs increasingly seeking false psychosis diagnoses to avoid inappropriate antipsychotic citations.<sup>119, 120</sup>

Another potential reason for the reduction in antipsychotic citations could be the change in surveyor guidance. In November 2016, CMS provided new citation tagging methods and interpretative guidance to state surveyors as a means to implement an updated survey process as part of the Obama-era 2016 updates to the RoPs in long-term care facilities. The change in citation tagging, which was implemented in late November 2017, may have led to surveyors incorrectly tagging inappropriate antipsychotic use and may at least partially explain the 22 percent reduction in citation rates from 2017 to 2018. Still, other elements of this updated survey process could have led to *increased* citation rates, including increasing the resident sample size included in each survey and tripling the interview, observation, and screening time.

Although it is impossible to determine which (if any) external factors affected the rate of antipsychotic prescribing in SNFs during the period of study, two important points are clear: 1) the data revealed two distinct time periods (2015-2017 and 2017-2018) of prescribing patterns that align with a shift in administrations and 2) regardless of the period of prescribing, the rate of antipsychotic use remains inappropriately high in SNFs across the entire country. Together, these points indicate that policymakers must continue to implement interventions aimed at reducing use of antipsychotics as a chemical restraint *in lieu of appropriate staffing* – and that the right

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<sup>118</sup> National Partnership to Improve Dementia Care in Nursing Homes: Antipsychotic Medication Use Data Report, *Centers for Medicare and Medicaid Services*, (2019). Available at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Antipsychotic-Medication-Use-Data-Report.pdf>

<sup>119</sup> Flamm, Hannah, Why are nursing homes drugging dementia patients without their consent? *The Washington Post*, (2018). Available at: [https://www.washingtonpost.com/outlook/2018/08/10/8baff64a-9a63-11e8-8d5e-c6c594024954\\_story.html](https://www.washingtonpost.com/outlook/2018/08/10/8baff64a-9a63-11e8-8d5e-c6c594024954_story.html)

<sup>120</sup> Improving antipsychotic prescribing practices in nursing facilities: The role of surveyor methods and surveying agencies in upholding the Nursing Home Reform Act, *Research in Social and Administrative Pharmacy* (2016); 12:91–103.

interventions may have success in changing behavior, given that the findings in this study suggest external factors may play a large role in influencing behavioral change in SNFs.

### **Recommendations**

Given the ubiquity of antipsychotic use in SNFs, a number of organizations have provided policy recommendations to CMS and other federal agencies. A sampling of these recommendations can be found in Table 2.

**Table 2. Recommendations to Reduce Inappropriate Antipsychotic Use in SNFs**<sup>121, 122, 123</sup>

Organization	Year	Recommendations
<b>Long Term Care Community Coalition (LTCCC)</b>	2020	<ul style="list-style-type: none"> <li>• Establish minimum nurse staffing levels for facilities or other effective measures for addressing understaffing, inadequate training, and high turnover rates.</li> <li>• Strengthen the enforcement of requirements linked to inappropriate antipsychotic drug use, such as care planning, as well as transfer and discharge standards.</li> <li>• Follow CMS guidance indicating that many inappropriate antipsychotic drug uses amount to Actual Harm or Immediate Jeopardy violations.</li> </ul>
<b>Substance Abuse and Mental Health Services Administration (SAMHSA)</b>	2019	<ul style="list-style-type: none"> <li>• Create a clear person-centered care plan with specific behavior modification strategies.</li> <li>• SNFs should link caregivers to services, such as respite care, information and assistance, counseling, and training.</li> <li>• Informed consent must be used with these drugs, considering side effect profiles of antipsychotics and balancing them with patient risk.</li> <li>• Employ nonpharmacological approaches prior to antipsychotic use.</li> </ul>
<b>Human Rights Watch (HRW)</b>	2018	<ul style="list-style-type: none"> <li>• Use more existing regulatory and enforcement tools to reduce the inappropriate use of antipsychotics.</li> <li>• Establish federal regulations on a right to informed consent and minimum nurse staffing levels for facilities.</li> <li>• Increase the severity of violations for SNFs that were cited for Level 3 or 4.</li> </ul>

<sup>121</sup> Flamm, Hannah, They Want Docile, *Human Rights Watch*, (2018). Available at: <https://www.hrw.org/report/2018/02/05/they-want-docile/how-nursing-homes-united-states-overmedicate-people-dementia>

<sup>122</sup> Antipsychotic Drug Use: HHS has Initiatives to Reduce Use among Older Adults in Nursing Homes but Should Expand Efforts to Other Settings, *Government Accountability Office*, (2015). Available at: <https://www.gao.gov/assets/670/668221.pdf>

<sup>123</sup> Levinson, Daniel, Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents, *Department of Health and Human Services*, (2011). Available at: <https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf>

Organization	Year	Recommendations
<b>American Psychiatric Association (APA)</b>	2016	<ul style="list-style-type: none"> <li>• Use a comprehensive treatment plan that includes appropriate person-centered nonpharmacological and pharmacological interventions, particularly for dementia patients.</li> <li>• Review clinical response to nonpharmacological interventions prior to nonemergency use of an antipsychotic medication.</li> <li>• Before nonemergency treatment with an antipsychotic is initiated in patients with dementia, a clinician must assess the potential risks and benefits from antipsychotic medication. Risks must be discussed with the patient (if clinically feasible) as well as with the patient’s surrogate decision-maker (if relevant) with input from family or others involved with the patient.</li> </ul>
<b>Government Accountability Office (GAO)</b>	2015	<ul style="list-style-type: none"> <li>• HHS officials should focus on reducing antipsychotic use in other care settings outside nursing homes, including assisted living facilities or individuals’ homes.</li> <li>• Extend educational efforts to caregivers and providers who do not work in SNFs.</li> </ul>
<b>Health and Human Services Office of the Inspector General (HHS OIG)</b>	2011	<ul style="list-style-type: none"> <li>• CMS should facilitate access to information to improve prescription accuracy.</li> <li>• CMS must assess whether the survey and certification processes offer adequate safeguards against unnecessary antipsychotic use.</li> <li>• CMS should explore alternative methods beyond survey and certification processes to promote compliance with federal standards regarding unnecessary drug use in nursing homes.</li> </ul>
<b>Center for Medicare Advocacy (CMA)</b>	2011	<ul style="list-style-type: none"> <li>• CMS should adopt the 1992 proposed rules on chemical restraints, including providing specific written informed consent for antipsychotic drug use.</li> <li>• CMS should conduct trainings on all CMS regulations on antipsychotic drugs.</li> <li>• CMS should revise the new Quality Indicator Survey to include residents using antipsychotic drugs in every resident survey sample</li> </ul>

**Considerations**

The results the Committee presents in this report are meant neither to make a case for a specific policy proposal nor to highlight the behavior of particular state surveyors relative to others. Instead, the findings are meant to broadly illustrate the troubling trends in antipsychotic overuse across the nation – regardless of administration – and the harmful implications for patients and their families. Given that the “true” rate of antipsychotic misuse remains unknown, more work needs to be done to understand prescribing patterns, identify solutions, and implement change across nursing home settings. With the backdrop of the devastation COVID-19 has inflicted on nursing homes across the country, focus on all components of patient safety in these settings is paramount.

In particular, future work could examine the relationship between staffing levels and antipsychotic use to determine whether or not states with lower average staffing rates tend to have higher antipsychotic rates. Furthermore, factors such as updated surveyor guidance, increased enforcement mechanisms, and increases in psychosis diagnoses may have all affected the change in antipsychotic citation rates from 2015-2018. Additional research could use adjusted analysis techniques to isolate these variables and examine their relationship with the change in citation rates.

## CONCLUSION

In May, 2011 HHS Inspector General Levinson stated “Too many [nursing homes] fail to comply with federal regulations designed to prevent overmedication, giving nursing home patients antipsychotic drugs in ways that violate federal standards for unnecessary drug use...Government, taxpayers, nursing home residents, as well as their families and caregivers should be outraged – and seek solutions.”<sup>124</sup>

Since the Inspector General’s sharp warning, CMS has initiated a program aimed at reducing the inappropriate use of antipsychotic drugs for residents in SNFs who do not have qualifying diagnoses – but more work must be done. Still, several years later in November 2019, Richard Mollot described similar issues in his testimony before the Ways and Means Committee:

*“Over 40 percent of U.S. nursing homes have what we call chronic deficiencies: repeated violations of the same regulatory requirement year after year after year. Abuse, neglect, even crimes against residents are persistent and pervasive. Approximately 20 percent of residents are administered antipsychotic drugs every day, despite the FDA’s black box warning not to use these drugs on elderly people due to substantial risk of harm and even death.”*<sup>125</sup>

*It is reasonable to conclude that the overuse and misuse of antipsychotics is pervasive and continues to occur at unacceptably high rates. Incremental change is just that – incremental – and insufficient for the thousands of families who have entrusted their loved ones to nursing homes only later to face unnecessary hospitalizations or even death.*

Whatever the reason for the changes in antipsychotics prescribing patterns documented in this study, it is reasonable to conclude that the overuse and misuse of antipsychotics is pervasive and continues to occur at unacceptably high rates. Incremental change is just that – incremental – and insufficient for the thousands of families who have entrusted their loved ones to nursing homes only later to face unnecessary hospitalizations or even death.

The NHRA in 1987 was evidence that policymakers, experts, and advocates believed there was a better future possible for nursing home residents – one where human dignity and personalized care trumped all other concerns. The health system’s stagnation in eliminating chemical restraints in nursing homes reflects an inability to realize the goals of Congress more than 30 years ago, when Americans hoped for a better future for the system’s most vulnerable. Today, the stark reality of COVID-19 has brought this fact to the public’s consciousness. As the population continues to age and more Baby Boomers are relying on SNFs for rehabilitation services and long-term care, it is critical that policymakers and regulators continue to address antipsychotic misuse in the nursing home setting and ensure the nation adequately addresses the

<sup>124</sup> Levison, Daniel R, et al., Overmedication of Nursing Home Patients Troubling, *Department of Health and Human Services, Office of the Inspector General*, (2011). Available at: [https://oig.hhs.gov/newsroom/testimony-and-speeches/levinson\\_051011.asp](https://oig.hhs.gov/newsroom/testimony-and-speeches/levinson_051011.asp)

<sup>125</sup> Richard Mollot. Quote from: U.S. Congress. Hearing of the Committee on Ways and Means. “Caring for Aging Americans.” (2019). Available at: <https://waysandmeans.house.gov/legislation/hearings/caring-aging-americans>

needs of these vulnerable patient groups. As the Inspector General stated in 2011, Americans should continue to be outraged, and those who rely on nursing homes deserve better.

## APPENDIX A: METHODOLOGY AND LIMITATIONS

In response to Chairman Neal’s January 22, 2019, letter to CMS on antipsychotic use in nursing homes, CMS provided the Committee with data on antipsychotic citations for nursing homes from 2015-2018. For this report, the Committee utilized two specific datasets:<sup>126</sup>

1. Skilled Nursing Facilities Cited for Unnecessary Medications in 2015, 2016, 2017, and 2018: Lists all nursing facilities cited for deficiencies in 2015-2018; the dataset specifies the provider number, name, state, ZIP code, and survey date for each antipsychotic citation reported. Data include all SNFs cited for tags F0222, F0605 (Free from Chemical Restraints), F0329, and F0758 (Free from Unnecessary Drugs). F0605 and F0758 replaced F0222 and F0329 beginning on November 28, 2017.
2. Skilled Nursing Facilities Cited for Unnecessary Medication and Resident Harm with Corresponding Penalties in 2017 and 2018: Lists all nursing facilities cited for unnecessary medications with a Severity Level 3 or higher deficiency in 2017 and 2018. The severity of a deficiency is based on a level of 1 to 4, where a Level 1 deficiency implies no actual harm with the potential for minimal harm and a Level 4 deficiency implies Immediate Jeopardy to Resident Health or Safety.<sup>127</sup> The CMS-provided data included any facility that received a Level 3 (Actual Harm that is Not Immediate Jeopardy) or a Level 4 (Immediate Jeopardy to Resident Health or Safety). See Table 1, Interpretation of Scope and Severity of Unnecessary Medication Citation.

To account for nursing home population size, the Committee also used two datasets from the Kaiser Family Foundation. One dataset included the total number of residents in certified nursing facilities for every state in 2017.<sup>128</sup> The second included the number of certified nursing facilities for every state in 2017.<sup>129</sup> Using CMS-provided 2015-2018 antipsychotic citation data and 2017 nursing home facility and population data from the Kaiser Family Foundation, the Committee conducted five state-level analyses across all 50 states to calculate:

- State and national percent change in citations from 2015-2018
- Number of citations per 10,000 residents in 2018
- Percent of facilities that had at least one citation in 2018
- Number of facilities with a G or higher level citation from 2017-2018
- Percent change in citations from 2016-2018

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<sup>126</sup> Centers for Medicare & Medicaid Services, e-mail message to authors, June 14, 2019.

<sup>127</sup> Nursing Home Enforcement – Frequently Asked Questions, *Centers for Medicare and Medicaid Services*, Available at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationEnforcement/Downloads/NH-Enforcement-FAQ.pdf>

<sup>128</sup> Total Number of Certified Nursing Facilities, *Kaiser Family Foundation*, (2017). Available at: <https://www.kff.org/other/state-indicator/number-of-nursing-facilities/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>

<sup>129</sup> *Id.*

## *Limitations*

This study had several important limitations. First, this report was conducted at the state-level, which limited the Committee's ability to analyze the effects of facility-level factors, such as staffing levels or ownership type, which may impact antipsychotic use in SNFs. To control for the number of facilities and nursing home residents, the Committee used 2017 Kaiser Family Foundation data (the latest year of data available at the time of this study) alongside 2018 antipsychotic citation data. Thus, we assumed that nursing home population and the number of facilities remained stagnant from 2017 to 2018. Prior years of data suggest the number of nursing facilities have remained relatively constant from year to year.<sup>130</sup> Additionally, the Kaiser data included both SNFs and nursing facilities (Medicaid-only), yielding a slight overestimation of the number of nursing homes and nursing home residents nationwide. Still, the Medicare Payment Advisory Commission estimates approximately 15,000 SNFs operate nationwide, so the Kaiser total of 15,483 facilities was not too extreme.<sup>131</sup>

Second, with the exception of facilities fined for Level G or higher citations, CMS did not provide the Committee with data on the penalty amounts for facilities cited, which limited the scope of this study. For the analysis of Severity Level G or higher citations, CMS provided data on nursing facilities cited for *any* unnecessary medications, which include any medication for which there is an excessive dose, duration and/or a drug used without adequate monitoring or adequate indication for its use.<sup>132</sup> These data also include unnecessary medications other than antipsychotic drugs, such as opioids, anticoagulants, insulin, and antibiotics.<sup>133</sup> Thus Committee staff used descriptions provided alongside each citation to determine whether the citation related to antipsychotic misuse.

Third, data were not provided on citation rates in the U.S. territories, which limited the scope of the analysis to U.S. states.

Finally, variations in state surveying practices may create some of the differences in citation rates across states, rather than true differences in prescribing patterns; however, the Committee did not have data to control for this variable in its analysis.

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<sup>130</sup> Total Number of Certified Nursing Facilities, *Kaiser Family Foundation*, (2017). Available at: <https://www.kff.org/other/state-indicator/number-of-nursing-facilities/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>

<sup>131</sup> Report to Congress: Medicare Payment Policy, *Medicare Payment Advisory Commission*, (2020). Available at: [http://www.medpac.gov/docs/default-source/reports/mar20\\_entirereport\\_sec.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf?sfvrsn=0)

<sup>132</sup> Unnecessary Medications, Psychotropic Medications, and Medication Regime Review Critical Element Pathway, *Department of Health and Human Services and Centers for Medicare and Medicaid Services*, (2017). Available at: <https://www.nehca.org/wp-content/uploads/CMS-20082-Unnecessary-Medications.pdf>

<sup>133</sup> *Id.*

**APPENDIX B: STATE-LEVEL ANTIPSYCHOTIC CITATION TABLES FOR SKILLED NURSING FACILITIES**

**Table 3. Number of State-Level Antipsychotic Citations for Skilled Nursing Facilities, 2015-2018**

Number of Citations				
	2015	2016	2017	2018
AL	6	1	9	3
AK	4	5	4	9
AZ	10	19	21	29
AR	13	34	12	18
CA	147	427	462	273
CO	19	83	62	31
CT	16	71	43	20
DE	7	23	19	21
DC	2	3	5	2
FL	35	119	105	82
GA	5	25	33	46
HI	3	14	19	5
ID	6	25	21	17
IL	44	113	157	191
IN	55	166	196	118
IA	22	73	34	48
KS	57	135	94	56
KY	5	8	3	20
LA	22	35	35	10
ME	2	10	18	7
MD	25	89	88	42
MA	4	17	28	28
MI	52	117	102	105
MN	37	98	87	56
MS	7	5	2	8
MO	23	42	62	108
MT	8	7	18	20
NE	25	56	57	36
NV	4	30	20	11
NH	1	3	2	0
NJ	18	63	36	37
NM	6	22	30	22
NY	36	150	118	64

Number of Citations				
	2015	2016	2017	2018
NC	15	48	52	37
ND	6	15	13	9
OH	63	232	257	167
OK	35	93	85	83
OR	15	49	51	41
PA	49	156	137	96
RI	1	13	12	6
SC	7	26	37	26
SD	1	9	9	13
TN	7	17	24	25
TX	61	212	141	165
UT	15	39	53	25
VT	4	15	6	5
VA	25	95	70	63
WA	29	109	139	104
WV	9	24	17	14
WI	45	84	90	62
WY	3	13	12	13
<b>TOTAL</b>	<b>1116</b>	<b>3337</b>	<b>3207</b>	<b>2497</b>

*Source: All data provided by CMS.*

*Notes: Table includes any level of deficiencies cited.*

**Table 4. Change and Percent Change in Number of Antipsychotic Citations for Skilled Nursing Facilities, 2015-2018**

Change in Citations				Percent Change in Citations			
	2015-2016	2016-2017	2017-2018		2015-2016	2016-2017	2017-2018
AL	-5	8	-6	AL	-83.3%	800.0%	-66.7%
AK	1	-1	5	AK	25.0%	-20.0%	125.0%
AZ	9	2	8	AZ	90.0%	10.5%	38.1%
AR	21	-22	6	AR	161.5%	-64.7%	50.0%
CA	280	35	-189	CA	190.5%	8.2%	-40.9%
CO	64	-21	-31	CO	336.8%	-25.3%	-50.0%
CT	55	-28	-23	CT	343.8%	-39.4%	-53.5%
DE	16	-4	2	DE	228.6%	-17.4%	10.5%
DC	1	2	-3	DC	50.0%	66.7%	-60.0%
FL	84	-14	-23	FL	240.0%	-11.8%	-21.9%
GA	20	8	13	GA	400.0%	32.0%	39.4%
HI	11	5	-14	HI	366.7%	35.7%	-73.7%
ID	19	-4	-4	ID	316.7%	-16.0%	-19.0%
IL	69	44	34	IL	156.8%	38.9%	21.7%
IN	111	30	-78	IN	201.8%	18.1%	-39.8%
IA	51	-39	14	IA	231.8%	-53.4%	41.2%
KS	78	-41	-38	KS	136.8%	-30.4%	-40.4%
KY	3	-5	17	KY	60.0%	-62.5%	566.7%
LA	13	0	-25	LA	59.1%	0.0%	-71.4%
ME	8	8	-11	ME	400.0%	80.0%	-61.1%
MD	64	-1	-46	MD	256.0%	-1.1%	-52.3%
MA	13	11	0	MA	325.0%	64.7%	0.0%
MI	65	-15	3	MI	125.0%	-12.8%	2.9%
MN	61	-11	-31	MN	164.9%	-11.2%	-35.6%
MS	-2	-3	6	MS	-28.6%	-60.0%	300.0%
MO	19	20	46	MO	82.6%	47.6%	74.2%
MT	-1	11	2	MT	-12.5%	157.1%	11.1%
NE	31	1	-21	NE	124.0%	1.8%	-36.8%
NV	26	-10	-9	NV	650.0%	-33.3%	-45.0%
NH	2	-1	-2	NH	200.0%	-33.3%	-100.0%
NJ	45	-27	1	NJ	250.0%	-42.9%	2.8%
NM	16	8	-8	NM	266.7%	36.4%	-26.7%
NY	114	-32	-54	NY	316.7%	-21.3%	-45.8%
NC	33	4	-15	NC	220.0%	8.3%	-28.8%
ND	9	-2	-4	ND	150.0%	-13.3%	-30.8%
OH	169	25	-90	OH	268.3%	10.8%	-35.0%
OK	58	-8	-2	OK	165.7%	-8.6%	-2.4%

Change in Citations				Percent Change in Citations			
	2015-2016	2016-2017	2017-2018		2015-2016	2016-2017	2017-2018
OR	34	2	-10	OR	226.7%	4.1%	-19.6%
PA	107	-19	-41	PA	218.4%	-12.2%	-29.9%
RI	12	-1	-6	RI	1200.0%	-7.7%	-50.0%
SC	19	11	-11	SC	271.4%	42.3%	-29.7%
SD	8	0	4	SD	800.0%	0.0%	44.4%
TN	10	7	1	TN	142.9%	41.2%	4.2%
TX	151	-71	24	TX	247.5%	-33.5%	17.0%
UT	24	14	-28	UT	160.0%	35.9%	-52.8%
VT	11	-9	-1	VT	275.0%	-60.0%	-16.7%
VA	70	-25	-7	VA	280.0%	-26.3%	-10.0%
WA	80	30	-35	WA	275.9%	27.5%	-25.2%
WV	15	-7	-3	WV	166.7%	-29.2%	-17.6%
WI	39	6	-28	WI	86.7%	7.1%	-31.1%
WY	10	-1	1	WY	333.3%	-7.7%	8.3%
<b>TOTAL</b>	<b>2221</b>	<b>-130</b>	<b>-710</b>	<b>TOTAL</b>	<b>199.0%</b>	<b>-3.9%</b>	<b>-22.1%</b>

*Sources: All data provided by CMS.*

*Notes: Table includes all levels of deficiencies cited.*

## APPENDIX C: CMS ADMINISTRATIVE ACTIONS TO REDUCE OR ELIMINATE NURSING HOME PROTECTIONS

Below are summaries of major CMS policies and actions related to reducing or eliminating nursing home regulations from May 2017-March 2020 (at the beginning of the COVID-19 pandemic).

**Table 5. CMS Administrative Actions to Reduce or Elimination Nursing Home Protections, 2017-2020**

CMS Administrative Actions to Reduce or Eliminate Nursing Home Protections			
Type of Action	Action Description	Reference	Date
<b>Proposed Rule</b>	CMS solicits comments on three possible areas where nursing home standards might be eliminated or reduced: <ul style="list-style-type: none"> <li>• Notice to Long-Term Care Ombudsman Program when nursing home is evicting resident;</li> <li>• Standards for handling resident grievances; and</li> <li>• Requirement that facilities develop quality improvement programs. CMS also seeks “feedback regarding any additional areas of burden reduction and cost savings in [nursing homes].”</li> </ul>	<a href="#"><u>Proposed Rules, 82 Fed. Reg. 21,014, 21,089</u></a>	May 4, 2017
<b>Proposed Rule</b>	CMS proposes to eliminate ban of arbitration agreements and, instead, allow nursing homes to require such agreements as a condition of admission.	<a href="#"><u>Proposed Rules, 82 Fed. Reg. 26,649</u></a>	June 8, 2017
<b>Moratorium on Policies</b>	CMS announces that for one year it will not impose fines or any other meaningful penalties for violations of certain regulations scheduled to go into effect November 2017.	<a href="#"><u>CMS Survey and Certification (S&amp;C) Memo 17-36-NH</u></a>	June 30, 2017
<b>Revision of CMP Policies</b>	CMS changes its policies to reduce amount and frequency of nursing home fines. Fines will be assessed on a per-day basis, rather than a per-instance basis, when the violation occurred prior to inspection. In addition, per-instance fines will be used even for an ongoing violation considered a “single isolated incident.”	<a href="#"><u>CMS S&amp;C Memo, 17-37-NH</u></a>	July 7, 2017

CMS Administrative Actions to Reduce or Eliminate Nursing Home Protections			
Type of Action	Action Description	Reference	Date
<b>Revision of CMP Policies</b>	CMS proposes to repeal previous S&C (survey and certification) Memo 16-31-NH and reduce imposition of fines against nursing homes. Proposed changes include giving nursing homes more opportunities to delay or potentially avoid fines and, even in Immediate Jeopardy situations, allowing fines only in cases of serious injury or death.	<a href="#">CMS S&amp;C Memo 18-01-NH</a>	Oct. 27, 2017
<b>Program Launch</b>	CMS launches “Patients Over Paperwork” initiative to eliminate or weaken regulations governing health care providers.	<a href="#">CMS press release</a>	Oct. 30, 2017,
<b>Notice of Proposed Rulemaking (NPRM)</b>	CMS indicates intent by June 2018 to issue proposed nursing home regulations that would eliminate or revise regulations that allegedly are excessively burdensome, unnecessary, or obsolete.	<a href="#">Unified Agenda of Regulatory and Deregulatory Actions, RIN 0938-AT36</a>	Fall 2017
<b>Notice of Proposed Rulemaking (NPRM)</b>	CMS issues Notice of Proposed Rulemaking (NPRM) to allow nursing homes to review their emergency preparedness programs and train staff to carry out those plans every two years rather than annually.	<a href="#">Proposed Rule, 83 Fed. Reg. 47,686, 47,725-47,727</a>	Sept. 20, 2018
<b>White House Budgetary Proposal</b>	The Trump Administration's Fiscal Year 2020 Budget suggests reducing the frequency of SNF surveys for top-performing nursing homes. CMS Administrator Seema Verma also indicates that the agency is interested in the idea; however, studies indicate that even high-rated nursing homes continue to violate residents’ rights and protections. As a July 2019 GAO’s report suggests, more than 20 percent of nursing homes considered “above average” and “much above average” by CMS have been cited for abuse in a single year.	<a href="#">The President's FY 2020 Budget</a>	March, 2019

CMS Administrative Actions to Reduce or Eliminate Nursing Home Protections			
Type of Action	Action Description	Reference	Date
<b>Proposed Rule</b>	CMS proposes reducing the frequency that nursing facilities are required to conduct facility assessments, allowing them to streamline their compliance and ethics programs. The proposal also considers other de-regulation policies related to independent dispute resolutions and Quality Assurance Program Improvement (QAPI).	<a href="#">Proposed Rules, 84 Fed. Reg. 34,737</a>	July 18, 2019
<b>Final Rule</b>	CMS finalizes rule amending the Long-Term Care Requirements of Participation (RoPs). Most notably, the Final Rule removes the requirement prohibiting facilities from entering into pre-dispute arbitration agreements with residents, while maintaining the 2016 ban on requiring residents to agree to arbitration as a condition of admission or as a requirement for continued care.	<a href="#">Final Rule, 84 Fed. Reg. 34,718</a>	July 18, 2019
<b>Payment Model Implementation</b>	CMS began implementing a new payment system, called the “Patient Driven Payment Model” (PDPM), for Medicare-covered nursing home care. PDPM creates a new set of financial incentives for nursing homes to consider when admitting and discharging residents, as well as providing resident care. While it will take some time to assess PDPM’s effects on resident care, PDPM also allows 25 percent of a resident’s total therapy regimen, by discipline, to be provided in group and/or concurrent therapy settings.	<a href="#">Payment Driven Payment Model (PDPM)</a>	Oct. 1, 2019

*Source: 2017 CMS Administrative Actions were provided by the Long Term Care Community Coalition (LTCCC) and can be found here: <https://nursinghome411.org/how-cms-is-rolling-back-nursing-home-protections-table/>. 2018 and 2019 Administrative actions related to nursing home care were provided by the LTCCC through personal correspondence.*

**APPENDIX D: SUMMARIES OF SELECT SKILLED NURSING FACILITIES CITATION FOR UNNECESSARY MEDICATIONS AND RESIDENT HARM (G OR HIGHER LEVEL CITATION), 2017-2018**

Below are summaries from select G or higher level (i.e., G, H, I, J, and K) citations SNFs received in 2017 or 2018. To protect anonymity, the Committee removed facility name and provider number.

**Table 6. Summaries of Select Skilled Nursing Facilities Citations for Unnecessary Medications and Resident Harm (G or Higher Level Citation), 2017-2018<sup>134</sup>**

Summaries of Nursing Facilities Citation for Unnecessary Medications and Resident Harm (G or Higher Level Citation), 2017-2018								
State	Date	Overall Star Rating	Inspection Survey Rating	Survey Type	Severity Code	Remedy Imposed	Civil Money Penalty	Summary of Citation
California	2/2/2018	5	4	Complaint	G	No enforcement imposed based on regional office review	N/A	The facility failed to recognize the cumulative side effects of multiple psychotropic medications and ensure the prescriber was notified of the resident response and behavioral assessments. A resident was admitted to the SNF with diagnoses, which included alcohol dependence and withdrawal delirium, but the resident’s admission assessment stated he was alert and able to walk with assistance. The physician ordered multiple anti-anxiety and antidepressant medications in combination with 10mg of Haldol a day. Later reports showed this combination of antipsychotics and anti-anxiety medication led the patient to lose alertness and even forgo his meals. Documentations showed that the SNF staff did not document his behavioral changes or the resident’s excessive sedation. The resident could no longer walk, eat, use the bathroom on his own, hold a phone, or even speak.

<sup>134</sup> The severity of a deficiency is based on a level of 1 to 4, where a Level 1 deficiency implies No Actual Harm with the Potential for Minimal Harm and a Level 4 deficiency implies Immediate Jeopardy to Resident Health or Safety. A Level 3 or Higher deficiency level corresponds to a Level “G” or higher deficiency level. See Table 1 for more information.

Summaries of Nursing Facilities Citation for Unnecessary Medications and Resident Harm (G or Higher Level Citation), 2017-2018								
State	Date	Overall Star Rating	Inspection Survey Rating	Survey Type	Severity Code	Remedy Imposed	Civil Money Penalty	Summary of Citation
California	8/22/2017	2	1	Complaint	J	Civil Money Penalty	\$25,198 (Per-Day)	Based on observation, interview, and record review, the facility failed to ensure the resident was free of unnecessary drugs. The resident was receiving excessive amounts of narcotics and psychotropic medications without adequate monitoring and indication for its use, in duplication and without attempting a gradual dose reduction. The resident's diagnoses included multiple sclerosis, major depressive disorder, anxiety disorder, and insomnia. In May of 2017, following multiple diagnoses, the resident took Ambien, Xanax, Valium, and Lexapro nearly 30 times each in one month.
Florida	4/13/2017	2	2	Complaint	K	Civil Money Penalty	\$350,628.20 (Per Instance)	The facility failed to ensure the resident's drug regimen was free of unnecessary drugs. Based on a review of records, the resident had an order placed in her chart in error for Coumadin for diagnoses of Cerebrovascular Accident. The resident did not have this diagnosis and the order was never signed off by any staff members. The resident received the drug without monitoring of the high-risk medication and developed a significant intracranial hemorrhage (bleeding in the brain) per local hospital records. The actions of the medical and nursing staff who failed to order the necessary laboratory tests to monitor clotting times and identify the transcription error subsequently resulted in the resident developing a significant intracranial bleeding and Coumadin toxicity. This resulted in the resident's death.

**Summaries of Nursing Facilities Citation for Unnecessary Medications and Resident Harm (G or Higher Level Citation), 2017-2018**

State	Date	Overall Star Rating	Inspection Survey Rating	Survey Type	Severity Code	Remedy Imposed	Civil Money Penalty	Summary of Citation
Florida	1/5/2018	1	1	Complaint	J	Civil Money Penalty	\$98,455 (Per-Day)	One of the sampled residents received the antipsychotic medication, Haldol, without documented evidence of an indication for use and in the absence of any behavioral symptoms that presented a danger to the resident or others. The resident received an excessive dose that was 80 times the ordered amount and continued to receive the excessive doses of Haldol after she began experiencing adverse consequences. The resident was supposed to receive a 0.25mg dose of Haldol, but due to an error, the resident received a 20mg dose of Haldol. The resident was placed on 24-hour crisis care and was transferred to the hospital. Her admitting hospital diagnosis was acute encephalopathy (brain damage), "probably medication-induced from Haldol from overdose at the nursing home." The resident needed extensive assistance for bed mobility transfers, locomotion, dressing, toilet use, personal hygiene, and bathing.

Summaries of Nursing Facilities Citation for Unnecessary Medications and Resident Harm (G or Higher Level Citation), 2017-2018								
State	Date	Overall Star Rating	Inspection Survey Rating	Survey Type	Severity Code	Remedy Imposed	Civil Money Penalty	Summary of Citation
Illinois	11/5/2018	1	1	Standard	G	No enforcement imposed based on regional office review	N/A	The facility failed to ensure a resident was offered the right to refuse an intramuscular psychotropic medication or provided the least restrictive means of medication intervention. The resident had been having loose stools and was instructed to pull the emergency cord in her room every time she had a bowel movement. However, when she pulled the emergency cord, one of the nurses instructed her not to use the cord and locked the resident's private bathroom. The resident was incontinent and had soiled herself. The nursing staff then phoned the physician and ordered Ativan and Haldol injections. The physician orders did not have any type of necessary diagnoses in order to use psychotropic medications. A member of the nursing staff said the resident should be in a mental institute and administered the antipsychotic medication. While omitted from the nurse's notes, the resident refused the medication, but was given an intramuscular injection for these chemical restraints anyway.
Kentucky	11/17/2017	1	1	Complaint	K	Civil Money Penalty	\$366,709.85 (Per-Day)	The facility failed to ensure that four different sampled residents were free from unnecessary medications. The facility administered an antipsychotic medication to four residents without adequate monitoring to ensure the residents were receiving a safe, therapeutic dosage of medications, resulting in kidney damage and subsequent death for one resident. An evaluation showed that there was no evidence that the resident's clinical condition was reviewed for the continued need for the medication.

Summaries of Nursing Facilities Citation for Unnecessary Medications and Resident Harm (G or Higher Level Citation), 2017-2018								
State	Date	Overall Star Rating	Inspection Survey Rating	Survey Type	Severity Code	Remedy Imposed	Civil Money Penalty	Summary of Citation
Maryland	1/19/2017	3	1	Standard	K	Civil Money Penalty	\$884,711.88 (Per-Day)	The facility failed to have a system in place for accurate documentation of the administration of medications within physician ordered parameters. Residents were receiving medications for blood pressure or heart medications as well as antipsychotics. The facility lacked documentation that a physician authorized the administration of a number of these drugs. As a result, a total of 58 medication errors were evident for five residents reviewed during the survey.
Michigan	3/31/2017	5	4	Complaint	G	Civil Money Penalty	\$6,500 (Per Instance)	The facility failed to monitor international normalized ratio (INR) for anticoagulant monitoring levels during the use of various medications. The deficient practice resulted in abnormally high medication level causing excessive bleeding, which may have contributed to death. The resident had multiple diagnoses, including anemia and atrial fibrillation and started on Coumadin. While Coumadin levels were high, the orders for testing were missed on the admission orders. No prothrombin time (PT) or INR tests were ordered. The residents died within a few days with primary diagnosis of low blood volume and septic shock.
New Mexico	7/19/2018	1	1	Standard	J	Civil Money Penalty	\$224,779 (Per-Day)	During the annual survey, it was determined that a nurse gave a resident the antipsychotic medication Seroquel for aid with sleep. The resident and his wife reported that on the next day, he was over-sedated. The resident further reported that he was anxious about getting his medication. Based on record review, interview, and observation, the facility failed to ensure Seroquel was given for an appropriate indication for the resident. This deficient practice resulted in unnecessary fear, worry and anxiety, and over-sedation.

Summaries of Nursing Facilities Citation for Unnecessary Medications and Resident Harm (G or Higher Level Citation), 2017-2018								
State	Date	Overall Star Rating	Inspection Survey Rating	Survey Type	Severity Code	Remedy Imposed	Civil Money Penalty	Summary of Citation
Ohio	3/16/2018	1	1	Standard	J	Civil Money Penalty	\$13,627.25 (Per Instance)	The facility failed to ensure one resident had a qualifying diagnosis for a psychotropic medication. The diagnosis was based on incorrect information that the resident was delusional. The resident's physician prescribed a psychotropic medication without a supporting diagnoses or documented rationale for use. The resident was observed with severe cognitive impairment, lethargy, decreased oral intake, excessive sleeping, decreased physical abilities, and decreased participation in activities. The facility failed to monitor the resident for effectiveness or adverse effects of the antipsychotic medication. The facility identified seven residents residing in the facility who received antipsychotic medications.
Washington	5/4/2017	4	3	Complaint	G	No enforcement imposed based on regional office review	N/A	The facility failed to ensure a resident was treated with dignity and respect. The staff combined chemical restraints, in the form of injections of 5mg of Olanzapine, 10mg of Haldol and a sedating anti-histamine (50mg of injectable Benadryl), for behavioral management. However, the resident experienced psychosocial harm and over-sedation as a result of the imposed medications.

*Source: Summaries of select unnecessary medication citations with a Severity Level 3 or higher were provided from CMS data on all unnecessary medication citations with a Severity Level 3 or higher from 2017 and 2018.*

*Notes: The severity of a deficiency is based on a level of 1 to 4, where a Level 1 deficiency implies No Actual Harm with the Potential for Minimal Harm and a Level 4 deficiency implies Immediate Jeopardy to Resident Health or Safety. A Level 3 or Higher deficiency level corresponds to a Level "G" or higher deficiency level. See Table 1 for more information.*