A DECADE OF DRUGGING

Sedation of Nursing Home Residents with Dangerous Antipsychotic Drugs Persists Despite Federal Partnership



Long Term Care Community Coalition

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This report is dedicated to Lucette Lagnado (1956-2019), an award-winning reporter whose work focused on conditions in hospitals and nursing homes. Lagnado's 2007 Wall Street Journal report, "Nursing Homes Struggle to Kick Drug Habit," brought much needed attention to the widespread use of antipsychotics in nursing homes.



Introduction

More than one million people live in US nursing homes and each week, one in five of them are given dangerous antipsychotic (AP) drugs. In most cases these drugs are administered ***without*** clinical justification.

AP drugs are a persistent staple of the nursing home drug regimen despite their risk of causing serious physical and emotional harm to residents. AP drugs are associated with significant adverse outcomes in the elderly, including heart attacks, strokes, Parkinsonism, falls, and death. Numerous government interventions over several decades – from the 1987 Nursing Home Reform Law to the 2012 National Partnership to Improve Dementia Care – have aimed to mitigate AP drug use, but these potent drugs continue to flood nursing homes, inflicting immeasurable harm on residents and burdening the nation's long-term care system.

This report looks back at the decade in drugging and explores how dementia care has – and hasn't – changed since the launch of the 2012 Partnership. Our analysis is based on public antipsychotic drugging data, academic research, government reports, media investigations, and discussions with long-term care stakeholders including residents, families, ombudsmen, providers, and advocates.

We find that a once-promising campaign has sputtered and fallen short of its goals to curb AP drug use in nursing homes. Understaffed and underenforced, nursing homes are too often turning to dangerous AP drugs instead of implementing the non-pharmacological approaches to dementia care that have been required for over 30 years. Troublingly, we find that some nursing homes are obfuscating the true number of residents receiving AP drugs to preserve their reputation and bottom lines. This practice is fostered by a federal government that provides minimal oversight and data transparency on antipsychotic drugs.

Purpose of this Report

In 2012, following a devastating federal report on the rampant misuse of dangerous antipsychotic drugs in U.S. nursing homes, the federal Centers for Medicare and Medicaid Services (CMS) launched the National Partnership to Improve Dementia Care to address this problem. The purpose of this report is to assess the extent to which the promise of the Partnership has been realized in the lives of nursing home residents in the 10 years since it was launched.

Our goals in this report include:

- **Raising awareness** of the continued rampant misuse of antipsychotic drugs and the damage that is inflicting on residents, their loved ones, and the public.
- **Evaluating the effectiveness** to date of the federal campaign to reduce inappropriate AP drugging of nursing home residents.
- **Providing recommendations** to address the persistence of widespread inappropriate AP drugging including strengthening enforcement and enhancing transparency.

We begin the report with a background on antipsychotics and the National Partnership. This section will cover federal law on antipsychotics and informed consent, research on the harm associated with AP drugging, and the events that led to the formation of the Partnership. Next, we evaluate the outcomes of the Partnership, including trends in AP drugging rates since 2012, when the Partnership was launched, and the unintended consequences of the campaign. Lastly, we examine the role of enforcement and transparency in dementia care and provide recommendations for reducing AP drugging in nursing homes.

Notes

- This report follows up on two prior LTCCC assessments of the National Partnership published in 2014. "Left Behind: The Impact of The Failure To Fulfill The Promise of The National Campaign To Improve Dementia Care," focused on the individuals left behind by the failure to enforce longstanding minimum standards of care or even achieve and continue the modest rate of reduction promised at the start of the campaign. "Left Out: Results Of A Survey Of Nursing Home Resident Representatives On The National Campaign To Improve Dementia Care," presented the results of a national survey of nursing home resident representatives on their knowledge of, and participation in, the CMS campaign, and found that despite substantial interest among resident representatives in the "stakeholder" calls and other CMS campaign activities, few resident representatives participate because CMS's outreach efforts focused almost exclusively on the industry.
- **Antipsychotic (AP) drugs** refer to a type of psychotropic drug that specifically treats the symptoms of psychosis. See nursinghome411.org/ap-list for a list of common AP drugs (such as Haldol, Abilify, and their generic equivalents).
- **Psychotropic drugs** refer to any drug that affects the mind and is a broad term for a range of drugs including antipsychotics, antidepressants, anti-anxiety medications, and stimulants.
- **Antipsychotic drugging rates in nursing homes are calculated in two different ways:**
    - **Risk-adjusted:** This excludes residents who are receiving antipsychotic drugs but have a diagnosis of schizophrenia, Tourette's Syndrome, or Huntington's Disease.
    - **Non-risk-adjusted**: All residents receiving antipsychotic drugs. For more information and data, see nursinghome411.org/decade-drugs/data.
- **Methodology:** In this report, LTCCC estimates the number of residents that ***have*** received antipsychotics since the start of the partnership and the number of residents that ***could have*** avoided antipsychotics had CMS achieved annual reduction goals of 20% from 2011 to 2021. These estimates are based on crude measurements and do not account for resident turnover. See Page 10 for more information on methodology.
- **Real examples of antipsychotic drugging in nursing homes** are highlighted throughout the report. These examples are from news reports, deficiency statements, and consumer submissions to LTCCC.

A Campaign Sedated

AP History & Law

Antipsychotic (AP) medications have been rampant in U.S. nursing homes since they emerged in the mid-20th century. Though intended for people with severe mental illness, AP drugs are routinely used inappropriately to sedate residents, particularly residents with dementia.

From the nursing home's perspective, antipsychotic drugging is more efficient and cost-effective than non-pharmacological interventions that provide residents with the care and services that they need (and are entitled to under federal law). Docile residents require fewer facility resources and ease the burden of overworked staff.[1] AP drugs administered without clinical justification, however, can be extremely dangerous. In addition to unnecessary sedation, AP drugs are associated with serious physical and psychological health effects, including heart attacks, tremors, strokes, and death.

The U.S. government has long acknowledged the seriousness of the crisis surrounding the inappropriate antipsychotic drugging of nursing home residents, yet with its lenient approach to enforcement, continues to abet this illegal and immoral practice.

In 1975, a Senate Special Committee on Aging report detailed how AP drugs were being widely misused to tranquilize residents in nursing homes. According to the report, "the flow of drugs through most of America's 23,000 nursing homes is almost totally without controls; it is haphazard, inefficient, costly, and, most of all, dangerous to the patients who must trust others for their protection." A 1986 Institute of Medicine (IOM) report cited the misuse of AP drugs as a significant cause of inadequate care. In 2008, the Food and Drug Administration imposed a "black-box warning" of increased mortality risk on all antipsychotic medications for elderly patients with dementia.[2] A 2011 OIG report found that less than half of the Medicare drug claims for AP drugs were used for medically accepted indications or documented correctly. A 2020 U.S. House Ways and Means Committee Analysis, "Under-Enforced and Over-Prescribed,"

A 2020 U.S. House Ways and Means Committee Analysis, "Under-Enforced and Over-Prescribed," found that many nursing homes continue to administer "potentially dangerous drugs as a chemical restraint – in lieu of proper staffing – which has the potential to harm hundreds of thousands of patients."

[1] Human Rights Watch, "They Want Docile," (February 5, 2018). Available at https://www.hrw.org/report/2018/02/05/they-want-docile/how-nursing-homes-united-states-overmedicate-people-dementia.

[2] The FDA announcements of black-box warnings for atypical (2005) and first-generation (2008) antipsychotic drugs no longer appear on the agency's website. For currently available information, see Jun Yan, "FDA Extends Black-Box Warning to All Antipsychotics," *Psychiatric News*, American Psychiatric Society, July 18, 2008, https://doi.org/10.1176/pn.43.14.0001.

found that many nursing homes continue to administer "potentially dangerous drugs as a chemical restraint – in lieu of proper staffing – which has the potential to harm hundreds of thousands of patients."[3]

The 1987 Nursing Home Reform Law requires nursing homes to provide every resident – including those with dementia – care and quality of life services sufficient to attain and maintain their highest practicable physical, emotional, and psychosocial well-being.[4] Yet, far too often, nursing homes provide substandard care and services, using potent drugs to ensure submission of the residents entrusted to their care.

Nursing Home Reform Law

- **Informed Consent:** Residents have the right to be informed about the risks and benefits of any medication.
- **Right to Refuse:** Residents have the right to refuse a medication (even if refusal may be detrimental).
- **Freedom from Chemical Restraints:** Each resident's drug regimen must be free from unnecessary drugs.

In fact, federal law protects residents from the inappropriate use of AP drugs. The Reform Law proscribes the use of psychotropic drugs as chemical restraints to control or sedate residents for the convenience of staff. Residents have the right to be informed about the risks and benefits of any medication (or other proposed treatment), to refuse a medication, and to be free from unnecessary medications.[5]

Assault by Haldol

"My mother was pharmaceutically raped by being penetrated with a hypodermic needle full of Haldol… She died in an irreversible vegetative state just days later with dehydration, dysphagia (trouble swallowing), urinary tract infection, AFIB, multiple organ failure and a fractured spine! She had none of those conditions when she entered that facility."

-Family member, "Tell Your Story," LTCCC

[3] *Under-Enforced and Over-Prescribed: The Antipsychotic Drug Epidemic Ravaging,* Committee on Ways and Means, (July 2020). Available at https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/WMD%20Nursing%20Home%20Report_Final.pdf

[4] The Nursing Home Reform Act passed into law as part of H.R.3545 - Omnibus Budget Reconciliation Act of 1987. On 12/22/1987 it became Public Law No: 100-203. Available at https://www.congress.gov/bill/100th-congress/house-bill/3545/text. Henceforth, "Nursing Home Reform Law" or "Reform Law."

[5] 42 C.F.R. §483.10. Accessed at http://www.law.cornell.edu/cfr/text/42/483.10.

'Families and caregivers should be outraged'

No Idea

"I had no idea, not at all, that the drugs were dangerous. I had no idea… I'm guessing most people have no idea."

- Daughter of a nursing home resident, Human Rights Watch report

In 2011, the Office of Inspector General (OIG) of the US Department of Health & Human Services published a bombshell report exposing rampant AP drug use in US nursing homes. The report, requested by U.S. Senator Charles Grassley, found that half (51%) of Medicare claims for atypical antipsychotic drugs for elderly nursing home residents were erroneous, at an estimated annualized cost of $232 million in 2007. Elderly patients with dementia – a population facing increased mortality risk from antipsychotics – accounted for 88% of antipsychotic prescriptions, according to the review.[6]

"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," Inspector General Daniel R. Levinson wrote in a statement on the overmedication of nursing home patients. "…Government, taxpayers, nursing home residents, as well as their families and caregivers should be outraged – and seek solutions."

Following publication of the Inspector General's report and statement, LTCCC and other resident advocates[7] met with Dr. Donald M. Berwick, then-acting administrator of CMS, to press for CMS action to address this problem. This meeting led to the launching of a federal campaign to address inappropriate and dangerous antipsychotic drugging, known as the National Partnership to Improve Dementia Care.

"We want our loved ones with dementia to receive the best care and the highest quality of life possible," said then-acting administrator Marilyn Tavenner in the press release announcing the Partnership.[8]

But a decade into the campaign, residents continue to receive AP drugs at disturbingly high rates. CMS has failed to deliver on its promise to ensure that residents with dementia are receiving the best care and highest quality of life possible.

Moving – and Lowering – the Goalposts

The campaign began with modest short-term goals and promises of ambitious long-term outcomes. But in the last 10 years, CMS and its industry partners have been moving – and

[6] *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*, report number OEI-07-08-00150, Office of Inspector General, US Department of Health and Human Services (May 4, 2011). Available at https://oig.hhs.gov/oei/reports/oei-07-08-00150.asp. Hereinafter, *OIG 2011*.

[7] The advocates included representatives from the California Advocates for Nursing Home Reform, Center for Medicare Advocacy, Long Term Care Community Coalition, National Consumer Voice for Quality Long-Term Care, and the Virginia Legal Aid Justice Center.

[8] *CMS Announces Partnership to Improve Dementia Care in Nursing Homes*, May 30, 2012. Available at https://www.cms.gov/newsroom/press-releases/cms-announces-partnership-improve-dementia-care-nursing-homes.

lowering – the goalposts for reducing AP drug use in nursing homes. Despite claims of ambitious goals and significant achievements, the once-promising Partnership has yielded only marginal reductions. As a result, every year, hundreds of thousands of nursing home residents are administered harmful and unnecessary drugs with impunity.

When the Partnership launched in March 2012, nearly one in four nursing home residents (23.9%, risk-adjusted) were receiving AP drugs.[9] A decade later, the risk-adjusted AP drugging rate is 14.5%.[10] While in another situation this would be considered great progress, it is critical to understand that these are the risk-adjusted rates which, under CMS's risk-adjustment methodology, exclude residents who received AP drugs but have a diagnosis of schizophrenia, Huntington's Disease, or Tourette's Syndrome (whether or not that diagnosis is accurate or if the drugs are providing a benefit to those residents). Only 2% of the general population will ever have a diagnosis for one of these conditions. Yet, the difference between the risk-adjusted and non-risk-adjusted rates of AP drugging in nursing homes has consistently been much greater than 2%, which indicates significant fraud in resident diagnoses. For this reason, this report largely focuses on the non-risk-adjusted rates.

Non-risk-adjusted rate

- Includes all residents receiving AP drugs according to MDS 3.0 reports.

Risk-adjusted rate

- Excludes residents with a diagnosis of schizophrenia, Huntington's Disease, or Tourette's Syndrome. This is the primary AP drugging metric used by CMS.

Why is this distinction important?

- The purpose of risk-adjusting is to exclude incidence of drugging that may be appropriate from a facility's rate.
- Unfortunately, risk-adjustment is prone to fraud and abuse.
- Data indicate high rates of phony diagnoses of AP drugging in nursing homes. Facilities can give a phony diagnosis of schizophrenia in order to administer AP drugs with impunity.
- Due to strong evidence of widespread fraud, we believe the non-risk-adjusted rates are more valuable.

The Partnership campaign moved slowly from the start. In March 2012, CMS announced its initial reduction goal of 15% by the end of that calendar year (20% prorated annually).[11] The initial reduction goal – viewed as modest by consumer advocates – was intended to "get the ball rolling," according to CMS, which promised more ambitious targets would follow.

[9] Risk-adjusted and non-risk-adjusted antipsychotic drugging data are obtained, respectively, from CMS Partnership reports and MDS 3.0 Frequency Reports. LTCCC has compiled and published these data at https://nursinghome411.org/decade-drugs/data. For CMS Partnership data, see "Antipsychotic Medication Use Data Report 2021Q4 - Updated 07.29.2022" available in the Downloads section on https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/National-Partnership-to-Improve-Dementia-Care-in-Nursing-Homes. For MDS 3.0 Frequency Reports, see 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.

[10] The latest rate is that reported by the Partnership on July 29, 2022, for the last quarter of 2021.

[11] Nursing Home Initiative on Behavioral Health & Antipsychotic Medication Reduction, CMS (March 28, 2012). Available at https://www.youtube.com/watch?v=U1_rpO0bwbM.

The ball only rolled slowly, never gained momentum, and eventually, essentially, came to a halt. Initial goals were met past their deadlines; the promised ambitious longer-term goals were never even set.

The initial 15% goal was met 21 months after it was established – a full year late. Some researchers speculate that the program did not contribute to this initial reduction.[12] Rather than strengthening enforcement of regulatory standards on inappropriate drug use and chemical restraints, as its mission requires, CMS responded by merely continuing outreach and engagement activities. The next targets, established in 2014, were even weaker: 5% annual reductions in 2015 and 2016.[13] Since then, with the exception of a target reduction goal for a subset of facilities CMS calls "late adopters,"[14] CMS has failed to follow through on its promise of ambitious long-term reduction goals.

This lack of urgency through the decade has been costly. The 14.5% (risk-adjusted) AP drugging rate reported for Q4 2021 could have been as low as 2.6% had nursing homes consistently met the original annual reduction target of 20% (see Figure 1).[15] Even a more modest

Antipsychotics by the Numbers

- **250,000:** Nursing home residents receiving dangerous AP drugs each week.
- **1.1 million:** Residents that could have been spared from the use of dangerous AP drugs had CMS set and achieved an annual reduction goal of 20%.
- **1 in 3:** Residents reported in the MDS as having schizophrenia without evidence of the diagnosis in their Medicare claims history.
- **1975:** The year a Senate report detailed how AP drugs were being widely misused to tranquilize nursing home residents.
- **1 in 200:** The odds of a psychotropic drug citation being categorized as causing harm**.**
- **80%:** The rate of residents receiving psychotropic drugs (which has remained constant since 2011).
- **40%:** Anticonvulsant drug use among long-stay residents in 2019, up from 28% in 2011.
- **51%:** Erroneous Medicare claims for atypical AP drugs, according to federal report.
- **$232 million:** Estimated annualized cost of those erroneous Medicare claims in 2007.
- **20.8 million:** Number of prescriptions for antipsychotic drugs in U.S. nursing homes and assisted living in 2020.

[12] In a 2018 JAMA study, researchers speculate the campaign did not appear to have accelerated the decline that was already occurring. Available at https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2674245.

[13] *National Partnership to Improve Dementia Care exceeds goal to reduce use of antipsychotic medications in nursing homes: CMS announces new goal*, CMS, Sept. 19, 2014. Available at https://www.cms.gov/newsroom/press-releases/national-partnership-improve-dementia-care-exceeds-goal-reduce-use-antipsychotic-medications-nursing.

[14] In October 2017, CMS announced a 15% target reduction goal for late adopters: nursing homes with higher rates of AP drug use. The risk-adjusted drugging rate for these nursing homes decreased from 40% to 16.8% in 2021, a rate that met the modest target goal but far exceeds the rate of the population that should be receiving AP drugs.

[15] The estimated risk-adjusted drugging rate was determined using a future value formula: $FV = PV(1-r)^n$, wherein FV is future value of AP rate, PV is Q4 2011 AP rate, *r* is reduction goal, and *n* is number of periods of reduction in years. For 20% reduction goal: $FV = .239(1-.2)^{10} = .026$ *or* 2.6%. For 10% reduction goal: $FV = .239(1-.1)^{10} = .083$ *or* 8.3%. Data available at https://nursinghome411.org/decade-drugs/data.

annual reduction target of 10% would have dropped the current rate to 8.3%. In both projections, hundreds of thousands of nursing home residents (more than a million for the 20% annual target) could have been spared from unnecessarily receiving dangerous antipsychotic drugs (see Figure 2).[16]

Instead, AP drugging remains rampant and the campaign's modest achievements, however marginal, have not been sustained. Risk-adjusted AP drug rates have flattened since 2016 and dropped only modestly since the start of the campaign. Each week, roughly 250,000 vulnerable nursing home residents are being chemically sedated with dangerous APs because of failures to enforce longstanding minimum standards of care or to even achieve and sustain the modest reduction rate goals.[17]

The risk-adjusted data, however striking, tell only part of the story of the decade in drugging. The next section explores the limitations of risk-adjusted data and the unintended consequences of the campaign.

Each week, roughly 250,000 vulnerable nursing home residents are being chemically sedated with dangerous APs because of failures to enforce longstanding minimum standards of care or to even achieve and sustain the modest reduction rate goals.

Methodology

In this report, LTCCC estimates the number of residents that ***have*** received antipsychotics since the start of the partnership and the number of residents that ***could have*** avoided antipsychotics had CMS set and achieved annual reduction goals from 2011 to 2021. These estimates are based on crude measurements and do not account for resident turnover. Data are obtained from CMS Partnership reports and MDS 3.0 Frequency Reports.

Number of residents receiving APs: Actual risk-adjusted AP rate multiplied by MDS census. $Example$: $0.239 * 1{,}446{,}226 = 345{,}648$.

Estimated risk-adjusted AP rate if CMS goal set and achieved annual goals is determined using a future value formula, retroactive to the start of the Partnership. $FV = PV(1-r)^n$, wherein *FV* is the estimated Q4 2021 value of risk-adjusted AP rate if goals achieved, *PV* is the Q4 2011 AP rate, *r* is the annual reduction goal, and *n* is number of periods of reduction in years. $Example$: $0.239(1-.2)^{10} = .026\ or\ 2.6\%$.

Estimated residents receiving APs if goals met: Estimated risk-adjusted AP rate multiplied by MDS census.

Excess drugging is the difference between residents receiving APs and estimated receiving APs if goals met. Cumulative excess drugging combines excess drugging estimates from 2012 to 2021. Data used in this report is available at https://nursinghome411.org/decade-drugs/data.

[16] Excess drugging – the number of residents who could have avoided APs if CMS achieved annual reduction goals – is an estimate based on CMS setting and achieving annual reduction goals of 20%. See Methodology and Figure 2.
[17] Non-risk-adjusted AP drugging data for Q4 2021 obtained via MDS 3.0 Frequency Reports (N0410A). Data available at https://nursinghome411.org/decade-drugs/data.

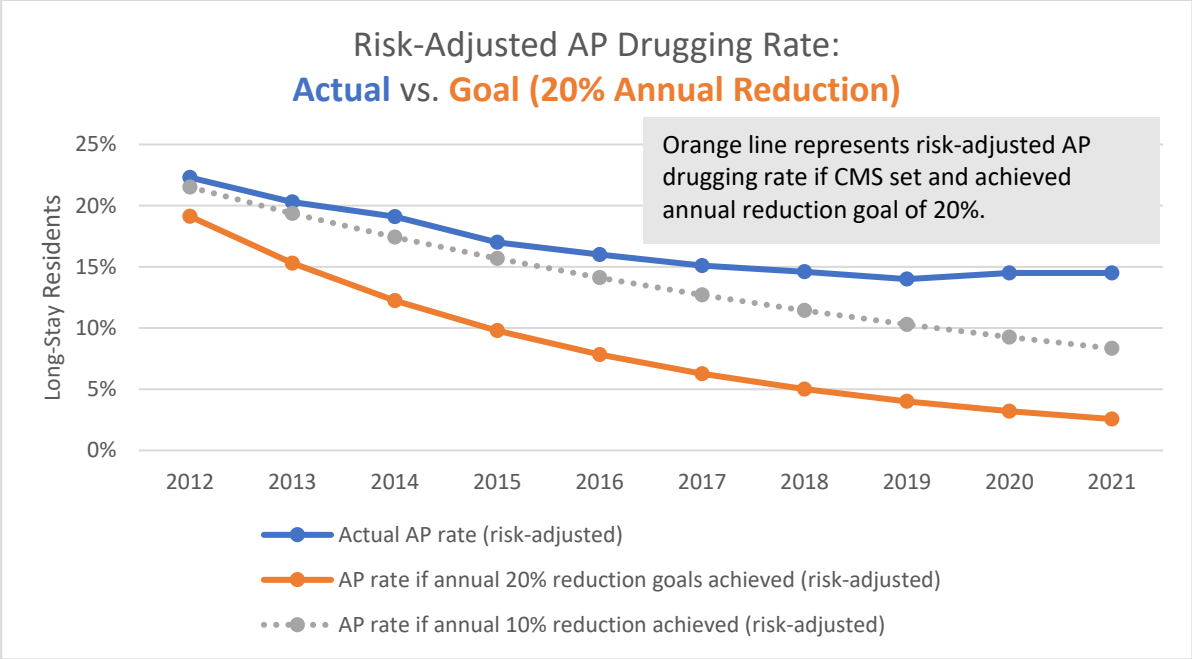


Figure 1: Risk-adjusted AP drugging rate since the start of the partnership vs. estimated risk-adjusted drugging rate if Partnership achieved annual reduction goals of 20% or if Partnership achieved half of initial reduction goal (10%). See Methodology (p. 10).

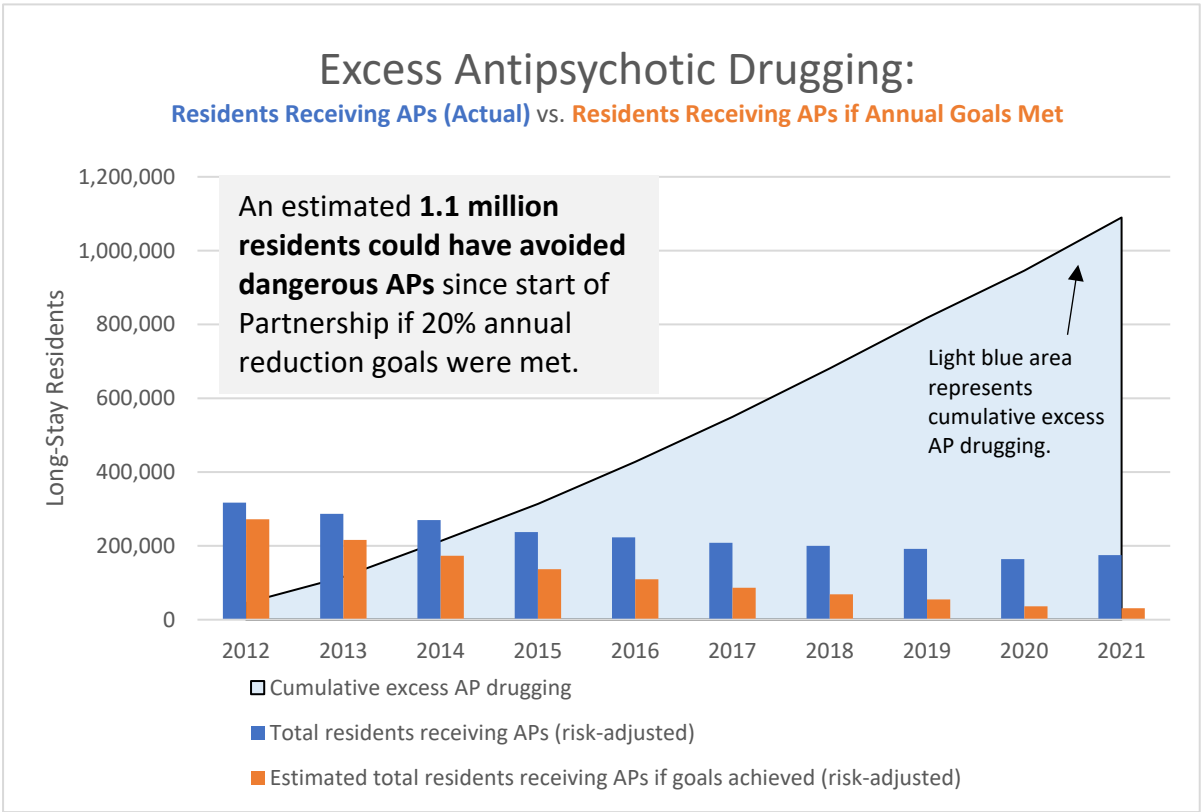


Figure 2: Excess AP drugging is the estimated number of long-stay residents who could have avoided dangerous APs if Partnership achieved annual reduction goals of 20%. Based on projected risk-adjusted AP drug rates and MDS census in Q4 of each year. It does not account for resident turnover. See Methodology (p. 10).

Risky (Adjusted) Business

David Blakeney, 63, was a new resident at Dundee Manor, a nursing home in rural South Carolina. Restless and agitated, Mr. Blakeney was prescribed an antipsychotic medication called Haldol, a powerful antipsychotic sedative. Though the doctor's order stated, "Add Dx of schizophrenia for use of Haldol," there was no evidence that Mr. Blakeney had schizophrenia, according to *The New York Times* investigation.[18]

"Eight months following his admission with a long list of ailments – and after round-the-clock sedation, devastating weight loss, pneumonia and severe bedsores that required one of his feet to be amputated – Mr. Blakeney was dead," according to *The Times*.

Mr. Blakeney's phony diagnosis serves as a cautionary tale about the unintended consequences of the national Partnership campaign. The Partnership placed significant government and stakeholder attention on the need to reduce the use of AP drugs. CMS developed, and distributed to every nursing home, a comprehensive training program called "Hand in Hand,"[19] developed mandatory trainings for state and federal surveyors (inspectors),[20] and promised more meaningful enforcement of the longstanding federal requirements which prohibit the use of unnecessary drugs as well as either physical or chemical restraints.[21]

Some nursing homes responded to the campaign by improving dementia care and focusing on non-pharmaceutical interventions.

Other nursing homes, however, responded by capitalizing on a schizophrenia loophole in the antipsychotic drugging regulations to bolster their reputations and bottom lines. As noted earlier, CMS's primary AP drugging metric is risk-adjusted, meaning it excludes residents with a diagnosis of schizophrenia, Huntington's Disease, or Tourette's Syndrome. An investigation by *The New York Times* found that many nursing homes are gaming the risk-adjusted metric by diagnosing residents with schizophrenia in order to administer these

Though CMS and its industry partners have relied on the risk-adjusted data to claim significant progress in reducing AP drugging, the non-risk adjusted data tell a story of the campaign's stagnation. LTCCC's analysis shows that the increase in schizophrenia diagnoses is widening the gap between risk-adjusted and non-risk adjusted AP drugging data.

[18] Thomas, K., Gebeloff, R., and Silver-Greenberg, J., "Phony Diagnoses Hide High Rates of Drugging at Nursing Homes," *The New York Times*, September 11, 2021. Available at https://www.nytimes.com/2021/09/11/health/nursing-homes-schizophrenia-antipsychotics.html.
[19] The training program is available at https://qsep.cms.gov/pubs/HandinHand.aspx.
[20] See CMS memo "Release of Mandatory Surveyor Training Program on Care of Persons with Dementia and Unnecessary Antipsychotic Medication Use – Release of Third Video," S&C: 13-34-ALL, May 24, 2013. Available at https://www.hhs.gov/guidance/document/release-mandatory-surveyor-training-program-care-persons-dementia-and-unnecessary-0.
[21] See the Partnership's website page for information on additional activities undertaken by CMS, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/National-Partnership-to-Improve-Dementia-Care-in-Nursing-Homes.

A 2021 OIG report found that nearly one in three residents reported in the MDS as having schizophrenia did not have any evidence of this diagnosis in their Medicare claims history.

drugs with impunity (by effectively hiding the true number of residents receiving these dangerous drugs).[22]

There is mounting evidence that a significant portion of these schizophrenia diagnoses are false. Though schizophrenia most commonly presents early in life,[23] schizophrenia diagnoses among nursing home residents (who tend to be elderly) have increased drastically since the start of the campaign. A 2021 OIG report[24] found that nearly one in three residents reported in the MDS[25] as having schizophrenia did not have any evidence of this diagnosis in their Medicare claims history. According to *The Times* analysis of Medicare data, the share of residents with a schizophrenia diagnosis has soared 70 percent since 2012, the year the government began publicly disclosing such prescriptions by individual nursing homes. *The Times* found that one in nine nursing home residents has received a schizophrenia diagnosis, compared to a rate of one in 150 people in the general population.

Though CMS and its industry partners have relied on the risk-adjusted data to claim significant progress in reducing AP drugging, the non-risk adjusted data tell a story of the campaign's stagnation. LTCCC analysis (Figures 3 & 4) shows that the increase in schizophrenia diagnoses is widening the gap between risk-adjusted and non-risk adjusted AP drugging data. As indicated by Figure 3, risk-adjusted AP drugging (CMS's primary metric) has fallen marginally, but far faster than its non-risk adjusted counterpart. The proportion of residents excluded by the risk-adjusted metric (32.6%) has more than tripled since the Partnership began. Residents like Mr. Blakeney – those most impacted by the policy – are being left out of the data.

Death Prison

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

-Director of Nursing, Kansas facility, Human Rights Watch report

[22] Thomas, K., Gebeloff, R., and Silver-Greenberg, J., "Phony Diagnoses Hide High Rates of Drugging at Nursing Homes," *The New York Times*, September 11, 2021. Available at https://www.nytimes.com/2021/09/11/health/nursing-homes-schizophrenia-antipsychotics.html.
[23] Maglione, J., Thomas, S., & Jeste, D. "Late-Onset Schizophrenia: Do Recent Studies Support Categorizing LOS as a Subtype of Schizophrenia?" Curr Opin Psychiatry, May 27, 2014. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4418466/.
[24] U.S. Department of Health and Human Services Office of Inspector General, "CMS Could Improve the Data It Uses to Monitor Antipsychotic Drugs in Nursing Homes," OEI-07-19-00490, May 3, 2021. Available at https://oig.hhs.gov/oei/reports/OEI-07-19-00490.asp. Hereinafter, *OIG 2021*.
[25] The Minimum Data Set (MDS) is a federally mandated process of clinical assessment for identifying the health status and needs of residents.

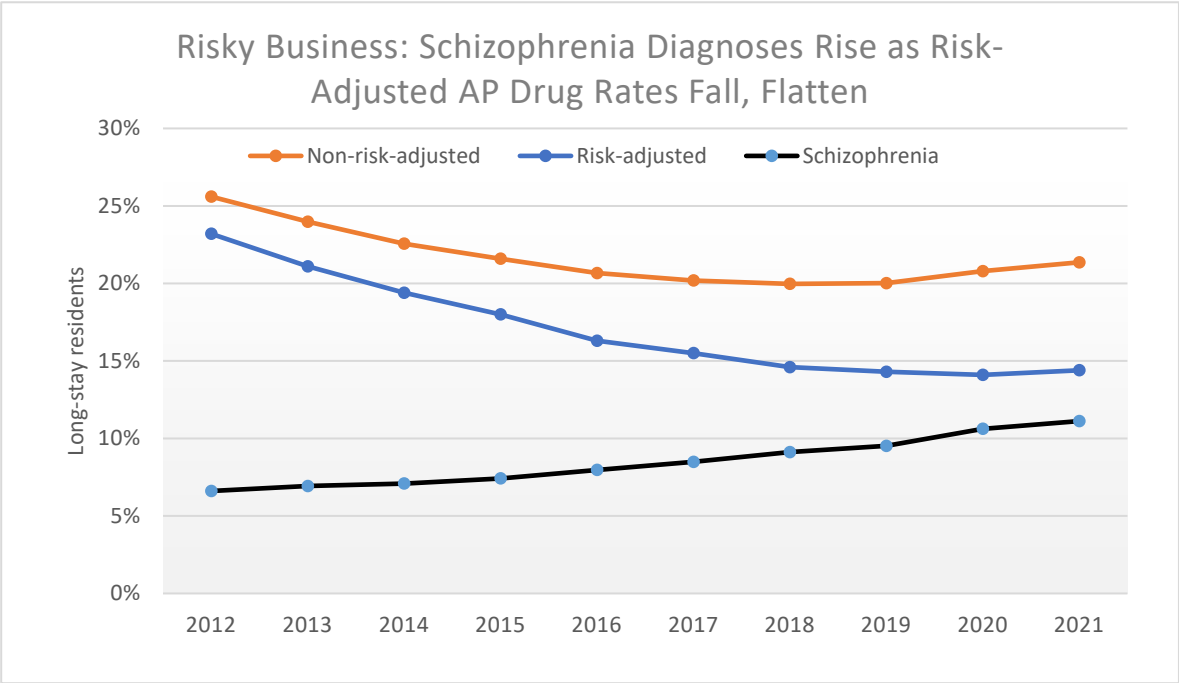


Figure 3: CMS's risk-adjusted AP drugging metric excludes residents with a diagnosis of schizophrenia, Huntington's Disease, or Tourette's Syndrome. Researchers have found that the modest declines in AP drugging rates stem, to a large degree, from significant increases in false schizophrenia diagnoses.

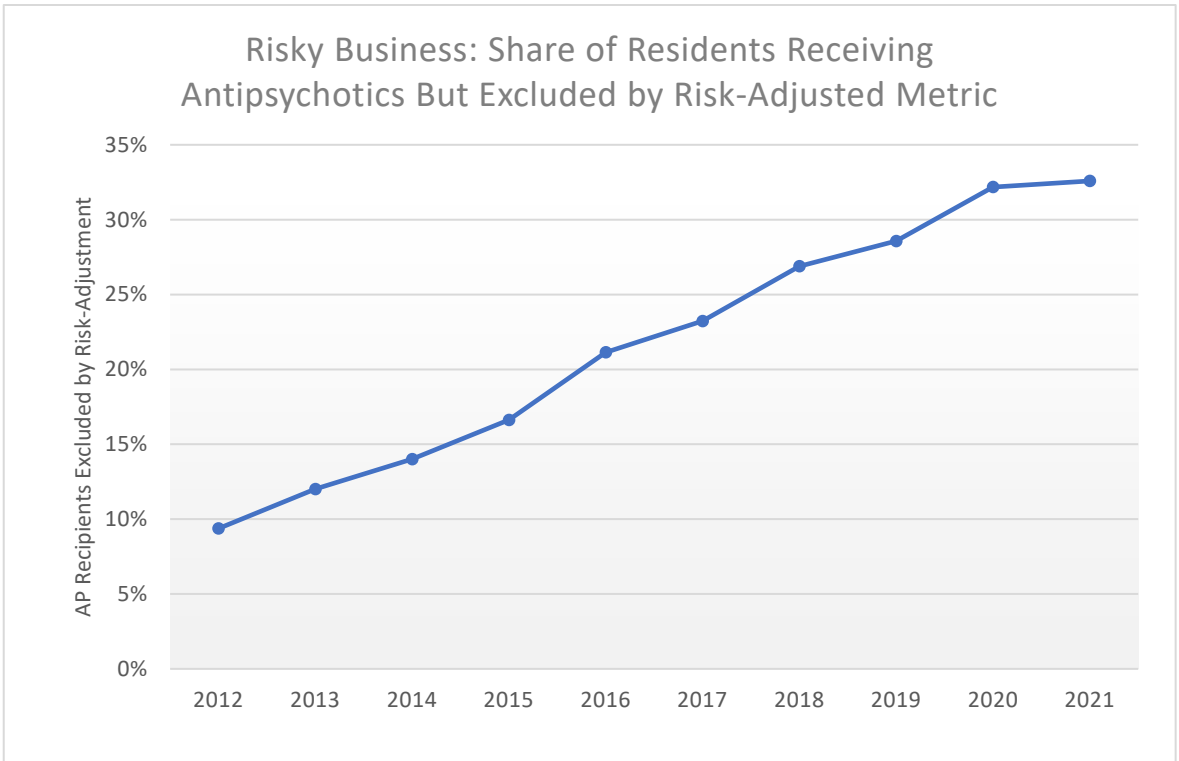


Figure 4: Since the start of the Partnership, the share of residents receiving APs but excluded by the risk-adjusted metric has nearly tripled, largely due to increases in false schizophrenia diagnoses. Based on MDS 3.0 and Partnership data from Q2 of each year.

Not Just Antipsychotics

The campaign was intended to encourage nursing homes to emphasize non-pharmacological approaches to resident care, particularly for residents with dementia.[26] Unfortunately, researchers have found that many providers merely substituted antipsychotics with other dangerous medications, including anticonvulsants, anxiolytic drugs (anti-anxiety medications), and sedative-hypnotic drugs.[27] [28] [29]

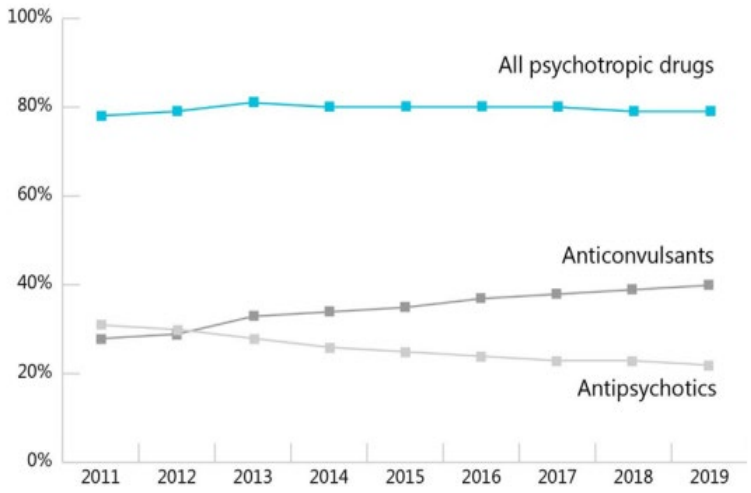


Figure 51: OIG analysis of MDS and Medicare claims data found that anticonvulsant drug use increased among long-stay residents aged 65 and older while overall psychotropic drug use remained constant. Chart by OIG.

As CMS focused its efforts on reducing antipsychotics, another category of psychotropics – anticonvulsants – has become more prevalent in nursing homes (see Figure 5). Similar to antipsychotics, several anticonvulsant medications have boxed warnings for serious and potentially life-threatening adverse reactions including vision loss, liver failure, and increased risk of suicidality.

According to a November 2022 OIG report, anticonvulsant drug use among long-stay residents aged 65 and older increased from 28% in 2011 to 40% in 2019. This increase counteracts the modest reductions in antipsychotic drug use and has contributed to the overall use of psychotropics remaining constant, at roughly 80%.

The government's focus on antipsychotics has paved the way for pharmaceutical companies to market other dangerous AP alternatives.[30] A CNN report found that Nuedexta, approved to treat a disorder marked by "emotional incontinence" (pseudobulbar affect, or PBA), was being

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[26] As noted elsewhere, longstanding federal requirements for nursing homes mandate the use of non-pharmacological approaches to resident care, including the so-called behavioral and psychological symptoms of dementia. For more information on these requirements and expected practices, see LTCCC's Dementia Care Advocacy Toolkit at https://nursinghome411.org/learn/dementia-care-advocacy-toolkit/.

[27] U.S. Department of Health and Human Services Office of Inspector General, "Long-Term Trends of Psychotropic Drug Use in Nursing Homes," November 2022. Available at https://oig.hhs.gov/oei/reports/OEI-07-20-00500.pdf.

[28] Lucas, J. & Bowblis, J. "CMS Strategies to Reduce Antipsychotic Drug Use in Nursing Home Patients with Dementia Show Some Progress," Health Affairs. July 2017. Available at https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.1439. Hereinafter, *OIG 2022*.

[29] Maust DT, Kim HM, Chiang C, Kales HC. "Association of the Centers for Medicare & Medicaid Services' National Partnership to Improve Dementia Care with the Use of Antipsychotics and Other Psychotropics in Long-term Care in the United States From 2009 to 2014," JAMA Intern Med. May 2018. Available at https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2674245.

[30] Ellis, B. & Hicken, M. "The little red pill being pushed on the elderly," CNN (October 12, 2017). Available at https://www.cnn.com/2017/10/12/health/nuedexta-nursing-homes-invs/index.html.

increasingly prescribed in nursing homes despite not being extensively studied in elderly patients. The number of Nuedexta pills increased 400% in four years through 2016 and more than half of the pills went to long-term care facilities.

"Rather than taking someone off an antipsychotic" and opting to treat the patient in ways that don't require medication, "providers search for a different 'magic bullet,'" Helen Kales, a geriatric psychiatrist and University of Michigan professor, told CNN.

Colorblind Policy

The Partnership has fallen short in its goals of reducing antipsychotic drug use among nursing home residents, and research indicates that African-American and low-income residents are disproportionately impacted by the policy failures.

"This national partnership could be implicated in some of these adverse outcomes. That's the kind of scary part that I think about the most."

-Shekinah Fashaw-Walters to The New York Times

According to the American Psychiatric Association, African-Americans are more frequently diagnosed with schizophrenia and less frequently diagnosed with mood disorders compared with whites with the same symptoms.[31] Nursing homes are no exception to this trend.

A 2021 study in the *Journal of the American Geriatrics Society* found that the increase in schizophrenia diagnoses in US nursing homes disproportionately impacted Black residents with dementia.[32]

"When clinicians talk to a Black or white patient who look otherwise similar symptom-wise, they overemphasize psychotic symptoms, delusions and hallucinations, relative to other symptoms in Black patients compared to how they do with white patients," Stephen Strakowski, vice dean of research at the Dell Medical School at the University of Texas at Austin, told The New York Times. "So it wouldn't be a terrible surprise that if you now incentivize the diagnosis, the difference will be magnified."

These racial disparities in schizophrenia diagnoses demonstrate the limitations of colorblind policies such as the federal Partnership, which did not account for potential unintended consequences on older adults of color.

[31] American Psychiatric Association. "Mental Health Disparities: African Americans," available at https://www.psychiatry.org/File%20Library/Psychiatrists/Cultural-Competency/Mental-Health-Disparities/Mental-Health-Facts-for-African-Americans.pdf.

[32] Fashaw-Walters, S., McCreedy, E., Bynum, J., Thomas, K., & Shireman, T. "Disproportionate increases in schizophrenia diagnoses among Black nursing home residents with ADRD," J Am Geriatr Soc. December 2021. Available at https://pubmed.ncbi.nlm.nih.gov/34590709/. Note: this study found that schizophrenia diagnoses for Black residents with ADRD increased 1.7% despite the rate declining 1.7% for non-Black residents with ADRD. The findings are based on a model that adjusts for age, gender, and other variables. Adjusted models are designed to isolate the variables of interest – in this case, race – while separating confounding variables such as age and gender. Unadjusted, schizophrenia diagnoses increased by significant margins for Black and non-Black residents with ADRD and without ADRD.

"There is such an increased risk with antipsychotics for all sorts of adverse outcomes, whether it's falls or death," Shekinah Fashaw-Walters, the study's lead author, told *The New York Times*. "This national partnership could be implicated in some of these adverse outcomes. That's the kind of scary part that I think about the most."

New research has also found significant socioeconomic disparities in psychotropic drug use. According to the 2022 OIG report, nursing homes with a greater share of residents with low-income subsidies had higher rates of psychotropic drug use.[33] The study found that 79% of residents received psychotropic drugs in nursing homes in which 95% of residents received a Medicare Part D low-income subsidy compared to 73% of residents in nursing homes in which 50% or fewer residents received the low-income subsidy. (Note: the 2022 OIG report also found a significant increase (194%) in the number of residents reported as having schizophrenia but lacking a corresponding schizophrenia diagnosis in Medicare claims and encounters from 2015 to 2019).

Pandemic Pills

The COVID-19 pandemic exposed and exacerbated longstanding problems in U.S. nursing homes, including issues related to low staffing and poor dementia care. A 2022 government study found that nursing home antipsychotic prescriptions increased from 2019 to 2020 despite a reduction in the nursing home resident population.[34] According to the study, nursing homes and assisted living facilities dispensed 20.8 million prescriptions for antipsychotics in 2020, a 1.5% increase from the 20.5 million prescriptions in 2019. The first quarter of 2020 saw an increase of 7.4% compared to the Q1 2019.

I Can't Even Talk

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

- Walter L., 81, Human Rights Watch report

Likely reasons for the significant increase in antipsychotic drugging rates during the pandemic are exacerbated staffing shortages and decreased government oversight (due to state agencies not conducting regular surveys or responding to most complaints during the early months of the pandemic). The prohibition of visits by families and friends (who, too often, are called upon to deliver care and monitoring that short-staffed facilities are unable or unwilling to provide) undoubtedly made both care and living conditions much worse for residents, particularly those who need significant assistance with communication and activities of daily living.

[33] *OIG 2022*, p. 11.

[34] "Antipsychotic Medication Prescribing in Long-Term Care Facilities Increased in The Early Months of The Covid-19 Pandemic," Assistant Secretary for Planning and Evaluation, March 8, 2022. Available at https://aspe.hhs.gov/sites/default/files/documents/c7cded0bf6f55567b55d78ef9e56687d/antipsychotic-medication-ltcf.pdf.

Overprescribed, Underenforced

The physical or chemical restraint of nursing home residents have been prohibited for over 30 years. When it formed the Partnership in 2012, CMS indicated that eliminating the inappropriate use of AP drugs in U.S. nursing homes had become a major priority of its oversight and quality assurance mission. Yet, 10 years later, roughly a quarter million nursing home residents are administered one or more antipsychotic drugs every week.

A "No Harm" Antipsychotics Deficiency

At a Florida nursing home, a resident was receiving PRN (as needed) antipsychotic medication for several months without justification for ongoing use and without a stop date on the order. Despite the risks posed by the potentially life-threatening side-effects of psychotropics, the surveyor cited the violation as no harm.

-LTCCC, "Broken Promises: An Assessment of Nursing Home Oversight"

Perhaps the biggest reason for this is that facilities rarely pay the price for inappropriate AP drug use. Our 2021 national study of enforcement data from 2018-2020 found that nursing homes were rarely cited for inappropriate AP drugging and, when they were, the citations were largely identified as not causing any harm or immediate jeopardy to residents.[35] As a result, it is unlikely that these facilities faced any penalty.

In the study, LTCCC reviewed citations for F758 (Free from Unnecessary Psychotropic Meds/PRN Use), which captures inappropriate antipsychotic drugging as well as the inappropriate use of other psychoactive drugs, such as antidepressants.[36] [There is no F-tag that solely addresses antipsychotics.] We found 6,157 F758 citations recorded over the entire three-year period, **a rate of just 8.1 citations for every 1,000 residents reported to be receiving antipsychotics.**

Of the 6,157 F758 citations recorded over the entire three-year period, 31 (less than one percent) were categorized as resulting in harm or immediate jeopardy to any resident (G+). In other words, even when surveyors substantiate inappropriate resident drugging, 99.5% of the time they find no resident harm.

These findings indicate that, despite years of training for both state surveyors and nursing home staff on the dangers of antipsychotic drugs, widespread antipsychotic drugging persists, and state surveyors are averse to holding nursing homes accountable for it. Our findings are consistent with those in a critical Human Rights Watch report, which found that issuing deficiency citations without financial sanctions "has little impact on the off-label use of these medications, raising concerns about the deterrent effect of current enforcement."[37]

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[35] "Broken Promises: An Assessment of Nursing Home Oversight," LTCCC, 2021. Available at https://nursinghome411.org/survey-data-report/.

[36] F-tags ("F" for "federal") constitute the system through which federal nursing home regulations are identified in the survey process. See https://nursinghome411.org/f-tags/ for a list of F-tags.

[37] Human Rights Watch, "They Want Docile," (February 5, 2018). Available at https://www.hrw.org/report/2018/02/05/they-want-docile/how-nursing-homes-united-states-overmedicate-people-dementia.

Fines are a critical tool for holding nursing homes accountable for meeting minimum standards of care, including those relating to freedom from inappropriate drugs and chemical restraints. But the failure to impose a fine or other penalty sends a message to nursing homes (and the industry as a whole) that this dangerous practice is acceptable.

Limitations of Self-Reported AP Drug Data

CMS relies on the Minimum Data Set (MDS) – self-reported by nursing homes – to measure AP drugging rates, though the 2021 OIG report finds that this dataset has significant limitations.[38]

The OIG report found significant discrepancies in AP drugging counts between the MDS and Part D claims datasets. Nearly 5% (12,091) of the 249,135 long-stay beneficiaries with a Part D claim for an antipsychotic drug were not reported in the MDS as having received an antipsychotic drug. As a result, the MDS 3.0 dataset may be significantly underestimating the total number of residents receiving AP drugs.

CMS's self-reported data may also be limited by the brevity of its assessment period. Nursing homes are required to record the number of days a resident received an antipsychotic drug during the 7 days prior to the assessment. Residents who were treated with AP drugs during the quarter, but not within the 7-day period, are thus excluded from the MDS data. Though CMS requires nursing homes (as of 2017) to report whether a resident has received AP drugs at any time since admission, these data are not used in the MDS assessment.

AP drugging data – whether MDS 3.0 or Part D claims – also fail to provide detail about the drugs. Analysis of AP data would benefit from inclusion of information on the specific drugs being dispensed, their quantities and strengths, and the duration they were administered.

How MDS Data Reporting Works

Nursing homes electronically submit self-reported MDS assessments to CMS at required intervals. These submissions include the number of days an antipsychotic was received by a resident during the seven days prior to the MDS assessment. This information is used in CMS's quality measure for the percentage of nursing home residents receiving antipsychotic drugs during the entire quarter.

State agencies, on behalf of CMS, use onsite surveys to validate this data. State agencies are expected to conduct standard certification surveys for nursing homes on, roughly, an annual basis.

Note: When CMS identified an increase in MDS reporting of schizophrenia—a diagnosis excluding residents from CMS's AP drugging metric—CMS responded by conducting surveys on this concern in select nursing homes.

The OIG report recommended that CMS take additional steps to validate MDS data by targeting oversight of nursing homes presenting inconsistent data in MDS 3.0 and Medicare Claims data. Further, it recommended that CMS

[38] *OIG 2021*, p. 6.

supplement the data used to monitor AP use by utilizing Part D data, which provides more detailed information (specific drugs, duration, etc.).

In June 2022, CMS took a positive step toward enhancing transparency by revising its guidance to investigate inaccurate diagnoses or coding of schizophrenia. [As discussed earlier, inaccurate diagnoses of schizophrenia has been a significant driver in the reduction of the risk-adjusted AP drugging rates which CMS publicly reports and uses in its policy-making.]

LTCCC looks forward to additional efforts to identify problematic diagnoses and refocus efforts to continue to bring down the inappropriate use of antipsychotic medications, as promised in the White House's Proposed Nursing Home Reforms.[39]

Note: CMS redacts the names of medications in the Statements of Deficiencies (SoDs) published on Care Compare. This prevents policymakers, researchers, and the public from identifying and assessing citations for inappropriate antipsychotic drugging. We recommend that CMS stop, or at a minimum, significantly limit these redactions.[40]

Recommendations

Quality Assurance & Accountability

State Survey Agencies and the CMS Locations (formerly known as Regional Offices) which oversee state agency performance must be directed to – and held accountable for – ensuring that the protections against the use of unnecessary drugs and chemical restraints are enforced.

1. CMS must develop and effectively implement processes to better identify, assess, and address patterns of low citations and infrequent identification of resident harm for inappropriate antipsychotic drugging[41] and fraudulent diagnoses with schizophrenia (which, as discussed earlier, are too often used by nursing home operators to obfuscate their true antipsychotic drugging rates).
2. Surveyors should be directed and expected to presume that any inappropriate antipsychotic drugging has resulted in harm or immediate jeopardy to a resident. Outside of a nursing home, administering a powerful and dangerous drug to someone without their consent would likely be considered a criminal offense. It should go without saying that nursing home residents deserve the same protection.
3. Every inappropriate use of a psychotropic drug deficiency (F757 or F758) should be paired with a chemical restraint deficiency (F603 or F604) and cited as abuse.
4. When inappropriate psychotropic drugging is suspected or identified, surveyors should be directed to review for adequate and competent staffing as well as potential deficiencies in medical direction, pharmacist review, and (particularly when more than a single instance is identified) administration.

[39] "LTCCC Applauds White House's Proposed Nursing Home Reforms," Long Term Care Community Coalition, Feb. 28, 2022. Available at https://nursinghome411.org/alert-white-house-reform-2022/.
[40] "Nursing Home Transparency: A Critical Tool to Improve the Quality of Nursing Home Care," Long Term Care Community Coalition. Available at https://nursinghome411.org/transparency/.
[41] While we explicitly reference antipsychotic drugs here, and throughout this report, this effort should include other psychotropic drugs that are administered to residents for, too often, inappropriate purposes.

5. Prescribers should be required to directly evaluate and interview residents prior to writing psychotropic drug prescriptions.
6. CMS should strengthen informed consent requirements to mandate that consent for the administration of antipsychotic drugs be provided…
    - in writing,
    - using a standardized form that is signed by both the prescriber and resident (or their representative), and
    - time-limited (renewable on, at most, a quarterly basis).
7. CMS should mandate increased survey frequency for facilities with high rates of antipsychotic drugging.
8. CMS should take meaningful steps to educate and engage residents, their families, and those who help them as active participants in ensuring appropriate resident care. [The failure to engage consumers, as promised when the Partnership was launched in 2012, has never been addressed.]

Data Transparency & Accuracy

1. CMS should implement the recommendations made by OIG in its 2021 report, including
    - "Take additional steps to validate the information reported in MDS assessments," and
    - "Supplement the data it uses to monitor the use of antipsychotic drugs in nursing homes" (for instance, "use Part D data to enhance its monitoring of overall and concerning prescribing patterns in nursing homes").[42]
2. CMS should audit the validity of schizophrenia diagnoses reported by facilities and downgrade the Quality Measure star rating on Care Compare to one-star for any facility that fails the audit. This would signal to all stakeholders that CMS is taking this widespread and persistent problem seriously, and that it expects nursing home to do likewise.
3. CMS should publish, on a quarterly basis, the actual (non-risk-adjusted) antipsychotic drugging rates for every nursing home.
4. CMS should cease redacting medication names and diagnoses on the Statements of Deficiencies published on its Care Compare website and on state nursing home websites. These redactions make it virtually impossible for the public to identify citations for inappropriate drugging and the use of chemical restraints on residents with dementia in the nursing homes in their communities.

[42] *OIG 2021*, pp. 9-10.

Conclusion: Flouting Standards, Touting Achievements

The campaign to reduce antipsychotic drugging has been marked by a series of underwhelming and unmet goals. Only by moving the goalposts and obfuscating the data have CMS and industry partners been able to claim modest achievements. More troublingly, however, are the campaign's unintended consequences, including phony schizophrenia diagnoses, rise in prescriptions of other unsafe drugs, and widening racial disparities burdening Black residents.

By any metric, CMS and its industry partners have failed to address the urgent issue of antipsychotic drugging in nursing homes. Nursing homes, abetted by CMS's lenient approach to enforcement, continue to flout AP drugging care standards while touting achievements in AP drug reductions. Until CMS takes meaningful action to strengthen enforcement and enhance transparency, too many residents will continue to pay the price: robbed of their dignity, their humanity, and, too often, their lives.



Visit **nursinghome411.org/decade-drugs** for additional materials from this report including data tables, interactive charts, and other dementia care resources.