LTCCC LONG TERM CARE COMMUNITY COALITION
Working to improve long term care through research, education & advocacy

Left Behind: The Impact Of The Failure To Fulfill The Promise of The National Campaign To Improve Dementia Care

This brief presents the second of two assessments undertaken by the Long Term Care Community Coalition (LTCCC) at the end of 2014 on the effectiveness, to date, of the national campaign to address the inappropriate and dangerous use of antipsychotic drugs on nursing home residents across the United States. In 2005, the FDA issued a "black-box" warning against the use of antipsychotics on elderly people with dementia. In 2011, the US Inspector General found widespread failure to comply with federal regulations designed to prevent overmedication and stated that "Government, taxpayers, nursing home residents, as well as their families and caregivers should be outraged…." Shortly thereafter, in early 2012, the Centers for Medicare and Medicaid Services (CMS) launched the federal campaign to reduce antipsychotic drugging. At that time, CMS promised swift, substantive change to protect nursing home residents and assure compliance with minimum standards. Nevertheless, at the end of 2014, approximately one in five nursing home residents (20%) are still being administered powerful and dangerous antipsychotic drugs.

The first brief presented the results of a national survey of nursing home resident representatives on their knowledge of, and participation in, the CMS campaign. Our findings indicated that while there is substantial interest among resident representatives in the "stakeholder" calls and other CMS campaign activities, few resident representatives participate because CMS's outreach efforts have focused almost exclusively on the industry.

This brief presents an assessment of the impact, to date, of the federal campaign on nursing home residents. CMS and the nursing home industry have both stated that there has been "fantastic" progress in reducing antipsychotic drugging, despite the fact that they failed to achieve the modest goal set at the beginning of the campaign. They talk about the numbers of people who have been saved from inappropriate drugging. Here, we endeavor to count the numbers of people who have been *left behind* by the failure to either enforce longstanding minimum standards of care or even achieve and continue the modest rate of reduction promised at the beginning of the campaign. Included are several resident stories, to help put a face in front of the numbers, and to help us remember that the Nursing Home Reform Law and regulatory standards apply to the care of each and every resident.

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We would like to acknowledge the valuable contributions of the following individuals to this report: Janet Wells, for her superb editing, and Deborah Truhowsky, Anthony Chicotel and Jeanette Sandor for providing the residents' stories featured at the end of the report.

For more information on dementia care and antipsychotic drugs, including educational & legal resources for consumers, providers and policymakers, visit www.nursinghome411.org.

The Long Term Care Community Coalition is pleased to offer expert services and trainings on a variety of elder care issues, including: (1) Improving dementia care & reducing the use of antipsychotic drugs; (2) Legal & regulatory standards for nursing home and assisted living care; and (3) Resident rights. For more information, e-mail info@ltccc.org or call 212-385-0355.

Background

Dementia is increasingly recognized as one of the most significant issues facing the elderly and their loved ones. Among older adults it is the second most feared condition (cancer being first). There is good reason for this fear: thirteen percent (13%) of all seniors suffer with Alzheimer's disease, the most notable (but not the only) type of dementia. Among our growing numbers of eldest elderly (people 85 or older), 43% have Alzheimer's or another form of dementia. The majority of nursing home residents suffer from dementia.

The inappropriate antipsychotic drugging of nursing home residents, particularly those with dementia, is a widespread, national problem. Despite Food and Drug Administration 'black box' warnings against using powerful and dangerous antipsychotics on elderly patients with dementia, they are frequently used to treat symptoms of the disease, including so-called behavioral and psychological symptoms of dementia.[1] These and other psychotropic drugs are often used as a form of chemical restraint, sedating residents so that not only their behaviors but also the underlying causes for those behaviors do not have to be addressed by staff (who are often overworked). In addition to destroying social and emotional well-being, these drugs greatly increase risks of stroke, heart attack, diabetes, Parkinsonism and falls.

In May 2011, a federal review 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.[2] U.S. Senator Charles Grassley had requested this review out of concern about the extent of prescribing dangerous antipsychotic drugs for elderly nursing home residents for "off-label" conditions (i.e., not related to psychotic conditions such as schizophrenia) in the presence of dementia.

The federal review, conducted by the Department of Health and Human Services Office of Inspector General (OIG), also determined "…that 83 percent of Medicare claims for atypical antipsychotic drugs for elderly nursing home residents were associated with off-label conditions and that 88 percent were associated with the condition specified in the FDA boxed warning. …[It] further determined through medical record review that 22 percent of the atypical antipsychotic drugs associated with the claims were not administered in compliance with CMS standards…."[3]

In light of these findings, Inspector General Daniel R. Levinson issued a statement on "overmedication of nursing home patients" in which he stated:

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[1] The danger of antipsychotic drug use on the elderly with dementia is addressed in the FDA's *Public Health Advisory: Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances*, US Food and Drug Administration (April 11, 2005). Available at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm053171.htm.

[2] *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. Henceforth "OIG Report"

[3] Summary of OIG Report on https://oig.hhs.gov/oei/reports/oei-07-08-00150.asp.

> With 46 million beneficiaries, any issue facing Medicare is a cause for concern.
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> 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.
>
> The report also found that these powerful, at times dangerous drugs were often prescribed for uses that are not approved by the Food and Drug Administration and do not qualify as medically accepted for Medicare coverage. Potentially most alarming, **88 percent of the time these drugs were prescribed for elderly patients with dementia, a population the FDA has warned faces an increased risk of death** from this class of drugs.
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> **Government, taxpayers, nursing home residents, as well as their families and caregivers should be outraged - and seek solutions**.[4]
>
> [Emphases added.]

Seeing this as a 'wake-up call' for federal and state oversight agencies, a small group of nursing home resident advocates asked for a meeting with then acting administrator of CMS, Dr. Donald M. Berwick.[5] Dr. Berwick convened top officials from his agency for the meeting, in which he concurred with the concerns raised by the OIG and the consumer advocates and asked not only his staff but also the nursing home and pharmaceutical industries to present him with plans to address the misuse of antipsychotic drugs in nursing homes. This set in motion activities which led to the current federal campaign to address inappropriate and dangerous antipsychotic drugging, known as the National Partnership to Improve Dementia Care.

The National Partnership: Goals & Outcomes

The Partnership campaign was launched in March 2012. In the video released by CMS to kick off the campaign on March 28, agency representatives announced the initial goal: to reduce the rate of inappropriate antipsychotic drugging by 15% by the end of that calendar year.[6] When consumer advocates expressed concern about the modesty of the goal – given the significant harm associated with antipsychotics and longstanding Medicare and Medicaid requirements that mandate the avoidance of unnecessary drugs and prohibit the use of chemical restraints—

[4] Levinson, Daniel, *Overmedication of Nursing Home Patients Troubling* (May 9, 2011). Available at https://oig.hhs.gov/newsroom/testimony-and-speeches/levinson_051011.asp.

[5] 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.

[6] Nursing Home Initiative on Behavioral Health & Antipsychotic Medication Reduction, available on CMS' YouTube channel at https://www.youtube.com/watch?v=U1_rpO0bwbM.

CMS assured them the initial goal was modest in order to "get the ball rolling" and that more ambitious goals would follow.

In fact, nursing homes failed to meet this modest goal in the time set. The industry-wide average for antipsychotic drug use did not decrease to the 15% target level for approximately 21 months – a full calendar year after the December 2012 deadline. Rather than taking stronger action to enforce regulatory standards on inappropriate drug use and chemical restraints, as its mission requires, CMS responded to the industry's failure to meet the initial goal by simply continuing its outreach and engagement activities. Moreover, no further goals were set in 2013. It was not until 2014 – after the initial goal had finally been reached and two full years after the campaign's launch – that new goals were established. Rather than being more ambitious than the initial goal, the new goals are significantly lower, calling for five percent (5%) additional reductions per year in 2015 and 2016.

Over three years after the US OIG's alarming report, almost 300,000 nursing home residents are being given antipsychotics inappropriately every day, greatly diminishing their quality of life and increasing the likelihood that they will suffer falls, Parkinsonism, heart attacks, strokes and even death.

As a result, despite both the 1987 Nursing Home Reform Law's[7] prohibitions against inappropriate drugging and chemical restraints and the federal campaign launched in 2012, in December 2014 approximately one in five nursing home residents are being given dangerous and debilitating antipsychotic drugs in US nursing homes every day, at considerable personal expense to them and their families and considerable financial expense to US taxpayers. Furthermore, by accepting the industry's failure to meet the initial goal, by setting even smaller goals for future years and by failing to adequately uphold minimum regulatory standards – as promised at the beginning of the campaign – CMS has set in motion a system in which many more elderly residents with dementia will be given dangerous antipsychotics than would otherwise be the case if CMS had simply accomplished and continued its initial, modest, promised rate of reduction over these years (no matter, as promised, set more ambitious goals after 2012).

[7] Nursing Home Reform Law, 42 U.S.C. §§1395i-3(a)-(h), 1396r(a)-(h) (Medicare and Medicaid, respectively) (December 1987). The Reform Law's text is available at: http://law.justia.com/cfr/title42/42-3.0.1.5.22.html#42:3..15.22.2. For information on the numerous regulatory standards relevant to protecting nursing home residents from inappropriate drugging, see LTCCC's report, *Federal Requirements & Regulatory Provisions Relevant to Dementia Care & The Use Of Antipsychotic Drugs* (2013). Available at http://www.nursinghome411.org/?articleid=10066.

Purpose of this Report

As advocates to improve care, quality of life and dignity for nursing home residents, we were alarmed (although not necessarily surprised) by the shocking extent of inappropriate and dangerous antipsychotic drugging identified in the OIG's 2011 report. Given the Nursing Home Reform Law's specific prohibitions, we turned to CMS to take action. Initially we were gratified by CMS's promises to both improve enforcement of the Reform Law's standards and engage the nursing home industry by setting concrete goals and conducting outreach activities. However, three years after our initial meeting with then Acting Administrator Berwick,[8] we are now deeply concerned that over 265,000 people are still being administered antipsychotic drugs every day in U.S. nursing homes.[9] For the vast majority of these individuals, this drugging is not medically indicated and is given to them in violation of longstanding minimum standards of care. For elderly residents with dementia, this drugging is particularly pernicious: as noted earlier, it greatly diminishes their quality of life and increases their likelihood of suffering falls, Parkinsonism, heart attacks, strokes, diabetes and even death.

"The purpose of this report is to provide insights into the numbers of residents with dementia who have been left behind: the people who could have and should have been saved from inappropriate drugging but were not as a result of the failures to enforce longstanding minimum standards of care or to even achieve and sustain the modest reduction rate goal set by CMS…."

CMS and the provider industry have touted the "fantastic" progress they have made in meeting "challenging" goals and the numbers of people that have been saved from inappropriate drugging as a result of the national campaign. The purpose of this report is to provide insights into the numbers of residents with dementia who have been left behind: the people who could have and should have been saved from inappropriate drugging but were not as a result of the failures to enforce longstanding minimum standards of care or to even achieve and sustain the modest reduction rate goal set by CMS, in collaboration with the industry, at the start of the national campaign.

[8] Dr. Berwick resigned from CMS in December 2011, having failed to win approval of enough Republican members of the Senate to be confirmed as administrator.

[9] This is based upon the risk-adjusted number reported by CMS on Nursing Home Compare. It is "risk-adjusted" to remove residents who have certain conditions for which these drugs may be appropriate. The MDS (Minimum Data Set) Frequency Report, which does not risk-adjust data, reported a 20.91% antipsychotic drugging rate for 1,326,919 nursing home residents for the third quarter of 2014, indicating 277,459 residents were actually receiving antipsychotics. These data were accessed on December 14, 2014 from https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Minimum-Data-Set-3-0-Public-Reports/index.html. Note: Though an individual may have a diagnosis for which these drugs are appropriate that does not mean that they were given the drugs appropriately. In other words, individuals with a diagnosis of a psychotic condition may also be given these drugs inappropriately and illegally, as punishment or chemical restraint. These incidences would not be captured by Nursing Home Compare and, thus, have largely been ignored by the federal campaign.

Understanding the Campaign & its Goals

Because CMS is responsible for both paying for services rendered to Medicare and Medicaid beneficiaries in nursing homes and for ensuring that minimum regulatory standards are met for all residents in those facilities (whether or not they are Medicare or Medicaid beneficiaries), the agency has significant power to influence provider behavior. The fact that it controls the 'purse strings' is, of course, particularly important. When a provider fails to meet minimum standards CMS can fine the facility, deny payment to it for future residents or even disqualify a facility from Medicare/Medicaid reimbursement altogether.[10] In addition to quality assurance and oversight activities – and the authority to levy sanctions when standards are not met – CMS provides a number of resources to educate and assist providers.[11]

When CMS launched its campaign to reduce antipsychotic drugging it announced that it would be utilizing both enforcement and provider engagement to address this issue. In addition to goal-setting, CMS officials stated that regulators would be enforcing dementia care and drugging standards for all nursing home residents through the survey system. In other words, CMS was not going to rely solely on goal-setting (and the voluntary actions by facilities to achieve those goals) to protect residents from inappropriate drugging. The agency was also going to ensure that state and federal surveyors enforced longstanding safeguards against inappropriate drugging through the annual survey and complaint response processes. Unfortunately (and despite the persistence of high rates of inappropriate drugging), enforcement of these standards, historically weak, has failed to increase substantially over the course of the campaign.[12]

As noted earlier, when CMS launched the campaign it set an initial goal of a 15% reduction in antipsychotic drugging between the end of March and the end of December 2012.[13] Since this was a nine-month period to accomplish a 15% reduction, it equates to an annual rate of reduction of 20%. In other words, if the first goal had been accomplished in the time-frame announced, and that initial modest rate of reduction simply sustained thereafter, drugging rates would have dropped by 15% in the last nine months of 2012, an additional 20% in calendar year 2013 and 20% more in 2014.

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[10] CMS also has a number of non-monetary penalties that it – or the state agencies – can impose.

[11] It is beyond the scope of this report to address why the federal government dedicates significant resources to training and educating providers who have contracts – and are paid – to provide appropriate, professional care for each and every individual in their facilities.

[12] For more on the failure to enforce dementia care, antipsychotic drugging and chemical restraint standards, see LTCCC's April 2014 study, *Antipsychotic Drug Use in NY State Nursing Homes: An Assessment of New York's Progress in the National Campaign to Reduce Drugs and Improve Dementia Care*. The study found that, nationwide, there has been little to no increase in enforcement of standards related to antipsychotic drugging. This report, including data tables for enforcement rates across the United States, can be accessed at http://www.nursinghome411.org/?articleid=10082. *See*, also, *CMA Report: Examining Inappropriate Use of Antipsychotic Drugs in Nursing Facilities*, available at http://www.medicareadvocacy.org/cma-report-examining-inappropriate-use-of-antipsychotic-drugs-in-nursing-facilities/.

[13] Though resident representatives advocated for CMS to address this issue, they were not included in the determination of this initial goal.

What does this mean in terms of the nursing home resident population? As indicated in Figure 1, below, 23.8% of nursing home residents were receiving antipsychotics in the last quarter of 2011, the baseline point for the national campaign.[14] A 15% reduction of the 23.8% of residents then receiving antipsychotics would amount to a reduction of 3.57 percentage points (15% of 23.8%). Thus, if the 2012 goal had been achieved and that initial rate of reduction continued, 20.23% of residents would have been receiving antipsychotics at the end of 2012, 16.18% of residents would have been receiving these drugs at the end of 2013 and, at the end of 2014, we could expect that antipsychotic drugging rates would be down to 12.95%. While this would still have been a far cry from the appropriate care that facilities are paid to provide for *each* resident, and the promised enforcement of these standards for *all* residents, it would have been a significant improvement over what was actually achieved. It would undoubtedly have made an enormous difference in the lives of tens of thousands of individuals and their families.

Instead, as Figure 1 shows, 22.3% of residents were being administered antipsychotics at the end of 2012; 20.3% were receiving these drugs at the end of 2013; and as of the middle of 2014 (the latest period reported in the *CMS Trend Update*), 19.4% of nursing home residents were still receiving antipsychotic drugs.[15]

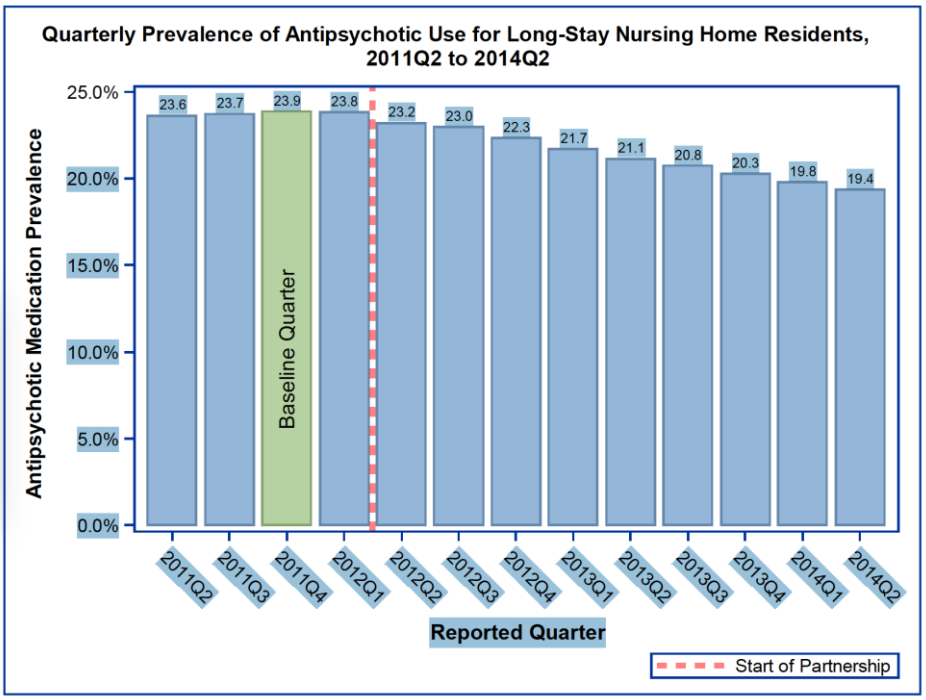


Figure 1: Antipsychotic Use 2011 Q2 – 2014 Q2

[14] *Partnership to Improve Dementia Care in Nursing Homes Antipsychotic Drug use in Nursing Homes Trend Update*, CMS (October 27,2014). (As noted in the *Update*, these data are from "CMS Quality Measure [for long-stay residents], based on MDS 3.0 data…."). Henceforth, *CMS Trend Update*.

[15] *CMS Trend Update*, p.1. Note: the most current reported antipsychotic drugging rates for individual US nursing homes can be accessed at any time on data.medicare.gov. Permalink: https://data.medicare.gov/Nursing-Home-Compare/Quality-Measures-Long-Stay/iqd3-nsf3.

Note: What Rates Are We Talking About?

The data used by CMS in the campaign are "risk-adjusted," meaning that they **exclude** nursing home residents who have a diagnosis of schizophrenia, Huntington's Disease or Tourette's Syndrome. **In other words, the rates are for people who, generally speaking, should *not* be receiving antipsychotic drugs.**

In addition, it is important to keep in mind that while these drugs might be appropriate for individuals with certain conditions, that does *not* mean that they are necessarily being given to those individuals appropriately. For instance, an individual with schizophrenia may not need or want to be treated with antipsychotic drugs, but is given them anyway by her facility (for instance to punish or chemically restrain her). While these uses are also inappropriate and illegal, they are not included in the risk-adjusted data.

The actual (not risk-adjusted) numbers of US nursing home residents who were given antipsychotics was 354,951 at the end of 2011 (26.2% of residents), the base year for the federal campaign, 306,977 at the end of 2013 (23.34% of residents) and 277,459 as of the 3rd quarter of 2014 (20.91% of residents). [Source: MDS Frequency Report.]

Beyond Percentages: What Does This Mean For the Residents?

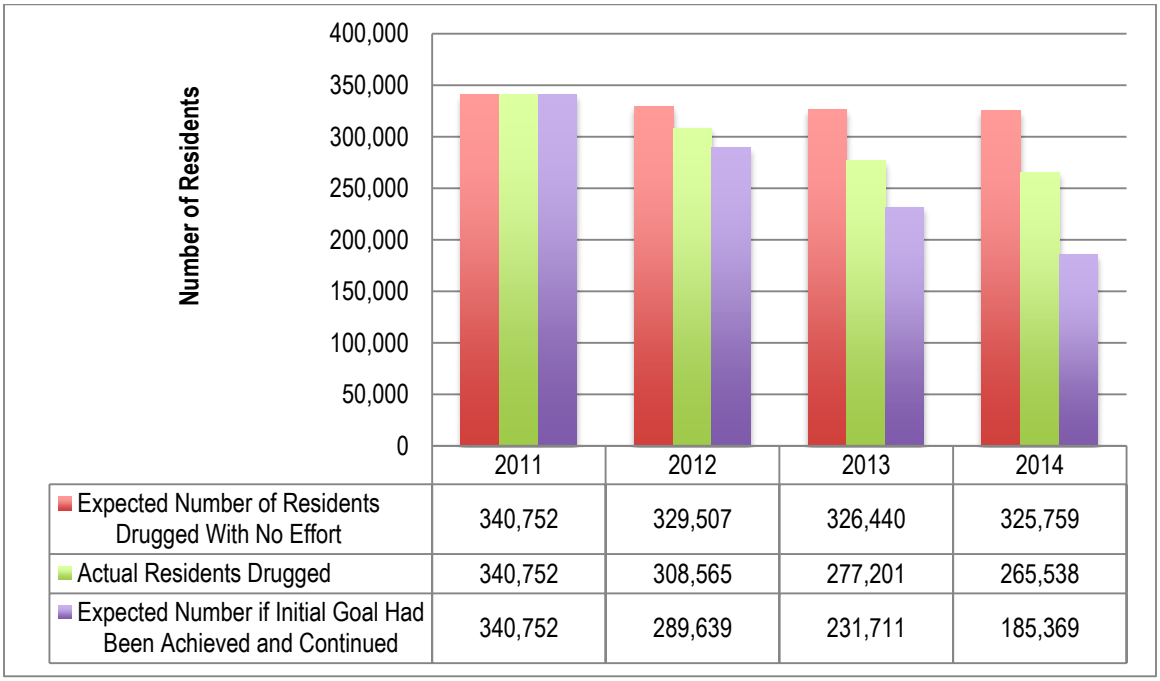
There were 1,431,730 residents in US nursing homes in 2011.[16] Thus, approximately 340,752 people living in nursing home were given antipsychotics in the baseline quarter of the campaign, 2011 Q3.[17] [As noted in the box above, it is important to remember that these numbers are risk-adjusted.] In 2012, there were 1,383,700 residents in US nursing homes.[18] In 2013 there were 1,372,284 residents and in 2014 there were 1,368,754.[19]

15,000 fewer residents would be on antipsychotics today even if the campaign had not existed.

Figure 2 presents the actual (albeit risk-adjusted) numbers of people estimated to be receiving antipsychotics for each year (since the 2011 baseline) of the campaign compared to the number of residents who would have received the drugs had CMS and the nursing home industry achieved their initial, modest goal and maintained that

[16] Nursing Home Data Compendium, Table 3.2. Demographic Characteristics of Nursing Home Residents, 2011, Centers for Medicare and Medicaid Services (from CASPER and MDS data) (2012).
[17] 23.8% of 1,431,730.
[18] Harris-Kojetin L, Sengupta M, Park-Lee E, Valverde R., *Long-term care services in the United States: 2013 overview*, CDC: National Center for Health Statistics (2013). Available at http://www.cdc.gov/nchs/fastats/nursing-home-care.htm.
[19] Figures for 2013 are from *LTC Stats: Nursing Facility Patient Characteristics Report*, Table 1: Nursing Facility Patient Overview, December 2013, American Health Care Association (2013). Figures for 2014 are from a query conducted by the author on data.medicare.gov on November 10, 2014.

modest rate of reduction over the course of the campaign to date.[20] Given that the overall nursing home population has decreased over this time period, we have included the numbers for residents that would likely have been drugged had there been no campaign effort or other intervention. As Figure 2 shows, irrespective of the campaign's existence, antipsychotic drugging would likely have declined by about 15,000 people (4.4% of those drugged in 2011), solely because the nursing home population as a whole declined over the course of these years.[21]



	2011	2012	2013	2014
Expected Number of Residents Drugged With No Effort	340,752	329,507	326,440	325,759
Actual Residents Drugged	340,752	308,565	277,201	265,538
Expected Number if Initial Goal Had Been Achieved and Continued	340,752	289,639	231,711	185,369

Figure 2: Actual vs. Expected Numbers of Residents Drugged

The columns in Figure 2 shows the widening discrepancy between the numbers of people who would have likely been drugged with no campaign effort *vs*. the numbers drugged with the campaign (as it was implemented by CMS) *vs*. the numbers of people who would have been drugged had the initial CMS goal rate of reduction been achieved and continued. These data indicate that about 60,000 fewer residents are receiving these drugs today as a result of the campaign. However, if the campaign had just accomplished and kept with its original, modest goal rate

80,000 residents are being given these drugs today, at great personal and financial cost, simply because CMS and the industry failed to achieve and sustain their initial goal.

[20] Notes on the data: We use the 2011 nursing home population as the basis for computation of the first year's reduction (2012 being the initial year of the campaign). The expected drugging rates for 2013 and 2014 are based on the nursing home population for those years and a proportional baseline drugging rate from 2012, adjusted to account for the annualized rate of reduction announced at the inception of the campaign (15% for the last nine months of 2012 equals an annual rate of 20% reduction).

[21] From a total of 340,752 in 2011 to 325,759 in 2014, as shown in Figure 2, "Expected Number of Residents Drugged With No Effort."

of reduction, that reduction would have been over 140,000. In other words, there are about 80,000 people receiving these drugs today, at great personal and financial cost, simply because CMS and the industry failed to achieve and sustain their initial, modest goal.

What Does the Future Hold?

In September 2014, CMS issued a press release announcing new goals of five percent (5%) further annual reductions from the 2011 baseline rate for 2015 and 2016.[22] Dr. Patrick Conway, CMS's chief medical officer, is quoted in that press release as stating "…we have set ambitious goals to reduce use of antipsychotics because there are – for many people with dementia – behavioral and other approaches to provide this care more effectively and safely."

This statement raises several critical questions: (1) What does "ambitious" mean in the context of the short – but disappointing - history of the campaign?; (2) What is the meaningfulness of setting *any* goals – whether the "modest" 15% reduction goal set in March 2012, or the "ambitious" 5% reduction goal set in September 2014 – if the goals are flouted with impunity?; and (3) How useful are longstanding requirements to utilize "other [non-pharmacological] approaches" to dementia care if CMS does not hold providers accountable when they fail to follow these requirements?

The latter question is particularly noteworthy given the substantial resources that CMS has invested over the course of the campaign in providing training and education to the nursing home industry and its professional staff on basic dementia care standards and practices. If nursing homes are already being paid to provide a professional level of care, does it make sense for the chief regulatory agency to devote a substantial portion of its limited resources to training the industry on basic care practices and standards, rather than holding it accountable for meeting those standards?[23] Should it make any difference that the services in question are for a population that is, for the most part, quite vulnerable and dependent on those services?

These are essential, and likely long term, policy issues. In the short term, however, the goals announced in 2014 provide a baseline for estimating the impact of CMS policies for residents in the immediate future. The following chart (Figure 3) presents projected numbers of residents who will be drugged at the end of 2015 and 2016 (respectively) based on the newly announced goals in comparison to expected drugging rates for those years if CMS had accomplished and sustained its original goal rate of reduction.

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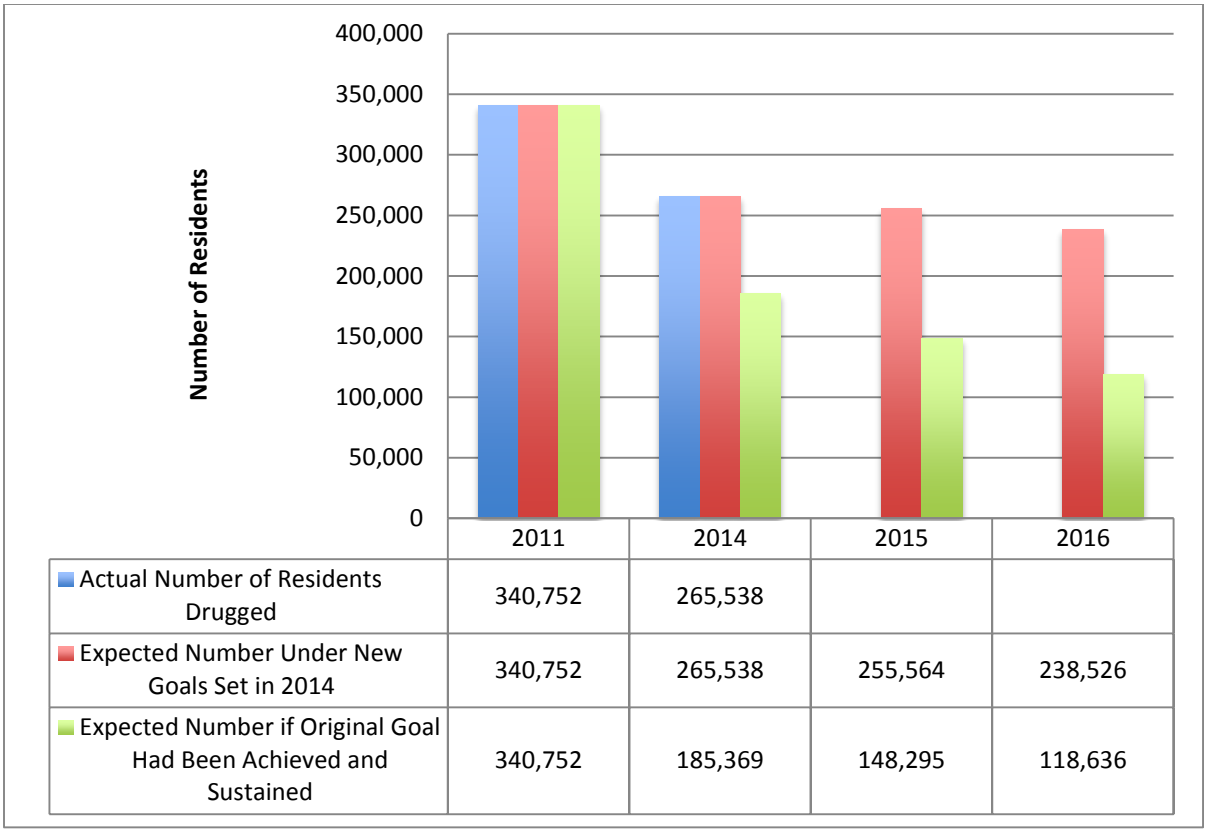
[22] *Press release: National Partnership to Improve Dementia Care exceeds goal to reduce use of antipsychotic medications in nursing homes: CMS announces new goal*, CMS (September 19, 2014). The goals are a total of 25% reduction from 2011 rates by the end of 2015 and 30% by the end of 2016. Available at http://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2014-Press-releases-items/2014-09-19.html.

[23] While a discussion of "other approaches" to dementia care is beyond the scope of this brief, it is important to note that longstanding nursing home standards prohibiting unnecessary drugging and the use of chemical restraints also require the use of non-pharmacological approaches to dementia care, such as assessing what is causing an individual to be upset (rather than just sedating him or her) and, when antipsychotic drugs are used, to develop and implement a plan of "gradual dose reduction" tailored to the needs of the individual resident.



	2011	2014	2015	2016
Actual Number of Residents Drugged	340,752	265,538		
Expected Number Under New Goals Set in 2014	340,752	265,538	255,564	238,526
Expected Number if Original Goal Had Been Achieved and Sustained	340,752	185,369	148,295	118,636

Figure 3: The 2011 Goal vs. The 2014 Goal

The first column, for the year 2011, is included to show the baseline number used by the CMS campaign. The second column, for 2014, also provides a point of comparison, showing actual drugging figures (265,538) and the estimated number had the initial CMS goal been accomplished and rate of reduction sustained (185,369). In the fourth and fifth columns, one can see the growing discrepancy between expected numbers under the new goal announced by CMS in 2014 vs. what could have been accomplished if the original goal had been achieved and sustained.[24] If CMS's new "ambitious" goal is achieved, 255,564 U.S. nursing home residents will be drugged at the end of 2015.[25] Under the rate anticipated in the original ("modest") goal, that number would have been reduced to 148,295. This is a difference of over 100,000 *additional* residents being drugged unnecessarily.[26] As the chart indicates, in 2016 the expected margin increases substantially, with an estimated difference of 119,890 *additional* residents being drugged under the new "ambitious" goal than would have been under the original "modest" goal. This is close to 120,000 residents who would have and could have been saved

[24] Note: Since 2015 and 2016 are in the future, there are no values for the *actual* number of residents drugged in those years.

[25] I.e., a 25% reduction from the 2011 baseline of 340,752.

[26] As noted earlier, these data relate solely to the campaign's goals and not to enforcement of standards of care in all nursing homes, as CMS promised in 2012. To that end, it is worthwhile to note that every licensed nursing home should have been surveyed at least twice (if not three times) since the campaign was launched to ensure that it was meeting or exceeding minimum standards of care.

from antipsychotic drugging if CMS had just accomplished and sustained the rate of reduction promised for 2012.

Conclusion

Though CMS and the nursing home industry have touted the "fantastic" success of the Partnership to Improve Dementia Care, at the end of 2014 there are still over 265,000 nursing home residents in the U.S. – close to one in five – who are being administered powerful and dangerous antipsychotics. Because these numbers are "risk-adjusted," the vast majority (if not all) of these individuals are receiving these drugs inappropriately and at considerable risk to their health and well-being.

While the Partnership appears to have had some effect in reducing inappropriate drugging rates, it failed – by a significant margin – to achieve even the modest goal CMS set, in consultation with the industry itself, at the beginning of the campaign. Rather than working to accelerate progress to meet that goal's rate of reduction after 2012, in response to this failure, CMS essentially sat on its hands, neither setting new goals nor improving regulatory enforcement in all of 2013. It was not until 2014, when data indicated that the 2012 goal had finally been achieved (at the end of 2013), that CMS set further goals. Rather than building on the initial goal, as originally promised, the future goals are considerably weaker, calling for a five percent (5%) annual reduction in 2015 and 2016. This is one-quarter of the annual rate of reduction that CMS called for in the initial goal.[27]

As noted in the beginning of this report, U.S. Inspector General Daniel Levinson raised the alarms in 2011 about widespread, inappropriate antipsychotic drugging of nursing home residents. Three years later, over 265,000 residents are still being administered these drugs. Furthermore, and perhaps most disheartening, 80,000 residents have been "left behind" by the failure of CMS to simply achieve and sustain the modest goals it set – in collaboration with the industry – when the campaign was launched.

Following are the personal stories of four of the residents who have been "left behind," a few of the many thousands who are harmed every day because of the failure to adequately enforce minimum standards of care or to even achieve and sustain the modest rate of reduction called for by CMS, the federal agency responsible for protecting the lives and well-being of all nursing home residents in our country.

[27] As discussed earlier, the campaign was launched with a fifteen percent (15%) reduction goal for the last nine months of 2012. This equals a 20% annual rate of reduction, which is four times the five percent (5%) annual rate of reduction goal announced in 2014 for the years 2015 and 2016.

The Residents Left Behind

Following are four brief personal stories of residents 'left behind' by the campaign to reduce inappropriate antipsychotic drugging: Rose, Bobbie, Richard and Jenny. Jenny's story, at the end, includes a timeline of events that illustrate the destructive snowball effect of repeated failures to provide appropriate care. These cascading failures – and resulting harm – would not be possible if nursing homes were held accountable when they fail to meet the standards of care that they agree to provide for their residents. Please note that we have changed the residents' names to protect their privacy.

Rose's Story

Rose is a woman in her 80s. When she entered the nursing home near her family, she was in the early stages of dementia but was highly functional and interested in the world around her. Before she went to the nursing home, this might have indicated that Rose was a social person, but in the facility she was identified as a "wanderer." Rather than being assisted in acclimating to her new environment, Rose was given antipsychotic drugs to stop her wandering. She was, literally, chemically restrained.

While being given these drugs, Rose rapidly declined in health and developed painful bedsores from lack of activity. Her granddaughter thought her declining health was the result of increasing dementia; she did not know that her grandmother was being given powerful antipsychotics until she asked the home to conduct a medical evaluation so that the family could move Rose to another facility.

When Rose left the first nursing home, her granddaughter helped to ensure that she was taken off the antipsychotics. Though she still has dementia, Rose has regained significant mental functioning and quality of life. The painful bedsores that she acquired while on the drugs have been treated. Unfortunately, she now suffers from permanent movement disorders, a problem associated with antipsychotic drugging, and can no longer walk on her own. Nobody will ever have to worry about Rose "wandering" again.

Bobbie's Story

Bobbie was admitted to a mid-sized, hospital-based nursing home in a rural county in 2013. Bobbie had dementia and moved to the facility because her husband was having a difficult time providing care for her. Prior to moving into the nursing home, Bobbie had never received a psychotropic drug of any kind. Immediately after her admission, she was prescribed an anti-anxiety drug and a sleeping drug. Her husband reluctantly consented but was not told that the nursing home was required by law to try alternative treatments. Over the course of the next four months, Bobbie received three different antipsychotic drugs at various times as well as an additional sleeping drug. Dosages were increased without Bobbie or her husband's knowledge.

When the facility told Bobbie and her husband that the doctor wanted to add Depakote, an anti-seizure drug often used to sedate and subdue residents, her husband finally complained to the state Department of Public Health. However, the Department of Public Health found no violations related to the drugging. Bobbie's husband eventually took Bobbie home and is now providing care for her with the help of his daughters.

Richard's Story

Until 2014, Richard lived at home alone and received help with chores twice a week from an in-home caregiver. He suddenly began experiencing hallucinations and was hospitalized. After a one-day stay, he was sent to a nursing home that promptly started him on Depakote, and after another hospitalization, he was sent to a second nursing home. Over the course of two weeks, Richard was drugged with four different antipsychotic drugs, an anti-anxiety drug, and a sleeping drug. Most of these drugs were initiated without consent and none of them were explained by Richard's doctor. Richard's family was horrified when they visited him as he had rapidly declined during the month since his episode of hallucinations. He could no longer walk or talk and slept all of the time. At this time, a complaint with the state Department of Public Health is still under investigation.

Jenny's Story

WHERE AM I? I WANT TO GO HOME. OHHHHH. Jenny screams and cries. A nurse enters the room. WHAT ARE YOU DOING HERE? Jenny screams some more. Another nurse enters room. An injection is administered. YOU STOP THAT! Jenny sobs. She holds her knees. Ohhhhh, It hurts. Thirty minutes later, she is sleeping in a wheelchair, her mouth open and drooling. A nurse aide enters with lunch and encourages Jenny to eat. Jenny is too lethargic. Food is forced into her mouth but she does not swallow. Nurse aide documents "poor appetite" and places tray outside of room. Jenny is placed back in bed.

Meet Jenny, an 80-year-old nursing home resident who suffered from dementia, hypertension, diabetes, and depression. She was hospitalized because of rectal bleeding, and what happened next is a common scenario for the elderly suffering from dementia. In the hospital, Jenny became agitated, commonly seen in patients with dementia due to the foreign environment. The staff's response to her agitated behaviors was to order Haldol (an antipsychotic) and Ativan (an anti-anxiety medication). Jenny was already taking an antidepressant. Now she was on three psychotropic medications, which were continued when Jenny returned to the nursing home. Jenny's return marked the beginning of an 86-day, downward spiral that ended in her death.

Timeline of events upon her return:

Day 1: Jenny was extremely agitated, screaming and crying to go home. The nursing home responded by injecting her with Haldol, 1mg intramuscularly. (This antipsychotic medication was on top of the daily dose carried over from the hospital stay).

Day 3: Jenny was lethargic and had hyperextension of her neck. (Both are known side effects of the antipsychotic medications.) She was sent to the ER for evaluation; the Haldol dose was reduced by 0.5 mg.

Day 13: Jenny refused to take her medications and had one episode of screaming and crying. The physician was notified. The facility's response was to change Haldol to liquid form for easier administration and to increase its dose. There are notations on this same day that Jenny's body was rigid and her appetite poor (both possible side effects of the medication).

Day 15: Jenny had increasing rigidity of her trunk and was unable to sit in the wheelchair, so she was placed in a reclining chair.

Day 28: Jenny expressed that she had pain in her knees; a cream was ordered to apply to her knees for the pain.

Day 38: Jenny had an elevated temperature and was found to have sepsis due to a Urinary Tract Infection. She was sent to the hospital.

Day 40: The hospital performed a swallow evaluation and concluded that Jenny's difficulty with eating was due to her decreased alertness. (Decreased alertness is a side effect of the antipsychotic medications.)

Day 41: Jenny was placed on another medication, Artane, which counteracts the adverse side effects of Haldol. Yet, the physicians kept Jenny on the same dose of Haldol.

Day 47: Jenny returned to the nursing home.

Days 47-56: Jenny again complained of knee pain. One day, she called out for her son. She was given Ativan. She was noted to be eating poorly.

Day 57: Haldol was increased to 1 mg 3 times per day; another psychotropic drug, Depakote, was ordered at the dose of 125mg twice daily.

Days 58-70: Jenny cried intermittently, which some nurses recognized as a result of her knee pain. She was given Tylenol.

Day 70: Depakote was increased to 250 mg twice daily for the episodes of crying out.

Day 71: Jenny had difficulty swallowing and needed to have her fluids thickened to prevent choking.

Day 75: Jenny was so constipated that she was impacted with stool and required a suppository. (Constipation is another frequent side effect of Haldol.)

Day 77: Jenny developed a pressure ulcer, also known as a bedsore. (Bedsores occur when patients are inactive and/or unable to reposition themselves.)

Day 83: Jenny was dehydrated and malnourished.

Day 85: Jenny developed pneumonia.

Day 86: Jenny died.

The story of Jenny is sad but true, and a common one in many nursing homes. Many people, including nursing home staff and regulators, do not trace the downward spiral in a case like Jenny's to the use of antipsychotic medications. It is easier to give agitated, elderly residents medication(s) that will calm them rather than determine the underlying cause(s) of the problem, particularly in a person who is unable to communicate her discomfort or needs. However, taking the easy road by administering these medications may be a form of slow killing—either directly from the powerful side effects of the drug (either singularly or in combination with other powerful medications) or indirectly by exacerbating rather than treating existing conditions.