

**Congress of the United States**  
**Washington, DC 20510**

April 3, 2020

**VIA ELECTRONIC SUBMISSION**

Ms. Christi Grimm  
Principal Deputy Inspector General  
U.S. Department of Health and Human Services  
Office of Inspector General  
330 Independence Avenue  
Washington, DC 2021

Dear Ms. Grimm:

We are writing to request that the Department of Health and Human Services (HHS) Office of Inspector General (OIG) examine the use of psychotropic drugs among residents of nursing homes, including trends since its last major analysis of this issue in 2011.<sup>1</sup> Specifically, we request that you review changes in inappropriate use of psychotropic drugs over the last decade, the adequacy of drug treatment planning or medication monitoring by providers prescribing and administering these medications, and whether additional legislative or regulatory actions are needed to protect against the inappropriate use of such drugs.

Policymakers and advocates have for decades voiced concerns about whether adequate safeguards are in place to protect against unnecessary antipsychotic drug use in nursing homes that participate in the Medicare and Medicaid programs.<sup>2</sup> Concerns about inappropriate use of such drugs persist, in part due to recent research suggesting that “individuals with dementia who reside in skilled nursing facilities have significantly greater rates of prescription of antipsychotic medications when compared with those individuals living in the community,”<sup>3</sup> and that

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<sup>1</sup> U.S. DEP’T OF HEALTH AND HUMAN SERV., OFFICE OF THE INSPECTOR GEN. (OIG), OEI 07-08-00510, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents* (May 4, 2011), available at <https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf>. See also D.V. Jeste et al., ACNP White Paper: *Update on use of antipsychotic drugs in elderly persons with dementia*, NEUROPSYCHOPHARMACOLOGY, VOL. 33 (2008), 957-970 (suggesting most of the deaths due to antipsychotic use in elderly individuals with dementia are related to cardiovascular or infectious events).

<sup>2</sup> See, e.g., U.S. SENATE SPECIAL COMM. ON AGING, SUBCOMM. ON LONG-TERM CARE, *Supporting Paper No. 2: Drugs in Nursing Homes; Misuse, High Costs and Kickbacks* at XI (Jan. 1975) (finding that “20 to 40 percent of nursing home drugs are administered in error,” and “[p]erhaps most disturbing is the ample evidence that nursing home patients are tranquilized to keep them quiet and make them easier to take care of,” and “[t]he atmosphere for abuse is particularly inviting when reimbursement systems under federal and state programs allow the nursing home to act as the ‘middle man’ between the pharmacy (which supplies the drugs) and the source of payment (private patient, Medicare, or Medicaid).”), available at <https://www.aging.senate.gov/imo/media/doc/reports/rpt175.pdf>.

<sup>3</sup> Rajesh R. Tampi et al., *Antipsychotic use in dementia: a systematic review of benefits and risks from meta-analyses*, *Therapeutic Advances in Chronic Disease* (Sep. 2016), Vol. 7(5), 229–245 (citing Maguire, 2013), available at [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4994396/pdf/10.1177\\_2040622316658463.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4994396/pdf/10.1177_2040622316658463.pdf).

“antipsychotics are often used in individuals with dementia for sustained periods...with limited monitoring of their effects.”<sup>4</sup>

Such evidence fueled widespread concerns about the use of these powerful drugs as inappropriate chemical restraints for nursing home residents whose behavior was disruptive or challenging to manage, many of whom have dementia. Antipsychotic drugs are approved by the Food and Drug Administration (FDA) to treat schizophrenia, Tourette’s syndrome, Huntington’s disease, and bipolar disorder. Notably, there are no antipsychotic drugs approved for the treatment of dementia or the behavioral and neuropsychiatric symptoms of dementia.<sup>5</sup> Other medical research also has uncovered serious side effects associated with the use of antipsychotic drugs—including enhanced risk of death in the elderly<sup>6</sup>—and suggested exploring non-pharmacological interventions to manage dementia.<sup>7</sup> As a result, in 2008, the FDA issued a black-box warning, stating that off-label use of antipsychotic medications can result in severe adverse effects.

A decade ago, the Finance Committee, led by Chairman Grassley, called for HHS OIG to investigate the practice of prescribing antipsychotics and other drugs for elderly nursing home residents. The OIG, in its 2011 report on this subject,<sup>8</sup> concluded that 14 percent of the Nation’s 2.1 million nursing home residents had Medicare claims for atypical antipsychotic drugs in a six-month period, these drugs often were prescribed to manage behavioral symptoms of patients with dementia,<sup>9</sup> and at least half of such “drug claims for elderly nursing home residents were erroneous, amounting to \$116 million in inappropriate Medicare reimbursement claims in that same period.”<sup>10</sup>

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<sup>4</sup> *Id.* (citing Wetzels et al. 2011; Barnes et al. 2012; Gustafsson et al. 2013; Chen et al. 2010; Gellad et al. 2012).

<sup>5</sup> See Human Rights Watch, “They Want Docile: How Nursing Homes in the United States Overmedicate People with Dementia” (Feb. 5, 2018), available at <https://www.hrw.org/report/2018/02/05/they-want-docile/how-nursing-homes-united-states-overmedicate-people-dementia>.

<sup>6</sup> See OEI 07-08-00510, *supra* note 1. See also D.V. Jeste et al., ACNP White Paper: *Update on use of antipsychotic drugs in elderly persons with dementia*, NEUROPSYCHOPHARMACOLOGY, Vol. 33, 957-970 (2008) (suggesting that most of the deaths due to antipsychotic use in elderly individuals with dementia are related to cardiovascular or infectious events).

<sup>7</sup> L. Avalon et al., *Effectiveness of non-pharmacological interventions for the management of neuropsychiatric symptoms in patients with dementia: a systematic review*, ARCH INTERN MED. Vol. 166, Issue 320, 2182-8 (Nov. 13, 2016) (finding one trial, which indicated that elderly individuals with dementia who display agitation and disruptive behaviors often do so in an attempt to communicate, and “acting out” can stem merely from frustration over unmet needs or symptoms—such as pain, constipation, responses to noise, or interactions with others.), available at <https://www.ncbi.nlm.nih.gov/pubmed/17101935>.

<sup>8</sup> That same year, Senator Grassley also cosponsored bipartisan legislation that, if enacted, would have required the Secretary of the U.S. Department of Health and Human Services to issue standardized protocols for obtaining informed consent, or authorization from patients or their designated representatives, acknowledging the potential risks and side effects associated with the use of these drugs. See also OEI 07-08-00510, *supra* note 1 at ii (noting that Medicare requires that such drugs are eligible for reimbursement “for medically accepted indications supported by one or more of three compendia.”).

<sup>9</sup> See OEI07-08-00510, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*, *supra* note 1 at i.

<sup>10</sup> *Id.* at ii. See also Human Rights Watch, *supra* note 6 (indicating that nursing facilities in the United States ordinarily administer antipsychotic drugs on an average week to over 179,000 people who do not have diagnoses for

In 2012, HHS's Centers for Medicare & Medicaid Services (CMS) launched its "Partnership to Improve Dementia Care in Nursing Homes" (National Partnership).<sup>11</sup> As part of this initiative, CMS set a goal of reducing the rate of antipsychotic usage in nursing homes and encouraging the use of non-pharmacologic and person-centered dementia care. The National Partnership led to the distribution of training materials to nursing homes, mandatory training for surveyors, and more. Currently, nursing homes report the percentage of long-stay and short-stay residents who are receiving or newly receiving an antipsychotic medication, excluding residents diagnosed with schizophrenia, Huntington's Disease, or Tourette's Syndrome, to CMS through the Minimum Data Set (MDS). However, the National Partnership only uses the long-stay measures in its reporting.

In January, through the National Partnership, CMS released two reports which showed a reduction in the inappropriate use of antipsychotics in nursing homes. In the fourth quarter of 2011, 23.9 percent of long-stay nursing home residents reportedly received such a drug, while just 14.6 percent of such residents received this medication in 2018—a 39 percent reduction.

Still, many continue to raise questions about whether we have made sufficient progress in reducing the prevalence and use of antipsychotic drugs to care for the elderly. Any inappropriate prescribing of antipsychotic medications is too much, and reports have continued to demonstrate the harm nursing home residents are experiencing as a result.<sup>12</sup>

Additionally, pressure to reduce the use of antipsychotic drugs in nursing homes, and the associated CMS measures, may have unintended consequences.<sup>13</sup> For example, studies have

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which the drugs are approved, and the drugs' sedative effect, rather than any anticipated medical benefit, drives the high prevalence of use in such dementia patients).

<sup>11</sup> CTRS. FOR MEDICARE & MEDICAID SERV. (CMS), *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>; but cf. Chuck Grassley, U.S. Senator, Press Release: "Kohl, Grassley, and Blumenthal Seek to Cut Misuse of Antipsychotics" (May 22, 2012) (describing the proposed amendment requiring for HHS to adopt standardized protocols for obtaining informed consent, or authorization from patients or their designated representatives, acknowledging the potential risks and side effects associated with the use of these drugs, to S. 3187, the Food and Drug Administration Safety and Innovation Act, in the 112th Congress) (However, this amendment, which would have required HHS to adopt protocols for obtaining patients' informed consent acknowledging these drugs' risks, was never adopted), available at <https://www.grassley.senate.gov/news/news-releases/kohl-grassley-and-blumenthal-seek-cut-misuse-antipsychotics>.

<sup>12</sup> See Human Rights Watch, *supra* note 6.

<sup>13</sup> At least one article, citing a study published in the *Journal of American Medical Directors Association*, also raises questions about whether efforts to further reduce the use of certain drugs in nursing homes may be correlated to a rise in risk factors for avoidable and non-avoidable hospitalization among residents with behavioral health issues. That study, conducted by researchers at the University of Rochester found that residents with behavioral health issues had a 15 percent higher risk of non-avoidable hospitalizations, and a nine percent greater risk for potentially avoidable hospitalizations. According to one of the study authors, the results raise a question about whether the use of antipsychotic medication is over-regulated—a problem that could be fueled by the lack of access to psychiatric expertise in nursing homes. See Lyndee Yamshon, "Push to Reduce Antipsychotic Drugs in Nursing Homes May Have Boosted Costly Hospitalizations," SKILLED NURSING NEWS (Oct. 27, 2019) (citing Helena Temkin-Greener et al., *Preventable Hospitalizations Among Nursing Home Residents With Dementia and Behavioral Health Disorders*, J. OF AMERICAN MEDICAL DIRECTORS ASS'N, Vol. 20 (Issue 10), 1280–1286), available at

shown an increase in diagnoses of schizophrenia, leading some to raise concerns that such diagnoses may be made to “justify” the prescribing of antipsychotics.<sup>14</sup> While the onset of bipolar disorder and schizophrenia rarely occur in people over the age of 30, there has been a 30 percent overall increase in schizophrenia diagnoses from 2011 to 2017.<sup>15</sup> According to a 2016 study, almost 40 percent of state surveyors said they had identified a new but incorrect diagnosis of psychosis in a nursing home to justify an inappropriate antipsychotic prescription.<sup>16</sup> Chairman Neal also expressed this concern in two recent letters to CMS,<sup>17</sup> and the Ways and Means Committee explored this issue further in its November 2019 hearing, “Caring for Aging Americans.” At the same time, the number of prescriptions for other psychotropic drugs also has increased in recent years, indicating that providers possibly may be substituting these drugs for antipsychotics.<sup>18</sup>

Given the continued prevalence of psychotropic drug use in nursing homes and the documented harm it poses to patients, we request that HHS OIG conduct a follow-up study to reexamine the prevalence of antipsychotic drug use in nursing homes, the adequacy of federal efforts to promote compliance with federal standards, and the need for, and challenges to adopting, additional safeguards to promote appropriate use of these drugs.

To this end, we ask that HHS OIG:

1. Conduct a longitudinal analysis (covering the last 10 years) examining the number and percent of nursing home residents who receive psychotropic drugs, broken down by class of drug (e.g., antipsychotic drugs, benzodiazepines, and anti-depression and anti-anxiety), and the length of time on the drug.
  - a. Determine total Medicare Part A costs from hospitalizations resulting from inappropriate psychotropic use during this same period.

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<https://skillednursingnews.com/2019/10/push-to-reduce-antipsychotic-drugs-in-nursing-homes-may-have-boosted-costly-hospitalizations/>.

<sup>14</sup> See “National Partnership to Improve Dementia Care in Nursing Homes & Quality Assurance and Performance Improvement (QAPI),” MEDICAL LEARNING NETWORK at 10 (Jun. 15, 2017) (citing statement from Feb. 21, 2017, by the Society for Post-Acute and Long-Term Care Medicine), available at <https://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/2017-06-15-Dementia-Care-Presentation.pdf>.

<sup>15</sup> Johns Hopkins Medicine, *Science Daily* (2019) (The study suggests over diagnosis of schizophrenia: Reported symptoms of anxiety and hearing voices most common reasons for misdiagnosis by non-specialty physicians), available at <https://www.sciencedaily.com/releases/2019/04/190422090842.htm>.

<sup>16</sup> Urick, Kaskie, Carnahan, “Improving Antipsychotic Prescribing Practices in Nursing Facilities: The Role of Surveyor Methods and Surveying Agencies in Upholding the Nursing Home Reform Act.” *RES SOCIAL ADMIN PHARM* (2016) (Jan-Feb;12(1):91-103).

<sup>17</sup> See Letter from Chairman Neal to CMS Administrator Verma (July 25, 2018); see also Letter from Chairman Neal to CMS Administrator Verma (Jan. 22, 2019) (“I am concerned that the ‘improvement’ is not the result of changed prescribing behavior but, instead, stems from some nursing homes falsifying psychosis diagnoses, making incidence of this contra-indicated prescribing appear improved when it is, in fact, not.”), available at [https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/SNF\\_Antipsychotics%20letter%20to%20CMS\\_January%202019.pdf](https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/SNF_Antipsychotics%20letter%20to%20CMS_January%202019.pdf).

<sup>18</sup> Helen C. Kales MD, Laura N. Gitlin PhD, FGSA, FAAN, Constantine G. Lyketsos MD, MHS, *When Less is More, but Still Not Enough: Why Focusing on Limiting Antipsychotics in People with Dementia is the Wrong Policy Imperative*, J. OF THE AMERICAN MEDICAL DIRECTORS ASS’N, 1-6 (2019).

2. Analyze patterns of off-label use of psychotropics in nursing homes over the last ten years, including whether there are individual nursing homes, chains of nursing homes, or homes with common ownership interests where such use is persistent.
3. Determine the extent to which Medicare drug claims for nursing home residents are erroneous or still result in inappropriate Medicare reimbursement claims (an issue identified by the OIG in its 2011 report on this subject).
4. Evaluate the effectiveness of current CMS initiatives, such as the “Partnership to Improve Dementia Care in Nursing Homes,” or other HHS initiatives in ensuring the appropriate use of psychotropic drugs for nursing home residents. More specifically:
  - a. To what extent has CMS issued citations or assessed penalties against facilities that were found to have violated Federal requirements since its inception? How much have these penalties increased/decreased over time? How often are citations linked to resident harm or immediate jeopardy (i.e., G+ citations) penalties? To what extent are the citations and penalties levied on the same nursing homes over time?
  - b. To what extent, if any, have the rates of use of non-pharmacologic approaches for the treatment of behavioral and neuropsychiatric symptoms of dementia increased since the launch of the National Partnership and/or use of antipsychotic drug-related quality measures under the MDS?
5. Please indicate whether there has been an increase, since CMS launched its National Partnership, in the number and percentage of nursing home residents (including non-elderly residents) diagnosed with conditions for which the use of antipsychotics is approved and use is not tracked in Medicare, specifically schizophrenia, Tourette’s Syndrome, and Huntington’s Disease. Please compare these data to rates of diagnosis for these conditions among the general elderly population.
6. Evaluate the effectiveness of state laws and/or regulations requiring written informed consent before administration of a psychotropic drug in changing the frequency of prescribing and appropriate use of such medications to older adults with dementia, as well as any impact of such policies on ability to hold nursing homes accountable for inappropriate prescribing and off-label use. As part of this evaluation, please include states that have monetary incentive programs and include specific target thresholds for psychotropic use among skilled nursing facility long-stay residents.
7. Determine the effects, if any, of regulation of psychotropic drugs on admissions to nursing homes for those struggling with mental illness.
8. Assess the effectiveness of current quality measures for antipsychotic use under the MDS, including receipt of antipsychotics for short-stay residents and receipt of

antipsychotics for long-stay residents, in reflecting the true rates of medically inappropriate prescribing.

9. Assess the potential positive and negative impacts of creating a requirement for facilities to obtain written informed consent before issuing a prescription for psychotropic drugs to nursing home residents under the Medicare and Medicaid programs.
10. To the extent feasible, assess the adequacy of medication monitoring, including frequency of pharmacist review and visits with the prescriber, for nursing home residents who use psychotropic drugs.

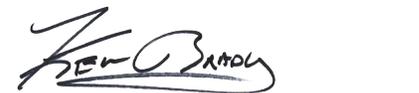
We greatly appreciate your assistance and look forward to working with you on this important matter. If you have any questions about our request, please contact Evelyn Fortier of Chairman Grassley's staff or Dave Berick of Ranking Member Wyden's staff at (202) 224-4515, or Rachel Dolin of Chairman Neal's staff at (202) 225-3625, or Jay Gulshen of Ranking Member Brady's staff at (202) 225-4021.

Sincerely,

  
Charles E. Grassley  
Chairman  
Committee on Finance  
United States Senate

  
Richard E. Neal  
Chairman  
Committee on Ways and Means  
U.S. House of Representatives

  
Ron Wyden  
Ranking Member  
Committee on Finance  
United States Senate

  
Kevin Brady  
Ranking Member  
Committee on Ways and Means  
U.S. House of Representatives

  
Richard Blumenthal  
Member  
Committee on the Judiciary  
United States Senate