

## COMMITTEE ON WAYS AND MEANS

U.S. HOUSE OF REPRESENTATIVES

WASHINGTON, DC 20515

January 22, 2019

Ms. Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Room 445-G  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Re: Continued concern with overuse of antipsychotics in nursing homes

Dear Administrator Verma:

I write to follow-up to your November 20, 2018, response to my letter of July 25, 2018, which, along with the Centers for Medicare & Medicaid (CMS)'s December release of the National Partnership to Improve Dementia Care data, indicated the agency was making progress on curbing inappropriate prescribing of antipsychotic drugs to nursing home residents with dementia.

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

*Inappropriate prescribing of antipsychotics to nursing home residents is still a major problem.* The Food and Drug Administration (FDA) black box warning on antipsychotic drugs states that elderly patients with "dementia-related psychosis," who are treated with antipsychotic drugs face a two-fold risk of death.<sup>i</sup> Though some progress has been made since the Department of Health and Human Services Office of the Inspector General (OIG) first identified the problem seven years ago, both the latest CMS data and other studies show that between 15 and 18 percent of all nursing home residents are prescribed antipsychotics with no qualifying conditions.<sup>ii iii</sup>

*Inappropriate prescribing of antipsychotics to nursing home patients causes harm to residents and constitutes a high public cost.* A 2015 literature review showed that antipsychotic medication use in nursing homes resulted in increased risk of many adverse events, including mortality, hip fractures, thrombotic events, cardiovascular events, and hospitalizations.<sup>iv</sup> In fact, persons over 70 are 3.5 times more likely than younger individuals to be admitted to the hospital

due to adverse drug reactions associated with psychotropic medications.<sup>v</sup> Thus, inappropriately prescribing antipsychotics not only constitutes a human rights issue – but it also likely increases Medicare spending due to increased hospitalizations.

*Despite this serious problem, recent national survey data suggest that nursing facilities are getting away with this practice.* CMS introduced a separate citation category specifically focused on inappropriate psychotropic drug use in November 2017, as well as new guidance for surveyors to identify when this inappropriate prescribing of antipsychotics constitutes resident harm. Despite estimates that 15 percent of nursing home residents are inappropriately prescribed antipsychotics, less than one percent of all citations related to inappropriate use also identified resident harm.<sup>vi</sup> Because the research is clear that inappropriate prescribing of antipsychotics does indeed result in resident harm, these data suggest severe under-enforcement persists.

*Even more problematic are the recent reports that the mandate to reduce inappropriate prescribing of antipsychotics has actually increased false diagnoses of psychosis in nursing homes.* According to one 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>vii</sup> To address this, CMS Partnership staff and state survey and certification teams should closely review increasing rates of new diagnoses of schizophrenia, bipolar disorder, Tourette Syndrome, and other qualifying diagnoses that may have been created to prescribe an “on-label” use of an antipsychotic.<sup>viii</sup>

I applaud the National Partnership’s offering trainings for nursing home providers and staff – but training alone is inadequate in the face of this crisis.<sup>ix</sup> Research shows that inappropriate use of antipsychotics is inextricably linked to lower Registered Nurse (RN) staffing levels: For residents with and without dementia, one additional RN hour per resident-day could reduce the odds of antipsychotic use by 52 percent and 56 percent, respectively.<sup>x</sup>

While the work of the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC) is no doubt important to monitoring outlier prescribing patterns as you noted in your letter, I am also seeking more detailed information about how facilities and Part D plans are *required to act on those reports* and what CMS is doing to follow-up on these outlier data once they are identified.

In my previous letter, I posed a number of questions about Part D plan responsibilities for monitoring prescriptions of these medications, including the tools they have at their disposal to oversee the use of antipsychotics for individuals for whom such medication is contra-indicated and, when medically appropriate, deny coverage. In addition to these questions posed in my July 2018 letter, I respectfully request that you respond to the following:

1. While CMS efforts through the Partnership and the NBI MEDIC have resulted in a slight reduction in inappropriate use of antipsychotics in many nursing homes, as you noted in your response, these activities remain a widespread problem. My concern is that nursing homes are neither being appropriately cited nor penalized for this inappropriate prescribing.

- a. Please provide a list of which homes were cited in surveys during the past two years (2017 and 2018) for inappropriate prescribing of antipsychotics and the corresponding penalty imposed.
  - b. What specific enforcement actions is CMS taking to ensure that beneficiaries are only prescribed atypical antipsychotics when warranted and appropriate? Is CMS planning to provide more specific guidance to enforce penalties for facilities that are cited? If so, please describe.
  - c. Please describe how CMS is working to ensure that facilities use gradual dose-reduction and non-pharmacological interventions as federal standards have for decades required.
2. At the moment, survey reports indicate that even when inappropriate use of antipsychotics is cited, it is almost never identified as having caused resident harm.
  - a. Please describe any existing or new survey procedures and/or trainings CMS is planning for state surveyors.
  - b. Please specifically describe how CMS is planning to more effectively guide state surveyors to identify both inappropriate prescriptions and cases where these prescriptions should be designated as causing resident harm.
  - c. Considering that we know inappropriate prescribing of antipsychotics for people with dementia causes harm, can you please provide the rationale behind the large number of cases in which inappropriate diagnosis is cited but resident harm is not?
  - d. Please provide a list of the nursing homes that were cited for *both* inappropriate prescribing of antipsychotics and resident harm (in 2017 and 2018), a description of the reasons the surveyor determined these cases were harmful, the penalties imposed, and any other remediation actions CMS is planning to take.
3. What steps is CMS taking to review and ultimately address nursing homes *falsifying psychotic condition diagnoses* primarily for the purpose of facilitating inappropriate prescribing of antipsychotics to be used as a chemical restraint?
  - a. Has CMS examined trends in diagnoses of psychosis or other qualifying disorders that result in the use of antipsychotics during nursing home stays using the Minimum Data Set (MDS) or other data sources? If the agency has, please provide such analysis. If it has not, please either provide details on any plans for such analysis or the rationale for this omission from CMS analytic oversight activities.
  - b. For facilities with significant reductions in antipsychotic prescribing between 2015 and 2018, to what extent has the agency compared trends in qualifying disorders (i.e., bipolar and psychotic disorders) during this time period with previous years? Have you identified a spike in qualifying disorders that exceed expectations based on national longitudinal trends that could indicate some facilities are falsifying diagnoses? Please provide these data.
4. The relationship between nursing home staffing (specifically RNs) and antipsychotic misuse has been well established. To what extent have you been tracking the relationship between facilities with high rates of antipsychotic use and their staffing levels? Please provide any analyses the agency has conducted.

5. In response to the CMS Partnership, nursing home providers and staff have received trainings about care for patients with dementia that are designed to also reduce inappropriate use of antipsychotics.
  - a. How have you evaluated these trainings? Please describe which trainings have been most successful and least successful in impacting the rate of antipsychotics prescribing.
  - b. Please provide any guidance or educational materials CMS has issued to nursing home medical directors and/or staff and consultant pharmacists employed in nursing facilities to provide education on appropriate prescribing and dispensing of these medications.
6. The inappropriate use of antipsychotics for nursing home residents increases the risk of adverse events and, thus, hospitalizations. How much Medicare spending is likely attributable to adverse events from inappropriate antipsychotic prescribing in nursing homes? Please provide data on the relationship between antipsychotic use, hospitalizations, and associated Medicare spending.

We would like to begin this conversation by scheduling a briefing within two weeks of this letter during which we can discuss a timeframe for CMS's providing a written report with responses to the questions posed in this letter. Please contact Amy Hall of the Committee on Ways and Means Majority staff to schedule the briefing at (202) 225-3625.

Thank you for your attention to this critical matter. I know we can both agree that many Medicare beneficiaries are being needlessly harmed by these inappropriate patterns of prescribing, and I look forward to continuing to work with CMS to remedy this issue.

Sincerely,



Richard E. Neal  
Chairman

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<sup>i</sup> Food and Drug Administration (FDA), "Information for Healthcare Professionals: Conventional Antipsychotics," June 16, 2008, <https://www.fda.gov/Drugs/DrugSafety/ucm124830.htm> (accessed September 23, 2017); FDA,

<sup>ii</sup> <https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf>; 252,335 residents (as per MDS Frequency Report 2018 Q2)

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

<sup>iv</sup> Chiu, Bero, Hessol, Lexchin, Harrington. A literature review of clinical outcomes associated with antipsychotic medication use in North American nursing home residents. *Health Policy*. 2015  
<http://dx.doi.org/10.1016/j.healthpol.2015.02.014>

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

<sup>vi</sup> <https://nursinghome411.org/wp-content/uploads/2018/11/LTCCC-Advisory-Nursing-Home-Drugging-Citations-November-2018.pdf>



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<sup>vii</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>viii</sup> <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Pharmacy-Education-Materials/Downloads/atyp-antipsych-adult-factsheet11-14.pdf>

<sup>ix</sup> <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SC-Letter-16-28-Partnership-Update-Report.pdf>

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