

# COMMITTEE ON WAYS AND MEANS

U.S. HOUSE OF REPRESENTATIVES  
WASHINGTON, DC 20515

August 28, 2019

Bill Osborn, PharmD, President  
National Community Pharmacists Association  
Long Term Care Division  
205 Daingerfield Road,  
Alexandria, VA 22314

Re: Inquiry regarding overuse of antipsychotics in nursing homes

Dear Dr. Osborn:

I remain concerned about the persistent overuse of antipsychotics in nursing homes as a chemical restraint. As you know, the Food and Drug Administration (FDA) issued a black box warning for the use of these drugs, indicating that when elderly patients with dementia are treated with antipsychotics, they face a two-fold risk of death, as well as other adverse events, such as hip fractures, thrombotic events, cardiovascular events, and hospitalizations.<sup>1</sup> Furthermore, patients over 70 are 3.5 times more likely than younger individuals to be hospitalized due to antipsychotic-related adverse drug reactions, with negative implications for Medicare spending.<sup>2</sup> Long-term care (LTC) pharmacies could play a vital role in the monitoring and oversight of this problem.

Currently, more than 20 percent of all nursing home residents continue to receive antipsychotics, while only about two percent have qualifying conditions that would medically indicate such drugs are appropriate.<sup>3</sup> Data recently provided to the Ways and Means Committee by the Centers for Medicare & Medicaid Services (CMS) documents that approximately 5,700 nursing homes received a citation for the misuse of antipsychotics in 2017-2018, constituting more than a third of all nursing homes in the country. Furthermore, the latest CMS *National Partnership to Improve Dementia Care* data, released in December 2018, indicated that nursing homes have made only limited progress toward CMS's goal of curbing the practice of

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<sup>1</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). Chiu, Bero, Hessel, 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>2</sup> Brooks, Hoblyn. Neurocognitive costs and benefits of psychotropic medications in older adults. *Journal of Geriatric Psychiatry and Neurology*. 2007;20:199-214.

<sup>3</sup> <https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf> ; 252,335 residents (as per MDS Frequency Report 2018 Q2). 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. <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.htm>

inappropriately prescribing antipsychotics to nursing home residents.<sup>4</sup> I am concerned that CMS's cited progress in reducing inappropriate prescribing may not reflect a true reduction in antipsychotic use but, instead, may stem from falsified psychosis diagnoses.<sup>5</sup>

If antipsychotics are used for off-label treatment of seniors with non-qualifying diagnoses, informed consent must be given by the patient or family; but evidence shows that is not happening.<sup>6</sup> Furthermore, the American Psychiatric Association (APA) recommends that if antipsychotics cannot be avoided, then: 1) the dosage should be started as low as possible; 2) second generation antipsychotics are preferable; 3) clinical benefits should be closely observed; 4) medications should be discontinued if no benefit is observed; and 5) an attempt to taper patients off antipsychotics should occur every four months.<sup>7</sup>

Given the role of LTC pharmacies in monitoring and guiding nursing facilities in best practices for medication administration, I am examining specific activities, strategies, and monitoring of antipsychotics that LTC pharmacies could engage in to help rectify this problem. To begin the dialogue, I ask that you address the following questions:

1. Please describe industry best practices that LTC pharmacies should employ to mitigate the incidence of off-label prescribing of antipsychotics among nursing home residents without qualifying conditions. What goal has the National Community Pharmacists Association set (and over what time period) to reduce the incidence of such inappropriate prescriptions to match the two percent incidence of need found in the population?
2. As referenced above, the APA has made a number of recommendations relating to usage of antipsychotics in the elderly population, including appropriate dosage, obtaining informed consent, and regular attempts to taper.
  - What processes are recommended by the National Community Pharmacists Association to ensure that the APA guidelines are being followed for those being administered antipsychotics for off-label use? To what extent has your organization engaged in campaigns to educate LTC pharmacists about these guidelines?
  - What kinds of opportunities for continuing education are available to LTC pharmacists? To what extent are there requirements for such additional training?
  - Does the National Community Pharmacists Association monitor or otherwise collect data on pharmacy adoption of best practices for the prescription of antipsychotics to nursing home residents for off-label use?

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<sup>4</sup> <https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf>

<sup>5</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. <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Pharmacy-Education-Materials/Downloads/atyp-antipsych-adult-factsheet11-14.pdf>

<sup>6</sup> Human Rights Watch. Abuse of Antipsychotics in Nursing Homes: The Human Tragedy. 2018. <https://www.hrw.org/video-photos/interactive/2018/02/05/nursing-homes>

<sup>7</sup> Substance Abuse and Mental Health Services Administration. Guidance on Inappropriate Use of Antipsychotics: Older Adults and People with Intellectual and Developmental Disabilities. April, 2019. [https://store.samhsa.gov/system/files/pep19-inappuse-br\\_0.pdf](https://store.samhsa.gov/system/files/pep19-inappuse-br_0.pdf)

3. What safeguards do LTC pharmacies employ to ensure that off-label antipsychotics are only dispensed with informed consent forms signed by patients, families or guardians?
  - Are such pharmacies required to or expected to follow best practices with respect to obtaining and maintaining consent forms?
  - Where or how are these consent forms kept on file?
4. In the event an LTC pharmacy or pharmacist operating therein has concerns about inappropriate antipsychotic prescribing, what steps are available to them to address the situation?
  - What is the responsibility of the National Community Pharmacists Association when it determines that APA guidelines for the prescription of antipsychotics to nursing home patients are not being followed?
  - Does the National Community Pharmacists Association monitor or otherwise collect data on pharmacy adherence to APA guidelines for prescription of antipsychotics to nursing home patients?
5. Does your organization conduct analyses to identify facilities with high rates of “new” psychosis, Huntington’s disease, or Tourette’s syndrome diagnosis for older adults after nursing home admission? If so can you provide such analyses?
6. We are concerned that hospitalizing nursing home residents might increase their use of antipsychotics, even when they return to the facility. Specifically, when a nursing home resident is sent to the hospital and prescribed antipsychotics during his/her stay, does medication reconciliation occur at the point of readmission to the nursing home to determine if continued use is necessary?
  - Can you provide data on the relationship between hospitalizations and new or increased use of antipsychotics among nursing home residents?

I know we all share the goal of improving patient care for residents in nursing home facilities, and I look forward to working with your member pharmacies to address this crisis. I ask that, within two weeks, you schedule a time to brief my staff and discuss a plan for developing written responses to the aforementioned questions. Please contact Amy Hall of the Committee on Ways and Means Majority staff to schedule the briefing at (202) 225-3625 or Amy.Hall@mail.house.gov.

Sincerely,

  
Richard E. Neal  
Chairman