

COMMITTEE ON WAYS AND MEANS

U.S. HOUSE OF REPRESENTATIVES

WASHINGTON, DC 20515

July 25, 2018

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, D.C., 20201

Re: Antipsychotics in individuals with dementia-related psychosis

Dear Administrator Verma:

Each week, more than 179,000 nursing home residents across the country receive antipsychotic drugs without their informed consent or clinical rationale.ⁱ According to the Food and Drug Administration (FDA) black box warning on the drugs, elderly patients with “dementia-related psychosis,” who are treated with antipsychotic drugs, face a two-fold risk of death.ⁱⁱ While only one percent of the U.S. population has schizophrenia, some nursing home facilities have rates of antipsychotic drug use in excess of 50 percent.ⁱⁱⁱ

Inappropriate use of antipsychotic drugs is in violation of long-standing federal rules, which stipulate that, “Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record.”^{iv} Unfortunately, there appears to be a disconnect between Medicare coverage of these drugs and the rules regarding when beneficiaries should receive them.^v Given these urgent concerns, I write to better understand the Centers for Medicare & Medicaid Services’ (CMS) guidance relating to the use of antipsychotics in nursing homes, particularly with respect to the responsibility of Part D prescription drug plan oversight.

Medicare Part D plans pay for prescriptions for many nursing home residents. As such, I would like to better understand how CMS can leverage Part D plans and sponsors to promote proper prescribing and use of these medications to improve

patient safety – similar to the way the agency is handling the opioid epidemic. I ask that you respond to the following questions:

- What guidance has the agency provided on the coverage of antipsychotics for individuals in nursing facilities to Part D plans?
- What responsibilities do Part D plans have to monitor prescriptions of these medications?
 - Are Part D plans required to identify and report suspicious prescribing patterns whereby a plan experiences a significant number of anti-psychotic prescriptions provided to individuals residing in facilities?
 - What action can CMS or the plan take upon identification of any suspicious prescribing patterns? What are the internal mechanisms in place at CMS to handle these reports?
 - Are plans required to educate beneficiaries or the family or surrogate health decision maker about use of anti-psychotics in individuals with dementia-related illnesses?
- What efforts are underway at CMS to identify facilities with extreme use of anti-psychotics and educate facility staff and administrators on appropriate prescribing of such medicines? What tools does CMS have to address bad actors and improper prescribing patterns? Does CMS have a threshold percentage of patients taking antipsychotics that would trigger an audit? If so, what is that threshold?
- While these drugs fall into the “protected class” category of Part D, it is still incumbent on the Part D plan to ensure enrollees being prescribed medications in accordance with standards of care and FDA warnings. What tools do plans have to monitor use of antipsychotics for individuals for whom such medication is contra-indicated and deny coverage of drugs when they are not medically appropriate?
 - How is CMS monitoring plans’ efforts in protecting patients against inappropriate prescribing patterns, as many of these patients may be unable to advocate for themselves?

Finally, I request that CMS provide a list of the facilities on the *Nursing Home Compare* website that have antipsychotic use greater than 25 percent, noting whether surveyors have cited any facilities on such list for either an antipsychotic drug deficiency (“unnecessary drug” deficiency) or inappropriate use of chemical restraints. Please also indicate whether such facilities have been audited to determine whether the use of an antipsychotic is contra-indicated for individual patients.

Thank you for your attention to this important matter. I look forward to working with you to ensure that our family members and neighbors and friends in nursing homes across the country receive appropriate medical care and are treated with the respect and dignity they so deserve.

Sincerely,



Richard E. Neal
Ranking Member

ⁱ <https://www.hrw.org/video-photos/interactive/2018/02/05/nursing-homes>

ⁱⁱ 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, “Public Health Advisory: Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances,” April 11, 2005, <https://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm053171> (accessed September 23, 2017).

ⁱⁱⁱ <https://www.hrw.org/video-photos/interactive/2018/02/05/nursing-homes>

^{iv} 42 C.F.R. sec. 483.45(e)(1)-(2)

^v Office of Inspector General, “Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents,” <https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf> pp. 7, 15.