



February 16, 2021

The Honorable Xavier Becerra
Secretary-designate, U.S. Department of Health and Human Services
Attorney General, State of California
1300 I Suite, Suite 1740
Sacramento, California 95814-2954

RE: Comments on the Proposed Rule “Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Efficiency, and Transparency,” 84 Fed. Reg. 34737 (July 18, 2019), file code CMS-3347-P

Dear Secretary-designate Becerra,

We, the undersigned organizations, appreciate your engagement in the important issue of safe, high-quality, nursing home care for older adults. We are writing today in reference to your September 16, 2019 letter to the Centers for Medicare and Medicaid Services (CMS) regarding the center’s proposed rule to improve oversight of antipsychotic medications in long-term care facilities (LTCF) and nursing home throughout the country.¹ We share in your concerns related to the inappropriate use of antipsychotics and the rules related to their management. Our collective organizations have a strong, collaborative track record aimed at ensuring the appropriateness of antipsychotic use in post-acute and long-term care settings. We would like to take this opportunity to convey some of the joint work that our organizations have undertaken towards our shared goal, which build upon the expertise of our patients and professions.

Our organizations have joined together under Project PAUSE (Psychoactive Appropriate Use for Safety and Effectiveness), an ad hoc coalition of national patient and professional organizations collectively advocating on clinical care regulatory and legislative issues in long-term care and the community, including an improved metric on antipsychotic drug use in long-term care settings for the diagnosis and management of behavioral and neuropsychiatric symptoms (NPS) in dementia. Project PAUSE aims to educate policymakers and the public about clinical care issues in long-term care and the

¹ [Comments on the Proposed Rule “Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Efficiency, and Transparency,” 84 Fed. Reg. 34737 \(July 18, 2019\), file code CMS-3347-P](#)

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community, and collectively advocate for effective solutions. Project PAUSE has been engaging with the Centers for Medicare & Medicaid Services (CMS) and national representatives to promote policies in LTC settings that will curb the inappropriate use of antipsychotics and ensure access and appropriate use of these medications by patients who may clinically benefit.

The important decision to reduce and/or eliminate medications is one based on diagnosis, evidence, and thorough evaluation of patient welfare. Relying on professional clinical medication recommendations from health care practitioners is the only effective instrument in reducing the inappropriate use of medications, but there are inconsistencies within the current regulatory framework that does not provide a clear path to appropriate antipsychotic documentation and management. As a result, Project PAUSE asserts that CMS’ July 18, 2019 proposed rule is a step in the right direction that empowers clinicians to make clinically appropriate decisions in coordination with their patients or legal guardians.

We are concerned that the comments made in your September 16, 2019 letter to CMS would negatively impact patient care and the clinician-patient relationship. In the letter you stated, "Easing the restrictions on the overprescription of these drugs by eliminating the distinction between antipsychotics and other classes of psychopharmacologic drugs, furthers a dangerous policy that is in conflict with the plain language of the SSA, which states that these medications should be used only “to eliminate or modify the symptoms for which the drugs are prescribed.” However, the proposed rule does not suggest that antipsychotics would be more likely to be overprescribed, used inappropriately, or used for an unacceptable symptom or condition. CMS clearly states in their proposed rule that their recommended change applies only to antipsychotics that are used on an “as needed” or PRN basis. CMS’s proposed changes to the antipsychotic PRN limitation - which currently requires an in-person evaluation by the physician before the physician can extend the PRN use beyond 14 days – would mimic the PRN limitation applied to all other psychotropic drugs and allow the prescriber to extend the 14-day limit through a telephone conversation with the nurse or a telehealth visit with the resident. CMS explains that this change is in response to situations where rural facilities do not have access to psychiatrists or attending physician who can make an in-person visit to the facility for the purpose of evaluating the resident for an extension of their PRN order.

CMS further states that their concerns apply to the strict “in-person” visit requirement on PRN antipsychotic use that may result in residents being placed on routine antipsychotics when they could have been better managed on a PRN basis. The proposed change continues to mandate all the other requirements for antipsychotic use

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such as non-pharmacological interventions, appropriate indication for use, appropriate monitoring in place, and periodic consideration of the need for a gradual dose reduction or discontinuation. This assurance of appropriate use applies to PRN use of an antipsychotic while reducing the risk that a NF resident may go untreated (once the 14-day PRN expires) or may be exposed to more antipsychotic treatment than needed (if PRN is changed to routine).

Both national nursing home organizations, Project PAUSE, and nearly every LTC professional organizations supported the proposed change as a positive step to improve patient care. Antipsychotics are rarely prescribed on a PRN basis, but when they are, the prescriber should be able to determine the appropriate length of therapy based on the patient’s individual condition and needs.

We encourage support for our nation’s most medically vulnerable citizens and request your partnership in strengthening clinician and staff’s ability to appropriately meet patient needs. We ask you to help us ensure that regulations align with the highest standard of care and support. We welcome the opportunity to meet with you or a member of your staff to discuss our concerns and the safety of our patients in more detail. If your staff are available for a meeting, please have them contact Michael Ward at mward@agingresearch.org to coordinate. Once again, thank you for your leadership on this important issue.

Sincerely,

Alliance for Aging Research
AMDA, The Society for Post-Acute and Long-Term Medicine
American Association for Geriatric Psychiatry
American Association of Post-Acute Care Nursing
American Society of Consultant Pharmacists
Caregiver Action Network
Gerontological Society of America
National Community Pharmacy Association

Cc: HHS Acting Secretary Norris Cochran, HHS Chief of Staff Sean McCluskie, CMS Acting Administrator Elizabeth Richter