Congress of the United States

Washington, DC 20515

September 27, 2023

The Honorable Chiquita Brooks-LaSure Administrator Centers for Medicare and Medicaid Services U.S. Department of Health and Human Services 200 Independence Avenue, SW Washington, DC 20201

Dear Administrator Brooks-LaSure:

We appreciate your attention to the health and well-being of individuals residing in skilled nursing facilities (SNFs) and other long-term care facilities. Therefore, we write to express support for a provider and patient-driven update to the Centers for Medicare and Medicaid Services' (CMS) quality measures pertaining to the use of antipsychotic medications in nursing homes.

We fully recognize that over prescribing antipsychotic medications harms patients and strongly support safeguards to deter misuse and overuse. We applaud recent CMS efforts to thwart the over utilization and over-prescribing as antipsychotic medications as approximately 20 percent of all skilled nursing facility (SNF) residents (300,000 Americans) in the United States receive some type of antipsychotic medication, most without any psychosis diagnosis. Long-term care facilities continue to give these powerful drugs despite the Food and Drug Administration's (FDA) black box warning specifically stating that the use of off-label antipsychotics among seniors with dementia can result in injuries, hospitalizations, and even death.

CMS has placed an important focus on stopping and preventing the misuse of antipsychotic medications and promoting policies to prevent chemical restraints.³ We agree that this is a worthwhile pursuit, however, data utilized to comprise the current measure is incomplete, assessing only the total number of residents receiving antipsychotic medications and not analyzing the appropriateness of the use.⁴ In 2021, the U.S. Department of Health and Human

¹ Committee on Ways and Means, Majority, *Under-Enforced and Over-Prescribed: The Antipsychotic Drug Epidemic Ravaging America's Nursing Homes*, U.S. HOUSE OF REPRESENTATIVES (July 2020), https://democrats-waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/WMD%20Nursing%20Home%20Report Final.pdf.

² Atypical Antipsychotic Medications: Use in Adults, CTRS. FOR MEDICARE & MEDICAID SERVS. (Oct. 2015), https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Pharmacy-Education-Materials/Downloads/atyp-antipsych-adult-factsheet11-14.pdf.

³ Biden-Harris Administration Takes Additional Steps to Strengthen Nursing Home Safety and Transparency, CTRS. FOR MEDICARE & MEDICAID SERVS. (Jan. 18, 2023), https://www.cms.gov/newsroom/press-releases/biden-harris-administration-takes-additional-steps-strengthen-nursing-home-safety-and-transparency.

⁴ CMS Quality Measures, MDS QM User's Manual V15 (effective Jan 1, 2022), *available at* https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIQualityMeasures. Last visited July 10, 2023.

Services' Office of the Inspector General concluded that the current CMS measures related to the use of antipsychotics are insufficient.⁵ As such, we respectfully request consideration of adding a supplementary measure to capture information regarding appropriate or inappropriate uses.

Monitoring both the appropriate and inappropriate use of antipsychotics will protect the well-being of beneficiaries and will also advance the goal of increasing high-quality, patient-centered care. The supplementary measure should calculate the appropriate use of antipsychotic medications by following the standards and guidelines in the Resident Assessment Instrument User Manual. This proposed supplemental measure would continue to require prescribers to document their clinical rationale before prescribing an antipsychotic medication. Additionally, the facility's consultant pharmacist would be required to document gradual dose reduction attempts and other medication regimen review information. It is our recommendation that both providers will be required to continue monitoring the patient for continued clinical benefit, as required by law and existing clinic guidance. These three distinct requirements provide CMS with a line of sight into how many residents are receiving antipsychotics and the appropriateness or inappropriateness of the medicine for a specific patient. Most importantly, this process facilitates patient access to FDA-approved medications, including antipsychotics, as part of their comprehensive care plan.

While we strongly believe that this supplemental measure is needed, we recognize that the safeguards provided by the current measure have tremendous value. As such, the process for reporting and investigating the unnecessary use of a medication must continue. Under the proposed measure, should a state surveyor not find the three-pronged documentation certifying appropriate utilization for the patient, the facility should face scrutiny and potential civil monetary penalties by CMS. The combination of the current and proposed supplemental measure would allow CMS to comprehensively identify potential abuse and take corrective action.

We appreciate your attention to these concerns as we work together to increase the quality of care for all, especially Americans residing in SNFs. We look forward to your response.

Sincerely,

⁵ Office of Inspector General, CMS Could Improve the Data it Uses to Monitor Antipsychotic Drugs in Nursing Homes, U.S. DEPT. OF HEALTH AND HUMAN SERVS. (May 2021), https://oig.hhs.gov/oei/reports/OEI-07-19-00490.pdf.

⁶ Minimum Data Set (MDS) 3.0 Resident Assessment Instrument (RAI) Manual, *available at* https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/mds30raimanual. Last visited July 10, 2023.

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