



June 7, 2021

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

**Re: CMS–1746–P: Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2022**

Dear Administrator Brooks-LaSure:

Project PAUSE (Psychoactive Appropriate Use for Safety and Effectiveness) represents an ad hoc coalition of national patient and professional organizations that collectively advocates on clinical care regulatory and legislative issues in long-term care and the community. Project PAUSE has been engaging with the Centers for Medicare & Medicaid Services (CMS) and national representatives to promote policies in long-term care (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 coalition appreciates the opportunity to submit public comment on the rule. Many members of Project PAUSE will submit individual comment letters to CMS, reflecting their broad interest in the proposed skilled nursing facility (SNF) prospective payment system (PPS) rule. Given the focus of our coalition, our coalition letter focuses on proposed quality measurement provisions included in the proposed rule.

**Potential Future Measures for the SNF VBP Program**

In the proposed rule, CMS requests comments on potential future measures for the SNF value-based payment (VBP) Program and notes consideration of the “percentage of long-stay residents who got an antipsychotic medication” as a potential measure for inclusion. However, longstanding concerns exist about the accuracy and the relevance of this measure in reinforcing appropriate utilization of antipsychotics. Incorporation of this measure would be inappropriate

## Project PAUSE

Re: CMS–1746–P: Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2022

given failures in the current reporting mechanism, a lack of clarity on the definition of key terms used to determine this measure, and no demonstrated link to quality or value.

Ensuring appropriate care for patients with dementia is essential. Non-pharmacological approaches are the first choice for treatment for patients; this should continue to be the case. However, in cases where patients are suffering from advanced dementia or present a threat to others, antipsychotic medications should be viewed as an option if non-pharmacological treatments have been attempted – and appropriately documented in the clinical record – yet fail to meet the patients’ needs. Neuropsychiatric symptoms (NPS) are associated with earlier death, supporting the need for active treatment of these symptoms to prolong and improve quality of life.<sup>1</sup> Multiple studies<sup>2,3,4</sup> have illustrated the safety of the use of antipsychotics in treating NPS and their efficacy in alleviating symptoms, especially when an approach is well-targeted for patients.<sup>5</sup>

Unfortunately, rates of dementia and related symptoms continue to grow, especially for older adults. Clinical data shows that nearly all dementia patients will develop at least one NPS over the course of their disease<sup>6</sup> and one-third of dementia patients will present depression as their earliest observable symptom.<sup>7</sup> Specific to long-term care, especially at facilities specializing in caring for individuals with dementia, NPS associated with dementia may include psychosis, wandering, sleep issues, agitation, depression, apathy, and aggression, and can create challenges that disturb or harm the patient themselves or other patients in the facility. For patients that suffer from severe NPS, antipsychotic drugs can be used as part of a multidisciplinary care plan to successfully manage symptoms for patients, both in and out of long-term care settings.

---

<sup>1</sup> Peters ME, et al., Neuropsychiatric symptoms as predictors of progression to severe Alzheimer’s dementia and death: The Cache County Dementia Progression Study, *Am J Psychiatry*. 2015 May 1; 172(5):460–465.

<sup>2</sup> Schneider LS, et al. “Effectiveness of Atypical Antipsychotic Drugs in Patients with Alzheimer’s Disease”. *The New England Journal of Medicine*. 2006. 355(15):1525-38

<sup>3</sup> Porsteinsson AP, et al. Effect of citalopram on agitation in Alzheimer disease: the CitAD randomized clinical trial. *JAMA*. 2014;311(7):682–691. [www.ncbi.nlm.nih.gov/pubmed/24549548](http://www.ncbi.nlm.nih.gov/pubmed/24549548)

<sup>4</sup> Cummings, JL, et al. Effect of Dextromethorphan-Quinidine on Agitation in Patients with Alzheimer Disease Dementia: A Randomized Clinical Trial, *JAMA*. 2015;314(12) 1242-1254. <https://jamanetwork.com/journals/jama/fullarticle/2442936>

<sup>5</sup> Devanand DP, et al. (2012). Relapse risk after discontinuation of risperidone in Alzheimer’s disease. *The New England Journal of Medicine*, 367 16, 1497-507.

<sup>6</sup> Kales HC, Gitlin LN, Lyketsos CG. *State of the Art Review: Assessment and management of behavioral and psychological symptoms of dementia*. *British Medical Journal* 2015;350:h369.

<sup>7</sup> Masters MC, Morris JC, Roe CM. *Noncognitive Symptoms of Early Alzheimer Disease: A longitudinal analysis*. *Neurology* 2015; 84:617–622.

## Project PAUSE

Re: CMS–1746–P: Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2022

Numerous other health professional organizations have highlighted the need for appropriate use of antipsychotics, including in SNFs. In 2012, American Medical Association (AMA) established Policy D-120.951 or the Appropriate Use of Antipsychotic Medication in Nursing Homes.<sup>8</sup> At the June 2019 AMA House of Delegates meeting in Chicago, IL, amended resolution 708 was adopted. The resolution stated: “RESOLVED, That our AMA ask CMS to discontinue the use of psychotropic medication as a factor contributing to the Nursing Home Compare rankings, unless the data utilized is limited to medically inappropriate administration of these medications.” Further, a May 2021 Office of the Inspector General (OIG) report also plainly states, “These drugs can be effective in treating a range of conditions, but they carry risk and must be prescribed appropriately.”<sup>9</sup> This class of drugs are recognized as having an appropriate role in care – though one that merits continued monitoring and evaluation to determine the appropriate use case for a patient that incorporates potential benefits and risks – and quality measures should reflect, rather than impede, clinical best practices.

However, the antipsychotic measure included in the SNF Five-Star Quality Program, as it is currently calculated, does not meet this standard. The current measure provides a basic calculation of the number of patients currently taking an antipsychotic divided by the facility’s patient census. This measurement is not reflective of clinical best practice, nor does it provide accurate information on the quality or value of care provided by the SNF. Rather, the measure has created perverse incentives including denial of admissions for those with pre-existing use of antipsychotic medications and the re-admission of those who were hospitalized and placed on antipsychotics during their hospitalization. These incentives exist because the current measure reflects any use of antipsychotics, rather than inappropriate use. This creates incentives to utilize other, less appropriate medications (for example, anti-epileptic medications) that are not included in the metric. Project PAUSE is concerned that continued reliance on this measure, both in the Five Star Ratings and in a SNF VBP assessment, will have unintended consequences that worsen patient outcomes, reduce appropriate management of mental health conditions, increase health inequities, and cause preventable patient harm.

The current reporting mechanism for this measure also does not allow for variation between facilities, which can drive greater health inequities. Many SNFs specialize in the care of older adults with dementia and many rural SNFs admit a higher ratio of residents with psychosis than

---

<sup>8</sup> American Medical Association. *Appropriate Use of Antipsychotic Medications in Nursing Homes*. Accessed May 2021. Policy last updated in 2019. <https://policysearch.ama-assn.org/policyfinder/detail/Appropriate%20Use%20of%20Antipsychotic%20Medications%20in%20Nursing%20Home%20Patients%20D-120.951?uri=%2FAMADoc%2Fdirectives.xml-0-77.xml>

<sup>9</sup> Department of Health and Human Services, Office of Inspector General. *CMS Could Improve the Data It Uses to Monitor Antipsychotic Drugs in Nursing Homes*. May 2021. <https://oig.hhs.gov/oei/reports/OEI-07-19-00490.pdf>

## Project PAUSE

Re: CMS–1746–P: Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2022

urban facilities.<sup>10,11</sup> Because of the case-mix of residents they accept, these facilities may have a higher percentage of residents that utilize antipsychotics, under the prescription of medical professionals. However, current quality scores report only the frequency of use, rather than assessing the quality of care provided. As a result, it can be unclear whether a poor score reflects poor resident care or merely the demographics of the resident population or SNF location. The lack of direct relation to quality in the metric's score could steer patients with dementia away from facilities most adept at providing appropriate treatment for their condition.

We strongly recommend that CMS not use the current “Percentage of Long-Stay Residents who got an Antipsychotic Medication” measure in the SNF VBP Program. While tracking appropriate utilization of antipsychotic medication use is vital, the measure fails to meet this goal. We instead encourage CMS to evaluate a revision of this measure, including a thorough discussion of appropriate alternative measure specifications aligned to include antipsychotic utilization as determined through the Long-Term Care Facility Resident Assessment Instrument (RAI) User Manual. By existing CMS regulation, consultant pharmacists frequently review a patient's prescribed medications, at least on a monthly basis, and actively communicate their review with the prescriber. We urge CMS to incorporate a multidisciplinary review, including by a consultant pharmacist, of antipsychotic medications in the documentation of antipsychotic use. This process would support accurate documentation of medication management and medication regime review that can then support the quality measure. Project PAUSE recently published a proposed framework for a measure<sup>12</sup> that would more closely and accurately reflect inappropriate antipsychotic usage and support the ability of surveyors to investigate inappropriate prescribing of antipsychotics. Project PAUSE is committed to appropriate measurement and ongoing validation of the appropriateness of antipsychotic medications to support patient-centered care. We look forward to working with CMS and other stakeholders in this effort.

---

<sup>10</sup> Rural Policy Research Institute. *Assessing the Unintended Consequences of Health Policy on Rural Populations and Places*. December 2018. <https://rupri.org/wp-content/uploads/Evaluating-the-Impact-of-Policy-Changes-on-Rural-Populations.pdf>

<sup>11</sup> Bowblis JR, Meng H, Hyer K. The Urban-Rural Disparity in Nursing Home Quality Indicators: The Case of Facility-Acquired Contractures. *Health Services Research*. February 2013; 48(1): 47-69. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3589954/>

<sup>12</sup> Project PAUSE. *Project PAUSE: Effective Solutions for Improving Clinical Care in Long-Term Care Settings*. [https://www.agingresearch.org/app/uploads/2020/12/Project\\_PAUSE\\_Final.pdf](https://www.agingresearch.org/app/uploads/2020/12/Project_PAUSE_Final.pdf)

**Project PAUSE**

Re: CMS–1746–P: Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2022

**Conclusion**

Project PAUSE appreciates the opportunity to provide feedback on the SNF VBP program quality measures. We welcome the opportunity to be a resource to CMS on these important issues and ensuring appropriate utilization. For additional information, please contact Michael Ward, vice president of public policy for the Alliance for Aging Research, at [mward@agingresearch.org](mailto:mward@agingresearch.org).

Signed,

Alliance for Aging Research  
AMDA - The Society for Post-Acute and Long -Term Care Medicine  
American Association for Geriatric Psychiatry  
American Association of Post-Acute Care Nursing (AAPACN)  
American Society of Consultant Pharmacists  
Caregiver Action Network  
National Community Pharmacists Association  
National Minority Quality Forum  
The Gerontological Society of America