



June 10, 2022

The Honorable Chiquita Brooks-LaSure
Administrator, Center for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244-8013

RE: CMS-1765-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 2023; Request for Information on Revising the Requirements for Long-Term Care Facilities to Establish Mandatory Minimum Staffing Levels

Dear Administrator Brooks-LaSure:

On behalf of Project PAUSE (Psychoactive Appropriate Use for Safety and Effectiveness), convened by the Alliance for Aging Research and the American Society of Consultant Pharmacists (ASCP), we are writing to thank you for the opportunity to submit comments on the proposed rule *CMS-1765-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 2023; Request for Information on Revising the Requirements for Long-Term Care Facilities to Establish Mandatory Minimum Staffing Levels*.

Project PAUSE seeks to ensure that all individuals who have Alzheimer's disease, dementia, serious mental health, and other conditions and who reside in long-term care settings (LTC) – such as a Skilled Nursing Facility (SNF), nursing home, or an assisted-living setting – receive high-quality, patient-centered, appropriate care and treatment without facing stigma or barriers. To that end, our comments below focus on the SNF Quality Reporting Program (QRP) Quality Measures and the Overarching Principles for Measuring Equity and Healthcare Quality Disparities Across CMS Quality Programs Request for Information (RFI).

We thank you in advance for your consideration of our views. Please know that we stand ready to work with you and your colleagues to develop and implement policies and programs to ensure that Medicare beneficiaries whose providers have determined they would benefit from antipsychotic medications have access to them.

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Background on Neuropsychiatric Symptoms

As we age, diseases and injuries that damage the brain can lead to significant and disabling behavioral and psychological symptoms, also referred to as neuropsychiatric symptoms (NPS). Those NPS that lead to mood and emotional changes are the symptoms that almost no one talks about, but they are common in Alzheimer’s disease and other dementias, Parkinson’s disease, multiple sclerosis; and brain tumors, infections, and injuries. For example, while cognitive impairment is regarded as the hallmark indicator of dementia, NPS are nearly as universal, with one or more symptoms affecting nearly all people with dementia over the illness course. NPS are associated with earlier death, supporting the need for active treatment of these symptoms to prolong and improve quality of life.¹ Multiple studies^{2,3,4} have illustrated the efficacy in alleviating symptoms and safety of the use of antipsychotics in treating NPS, especially when an approach is well-targeted for patients.⁵

Earlier generations of antipsychotics drugs have historically been overused. However, new therapeutics are now available, and others are under development that have improved clinical safety and efficacy outcomes compared to their precursors. The use of antipsychotics among LTC residents has received significant attention from policymakers, patient advocacy organizations, and health professional societies, with a particular focus on ensuring these drugs are not used as “chemical restraints.” We agree that safeguards are necessary to ensure appropriate utilization. Further, we support the primary use of non-pharmacologic interventions and environmental supports to manage NPS. At the same time, an August 2020 final systematic evidence review by AHRQ of non-pharmacologic interventions found, “Despite hundreds of studies, very little evidence supports widespread dissemination of any general care approaches for PLWD [people living with dementia] or caregivers. This review demonstrates the need for larger, longer-term, and more rigorous studies of interventions.”⁶ Many Medicare beneficiaries suffer from a range of

¹ 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.

² 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

³ 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

⁴ 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>

⁵ 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.

⁶ Butler M, et al. *Care Interventions for People Living with Dementia and Their Caregivers. Comparative Effectiveness Review No. 231*. (Prepared by the Minnesota Evidence-based Practice Center under Contract No. 290-2015-00008-I.) AHRQ Publication No. 20-EHC023. Rockville, MD: Agency for Healthcare Research and Quality; August 2020. Posted final reports are located on the Effective Health Care Program search page. DOI: <https://doi.org/10.23970/AHRQEPCER231>.

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NPS and could benefit from treatment, which may include the use antipsychotics when clinically appropriate to manage symptoms. As such, it is imperative that our nation's policies, programs, and practices facilitate access to appropriate use of antipsychotics while preventing inappropriate use and incorporating inappropriate incentives that do not align with best care practices. It is with this dual goal in mind we offer the following comments.

SNF QRP Quality Measures Under Consideration for Future Years: Request for Information (RFI)

We appreciate that the agency regularly solicits input from the public regarding quality measures it is considering for the SNF QRP. Last year, during the public comment period, we provided feedback on the agency's proposal to incorporate the *Percentage of Long-Stay Residents who got an Antipsychotic Medication into the SNF Value-Based Purchasing Program* (SNF VBP Program). As the agency noted in its final FY 2022 SNF payment regulation, "Many commenters generally supported the adoption of new measures in the SNF VBP Program. However, many commenters did not support the Percentage of Long-Stay Residents who got an Antipsychotic Medication measure noting concerns with disincentivizing clinically appropriate access to FDA-approved medications, impact on patient care and outcomes, and that the measure is not NQF-endorsed."

We thank you and your colleagues for listening to public feedback in this regard and not including this flawed measure in the VBP. Moreover, we appreciate that CMS is not currently proposing that the measure be included in the SNF QRP in the future. However, we remain very concerned about the use of this measure in the CMS Minimum Data Set (MDS), which is used to calculate the SNF star ratings. As such, we have developed an alternative measure that we ask the agency to consider as a replacement of the existing one. If CMS' goal of high-quality, patient-centered care for all Medicare and Medicaid beneficiaries is to be realized, all SNF and LTC residents who would benefit from antipsychotics prescribed by their providers should receive them, while those for whom they are inappropriate should not. CMS policies and programs should align with this dual goal.

To that end, we suggest that the existing measures (both the long-stay and short-stay version) be removed and our new measure (further explained below) first be incorporated into the SNF MDS and be tested and validated before it is considered for incorporation into either the SNF VBP or SNF QRP. The current CMS policy and measurement approach to antipsychotic use is not informed in any way by clinical need or individual patient nuance; it is a blunt instrument that merely captures the percentage of patients receiving antipsychotics without any line of sight into whether that use is appropriate and fails to consider data regarding those patients who should be receiving antipsychotics and who are not. 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. The current approach does not facilitate high-quality, patient-centered care.

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- A May 2021 HHS Office of Inspector General report found the current CMS antipsychotic quality measure fails to distinguish between appropriate and inappropriate use. Rather, the measure only reports the percent of residents who use antipsychotics rather than identifying inappropriate use.⁷
- The current measure hampers clinicians from following best practices for clinical care, requires changes of medication regimens even for well-managed patients, and harms the ability for patients, families, and their clinicians to appropriately manage care.
- Because the measure is inextricably linked to the star ratings – and if included in the VBP program in the future, would impact reimbursement – there is a perverse incentive dynamic for SNFs to avoid appropriate care for patients whose dementia may require the use of antipsychotics. The quality metric is focused on lowering all use of anti-psychotics not on appropriate use. Therefore, these harmful incentives can result in:
 - Lower quality scores and reimbursement for SNFs that specialize in dementia and/or psychosis care, or for rural facilities that tend to have higher percentages of dementia and/or psychosis patients.
 - Clinicians prescribing less efficacious and less safe medications (such as antiepileptics) for symptom management, due to their omission from the measure.
 - SNF and LTC providers declining admission to certain patients that have a well-managed antipsychotic medication schedule, as the SNF would be required to attempt to wean the patient off the antipsychotic due to gradual dose reduction requirements and the pressure to reduce antipsychotic prescribing overall.

CMS has been utilizing the current measures for ten years. While overall antipsychotic medication use has decreased, **CMS and the public still have no accurate information regarding inappropriate utilization of antipsychotics.** Further, as the population of people over 65 years old continues to increase, the absolute number of patients suffering from NPS also will continue to grow. The current quality measure utilized by The [National Partnership to Improve Dementia Care in Nursing Homes](#) stresses only that “lower is better,” which fails to incorporate medical appropriateness or patient and family preferences. The lack of precision in the measurement leads to inaccurate assessments of quality, misaligned incentives for high-quality care, and a regulatory environment that discourages investment in specialized dementia care services. This is not aligned with CMS’ goals of ensuring high quality, patient-centered care.

While the rationale behind the current measure is well-intended, its unintended effects include:

⁷ HHS Office of the Inspector General. *CMS Could Improve the Data It Uses To Monitor Antipsychotic Drugs in Nursing Homes*. 3 May 2021. <https://oig.hhs.gov/oei/reports/OEI-07-19-00490.asp>

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- Inappropriate management of serious mental health conditions;
- Poor resident outcomes for those for whom antipsychotics are indicated;
- **Increased health inequities**; and
- Preventable patient harm.

Numerous health professional organizations have highlighted the need for appropriate use of antipsychotics, including in SNFs. In 2012, the American Medical Association (AMA) established Policy D-120.951 on the Appropriate Use of Antipsychotic Medication in Nursing Homes.⁸ 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.*”

Again, for CMS to achieve its stated goal of high-quality, patient-centered care, the agency needs a measure that differentiates between appropriate and inappropriate use of antipsychotics among SNF residents.

Overarching Principles for Measuring Equity and Healthcare Quality Disparities Across CMS Quality Programs – Request for Information (RFI)

We commend CMS for including this RFI within the proposed rule. We support the agency’s efforts “to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our beneficiaries need to thrive.” To that end, we strongly urge the agency to recognize that the current measure capturing only antipsychotics use in SNFs does not advance equity and, in fact, may exacerbate existing inequities and disparities in care and outcomes given the demographics of Alzheimer’s disease and related dementias and the associated NPS.

For example, the Centers for Disease Control and Prevention (CDC) found that “Among people ages 65 and older, African Americans have the highest prevalence of Alzheimer’s disease and related dementias (13.8 percent), followed by Hispanics (12.2 percent), and non-Hispanic whites (10.3 percent), American Indian and Alaska Natives (9.1 percent), and Asian and Pacific Islanders (8.4 percent).”⁹ As such, appropriately treating the NPS associated with Alzheimer’s disease and related dementias is inextricably linked to addressing health disparities and advancing equity. Of

⁸ 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>

⁹ Centers for Disease Control and Prevention. *U.S. burden of Alzheimer’s disease, related dementias to double by 2060*. 20 Sept 2018. <https://www.cdc.gov/media/releases/2018/p0920-alzheimers-burden-double-2060.html>

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serious concern are reports that the manner in which antipsychotics are being used in SNFs differs based on race. In Fall 2021, *The New York Times*¹⁰ reported that

“A 2012 government effort to reduce unnecessary antipsychotic drug use in nursing homes included an exemption for residents with schizophrenia. Since then, the diagnoses have grown by 70 percent. Experts say some facilities are using the schizophrenia loophole to continue sedating dementia patients instead of providing the more costly, staff-intensive care that regulators are trying to promote. The impact of this has been more severe on Black residents, a new study in the *Journal of the American Geriatrics Society* has found. Since the new rules went into place, Black Americans with dementia have been 1.7 times as likely as their white nursing home neighbors to be diagnosed with schizophrenia, said Shekinah A. Fashaw-Walters, a public health researcher at the University of Minnesota and the study’s lead author.”

This article underscores the problem with the current measure; it does not provide any insights into appropriate or inappropriate use of antipsychotics, and it is contributing to health inequities. As *The New York Times* reported, “more than half of the officially reported reduction in drug [antipsychotic] use was attributable to the increase in schizophrenia diagnoses from the loophole in the new rules.” Moreover, we believe it is unconscionable for providers to use a diagnosis of schizophrenia to “to skirt the rules” as geriatrician and former nursing home executive Dr. Michael Wasserman told *The New York Times* in a related article.¹¹ The measure is flawed, and it is incentivizing the wrong behavior; it does not support the provision of – or result in – patient-centered care. Quality care should be centered on appropriate antipsychotic use.

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 urban facilities. Because of the case-mix of residents they accept, these facilities may have a higher percentage of residents who utilize antipsychotics under the prescription and guidance 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.* Further, rural facilities also serve as the primary source of care for dementia patients in their communities. Due to their

¹⁰ Gebeloff, R. *A Racial Disparity in Schizophrenia Diagnoses in Nursing Homes.* *The New York Times*, October 15, 2021.

¹¹ Gebeloff, Robert and Jessica Silver-Greenberg. *Phony diagnoses hide high rates of drugging at nursing homes.* *The New York Times*, September 11, 2021.

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smaller patient census, even a small number of additional patients that receive an antipsychotic as part of their care can significantly impact a facility's score on the quality measure.

We encourage CMS to consider these differential impacts and how they negatively harm equity across underserved populations. *It is unacceptable that a government measure meant to advance quality is operationalized in a manner that results in inequities and exacerbates existing health disparities.* Further, the measure's design presumes that all prescribing of antipsychotics is inappropriate. There are specified clinical circumstances under which the prescribing of antipsychotics is clinically indicated and warranted. Moreover, often patients themselves and/or their family members request treatment to alleviate NPS. All beneficiaries – those who would benefit from antipsychotics and those for whom they are inappropriate – deserve policies that ensure they receive the care and treatment that is best for them.

Proposed New SNF MDS Measure to Support Appropriate Antipsychotic Prescribing and Advance Equity

It is imperative that CMS begin to measure and monitor both the appropriate and inappropriate use of antipsychotics to protect beneficiary well-being and advance quality, patient-centered beneficiary care. Fortunately, there already exists information within a patient's medical record to support the assessment as to whether an antipsychotic is appropriate and there are federal and clinical standards in place to help mitigate inappropriate antipsychotic usage.

- The LTC Facility Resident Assessment Instrument (RAI) is used by SNFs to gather information on a resident's clinical needs, and it allows care teams to objectively document care plans, including whether a patient requires an antipsychotic medication and if so, whether a gradual dose reduction (GDR) is needed, and whether an antipsychotic medication is clinically contraindicated.
- Medication management is a clinical tool centered around the unique pharmacologic expertise of a consultant pharmacist and a patient's primary health care provider to tailor a patient's medication usage to their individual needs. Medication management standards are published in the State Operations Manual (SOM), which provides each individual state and CMS with regulatory oversight and authority.
- Generally, the prescribing clinician (physician or advanced practice practitioner) already documents the clinical rationale for antipsychotic use and the consultant pharmacist documents any GDR, safety, and regimen review information. The system has checks-and-balances based on the professional recommendation of at least two, independent health care providers and allows for patient-centric care and greater family input. However, affirming whether this documentation has occurred, and that treatment is aligned with the clinical record, is not currently part of the quality measure.

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Project PAUSE proposes that CMS retire the existing measures (long-stay and short-stay) and implement an updated, more refined metric that captures only those residents found to be receiving antipsychotics inappropriately. The MDS would document that the prescribing clinician and the consultant pharmacist performed their required reviews.

- **Numerator:** The number of residents (for the long-stay measure or the short stay measure) that have been prescribed antipsychotics for whom the prescribing clinician and consultant pharmacist have **not** documented **EITHER** that the use and dose are clinically appropriate **OR** have documented that a GDR is clinically contraindicated.
- **Denominator:** Total number of long stay residents or total number of short stay patients, as relevant to the associated measure.

Under this proposed measure:

- (1) Prescribing clinicians would continue to be required to document their clinical rationale for prescribing an antipsychotic medication.
- (2) Independently, the facility's consultant pharmacist would be required to document GDR and medication regimen review information. This allows improved CMS oversight of antipsychotic usage in SNFs, provides a well-documented process to support interdisciplinary clinical decision-making, and creates a measure that is adaptable to new evidence and clinical guidelines for treating NPS.
- (3) CMS would gain a line of sight into how many residents are receiving antipsychotics for whom the medication is inappropriate.

Any concern regarding an unnecessary use of a medication would still be investigated and reported by the surveyor, which is current practice. An accurate and appropriately sensitive measurement that reports on inappropriate use will make it easier for CMS to identify potential negligence, rather than relying on subjective criteria or judgment calls. Should a state surveyor not find the three-pronged documentation certifying antipsychotic utilization in a facility, the facility would face substantively supported citation and review for inappropriately prescribing antipsychotic medications. Together, these changes will advance equity and high quality, patient-centered care.

Conclusion

We are committed to reducing disparities, advancing equity, and improving outcomes, particularly for our nation's most vulnerable and underserved individuals, which includes those with Alzheimer's disease and related dementias. Project PAUSE stands ready to work with Congress and CMS to develop and implement policies to curb the inappropriate use of antipsychotics and ensure access and appropriate use of these medications for beneficiaries who need them. To that end,

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Project PAUSE believes that the first step toward achieving this dual goal is implementation of our proposed new measure and retirement of the existing measures.

We thank you for your consideration of our views and welcome the opportunity to discuss our suggestions further. Please contact Michael Ward at mward@agingresearch.org or Jim Lewis at jlewis@ascp.com for additional information on the recommendations included in this letter.

Sincerely,

Alliance for Aging Research
Alzheimer's Foundation of America
AMDA, The Society for Post-Acute and Long-Term Care Medicine
American Society of Consultant Pharmacists
Caregiver Action Network
The Gerontological Society of America
National Community Pharmacists Association
National Minority Quality Forum