April 17, 2025

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Dear Mr. Masi and Dr. Chernew,

On behalf of Project PAUSE (Psychoactive Appropriate Use for Safety and Effectiveness), thank you for addressing "*Regulations, star ratings, and FFS Medicare policies aimed at improving nursing home quality*" during the second day of your recent April meeting. We commend the Commission staff for an excellent presentation and appreciated the robust discussion among the commissioners regarding the failure of the current system to improve quality of care and outcomes for Medicare beneficiaries in nursing homes and skilled nursing facilities (SNFs). Project PAUSE is an ad hoc coalition of national organizations advocating about improvements in clinical, regulatory, and legislative policies in long-term care.

We had the pleasure of meeting with Mr. Masi and the MedPAC staff earlier this year during which we shared our concerns regarding how the current SNF star ratings long-stay measure related to antipsychotic use is having unintended consequences on the quality of care for beneficiaries with neurocognitive impairment. Given the recent Commission discussion about the flaws in the star ratings system, we wanted to share with you correspondence Project PAUSE recently submitted to Secretary of Health and Human Services Secretary Kennedy and Dr. Oz, Administration of the Centers for Medicare and Medicaid Services (CMS) calling for the elimination of this measure due to its distorting effects on the star ratings system and lack of evidence that the measure is improving care, safety, and outcomes.

We were particularly encouraged by the recognition among both MedPAC staff and commissioners that two key missing components of the star ratings system are patient experience and social risk factors. In our experience, the highest quality facilities with respect to care for individuals with neurocognitive impairment are those that specialize in care for that patient population; yet the long-term antipsychotic use measure makes no adjustment for facilities that focus on these special needs populations. Further, we also note that capturing the lived experience of patients with Alzheimer's and their loved ones is an essential factor in understanding what is – and is not – quality care. Family members regularly share with us the terrible challenges they face in securing the treatment their loved ones need, citing the overly restrictive Medicare policy related to antipsychotics as one often unsurmountable barrier to quality care.

We hope that the attached correspondence is helpful to you, the MedPAC staff, and the commissioners as you further explore this important topic and prepare the June Report to Congress. Please do not hesitate to reach out to us if we can be of any assistance on this or other topics of priority interest to MedPAC.

Best,

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Alliance for Aging Research
Co-Chair, Project PAUSE

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Enclosure: Correspondence to HHS Secretary Kennedy and CMS Administrator Oz

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April 9, 2025

The Honorable Robert F. Kennedy
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Mehmet Oz, MD, MBA
Administrator
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Dear Secretary Kennedy and Administrator Oz,

The undersigned members of Project PAUSE and other partners are writing to strongly urge you to take steps this spring to **eliminate the Long-Stay Antipsychotic Medication quality measure from the SNF Five-Star Quality Rating System** because it is wholly ineffective and impedes the provision of individualized, patient-centered care. Project PAUSE (Psychoactive Appropriate Use for Safety and Effectiveness) is an ad hoc coalition of national organizations advocating about improvements in clinical, regulatory, and legislative policies in long-term care.

During the previous administration, we engaged extensively with the Centers for Medicare and Medicaid Services (CMS), meeting with leadership numerous times over a period of several years to provide evidence on the unintended consequences of the current measure. Unfortunately, despite our repeated efforts, the Biden-Harris CMS was unwilling to reconsider its position, leaving SNFs and residents without a viable path forward to ensure appropriate and necessary care for neuropsychiatric symptoms (NPS) associated with neurocognitive impairment.

With the transition to new leadership within the Department of Health and Human Services (HHS) and CMS and the commitment from the Trump Administration to reduce burdensome regulations and eliminate requirements that do not contribute positively to patient care, we are hopeful that you will take a fresh look at this issue and work with us to ensure that nursing home residents living with all forms of neurocognitive impairment receive the care they need. By addressing this problem, HHS and CMS can support policies that allow these vulnerable individuals to live with dignity, receive clinically appropriate treatment, and avoid unnecessary suffering; at the same time HHS and CMS can reduce unnecessary regulatory burdens and eliminate a quality measure that does not provide meaningful information to patients and families.

We thank you for your consideration of our concerns and recommendations. We welcome an opportunity to discuss these critical issues with you further and will follow up with your staff shortly to identify a time to meet at your convenience.

Executive Summary

We advocate for the elimination of the CMS's Long-Stay Antipsychotic Medication quality measure from the Nursing Home Care Compare Star Ratings system because it counts ***all*** antipsychotic prescriptions, failing to distinguish whether the medication is being used appropriately or unnecessarily in patients with NPS associated with neurocognitive impairment and other conditions, only excluding individuals with schizophrenia, Huntington's disease, or Tourette's syndrome. This measure has led to clinically necessary treatments being withheld, potential residents being denied admission to nursing homes, and the application of an exempt diagnosis to some patients when the criteria for that diagnosis has not

been met.[1] All of this causes harm to residents and burdens providers. Moreover, the measure is not aligned with clinical practice guidelines published by the American Psychiatric Association.[2] As such, we urge you to consider removing this measure because it:

1. Interferes in the practice of medicine and prevents patients from receiving the treatment their physician deems clinically necessary and appropriate and as such, conflicts with the provision of patient-centered care; and

2. It has an outsized impact compared to other measures on CMS's Nursing Home[3] Care Compare and the Star Rating System and in turn, misleads beneficiaries and their families regarding nursing home care safety and quality.

While the label "quality measure" implies a connection to safety or clinical care guidelines, multiple reviews between 2011-2022 by the HHS Office of the Inspector General (OIG) found that CMS's Long-Stay Antipsychotic Medication measure has not only failed to capture meaningful data to distinguish between appropriate and unnecessary prescribing of antipsychotics, it may also have contributed to increased inappropriate prescribing of *other* psychotropics.[4] Unfortunately, rather than adopting OIG's or other recommendations to fix the measure—such as specific language and methodologies proposed to CMS over the past four years—CMS has doubled down on identified measure weaknesses to increase its own surveyor issuance of nursing home citations and fines. CMS's sole focus is on driving down overall prescribing rates without any regard to unique patient clinical needs, specific patient census characteristics of a particular nursing home (e.g., facilities that specialize in patients with complex neuropsychiatric needs), or considering the availability of newer antipsychotics that have different mechanisms of action and side effect profiles.

These actions by CMS have significantly restricted access to FDA-approved medications for residents living with NPS of Alzheimer's and Parkinson's disease solely based on their care setting, compared to those residing in community-based settings. This runs counter to three of the four stated goals of CMS's National Partnership to Improve Dementia Care to "1) Enhance the quality of life for people living with dementia, 2) Protect them from substandard care, and 3) Promote goal-directed, person-centered care for every nursing home resident."[5]

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[1] "Phony Diagnoses Hide High Rates of Drugging at Nursing Homes," by Katie Thomas, Robert Gebeloff and Jessica Silver-Greenberg, The New York Times, September 11, 2021. https://www.nytimes.com/2021/09/11/health/nursing-homes-schizophrenia-antipsychotics.html?searchResultPosition=1

[2] The American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia. https://psychiatryonline.org/doi/epdf/10.1176/appi.books.9780890426807

[3] For the purposes of this correspondence, the term nursing home and SNF are interchangeable.

[4] HHS OIG, "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

[5] CMS National Partnership to Improve Dementia Care. https://www.cms.gov/medicare/health-safety-standards/quality-safety-oversight-general-information/national-partnership-improve-dementia-care-nursing-homes#:~:text=We%20at%20the%20Centers%20for,for%20every%20nursing%20home%20resident

As such, we strongly oppose the current measure and continue to recommend CMS eliminate the measure and adopt alternative approaches that will capture what the agency should be examining: how many Medicare beneficiaries are receiving antipsychotics who do not have a valid clinical need for them? The current measure aggregates all antipsychotic use together and assumes—wrongly—that all use of these therapies is unnecessary, except for a handful of specific conditions (Huntington's disease, Tourette's syndrome, and schizophrenia). This approach is not patient-centered and reflects an antiquated approach that is more than 13 years old.

Our detailed rationale is below. We wish to note that nothing in our comments should be interpreted to encourage off-label use of antipsychotics. Again, we thank you for your consideration of our request to eliminate the Long-Stay Antipsychotic Medication quality measure from the SNF Five-Star Quality Rating System and welcome an opportunity to discuss this important quality of care issue with you further. We hope the following table of contents assists you in review of our comments.

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Background and History of the Flawed Measure

According to the CMS website, the agency uses quality measures to quantify health care processes, outcomes, and organizational systems associated with high-quality health care and/or that relate to one or more quality goals for health care, including: "effective, safe, efficient, patient-centered, equitable, and timely care."[6] CMS explains that "The rating system comprises three rating domains: health inspections, staffing, and quality measures (QMs). *One of the QMs reported on Nursing Home Care*

[6] CMS, "What are Quality Measures?" https://www.cms.gov/medicare/quality/measures.

Compare and included in the star rating calculation is the percentage of long-stay residents who are receiving antipsychotic drugs [emphasis added]." [7]

Long-Stay Quality Measure: Antipsychotic Use in Nursing Home Residents

CMS uses this quality measure to quantify the percentage of long-stay nursing home residents (i.e., those with a stay of 101 days or longer) who received an antipsychotic drug. CMS uses the Minimum Data Set (MDS) as the data source for this measure and publishes these findings in Care Compare and the Star Rating System.[8] The MDS is part of the federally mandated process for nursing homes to report clinical assessments of all residents. These assessments collect information about each resident's health, physical functioning, mental status, and general well-being, including use of antipsychotic drugs and certain diagnoses. The MDS serves as the data source for Care Compare and the Star Rating System, the publicly available Web-based tool that provides basic information about quality of care at all Medicare- and Medicaid-certified nursing homes.[9]

More than a decade ago, CMS created a long-stay antipsychotic measure to curb what the agency believed was an inappropriately high percentage of residents on antipsychotics in nursing homes. **The measure is a formula of the "percent of residents who received an antipsychotic medication" and it is calculated by dividing the number of residents on a medication by the total number of residents in the SNF.** CMS requires nursing homes to record the number of days during the preceding seven days that antipsychotic drugs were received by each resident. As noted earlier, the measure excludes residents with MDS-reported diagnoses of schizophrenia, Huntington's disease, or Tourette's syndrome.[10]

OIG Findings

In May 2021, OIG published an Issue Brief that determined that CMS's use of the MDS as the sole data source to count the number of nursing home residents using antipsychotic drugs did not always provide complete information.[11] By comparing Medicare claims to MDS records for nursing home residents aged 65 and older in 2018, OIG found that many beneficiaries had Medicare Part D claims for antipsychotic drugs but were not reported in the MDS as receiving an antipsychotic drug. Furthermore, nearly one-third of residents who were reported in the MDS as having schizophrenia—which is a diagnosis that

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[7] CMS, "Adjusting Quality Measure Ratings Based on Erroneous Schizophrenia Coding and Posting," January 2023. https://www.cms.gov/files/document/qso-23-05-nh-adjusting-quality-measure-ratings-based-erroneous-schizophrenia-coding-and-posting.pdf

[8] CMS, "Design for Nursing Home Compare Five-Star Quality Rating System: Technical Users' Guide," January 2025. https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcomplianc/downloads/usersguide.pdf

[9] https://www.medicare.gov/care-compare/

[10] The conditions that CMS excludes from its calculation of the number of residents receiving antipsychotics are on the list of FDA-approved adult indications for antipsychotic medications, however it is not inclusive of all FDA-approved adult indications for antipsychotic medications. CMS, "Atypical Antipsychotic Medications: Use in Adults." https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Pharmacy-EducationMaterials/Downloads/atyp-antipsych-adult-factsheet11-14.pdf

[11] HHS OIG, "CMS Could Improve the Data It Uses To Monitor Antipsychotic Drugs in Nursing Homes, OEI-07-19-00490," May 2021. https://oig.hhs.gov/documents/evaluation/3089/OEI-07-19-00490-Complete%20Report.pdf

excludes them from CMS's measure of antipsychotic drug use—did not have any Medicare service claims for that diagnosis. Finally, even for those residents included in the MDS counts, the MDS does not provide important details about the drug use (e.g., which antipsychotic drugs were prescribed, at what quantities and strengths; and for what durations).

OIG recommended that CMS: (1) take additional steps to validate the information reported in MDS assessments and (2) supplement the data it uses to monitor the use of antipsychotic drugs in nursing homes. CMS concurred with both recommendations, noting in its response to OIG that CMS efforts were underway to supplement the data used to monitor the use of antipsychotic drugs in nursing homes. CMS directed the Plan Program Integrity Medicare Drug Integrity Contractors (PPI MEDIC) to increase their focus on proactive data analysis in Part D to identify inappropriate payments, potential program vulnerabilities, and address issues, such as abusive prescribing.

A subsequent OIG report[12] issued in November 2012 found that the measure fails to distinguish between appropriate and inappropriate/unnecessary prescribing, instead merely tracking total use. The current methodology has led to misleading quality assessments, and OIG recommended improvements that CMS has not yet adopted.

Additionally, the measure does not count how much of a percentage decrease in antipsychotic use may be due to involuntary discharges by facilities. A 2022 report from the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), "Resident and Facility Factors Associated with High Risk of Discharge from Nursing Facilities, 2012-2017,"[13] found that behavioral symptoms and psychiatric and mood disorders are the most prominent risk factors for live discharge. It is unclear how many residents with behavioral symptoms and psychiatric and mood disorders may be discharged due to factors that could otherwise be medically managed except for the overly strict prescribing regulations. This is a data gap and potential unintended consequences of the current policy should be explored.

Attempts at Measure Reform

As part of our long-standing efforts to improve the quality of care for beneficiaries who require treatment with antipsychotics, for several years we urged CMS to convene a group of experts to discuss the measure and solicit input regarding better ways to capture the use of antipsychotics and determine when they are being used inappropriately or unnecessarily.

We very much appreciate that in 2024 CMS convened a Technical Expert Panel (TEP) to help inform any re-specification efforts for the measure. However, unfortunately CMS did not concur with the OIG's most impactful recommendation, which is that the current measure is insufficient.[14] Furthermore,

[12] HHS OIG, "Long-Term Trends of Psychotropic Drug Use in Nursing Homes, OEI-07-20-00500," November 22. https://oig.hhs.gov/reports/all/2022/long-term-trends-of-psychotropic-drug-use-in-nursing-homes/
[13] HHS ASPE, "Resident and Facility Factors Associated with High Risk of Discharge from Nursing Facilities, 2012-2017: Final Report," September 2022. https://aspe.hhs.gov/sites/default/files/documents/cc0772c12db75f3e2bce766e3d9d21c8/high-risk-discharge-report.pdf
[14] HHS OIG, "CMS Could Improve the Data It Uses To Monitor Antipsychotic Drugs in Nursing Homes," May 2021. https://oig.hhs.gov/documents/evaluation/3089/OEI-07-19-00490-Complete%20Report.pdf

members who sat on the TEP (including several signatories of this letter) felt that the results were a foregone conclusion since TEP advisors' concerns with the current measure were not reflected in the final TEP report.[15] It is concerning and disappointing that the agency did not use this opportunity to undertake a more holistic approach to reviewing its current approach to antipsychotic prescribing within SNFs, which includes recognizing that not all prescribing is inappropriate or unnecessary and not all beneficiaries should be involved in dose reduction efforts. It is clear from this experience that unfortunately this was not a serious exercise focused on ensuring patient-centered care for vulnerable Medicare beneficiaries but rather an effort to generate confirmation bias toward the agency's preexisting position.

The Long-Stay Antipsychotic Medication Quality Measure Interferes in Medical Practice and Thwarts Patient-Centered Care

Interference in Practice of Medicine

CMS's deployment of the Long-stay Antipsychotic Medication quality measure raises a threshold issue: It appears that CMS's justifications for using the Long-Stay Antipsychotics quality measure may contravene the Medicare Act. CMS explains the intent of surveyor requirements on psychotropics is "to ensure residents only receive psychotropic medications ***when other nonpharmacological interventions are clinically contraindicated*** [emphasis added]. Also, residents must only remain on psychotropic medications when a gradual dose reduction and behavioral interventions have been attempted and/or deemed clinically contraindicated. Additionally, medication should only be used to treat resident's medical symptoms and not used for discipline or staff convenience, which would be deemed a chemical restraint."[16] Here CMS is asserting that the preferred treatment for beneficiaries is a nonpharmacological intervention and is creating a clinical standard: SNFs may only use psychotropic medications when other nonpharmacological interventions are contraindicated. CMS further dictates medical practice by requiring that gradual dose reduction be attempted. There is no statement here about treatment efficacy or patient medical need or medical/clinical history.

We do not oppose using gradual dose reduction or suggested limitations on the duration of treatments; what is objectionable is that CMS is imposing a one-size-fits-all approach to the use of antipsychotics for nursing home residents without regard for individualized needs. **CMS is saying: SNFs must not use pharmacological treatment unless other options are contraindicated—full stop. This is dictating and controlling the practice of medicine.**

But the explanation flies counter to the statutory mandate. Section 1801 of the Act provides, in relevant part:

> *Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or the selection, tenure, or compensation of any officer or*

[15] CMS, "Nursing Home Antipsychotics Technical Expert Panel Summary Report," February 2023. https://mmshub.cms.gov/sites/default/files/NH-Antipsychotics-TEP-Summary-Report-Feb-2023.pdf
[16] CMS, "QSO-25-12-NH: Nursing Home Quality and Accountability," January 2025. https://www.cms.gov/files/document/qso-25-12-nh.pdf

> *employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.*[17]

The plain meaning of Section 1801 suggests that CMS cannot interfere with the practice of medicine, including who can provide health care services, what types of services they can provide, how they can provide those services, and where they can provide those services. Yet the 917-page, Revised Long-Term Care (LTC) Surveyor Guidance[18]—which went into effect on March 24, 2025—includes nearly 20 pages related to surveying the prescribing of psychotropics:

- Definitions (e.g., adequate indications for use, adverse consequence)
- Dosing instructions that include "PRN [as needed] orders" limited to "14 days" and "gradual dose reduction," with extensive requirements
- Assessment and behavioral intervention
- How to determine necessity to use psychotropic medications
- Monitoring and adverse consequences
- Investigative procedures
- Potential tags for additional investigation
- Examples of deficiencies and harm levels

Despite the added regulations on psychotropic prescribing and surveyor requirements to see detailed documentation that rules out abuse/neglect, page 129 of CMS's Guidance maintains:

> *The regulations and guidance are not intended to supplant the judgment of a practitioner in consultation with facility staff, the resident, and his/her representatives and in accordance with professional standards of practice.* ***Rather, the regulations and guidance are intended to ensure psychotropic medications are used only when a practitioner determines that the medication(s) is appropriate to treat a resident's specific, diagnosed, and documented condition and the medication(s) is beneficial to the resident, as demonstrated by monitoring and documentation of the resident's response to the medication(s)*** *[emphasis added]. However, surveyors must review the resident's medical record for evidence which supports and documents the clinical indication for psychotropic medication use.*

Nowhere in the above highlighted guidance language does CMS acknowledge that it elsewhere has stated that antipsychotics are only to be used if nonpharmacological interventions are contraindicated. By asserting that there is only one instance in which antipsychotics are deemed appropriate—if a nonpharmacological intervention is contraindicated, CMS is in fact supplanting the judgment of practitioners and staff. CMS is inconsistent in its guidance at best, and duplicitous at worst. CMS has clearly asserted that it believes nonpharmacological interventions are the principal treatment for patients with NPS and any deviation from that preferred

[17] 8 42 U.S.C. § 1395.
[18] CMS, "Center for Clinical Standards and Quality, Revised Long-Term Care (LTC) Surveyor Guidance: Significant revisions to enhance quality and oversight of the LTC survey process, QSO-25-12-NH," January 15, 2025. https://www.cms.gov/files/document/qso-25-12-nh.pdf

treatment requires significant documentation and rationale, which has been publicly, and on-the-record asserted by CMS staff.

An October 2024 story in *McKnight's Long-Term Care News*[19] quoted non-clinician, and CMS Director of the Division of Nursing Homes, Evan Schulman speaking about the intent behind CMS's updated regulations on psychotropic prescribing:

> *"There's a preponderance of evidence that suggests taking them off those drugs is not only better for their quality of life, but it reduces those health risks, and that's why we want it to be a last resort," Shulman said in response to an audience question. "That doesn't mean you cannot have someone on an antipsychotic…" "But in every case [where a schizophrenia diagnosis is recorded] we need to see the rationale," he later added.*

Do CMS's requirements to "see the rationale" equate to interfering in the practice of medicine? Courts have considered whether Section 1801 would be violated in similar contexts to those presented here. In American Medical Association v. Weinberger, the district court raised a potential Section 1801 question when the Secretary of then-Health, Education & Welfare sought to enforce regulations that would have conditioned Medicare and Medicaid reimbursement on the establishment by hospitals of "utilization review" committees, which were charged with assessing "medical necessity of a patient's admission within 24 hours thereof."[20] The court opined that, "[i]f the regulations do in fact produce decisions by doctors to admit, the Secretary by promulgating them has 'exercis(ed) ... supervision or control over the practice of medicine.'"[21] Here, courts may likewise find that CMS's attempt to control nursing home prescribing practices violates the statute.

We agree with CMS that nursing home residents, like all Americans, should not receive antipsychotic medications unless clinically indicated and that they should only be prescribed such medications if they are likely to have a benefit. But the blunt instrument of the current quality measure does not, and cannot, address these problems. Nor under the statute may CMS use quality measures or surveyor guidance to control the practice of medicine.

Conflicting with Patient-Centered Care

We appreciate that CMS strives for quality patient care within its programs. However, the current measure pressures SNFs to reduce or eliminate antipsychotic use entirely, even when medically necessary and clinically appropriate. This has resulted in some facilities substituting less effective or riskier treatments (e.g., anticonvulsants) to avoid penalties, which in turn means patients are not getting the individualized care they need and deserve. To this point, in 2022 OIG reported that:

> *The focus of CMS's targeted monitoring of antipsychotic drugs likely contributed to a decline in antipsychotic drug use among nursing home residents; however, anticonvulsant drug use*

[19] "Broader authority for surveyors will usher in more equitable approach to fines: CMS leader," by Kimberly Marselas, McKnights Long-Term News, October 30, 2025. https://www.mcknights.com/news/broader-authority-for-surveyors-will-usher-in-more-equitable-approach-to-fines-cms-leader/
[20] Am. Med. Ass'n v. Weinberger, 395 F. Supp. 515, 524 (N.D. Ill. 1975).
[21] Id.

> *increased during this effort. In 2012, following OIG's report, CMS started monitoring antipsychotic drug use in nursing homes, which coincides with the decline in antipsychotic drug use. In 2015, CMS began using the long-stay quality measure that tracks antipsychotic use in nursing homes in its Nursing Home Five-Star Quality Rating System calculations.* ***Antipsychotic drug use continued to decline while anticonvulsant drug use continued to increase after CMS made this change*** *[emphasis added].*[22]

Further, since the measure was implemented, there have been significant advancements in antipsychotic treatments that target specific NPS. However, because the measure penalizes facilities for prescribing all antipsychotics, even newer therapies with specific FDA-approved indications, appropriate access to these medications for residents, some of whom were on the medications prior to entering the SNF, is limited. If a Medicare beneficiary has been on a particular medication while a resident in the community, they should not lose access to that treatment just because they are admitted to a SNF.

Currently, because of the flawed, one-size-fits-all approach to antipsychotic medications and the significant pressure from CMS via the quality measure and surveyor program to move all patients on these medications to gradual dose reduction, patients in SNFs often are taken off medications they require. Patients' access to medically necessary medication should not be dependent on where they reside.

We regularly hear poor patient outcomes stories from families, caregivers, physicians, nurses, and pharmacists; they provide poignant examples from their lives illustrating how, because of the immense pressure SNFs experience to keep as many patients off antipsychotics as possible, patients experience subpar care and outcomes. For example:

> *A military veteran with Alzheimer's disease was exhibiting agitation and aggressive behavior—putting himself and those around him at-risk. His geriatric psychiatrist recommended he be put on an antipsychotic to manage his symptoms and the patient responded well and returned to his usual jovial and congenial self. However, after two weeks of being stable on the medication, he was taken off the medication; his family was informed by the facility that they were required to reduce and eventually stop the specific drug. Despite pleas from the family to keep him on the therapy, the facility embarked on gradual dose reduction and eventually ceased the treatment. Unfortunately, the symptoms returned and worsened; only after the patient pushed a young adult who was visiting another resident did the facility resume the treatment. The patient clearly needed to be on the medication without interruption—a course of treatment that would have been best for the beneficiary and for those around him.*

CMS's insistence that all antipsychotic prescribing is generally unnecessary overrides clinician judgment, family preference, and patient needs – this is completely inconsistent with patient-centered, quality care. Similarly, long-term care nurse, Amy Stewart, and her family experienced first-hand how the

[22] HHS OIG, "Long-Term Trends of Psychotropic Drug Use in Nursing Homes, OEI-07-20-00500," November 2022. https://oig.hhs.gov/reports/all/2022/long-term-trends-of-psychotropic-drug-use-in-nursing-homes/

pressure to wean patients off antipsychotics had an adverse impact on her father's health and well-being. In an op-ed she penned about her family's journey with her father's Alzheimer's she explained[23]

> *In the case of agitation, his doctors tried to work with us to prescribe medications that would blunt its effects, despite the repercussions for their organizations. But rules, overseen by the Centers for Medicare & Medicaid Services, forced prescribers to gradually reduce his dosage. We were eventually forced to move him to another facility that was able to provide better care, but the gradual dose reductions resulted in multiple hospitalizations and more expensive medications.*

The Long-Stay Antipsychotic Medication Measure Has an Outsized Impact That Misleads Beneficiaries and Families

Under the Biden Administration, in January 2023, CMS announced that the agency would commence audits of schizophrenia coding within the MDS and noted that any SNFs with "coding inaccuracies identified through the schizophrenia audit will have their Quality Measure (QM) ratings adjusted" in several ways, including downgrading both the overall quality measure and long-stay quality measure ratings to one star for six months—decreasing the "facility's overall star rating by one star."[24,25,26]

The result is that if, in the opinion of the nursing home surveyor, a nursing home has "erroneously coded residents as having schizophrenia" the facility will experience an immediate negative impact on its star ratings.

The chart on the following page illustrates the impact of this change in policy:

[23] McCarthy, L. (2024). "Alzheimer's patients lost in the system." *MinnPost*. https://www.minnpost.com/community-voices/2024/04/alzheimers-patients-lost-in-the-system/
[24] CMS, "User's Guide for the Medicare Provider Enrollment and Certification Process," January 2025. https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcomplianc/downloads/usersguide.pdf
[25] CMS, "Adjusting Quality Measure Ratings Based on Erroneous Schizophrenia Coding and Posting," January 2023. https://www.cms.gov/files/document/qso-23-05-nh-adjusting-quality-measure-ratings-based-erroneous-schizophrenia-coding-and-posting.pdf
[26] Ibid.

Example Facility Ratings Prior to Schizophrenia Coding Audit	Example Facility Ratings After Schizophrenia Coding Audit
Overall Rating:☆☆☆☆	**Overall Rating:**☆☆☆
Health Rating: ☆☆☆	**Health Rating:** ☆☆☆
Staffing Rating: ☆☆☆☆☆	**Staffing Rating:** ☆☆☆☆☆
QM (Quality Measure) Rating: ☆☆☆ **Long-Stay QM:** ☆☆☆ **Short-Stay QM:** ☆☆☆ **Long-Stay Antipsychotic QM (Percentage of long-stay residents who got an antipsychotic medication):** 14.7%	**QM (Quality Measure) Rating:** ☆*(for six months)* **Long-Stay QM:** ☆*(for six months)* **Short-Stay QM:** *Suppressed for six months* **Long-Stay Antipsychotic QM:** *Suppressed for 12 months* **The suppression of the data means that consumers cannot get a line of sight into the facility's quality measures and likely will deter consumers from using that facility. So even a facility that has very low long-stay antipsychotic prescribing percentages would not be able to have this data displayed if a surveyor believes they have a single erroneous schizophrenia diagnosis.

Meaningfulness of the Measure for Consumer Awareness and Understanding is Questionable

The outsized weighting of the Long-Stay Antipsychotic Medication quality measure over other nursing home quality measures can mislead beneficiaries and their families regarding a local nursing facility's overall safety. On CMS's Care Compare, each facility's reported "percentage of long-stay residents who received antipsychotic medication" is listed, and the national average and state average percentages are listed below it for comparison. No further information is provided to offer context on how to interpret results for this measure, except two general statements "lower percentages are better" (with a downward pointing arrow) and "antipsychotic medications can be used to treat certain mental health conditions." While this reported percentage may reflect a facility's adherence to CMS's overly detailed reporting requirements (described earlier), it does not tell individuals and families anything about the quality of care at each facility with respect to appropriate and necessary medication use broadly or antipsychotics specifically. Again, this is because the measure only counts how many people receive an antipsychotic without any regard for medical necessity.

Of further concern is that the measure particularly penalizes SNFs for appropriately treating residents with NPS, as facilities that provide high-quality neurocognitive impairment and psychiatric care appear to have higher antipsychotic prescribing rates than their peer institutions, but this is simply due to their patient census and their patients' specific needs. Families seeking specialized care for their loved ones with complex conditions like neurocognitive impairment or Alzheimer's disease often seek to place their family member in a facility designed for those patient populations; yet, if these families look at the Long-Stay Antipsychotic Medication quality measure they may see higher than average percentages. This is not because of malfeasance or neglect; it is because of the clinical profile of the residents. This, in turn, can have a significant negative impact on families' decisions about the facility—leading them to think the nursing home is low quality, when in fact, it is delivering patient-centered, clinically appropriate, medically necessary care to its residents with NPS.

Reducing Regulatory Burden and the Opportunity for Reform

It is well-documented that the nursing home industry is the most heavily regulated sector in the country, with layers of federal and state oversight that impact day-to-day operations. While oversight is essential to ensuring patient safety and well-being, excessive or misguided regulations can have unintended negative consequences, especially when they create distorted incentives that prioritize regulatory compliance over the provision of patient-centered care.

We very much appreciate that the Trump Administration has been vocal about the importance of reducing unnecessary regulatory burdens to ensure that providers can focus on delivering high-quality care rather than being consumed by compliance metrics that do not accurately reflect quality of care or patient outcomes. Removing this flawed measure aligns completely with the Trump Administration's commitment to streamlining regulations[27] while maintaining strong protections for Medicare beneficiaries. By eliminating a measure that fails to differentiate between appropriate and unnecessary antipsychotic prescribing, CMS can remove a barrier to patient-centered care and help facilitate better outcomes for patients.

Additionally, the recent efforts related to reduction in force at CMS, particularly in the Center for Clinical Standards and Quality (CCSQ) underscore the need to revisit current measures. CCSQ is responsible for overseeing quality measures and provider certifications, yet with fewer surveyors and staff available to maintain and refine measures, CMS should take this opportunity to reassess the measures that remain. Removing the Long-Stay Antipsychotic Medication quality measure not only reduces administrative burden but also allows CMS to focus its remaining resources on truly impactful quality initiatives.

President Trump's promise to put patients first importantly prioritizes streamlining regulations and improving patient outcomes. The current antipsychotic measure contradicts this vision by maintaining a one-size-fits-all standard that discourages appropriate, individualized treatment. Given the overwhelming evidence of harm and the lack of meaningful quality insights from this measure, its removal is imperative to ensure patients receive the care and treatments they need while residing in

[27] Unleashing Prosperity Through Deregulation, Executive Order 14192 of January 31, 2025, https://www.federalregister.gov/documents/2025/02/06/2025-02345/unleashing-prosperity-through-deregulation

nursing homes. Now is the time to ensure that regulatory policy reflects the Trump Administration's clear commitment to personalized, high-quality care.

Recommendation and Request for Action

To ensure continued access to appropriate, evidence-based care for residents in SNFs, we strongly urge CMS to remove the Long-Stay Antipsychotic Medication measure from the SNF Five-Star Quality Rating System, which we understand can be promulgated via subregulatory means, such as a CCSQ "QSO" memo to State Survey Agency Directors, and other related communications such as the Design for Care Compare Nursing Home Five-Star Quality Rating System: Technical Users' Guide. Additionally, we recommend CMS engage with stakeholders, including clinicians, pharmacists, caregivers, and long-term care experts, to identify evidence-based policies to help reduce inappropriate and unnecessary antipsychotic use while not restricting access to medically necessary treatments.

CMS Authority to Remove the Measure

We believe CMS has clear regulatory authority to eliminate this quality measure through subregulatory means because CMS has previously modified, suspended, or retired certain quality measures via subregulatory means when they lead to adverse patient outcomes or do not align with clinical best practices.[28]

Ensuring CMS and the Public Have Necessary Data and Insights

With the elimination of the flawed measure, it will be imperative to ensure that CMS and the public continue to have a line of sight into nursing home prescribing patterns of antipsychotics. To that end, we note that nursing homes will still be required to report on the use of psychoactive medications via the MDS system. We believe that the MDS should be expanded to capture additional information to help surveyors and those accessing the MDS data discern between all prescribing of antipsychotics and the prescribing that is documented to be clinically necessary and appropriate and prescribing that has not been appropriately documented. As such, we recommend that starting in the program year 2026, the Antipsychotic Medication Review section of the MDS be modified to:

- Expand the reasons for why gradual dose reduction has not been attempted to include a new category stating: "documented use of the drug and dose as clinically appropriate;" and

- Require that in cases where gradual dose reduction has not been attempted, both a physician and a pharmacist must **independently** document that gradual dose reduction is either clinically contraindicated or that the use of the drug and dose are clinically appropriate.

[28] Certain measures, like those in the SNF Quality Reporting Program (QRP), are promulgated via the annual SNF Prospective Payment System (PPS). However, the Long-Stay Antipsychotic quality measure is not governed by the SNF PPS process.

Conclusion

The members of Project PAUSE, which include experienced clinicians, patient advocates, and long-term care professionals, are eager to serve as a resource to you and your colleagues in identifying additional opportunities to reduce the regulatory and guidance burden on nursing homes while maintaining high standards of care. We welcome the opportunity to collaborate with CMS in shaping a modernized, evidence-based approach to quality measurement in long-term care.

Again, we appreciate CMS's ongoing efforts to improve quality measures and ensure safe prescribing practices in SNFs to protect vulnerable Medicare beneficiaries. We stand ready to work with CMS to develop a more effective approach that ensures patient access to clinically necessary treatments while ensuring inappropriate prescribing is identified and addressed. We welcome further discussions on these recommendations and collaborating with CMS in developing a more precise and effective approach to monitoring the use of antipsychotic medications in long-term care settings.

Thank you for your attention to this urgent issue. Please do not hesitate to contact Sue Peschin, President and CEO of the Alliance for Aging Research (speschin@agingresearch.org or 301-802-4850) or Chad Worz, President and CEO of the American Society of Consultant Pharmacists (cworz@ascp.com or 513-746-5087) with any questions. We look forward to working with you and your colleagues on this and other important quality of care matters.

Sincerely,

Alliance for Aging Research
American Association for Geriatric Psychiatry
American Association of Post-Acute Care Nursing
American Association of Psychiatric Pharmacists
American Society of Consultant Pharmacists
Caregiver Action Network
CaringKind
Depression and Bipolar Support Alliance
Global Coalition on Aging
HealthyWomen
Huntington's Disease Society of America
LeadingAge
National Alliance for Caregiving
National Community Pharmacists Association
National Hispanic Council on Aging
National Minority Quality Forum
Partnership to Fight Chronic Disease
Rural Minds
The Balm In Gilead, Inc.
Voices of Alzheimer's

cc:

Hannah Anderson, HHS Deputy Chief of Staff, Policy
John Brooks, CMS Deputy Administrator & Chief Policy and Regulatory Officer
Stephanie Carlton, CMS Deputy Administrator & Chief of Staff
Heather Flick Melanson, HHS Chief of Staff
Stefanie Spear, HHS Principal Deputy Chief of Staff / Senior Counselor to the Secretary