Proposed Modifications to MDS 3.0 Version 1.20.1v3 Effective 10/1/2025
Section N – Medications, N0450. Antipsychotic Medication Review

On behalf of Project PAUSE, enclosed are suggested modifications to the Minimum Data Set (MDS) *Section N – Medications, N0450: Antipsychotic Medication Review*. To aid in contextual review, we have incorporated the suggestions into the most recently issued version of the MDS released by CMS on August 15, 2025, and set to take effect October 1, 2025.[1] The proposed modifications are limited to questions N0450B, N0450D, and N0450E, which are highlighted in yellow, and our specific suggested language modifications for each of these questions are denoted in **red**. No modifications are proposed for N0450A or N0450C.

Section N – Medications, N0450: Antipsychotic Medication Review appears on page 45 of the Nursing Home Comprehensive (NC) Item Set and on page 42 of the Quarterly NC Item Set. As such, we note that all our suggestions apply to the NC set, while "too soon to assess" would not be appropriate for the quarterly version.

We propose these adjustments as one way to strengthen oversight and accountability with respect to discerning clinically appropriate and inappropriate prescribing of antipsychotics. We welcome ongoing dialogue with CMS and CCSQ with respect to alternative approaches to achieve our shared goal of ensuring Skilled Nursing Facility (SNF) residents receive quality care and that those who need antipsychotics have ongoing access, while safeguarding other residents against abuse.

Rationale for Suggested Modifications

Project PAUSE appreciates the improvements included in the most recently issued MDS that specify the physician's role in documenting gradual dose reduction (GDR) in the Antipsychotic Medication Review section. To further strengthen documentation and clinician review of antipsychotic use, Project PAUSE proposes the following complementary, low-burden MDS changes to advance clinically appropriate, patient-centered care:

1. Requiring documentation from a pharmacist in addition to a physician;
2. Expanding the acceptable reasons for not attempting GDR to include cases where both a physician and a pharmacist document that the drug and dose are clinically appropriate, or the assessment timing is too soon based on admission date; and
3. Requiring both a physician and a pharmacist to independently document when GDR is either clinically contraindicated, when continued use of the drug and dose are clinically appropriate and beneficial, or when the assessment timing is too soon.

Expanding the list of permissible reasons for not attempting GDR will help ensure that CMS policy accurately reflects the full range of clinical scenarios and FDA-approved available therapies pertaining for beneficiaries with Alzheimer's disease and related neurocognitive impairments, including those with conditions beyond the three exempted categories. Additionally, requiring dual attestation by both a physician and a pharmacist when GDR is not attempted will strengthen oversight and better reflect the full care team involved in prescribing, dispensing, and monitoring these medications. Together, we believe these additions will generate more meaningful, nuanced, and accurate data to help CMS, surveyors, facilities, providers, patients, and families comprehensively assess whether antipsychotic use is clinically appropriate. Moreover, we believe this approach—coupled with removing the existing Long-Stay Antipsychotic measure from the Nursing Home Care Compare Five-Star Rating System—will help reduce barriers to clinically appropriate, guideline-concordant care, while also safeguarding against the misuse and abuse of these medications for SNF residents.

[1] Centers for Medicare & Medicaid Services. Minimum Data Set (MDS) - Version 3.0 Resident Assessment and Care Screening. Nursing Home Comprehensive (NC) Item Set. Section N – Medications, N0450 Antipsychotic Medication Review. Section N – Medications, N0450. Version 1.20.1v3. Effective Date October 1, 2025. https://www.cms.gov/medicare/quality/nursing-home-improvement/resident-assessment-instrument-manual

PROJECT pause

Proposed Modifications to MDS 3.0
Version 1.20.1v3 - Effective 10/01/25
Section N – Medications, N0450. Antipsychotic Medication Review

Section N - Medications

N0450. Antipsychotic Medication Review

Enter Code ☐

A. Did the resident receive antipsychotic medications since admission/entry or reentry or the prior OBRA assessment, whichever is more recent?

0. **No** - Antipsychotics were not received → Skip N0450B, N0450C, N0450D, and N0450E
1. **Yes** - Antipsychotics were received on a routine basis only → Continue to N0450B, Has a GDR been attempted?
2. **Yes** - Antipsychotics were received on a PRN basis only → Continue to N0450B, Has a GDR been attempted?
3. **Yes** - Antipsychotics were received on a routine and PRN basis → Continue to N0450B, Has a GDR been attempted?

No changes to N0450A.

Enter Code ☐

B. Has a gradual dose reduction (GDR) been attempted?

0. **No** → Skip to N0450D, Physician documented GDR as clinically contraindicated
1. **Yes** → Continue to N0450C, Date of last attempted GDR

Amend N0450B:

0. Yes → Continue to N0450C, Date of last attempted GDR
1. No → Skip to N0450D, physician and pharmacist documented GDR as clinically contraindicated
2. No → Skip to N0450D, physician and pharmacist documented drug and dose as clinically appropriate
3. No → Skip to N0450D, too soon for assessment

C. Date of last attempted GDR:

☐☐ – ☐☐ – ☐☐☐☐
Month Day Year

No changes to N0450C.

Enter Code ☐

D. Physician documented GDR as clinically contraindicated

0. **No** - GDR has not been documented by a physician as clinically contraindicated → Skip N0450E, Date physician documented GDR as clinically contraindicated
1. **Yes** - GDR has been documented by a physician as clinically contraindicated → Continue to N0450E, Date physician documented GDR as clinically contraindicated

Amend N0450D:

D. Physician and Pharmacist Documentation

0. No → There is not documentation by both the physician and pharmacist that GDR is clinically contraindicated → Skip N0450E, Date of Clinician Documentation/Attestation
1. No → There is not documentation by both the physician and pharmacist that drug and dose are clinically appropriate → Skip N0450E, Date of Clinician Documentation/Attestation
2. Yes → There is documentation by both the physician and pharmacist that GDR is clinically contraindicated → Continue to N0450E, Date of Clinician Documentation/Attestation
3. Yes → There is documentation by both the physician and pharmacist that drug and dose are clinically appropriate → Continue to N0450E, Date of Clinician Documentation/Attestation
4. Yes → Physician and pharmacist attest too soon for assessment → Continue to N0450E, Date of Clinician Documentation/Attestation

E. Date physician documented GDR as clinically contraindicated:

☐☐ – ☐☐ – ☐☐☐☐
Month Day Year

Amend N0450E:

E. Date of Clinician Documentation/Attestation

Physician

☐☐ – ☐☐ – ☐☐☐☐
Month Day Year

Pharmacist

☐☐ – ☐☐ – ☐☐☐☐
Month Day Year

manatt

OCTOBER 2025

Assessing the Impact of the Long-Stay Antipsychotic Medication Quality Measure on Treatment of Neuropsychiatric Symptoms of Alzheimer's and Related Diseases

Unintended Consequences of Measure Design and Potential Strategies to Improve Access to Patient-Centered Care

Acknowledgments

This paper was made possible through the generous support of the Alliance for Aging Research.

About the Alliance for Aging Research

Since 1986, the Alliance for Aging Research has been the leading national nonprofit organization dedicated to changing the narrative to achieve healthy aging and equitable access to care. The Alliance strives for a culture that embraces healthy aging as a greater good and values science and investments to advance dignity, independence, and equity. Learn more about the Alliance at www.agingresearch.org.

About Manatt Health

Manatt Health integrates legal and consulting services to better meet the complex needs of clients across the health care system.

Combining legal excellence, firsthand experience in shaping public policy, sophisticated strategy insight and deep analytic capabilities, we provide uniquely valuable professional services to the full range of health industry players.

Our diverse team of more than 200 attorneys and consultants from Manatt, Phelps & Phillips, LLP, and its consulting subsidiary, Manatt Health Strategies, LLC, is passionate about helping our clients advance their business interests, fulfill their missions and lead health care into the future. For more information, visit https://www.manatt.com/Health.

Key Terms

Alzheimer's and Related Diseases (ADRD)[1]—debilitating neuropsychiatric conditions that impair memory, thought processes, and functioning, primarily among older adults.

Antipsychotics[2]—a class of psychotropic medications primarily used for the treatment and management of symptoms associated with various psychiatric disorders.

Boxed Warning[3]**—**the most significant warning included in United States Food and Drug Administration (FDA) documentation, intended to highlight risks that are so severe in proportion to the potential benefit from a drug that providers are obligated to consider them before prescribing. It may also signal the risk of severe adverse reactions that can be mitigated through careful patient selection or other prescribing choices, or the presence of specific restrictions that the FDA included in its approval to ensure safe use.

Gradual Dose Reduction (GDR)[4]—the stepwise tapering of a dose to determine if symptoms, conditions, or risks can be managed by a lower dose or if the dose or medication can be discontinued.

Long-Stay Resident[5]—an individual residing in a skilled nursing facility for 101 or more consecutive days. This definition is used for quality reporting purposes.

Neuropsychiatric Symptoms (NPS)[6]—a collection of distressing non-cognitive symptoms that include agitation, aggression, delusions, hallucinations, depression, anxiety, apathy, disinhibition, and sleep disturbances and that afflict most patients with ADRD, including up to 97% of those with Alzheimer's disease.

Nursing Home Care Compare Five-Star Quality Rating System[7]—a website maintained by the United States Centers for Medicare & Medicaid Services (CMS) that allows users to locate and compare Medicare-certified SNFs in their geographic area based on their health inspection results, staffing levels, and the quality of care they provide to residents. The website assigns each SNF a rating of between 1 and 5 stars, with 5 stars considered much above average quality and 1 star considered much below average quality.

Psychotropics[8]—medications that affect the mind, emotions, and behavior and typically belong to one of five classes: antipsychotics, antidepressants, anxiolytics, hypnotics, and mood stabilizers.

Skilled Nursing Facility (SNF)[9]—an institution (or a distinct part of an institution) that is primarily engaged in providing skilled nursing care and related services for residents who require ongoing medical or nursing care, or rehabilitation services for residents who are injured, disabled, or sick, and is not primarily for the care and treatment of mental diseases. SNFs must be in compliance with the requirements in 42 Code of Federal Regulations (CFR) Part 483, Subpart B to receive payment under the Medicare or Medicaid program.

Assessing the Impact of the Long-Stay Antipsychotic Medication Quality Measure on Treatment of Neuropsychiatric Symptoms of Alzheimer's and Related Diseases

Unintended Consequences of Measure Design and Potential Strategies to Improve Access to Patient-Centered Care

Table of Contents

Assessing the Impact of the Long-Stay Antipsychotic Medication Quality Measure on Treatment of Neuropsychiatric Symptoms of Alzheimer's and Related Diseases

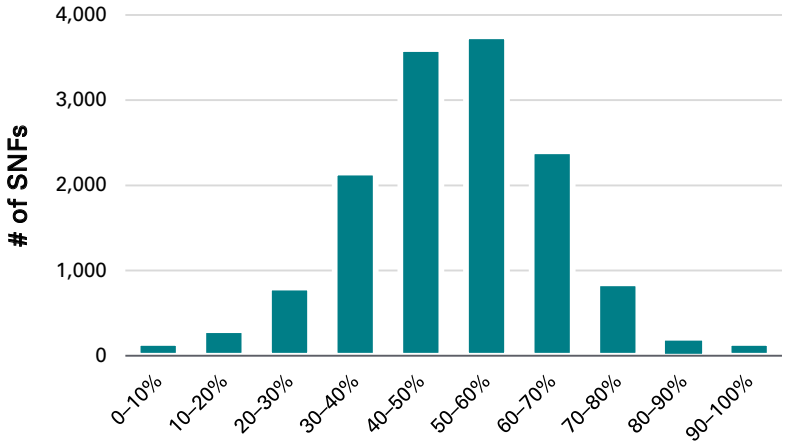
Unintended Consequences of Measure Design and Potential Strategies to Improve Access to Patient-Centered Care

The Challenge of Supporting Skilled Nursing Facility Residents With Alzheimer's and Related Diseases

Millions of Americans are living with neurodegenerative diseases that affect their cognitive abilities, reshaping their lives and the lives of their loved ones. Alzheimer's disease is the most common neurodegenerative disease; more than seven million Americans live with Alzheimer's, and nearly 13 million diagnoses are expected by 2050.[10] The vast majority of Americans diagnosed with Alzheimer's disease are older adults, and many reside in SNFs, where they can receive specialized care.[11] Between 2017–2019, more than three million SNF residents were diagnosed with ADRD, representing nearly 40% of all SNF residents over that period nationwide.[12,13] More than half of SNF residents live in facilities where ADRD affects at least half of their neighbors; the vast majority live in facilities where ADRD affects at least one in three.[14]

SNF Residents Nationwide

SNFs With Residents With ADRD[15]



Source: Dana B. Mukamel, Debra Saliba, Heather Ladd, et al., "Dementia Care is Widespread In US Nursing Homes; Facilities With The Most Dementia Patients May Offer Ways to Better Care," Appendix Exhibit A1, available at https://pmc.ncbi.nlm.nih.gov/articles/PMC10796080/#SM1.

While cognitive decline is the main symptom of ADRD, NPS—including agitation, aggression, delusions, hallucinations, depression, anxiety, apathy, disinhibition, and sleep disturbances—are also quite common, with nearly half of all patients with neurocognitive impairment and up to 97% of those with Alzheimer's disease experiencing one or more NPS.[16,17,18] Managing these symptoms is both a science and an art, as patients present with a variety of medical and psychosocial needs that require constant monitoring and treatment adaptation. Ensuring patient access to a range of treatment options, educating clinicians, SNF providers, families, and caregivers about these options, and maximizing flexibility are essential to delivering individualized, patient-centered care to a rapidly growing cohort of older adults with NPS and improving their quality of life.

In addition to an array of other pharmacological and nonpharmacological interventions, antipsychotic medications are one class of treatment for older adults with NPS of ADRD.[19] In July 2012, responding to publicized concerns about overprescription of antipsychotics among long-stay SNF residents, CMS deployed a quality measure to monitor antipsychotics given to long-stay SNF residents.[20] While the quality measure was intended to ensure patient safety and protect against the improper use of antipsychotics as chemical restraints, it contains multiple flaws that penalize SNFs for prescribing antipsychotics unless the patient has one of a narrow set of diagnoses, thus restricting patients' access to medications that are clinically indicated for the treatment of NPS. Clinicians, quality measure experts, government agencies, researchers, and advocates have repeatedly pressed CMS to address these deficiencies.

In June 2025, CMS announced its intent to revise the quality measure for the first time since its deployment by supplementing its sole data source with three additional sources.[21] The revision seeks to address some longstanding concerns with the measure's accuracy and ensure that all long-stay SNF residents' use of antipsychotics is captured accurately and their indications are accounted for. While CMS' action represents a step toward better measure design, it leaves other significant and longstanding problems with the measure unaddressed. This paper further describes the importance of this clinical issue and the continuing opportunities for CMS to strengthen quality measurement in this area while preserving access to patient-centered care for SNF residents with NPS.

Burden of NPS

NPS of ADRD are associated with accelerated disease progression and functional decline as well as decreased quality of life, increased risk of hospitalization, earlier SNF placement, higher cost of care, greater caregiver burden, and earlier death.[22] People living with ADRD tend to present with NPS in the later stages of their diseases, and these symptoms worsen with disease progression, raising important safety concerns.[23] Multiple studies indicate that NPS are significantly associated with a higher risk of falls and injuries at SNFs and are among the leading causes of facility-initiated discharges.[24,25] CMS defines a facility-initiated discharge as one that "the resident objects to, or did not originate through a resident's verbal or written request, and/or is not in alignment with the resident's stated goals for care and preferences."[26] Facility-initiated discharges cause SNF residents with ADRD to lose their placement, leading to disrupted care, increased acute care utilization, and a higher risk of mortality for the patient, as well as significant upheaval for family members as they search for a new facility that will accept their loved one—a task made more challenging when that person is experiencing poorly-controlled NPS.[27]

Guidelines for Management of NPS

Recognizing the challenges of caring for older adults with NPS, government agencies, national health professional societies, and provider associations have developed guidelines for SNFs. In 2012, CMS launched the National Partnership to Improve Dementia Care, which promotes comprehensive, patient-centered care and therapeutic interventions to increase the quality of life for SNF residents with dementia-related behaviors.[28,29] Through the Partnership, CMS has engaged health professional societies and provider associations, clinicians, researchers, federal and state government agencies, and SNF residents and their families to raise awareness of NPS and advocate for a range of treatment options for patients, including, but not limited to, consistent staff assignments, increased exercise or time outdoors, improved monitoring and management of acute and chronic pain, and individual activity planning.[30]

Use of Antipsychotic Medications for Older Adults With NPS

Prescribing antipsychotics for the management of NPS requires individualized knowledge of the patient and specific clinical expertise. There are risks associated with overprescription and inappropriate use of antipsychotics among this patient population, and a clinician's decision to use medications, including antipsychotics, for patients with ADRD who are experiencing NPS such as agitation is nuanced and highly context-dependent. Multiple national provider associations—including the American Psychiatric Association (APA), the American Association for Geriatric Psychiatry, the American Academy of Family Physicians, and the American Academy of Physician Associates—and peer-reviewed research concur that pharmacologic treatment, including use of antipsychotics, can be appropriate to manage agitation in SNF settings once nonpharmacologic interventions have been attempted and medical causes of agitation, such as infection or pain, have been ruled out, and taking into account the individual patient's needs and risk factors.[31] **This inherent complexity, where the treating clinician's decision to use antipsychotic medication is not universally "right" or "wrong," but rather the culmination of a personalized assessment, makes the use of these medications a challenging clinical area for quality measurement.**

In 2005, the FDA added a boxed warning on all antipsychotics for older adults with dementia-related psychosis, citing an increased risk of mortality associated with their use.[32,33] Boxed warnings, the most significant warnings included in FDA documentation, are intended to highlight risks that are so severe in proportion to the potential benefit from a drug that providers are obligated to consider them before prescribing.[34] They may also signal the risk of severe adverse reactions that can be mitigated through careful patient selection or other prescribing choices, or the presence of specific restrictions that the FDA included in its approval to ensure safe use.[35] Clinical knowledge of and attitudes toward antipsychotic use for NPS have since evolved, within both the medical community and the federal government.

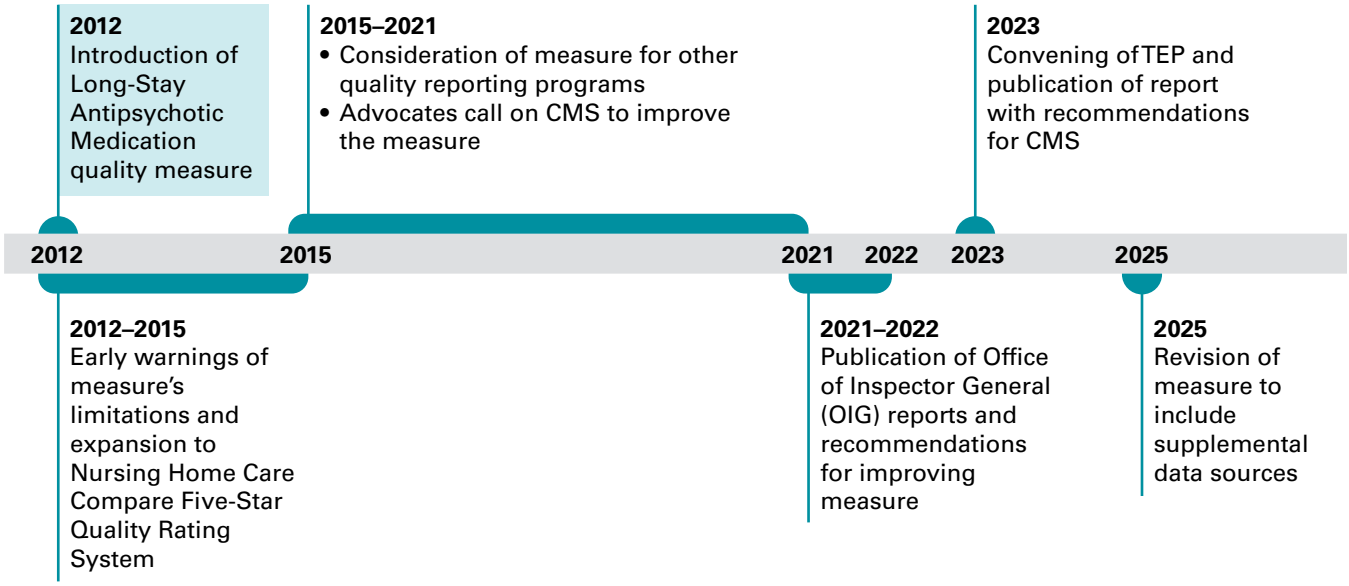
In 2016, the APA issued a practice guideline recommending the use of "nonemergency" antipsychotic medications to treat agitation or psychosis in patients with ADRD, if supported by a risk/benefit assessment, "when symptoms are severe, are dangerous, and/or cause significant distress to the patient."[36]

APA included recommendations in the guideline for the dosing, duration, and monitoring of antipsychotic treatment. Additionally, by 2024 the FDA had approved two antipsychotics to treat specific NPS, which included (1) brexipiprazole for agitation in Alzheimer's disease (May 2023) and (2) pimavanserin for hallucinations and delusions in Parkinson's disease (April 2016).[37,38] In March 2024, given the availability of additional scientific evidence, issuance of updated clinical practice guidelines, and introduction of new treatments to the market for NPS of ADRD, the United States Congress directed the FDA to reevaluate its boxed warning; in response, the FDA hosted a convening to support reevaluation in December 2024.[39] While the two FDA approvals have granted certain patients access to antipsychotic treatment, and reevaluation of the boxed warning appears to be in progress, it remains in effect (as of October 2025) and applies to the two approved antipsychotics for NPS as well as any others prescribed off-label.[40]

In 2012, however, the APA had not yet issued its practice guideline on antipsychotic use to treat NPS of ADRD, and the FDA had not yet approved any medications for this specific purpose. The imposition of the boxed warning heightened concerns among some health care providers, patient advocates, regulators,

and members of Congress about antipsychotic overprescription among SNF residents with NPS, creating a federal policy environment in which devising a quality measure to promote patient safety was a logical course of action.[41]

Timeline of Events



Introduction of the SNF Long-Stay Antipsychotic Medication Quality Measure

In response to concerns raised about the inappropriate use of antipsychotics by SNFs prescribing antipsychotic medications to older adults with NPS, and the risk of potentially fatal consequences, CMS developed the Long-Stay Antipsychotic Medication quality measure. The goal of this quality measure is to reduce the use of antipsychotic medications as a form of chemical restraint, in clinical scenarios such as agitation related to ADRD, where the use of antipsychotics might be avoided through deployment of staff and other behavior modification approaches.[42,43] Although the measure only captures use of antipsychotic medications, chemical restraint can involve many classes of medication, including benzodiazepines and anticonvulsants, the effects of which are discussed later in this paper.[44]

In July 2012, CMS added the Long-Stay Antipsychotic Medication quality measure to the Nursing Home Care Compare Five-Star Quality Rating System to track the progress of the CMS National Partnership to Improve Dementia Care in Nursing Homes, and the measure is still reported via this system.[45] Maintained by CMS, the Nursing Home Care Compare Five-Star Quality Rating System is a website that allows users to locate and compare Medicare-certified SNFs in their geographic area based on their health inspection results, staffing levels, and the quality of care they provide to residents.[46] Combining performance on individual quality

measures in each of these three domains, the website assigns each SNF a rating of between 1 and 5 stars, with 5 stars considered much above average quality and 1 star considered much below average quality.[47] SNFs receive a star rating for each domain and an overall star rating. For this quality measure, the website reports the national average for the percentage of long-stay SNF residents who received an antipsychotic across the most recent three quarters of available data, adjusted by the denominator for each quarter.[48] This quality measure's value is only reported on a facility's webpage if there are at least 30 long-stay residents (e.g., those residing in the facility for 101 or more consecutive days) included in its denominator.[49]

Since its inception, the measure has come under public review on multiple occasions. In addition to its use in the Nursing Home Care Compare Five-Star Quality Rating System, in the calendar year (CY) 2022 proposed SNF Prospective Payment System (PPS) regulation, CMS solicited feedback on the measure for use in the SNF Value-Based Payment (VBP) program. In the final CY 2022 SNF PPS rulemaking documents, CMS announced it had decided not to add the measure to the VBP and acknowledged that respondents had expressed concerns that the measure would disincentivize clinically appropriate access to FDA-approved medications, put patient care and outcomes at risk, and that the measure was not National Quality Forum-endorsed.[50] In response to reports and recommendations published by the United States Department of Health and Human Services (HHS) Office of Inspector General (OIG) in 2021 and 2022 highlighting the measure's data limitations, CMS announced its intent to improve the measure by adding new data sources.[51] CMS initially committed to incorporating the updated measure in the Nursing Home Care Compare Five-Star Quality Rating System in October 2025; however, its incorporation has since been delayed until January 2026.[52] Even with this planned revision taken into account, CMS' measure will continue to limit patient access to medication treatment and play an outsized role in SNF quality reporting, and, as a result, impact clinical care.

Elements of the Long-Stay Antipsychotic Medication Quality Measure

The Long-Stay Antipsychotic Medication quality measure assesses the percentage of long-stay SNF residents who receive antipsychotic drugs in the target period. Quality measures are typically described as having a denominator (the population where a process or outcome of interest **could potentially** happen) and a numerator (the population where the process or outcome of interest **did** happen). This

measure's denominator includes all long-stay SNF residents except for those with excluded diagnoses, and its numerator is all residents with a record of receiving an antipsychotic medication. Residents with certain diagnoses (schizophrenia, Tourette's syndrome, and Huntington's disease) are excluded from the denominator of the calculation, on the grounds that these patients may be taking antipsychotics to treat the specified conditions, rather than for management of NPS related to ADRD.[53] Until recently, the measure has relied exclusively on the Minimum Data Set (MDS)—a standardized CMS assessment that uses manual patient chart reviews and, where applicable, resident interviews to collect a wide range of data about SNF care—as its sole data source.[54] The revised measure, which will replace the existing measure in the Nursing Home Care Compare Five-Star Quality Rating System on January 28, 2026 (as described above), will incorporate Medicare and Medicaid claims data and Medicare Advantage encounter data to supplement the data collected from the MDS.[55]

As with other quality measures, this measure's specification is maintained by a measure steward (in this case, CMS), which can change any aspect of how the measure is calculated to ensure that it conforms to current evidence and best practices. Since its June 2025 announcement, CMS has not released any additional information regarding the updated measure specification and how the changes might impact performance rates; the agency has suggested how the revised measure will impact star ratings. Under the existing measure, 14.64% of all long-stay SNF residents nationwide are reported as receiving an antipsychotic; this figure is expected to increase to 16.98% due to the revised measure's inclusion of additional data.[56] In terms of star rating calculation, the cut points for this measure will be set to place SNFs into ten equal deciles based on the distribution of their performance under the revised measure.[57] CMS' announced revision is one approach to addressing the measure's limitations, but measure stewards also have the option to retire a measure and/or recommend its removal from quality measurement programs when it is no longer useful or scientifically sound.[58] **Importantly, there is no absolute evidence-based benchmark or targeted range of values for antipsychotic use among long-stay SNF residents; as a result, the Long-Stay Antipsychotic Medication quality measure—even the revised version—imposes a "one-size-fits-all" approach to quality measurement at SNFs. CMS continues to assert that "lower is better," and the construct of the measure places relentless downward pressure on SNFs to continually reduce antipsychotic use, without regard for patient need.**

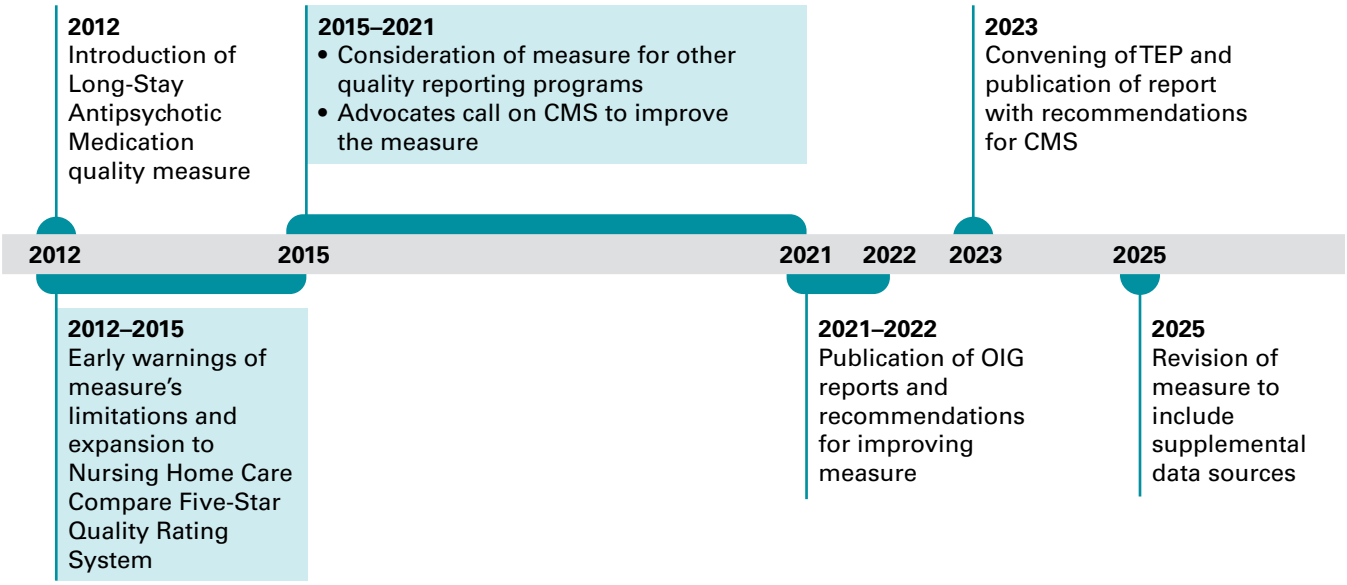
Quality measure development typically follows an extensive process described in the CMS Measures Management System (MMS) Blueprint, designed to ensure that the measure's specification is precise enough to ensure consistency in measurement and takes into account the full range of evidence and stakeholder feedback relevant to the clinical concept being assessed.[59] This process includes:

- Convening a technical expert panel (TEP) comprising clinical experts, methodologists, and patients or family members with lived experience;
- Defining and revising the concepts being measured based on the TEP's feedback; and
- Undergoing rigorous testing to ensure the measure was drafted reliably and accurately distinguishes between high- and low-quality care in a way that is helpful to the entities that interface with quality measures, including payers, regulators, and consumers.

Quality measures that demonstrate these characteristics can be submitted for endorsement, during which a consensus-based entity designated by CMS performs a thorough review of the measure's specification and supporting documentation, including its measure testing results, and formally endorses measures that meet

consensus standards of excellence. While endorsement is not required for a quality measure to be included in a quality measurement system, such as the Nursing Home Care Compare Five-Star Quality Rating System, it is considered an indicator of the measure's strength.[60] **The Long-Stay Antipsychotic Medication quality measure does not appear to have undergone this endorsement process.**[61]

Timeline of Events



Consideration and Inclusion of the Measure in Quality Reporting Programs Despite Expert Concerns

Once a measure is established, the measure steward (CMS, in the case of the Long-Stay Antipsychotic Measure) can submit it for consideration for inclusion in Medicare quality reporting programs (QRPs). This involves a second multistep process:

1. Measures are placed on CMS' list of Measures Under Consideration (the MUC list), where CMS solicits public comment on each measure.
2. Each measure is discussed with a workgroup assigned to consider all proposed measures for one or more CMS QRPs; the workgroup makes nonbinding recommendations.
3. CMS lists measures slated for inclusion in proposed rulemaking related to the relevant QRP to solicit further comment.

Commentors at every step of this process have warned CMS about the Long-Stay Antipsychotic Medication quality measure's limitations. For example, CMS added the measure to the Nursing Home Care Compare Five-Star Quality Rating System in 2012. In 2013, the measure was included in the MUC list for consideration by the Measure Application Partnership (MAP).[62] The MAP's Post-Acute Care/Long-Term Care (PAC/LTC) Workgroup was tasked with considering this measure, along with a companion measure for short-stay

hospitalizations, for inclusion in the Nursing Home Quality Initiative and the Nursing Home Care Compare Five-Star Quality Rating System.[63] While the MAP supported the overall direction of these measures, **its report noted that the measures were not ready for implementation and recommended that they be submitted for formal endorsement**.[64] In addition, the report noted that public comments collected through the American Health Care Association (AHCA) did not align with even the MAP's conditional support, and instead called for the measure to be revised to exclude all diagnoses for which the medications are indicated by the FDA.[65,66] Despite this, in 2015, CMS incorporated the un-revised and un-endorsed measure into its Nursing Home Care Compare Five Star Quality Rating System. This addition was particularly significant, given the role of this rating system in SNFs' ability to participate in certain waivers and payment arrangements and its importance as a quality reference for patients and their families. A SNF's star rating is prominently displayed on this website and can impact patient and family selection of a facility.

In addition to the measure's use in the Nursing Home Care Compare Five-Star Quality Rating System, CMS has continued to consider it for additional programs despite concerns from quality measure experts and other stakeholders. For example, in comments on an April 2017 proposed rule in which CMS proposed consideration of the measure for the LTC Hospital QRP, commentors noted that "measures implemented for this purpose should account for informed consent, preference, and potential improvements in the quality of life in order to accurately measure appropriate use of such medications," that **"there is no existing baseline measurement to provide [the measure] with meaning as a measure of quality of care," and that the measure lacked sensitivity and failed to distinguish between appropriate and inappropriate medication use. CMS responded that it "recognize(s) the potential limitations to the inclusion of this type of measure, as stated by the commenters, [and] will take the commenters' recommendations into consideration in our measure development and testing efforts."**[67] CMS ultimately did not incorporate the measure in the LTC Hospital QRP but listed it as a measure under consideration for incorporation in future years, as noted in the final rule, which was published in the Federal Register in August 2017.[68] To date, CMS has not incorporated the measure into other QRPs or any payment programs.

Beyond the deployment of the Long-Stay Antipsychotic Medication quality measure, CMS has pursued additional strategies to monitor antipsychotic use in SNFs. In 2017, CMS identified a cohort of SNFs as 'late adopters', reflecting higher rates of antipsychotic prescribing.[69] These SNFs, and their parent corporations where applicable, faced enhanced oversight.[70] CMS also enacted federal regulations barring the prescription of antipsychotics to residents unless clinically indicated, requiring gradual dose reduction (GDR) for appropriately prescribed antipsychotics, and limiting providers' ability to prescribe antipsychotics on an as-needed basis.[71] In addition, CMS revised the resident rights section of federal SNF regulations to require a physician or other practitioner or health professional to provide informed consent to a SNF resident or their designated representative in advance of antipsychotic treatment.[72] These regulations are independent of the quality measure, providing an additional safeguard against inappropriate antipsychotic prescribing to SNF residents.

Despite repeated feedback from health care providers and families about the flawed nature of the measure and its adverse impact on patient-centered, individualized care (summarized above and detailed below), in 2023, CMS doubled down on the measure's role in the Nursing Home Care Compare Five-Star Quality Rating System and revised the star rating methodology with specific and direct methodological changes predicated on the Long-Stay Antipsychotic Medication quality measure.[73] This revision was intended to penalize providers who inaccurately document diagnoses of schizophrenia in the MDS to consequently exclude selected patients in their SNFs from measurement.[74] CMS began auditing MDS data to assess the accuracy of schizophrenia diagnoses.[75] Under the new approach, any SNF that CMS determined had a single unjustified diagnosis of schizophrenia would see its overall star rating drop by one star, its overall quality measure rating drop to one star for six months, its long-stay quality measure rating downgraded to one star for six months, its Short-Stay Antipsychotic Medication quality measure rating suppressed for six months, and its Long-Stay Antipsychotic Medication quality measure rating suppressed for 12 months.[76] While a suppression is a lesser penalty than a star downgrade, it means that patients and family members cannot see and learn from the SNF's rating, regardless of how well or poorly it may have performed on other measures.[77] CMS' decision to make this quality measure so critical puts further scrutiny not only on SNFs' use of antipsychotics, but on physicians' decisions in diagnosing patients who may present complex clinical pictures. These actions 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.

Unintended Consequences of Measure Design Prompt Reassessments and One Revision

As CMS incorporated or considered incorporating the Long-Stay Antipsychotic Medication quality measure into Medicare QRPs, multiple stakeholders expressed concerns regarding its effects on quality of care, which prompted a series of formal reviews, including by OIG (see further below), intended to address unintended consequences for documentation. At the prompting of advocates and members of Congress, CMS convened a TEP to advise on measure respecification. **CMS has acknowledged the TEP findings and, in June 2025, acted on one OIG recommendation but has yet to take action on the others, raising concerns among advocates that the pressure to avoid antipsychotic use in SNFs, even where clinically indicated, will continue to increase.**

Impact on Clinicians' Ability to Treat Patients

Today, clinicians who determine that antipsychotics are the best—or only—way to treat a patient's NPS will put a SNF's star rating at risk by simply prescribing them. Such medical decisions are shielded from this risk only when the patient has one of three diagnoses, though, as described above, a perceived diagnostic error can have even more significant star rating consequences. Given the lack of an evidence-based benchmark

or targeted range of values for antipsychotic use in this patient population, the Nursing Home Care Compare Five-Star Quality Rating System scores SNFs based on their performance decile relative to other SNFs, with performers in the lowest performing decile (that is, with the most non-excluded patients using antipsychotic medications) receiving the fewest points toward their star rating.[78]

As the measure has its intended effect of lowering antipsychotic use across the long-stay SNF resident population as a whole, absolute performance levels that would have earned an individual SNF a high score may become neutral or even unfavorable, creating **continuous pressure to ratchet down antipsychotic prescribing or even rapidly discontinue medication inappropriately**. However, while many SNFs may have initially been able to improve performance by identifying and remedying clear-cut cases of misuse, over time, **the relentless pressure of the measure's formula forces them to halt antipsychotic use in cases where these medications are clinically appropriate or even essential**—particularly for the SNFs most willing to accept ADRD patients with significant NPS.

These concerns about the unintended effects of quality measure design are not new and are not unique to the Long-Stay Antipsychotic Medication measure. More than a decade ago, a physician discussing a measure of blood pressure control wrote:

> The unintended consequences of quality measurement are well-recognized and include a loss of professionalism, and potential patient harm, when clinicians focus on achieving the performance measure rather than what may be best for the patient.[79]

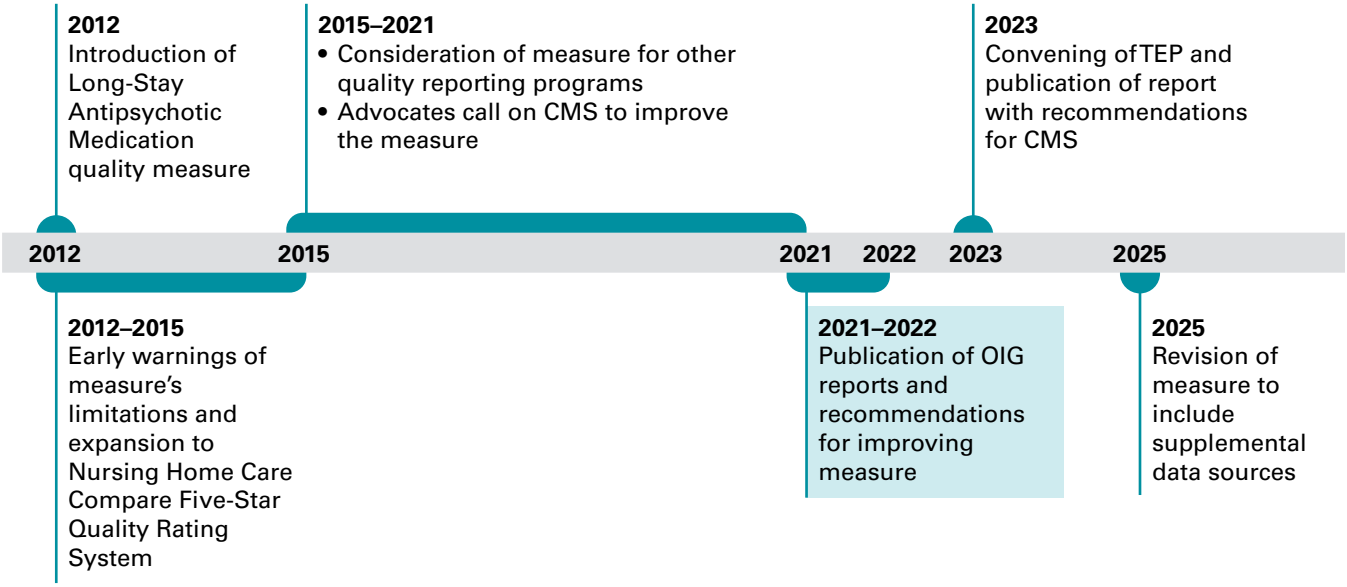
Rather than rewarding continuous improvement in measure scores as a goal, even in cases where a provider may consider a measured intervention to be detrimental to an individual patient, the Agency for Healthcare Research and Quality set an evidence-based benchmark for a widely-used measure of blood pressure control of 70% in the primary care setting to determine whether primary care providers were following best practices effectively.[80] This approach assumes that providers need discretion to address individual patients' needs and circumstances, with the proportion of patients for whom a provider is expected to use that discretion (in this case, nearly a third) reflecting a detailed evidence review. Advocates have been urging the agency to adopt a similar evidence-driven approach for the Long-Stay Antipsychotic Medication quality measure.

Impact on Patients' and Families' Ability to Understand Star Ratings

Research has shown that SNFs' star ratings shape patient and family decisions about where to seek care.[81] The methodological flaws of the measure explored above are compounded by CMS' failure to contextualize measure results appropriately for patients and families. While the Nursing Home Care Compare Five-Star Quality Rating System website notes next to a SNF's Long-Stay Antipsychotic Medication score that "antipsychotic medications can be used to treat certain mental health conditions," explains that "lower percentages are better" and specifies the national average and state average (if available), it omits vital context required for patients and families to accurately interpret, and act upon, a SNF's score. Clinical guidelines for the management of NPS among older adults with ADRD have evolved significantly since the

measure was designed and implemented, as shown by the APA's issuance of a clinical guideline and the FDA subsequent approval of two medications specifically to treat NPS of ADRD.[82] Despite these developments, SNFs that use antipsychotics to treat NPS, even in cases where this treatment is concordant with APA guidelines and FDA labeling, risk their star ratings being downgraded, which, in turn, could lead families to believe that such SNFs are misusing these treatments when they are, in fact, providing patient-centered, individualized care for patients with ADRD.

Timeline of Events



OIG Reports Lead to Revision

The MDS has been a key element in the Long Stay Antipsychotic Medication quality measure since its original specification, and it remains so in the revised specification. In contrast, measures of pharmaceutical use in most settings rely on standardized analyses of claims, administrative, or electronic health record (EHR) data.[83] Clinicians, researchers, government agencies, SNF providers, advocates, and SNF residents and their families have expressed concerns about the validity and reliability of the MDS data that are currently captured and utilized as a reference source for antipsychotic use and exclusion criteria. In a May 2021 Issue Brief and a subsequent report in November 2022, OIG critiqued the measure's reliance on the MDS as its sole data source and its failure to distinguish between appropriate and inappropriate antipsychotic prescriptions which generated misleading assessments of quality.[84,85] Specifically, OIG advised CMS to:

- Further validate data received from MDS assessments and supplement it with other data on the use of antipsychotics in SNFs, then determine whether to take further action to ensure appropriate use;
- Leverage existing data to monitor specific SNFs or characteristics of SNFs with higher rates of antipsychotic prescription than expected given their resident population, and strengthen oversight of those where trends indicate inappropriate use; and
- Expand the required data elements on Medicare Part D claims to include a diagnosis code.[86]

In 2022, following the second report's publication, CMS concurred with OIG's first two recommendations but not with its third.[87] CMS directly addressed some of the OIG's concerns in June 2025, when the agency announced that it would add new data sources to supplement the data in the MDS with claims and encounter data, creating a more robust database and seeking to improve the measure's accuracy.[88] CMS can take other steps to address the problems created by the measure.

The data shortcomings that OIG highlighted are not unique to CMS' SNF Long-Stay Antipsychotic Medication quality measure. In 2013, the Pharmacy Quality Alliance (PQA) endorsed a similar SNF quality measure, Antipsychotic Use in Persons with Dementia, which assesses the percentage of long-stay SNF residents with dementia who are receiving an antipsychotic medication without evidence of a psychotic disorder or related condition.[89,90] Like CMS' measure, PQA's measure excluded residents with schizophrenia, Huntington's disease and Tourette's syndrome from the calculation but added bipolar disorder to the list of exclusions. PQA's measure also relied solely on the MDS, making it subject to many of the same vulnerabilities as the original CMS measure.[91] In December 2022, PQA recommended its quality measure for retirement, citing in its rationale that the costs outweighed the benefits of undertaking what would be an extensive process to convene subject matter experts, solicit their input on how the measure could be improved, and update and reissue the measure.[92] PQA's decision to retire its MDS-sourced measure is a clear indicator of its current limitations for quality measurement in this clinical area and of the level of effort that would be required, should CMS attempt to further revise its similar measure.

Five Key Concerns

Since the Long-Stay Antipsychotic Medication quality measure's debut in 2012, government entities, health care professionals, clinical societies and provider associations, quality measure experts, and patient advocacy groups, including the Alliance for Aging Research, American Society of Consultant Pharmacists (ASCP), and members of Project PAUSE (Psychoactive Appropriate Use for Safety and Effectiveness) have warned CMS about its potential for unintended consequences in quality of care and patient outcomes. These warnings can be summarized in the following five key concerns:

1. The measure **fails to distinguish between clinically appropriate and inappropriate use** of antipsychotic medications.
2. The measure **may have increased inappropriate prescriptions of other psychotropics (e.g., anticonvulsants, antidepressants, anxiolytics) and opioids** as substitutes for antipsychotics.
3. The measure **does not reflect current clinical guidelines** and **limits patient access to medically necessary care**.
4. The measure **incorporates inaccurate diagnosis coding and insufficient exclusion criteria**.
5. The measure's use in the Nursing Home Care Compare Five—Star Quality Rating System **lacks critical context** for patients, families, and caregivers.

Impact of Medication Denial on Patients

In addition to analyzing the data limitations of the original quality measure, the 2021 and 2022 OIG reports also evaluated how pressure to reduce antipsychotic prescribing had changed prescribing trends more broadly. The measure's numerator is limited to patients receiving antipsychotics, but many other classes of medication—often with their own significant risks—are used to manage NPS. While antipsychotic use among SNF residents decreased from 31% to 22% between 2011 and 2019 following the quality measure's implementation, anticonvulsant use increased from 28% to 40% during the same time period, raising questions about the appropriateness of these anticonvulsant prescriptions.[93] **Anticonvulsants (also referred to as antiepileptics) are a category of psychotropic medications that are FDA-approved for the prevention and treatment of seizures, as well as a range of other medical conditions; however, they are not FDA-approved to treat NPS of ADRD, though they are used off-label for that purpose.**[94] **This means that an SNF using an antipsychotic that is FDA-approved for management of NPS in ADRD would be penalized in the Nursing Home Care Compare Five-Star Quality Rating System, while a SNF that uses an anticonvulsant off-label for the same purpose would not. There are serious and life-threatening side effects associated with anticonvulsant use among older adults, including, but not limited to, an increased risk of falls, dose-dependent sedation, and cognitive impairment.**[95]

As antipsychotic use in SNFs has declined, there is also evidence of increased prescribing of antidepressants and anxiolytics (two other categories of psychotropics) and opioids among SNF residents with ADRD, despite their lack of FDA approval for use to treat NPS.[96]

Each of these medication types is associated with adverse side effects for which older adults are at increased risk, in addition to the risks associated with anticonvulsants described above.

- **Antidepressants** can cause gastrointestinal bleeds, hemorrhagic stroke, sleep disturbances, and dizziness, which can lead to falls.[97]
- The adverse effects of **benzodiazepines**, the most common anxiolytics prescribed to older adults, are magnified in this patient population compared to younger adults and include increased risk of cognitive decline, poor functional autonomy, sleep disturbances, and dependence or addiction for long-term use (more than 30 days).[98]
- Typically only FDA-approved for pain management, **opioids** can cause sedation, mild cognitive impairment, and an increased risk of substance use disorder when taken by older adults for other conditions.[99]

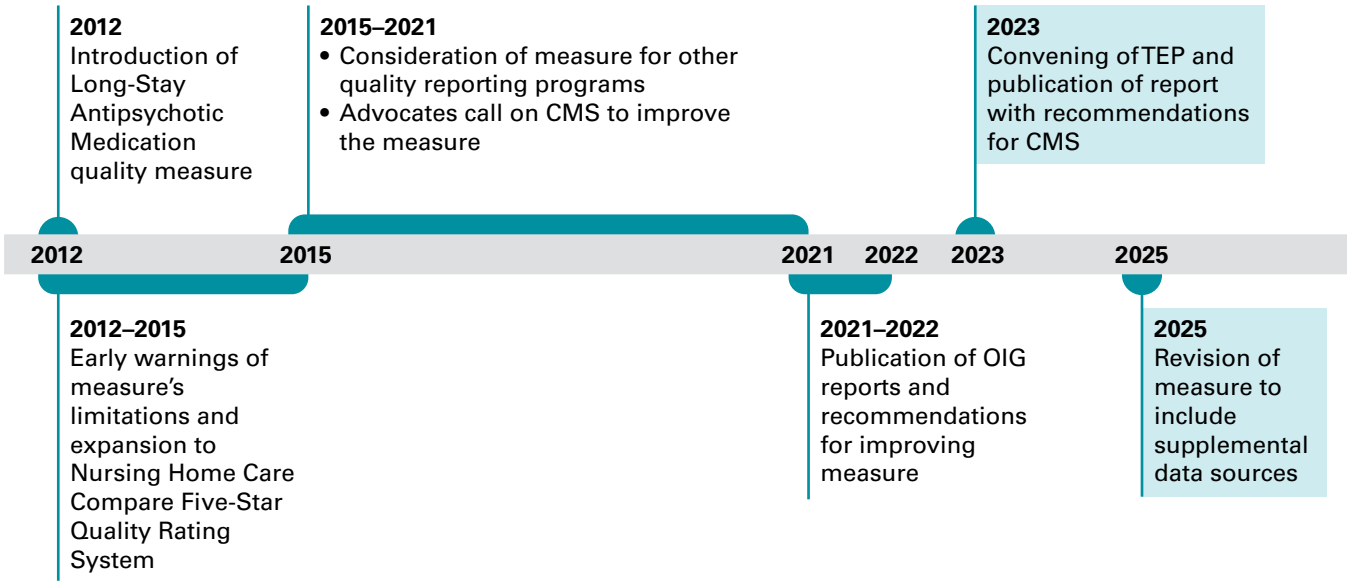
These data suggest that that alternative medications not penalized by the Long-Stay Antipsychotic Medication quality measure also have significant adverse effects and/or may be clinically contraindicated for individual patients.

The utilization of these other medications that may have an adverse effect on SNF residents illustrates a significant and serious unintended clinical care consequence of CMS' sole focus on decreasing the across-the-board use of antipsychotics, driving providers to utilize treatments that may be less effective and potentially more harmful as patients with NPS should not be left untreated.

Selection of Exclusions

While OIG's reports focused on documentation of exclusions, selection of exclusions is meaningful as well. CMS has not publicly stated why its measure, unlike the now-retired PQA measure, does not consider bipolar disorder a qualifying exclusion, nor has it communicated its intent to add other psychotic disorders or major depressive disorder—both FDA indications for antipsychotics—as exclusions.[100] One study looked at a hypothetical measure that excludes all FDA-indicated antipsychotic use, rather than the current CMS exclusions, and found that only approximately 50% of antipsychotic use would be considered inappropriate, compared with 85% for the current CMS measure.[101] This limitation is **particularly challenging for specialized SNFs**, such as those with dementia special care units, which may have large populations of patients with non-excluded diagnoses for which antipsychotic use is appropriate, and thus they have higher reported rates of appropriate use.[102,103] Even individuals who were being successfully treated with antipsychotics for any condition other than schizophrenia, Huntington's and Tourette's when they resided in the community could cause a SNF to lose star rating points for providing continuity of care and treating those patients with the same medications they were using prior to SNF admission. As a result, those individuals may be at **increased risk for inappropriate GDR or medication discontinuation** upon SNF admission.

Timeline of Events



TEP Calls for Measure Redesign

In response to patient advocate input and Congressional attention, in February 2023, CMS convened a TEP to inform the respecification of its Long-Stay Antipsychotic Medication quality measure.[104] The TEP comprised 12 individuals with clinical, policy and program, quality measure development, and patient, family, and/or caregiver expertise.[105] In addition to reviewing data concerns described above, which CMS recently addressed, panelists also discussed limitations of the measure's numerator and denominator, which

include all antipsychotic use for eligible residents and do not differentiate between clinically appropriate and inappropriate use, regardless of whether the prescription conforms to clinical guidelines or FDA indication.[106] Instead, the measure assumes that all antipsychotic prescribing to long-stay SNF residents is **inappropriate** except to those residents with the three exempted diagnoses.

Panelists concluded that an effective quality indicator of long-stay antipsychotic medication use should:[107]

- Identify the percentage of long-stay SNF residents who are **inappropriately prescribed** antipsychotics, rather than the percentage of residents who receive antipsychotics.
- Expand list of measure exclusions to include additional severe mental illnesses and account for all FDA indications for antipsychotic medication.
- Incorporate lived experience into the re-specification of the measure.
- Use the most recent data available and report timely results.
- Leverage existing resources to improve appropriate antipsychotic medication use and coding.

These changes would require CMS to systematically reexamine and respecify the measure's numerator, denominator, and exclusions. The panelists' recommendations could mitigate many of the measure's most important weaknesses and risks, though likely at a considerable financial cost.[108] CMS publicly posted the TEP report in September 2023 and partially addressed the TEP's fourth recommendation—using the most recent data available and reporting timely results—in June 2025.[109] **CMS has not taken any public steps to address the TEP's other four recommendations for improving the measure.**

Potential Approaches to Mitigating Concerns

Now that CMS is poised to mitigate one concern raised about the Long-Stay Antipsychotic Medication quality measure, there are multiple avenues through which the agency could operationalize OIG, TEP, and advocates' other recommendations. These include options to **further revise, suspend, or retire** the measure and are listed below on a continuum along with their respective pros and cons. The options marked with an asterisk would satisfy one or more TEP recommendations. CMS has clear authority to pursue any of the below options, as the agency has a process for doing and has previously done when a quality measure has shown to be misaligned with clinical best practices and/or contributing to adverse patient outcomes.[110] CMS may pursue multiple options on the list below, as they are not mutually exclusive.

CMS' commitment to eliminating episodes of inappropriate antipsychotic prescribing and ensuring accurate data on the number of long-stay SNF residents who are prescribed antipsychotics would suggest that further revising the measure is the agency's preferred option. However, CMS has only revised the measure once, more than a decade after its launch, despite repeated calls to do so by a wide range of stakeholders, including quality measure experts and HHS' own Inspector General. This may reflect the financial and bandwidth costs associated with revising the measure, which were significant enough to prompt the PQA to opt for retiring, rather than revising, its similar measure. Alternatively, it could indicate that CMS was committed to maintaining the measure as originally written.

Waiting another decade—or longer—for further updates to take place, however, will leave many patients, family members, and providers without access to the full range of recommended treatments to provide relief from NPS. Suspending or retiring the measure altogether would most efficiently signal CMS' support for guideline-concordant, patient-centered care at SNFs, including for older adults with NPS of ADRD, while removing the measure's unintended effects on prescribing of other classes of psychotropics and avoidable facility-initiated discharges.

Further Revise Quality Measure

Identify Evidence-Based Benchmark

Pros	Cons
• Provides families, caregivers, SNFs, other providers, and SNF regulators with the necessary context to interpret an SNF's performance on this quality measure. • Recognizes that, in some cases, use of antipsychotics reflects guideline-concordant, person-centered, collaborative treatment because they are most appropriate for that patient's specific needs.	• Provides a population-level benchmark but does not distinguish between appropriate and inappropriate antipsychotic use at the individual patient level. • Requires research investment to determine appropriate benchmark, including the development and testing of an appropriate risk adjustment approach to ensure that SNFs specializing in or are willing to accept higher-risk patients (e.g., SNFs with dementia special care units) and are not unduly penalized for delivering appropriate care to those patients.

Expand Exclusion Criteria*

Pros	Cons
• Accounts for the full range of relevant psychiatric diagnoses for which antipsychotics are indicated according to the FDA, ensuring that patients with those diagnoses are not subjected to GDR unless contraindicated nor denied access to medication treatment.	• Requires research investment to document clear, evidence-based rationale for each exclusion that addresses both indications and common off-label uses and why GDR was not attempted. • Requires additional time and resources to identify valid, accurate, and reliable ways to document selected exclusions and conduct testing of revised measure.

Conduct Additional Stakeholder Engagement to Support Further Respecification*

Pros	Cons
• Designs a measure that incorporates patient, family, caregiver, clinician, and SNF perspectives. • Raises awareness of and encourages additional advocacy around medication access for long-stay SNF residents.	• Convening an augmented TEP or otherwise conducting stakeholder outreach requires additional time and resources. • Stakeholder feedback may be challenging to incorporate into actionable measures due to complexity of available measurement concepts and limitations of evidence base.

Develop Supplemental Quality Measure

Pros	Cons
• Supplemental measure distinguishes between appropriate and inappropriate antipsychotic use at the individual patient level, ensuring medication access for those who would benefit from it and safeguarding against abuse. • May, in time, lead to the retirement of the original measure.	• Measure development requires significant time and resource investments and has the potential to incur substantial monitoring costs. • Presence of multiple measures may cause confusion for SNFs, families, and caregivers.

Remove Quality Measure from Nursing Home Care Compare Five-Star Quality Rating System

Reclassify Current Measure as Information-Only and Provide Necessary Context for Results

CMS has six long-stay SNF quality measures that are already classified as information-only (e.g., not publicly reported or included in the Nursing Home Care Compare Five-Star Quality Rating System but available for provider preview), setting a precedent for the Long-Stay Antipsychotic Medication quality measure to follow.[111]

Pros	Cons
• Ensures access to antipsychotics for patients who would benefit from them to manage NPS and maintain SNF placement. • Mitigates quality measure's current impact on SNF quality ratings and public misperception by making data available only to CMS and SNF surveyors, not the public. • Acts on recommendations made by patients, families, providers, and advocates since the measure was first implemented in 2012.	• May require development of supplemental strategies to promote appropriate prescribing; CMS may deem informational measure and survey process insufficient to address instances of inappropriate antipsychotic prescribing in SNFs. • Necessary context would require identifying appropriate reasons for variation and identifying SNFs that specialize in certain diagnoses for which antipsychotic use reflects standard of care (e.g., those with dementia special care units), which could be challenging to provide.

Suspend Public Reporting of Current Measure and Charge United States Government Accountability Office (GAO) with Studying Clinically Appropriate vs. Inappropriate Antipsychotic Prescribing

Pros	Cons
• Limits unintended consequences of measure during period of pause. • Pursues a focused, cost-effective research investment that could generate improvements to measurement approach if acted upon.	• Does not necessarily incorporate lived experience or a broad range of perspectives unless specifically included in GAO remit. • CMS would still need to operationalize study results and revise or retire measure accordingly.

Suspend Public Reporting of Current Measure and Respecify to Define as Antipsychotic Use Without Indication or Documentation of Appropriateness Criteria*

CMS could respecify the measure as follows:

- **Numerator**: Number of long-stay residents who have been prescribed antipsychotics for whom:
  - The antipsychotic medication is NOT FDA-approved to treat NPS of ADRD or another excluded condition (e.g., schizophrenia, Tourette's syndrome, Huntington's disease, bipolar disorder); and
  - The prescribing clinician and pharmacists have NOT documented that the use and dose are clinically appropriate based on recognized guidelines issued by the APA or another national health care provider organization or that GDR is clinically contraindicated.
- **Denominator**: Total number of long-stay residents.

Pros	Cons
• Distinguishes between appropriate and inappropriate antipsychotic use at the individual patient level, ensuring medication access for those who would benefit from it and safeguarding against abuse. • Creates a measure that is adaptable to new evidence and clinical guidelines for treating NPS of ADRD. • Provides substantial documentation to support interdisciplinary clinical decision making. – Requires the prescribing clinician to document their clinical rationale for prescribing an antipsychotic medication in the MDS. – Requires SNF's consultant pharmacist to document in the MDS GDR and medication regimen review information, allowing for improved CMS oversight of antipsychotic use in SNFs. • Any concern regarding inappropriate medication use would still be investigated and reported by a SNF surveyor, maintaining current practice. • Acts on recommendations made by patients, families, providers, and advocates since the measure was first implemented in 2012.	• Individualized documentation requirement could add burden for providers and SNF staff. • May require significant socialization of newly respecified measure with clinicians, pharmacists, and SNF staff to promote appropriate antipsychotic prescribing. • CMS may deem documentation-based measures and survey processes insufficient to address instances of inappropriate antipsychotic prescribing in SNFs. • CMS may request a solely FDA indication-based numerator, which would require time and resources to identify, define, and test additional indications. • While use of indicated medications can be captured in claims, it may be more challenging to identify additional data sources to document clinical rationale and could require exploration of unstructured EHR data.

[Continued on next page]

Retire Quality Measure

Pros	Cons
• Ensures access to antipsychotics for patients who would benefit from them to manage NPS and maintain SNF placement. • Mitigates measure's current impact on SNF quality ratings and patient/family choice. • While an alternative tool (e.g., an enhanced MDS) would need to be developed to address the challenge of inappropriate prescribing of antipsychotics and other medications, this topic is already addressed in federal regulations and the survey process, minimizing the need for additional financial investment.[112]	• Does not invite input from patients, families, caregivers, clinicians, or SNF providers unless CMS takes on what may be an extensive process. • Requires explanation of why measure was retired; may elicit questions and criticism.

Conclusion

Suspending or eliminating public reporting of the Long-Stay Antipsychotic Medication quality measure in the Nursing Home Care Compare Five-Star Quality Rating System to allow for further respecification would be a step toward improving the quality of care and quality of life of all long-stay SNF residents. If further respecification beyond the inclusion of new data sources or pursuit of other methods (e.g., MDS changes) to conduct oversight of antipsychotic prescribing is not feasible, retiring the measure may be a necessary step. CMS has both the required authority and a broad base of support to enact these changes and demonstrate its commitment to strengthening access to medication treatment for long-stay SNF residents, including and especially older adults with NPS of ADRD.

CMS has an opportunity in the current federal environment to streamline Medicare regulations and remove unnecessary administrative burdens on SNF providers with the goal of reducing private health care expenditures. The Long-Stay Antipsychotic Medication quality measure could be removed from the Nursing Home Care Compare Five-Star Quality Rating System through a variety of subregulatory channels, including issuance of Quality Safety & Oversight memoranda or updates to the Nursing Home Care Compare Technical Users Guide, at a low cost. Any of these actions could be undertaken without compromising patient safety or the integrity of the Medicare program.

Next Steps and Contacts

Role of the Alliance for Aging Research

The Alliance for Aging Research works with patients, federal agencies, elected officials, and partner organizations to advance policies that support research and healthy aging, including several projects to address current obstacles in the lack of treatments for ADRD and adequate care for this patient group.

The Alliance has partnered with the ASCP to convene Project PAUSE (Psychoactive Appropriate Use for Safety and Effectiveness), an ad hoc coalition of national patient and professional organizations collectively addressing LTC clinical regulatory and legislative issues. Project PAUSE provides educational opportunities for policymakers and the public on effective solutions for improving clinical care in LTC settings by advocating for streamlined, clinical surveyor training, improved quality measures to appropriately determine antipsychotic drug use LTC settings, and other solutions aimed at improving the diagnosis and management of NPS of ADRD. Its membership includes patient and family caregiver organizations, LTC groups, primary care associations, geriatric and mental health specialty provider associations, and ADRD groups as well as mental health organizations.

Next Steps for Interested Parties

If you are interested in learning more, please email info@agingresearch.org.

1. "What is Alzheimer's Disease and Related Dementias," NAPA - National Alzheimer's Project Act, Office of the Assistant Secretary for Planning and Evaluation (ASPE), U.S. Department of Health and Human Services, last accessed September 18, 2025, https://aspe.hhs.gov/collaborations-committees-advisory-groups/napa/what-ad-adrd#:~:text=Alzheimer%27s%20disease%20and%20related%20dementias%20(AD/ADRD)%20are%20debilitating,ADRD%20and%20for%20their%20families.

2. Muhammad Atif Ameer, Preeti Patel, and Abdolreza Saadabadi, "Neuroleptic Medications," StatPearls [Internet] (StatPearls Publishing, 2025), https://www.ncbi.nlm.nih.gov/books/NBK459150/#:~:text=Continuing%20Education%20Activity,are%20currently%20considered%20off%2Dlabel.

3. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), "Guidance for Industry: Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products – Content and Format," issued October 2011, https://www.fda.gov/media/71866/download.

4. "State Operations Manual (SOM) Surveyor Guidance Revisions Related to Psychosocial Harm in Nursing Homes," Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality/Survey & Certification Group, issued March 25, 2026, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-15.pdf.

5. "Quality Measures: What's New," Centers for Medicare & Medicaid Services, last modified September 12, 2019, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/Archive_-NH-Quality-Measures_10819.pdf.

6. Stephanie V. Phan, Sharmon Osae, John C. Morgan, et al., "Neuropsychiatric Symptoms in Dementia: Considerations for Pharmacotherapy in the USA," Drugs in R&D 19, no. 2 (2019): 93-115, https://doi.org/10.1007/s40268-019-0272-1; Andrew Pless, Destany Ware, Shalini Saggu, et al., "Understanding neuropsychiatric symptoms in Alzheimer's diseases: challenges and advances in diagnosis and treatment," Frontiers in Neuroscience 17: 1263771 (2023), https://doi.org/10.3389/fnins.2023.1263771.

7. "Find & Compare Providers Near You," Medicare, Providers & Services, Centers for Medicare & Medicaid Services, last accessed September 18, 2025, https://www.medicare.gov/care-compare/?redirect=true&providerType=NursingHome.

8. Kimberly Ernstmeyer and Elizabeth Christman, Nursing: Mental Health and Community Concepts (Chippewa Valley Technical College, 2022), chap. 6: Psychotropic Medications, https://www.ncbi.nlm.nih.gov/books/NBK590034/; Filippo Caraci, Sam J. Enna, Joseph Zohar, et al., "A New Nomenclature for Classifying Psychotropic Drugs," British Journal of Clinical Pharmacology 83, no. 8 (2017): 1614-1616, https://doi.org/10.1111/bcp.13302.

9. "Revisions to State Operations Manual Appendix PP - Guidance to Surveyors for Long Term Care Facilities," Centers for Medicare & Medicaid Services, CMS Manual System Pub. 100-07 State Operations Provider Certification: Transmittal 19, June 1, 2006, https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r19soma.pdf; "Nursing Homes," Certification & Compliance, Health & Safety Standards, Medicare, Centers for Medicare & Medicaid Services, last modified July 30, 2025, https://www.cms.gov/medicare/health-safety-standards/certification-compliance/nursing-homes.

10. "Alzheimer's Disease Facts and Figures," About Alzheimer's & Dementia, Alzheimer's Association, last modified 2025, https://www.alz.org/alzheimers-dementia/facts-figures#:~:text=Over%207%20million%20Americans%20have,older%20(11%25)%20has%20Alzheimer%27s.

11. "Alzheimer's Disease Facts and Figures," About Alzheimer's & Dementia, Alzheimer's Association, last modified 2025, https://www.alz.org/alzheimers-dementia/facts-figures#:~:text=Over%207%20million%20Americans%20have,older%20(11%25)%20has%20Alzheimer%27s.

12. Dana B. Mukamel, Debra Saliba, Heather Ladd, et al., "Dementia Care is Widespread In US Nursing Homes; Facilities With The Most Dementia Patients May Offer Ways to Better Care," *Health Affairs* 42, no. 6 (June 2023): 795-803, https://doi.org/10.1377/hlthaff.2022.01263; "2025 Alzheimer's Disease Facts and Figures," Alzheimer's Association, 2025, https://www.alz.org/getmedia/ef8f48f9-ad36-48ea-87f9-b74034635c1e/alzheimers-facts-and-figures.pdf.

13. Dana B. Mukamel, Debra Saliba, Heather Ladd, et al., "Dementia Care is Widespread In US Nursing Homes; Facilities With The Most Dementia Patients May Offer Ways to Better Care," *Health Affairs* 42, no. 6 (June 2023): Appendix Exhibit A1 [data set], https://pmc.ncbi.nlm.nih.gov/articles/PMC10796080/#SM1; Dana B. Mukamel, Debra Saliba, Heather Ladd, et al., "Dementia Care is Widespread In US Nursing Homes; Facilities With The Most Dementia Patients May Offer Ways to Better Care," *Health Affairs* 42, no. 6 (June 2023): https://doi.org/10.1002/gps.4098 Appendix Exhibit A1 [data set omitted in final publication, available in online version at https://pmc.ncbi.nlm.nih.gov/articles/PMC10796080/#SM1; "2025 Alzheimer's Disease Facts and Figures," Alzheimer's Association, 2025, https://www.alz.org/getmedia/ef8f48f9-ad36-48ea-87f9-b74034635c1e/alzheimers-facts-and-figures.pdf.

14. Dana B. Mukamel, Debra Saliba, Heather Ladd, et al., "Dementia Care is Widespread In US Nursing Homes; Facilities With The Most Dementia Patients May Offer Ways to Better Care," *Health Affairs* 42, no. 6 (June 2023): Appendix Exhibit A1 [data set], https://pmc.ncbi.nlm.nih.gov/articles/PMC10796080/#SM1; Dana B. Mukamel, Debra Saliba, Heather Ladd, et al., "Dementia Care is Widespread In US Nursing Homes; Facilities With The Most Dementia Patients May Offer Ways to Better Care," *Health Affairs* 42, no. 6 (June 2023): https://doi.org/10.1002/gps.4098 Appendix Exhibit A1 [data set omitted in final publication, available in online version at https://pmc.ncbi.nlm.nih.gov/articles/PMC10796080/#SM1; "2025 Alzheimer's Disease Facts and Figures," Alzheimer's Association, 2025, https://www.alz.org/getmedia/ef8f48f9-ad36-48ea-87f9-b74034635c1e/alzheimers-facts-and-figures.pdf.

15. Dana B. Mukamel, Debra Saliba, Heather Ladd, et al., "Dementia Care is Widespread In US Nursing Homes; Facilities With The Most Dementia Patients May Offer Ways to Better Care," *Health Affairs* 42, no. 6 (June 2023): Appendix Exhibit A1 [data set], https://pmc.ncbi.nlm.nih.gov/articles/PMC10796080/#SM1; Dana B. Mukamel, Debra Saliba, Heather Ladd, et al., "Dementia Care is Widespread In US Nursing Homes; Facilities With The Most Dementia Patients May Offer Ways to Better Care," *Health Affairs* 42, no. 6 (June 2023): https://doi.org/10.1002/gps.4098 Appendix Exhibit A1 [figure omitted in final publication, available in online version at https://pmc.ncbi.nlm.nih.gov/articles/PMC10796080/#SM1.

16. NPS of Alzheimer's and related diseases are also referred to as behavioral and psychological symptoms of dementia (BPSD) in some clinical contexts.

17. "Mortality and Antipsychotic Use in Dementia-related Behavioral Disorders," Duke-Margolis Institute for Health Policy, issued December 10, 2024, https://healthpolicy.duke.edu/sites/default/files/2024-12/Slides%20Mortality%20and%20Antipsychotic%20Use%20in%20Dementia-related%20Behavioral%20Disorders%20Virtual%20Public%20Workshop.pdf.

18. Andrew Pless, Destany Ware, Shalini Saggu, et al., "Understanding neuropsychiatric symptoms in Alzheimer's diseases: challenges and advances in diagnosis and treatment," Frontiers in Neuroscience 17: 1263771 (2023), https://doi.org/10.3389/fnins.2023.1263771.

19. American Psychiatric Association, *The American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia* (American Psychiatric Association, 2016), https://doi.org/10.1176/appi.ajp.2015.173501.

20. "Description of Antipsychotic Medication Quality Measures on Nursing Home Compare," Certification & Compliance, Centers for Medicare & Medicaid Services, https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcomplianc/downloads/antipsychoticmedicationqm.pdf.

21. "Updates to Nursing Home Care Compare," Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services, June 18, 2025, https://www.cms.gov/files/document/qso-25-20-nh.pdf.

22. "Mortality and Antipsychotic Use in Dementia-related Behavioral Disorders," Duke-Margolis Institute for Health Policy, issued December 10, 2024, https://healthpolicy.duke.edu/sites/default/files/2024-12/Slides%20Mortality%20and%20Antipsychotic%20Use%20in%20Dementia-related%20Behavioral%20Disorders%20Virtual%20Public%20Workshop.pdf; Andrew Pless, Destany Ware, Shalini Saggu, et al., "Understanding neuropsychiatric symptoms in Alzheimer's diseases: challenges and advances in diagnosis and treatment," Frontiers in Neuroscience 17: 1263771 (2023), https://doi.org/10.3389/fnins.2023.1263771; Aaron Choi, Anthony Martyr, Linda Clare, et al., "Impact of Psychotic Symptoms and Concurrent Neuropsychiatric Symptoms on the Quality of Life of People With Dementia Living in Nursing Homes," *Journal of the American Medical Directors Association* 23, no. 9 (1474-1479.E1), https://doi.org/10.1016/j.jamda.2022.03.017.

23. "Mortality and Antipsychotic Use in Dementia-related Behavioral Disorders," Duke-Margolis Institute for Health Policy, issued December 10, 2024, https://healthpolicy.duke.edu/sites/default/files/2024-12/Slides%20Mortality%20and%20Antipsychotic%20Use%20in%20Dementia-related%20Behavioral%20Disorders%20Virtual%20Public%20Workshop.pdf.

24. Not all older adults with Alzheimer's and related diseases reside in SNFs. Many reside in assisted living facilities, continuing care retirement communities, subsidized senior housing, group living arrangements, or at home and receive long-term care services (e.g., personal care assistance, home-delivered meals, adult day health care).

25. Hanna-Maria Roitto, Hannareeta Öhman, Karoliina Salminen, et al., "Neuropsychiatric Symptoms as Predictors of Falls in Long-Term Care Residents With Cognitive Impairment," *Journal of the American Medical Directors Association* 21, no. 9 (1243-1248), https://doi.org/10.1016/j.jamda.2020.04.003; "Nursing Home Residents with Endangering Behaviors and Mental Health Disorders May Be Vulnerable to Facility-Initiated Discharges," U.S. Department of Health and Human Services Office of Inspector General, issued March 2024, https://oig.hhs.gov/documents/evaluation/9849/OEI-01-18-00252.pdf; Elizabeth E. Hathaway, Jennifer L. Carnahan, Kathleen T. Unroe, et al., "Nursing Home Transfers for Behavioral Concerns: Findings from the OPTIMISTIC demonstration project," Journal of the American Geriatrics Society 69, no. 2 (2021): 415-243, https://doi.org/10.1111/jgs.16920; "Resident and Facility Factors Associated with High Risk of Discharge from Nursing Facilities, 2012-2017: Final Report," U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation, issued September 2022, https://aspe.hhs.gov/sites/default/files/documents/cc0772c12db75f3e2bce766e3d9d21c8/high-risk-discharge-report.pdf.

26. "Nursing Home Residents with Endangering Behaviors and Mental Health Disorders May Be Vulnerable to Facility-Initiated Discharges," U.S. Department of Health and Human Services Office of Inspector General, issued March 2024, https://oig.hhs.gov/documents/evaluation/9849/OEI-01-18-00252.pdf.

27. "Resident and Facility Factors Associated with High Risk of Discharge from Nursing Facilities, 2012-2017: Final Report," U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation, issued September 2022, https://aspe.hhs.gov/sites/default/files/documents/cc0772c12db75f3e2bce766e3d9d21c8/high-risk-discharge-report.pdf.

28. "National Partnership to Improve Dementia Care," Quality, Safety, & Oversight General Information, Centers for Medicare & Medicaid Services, last updated December 20, 2024, https://www.cms.gov/medicare/health-safety-standards/quality-safety-oversight-general-information/national-partnership-improve-dementia-care-nursing-homes.

29. While this paper refers to "Alzheimer's and related diseases," as opposed to "dementia," to align with the efforts of patient advocates, we kept the terms "National Partnership to Improve Dementia Care" and "dementia-related behaviors" here in deference to CMS.

30. "National Partnership to Improve Dementia Care," Quality, Safety, & Oversight General Information, Centers for Medicare & Medicaid Services, last updated December 20, 2024, https://www.cms.gov/medicare/health-safety-standards/quality-safety-oversight-general-information/national-partnership-improve-dementia-care-nursing-homes; "CMS Announces Partnership to Improve Dementia Care in Nursing Homes," Press Releases, "Centers for Medicare & Medicaid Services, issued May 30, 2012, https://www.cms.gov/newsroom/press-releases/cms-announces-partnership-improve-dementia-care-nursing-homes#:~:text=Alternatives%20to%20antipsychotic%20medication%3A%20CMS,pain%2C%20and%20planning%20individualized%20activities.

31. American Psychiatric Association, *The American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia* (American Psychiatric Association, 2016), https://doi.org/10.1176/appi.ajp.2015.173501; Aaron Gale, Kirsten Stoesser, Katherine Fortenberry, et al., "Pharmacologic Management of Agitation in Patients with Dementia," *American Family Physician* 104, no. 1 (2021): 91-92, https://www.aafp.org/pubs/afp/issues/2021/0700/p91.html; Huixuan Ma, Xinliang Lu, Aihong Zhou, et al., "Clinical Practice Guidelines for the Management of Behavioral and Psychological Symptoms of Dementia: A Systematic Review with AGREE II," *Frontiers in Neurology* 13 (May 2022): 799723, https://doi.org/10.3389/fneur.2022.799723.

32. "Mortality and Antipsychotic Use in Dementia-related Behavioral Disorders," Duke-Margolis Institute for Health Policy, issued December 10, 2024, https://healthpolicy.duke.edu/sites/default/files/2024-12/Slides%20Mortality%20and%20Antipsychotic%20Use%20in%20Dementia-related%20Behavioral%20Disorders%20Virtual%20Public%20Workshop.pdf.

33. While this paper refers to "Alzheimer's and related diseases," as opposed to "dementia," to align with the efforts of patient advocates, we kept the term "dementia-related psychosis" here in deference to the FDA.

34. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), "Guidance for Industry: Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products – Content and Format," issued October 2011, https://www.fda.gov/media/71866/download.

35. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), "Guidance for Industry: Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products – Content and Format," issued October 2011, https://www.fda.gov/media/71866/download.

36. American Psychiatric Association, *The American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients With Dementia* (American Psychiatric Association, 2016), https://psychiatryonline.org/doi/epdf/10.1176/appi.books.9780890426807.

37. "Mortality and Antipsychotic Use in Dementia-related Behavioral Disorders," Duke-Margolis Institute for Health Policy, issued December 10, 2024, https://healthpolicy.duke.edu/sites/default/files/2024-12/Slides%20Mortality%20and%20Antipsychotic%20Use%20in%20Dementia-related%20Behavioral%20Disorders%20Virtual%20Public%20Workshop.pdf; "FDA Approves First Drug to Treat Agitation Symptoms Associated with Dementia due to Alzheimer's Disease," Press Announcements, U.S. Food & Drug Administration, issued May 11, 2023, https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-treat-agitation-symptoms-associated-dementia-due-alzheimers-disease; Amanda K. Kitten, Sarah A. Hallowell, Stephen R. Saklad, et al., "Pimavanserin," *Innovations in Clinical Neuroscience* 15, no. 1-2 (February 2018): 16-22, https://pmc.ncbi.nlm.nih.gov/articles/PMC5819716/.

38. Parkinson's disease is the second most common neurodegenerative disease, affecting more than one million Americans.

39. "H. Rept. 118-124 – Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2024," 118th Congress (2023 – 2024), https://www.congress.gov/committee-report/118th-congress/house-report/124/1; "FDA Convening: Mortality and Antipsychotic Use in Dementia-Related Behavioral Disorders," Duke-Margolis Institute for Health Policy, https://healthpolicy.duke.edu/events/mortality-and-antipsychotic-use-dementia-related-behavioral-disorders.

40. "Mortality and Antipsychotic Use in Dementia-related Behavioral Disorders," Duke-Margolis Institute for Health Policy, issued December 10, 2024, https://healthpolicy.duke.edu/sites/default/files/2024-12/Slides%20Mortality%20and%20Antipsychotic%20Use%20in%20Dementia-related%20Behavioral%20Disorders%20Virtual%20Public%20Workshop.pdf.

41. "Mortality and Antipsychotic Use in Dementia-related Behavioral Disorders," Duke-Margolis Institute for Health Policy, issued December 10, 2024, https://healthpolicy.duke.edu/sites/default/files/2024-12/Slides%20Mortality%20and%20Antipsychotic%20Use%20in%20Dementia-related%20Behavioral%20Disorders%20Virtual%20Public%20Workshop.pdf; "Grassley Seeks Probe on Antipsychotic Use in Nursing Homes," Morning Briefing, *KFF Health News*, June 11, 2009, https://kffhealthnews.org/morning-breakout/dr00049252/.

42. Catherine Hupé, Caroline Larue, and Damien Contandriopoulos, "Defining chemical restraint: A preliminary step towards measurement and quality assessment," *Aggression and Violent Behavior* 77 (July – August 2024): 101926, https://doi.org/10.1016/j.avb.2024.101926.

43. Chemical restraint has been defined as "an emergency (STAT), as needed (PRN), regular or continuous medication with sedative properties, administered with the intention of preventing or controlling harmful behaviours or behaviours that interfere with diagnostic or therapeutic interventions, AND/OR administered to avoid physical restraint or seclusion; AND/OR without the person's consent.

44. Lauren M. Robins, Den-Ching A. Lee, J. Simon Bell, et al., "Definition and Measurement of Physical and Chemical Restraint in Long-Term Care: A Systematic Review," *International Journal of Environmental Research and Public Health* 18 (no. 7): 3639, https://doi.org/10.3390/ijerph18073639.

45. "Description of Antipsychotic Medication Quality Measures on Nursing Home Compare," Centers for Medicare and Medicaid Services, 2012, https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcomplianc/downloads/antipsychoticmedicationqm.pdf.

46. Centers for Medicare & Medicaid Services, "Five-Star Quality Rating System," last updated July 2025, https://www.cms.gov/medicare/health-safety-standards/certification-compliance/five-star-quality-rating-system.

47. Centers for Medicare & Medicaid Services, "Five-Star Quality Rating System," last updated July 2025, https://www.cms.gov/medicare/health-safety-standards/certification-compliance/five-star-quality-rating-system.

48. "Description of Antipsychotic Medication Quality Measures on Nursing Home Compare," Centers for Medicare and Medicaid Services, 2012, https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcomplianc/downloads/antipsychoticmedicationqm.pdf.

49. "Description of Antipsychotic Medication Quality Measures on Nursing Home Compare," Centers for Medicare and Medicaid Services, 2012, https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcomplianc/downloads/antipsychoticmedicationqm.pdf.

50. Centers for Medicare & Medicaid Services, "Final Rule: 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; and Technical Correction to Long-Term Care Facilities Physical Environment Requirements," *Federal Register* 86, no. 147 (August 4, 2021), https://www.federalregister.gov/documents/2021/08/04/2021-16309/medicare-program-prospective-payment-system-and-consolidated-billing-for-skilled-nursing-facilities.

51. U.S. Department of Health and Human Services Office of Inspector General, "Issue Brief: 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.

52. "REVISED Updates to Nursing Home Care Compare," Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services, September 10, 2025, https://www.cms.gov/files/document/qso-25-20-nh-revised-2025-09-10.pdf.

53. "Minimum Data Set (MDS) 3.0 Quality Measures User's Manual (v16.0), Centers for Medicare & Medicaid Services, effective October 1, 2023, https://www.cms.gov/files/document/mds-30-qm-users-manual-v160pdf.pdf.

54. Information about the MDS can be found here (last accessed May 13, 2025).

55. "Updates to Nursing Home Care Compare," Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services, June 18, 2025, https://www.cms.gov/files/document/qso-25-20-nh.pdf; "REVISED Updates to Nursing Home Care Compare," Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services, September 10, 2025, https://www.cms.gov/files/document/qso-25-20-nh-revised-2025-09-10.pdf.

56. "Updates to Nursing Home Care Compare," Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services, June 18, 2025, https://www.cms.gov/files/document/qso-25-20-nh.pdf.

57. "Updates to Nursing Home Care Compare," Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services, June 18, 2025, https://www.cms.gov/files/document/qso-25-20-nh.pdf.

58. CMS' definition of measure stewardship can be found here (last accessed July 2, 2025).

59. "Blueprint Measure Lifecycle Overview," Measures Management System (MMS), Centers for Medicare & Medicaid Services, last updated December 2024, https://mmshub.cms.gov/blueprint-measure-lifecycle-overview.

60. Partnership for Quality Measurement, "Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review (PRMR) and Measure Set Review (MSR), https://p4qm.org/sites/default/files/2024-07/OP1-Final-Draft-Multi-Stakeholder-Group-Guidebook-of-Policies-and-Procedures.pdf.

61. A similar but not identical measure stewarded by the Pharmacy Quality Alliance (PQA) did undergo review and receive endorsement, but that endorsement has since been removed.

62. "MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS, Final Report," Measure Applications Partnership, National Quality Forum, issued February 2013, https://cms.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx.

63. "MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS, Final Report," Measure Applications Partnership, National Quality Forum, issued February 2013, https://cms.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx.

64. "MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS, Final Report," Measure Applications Partnership, National Quality Forum, issued February 2013, https://cms.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx.

65. "MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS, Final Report," Measure Applications Partnership, National Quality Forum, issued February 2013, https://cms.qualityforum.org/Publications/2013/02/MAP_Pre-Rulemaking_Report_-_February_2013.aspx.

66. The American Health Care Association/National Center for Assisted Living (AHCA/NCAL) is the largest association of long-term and post-acute care providers in the United States. Its members include non-profit and proprietary skilled nursing facilities, assisted living communities, sub-acute centers, and homes for individuals with intellectual and developmental disabilities. AHCA provided feedback on the Long-Stay Antipsychotic Medication quality measure during the MAP-facilitated public comment period; it is unclear whether NCAL also provided feedback.

67. "42 CFR Parts 405, 412, 413, 414, 416, 486, 488, 489, and 495 [CMS 1677-P], RIN 0938-AS98: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long- Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices," Centers for Medicare & Medicaid Services, issued April 28, 2017, https://www.govinfo.gov/content/pkg/FR-2017-04-28/pdf/2017-07800.pdf.

68. "42 CFR Parts 405, 412, 413, 414, 416, 486, 488, 489, and 495 [CMS-1677-F], RIN 0938-AS98: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long- Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices," Centers for Medicare & Medicaid Services, issued August 14, 2017, https://www.govinfo.gov/content/pkg/FR-2017-08-14/pdf/2017-16434.pdf.

69. "Letter to State Survey Agency Directors on Enhanced Oversight and Enforcement of Non-Improving Late Adopters," Center for Clinical Standards and Quality/Quality, Safety & Oversight Group, Centers for Medicare & Medicaid Services, issued March 1, 2019, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO19-07-NH.pdf.

70. "Letter to State Survey Agency Directors on Enhanced Oversight and Enforcement of Non-Improving Late Adopters," Center for Clinical Standards and Quality/Quality, Safety & Oversight Group, Centers for Medicare & Medicaid Services, issued March 1, 2019, https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO19-07-NH.pdf.

71. "Letter to Kansas House Children and Seniors Committee: New Federal Regulations on Antipsychotics and Informed Consent," *LeadingAge Kansas*, issued February 13, 2019, https://kslegislature.gov/li_2020/b2019_20/committees/ctte_h_children_and_seniors_1/documents/testimony/20190213_08.pdf.

72. "Letter to Kansas House Children and Seniors Committee: New Federal Regulations on Antipsychotics and Informed Consent," *LeadingAge Kansas*, issued February 13, 2019, https://kslegislature.gov/li_2020/b2019_20/committees/ctte_h_children_and_seniors_1/documents/testimony/20190213_08.pdf.

73. "Updates to the Nursing Home Care Compare Website and Five Star Quality Rating System: Adjusting Quality Measure Ratings Based on Erroneous Schizophrenia Coding, and Posting Citations Under Dispute," Center for Clinical Standards and Quality/Quality, Safety, & Oversight Group, January 18, 2023, https://www.cms.gov/files/document/qso-23-05-nh-adjusting-quality-measure-ratings-based-erroneous-schizophrenia-coding-and-posting.pdf.

74. "Updates to the Nursing Home Care Compare Website and Five Star Quality Rating System: Adjusting Quality Measure Ratings Based on Erroneous Schizophrenia Coding, and Posting Citations Under Dispute," Center for Clinical Standards and Quality/Quality, Safety, & Oversight Group, January 18, 2023, https://www.cms.gov/files/document/qso-23-05-nh-adjusting-quality-measure-ratings-based-erroneous-schizophrenia-coding-and-posting.pdf.

75. "Updates to the Nursing Home Care Compare Website and Five Star Quality Rating System: Adjusting Quality Measure Ratings Based on Erroneous Schizophrenia Coding, and Posting Citations Under Dispute," Center for Clinical Standards and Quality/Quality, Safety, & Oversight Group, January 18, 2023, https://www.cms.gov/files/document/qso-23-05-nh-adjusting-quality-measure-ratings-based-erroneous-schizophrenia-coding-and-posting.pdf.

76. "Updates to the Nursing Home Care Compare Website and Five Star Quality Rating System: Adjusting Quality Measure Ratings Based on Erroneous Schizophrenia Coding, and Posting Citations Under Dispute," Center for Clinical Standards and Quality/Quality, Safety, & Oversight Group, January 18, 2023, https://www.cms.gov/files/document/qso-23-05-nh-adjusting-quality-measure-ratings-based-erroneous-schizophrenia-coding-and-posting.pdf.

77. "Design for *Care Compare* Nursing Home Five-Star Quality Rating System: Technical Users Guide," Centers for Medicare & Medicaid Services, January 2025, https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcomplianc/downloads/usersguide.pdf.

78. For this quality measure, SNFs are grouped into deciles based on the national distribution of the quality measure. SNFs in the lowest performing decile receive 15 points for the measure. Points are increased in 15-point intervals for each decile so that SNFs in the highest performing decile receive 150 points.

79. Dan Berlowitz, "Hypertension Control in the Elderly: Too Much of a Good Thing?", *Journal of Clinical Hypertension* 16, no. 4 (March 2014): 265-266, http://doi.org/10.1111/jch.12279.

80. "Blood Pressure Control Evidence and Resources," EvidenceNOW, Agency for Healthcare Research and Quality, last updated March 2021, https://www.ahrq.gov/evidencenow/projects/heart-health/evidence/blood-pressure.html#:~:text=How%20did%20EvidenceNOW%20evaluate%20whether,140/90%20mmHg%20or%20less.&text=The%20EvidenceNOW%20goal%20for%20primary,140/90%20mmHg%20or%20less.

81. Rachel M. Werner, R. Tamara Konetzka, and Daniel Polsky, "Changes in Consumer Demand Following Public Reporting of Summary Quality Ratings: An Evaluation in Nursing Homes," Health Services Research 51, Suppl 2 (February 2016): 1291-1309, http://doi.org/10.1111/1475-6773.12459.

82. American Psychiatric Association, *The American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia* (American Psychiatric Association, 2016), https://psychiatryonline.org/doi/epdf/10.1176/appi.books.9780890426807; "FDA Approves First Drug to Treat Agitation Symptoms Associated with Dementia due to Alzheimer's Disease," Press Announcements, U.S. Food & Drug Administration, issued May 11, 2023, https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-treat-agitation-symptoms-associated-dementia-due-alzheimers-disease; Amanda K. Kitten, Sarah A. Hallowell, Stephen R. Saklad, et al., "Pimavanserin," *Innovations in Clinical Neuroscience* 15, no. 1-2 (February 2018): 16-22, https://pmc.ncbi.nlm.nih.gov/articles/PMC5819716/.

83. Emily R. Carrier and Tracy A. Massel, "The Complete Health Tech Guide to Quality Measurement," Manatt Health, February 2025, https://www.manatt.com/insights/white-papers/2025/the-complete-health-tech-guide-to-quality-measurement.

84. "CMS Could Improve the Data It Uses To Monitor Antipsychotic Drugs in Nursing Homes," U.S. Department of Health and Human Services Office of Inspector General, issued May 2021, https://oig.hhs.gov/documents/evaluation/3089/OEI-07-19-00490-Complete%20Report.pdf.

85. In May 2021, OIG released an Issue Brief stating that the MDS provides incomplete information and should not be the sole data source informing CMS' Long-Stay Antipsychotic Medication quality measure. OIG found that some long-stay SNF residents' use of antipsychotics was not detected by the quality measure. In addition, in 2018, 5% of all Medicare Part D beneficiaries who were long-stay SNF residents age 65 and older had a Part D claim for an antipsychotic medication but were not reported in the MDS as having received that drug, and almost one third of residents with schizophrenia—which would exclude them from CMS' reporting on this measure—had no Medicare service claims for that diagnosis. Even for those residents whose medication use was detected, the MDS failed to specify which medications they were prescribed, at what quantities and strengths, and for how long, which are essential details when assessing the quality of care received. In November 2022, OIG released another report on the measure, explaining that, because CMS does not collect diagnoses (e.g., schizophrenia) on Medicare Part D claims, SNFs could misreport residents as having schizophrenia (or another exempted condition) to conceal inappropriate antipsychotic prescription and improve their score on this quality measure. Like the measure itself, OIG's review did not assess the actual administration or medical necessity of antipsychotic medications for SNF residents; it was limited to assessing the validity of the MDS as a data source. The November 2022 OIG report refers broadly to psychotropic drugs (e.g., any drug that affects brain activities associated with mental processes and behavior), of which antipsychotics are one category; the authors of this paper refer to antipsychotics for consistency. As discussed, CMS' attempts to reduce antipsychotic prescriptions among SNF residents have resulted in increased prescriptions of other psychotropic drugs for this patient population. Sources: "CMS Could Improve the Data It Uses To Monitor Antipsychotic Drugs in Nursing Homes," U.S. Department of Health and Human Services Office of Inspector General, issued May 2021, https://oig.hhs.gov/documents/evaluation/3089/OEI-07-19-00490-Complete%20Report.pdf; "Long-Term Trends of Psychotropic Drug Use in Nursing Homes," U.S. Department of Health and Human Services Office of Inspector General, issued November 10, 2022, https://oig.hhs.gov/reports/all/2022/long-term-trends-of-psychotropic-drug-use-in-nursing-homes/.

86. "CMS Could Improve the Data It Uses To Monitor Antipsychotic Drugs in Nursing Homes," U.S. Department of Health and Human Services Office of Inspector General, issued May 2021, https://oig.hhs.gov/documents/evaluation/3089/OEI-07-19-00490-Complete%20Report.pdf; "Long-Term Trends of Psychotropic Drug Use in Nursing Homes," U.S. Department of Health and Human Services Office of Inspector General, issued November 10, 2022, https://oig.hhs.gov/reports/all/2022/long-term-trends-of-psychotropic-drug-use-in-nursing-homes/.

87. "Long-Term Trends of Psychotropic Drug Use in Nursing Homes," U.S. Department of Health and Human Services Office of Inspector General, issued November 10, 2022, https://oig.hhs.gov/reports/all/2022/long-term-trends-of-psychotropic-drug-use-in-nursing-homes/.

88. "Updates to Nursing Home Care Compare," Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services, June 18, 2025, https://www.cms.gov/files/document/qso-25-20-nh.pdf.

89. The Pharmacy Quality Alliance is a national quality organization dedicated to improving medication safety, adherence, and appropriate use. It was established in 2006 as a public-private partnership with CMS and now has 175 members across the health care sector, including pharmacies, health plans, providers, pharmacy benefit managers, biopharmaceutical companies, technology vendors, government agencies, associations, health information technology organizations, researchers, accrediting organizations, and academic institutions.

90. While this paper refers to "ADRD," as opposed to "dementia," to align with the efforts of patient advocates, we kept the term "dementia" here in deference to PQA and the title of its quality measure.

91. "Four PQA-Endorsed Health Plan Performance Measures Recommended for Retirement," Pharmacy Quality Alliance, issued 2022, https://www.pqaalliance.org/assets/docs/Retirement_Summary-Key_Points_APD-MDS_IOP-HD_IOP-LA_OHDMP.pdf#:~:text=Antipsychotic%20Use%20in%20Persons%20with%20Dementia:%20MDS,denominator%20includes%20individuals%20%E2%89%A518%20years%20of%20age.

92. "Four PQA-Endorsed Health Plan Performance Measures Recommended for Retirement," Pharmacy Quality Alliance, issued 2022, https://www.pqaalliance.org/assets/docs/Retirement_Summary-Key_Points_APD-MDS_IOP-HD_IOP-LA_OHDMP.pdf#:~:text=Antipsychotic%20Use%20in%20Persons%20with%20Dementia:%20MDS,denominator%20includes%20individuals%20%E2%89%A518%20years%20of%20age.

93. "Long-Term Trends of Psychotropic Drug Use in Nursing Homes," U.S. Department of Health and Human Services Office of Inspector General, issued November 10, 2022, https://oig.hhs.gov/reports/all/2022/long-term-trends-of-psychotropic-drug-use-in-nursing-homes/.

94. "Anticonvulsant Medications: U.S. Food and Drug Administration-Approved Indications and Most Common Dosages for Use in Adults," Centers for Medicare and Medicaid Services, issued October 2015, https://www.cms.gov/sites/default/files/repo/ac%20adult%20dosing%20chart%20102915.pdf.

95. "Anticonvulsant Medications: U.S. Food and Drug Administration-Approved Indications and Most Common Dosages for Use in Adults," Centers for Medicare and Medicaid Services, issued October 2015, https://www.cms.gov/sites/default/files/repo/ac%20adult%20dosing%20chart%20102915.pdf; "Long-Term Trends of Psychotropic Drug Use in Nursing Homes," U.S. Department of Health and Human Services Office of Inspector General, issued November 10, 2022, https://oig.hhs.gov/reports/all/2022/long-term-trends-of-psychotropic-drug-use-in-nursing-homes/; Lourdes Vélez and Linda M. Selwa, "Seizure Disorders in the Elderly," American Family Physician 67, no. 2 (2003): 325-332, https://www.aafp.org/pubs/afp/issues/2003/0115/p325.html.

96. Lauren B. Gerlach, Donovan T. Maust, Helen C. Kales, et al., "Evaluation of Antipsychotic Reduction Efforts in Patients with Dementia in Veterans Health Administration Nursing Homes," *American Journal of Psychiatry* 179, no. 8 (2022): 544-552, https://doi.org/10.1176/appi.ajp.21060591.

97. Lindsay Robertson, Federico Bertolini, Nicholas Meader, et al., "Antidepressants for major depression disorder in older people: a network meta-analysis," *Cochrane Database of Systematic Reviews* 2019 (no. 9): CD013394, https://doi.org/10.1002/14651858.CD013394.

98. Pamela L. Lindsey, "Psychotropic Medication Use among Older Adults: What All Nurses Need to Know," *Journal of Gerontological Nursing* 35 (no. 9): 28-38, https://doi.org/10.3928/00989134-20090731-01.

99. Diane L. Chau, Vanessa Walker, Latha Pai et al., "Opiates and elderly: Use and side effects," *Clinical Interventions in Aging* 3 (no. 2): 273-278, https://doi.org/10.2147/CIA.S1847; "Treating Substance Use Disorder in Older Adults," Treatment Improvement Protocol (TIP) 26, Substance Abuse and Mental Health Services Administration, updated 2020, https://www.ncbi.nlm.nih.gov/books/NBK571029/pdf/Bookshelf_NBK571029.pdf.

100. Robert Christian, Lissette Saavedra, Bradley N. Gaynes, et al., "Future Research Needs for First- and Second-Generation Antipsychotics for Children and Young Adults," *Agency for Healthcare Research and Quality Future Research Needs Papers*, no. 13 (February 2012), https://www.ncbi.nlm.nih.gov/books/NBK84656/.

101. Judith A. Lucas, Sujoy Chakravarty, John R. Bowblis, et al., "Antipsychotic medication use in nursing homes: a proposed measure of quality," *International Journal of Geriatric Psychiatry* 29, no. 10 (March 2014): 1049–1061, https://doi.org/10.1002/gps.4098.

102. Dana B. Mukamel, Debra Saliba, Heather Ladd, et al., "Dementia Care is Widespread In US Nursing Homes; Facilities With The Most Dementia Patients May Offer Ways to Better Care," *Health Affairs* 42, no. 6 (June 2023): Appendix Exhibit A1 [data set], https://pmc.ncbi.nlm.nih.gov/articles/PMC10796080/#SM1; Dana B. Mukamel, Debra Saliba, Heather Ladd, et al., "Dementia Care is Widespread In US Nursing Homes; Facilities With The Most Dementia Patients May Offer Ways to Better Care," *Health Affairs* 42, no. 6 (June 2023): https://doi.org/10.1002/gps.4098 Appendix Exhibit A1 [data set omitted in final publication, available in online version at https://pmc.ncbi.nlm.nih.gov/articles/PMC10796080/#SM1; "2025 Alzheimer's Disease Facts and Figures," Alzheimer's Association, 2025, https://www.alz.org/getmedia/ef8f48f9-ad36-48ea-87f9-b74034635c1e/alzheimers-facts-and-figures.pdf; Nina R. Joyce, Thomas G. McGuire, Stephen J. Bartels, et al., "The Impact of Dementia Special Care Units on Quality of Care: An Instrumental Variables Analysis, Health Services Research 53, no. 5 (May 2018): 3657-3679, https://doi.org/10.1111/1475-6773.12867; Judith A. Lucas, Sujoy Chakravarty, John R. Bowblis, et al., "Antipsychotic medication use in nursing homes: a proposed measure of quality," *International Journal of Geriatric Psychiatry* 29, no. 10 (March 2014): 1049-1061, https://doi.org/10.1002/gps.4098; Rebecca Orfaly Cadigan, David C. Grabowski, Jane L. Givens, et al., "The Quality of Advanced Dementia Care in the Nursing Home: The Role of Special Care Units," *Medical Care* 50, no. 10 (October 2012): 856-862, https://doi.org/10.1097/MLR.0b013e31825dd713.

103. While this paper refers to "ADRD," as opposed to "dementia," to align with the efforts of patient advocates, we kept the term "dementia special care units" here and throughout the paper in deference to the Alzheimer's Association and medical journals which use this term.

104. "Technical Expert Panel (TEP) for Refinement of the Nursing Home (NH) Antipsychotic Medication Measures: Summary Report," Acumen, LLC, issued September 2023, https://mmshub.cms.gov/sites/default/files/NH-Antipsychotics-TEP-Summary-Report-Feb-2023.pdf.

105. "Technical Expert Panel (TEP) for Refinement of the Nursing Home (NH) Antipsychotic Medication Measures: Summary Report," Acumen, LLC, issued September 2023, https://mmshub.cms.gov/sites/default/files/NH-Antipsychotics-TEP-Summary-Report-Feb-2023.pdf.

106. Steven A. Levenson, "Antipsychotics in Perspective: Past, Present, and Future (Article 1 of 3)," *Journal of the American Medical Directors Association* 25, no. 1 (2024): 1–5, https://doi.org/10.4140/TCP.n.2024.5.

107. "Technical Expert Panel (TEP) for Refinement of the Nursing Home (NH) Antipsychotic Medication Measures: Summary Report," Acumen, LLC, issued September 2023, https://mmshub.cms.gov/sites/default/files/NH-Antipsychotics-TEP-Summary-Report-Feb-2023.pdf.

108. Rishi K. Wadhera, Jose F. Figueroa, Karen E. Joynt Maddox, et al., "Quality Measure Development and Associated Spending by the Centers for Medicare & Medicaid Services," *Journal of the American Medical Association* 323 (no. 16): 1614–1616, https://doi.org/10.1001/jama.2020.1816.

109. "Technical Expert Panel (TEP) for Refinement of the Nursing Home (NH) Antipsychotic Medication Measures: Summary Report," Acumen, LLC, issued September 2023, https://mmshub.cms.gov/sites/default/files/NH-Antipsychotics-TEP-Summary-Report-Feb-2023.pdf. "Updates to Nursing Home Care Compare," Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services, June 18, 2025, https://www.cms.gov/files/document/qso-25-20-nh.pdf.

110. "Measure Maintenance Reviews of Quality Measures," Measures Management System (MMS) Hub, Centers for Medicare & Medicaid Services, updated December 2022, https://mmshub.cms.gov/sites/default/files/Measure-Maintenance-Reviews.pdf.

111. The following CMS long-stay SNF quality measures are classified as information-only: Percent of Residents Who Received the Seasonal Influenza Vaccine; Percent of Residents Who Were Offered and Declined the Seasonal Influenza Vaccine; Percent of Residents Who Did Not Receive, Due to Medical Contraindication, the Seasonal Influenza Vaccine; Percent of Residents Who Received the Pneumococcal Vaccine; Percent of Residents Who Were Offered and Declined the Pneumococcal Vaccine; Percent of Residents Who Did Not Receive, Due to Medical Contraindication, the Pneumococcal Vaccine. This is analogous to the use of quality measures related to contraception in Medicaid, which are reported for informational purposes but are not included in any value-based payment or benchmarking.

112. "State Operations Manual Appendix PP – Guidance to Surveyors for Long-Term Care Facilities," Centers for Medicare & Medicaid Services, issued August 8, 2024, https://www.cms.gov/medicare/provider-enrollment-and-certification/guidanceforlawsandregulations/downloads/appendix-pp-state-operations-manual.pdf.

manatt

McKnights Long-Term Care News

NEWS

CMS quality measure hindering access to dementia treatments: report

KIMBERLY MARSELAS

@KIMMARSELAS

NOVEMBER 19, 2025

SHARE

A federal quality measure intended to prevent inappropriate use of antipsychotic drugs in nursing homes is restricting access to "safe and effective treatments" for many residents with Alzheimer's and related conditions, according to a report published Wednesday.

The white paper, published by Manatt Health with support from the Alliance for Aging Research, argues that the 13-year-old Centers for Medicare & Medicaid Services measure of antipsychotic use among long-stay residents is discouraging use of needed medications. Outside of nursing homes, some antipsychotics are used often to help ease distressing neuropsychiatric symptoms (NPS) that affect 97% of patients with Alzheimer's disease.

The report traces changes in prescribing concerns, evolving clinical indications for existing medications, and the advent of new medications over the last two decades. It also said CMS has failed to keep up with those changes and come up short in its efforts to refine its related measure and its role in the agency's quality ratings system.

"Clinicians who determine that antipsychotics are the best — or only — way to treat a patient's NPS will put a SNF's star rating at risk by simply prescribing them," the report states.

"As the measure has its intended effect of lowering antipsychotic use across the long-stay SNF population across the board, its relentless pressure forces many SNFs to halt antipsychotic use in cases where these medications are clinically appropriate or even essential."

The report urges CMS to reform or retire the measure to open appropriate access to the medications.

CMS did not immediately respond to a request for comment on the report, but a spokesman said he would provide a response later.

Manatt's authors note that people living with Alzheimer's disease and related dementias tend to present with neuropsychiatric symptoms in the later stages of their diseases, raising important safety concerns. They cited multiple studies that linked those symptoms with a higher risk of falls and injuries at SNFs and found that they are a leading cause of facility-initiated discharges.

Numerous concerns expressed

Calling management of dementia's neuropsychiatric symptoms "both a science and an art," they urged CMS to ensure access to the full range of treatment options.

"We all share a mission to protect nursing home residents and all older adults from any potential medication risks," Chad Worz, chief executive of the American Society of Consultant Pharmacists, said in a statement accompanying the paper. "However, the current CMS long-stay antipsychotic quality measure inadvertently misaligns risk-benefit and interferes in clinical care decision making between patients and their medical team. Clinicians should be able to prescribe FDA-approved treatments for residents living with neuropsychiatric symptoms and other serious mental health conditions, when they need them, to enhance their safety, quality of life and dignity."

ASCP is working with The Alliance on Project PAUSE, a coalition of national patient and professional organizations addressing LTC clinical, regulatory and legislative issues.

The group has previously highlighted its concerns with antipsychotic policies. But CMS has only revised its long-stay measure once. In an announcement made this spring, CMS said it would pull more claims into its calculation of antipsychotic use, spiking rates for most providers. Implementation of that change has been delayed until January.

While CMS' action represents a step toward better measure design, it leaves other significant concerns unaddressed, the report said. Manatt said the measure:

- Fails to distinguish between clinically appropriate and inappropriate use of antipsychotic medications
- May have increased inappropriate prescriptions of other psychotropics, including anticonvulsants, antidepressants and opioids as substitutes
- Does not reflect current clinical guidelines
- Incorporates inaccurate diagnosis coding and insufficient exclusion criteria
- Lacks critical context for patients and families using the Five-Star Quality Rating System

Manatt said CMS has the regulatory authority to further refine or remove the measure "without compromising patient safety or the integrity of the Medicare program."

July 14, 2025

Filed Electronically via regulations.gov

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: HHS Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation to Make American Healthy Again (Docket ID No. AHRQ-2025-0001)

On behalf of Project PAUSE (Psychoactive Appropriate Use for Safety and Effectiveness), we thank you for the Request for Information (RFI) soliciting public input and recommendations regarding how the Department of Health and Human Services (HHS) can "better promote the health and well-being of the American people ... [and] dramatically deregulate across all areas the Department touches." We appreciate your leadership on this important initiative and are grateful for the opportunity to provide comments to inform "Ensuring Lawful Regulation and Unleashing Innovation to Make America Healthy Again." We thank you in advance for your consideration of our views and stand ready to partner with you and your staff to ensure that our nation's health programs and the regulations, guidances, rules, and requirements that govern them actively facilitate and enhance—rather than stifle—access to care, innovation, and improved health outcomes.

Executive Summary

Our comments primarily focus on general deregulatory recommendations under Executive Order 14192, "Unleashing Prosperity Through Deregulation," as outlined in question number 3 in the RFI. ***Project PAUSE respectfully proposes two opportunities for deregulation, one at the Centers for Medicare & Medicaid Services (CMS) and one at the Food and Drug Administration (FDA), which align with the goals of this RFI—particularly the criteria outlined below—and impose undue burdens on patients, providers, caregivers, and innovators working to deliver life-changing care for those living with Alzheimer's disease and related neurocognitive impairments.***

The specific Question #3 Criteria that we believe are implicated, include the following additional HHS regulations and/or guidance that:[1]

[1] Question provided under RFI Question #3.

- ✓ *"Are confusing or unnecessarily complicated";*
- ✓ *"Require an excessive number of reports or unreasonable record keeping, or information that is not needed or used effectively";*
- ✓ *"Carry excessive penalties";*
- ✓ *"Are conflicting";*
- ✓ *"Impede access to or delivery of care or services";*
- ✓ *"Impede efforts to innovate";*
- ✓ *"Are obsolete"; and/or*
- ✓ *"Otherwise interfere with the public or private sector's ability to address chronic health conditions or otherwise promote the health and wellbeing of Americans."*

About Project PAUSE

Project PAUSE (Psychoactive Appropriate Use for Safety and Effectiveness) is an ad hoc coalition of national patient and professional organizations collectively advocating on clinical regulatory and legislative issues in long-term care. Project PAUSE aims to educate policymakers and the public on effective solutions for improving clinical care in long-term care settings by advocating for streamlined, clinical surveyor training, improved quality measures to appropriately determine antipsychotic drug use in long-term care settings, and other solutions aimed at improving the diagnosis and management of neuropsychiatric symptoms in individuals with neurocognitive impairment. Project PAUSE is convened by the Alliance for Aging Research and the American Society of Consultant Pharmacists (ASCP).

Membership of Project PAUSE includes patient and family caregiver organizations, long-term care groups, primary care associations, geriatric and mental health specialty provider societies, and Alzheimer's disease and other groups representing individuals with neurocognitive impairments, as well as mental health organizations.

I. Deregulation Opportunity at CMS

1. Eliminate the Long-Stay Antipsychotic Medication Quality Measure from the CMS Nursing Home Care Compare Five-Star Quality Rating System.

A. Recommendation for Deregulation

To better align with best clinical practices and published provider guidelines, CMS should remove the Long-Stay Antipsychotic Medication quality measure from the Nursing Home Compare Five-Star Quality Rating System and instead modernize the Minimum Data Set (MDS) to better distinguish between appropriate and inappropriate use of antipsychotics among residents of skilled nursing facilities (SNFs) and long-term care facilities.

The existing Long-Stay Antipsychotic Medication quality measure meets the following deregulatory criteria included in RFI question #3:

- ✓ *"[Is] confusing or unnecessarily complicated";*
- ✓ *"Require[s] an excessive number of reports or unreasonable record keeping, or information that is not needed or used effectively";*
- ✓ *"Carr[ies] excessive penalties";*
- ✓ *"Are conflicting";*
- ✓ *"Impede[s] access to or delivery of care or services";*
- ✓ *"Impede[s] efforts to innovate";*
- ✓ *"[Is] obsolete"; and/or*
- ✓ *"Otherwise interfere[s]e with the public or private sector's ability to address chronic health conditions or otherwise promote the health and wellbeing of Americans."*

B. Background About the Long-Stay Antipsychotic Medication Quality Measure[2]

In 2012, CMS created an unscientific and punitive measure to curb the use of antipsychotics in nursing homes, regardless of the appropriateness for the patient. The measure is an unsophisticated, blunt formula of the "percent of residents who received an antipsychotic medication" calculated by dividing the number of residents on a medication by the total number of residents in the SNF. There are only three diagnoses exempted from the measure: schizophrenia, Huntington's disease, and Tourette's syndrome. As noted in the clinical guidance published by the American Psychiatric Association (APA), similar measures promulgated by the National Quality Forum (NQF) include bipolar disorder among the conditions exempted from the measure and many stakeholders have advocated it be added as an exemption to the CMS measure[3]–yet CMS only permits three exempted conditions. Further, as highlighted in the APA guidelines, ***the measure fails to distinguish between clinically appropriate and inappropriate prescribing, instead it merely captures total use of antipsychotics***. The measure has led to clinically necessary treatments being withheld, causing harm to residents and burdening providers. ***Specifically, this approach forces facilities to prioritize regulatory compliance over patient-centered care, often leading to unintended negative outcomes like the inappropriate discontinuation of medically necessary medications.*** While we agree that individuals should not be improperly medicated, there are legitimate and appropriate clinical uses of antipsychotic medications that is being suppressed due to this measure.

[2] *Enclosed is additional background and rationale on our recommendation to remove the CMS long-stay antipsychotic medication quality measure provided in a letter to Secretary Kennedy and CMS Administrator Mehmet Oz in April 2025.*

[3] American Psychiatric Association (APA), "The American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia." May 2016. https://psychiatryonline.org/doi/epdf/10.1176/appi.books.9780890426807

Between 2021 and 2025, we sought to work with CMS to improve measures related to antipsychotic medication use among nursing home and long-term care residents. As part

of this effort, we met with CMS leadership numerous times over a several years to provide evidence illustrating the unintended, adverse consequences of the current measure. Unfortunately, despite our repeated efforts, CMS was unwilling to reconsider its position, leaving SNFs and residents without a viable path to appropriate and necessary care for neuropsychiatric symptoms associated with neurocognitive impairment that are available in other care settings.

After years of seeking partnership with CMS to improve oversight on inappropriate antipsychotic use, in a QSO memo (QSO-25-20-NH) issued on June 18, 2025, we were disappointed and concerned to see that CMS announced changes to the Long-Stay Antipsychotic Medication quality measure that did not address our concerns or reflect any of our recommendations. Rather CMS doubled-down on the flawed measure and is moving to incorporate Medicare and Medicaid claims data, along with Medicare Advantage encounter data, in addition to existing MDS data, in an effort to "improve measure accuracy."[4] The revised measure will replace the current version and will be incorporated into the Nursing Home Compare Five-Star Quality Rating System on October 29, 2025. ***This revision fails to resolve the underlying issues with the measure. Instead, it overlays new data to an already flawed foundation and compounds the myriad unintended consequences for patient quality of care.***

Unfortunately, the recent QSO memo fails to provide sufficient background and contextual information on the development of the updated measure, which further contributes to an opaque regulatory environment for SNFs and could create additional confusion for caregivers and families who rely on the Nursing Home Care Compare Five-Star Quality Rating System. We are particularly concerned that the updated measure contains flawed analysis. On February 24, 2023, CMS convened a Technical Expert Panel (TEP) to review antipsychotic medication use in nursing facilities. During that meeting, the TEP determined that carbamazepine, an anticonvulsant or antiepileptic, had been incorrectly classified as an antipsychotic and called for its removal from the list of medications used to identify antipsychotic use in Part D claims.[5] More than two years later, we do not believe CMS has corrected this inaccuracy. As such, the basis for the updated measure could be inherently flawed if carbamazepine has been factored into the equation. Further, if carbamazepine remains included in the calculation of the updated

[4] CMS, "Updates to the Nursing Home Care Compare Long-Stay Antipsychotic Medication Quality Measure (QSO-25-20-NH)." June 2025. https://www.cms.gov/files/document/qso-25-20-nh.pdf
[5] Technical Expert Panel (TEP) for Refinement of the Nursing Home (NH) Antipsychotic Medication Measures. See pg. 5. September 2023. ttps://mmshub.cms.gov/sites/default/files/NH-Antipsychotics-TEP-Summary-Report-Feb-2023.pdf

measure, the new measure also will be fundamentally flawed. By counting a non-antipsychotic medication as an antipsychotic will contribute to erroneous higher reported rates of antipsychotic use, which is misleading to stakeholders and the public and harmful to SNFs star ratings.

Moreover, unlike MDS data, Medicare encounter data and Medicare Part D claims are not readily accessible to SNFs and are often subject to inaccuracies and reporting delays, which creates a barrier to real-time tracking of antipsychotic use among SNF residents. Further, while Medicare Part D claims data can confirm whether a prescription was ordered and reimbursed by the plan, such information cannot provide insight into whether a patient actually took any of the medication. By comparison, the MDS is based on the patient's medical chart, which provides detailed information regarding all medications provided, doses, duration, etc. While well-intended, we are concerned that incorporating these additional data sets into the quality measure may compromise the timeliness and accuracy of the measure and undermine the goal of the Nursing Home Care Compare Five-Star Quality Rating System, which is to provide meaningful, valid, and reliable information to beneficiaries and their caregivers.

Furthermore, the agency should not pursue incremental, patchwork changes nor continue to report the results of this flawed measure to the public. Continued interim revisions risk deepening confusion for providers and further distorting the Nursing Home Care Compare Five-Star Quality Rating System.

With the transition to new leadership within HHS and CMS and the commitment from the Administration to reduce burdensome regulations that restrict patients' access to care, we urge you to 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 and does not protect beneficiaries, but rather thwarts the provision of patient-centered, individualized care.

C. <u>Specific Concerns with the Existing Measure</u>

Is Confusing or Unnecessarily Complicated & Requires An Excessive Number of Reports or Unreasonable Record Keeping, or Information that is Not Needed or Used Effectively

The measure and related oversight protocols impose overly complex documentation requirements that may conflict with Section 1801 of the Social Security Act (42 U.S.C. § 1395).[6] These requirements dictate that nursing homes may only use antipsychotic medications when nonpharmacological interventions are contraindicated, requiring extensive documentation to justify their use. Additionally, CMS compels facilities to attempt gradual dose reduction,

regardless of a patient's medical history, clinical stability, or wishes. The result is a cycle in which residents are taken off medications they have successfully used, become destabilized, and then must be restarted on medication, often multiple times and with stops in emergency rooms and psychiatric wards along the way. This practice burdens clinicians and caregivers with excessive documentation and causes treatment disruptions, rather than supporting individualized, quality, evidence-based care.

> While the Revised Long-Term Care (LTC) Surveyor Guidance is directed at surveyors, the policies it instructs surveyors to enforce—such as rigid rules on PRN (as-needed) antipsychotic orders, mandatory behavioral intervention tracking, and ongoing gradual dose reduction requirements—translate directly into burdensome obligations for providers. Facilities must expend substantial resources creating and maintaining extensive documentation, not because it enhances clinical outcomes, but because it is necessary to demonstrate compliance with inflexible and untested federal standards.
>
> Further, the Long-Stay Antipsychotic Medication quality measure also duplicates existing medication review and quality assurance programs at the state level and overlaps internally with Medicare's own oversight mechanisms, such as the Plan Program Integrity Medicare Drug Integrity Contractors (PPI MEDICs). ***Additionally, the 917-page Revised LTC Surveyor Guidance already includes nearly 20 pages related to psychotropic medication use, including documentation of behavioral interventions, justification for medication use, and gradual dose reduction mandates, which facilities must already follow during survey and certification reviews***. As a result, the use of this measure in the Five-Star Rating System introduces unnecessary and overlapping scrutiny on top of what providers are already required to demonstrate through MDS documentation and during state surveys.
>
> ***Carries Excessive Penalties and Misleads Beneficiaries and Families***
>
> The measure's heavy weighting in the Nursing Home Care Compare Five-Star Rating system can result in significant star rating downgrades for minor documentation discrepancies, misrepresenting quality of care to families evaluating the long-term care

[6] MDS 3.0 Quality Measures User's Manual. See Table 2-27 (PDF pg.38).
https://www.cms.gov/files/document/mds-30-qm-users-manual-v170.pdf

facilities for their loved ones, and unfairly penalizing facilities serving high-need populations. 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 Nursing Home Care Compare Five-Star Rating system,[7] 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 detailed reporting requirements, it does not tell individuals and families anything about the quality of care at a facility with respect its appropriate use of medications. Again, this is because the measure only counts how many people receive an antipsychotic without any regard for medical necessity or appropriateness.

Conflicts with Patient-Centered Care and Published Guidelines

The current measure disregards and contradicts clinical practice guidelines published by the APA, as referenced earlier, which support the appropriate use of these medications in managing dementia-related agitation and psychosis and does not reflect the clinical standards used in other areas of care.[8]

The APA Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia importantly notes, "Available administrative data allow calculations of the rates of antipsychotic use in nursing homes (Partnership to Improve Dementia Care in Nursing Homes 2015) and other settings. Such data show significant regional and state-to-state variability; **however, they have a number of confounds and do not provide details about the reasons these medications are being prescribed or the severity of symptoms exhibited by the patient. Thus, these data reflect antipsychotic use but, like the currently endorsed NQF measures, do not provide information about appropriate use of antipsychotic medications in individuals with dementia** [emphasis added]."[9]

[7] https://www.medicare.gov/care-compare/?providerType=NursingHome
[8] American Psychiatric Association (APA), "The American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia." May 2016. https://psychiatryonline.org/doi/epdf/10.1176/appi.books.9780890426807
[9] Ibid.

The APA guideline reflects the medical consensus that antipsychotics can be both appropriate and beneficial for certain patients when nonpharmacological interventions are ineffective or contraindicated. By contrast, CMS's existing Long-Stay Antipsychotic

Medication quality measure imposes a one-size-fits-all rigid standard, effectively discouraging any pharmacologic intervention unless non-drug alternatives are exhausted. CMS's current framework not only contradicts expert clinical guidance but also conflicts with the agency's own stated intent to support care that is tailored to a resident's "specific, diagnosed, and documented condition." Yet in practice, CMS policies default to a blanket assumption that all use of antipsychotics is harmful, regardless of a particular patient's diagnosis, clinical history, wants, or response to treatment.

Impedes Access to or Delivery of Care or Services and Interferes in the Practice of Medicine

The original measure created in 2012 conflicts with Section 1801 of the Social Security Act, which expressly prohibits federal interference in the practice of medicine:

> *"SEC. 1801. [42 U.S.C. 1395] Nothing in this title 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 over the selection, tenure, or compensation of any officer or 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."*

Further, CMS's Revised Long-Term Care (LTC) Surveyor Guidance, referenced earlier, which directs oversight of antipsychotic prescribing practices, underscores CMS' interference with the practice of medicine as it includes extensive requirements for psychotropic prescribing, including strict rules for PRN (as needed) orders, behavioral intervention assessments, and gradual dose reduction mandates.[10] ***These requirements effectively dictate clinical practice by requiring facilities to document extensive justifications for any use of antipsychotics, regardless of patient-specific clinical needs. The measure creates an inflexible and burdensome framework that limits clinician judgment and ultimately prohibits patients from receiving the care they need***. The cumulative effect is a one-size-fits-all oversight model that lacks sensitivity to individual patient needs and clinical judgment, ultimately conflicting with the principle that CMS should not dictate medical practice. Moreover, as noted earlier, the measure often causes

[10]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.

beneficiaries who have been stable on antipsychotic medications while living in the community to be taken off of their medications once admitted for a long-stay in a SNF; the type of care and medication a beneficiary receives should be dictated by their diagnosis and specific clinical characteristics, not the site of care where they are being treated.

Impedes Efforts to Innovate

Because of the long-standing, inherent bias against all antipsychotic use, some pharmaceutical companies understandably are reticent to invest in research and development to identify newer therapeutics that might have different mechanisms of action and/or different side effect profiles. The federal government's "all antipsychotic prescribing is wrong" approach telegraphs to industry that an entire class of drugs is considered to be dangerous and generally not to be used among Medicare beneficiaries who are residents of nursing homes or long-term care facilities, unless they have one of three diagnoses. The federal government's one-size-fits-all policy to antipsychotics creates an environment that can have a chilling effect on innovation and investment.

Patients who need their neuropsychiatric symptoms managed effectively deserve a wider range of safe and effective treatments and the federal government's policies should encourage and facilitate development of improved therapeutics rather than stymie discovery within an entire category of medicines.

Is Obsolete and Lacks Meaning

It is important to note that in 2022, the Pharmacy Quality Alliance (PQA) recommended its similar measure, Antipsychotic Use in Persons with Dementia, for retirement.[11] The PQA measure also assessed the percentage of long-stay nursing home residents with dementia who received an antipsychotic medication without evidence of a psychotic disorder or related condition and also excluded residents with schizophrenia, Huntington's disease, and Tourette's syndrome from the calculation. The PQA measure, which also relied on the MDS, also includes bipolar disorder to the list of permitted exclusions, differing from the CMS measure in that regard. PQA noted the following regarding the recommendation to retire the measure:

- "Competing priorities exceed the level of effort necessary to seek subject matter input for measure update using MDS as a data source.

[11] "Four PQA-Endorsed Health Plan Performance Measures Recommended for Retirement," Pharmacy Quality Alliance, issued 2022, https://www.pqaalliance.org/assets/docs/Retirement_Summary-Key_Points_APD-MDS_IOP-HD_IOP-LA_OHDMP.pdf#:~:text=Antipsychotic%20Use%20in%20Persons%20with%20Dementia:%20MDS,denominator%20includes%20individuals%20%E2%89%A518%20years%20of%20age.

- Retirement of this measure would allow resources **to be allocated to areas with more meaningful impact** [emphasis added].

- The Quality Metrics Expert Panel (QMEP) voted (27 yes; 0 no; 0 abstain) to recommend the APD-MDS measure for PQA membership retirement consideration."[12]

Rather than following the lead of expert organizations, such as PQA, and retiring the measure, CMS recently proposed expanding the data utilized to include claims data, which only provides additional insights into verifying the types of prescribed medicines without the necessary context to determine clinically appropriateness. Even with the new data being incorporated, the measure still will only capture whether a resident received an antipsychotic, without documenting the clinical appropriateness, creating a one-size-fits-all approach that unfairly penalizes facilities for appropriately prescribing medications, including new medications that have been approved by the FDA since this measure's inception.

Also, it is important to note that the measure has no absolute evidence-based benchmark or targeted range of values, only that "lower is better." While the measure has had the overall intended effect of lowering antipsychotic use across the entire long-stay SNF population, since there is no target level to achieve, facilities that may have been initially able to improve their performance by identifying and addressing cases of inappropriate use, over time due to the incessant pressure of the measure's formula, facilities likely cease the use of antipsychotics in cases where the medications are appropriate and beneficial. As such, the measure only provides information about facilities' ability to reduce overall antipsychotic prescribing relative to one another and does not account for those facilities that may be most willing to accept and best able to treat beneficiaries with Alzheimer's disease and other neurocognitive impairments. As such, the measure lacks meaning and is obsolete as a tool for clinically differentiating facilities' quality of care.

Otherwise Interfere[s]e with the Public or Private Sector's Ability to Address Chronic Health Conditions or Otherwise Promote the Health and Wellbeing of Americans

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.[13] Further, while the label "quality measure" implies a connection to safety or clinical care

[12] Ibid.
[13] "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.

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.[14] 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 neuropsychiatric symptoms 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."

D. <u>Solution</u>

Eliminating the measure from public quality reporting while making several low-burden, meaningful changes to the MDS would support transparency, protect patient safety, and allow clinicians to provide individualized care consistent with the latest professional psychiatric standards. ***This measure, which is <u>not</u> governed by formal notice-and-comment rulemaking, could be removed through subregulatory channels, including issuing a Quality Safety & Oversight (QSO) memoranda or updates to the Nursing Home Care Compare Technical Users' Guide***. This flexible authority makes it a prime candidate for elimination under the Administration's deregulatory agenda. At the same time, Project PAUSE recommends that HHS and CMS work to change the MDS to:

(1) 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

(2) Require that in cases where gradual dose reduction has not been attempted, both a physician and a pharmacist must independently document that gradual dose

https://www.nytimes.com/2021/09/11/health/nursing-homes-schizophrenia-antipsychotics.html?searchResultPosition=1

[14] 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

reduction is either clinically contraindicated or that the use of the drug and dose are clinically appropriate and beneficial.

These low-burden improvements to the MDS would yield more meaningful information for oversight and facility surveyors. For instance, expanding the list of acceptable reasons for not attempting gradual dose reduction to include "documented use of the drug and dose as clinically appropriate and beneficial," and requiring attestation by both a

physician and a pharmacist in such cases, would add clinical nuance without adding significant reporting complexity. For patients who are stable on antipsychotic medication and have a documented on-going need for and benefit from treatment, ideally providers would not need to regularly restate why gradual dose reduction has not been attempted as they are clearly contraindicated. ***This tailored approach could significantly reduce administrative burden and maintain program integrity while allowing facilities and surveyors to focus on the quality of care provided to skilled nursing and long-term care residents.***

II. Deregulation Opportunity at FDA

1. Class-Wide Boxed Warning Approach On All Atypical Antipsychotic Medications

A. Recommendation for Deregulation

To reduce barriers to care and safeguard provider and patient choice, the FDA must prioritize and expedite its assessment of any needed changes to the class-wide boxed warning for antipsychotic medications to promote the health and safety of older adults living with Alzheimer's and related neurocognitive impairments .

The current class-wide boxed warning on all atypical antipsychotic medications meets the following deregulatory criteria included in RFI question #3:

- ✓ *"[Is] confusing or unnecessarily complicated";*
- ✓ *"Impede[s] access to or delivery of care or services";*
- ✓ *"Impede[s] efforts to innovate";*
- ✓ *"[Is] obsolete"; and/or*
- ✓ *"Otherwise interfere[s] with the public or private sector's ability to address chronic health conditions or otherwise promote the health and wellbeing of Americans."*

B. Background and Concerns with the Existing Labeling

There is a large unmet medical need in long-term care settings for the management of neuropsychiatric symptoms in individuals with neurocognitive impairments, including

psychosis, wandering, sleep issues, agitation, depression, apathy, and aggression. While cognitive impairment is regarded as the hallmark indicator of dementia, neuropsychiatric symptoms are nearly as universal, with one or more symptoms affecting nearly all people with dementia over the illness course. Effective management of these symptoms is crucial to patients, providers, and caregivers.

Since 2008, all atypical antipsychotic medications have carried a boxed warning related to older adults with dementia. In the 17 years since, the FDA has not reevaluated this warning, despite additional scientific evidence, updated clinical guidance, and new medicines entering the market. Regardless of a drug's specific safety profile, all atypical antipsychotics are required by the FDA to carry the same warning with no drug-specific assessment and no consideration of the type or severity of dementia and neurocognitive impairment, severity of behavioral and psychological symptoms, or the presence of comorbidities.

To address these concerns, Congress directed the FDA to hold a public workshop to reassess the application of the class-wide boxed warning for all atypical antipsychotic medications, with a specific focus on risks associated with their use in older adults.[15] On December 10, 2024, FDA convened the workshop as an initial step in reevaluating the warning.[16] The agency indicated it would use insights from the workshop to determine what additional data and analyses are needed to assess the warning's continued necessity but has not yet provided a timeline or framework for completing this review.

More recently, during consideration of FY 2026 appropriations, the House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies underscored its continued concern about the impact of the class-wide warning on patient access to appropriate care. The subcommittee further directed the FDA to "prioritize and expedite its review of data to characterize risk of mortality associated with use of antipsychotic medications in older adults with mental health conditions associated with dementia to determine if revisions to the boxed warning are needed," within 180 days of enactment of the FY 2026 appropriations measure. [17]

[15] U.S. House Committee on Appropriations. House Report 118-124: Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2024., accompanying H.R. 4368, 118th Cong., 1st Sess, pg. 75. https://www.congress.gov/118/crpt/hrpt124/CRPT-118hrpt124.pdf
[16] FDA Convening, "Mortality and Antipsychotic Use in Dementia-Related Behavioral Disorders." December 2024. https://healthpolicy.duke.edu/events/mortality-and-antipsychotic-use-dementia-related-behavioral-disorders
[17] U.S. House Committee on Appropriations. House Report: Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2024, 119th Cong., 1st Sess., pgs.74-75. Available: https://docs.house.gov/meetings/AP/AP00/20250611/118388/HMKP-119-AP00-20250611-SD002.pdf.

Access to clinically necessary care is critical for older adults living with Alzheimer's and other neurocognitive impairments—not only to protect their health, but to preserve their dignity as they navigate these progressive diseases. To that end, the FDA, in furtherance of EO 14192 and in response to congressional directive, must reexamine the class-wide boxed-warning labeling.

Obsolete FDA Labeling is Confusing, Impedes Patient-Centered Care and Clinical Decision-Making, Impedes Efforts to Innovate, and Interferes with the Promotion of Health and Wellbeing of Americans

The outdated and overly broad class-wide boxed warning on antipsychotic medications upholds obsolete regulatory determinations that no longer align with current scientific evidence or clinical best practices, which can be confusing to clinicians. The continued use of this outdated label is disproportionately influencing treatment guidance and prescribing practices, which, in turn, is restricting critical access to care for older adults with Alzheimer's and related neurocognitive impairments and discourages appropriate clinical decision-making. This can be seen in physician reluctance to prescribe antipsychotics even when clinically indicated, leading to undertreatment or reliance on older, less effective medications with their own risks and side effects. In some cases, unmanaged neuropsychiatric symptoms can result in traumatic nursing home discharges due to behaviors that pose a risk to the individual or others.[18]

The warning also risks stifling public and private innovation by inadvertently discouraging the development and market entry of newer therapies with improved safety profiles and different mechanisms of action. ***Maintaining a black boxed warning on an entire drug class—the strictest and most serious type labeling the FDA currently offers—despite new evidence and clinical guidelines reinforces an outdated regulatory determination and unnecessarily fosters a hostile environment for innovators. It creates additional barriers to product entry and marketability in an already complicated regulatory landscape and does so under outdated premises. Additionally, the current labeling may stifle new and breakthrough treatments for managing neuropsychiatric symptoms for older adults living with Alzheimer's and related neurocognitive impairments from even being discovered or advanced through the pipeline***.

Furthermore, the current labeling creates misaligned incentives for innovators to pursue new research and development for treatments that could afford new health benefits such as lesser side effects and better symptom management. Moreover, the 17-year-old black boxed warning on all atypical antipsychotic medications, which disregards advances in

[18] HHS ASPE, "Resident and Facility Factors Associated with High Risk of Discharge from Nursing Facilities, 2012-2017: Final Report," September 2022.

scientific evidence and clinical practice, undermines competition and innovation to the detriment of patients and their loved ones.

Conclusion

The members of Project PAUSE, which include patient advocates, family caregivers, long-term care professionals, physicians, nurses, and other clinicians, again thank you for the opportunity to provide comment on ways to reduce regulatory burdens across HHS in pursuit of a healthier, safer, stronger, and more prosperous America. We welcome the opportunity to further discuss these recommendations and collaborate with HHS, CMS, and FDA in shaping a modernized, evidence-based approach to ensuring quality of care for individuals with neurocognitive impairments who reside in long-term care settings, as well as working together to identify

additional opportunities to reduce the regulatory and guidance burden on nursing homes while maintaining high standards of care and assuring patient safety, health, and well-being, particularly of our nation's most vulnerable Medicare and Medicaid beneficiaries.

Thank you for your attention to these urgent issues. Please do not hesitate to contact Chad Worz, Chief Executive of the American Society of Consultant Pharmacists (cworz@ascp.com) with any questions.

Sincerely,

Susan Peschin

Susan Peschin, MHS
President and CEO
Alliance for Aging Research
www.agingresearch.org

Chad Worz, PharmD, BCGP, FASCP
Chief Executive
American Society of Consultant Pharmacists
www.ascp.com

cc:

Mehmet Oz, MD, MBA, Administrator, CMS
Martin A. Makary, MD, MPH, Commissioner, FDA
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
Chris Klomp, Director, Center for Medicare
Heather Flick Melanson, HHS Chief of Staff
Stefanie Spear, HHS Principal Deputy Chief of Staff / Senior Counselor to the Secretary
Sara Brenner, MD, MPH, FDA Principal Deputy Commissioner
Jim Traficant, FDA Chief of Staff
Grace Graham, FDA Deputy Commissioner for Policy, Legislation, and International Affairs

April 9, 2025

The Honorable Robert F. Kennedy
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

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]

---

[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.

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

---

[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