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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

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Key Terms

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

Antipsychotics²—a class of psychotropic medications primarily used for the treatment and management of symptoms associated with various psychiatric disorders.

Boxed Warning³—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 Resident⁵—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 System⁷—a website maintained by the United States Centers for Medicare & Medicaid Services (CMS) that allows users to locate and compare Medicarecertified 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.

Psychotropics8—medications that affect the mind, emotions, and behavior and typically belong to one of five classes: antipsychotics, antidepressants, anxiolytics, hypnotics, and mood stabilizers.

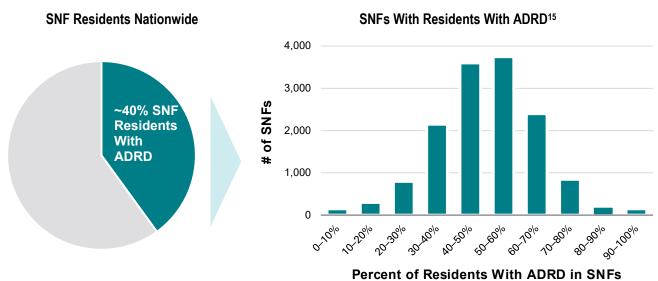
Skilled Nursing Facility (SNF)9—an institution (or a distinct part of an institution) that is primarily engaged in providing skilled nursing care and related services for residents who require ongoing medical or nursing care, or rehabilitation services for residents who are injured, disabled, or sick, 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.

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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



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, patientcentered 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 poorlycontrolled 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.

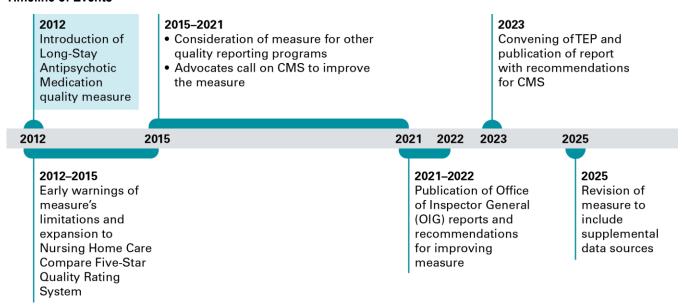
In 2005, the FDA added a boxed warning on all antipsychotics for older adults with dementia-related psychosis, citing an increased risk of mortality associated with their use. 32,33 Boxed warnings, the most significant warnings included in FDA documentation, are intended to highlight risks that are so 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

Nursing Home Care Compare Five-Star Quality Rating System



Based on the number, scope and severity of deficiencies identified in recent surveys and investigations



Based on measures of staffing level and staff turnover



Quality Measures

Based on performance on 15 of the quality measures currently posted on the Care Compare website

Long-Term Antipsychotic Measure

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,

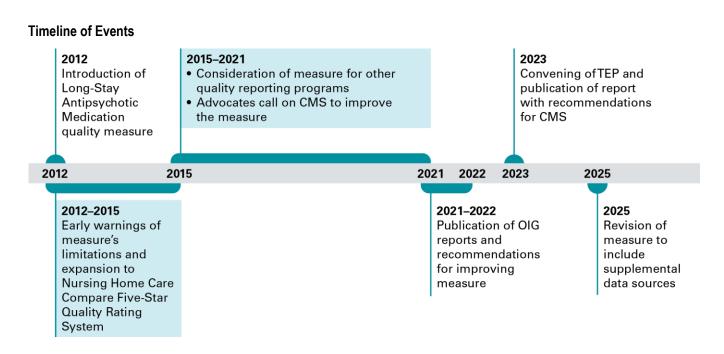
and Huntington's disease) are excluded from the denominator of the calculation, on the grounds that these patients may be taking antipsychotics to treat the specified conditions, rather than for management of NPS related to ADRD.53 Until recently, the measure has relied exclusively on the Minimum Data 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



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:

- 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.

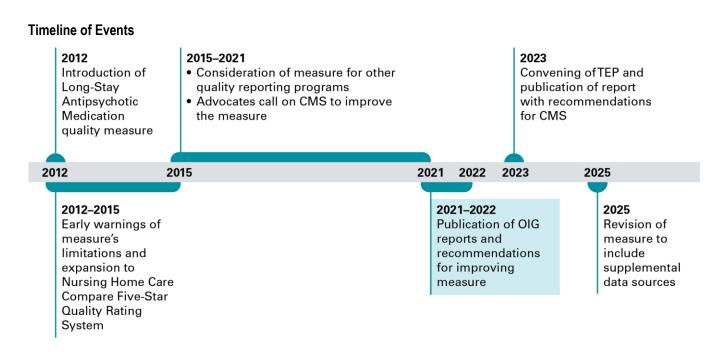
These concerns about the unintended effects of quality measure design are not new and are not unique to the Long-Stay Antipsychotic Medication measure. More than a decade ago, a physician discussing a measure of blood pressure control wrote:

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.



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 guality 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, dosedependent 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.

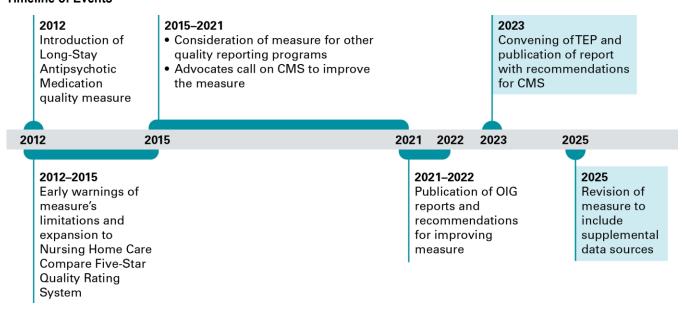
The utilization of these other medications that may have an adverse effect on SNF residents illustrates a significant and serious unintended clinical care consequence of CMS' sole focus on decreasing the acrossthe-board use of antipsychotics, driving providers to utilize treatments that may be less effective 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 guidelineconcordant, 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, 	 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
collaborative treatment because they are most appropriate for that patient's specific needs.	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 • Does not invite input from patients, families, caregivers, clinicians, or SNF providers unless CMS takes on what benefit from them to manage NPS and maintain SNF may be an extensive process. placement. Mitigates measure's current impact on SNF quality ratings • Requires explanation of why measure was retired; may and patient/family choice. elicit questions and criticism. • 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

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.

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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-druguse-in-nursing-homes/.

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