ORIGINAL RESEARCH

Changes in Antipsychotic Medication Use Among Medicare Patients in a Nursing Home, 2010 to 2015

Michele Berrios, CHFP; Bruce Pyenson, FSA, MAAA; Kyle Pérez, MPH; Heidi C. Waters, MBA, PhD

BACKGROUND: Concerns about the inappropriate or excessive use of antipsychotic medications in the nursing home setting have been an important focus of federal regulators and legislators for more than 3 decades. Because compliance with FDA-issued black box warnings that cautioned against the inappropriate use of antipsychotic medications in elderly patients was remarkably low, the Centers for Medicare & Medicaid Services (CMS) introduced a series of strategies aimed at reducing the unnecessary use of antipsychotic drugs in nursing homes (Star metrics). Quality metrics devised to limit unnecessary use of antipsychotic medications must be designed to guard against unintended adverse events.

OBJECTIVE: To evaluate the impact of the 2012 CMS Star metrics for antipsychotic medication use in nursing homes between 2010 and 2015.

METHODS: This study was a retrospective analysis of the 100% Medicare fee-for-service research identifiable administrative claims. Antipsychotic medication use in 5 annual cohorts of patients entering nursing homes (2011-2015) was examined. The patients were assigned to 1 of 3 cohorts based on conditions identified on medical claims: Star Excluded, which were patients with at least 1 FDA-approved but Star metric–excluded condition; Star Included, which were patients with at least 1 FDA-approved and Star metric–included condition and with no Star metric–excluded conditions; and Off-label/Star Included, which were patients who received antipsychotic medications for conditions outside of FDA-approved indications.

RESULTS: From 2011 to 2015, the number of Medicare beneficiaries entering nursing homes increased by 12%, whereas the number of those receiving antipsychotic medications decreased by 26%. Among the 3 cohorts, the largest decrease in antipsychotic drug use (43%) occurred among patients with off-label antipsychotic medication use (from 14.9% to 8.5%). The smallest decrease in antipsychotic drug use (2%) occurred among the Star Excluded cohort (from 75.6% to 74%). Among the patients who received antipsychotic medications for an FDA-approved condition and were included in the CMS Star metric, the use of antipsychotic medications decreased by approximately 19%.

CONCLUSIONS: The 2012 CMS Star metrics for antipsychotic medication use in nursing homes were associated with an intended reduction in antipsychotic drug use. Policymakers and quality metric developers should consider aligning quality metrics with the current and future FDA-approved indications to avoid creating an incentive for a potentially inappropriate reduction in the use of antipsychotic medications in certain patient populations.

KEY WORDS: antipsychotic medications, CMS Five-Star metric, Medicare, nursing home

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Concerns about the inappropriate or excessive use of antipsychotic medications in the nursing home setting have been an important focus of federal regulators and legislators for more than 3 decades.[1-4] Although the FDA issued black box warnings that cautioned against the use of antipsychotic drugs in elderly patients with behavioral disorders because of an increased mortality risk, the initial compliance with these warnings among

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prescribers was remarkably low.[5-7] Subsequently, in 2012, the Centers for Medicare & Medicaid Services (CMS) introduced a series of strategies aimed at reducing the unnecessary use of antipsychotic drugs in nursing homes.[8,9]

As part of the federally mandated clinical assessment of all US residents in Medicare- or Medicaid-certified nursing homes, CMS uses the Minimum Data Set (MDS)—data that are self-reported by nursing homes—to obtain information about nursing home residents and their use of antipsychotic drugs. Two MDS metrics were designed to capture information related to antipsychotic drugs: one for assessing short-stay nursing home residents (≤100 cumulative days) and a second for assessing long-stay nursing home residents (>100 cumulative days). The short-stay antipsychotic drug metric is used to determine the percentage of residents who are first prescribed an antipsychotic medication in a nursing home (ie, residents without a history of antipsychotic drug use before residing in a nursing home), whereas the long-stay antipsychotic medication metric indicates the percentage of nursing home residents who receive antipsychotic drugs, regardless of previous antipsychotic drug use, before residing in a nursing home.

Both quality metrics are part of the CMS Five-Star Quality Rating System, which is used for the purpose of enabling comparisons between nursing homes.[10] These metrics, which CMS uses as indicators of nursing home quality of care, are publicly reported for each nursing home in the United States. In designing these metrics, CMS acknowledged that some categories of antipsychotic drug use are necessary and appropriate. Accordingly, patients who have specific FDA-approved indications, including schizophrenia, Tourette syndrome, or Huntington disease (where in clinical practice antipsychotic drugs represent the first choice in the management of chorea) are excluded from the long-stay antipsychotic drug use quality metric.[10,11] Currently, however, patients who have been diagnosed with bipolar disorder or major depressive disorder (MDD), which are FDA-approved disorders for the use of antipsychotic drugs, are included in the long-stay antipsychotic medication use metric, and therefore undergo monitoring for antipsychotic drug use.[10]

Our study sought to capture the changes in antipsychotic drug use that may have occurred in response to strategies implemented by CMS, beginning in 2012. We aimed to ascertain the degree to which CMS-designated inclusions and exclusions from nursing home quality metrics may have affected antipsychotic drug use among various categories of patients. Although CMS has reported success in the reduction of antipsychotic drug use among long-stay nursing home residents, few studies to date have examined longitudinal changes in various patient cohorts, with a focus on whether FDA-approved

disorders were included in or excluded from the antipsychotic medication quality metric.

Methods

We analyzed Medicare 100% fee-for-service (FFS) Research Identifiable Files administrative claims data from 2010 to 2015. The patients residing in nursing homes for the first time were identified in the second quarter of each calendar year (2011-2015) and were observed over multiple years to evaluate the changes in antipsychotic drug use relative to the implementation of the antipsychotic medication quality metric in 2012.

The use of the data in this study was obtained through an application approved by the Western Institutional Review Board, which is an independent review board. The patient data accessed from the Medicare 100% Research Identifiable Files complied with a data use agreement with CMS, which was reviewed by the CMS Privacy Board to ensure that the beneficiary's privacy was protected and only the minimum data necessary were requested and justified. All data and summaries used in this study were reviewed by the CMS Chronic Conditions Data Warehouse analytical review team for compliance with CMS requirements to protect the privacy of the Medicare beneficiaries' data.

We created an algorithm to identify the patient days in nursing homes based on a patient's receipt of nursing home–specific evaluation and management (E&M) services, including initial nursing facility care, subsequent nursing facility care, nursing facility discharge care, and annual nursing facility assessment. Each nursing home E&M claim initiated a nursing facility period that lasted until the earliest occurrence of one of the following: a subsequent nursing home E&M claim, 75 consecutive days, a subsequent home health claim, patient death, or the end of the study period (ie, December 31, 2015). Although Medicare FFS typically does not cover residential nursing home long-term care days, Medicare Part B will pay for federally mandated visits that monitor and evaluate residents at least once every 30 days for the first 90 days after admission and at least once every 60 days thereafter per federal regulation 42 CFR 483.40(c)(1).[12]

Days within a nursing facility period were separately identified for 3 instances during which the measurement of our primary variable of interest (antipsychotic medications supplied through Medicare Part D) would be limited, including Part A–Covered Skilled Nursing Facility (SNF) Admission, Part A–Covered Inpatient Acute Admission, and Part A–Covered Hospice Stay. We limited our analysis to the nursing facility days that did not overlap with these Part A services, which are referred to in this analysis as residential nursing home days.

All calculations were limited to residential nursing

home days. A portion of the total nursing home days excluded was evaluated separately to determine if the remaining residential nursing home days were sufficient to account for a representative sample of total days. Acute nursing facility stays (Part A SNF admissions) accounted for less than 5% of the total nursing facility experiences for our sample population. Any medications provided during an SNF admission fall under the Part A–bundled payment and were excluded from this study.

All patients in our analysis were required to have continuous coverage of Medicare Part A, Part B, and Part D for the entire study period. The patients were assigned to an entrance cohort based on the date of their earliest nursing home E&M claim. A lookback period of 6 months was applied to limit our analysis to patients with relatively recent nursing home stays. For data processing convenience, the entrance cohorts included in our analysis were restricted to patients whose first nursing home E&M claim occurred during the second quarter (April 1-June 30) of each calendar year (2011-2015). To restrict the analysis to long-stay nursing home residents only, patients were required to have a cumulative combined total of more than 100 Part A–covered SNF days and residential nursing home days within the first 365 days of their observation period.

In all, 6 diagnosis-based condition categories were independently identified according to *International Classification of Diseases (ICD), Ninth Revision, Clinical Modification* and *ICD Tenth Revision, Clinical Modification (ICD-10-CM)* coding; CMS issued guidance that *ICD-10-CM* diagnosis codes be used for all healthcare services provided in the United States beginning October 1, 2015. The applicable diagnosis codes were limited to qualified claims (see **Supplementary Appendix** available at **www.AHDBonline.com**) and were used to identify schizophrenia, Tourette syndrome, Huntington disease, bipolar disorder, MDD, or no condition of interest.

The patients could be identified (with overlap) as having any or none of the 5 listed conditions of interest. The initial identification was based on the patient's 6-month clean period (before the first nursing home E&M claim), and the conditions were reassessed every 6 months. The patients who were assigned to a condition at any point in each subsequent 6-month reassessment period were classified with that disorder for the entirety of the 6 months.

The condition categories were used to determine 3 mutually exclusive condition cohorts. No patient was included in more than 1 cohort in a given month. The condition cohorts were determined to be Star Excluded (ie, patients with ≥1 FDA-approved but Star metric–excluded condition), Star Included (ie, patients with ≥1 FDA-approved and Star metric–included condition and with no Star metric–excluded conditions), and Off-label/

Star Included (ie, patients who received antipsychotic drugs for conditions that were not included in the drug's FDA-approved indications).

All drug use calculations in this analysis relied on the proportion of days covered, or days' supply per 30 residential nursing home days. Only medications that were covered under Medicare Part D were included in our analysis, and we required that the fill date coincide with a residential nursing home day. Medication coverage began at the fill date and extended through the fill date plus days' supply. All calculations that were based on the proportion of days covered in our analysis also required medication coverage overlap with a residential nursing home day. For example, if there was a 2-day inpatient acute admission beginning April 15 and a 30-day supply of an antipsychotic drug was provided while the patient was residing in a nursing home on April 1, the proportion of days covered would be 28/28 and would be represented as 30 days' supply per 30 residential nursing home days. Antipsychotic drugs provided by other routes of administration, such as long-acting injections covered under Medicare Part B, were not included in our analysis. Any covered days overlapping with a Part A–covered SNF stay, acute inpatient admission, or hospice stay were excluded from the calculation, because medications received during these stay types are the responsibility of the provider and not the Part D plan.

Results

From 2011 to 2015, we observed a 12% increase in the Medicare population entering nursing homes for the first time and a 26% overall decrease in nursing home residents receiving antipsychotic drugs. During that same period the US Social Security Administration Office of Retirement and Disability Policy estimated that enrollment in traditional FFS Medicare increased by approximately 3% (from 36 million to 37 million), indicating that the rate of beneficiaries who were entering residential nursing home long-term care outpaced the traditional Medicare enrollment growth.[13] Among new nursing home residents, the following changes in the distribution of condition categories were noted: Star Excluded conditions decreased by approximately 3% (from 3.8% to 3.7%) from 2011 to 2015, the prevalence of off-label conditions decreased by approximately 8% (from 64.1% to 58.6%), and Star Included conditions increased by approximately 17% (from 32.1% to 37.6%) between 2011 and 2015. These findings suggest that an increasing share of traditional Medicare beneficiaries moved into residential long-term care nursing home facilities, and among these beneficiaries the prevalence of conditions listed as approved by the FDA for treatment or management with antipsychotic drugs increased. These changes occurred in an environment where
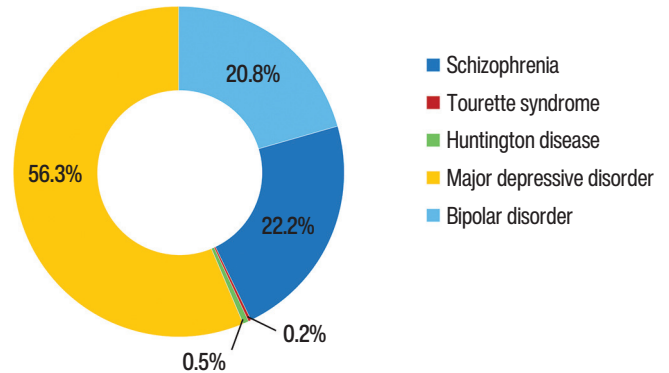
the treatment for patients with an FDA-approved/Star Included condition in the nursing home negatively affected the nursing home's quality score.

Among all of the patients in our study, more than 75% of long-stay nursing home residents who received an oral antipsychotic drug were in either Star Excluded or Star Included cohorts, with the majority of patients in the latter category (diagnosed with either MDD or bipolar disorder; **Figure 1**). This finding highlights the relative magnitude of the impact of a quality metric criterion that does not exclude most patients with an FDA-approved indication.

The reduction in the number of nursing home residents receiving antipsychotic drugs varied based on the conditions for which the patients received an antipsychotic medication. The largest decrease in antipsychotic drug use occurred among patients residing in a nursing home who received off-label antipsychotic drugs, with a 43% decrease (from 14.9% to 8.5%) from 2011 to 2015. The smallest change in antipsychotic drug use occurred among the Star Excluded patient cohort, for which there was a 2% decrease (from 75.6% to 74%) in antipsychotic drug use. Among patients who received antipsychotic drugs for an FDA-approved condition that was not excluded from the CMS Star metric, antipsychotic medication use decreased by approximately 19% (**Figure 2**).

Between 2011 and 2015, although the percentage of nursing home residents who were receiving antipsychotic drugs decreased over time, we did not observe a decrease in antipsychotic drug use (as measured by average days' supply per 30 days) for those patients who continued taking antipsychotic medications. For patients who were entering a nursing home in 2011, the average days' supply of antipsychotic drugs provided through Medicare Part D

in the first 6 months of residing in a nursing home were 26.2, 24.8, and 25.6 for the Star Excluded, Star Included, and Off-label cohorts, respectively. For the same cohorts, we observed that the average days' supply of antipsychotic drugs for new nursing home residents in 2015 were 26.2, 24.7, and 25.1, which were changes of 0%, −1%, and −2%, respectively (**Figure 3**).

In our analysis, there was a steady decrease in the percentage of nursing home residents who received an antipsychotic drug over time. The rate varied by entrance cohort for the same date (**Figure 4**). This finding suggests

Figure 1 Relative Prevalence of Conditions Among Residents Who Received an Antipsychotic Drug for an FDA-Approved Indication

- Schizophrenia
- Tourette syndrome
- Huntington disease
- Major depressive disorder
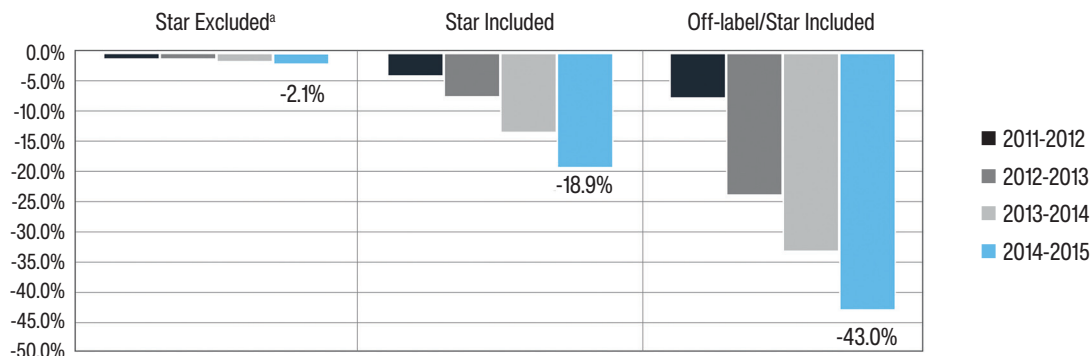- Bipolar disorder

20.8%
56.3%
22.2%
0.2%
0.5%

NOTE: Condition prevalence was determined using a condition hierarchy to assign only a single condition to each patient. The hierarchy used was (1) schizophrenia, (2) Tourette syndrome, (3) Huntington disease, (4) bipolar disorder, and (5) major depressive disorder.

Figure 2 Percent Decrease in Antipsychotic Drug Use by Condition Cohort, 2011-2015

Star Excluded[a] — −2.1%
Star Included — −18.9%
Off-label/Star Included — −43.0%

- 2011-2012
- 2012-2013
- 2013-2014
- 2014-2015

NOTES: Antipsychotic medication use is based on the average use by patients within each cohort for the first 6 months of residing in a nursing home (July 1-December 31 of each calendar year).
[a]Star Excluded includes conditions that are also FDA-approved indications for antipsychotic drugs.

Figure 3 Average Days' Supply Per 30 Days by Condition Cohort, 2011-2015
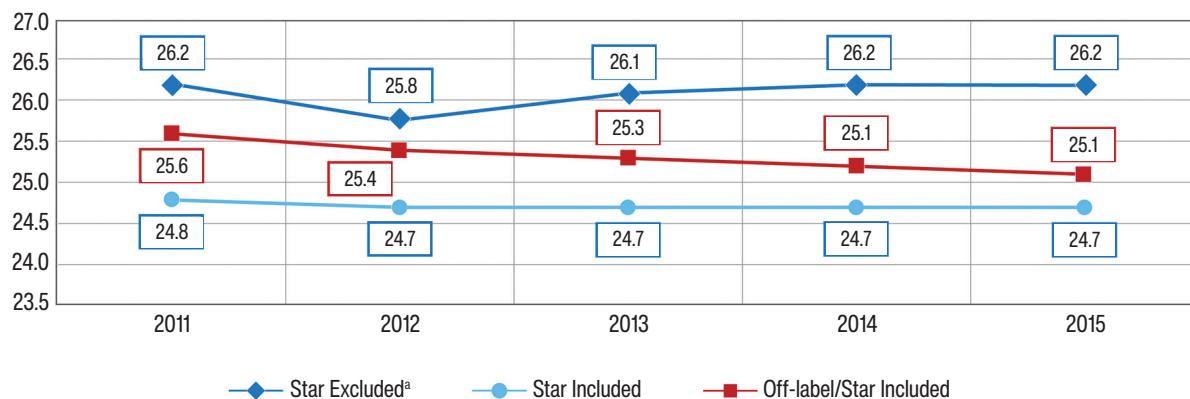
◆ Star Excluded[a]   ● Star Included   ■ Off-label/Star Included

[a]Star Excluded includes conditions that are also FDA-approved indications for antipsychotic drugs.

Figure 4 Percent of Patients Receiving an Antipsychotic Drug by Condition, December 2013
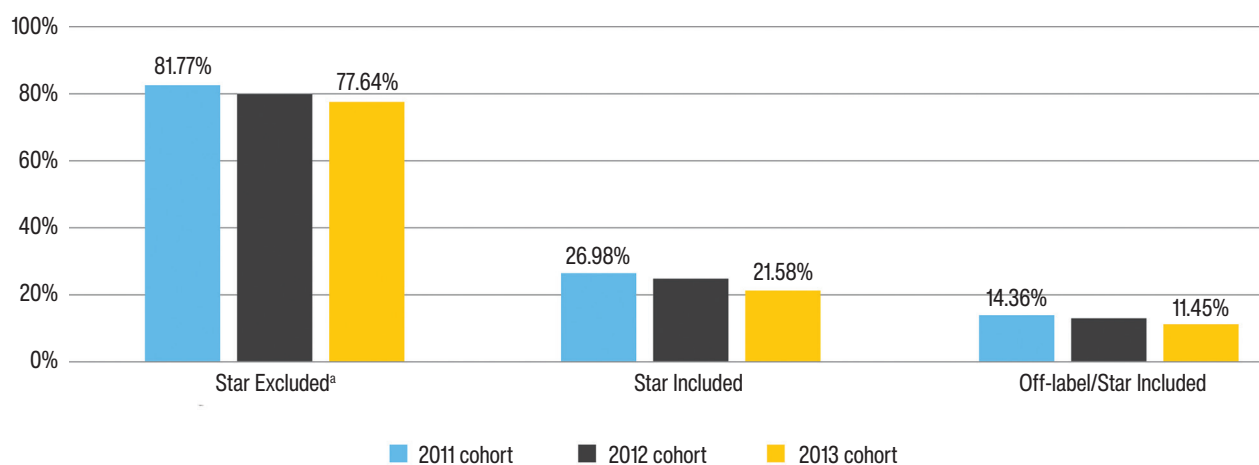
■ 2011 cohort   ■ 2012 cohort   ■ 2013 cohort

[a]Star Excluded includes conditions that are also FDA-approved indications for antipsychotic drugs.

that if a change in the prescribing patterns of antipsychotic drugs is occurring within the nursing home after the CMS policy intervention in 2012, it is disproportionately impacting new nursing home residents.

It is important to note that this analysis identified antipsychotic medications provided through Medicare Part D coverage; accordingly, antipsychotic drugs that were provided as part of a bundled Part A service were not included. However, for the nursing home long-stay residents, the contribution of acute nursing facility days to total days over a 6-month range was low, from 4.7% to 2.5%, for the 2011 to 2013 cohorts. All of the patients in our analysis had at least 101 total days of nursing home

facility stays within the 365 days after the first day of residing in a nursing home. This allowed us to limit our analysis to a population that was more likely to meet the CMS long-stay designation. Hence, there are sufficient nursing home days with Part D coverage for our subsequent findings to be representative of our study population's full experience.

Discussion

Our study suggests that mounting regulatory pressure on nursing homes to reduce the use of antipsychotic medications likely had the intended effect of contributing to a significant overall reduction in the use of these

drugs between 2011 and 2015. However, a reduction in antipsychotic drug use during this period varied among nursing home residents depending on how their antipsychotic medication was classified with regard to the CMS long-stay quality metric. Our findings that the off-label use of antipsychotic drugs declined dramatically (by 45%) among nursing home residents between 2011 and 2015, and that the decline in antipsychotic drug use among the Star Excluded cohort (2%) was minimal, may be considered in line with the intentions of the CMS Five-Star Quality Rating System. However, there was also a significant decrease in antipsychotic drug use (19%) among residents with bipolar disorder and MDD. Although these conditions are FDA approved for the use of antipsychotic drugs, they are not excluded from the Star metrics, such that antipsychotic medication use among these patients would count against the nursing home. This could potentially indicate that these patients, for whom antipsychotic drug use is FDA approved, may not have received appropriate treatment because of the regulatory pressure to reduce antipsychotic drug use in nursing homes.

The introduction of the CMS long-stay quality metric was designed to limit the unnecessary use of antipsychotic drugs. Yet, it is now widely recognized that the level of antipsychotic drug prescribing in US nursing homes is broadly used as a proxy for quality of care, such that higher levels of prescribing in a single nursing home are associated with relatively inferior quality of care, whereas lower levels of prescribing are associated with better quality of care.[14] Although there have been documented circumstances under which antipsychotic medications have been prescribed inappropriately,[15-18] the appropriate use of antipsychotic drugs for FDA-approved indications in elderly patients has been beneficial.[19,20]

Federal policies related to the public reporting of nursing home deficiencies and related deficiency citations may have a greater impact on nursing homes that accept a larger percentage of patients with chronic mental health conditions compared with those that accept fewer of these patients if appropriate treatment for serious mental illness is not safeguarded.

The ratings obtained by the Five-Star Quality Rating System are available on the Nursing Home Compare website (www.medicare.gov/care-compare/) and are used to help consumers make choices about US nursing homes. Quality measures also can affect CMS value-based payment systems, which, in turn, can affect the reimbursement of nursing homes. For these reasons, it is critical to determine the extent to which the current Five-Star quality measures accurately assess quality. Efforts to ensure appropriate clinical evaluation and mental healthcare management of nursing home residents will be a prerequisite for achieving sustainable improvements in antipsychotic medication use in US nursing homes.

Limitations

Our study has several limitations. First, changes in antipsychotic drug use over time were determined using the difference in average days' supply per 30 days. Increases or decreases in dose were not considered under this methodology, and changes resulting in different dosing patterns may affect the findings. For example, changing therapy from a medication that is dosed once daily to one that is dosed twice daily with half a dose would be identified as an increase in antipsychotic drug use.

Our review of antipsychotic drug use shows relatively consistent drug use for patients in the study population, although potential biases from our definition of changes in antipsychotic drug use should be considered. Our analysis evaluated only oral antipsychotic drug use, and it is possible that considering other antipsychotic treatment modalities (eg, long-acting injectables) may produce different outcomes or results.

Our analysis was limited to a Medicare FFS population between 2011 and 2015 with Parts A, B, and D coverage, and our findings may not be generalizable beyond this population and time period. In addition, longitudinal patterns were affected by survivor bias and changes in the patients' conditions over time.

Conclusion

Although the 2012 CMS Star metrics for antipsychotic drug use in nursing homes were associated with an intended reduction in antipsychotic medication use, policymakers and quality metric developers should consider aligning quality metrics with current and future FDA-approved indications to avoid creating an incentive for a potentially inappropriate reduction in the use of antipsychotic medications in certain populations.

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