CMS Could Improve the Data It Uses To Monitor Antipsychotic Drugs in Nursing Homes

Key Result

CMS's use of nursing homes' self-reported information to count the number of residents receiving antipsychotic drugs has important limitations.

The Centers for Medicare & Medicaid Services (CMS) has oversight of Medicare- and Medicaid-certified nursing homes that are responsible for the health and safety of vulnerable residents. CMS is required to monitor nursing home activities, including how nursing homes use antipsychotic drugs to treat residents' various conditions. These drugs can be effective in treating a range of conditions, but they carry risk and must be prescribed appropriately. CMS uses the Minimum Data Set (MDS)—i.e., data that nursing homes self-report—as its sole data source to count the number of nursing home residents receiving antipsychotic drugs. CMS has acknowledged the risk for inappropriate use of antipsychotic drugs. CMS has taken important steps to reduce the use of antipsychotic drugs in nursing homes and could further that progress by collecting more complete data on residents' use of these drugs.

Why This Issue Is Important

Nursing home residents and their families rely on nursing homes to provide quality care in a safe environment; however, there are reasons for concern specific to the use of antipsychotic drugs. Previous Office of Inspector General (OIG) work in 2011 raised quality and safety concerns regarding the high use of antipsychotic medications among nursing home residents. Since then, CMS has taken important steps to monitor the use of these drugs in nursing homes. However, CMS has acknowledged the potential for inconsistencies in the data—self-reported by nursing homes—that it uses to monitor nursing home quality and to monitor the safety of the use of antipsychotic drugs.

What OIG Found

We found that CMS's use of the MDS as the sole data source to count the number of nursing home residents using antipsychotic drugs may not always provide complete information. This means some residents' use of antipsychotics may not have been detected by CMS's quality measure intended to monitor these drugs. By analyzing a separate data source—Medicare claims—we found that using the MDS did not always result in a complete assessment of the number of residents who are prescribed antipsychotic drugs. Specifically, in 2018, 12,091 Part D beneficiaries who were long-stay residents age 65 and older—5 percent of all such beneficiaries—had a Part D claim for an antipsychotic drug but were not reported in the MDS as receiving an antipsychotic drug. Further, nearly one-third of residents who were reported in the MDS as having schizophrenia—a diagnosis that 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).

These findings suggest that CMS could enhance the information it uses to monitor antipsychotics in nursing homes by using additional data sources in its measurement of this complex issue that is critical for resident health and safety.

What OIG Recommends

So that CMS can enhance the information it uses to monitor antipsychotic drugs in nursing homes, we recommend 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.

Key Terms Regarding Antipsychotic Drugs Prescribed in Nursing Homes

- **Nursing Home Resident:** For the purposes of this review, "nursing home" refers to Medicare- and Medicaid-certified nursing facilities and skilled nursing facilities; and "resident" refers to a person residing in a nursing home who was 65 years old or older on January 1, 2018.

- **Antipsychotic drug:** Antipsychotic drugs are an important treatment for patients with certain mental health conditions.[1] However, the Food and Drug Administration (FDA) has warned that antipsychotic medications are associated with an increased risk of death when used in elderly patients with dementia-related psychosis.[2] These drugs may be effective for some residents in treating a wide range of conditions, but must be closely monitored for effectiveness, benefits, risks, and harm, and adjusted as necessary.[3]

- **National Partnership to Improve Dementia Care in Nursing Homes (Partnership):** In 2012, CMS formed the Partnership with Federal and State agencies, nursing homes, other providers, advocacy groups, and caregivers to improve comprehensive dementia care.[4] Though the initial focus was on reducing the use of antipsychotic medications, the Partnership's larger mission is to enhance the use of nonpharmacologic approaches and person-centered practices for dementia care.[5, 6]

- **We discuss two data sources in this report:**
  - **Minimum Data Set (MDS):** The MDS is part of the federally mandated process for nursing homes to self-report clinical assessments of all residents (i.e., both those who are Medicare beneficiaries and those who are not).[7] At routine intervals, nursing homes provide CMS with MDS assessments. 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.[8] The MDS is a 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] CMS requires nursing homes to record the number of days during the preceding 7 days that antipsychotic drugs were received by each resident.

  - **Medicare claims:** Medicare coverage is provided in four programs. Medicare Parts A, B, and C help cover the cost of services such as hospital care, office visits with doctors, home health care, durable medical equipment, and many preventive services. Diagnoses (i.e., the reasons for which residents received health services) are contained in claims data from these programs. Medicare Part D helps cover the cost of prescription drugs. Part D claims data include information about the drugs dispensed, but these data do not include diagnosis information because CMS does not require or collect diagnoses (i.e., the reasons for the drugs) for these items.

- **CMS monitors antipsychotic drug use in nursing homes using a quality measure and onsite survey:**
  - **Antipsychotic quality measure:** CMS uses quality measures as tools to quantify health care processes, outcomes, and organizational systems that are associated with effective, safe, and efficient health care.[10] CMS uses one such quality measure to quantify the percentage of long-stay residents (i.e., those with a stay of 101 days or longer) who received an antipsychotic drug. CMS uses the MDS as the data source for this measure and publishes these findings in Care Compare and the Star Rating System.[11] CMS excludes residents with MDS-reported diagnoses of schizophrenia, Huntington's disease, or Tourette's syndrome from inclusion in this measure.[12]

  - **Onsite survey conducted by State and Federal surveyors:** CMS works with State agencies to conduct onsite visits to nursing homes approximately once a year. CMS uses this survey process to ensure that nursing homes comply with Federal quality and safety standards, including those related to antipsychotic drugs.[13] See Appendix A regarding these standards.

Background

Antipsychotic drugs in nursing homes

CMS is required to monitor nursing home activities, including how nursing homes use antipsychotic drugs to treat residents' various conditions. These drugs can be effective in treating a range of conditions, but they carry risk and must be prescribed appropriately.

Nursing home residents and their families rely on nursing homes to provide quality care in a safe environment; however, there are reasons for concern specific to the use of antipsychotic drugs. Though CMS has taken important steps to monitor the use of these drugs in nursing homes, CMS has acknowledged the potential for inconsistencies in the data—self-reported by nursing homes—that it uses to monitor this concern.

CMS collects information to monitor the use of antipsychotic drugs in nursing homes

CMS uses Minimum Data Set (MDS) assessments as the data source to track its progress toward reducing the use of antipsychotic drugs for nursing home residents.[14, 15] Nursing homes electronically transmit their self-reported MDS assessments to CMS at required intervals.[16] CMS requires nursing homes to record the number of days an antipsychotic was received by a resident during the 7 days prior to the MDS assessment.[17] CMS uses this information to calculate results for its quality measure regarding the percentage of nursing home residents receiving antipsychotic drugs during the entire quarter.

CMS uses the onsite survey process to conduct validation of MDS information

Onsite nursing home surveys are a fundamental safeguard to ensure that nursing home residents are safe and receive quality care. CMS, in conjunction with States, oversees nearly 16,000 Medicare- and Medicaid-certified nursing homes to ensure that they meet Federal requirements.[18, 19, 20] On behalf of CMS, State agencies conduct standard certification surveys for nursing homes on average every 12 months but at least every 15 months.[21, 22] The accuracy and completeness of a nursing home's MDS assessments are among hundreds of regulatory requirements that surveyors may evaluate during surveys.[23, 24]

Through this onsite survey process, CMS and States have documented the potential for inaccuracies in information collected through MDS assessments, and CMS has increased some oversight activities in response.[25] CMS detected an increase in MDS reporting of schizophrenia—a diagnosis that excludes residents from measurement in the antipsychotic quality measure—and CMS conducted focused surveys on this concern in select nursing homes.[26]

Previous OIG work described quality and safety concerns regarding use of antipsychotic drugs in nursing homes

Previous OIG work found that nursing home residents who were prescribed antipsychotics were at risk for harm.[27] Specifically, 83 percent of Medicare claims for atypical antipsychotic drugs[28] were associated with conditions other than those for which FDA approved the use of the medication, and 88 percent were associated with a condition specified in the FDA black-box warning. The black-box warning states that elderly patients with dementia who are treated with these drugs are at an increased risk of death.

RESULTS

CMS's use of the MDS as the sole data source to count residents using antipsychotic drugs in nursing homes may not provide complete information

Part D claims identified more use of antipsychotic drugs among long-stay residents than the MDS did

In 2018, we found that 249,135 long-stay beneficiaries (23 percent of the 1,084,517 long-stay residents age 65 or older) had a Part D claim for an antipsychotic drug.[29] However, of these beneficiaries, 12,091 (5 percent) were not reported in the MDS as having received an antipsychotic drug in the same quarter in which they had a Part D claim.[30] Nursing homes are required to submit MDS assessments on all residents at regular intervals, including reporting antipsychotics that a resident received during the 7 days prior to the MDS assessment. As a way to monitor nursing home quality, CMS uses this self-reported information to calculate the quarterly percentage of all residents receiving antipsychotic drugs. However, CMS could expand its monitoring of the volume of antipsychotic drugs received by nursing home residents by analyzing the information provided in Part D claims data.

More than

1 in 5

long-stay residents age 65 and older received an antipsychotic drug in 2018

Part D claims identified

12,091

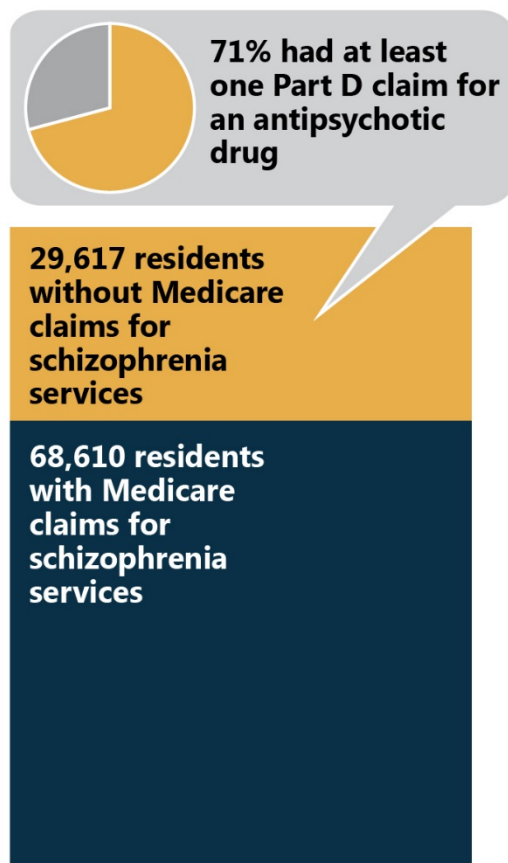more residents as receiving antipsychotics than in MDS assessments

There are limitations with CMS's use of the MDS as the sole data source to count the number of residents receiving antipsychotic drugs in nursing homes. Though the MDS provides useful data on many health status items, it may not provide enough information to comprehensively evaluate the use of antipsychotic drugs in nursing homes. MDS instructions require the nursing home to record the number of days a resident received an antipsychotic drug during the 7 days prior to the assessment. CMS then uses that 7-day response to calculate the percentage of residents who received an antipsychotic drug during the entire quarter. Because of the brevity of a 7-day assessment period, nursing homes' self-reporting of antipsychotic drug use may underestimate the actual number of residents who are treated with antipsychotics during the quarter. Further, though CMS uses limited edits (automated system processes) to confirm that nursing homes meet all technical requirements for

submitting their MDS assessments, CMS does not have a process to validate the accuracy of the information that nursing homes report regarding antipsychotic drugs. In October 2017, CMS added an MDS requirement for nursing homes to report whether a resident has received an antipsychotic drug at any time since admission; however, CMS stated it was not using this MDS assessment response for quality measurement.[31]

Nearly one in three residents reported in the MDS as having schizophrenia did not have any evidence of this diagnosis in their Medicare claims history

Exhibit 1: Over 29,000 residents reported by nursing homes as having schizophrenia did not have any evidence of this diagnosis in their Medicare claims; 71 percent of these residents had a Part D claim for an antipsychotic drug.

71% had at least one Part D claim for an antipsychotic drug

29,617 residents without Medicare claims for schizophrenia services

68,610 residents with Medicare claims for schizophrenia services

Residents reported as having schizophrenia in MDS

Source: OIG analysis of MDS and Medicare claims data, 2020.

According to 2018 MDS data, there were 98,227 residents age 65 and older whom nursing homes reported as having schizophrenia. Of those, 29,617 residents (30 percent) had no record of a schizophrenia diagnosis in any of their 2017 and 2018 Medicare Part A or B claims or Part C encounter data for visits, procedures, tests, or supplies. This means there was no evidence that these residents received care for the diagnosis that excluded them from being measured in the percentage of residents receiving antipsychotics. The same inconsistency was noted with regard to reporting of Huntington's disease and Tourette's syndrome; however, very few residents were reported in the MDS to have these conditions.[32]

Of those 29,617 residents whom nursing homes reported as having schizophrenia but who had no evidence of schizophrenia in their Medicare claims data, 71 percent (20,889 residents) had at least one Part D claim for an antipsychotic drug. This means these residents were prescribed an antipsychotic drug but qualified for exclusion from the antipsychotic measure because of MDS-reported schizophrenia.

This concern related to inconsistent reporting of schizophrenia in more than 29,000 residents is concentrated in certain nursing homes. Specifically, 52 nursing homes have 20 percent

or more of their residents with this type of MDS reporting that is inconsistent with Medicare claims history.[33] Though 69 percent of all nursing homes are classified as for-profit, we found for-profit nursing homes account for 78 percent of the MDS entries that are inconsistent in this way.[34]

This finding raises concerns. Because schizophrenia is one of the conditions that excludes nursing home residents from CMS's quality measure of antipsychotic use, it is possible that nursing homes may inaccurately report this diagnosis. It is also possible that these beneficiaries *do* have schizophrenia and that the lack of Medicare claims would therefore indicate that they are not receiving services for this serious diagnosis. CMS has noted similar concerns regarding inconsistencies in the reporting of schizophrenia. CMS has initiated an increased number of focused surveys and documented concerns with the quality of MDS data.[35] Though CMS uses limited edits to confirm that nursing homes meet all technical requirements for submitting their MDS assessments, CMS does not have a process to validate the accuracy of the diagnosis information that nursing homes report in the MDS.

The MDS does not provide important details about the use of antipsychotic drugs in nursing homes

Both the MDS and Part D claims provide information about the use of antipsychotic drugs in nursing homes. The MDS provides nursing homes' self-reported counts of the number of residents—even those who are not Medicare beneficiaries—who receive antipsychotic drugs, but the MDS does not provide any detail about the drugs. Part D claims data could enhance the analysis of these MDS data by providing—for a subpopulation of residents, i.e., those who are enrolled in Part D— objective measures regarding which specific drugs are being dispensed, at what quantities and strengths, and for what duration. CMS could use this information to validate and supplement the data reported in MDS assessments and gain important detail that would be useful in its work to protect residents.

CONCLUSION AND RECOMMENDATIONS

In 2018, more than one in five Medicare long-stay nursing home residents age 65 or over received an antipsychotic drug. Although antipsychotic drugs can be an important treatment for patients with certain mental health conditions, they also carry significant risks, including an increased risk of death when used in elderly patients with dementia. CMS uses MDS data to monitor the use of antipsychotic drugs for nursing home residents. However, CMS's use of MDS assessments as the sole data source to count the number of residents receiving antipsychotic drugs may not always provide a complete measure of the current use of these drugs. We found that Medicare Part D claims identified an additional 12,091 residents who received antipsychotic drugs beyond the residents whom MDS data identified. Additionally, we found evidence to suggest that up to 29,617 residents may have been inappropriately excluded from CMS's measure of antipsychotic drug use in nursing homes. These residents were reported in the MDS as having schizophrenia in 2018; however, there was no evidence of that diagnosis in their 2017 and 2018 claims in Medicare Part A or B, or in their encounter data in Part C.

These findings raise concerns about the vulnerabilities associated with CMS's use of limited data from the MDS as the sole source of information to count the number of nursing home residents receiving antipsychotic drugs. First, the findings in this issue brief show that nursing homes' self-reported data may underrepresent actual use of antipsychotic drugs and may inappropriately exclude residents from the quality measure regarding antipsychotic drugs. Second, CMS has very limited information about the use of antipsychotic drugs for the beneficiaries who are counted in the MDS data. CMS is missing an opportunity to use existing Part D data to conduct more robust monitoring that provides additional detail on antipsychotic drug use (e.g., medication strength, quantity, and duration) for a large subset of nursing home residents. CMS should enhance the information it uses to monitor antipsychotic drugs in nursing homes.

We recommend that CMS:

Take additional steps to validate the information reported in MDS assessments

CMS could consider using additional data analysis tools to ensure the accuracy of what nursing homes report in the MDS. For example, CMS could consider creating automated comparisons of claims and MDS information to detect inconsistencies between the two (e.g., a Part D claim for an antipsychotic drug for a resident for whom the MDS does not report any antipsychotic use). Using this information, CMS could increase its targeted oversight of nursing homes that submit MDS data that are

inconsistent with Medicare claims data, seem inconsistent with peer nursing homes, or meet thresholds that might warrant followup.

Supplement the data it uses to monitor the use of antipsychotic drugs in nursing homes

Additionally, CMS should reconsider whether the current MDS measure provides sufficient information to effectively monitor nursing homes, and CMS should take steps to supplement it. For example, CMS could use Part D data to enhance its monitoring of overall and concerning prescribing patterns in nursing homes. For a subpopulation of nursing home residents (i.e., those enrolled in Part D), Part D data provide additional information such as which specific drugs are being dispensed; at what quantities and strengths; and for what durations.

AGENCY COMMENTS AND OIG RESPONSE

CMS concurred with both of our recommendations.

In response to our first recommendation—for CMS to take additional steps to validate the information reported in MDS assessments—CMS stated that it would take steps to consider using additional data analysis tools to ensure the accuracy of what is reported on the MDS, as may be feasible.

In response to our second recommendation—for CMS to supplement the data it uses to monitor the use of antipsychotic drugs in nursing homes—CMS stated that it would consider whether alternative measures could be used to more effectively monitor the use of antipsychotics in nursing homes. CMS provided an example of action it has already taken to use Part D claims to calculate a related measure.

We appreciate CMS's continued commitment to reducing the unnecessary use of antipsychotic drugs in nursing homes, including the formation of the National Partnership to Improve Dementia Care in Nursing Homes, the use of quality measures for tracking, and its holding facilities accountable for compliance with Federal requirements.

Appendix B provides the full text of CMS's comments.

METHODOLOGY

Scope of inspection

We based this issue brief on a comparison of Medicare claims to MDS records for nursing home residents age 65 and older in 2018. The claims data include prescription drug event (PDE) records for Part D drugs; Medicare Part A and B claims data from the National Claims History File; and Part C encounter data. We determined the number of residents who had a Part D claim for an antipsychotic drug as compared to the number of residents whom the MDS reported as receiving these drugs. These analyses are not comparable to the CMS quality measure. Further, we determined the extent to which there were inconsistencies between residents' MDS-reported diagnoses of schizophrenia, Huntington's disease, or Tourette's syndrome and these residents' Medicare claims in 2017 and 2018 for each respective diagnosis.

Data Collection and Analysis

Residents who received antipsychotic drugs. We used several data sources to identify residents who received antipsychotic drugs. We collected all MDS records with an assessment date in 2018 for residents who were age 65 or older on January 1, 2018. Then, we determined the number of days of each resident's stay in the nursing home and limited the population to those with stays of 101 or more consecutive days. For those individuals identified, we collected all Part D claims with a date of service (i.e., date the prescription was filled) in 2018. We used First DataBank to determine the National Drug Codes (NDCs) that are categorized as antipsychotic drugs.

For the residents identified, we determined the number of residents with a Part D claim for an antipsychotic drug, and the number of residents with an MDS record in the same quarter that indicated they had received an antipsychotic drug. We then compared the two. To be included in the analysis, the resident had to have had at least one MDS assessment and at least one Part D claim in the same quarter. This analysis is not designed to be comparable to the CMS quality reporting; the methodology differs in various ways (e.g., limited to long-stay residents who are Part D beneficiaries, does not consider whether the resident has a diagnosis that is excluded from the quality measure).

Residents with schizophrenia, Huntington's disease, or Tourette's syndrome. For the residents identified as 65 or older for whom there were MDS assessments in 2018, we determined the extent to which, if any, there were inconsistencies in the prevalence of diagnoses that exclude residents from CMS's quality measure on the use of antipsychotic drugs. We determined the number of those residents for whom

there was an MDS-reported diagnosis of schizophrenia, Huntington's disease, or Tourette's syndrome in 2018. We then determined the number of those residents who did not have claims in Parts A or B or encounter data in Part C with a date of service in 2017 or 2018 with the corresponding MDS-reported diagnosis. We then compared residents in each analysis to determine if the data were inconsistent.

Structured interview with CMS. We collected written responses to a structured interview with CMS officials to gain information about the agency's efforts toward monitoring antipsychotic drug use in nursing homes. We asked about activities that CMS conducted in this area, including its use of technology and data to detect errors and trends in MDS reporting. We asked CMS about the extent to which it is using medical review to evaluate adherence to its guidance on documentation and MDS reporting.

Limitations

This study is limited to an evaluation of Medicare claims and MDS records. We did not conduct medical record review or in-person clinical assessments of residents. Therefore, we did not assess the accuracy of diagnoses, effectiveness of drug regimens, inappropriate use of drugs, or quality of care. Medicare claims data do not include claims for drugs or services that are self-paid or provided through other programs. Therefore, we may underestimate the use of antipsychotic drugs for the nursing home residents included in our review if they received drugs that were not billed to Medicare Part D. Likewise, our analysis would not capture any services that these residents may have received related to a schizophrenia diagnosis if those services were not billed to Medicare Parts A, B, or C.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

APPENDIX A

PART 483—Requirements for States and Long Term Care Facilities, Subpart B—Requirements for Long Term Care Facilities CFR 483.45

§483.45(c)(3) A psychotropic drug is any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories:

(i) Anti-psychotic;

(ii) Anti-depressant;

(iii) Anti-anxiety; and

(iv) Hypnotic

§483.45(e) Psychotropic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that--

§483.45(e)(1) Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record;

§483.45(e)(2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.[1]

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[1] The guidance section corresponding to § 483.45(d) Unnecessary drugs and § 483.45(c)(3) and (e) Psychotropic Drugs, found in Appendix PP of the *State Operations Manual,* states the intent is that:
• each resident's entire drug/medication regimen is managed and monitored to promote or maintain the resident's highest practicable mental, physical, and psychosocial well-being;
• the facility implements gradual dose reductions and nonpharmacological interventions, unless contraindicated, prior to initiating or instead of continuing psychotropic medication.
Use of psychotropic medications, other than antipsychotics, should not increase when efforts to decrease antipsychotic medications are being implemented, unless the other types of psychotropic medications are clinically indicated.
The resident's medical record must show documentation of adequate indications for a medication's use and the diagnosed condition for which a medication is prescribed. An evaluation of the resident by the interdisciplinary team helps to identify the resident's needs, goals, comorbid conditions, and prognosis to determine factors (including medications and new or worsening medical conditions) that are affecting signs, symptoms, and test results.
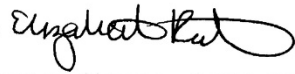
APPENDIX B

Agency Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

Date: April 9, 2021

To: Suzanne Murrin
Deputy Inspector General
Office of Inspector General

From: Elizabeth Richter
Acting Administrator
Centers for Medicare & Medicaid Services

Subject: Office of Inspector General Draft Report: CMS Could Improve the Data It Uses to Monitor Antipsychotic Drugs in Nursing Homes, OEI-07-19-00490

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General (OIG) draft report on CMS's use of data to monitor the number of nursing home residents receiving antipsychotic drugs.

CMS is committed to reducing the unnecessary use of antipsychotic drugs in nursing homes and holding facilities accountable for compliance with federal requirements. Nursing homes must ensure that residents are free from unnecessary medications (42 CFR 483.45). As such, CMS has implemented a number of strategies to reduce inappropriate antipsychotic use in long-term care settings as outlined below, and will continue pursuing additional innovative approaches including those recommended within the OIG's draft report.

One such effort is the National Partnership to Improve Dementia Care in Nursing Homes. The Partnership seeks to optimize quality of life for residents in America's nursing homes by improving comprehensive care approaches to better address the psychosocial and behavioral health needs of all residents, especially those with dementia. The Partnership's overall goals are to enhance the use of non-pharmacologic approaches and person-centered dementia care practices. This robust public-private collaboration has engaged providers and provider associations, clinicians, researchers, advocates, government agencies, residents and families in every state and has established a multidimensional strategy to address this public health issue.

CMS uses quality measures as tools to quantify health care processes, outcomes, and organizational systems that are associated with effective, safe, and efficient health care. CMS has developed two quality measures relating to antipsychotics that use self-reported Minimum Data Set (MDS) data to help safeguard against unnecessary antipsychotic use by nursing home residents: *Percent of Short-Stay Residents Who Newly Received an Antipsychotic Medication* (short-stay) and *Percent of Long-Stay Residents Who Received an Antipsychotic Medication* (long-stay). CMS publicly reports these quality measures on its Care Compare website and these measures are incorporated into the methodology for CMS's Five Star Rating System, which helps consumers, their families, and caregivers compare nursing homes more easily.

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There have been notable reductions in the prevalence of antipsychotic medication use in long-term nursing home residents since the launch of the Partnership, as indicated by these quality measures. Between 2011 and the second quarter of 2020, the national prevalence of antipsychotic medication use among long-stay nursing home residents was reduced by 41 percent to 14.1 percent nationwide, with every state showing reduced rates.

Monitoring resident safety and quality of care in facilities serving Medicare and Medicaid beneficiaries is an essential part of CMS's oversight. CMS works in partnership with State Survey Agencies (SSAs) to oversee nursing homes' compliance with federal requirements, and this is determined through unannounced on-site surveys conducted at least annually, but no later than every 15 months. Antipsychotic medication use are reviewed on every standard survey as well as surveys conducted in response to complaints, as appropriate.

As with all medications, the indication for any prescribed antipsychotic medication must be thoroughly documented in the medical record. During the survey, relevant resident medical records are reviewed to confirm that the prescribed psychotropic medications have a documented clinical indication for their use and other elements related to medication management, such as implementation of person-centered, non-pharmacological approaches to care and consideration of potential for tapering gradual dose reduction or rationale for clinical contraindication. If a surveyor determines that a facility is inappropriately using antipsychotic medications among its nursing home residents, the surveyor is required to document this in the facility's survey report. Facilities are then required to correct their noncompliance by demonstrating to surveyors that they have implemented a plan for discontinuing any unnecessary medications.

CMS has made significant outreach efforts to nursing homes who have continued to have high levels of antipsychotic medication use among long-stay nursing home residents, known as "late adopters." CMS implemented enhanced enforcement remedies for these late adopters, such as denial of payment for new admissions or per day civil monetary penalties (CMPs) imposed for nursing homes that have had a prior history of noncompliance citations in the areas of chemical restraints, dementia care, and psychotropic drugs, and that are determined in a current survey to be out of substantial compliance with those requirements. CMS continues to monitor these nursing homes to ensure that they achieve and maintain substantial compliance in these areas. In addition to this enhanced enforcement approach, CMS also engaged with corporate chains that owned or operated a significant number or percentage of nursing homes identified as late adopters to seek their assistance with addressing this critical issue at nursing homes owned or operated by these companies.

CMS requires that nursing facilities electronically transmit MDS assessments, which collect information about the residents' health, physical functioning, mental status, and general well-being, including use of antipsychotic drug and certain diagnoses. The MDS is the assessment instrument nursing homes use to self-report clinical assessments of all residents and is required to be submitted at routine intervals. CMS employs a process to validate the MDS assessments through the agency's Quality Improvement Evaluation System Assessment Submission and Processing system. When the provider-submitted transmission file is received by the system, it performs a series of validation edits to evaluate whether the data submitted meets certain

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required standards. MDS records are automatically verified to ensure that clinical responses are within valid ranges, that inputted dates are reasonable, and that records are in the proper order with regard to records that were previously accepted by the system for the same resident. If any fatal errors are found, the record will be rejected and the provider will be notified of the results of this validation process. In addition to this validation process, when residents are prescribed anti-psychotic medications, the surveyor will review the resident's medical record for documented clinical indication, which serves as an additional check to validate the accuracy and completeness of MDS responses. As OIG noted, when comparing MDS with Part D claims, there was 95 percent accuracy between the number of resident's receiving antipsychotic drugs and the number of residents' reported to be receiving antipsychotic drugs by the nursing homes.

CMS also uses quality measures to track trends in utilization across the Medicare prescription drug benefit program using Part D claims. In 2013, CMS began calculating a general atypical antipsychotic utilization rate for each Part D contract, called *Rate of Chronic Use of Atypical Antipsychotics by Elderly Beneficiaries in Nursing Homes*, for inclusion in the Part D display measures. This measure was replaced in 2016 when CMS began using a measure that was endorsed by the Pharmacy Quality Alliance, Antipsychotic Use in Persons with Dementia (APD), to monitor the use of antipsychotics overall for Part D beneficiaries in both nursing homes and community settings. At this same time, CMS also began using the measure, *Antipsychotic Use in Persons with Dementia (APD) - for Long-Term Nursing Home Residents.* CMS has provided monthly measure reports to Part D sponsors on the overall APD measure and the measure specific to the long-term nursing home setting. In addition to MDS data, the Part D measures are calculated using data from the Common Medicare Environment (CME) for enrollment information, Prescription Drug Event (PDE) for drug claims, and Risk Adjustment Processing System (RAPS) data, the Encounter Data Systems (EDS), and the Common Working File (CWF) for diagnoses. Through these reports, CMS has communicated with contracts about their performance on these APD quality measures, including sharing information about specific beneficiaries. Part D contracts who are outliers on each APD measure are encouraged to report to CMS on their plan to reduce inappropriate use.

Furthermore, CMS added the overall APD measure to the 2018 Part D display measures (based on 2016 data) on CMS.gov to draw attention to the use of antipsychotics in persons with dementia without a corresponding mental health diagnosis in both the community and nursing home settings.[1] CMS subsequently added the APD measures specific to long-term nursing home residents to the 2019 Part D display measures. CMS publicly displays the APD measures on CMS.gov at the Part D contract level in order to further increase visibility around antipsychotic use. Currently, the average APD measure rate based on the 2021 display measure using 2019 data remains relatively low and stable in the Part D program: 10 percent among Medicare Advantage Prescription Drug Plan (MA-PD) contracts and 9 percent among stand-alone Prescription Drug Plan (PDP) contracts.[2]

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[1] See Part C and D Performance Data, 2018 Star Ratings and Display Measures (ZIP), available at
https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.
[2] See Part C and D Performance Data, 2021 Display Measures (ZIP), available at
https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData.

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Another CMS effort that has addressed the prescribing rates of antipsychotic drugs for Part D beneficiaries is the use of the Plan Program Integrity Medicare Drug Integrity Contractor (PPI MEDIC), which identifies and investigates potential fraud, waste, and abuse in Medicare Part C and Part D. CMS has directed the PPI MEDIC to increase its focus on proactive data analysis in Part D to identify inappropriate payments, potential program vulnerabilities, and address issues, such as abusive prescribing. CMS produces reports to plan sponsors on specific data projects in CMS' Analytics and Investigations Collaboration Environment for Fraud, Waste, and Abuse system. One of those projects is intended to identify prescribers who may have abnormal or aberrant prescribing patterns with regard to certain atypical antipsychotic medications known to be targets for fraud, waste, and abuse. Plan sponsors may use the results of this project, along with their established protocols, to conduct supporting analyses to determine if potential fraud, waste, and abuse exists.

Through all of these efforts, CMS has worked diligently to optimize the quality of life for residents in America's nursing homes by taking actions to reduce antipsychotic overuse in nursing facilities and improve comprehensive care approaches to better address the psychosocial and behavioral health needs of all residents. CMS continues to look for opportunities to strengthen the survey process and enforcement efforts to ensure that nursing homes are focused on non-pharmacologic approaches and residents are not receiving medications that do not have a clinical basis. We appreciate the ongoing work of the OIG in this area and will continue to work with them as we make improvements to our oversight efforts.

OIG's recommendations and CMS's responses are below.

OIG Recommendation
Take additional steps to validate the information reported in MDS assessments.

CMS Response
CMS concurs with this recommendation to take steps to consider using additional data analysis tools to ensure the accuracy of what is reported on the MDS as may be feasible.

OIG Recommendation
Supplement the data it uses to monitor the use of antipsychotic drugs in nursing homes.

CMS Response
CMS concurs with this recommendation to consider whether alternative measures could be used to more effectively monitor the use of antipsychotics in nursing homes. As noted above, CMS is already taking considerable action to monitor use of antipsychotic drugs in nursing homes, including through Part D claims that are used to calculate the APD measures.

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[1] CMS, "Guidance to Surveyors for Long Term Care Facilities," Appendix PP, *State Operations Manual*, November 2017. Accessed at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf on March 6, 2019.

[2] CMS, "Guidance to Surveyors for Long Term Care Facilities," Appendix PP, *State Operations Manual*, November 2017. Accessed at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf on March 6, 2019.

[3] 42 CFR § 483.45(c)(3); CMS, "Guidance to Surveyors for Long Term Care Facilities," Appendix PP, *State Operations Manual*, November 2017. Accessed at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf on March 6, 2019.

[4] CMS, Memorandum to State Survey Agency Directors S&C 14-19-NH, "Interim report on the CMS National Partnership to Improve Dementia Care in Nursing Homes: Q4 2011-Q1 2014," April 2014. Accessed at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SC-Letter-14-19-Partnership-Interim-Report.pdf on May 1, 2019.

[5] CMS, Memorandum to State Survey Agency Directors S&C 14-19-NH, "Interim report on the CMS National Partnership to Improve Dementia Care in Nursing Homes: Q4 2011-Q1 2014," April 2014. Accessed at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SC-Letter-14-19-Partnership-Interim-Report.pdf on May 1, 2019.

[6] In its guidance to surveyors, CMS states that person-centered care means the facility focuses on the resident as the center of control and supports each resident in making his or her own choices. Person-centered care includes making an effort to understand what each resident is communicating, verbally and nonverbally; identifying what is important to each resident with regard to daily routines and preferred activities; and having an understanding of the resident's life before coming to reside in the nursing home. CMS outlines person-centered practices and the importance of sufficient and competent staffing in its guidance to surveyors. CMS states that nursing homes should have sufficient staff members who possess the basic competencies and skill sets to meet the behavioral health needs of residents. Nursing homes should implement person-centered approaches to care based upon comprehensive assessment and be guided by the interdisciplinary team (a team that includes but is not limited to the physician; a registered nurse; a nurse aide; a staff member from food and nutrition services; and (to the extent practicable) the resident and the resident's family/representative). This team must identify individualized interventions or approaches to care that support the resident's needs. Accessed at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf on March 6, 2019.

[7] CMS, "Minimum Data Set 3.0 Public Reports." Accessed at https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Minimum-Data-Set-3-0-Public-Reports/index.html on January 11, 2019.

[8] CMS, "Quality Measures." Accessed at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIQualityMeasures.html on January 11, 2019.

[9] CMS, "Design for Nursing Home Compare Five-Star Quality Rating System: Technical Users' Guide, October 2020." Accessed at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/downloads/usersguide.pdf on December 21, 2020.

[10] CMS, "Quality Measures." Accessed at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures on September 21, 2020.

[11] CMS, "Design for Nursing Home Compare Five-Star Quality Rating System: Technical Users' Guide, October 2020." Accessed at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/downloads/usersguide.pdf on December 21, 2020.

[12] These 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. The FDA-approved adult indications for antipsychotic medications include other conditions as well. CMS, "Atypical Antipsychotic Medications: Use in Adults." Accessed at https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Pharmacy-Education-Materials/Downloads/atyp-antipsych-adult-factsheet11-14.pdf on January 20, 2021.

[13] As a condition of participation in Medicare and Medicaid, nursing homes must comply with these standards. The guidance is intended to ensure that "psychotropic medications are used only when 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." We note both this regulation at 42 CFR § 483.45 and the corresponding guidance under the *State Operations Manual* (*SOM*) have been revised multiple times. The current study does not assess compliance with this regulation; past versions of this regulation; or the guidance corresponding to past versions or the current version of this regulation. CMS, "Guidance to Surveyors for Long Term Care Facilities," Appendix PP, *State Operations Manual*, November 2017. Accessed at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf on March 6, 2019.

[14] CMS, "Quality Measures." Accessed at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/NHQIQualityMeasures.html on June 26, 2020.

[15] CMS, "Minimum Data Set 3.0 Public Reports." Accessed at https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Minimum-Data-Set-3-0-Public-Reports/index.html on January 11, 2019.

[16] CMS, "Long-Term Care Facility Resident Assessment Instrument 3.0 User's Manual." Accessed at https://downloads.cms.gov/files/mds-3.0-rai-manual-v1.17.1_october_2019.pdf on September 21, 2020.

[17] CMS, "Long-Term Care Facility Resident Assessment Instrument 3.0 User's Manual." Accessed at https://downloads.cms.gov/files/mds-3.0-rai-manual-v1.17.1_october_2019.pdf on September 21, 2020.

[18] Social Security Act § 1864(a); 42 CFR § 488.330; CMS, *State Operations Manual (SOM)*, Pub. No. 10-07 ch. 1, "Program Background and Responsibilities," section 1002. Accessed at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c01pdf.pdf on December 4, 2020.

[19] When we refer to nursing homes, we make no distinction between Medicare-certified Skilled Nursing Facilities and Medicaid-certified Nursing Facilities. According to OIG analysis of CMS data, in 2018, there were 15,653 nursing homes certified by CMS (source: OIG analysis, 2020).

[20] Social Security Act §§ 1819(g) and 1919(g). Accessed at https://www.ssa.gov/OP_Home/ssact/title18/1819.htm and https://www.ssa.gov/OP_Home/ssact/title19/1919.htm, respectively, on December 4, 2020.

[21] 42 CFR § 488.308. Accessed at https://www.govinfo.gov/content/pkg/CFR-2010-title42-vol5/pdf/CFR-2010-title42-vol5-sec488-308.pdf on December 4, 2020.

[22] Sections 1819(g)(1)-(2) and 1919(g)(1)-(2) of the Social Security Act. Accessed at https://www.ssa.gov/OP_Home/ssact/title18/1819.htm and https://www.ssa.gov/OP_Home/ssact/title19/1919.htm, respectively, on December 4, 2020.

[23] CMS, "Guidance to Surveyors for Long Term Care Facilities," Appendix PP, *State Operations Manual*, November 2017. Accessed at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf on March 6, 2019. CMS, Federal Regulatory Groups for Long Term Care. Accessed at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/List-of-Revised-FTags.pdf on November 9, 2020.

[24] CMS, "Federal Regulatory Groups for Long Term Care." Accessed at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/List-of-Revised-FTags.pdf on November 9, 2020.

[25] CMS, Memorandum to State Survey Agency Directors S&C 14-19-NH, "Interim report on the CMS National Partnership to Improve Dementia Care in Nursing Homes: Q4 2011-Q1 2014," April 2014. Accessed at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SC-Letter-14-19-Partnership-Interim-Report.pdf on May 1, 2019.

[26] CMS, Memorandum to State Survey Agency Directors Admin Info 20-03-ALL, "Fiscal Year (FY) 2020 Mission & Priority document (MPD)," December 2019. Accessed at https://www.cms.gov/files/document/admin-info-20-03-all.pdf on August 27, 2020.

[27] OIG, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*, OEI-07-08-00150, May 2011. Accessed at https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf on August 15, 2019.

[28] Atypical antipsychotics—also known as second-generation antipsychotics and serotonin-dopamine antagonists—are a type of psychotropic drug that the Food and Drug Administration (FDA) has approved to treat medical conditions such as schizophrenia, Tourette's syndrome, Huntington's disease, and bipolar disorder. .

[29] The population of residents for this finding is limited to those with Medicare Part D claims; therefore, it does not include every nursing home resident.

[30] We report a quarterly finding because CMS calculates and reports the percentage of residents who received an antipsychotic drug during the entire quarter.

[31] CMS stated it has not completed analysis using this variable because it needs at least a full year of data before using the information in analysis, so this would not have been possible until January 2019.

[32] In 2018, of that same nursing home population, 59 percent (388 of 653 residents) of those reported as having Tourette's syndrome and 25 percent (344 of 1,390 residents) of those reported as having Huntington's disease did not have a 2017 or 2018 Medicare Part A or B claim or any Part C encounter data with the corresponding diagnosis. OIG analysis of MDS and Medicare data, 2020.

[33] According to OIG analysis of CMS data, in 2018, there were 15,653 nursing homes certified by CMS.

[34] According to OIG analysis of CMS data, approximately 69 percent of all nursing homes are classified as for-profit, 2020.

[35] Based on OIG analysis of data collected in its written interview with CMS, 2020.