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**Office of Inspector General**



# Long-Term Trends of Psychotropic Drug Use in Nursing Homes

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### Why OIG Did This Review

Nursing home residents and their families rely on nursing homes to provide quality care in a safe environment, and nursing homes are statutorily required to protect residents' rights in this regard. OIG work in 2011 raised quality and safety concerns about the high use of one category of psychotropic drug—antipsychotics—by nursing home residents. CMS began monitoring nursing home residents' use of antipsychotics in 2012, and in May 2021 OIG published a report that determined that CMS's existing methods for monitoring antipsychotic use by nursing home residents did not always provide complete information. Additionally, congressional stakeholders continue to raise concerns that nursing home residents may be inappropriately prescribed other types of psychotropic drugs and that potentially inappropriate use of those drugs may be going undetected.

### How OIG Did This Review

We used Minimum Data Set (MDS) assessment data from calendar years 2011 through 2019 to identify long-stay nursing home residents aged 65 and older and reviewed Medicare Part D psychotropic drug claims data for these residents. From these data, we identified the number of residents who received a prescription for any of these drugs. We then searched for patterns and characteristics in these data correlated with a higher use of psychotropic drugs in nursing homes. Our review did not assess the administration of or medical necessity of psychotropic drugs for nursing home residents.

## Long-Term Trends of Psychotropic Drug Use in Nursing Homes

### Key Takeaway

Overall, psychotropic drug use in nursing homes was relatively constant, prescribed to about 80 percent of nursing home residents from 2011 through 2019. Protecting nursing home residents from the potential harms of psychotropic drugs is essential yet remains challenging without the ability to comprehensively determine the scope of these drugs' use in nursing homes.

CMS has oversight of nursing homes that are responsible for the health and safety of vulnerable residents. CMS is required to monitor nursing home activities, including compliance with standards related to nursing homes' use of drugs to treat residents' various conditions.

Over the past 10 years, CMS took important steps to reduce the use of one category of psychotropic drug—antipsychotics. However, there continues to be concern about the use of psychotropic drugs among nursing home residents.

CMS defines psychotropic drugs as any drug that affects brain activities associated with mental processes and behavior. These medications can be effective in treating a range of conditions but carry risk and must be prescribed appropriately. CMS guidance acknowledges that medications beyond antipsychotics—such as anticonvulsants, mood stabilizers, and central nervous system agents—may affect brain activity and therefore must only be prescribed with a documented clinical indication. For this report, we refer to all of these medications as psychotropic drugs.

### What OIG Found

From 2011 through 2019, about 80 percent of Medicare's long-stay nursing home residents were prescribed a psychotropic drug. While CMS focused its efforts on reducing the use of one category of psychotropic drug—antipsychotics—the use of another category of psychotropic drug—anticonvulsants—increased. This increased use of anticonvulsants contributed to the overall use of psychotropics remaining constant.

In 2019, higher use of psychotropic drugs was associated with nursing homes that have certain characteristics. Nursing homes with lower ratios of registered nurse staff to residents were associated with higher use of psychotropic drugs. Nursing homes with higher percentages of residents with low-income subsidies were also associated with higher use of psychotropic drugs.

Additionally, over time the number of unsupported schizophrenia diagnoses increased and in 2019 was concentrated in relatively few nursing homes. Specifically, we found that from 2015 through 2019 the number of residents reported in the MDS as having schizophrenia but lacking a corresponding schizophrenia diagnosis in Medicare claims and encounter data increased by 194 percent. In 2019, the unsupported reporting of schizophrenia was concentrated in 99 nursing homes in which 20 percent or more of the residents had a report of schizophrenia in the MDS that was not found in the Medicare claims history.

CMS's long-stay quality measure that tracks antipsychotic use in nursing homes excludes residents who are reported as having schizophrenia in the MDS. Thus, nursing homes could misreport residents as having schizophrenia in the MDS to falsely impact CMS's quality measure.

By not collecting diagnoses on Medicare Part D claims, CMS is limited in its ability to effectively conduct oversight of psychotropic drugs. First, not having diagnoses on claims limits CMS's ability to detect patient risk and patterns of potentially inappropriate drug use. Second, the lack of diagnoses makes it difficult for CMS to systematically determine whether claims meet the payment requirement that drugs be used for medically accepted purposes.

### **What OIG Recommends and How the Agency Responded**

CMS should: (1) evaluate the use of psychotropic drugs among nursing home residents to determine whether additional action is needed to ensure that use among residents is appropriate, (2) use data to identify nursing homes or nursing home characteristics that are associated with a higher use of psychotropic drugs and focus oversight on nursing homes in which trends may signal inappropriate use, and (3) expand the required data elements on Medicare Part D claims to include a diagnosis code. CMS concurred with the first two recommendations and did not concur with the third recommendation in this report.

# TABLE OF CONTENTS

<b>BACKGROUND</b> .....	<b>1</b>
<b>FINDINGS</b> .....	<b>9</b>
Overall psychotropic drug use among nursing home residents was relatively constant from 2011 through 2019 at 80 percent; antipsychotic use declined while use of another category of psychotropic drug—anticonvulsants—increased.....	9
Higher use of psychotropic drugs was associated with nursing homes that had certain characteristics in 2019.....	10
By not collecting a diagnosis on Medicare Part D claims, CMS is limited in its ability to effectively conduct oversight of psychotropic drugs.....	13
<b>CONCLUSION AND RECOMMENDATIONS</b> .....	<b>15</b>
Evaluate the use of psychotropic drugs among nursing home residents to determine whether additional action is needed to ensure that use among residents is appropriate.....	15
Use data to identify nursing homes or nursing home characteristics that are associated with a higher use of psychotropic drugs and focus oversight on nursing homes in which trends may signal inappropriate use.....	16
Expand the required data elements on Medicare Part D claims to include a diagnosis code.....	16
<b>AGENCY COMMENTS AND OIG RESPONSE</b> .....	<b>17</b>
<b>APPENDICES</b> .....	<b>19</b>
Appendix A: CMS Enforcement Actions.....	19
Appendix B: Select CMS Regulatory Requirements.....	20
Appendix C: Agency Comments.....	21
<b>ACKNOWLEDGMENTS AND CONTACT</b> .....	<b>26</b>
<b>ABOUT THE OFFICE OF INSPECTOR GENERAL</b> .....	<b>27</b>
<b>ENDNOTES</b> .....	<b>28</b>

# BACKGROUND

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## OBJECTIVES

To examine:

1. the trends of psychotropic drugs used in nursing homes over time, and
  2. how the use of psychotropic drugs could be monitored using Medicare data.
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The Centers for Medicare & Medicaid Services (CMS) oversees nursing homes, which are responsible for the health and safety of vulnerable residents.<sup>1</sup> CMS is required to monitor nursing home activities including compliance with standards related to nursing homes' use of drugs to treat residents' various conditions.<sup>2</sup> Medications can be effective in treating a range of conditions, but all drugs carry risk and must be prescribed appropriately.

Recently, members of Congress expressed concerns about the use of psychotropic medications in nursing homes after reviewing clinical research and conducting their own investigative research.<sup>3</sup> Additionally, the White House announced new measures to improve the quality and safety of nursing homes that include a new effort to identify problematic diagnoses and refocus efforts to continue to bring down the inappropriate use of some medications.<sup>4</sup>

CMS defines a psychotropic drug as any drug that affects brain activities associated with mental processes and behavior.<sup>5, 6, 7</sup> Specifically, CMS states that psychotropic drugs include, but are not limited to: antipsychotic, antidepressant, antianxiety, and hypnotic drugs.<sup>8</sup> CMS guidance acknowledges that other medications—such as anticonvulsants, mood stabilizers, and central nervous system agents—may affect brain activity and therefore must only be prescribed with a documented clinical indication.<sup>9, 10</sup> For this report, we refer to all of these medications as psychotropic drugs.<sup>11</sup>

The use of psychotropic drugs in nursing homes can be concerning because of the serious side effects and risks associated with the use of psychotropic drugs such as antipsychotics—including increased risk of death among the elderly. The risk of adverse consequences varies based on both the number of medications being taken regularly and the specific pharmacological classes of medications, such as antipsychotics and anticonvulsants, that are taken.<sup>12, 13</sup> In 2008, the Food and Drug Administration (FDA) issued a boxed warning, stating that some off-label uses of antipsychotic medications can result in severe adverse effects (i.e., antipsychotics are associated with an increased risk of mortality in elderly patients treated for dementia-related psychosis).<sup>14</sup> Several anticonvulsant medications also have boxed warnings

that draw attention to serious and potentially life-threatening adverse reactions, which include vision loss, liver failure, and increased risk of suicidality.<sup>15</sup> Similarly, antidepressant medications are associated with several side effects to which elderly adults may be more vulnerable. These side effects range from headaches and gastrointestinal issues to cognitive impairment and increased risk for falls that can cause serious injury and lead to hospitalization.<sup>16</sup>

## CMS's efforts to reduce inappropriate use of one category of psychotropic drug—antipsychotics—in nursing homes

### National Partnership

CMS formed the National Partnership to Improve Dementia Care in Nursing Homes (the Partnership) to improve comprehensive dementia care. The Partnership is a public-private collaboration that engaged Federal and State agencies, nursing homes, other providers, advocacy groups, and caregivers.<sup>17</sup> Although its focus has centered 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.<sup>18</sup>

In CMS's 2014 interim report about the Partnership's progress, CMS described several possible reasons for the high use of antipsychotics in nursing homes.<sup>19</sup> CMS developed a targeted survey to supplement annual nursing home surveys and provide more focused oversight on the inappropriate prescribing of antipsychotics. CMS identified a lack of staff training and lower registered nurse (RN) staffing levels as possible reasons. Additionally, CMS reported that higher use of these drugs was more often found in for-profit nursing homes. Conversely, decreased use was associated with nursing homes with higher Medicaid payment rates.<sup>20</sup>

In 2016, CMS (through the Partnership) identified an issue of providers inappropriately coding residents as being diagnosed with schizophrenia to artificially improve their quality measure and Nursing Home Five-Star Quality Rating System performance. As a result, CMS piloted a targeted survey to exclusively review this issue and inform future actions.<sup>21</sup>

In 2017, CMS (through the Partnership) targeted nursing homes with high rates of antipsychotic medication use and little-to-no change over the years (i.e., late adopters). Nursing homes identified as late adopters were subject to more severe enforcement actions. CMS also sent letters to those nursing home chains with a large number of facilities identified as late adopters.<sup>22</sup>

In 2021, CMS's targeted surveys focused exclusively on investigating the inappropriate diagnosing and coding of residents with schizophrenia.

## Quality Measures

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. Since 2012, CMS has used one such quality measure to quantify the percentage of long-stay residents (i.e., those with a nursing home stay of 101 days or longer) who received one category of psychotropic drug—antipsychotics.<sup>23</sup> The Nursing Home Five-Star Quality Rating System and CMS's Care Compare website are key tools for consumers to use when choosing a nursing home. In 2015, CMS began using the long-stay quality measure that tracks antipsychotic use in nursing homes for one of its Nursing Home Five-Star Quality Rating System calculations.<sup>24</sup> This calculation, which excludes beneficiaries who are reported in the Minimum Data Set (MDS) as having schizophrenia, Huntington's disease or Tourette's syndrome, impacts the rating that nursing homes receive on the Care Compare website.<sup>25, 26</sup> This exclusion applies even when no support for these claims exist anywhere else in a resident's clinical records. Importantly, the data used for the nursing home long-stay quality measure calculation is self-reported by nursing homes in the MDS.<sup>27</sup>

## CMS's oversight activities to protect nursing home residents

CMS, in conjunction with States, oversees nearly 16,000 Medicare- and Medicaid-certified nursing homes to ensure that they meet Federal requirements.<sup>28</sup> Onsite nursing home surveys are one important oversight tool to ensure that nursing home residents are safe and receive quality care. States conduct standard certification surveys on behalf of CMS for nursing homes on average every 12 months but at least every 15 months. Compliance with standards related to medication management is among hundreds of regulatory requirements that surveyors may evaluate during surveys.<sup>29</sup> Through this onsite survey process, CMS and States have documented the potential for concerns related to medication management, and CMS has increased some oversight activities in response.

These oversight activities include enforcement actions such as citations and impositions of civil monetary penalties (CMPs). Citations correspond to a specific regulation within the Code of Federal Regulations and can be issued for a variety of concerns, such as the use of unnecessary medications. In 2018 and 2019, the number of citations issued by CMS related to the unnecessary use of psychotropics in nursing homes remained constant at approximately 3,000 citations per year. CMPs can vary in the dollar amount and duration and can depend on a variety of factors. Sometimes, large CMPs are a useful tool to incentivize nursing homes to come back into swift compliance with Federal rules. See Appendix A for additional information on enforcement actions and CMPs.

## Sufficient and competent staffing in nursing homes

Nursing homes are required to employ sufficient staff to provide care and services in assisting residents to attain or maintain their highest levels of physical, mental, and

psycho-social well-being.<sup>30</sup> CMS states that nursing homes should have sufficient staff members, including RNs, who possess the basic competencies and skill sets to meet the behavioral health needs of residents.<sup>31</sup> CMS describes sufficient and competent staffing more specifically in stating that nursing homes should implement person-centered approaches to care based on comprehensive assessments and be guided by interdisciplinary teams.<sup>32</sup> CMS requires nursing homes to report their daily staffing information based on payroll information to the Payroll Based Journal (PBJ). This data is used by CMS to calculate the staffing rating used in the Nursing Home Five-Star Quality Rating System.<sup>33</sup> See Appendix B for additional information on CMS regulatory requirements.

## Medicare Part D payment for psychotropic drugs

Comprehensive prescription drug coverage is available to all Medicare beneficiaries through Medicare Part D. Medicare beneficiaries generally have the option to enroll in a stand-alone prescription drug plan and receive all other Medicare benefits on a fee-for-service basis, or to enroll in a Medicare Advantage prescription drug plan and receive all of their Medicare benefits, including prescription drug coverage, through managed care. Long-term care pharmacies contract with Medicare prescription drug plans to provide drugs to their enrollees who are residents of the nursing homes that those pharmacies serve. Additionally, Medicare Part D helps cover the cost of prescription drugs and provides for extra help with prescription drug costs for eligible individuals whose income and resources are limited (i.e., low-income subsidy).

Medicare Part D claims data include elements that provide patient level information. The information included on Medicare Part D claims provides details such as the type of medication, dosage, number of days supply, volume of drugs, cost of the drug, and whether the beneficiary qualifies for a low-income subsidy.

For drugs to qualify for Medicare Part D reimbursement, the drugs must be used for medically accepted indications.<sup>34</sup> However, Medicare Part D claims data include information about the drugs dispensed but do not include diagnosis information because CMS does not require or collect diagnoses (i.e., the reasons for the drugs) for these items.

## Previous OIG work described quality and safety concerns in nursing homes related to antipsychotic drug use, adverse events, and staffing levels

Protecting the health, safety, and well-being of nursing home residents is a top priority for OIG, and we have a large portfolio of nursing home oversight work spanning decades. Some of this prior work, summarized below, is particularly relevant to concerns about psychotropic drug use.



Previous OIG work found that nursing home residents who were prescribed antipsychotics were at risk for harm.<sup>35</sup> Specifically, 83 percent of Medicare claims for atypical antipsychotics were associated with conditions other than those for which FDA approved the use of those medications (i.e., off-label use), and 88 percent were associated with a condition specified in the FDA boxed warning. The boxed warning states that elderly patients with dementia-related psychosis who are treated with these drugs are at an increased risk of death. OIG recommended that CMS facilitate access to information necessary to ensure accurate coverage and reimbursement determinations, such as expanding the required data elements to include a diagnosis code. CMS did not concur with that recommendation.

In 2012, OIG used medical record reviews to evaluate nursing home compliance with Federal quality and safety standards on assessment and care plans.<sup>36</sup> The study found that 59 percent of care plans did not include evidence of resident, family, and/or representative involvement or documentation as to why they were not involved in care planning.<sup>37</sup> The study also reported that 97 percent of care plans were not developed by an interdisciplinary team (e.g., a physician and RN team). These are aspects of care that must be conducted by a qualified health professional and require involvement of an interdisciplinary team. CMS concurred with and implemented all recommendations in the report.

Preventable, medication-related adverse consequences and events are a serious concern in nursing homes.<sup>38</sup> In 2014, OIG found that one in three short-stay (i.e., stay of 100 days or less) residents experienced an adverse event or temporary harm event.<sup>39</sup> Thirty-seven percent of these adverse events were related to medications and 66 percent of all medication-related events were preventable. Consequences of medication-related adverse events included prolonged nursing home stays, hospitalizations, life sustaining interventions, permanent harm, and deaths. In this report, OIG recommended that CMS raise awareness of adverse events in post-acute care and seek to reduce harm to nursing home residents through methods used to promote hospital safety. By 2018, CMS had implemented this recommendation by taking actions that included creating an Adverse Drug Event Trigger Tool, enabling nursing homes to identify adverse events in periodic medical record reviews.<sup>40</sup>

In 2020 and 2021, OIG reported findings regarding interdisciplinary staffing in nursing homes.<sup>41</sup> One report stated that 48 percent of nursing homes did not report any hours for at least one type of critical non-nurse staff, including staff required by all nursing homes (e.g., administrators, medical directors, and dietitians) and workers that provide required services (e.g., pharmacists). The report cited CMS's statement that "[s]taffing in nursing homes has a substantial impact on the quality of care and outcomes residents experience."<sup>42</sup> The other report found that 7 percent of nursing homes reported staffing levels below CMS's required levels for at least 30 total days in 2018. It also cited results of a survey to collect local ombudsman perspectives on residents' experiences when nursing homes report many days with staffing below required levels. The results revealed that a scarcity of nurses led to care issues, including medication management concerns.

In May 2021, OIG published an Issue Brief that determined that CMS's use of the MDS as the sole data source to count the number of nursing home residents using antipsychotic drugs did not always provide complete information.<sup>43</sup> By comparing Medicare claims to MDS records for nursing home residents aged 65 and older in 2018, OIG found that many beneficiaries had Medicare Part D claims for antipsychotic drugs but were not reported in the MDS as receiving an antipsychotic drug. Furthermore, nearly one-third of residents who were reported in the MDS as having schizophrenia—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). OIG recommended that CMS: (1) take additional steps to validate the information reported in MDS assessments and (2) supplement the data it uses to monitor the use of antipsychotic drugs in nursing homes. CMS concurred with both recommendations, noting in its response to OIG that CMS efforts were underway to supplement the data used to monitor the use of antipsychotic drugs in nursing homes. CMS directed the Plan Program Integrity Medicare Drug Integrity contractors to increase their focus on proactive data analysis in Part D to identify inappropriate payments, potential program vulnerabilities, and address issues, such as abusive prescribing.

## Methodology

### Data collection

For each year from 2011 through 2019, we identified beneficiaries who: (1) were aged 65 or older, (2) were enrolled in a Medicare Part D plan (including traditional fee-for-service or Part C managed care enrollment), (3) received at least one MDS assessment during a stay, and (4) were prescribed psychotropic drugs.

**MDS assessment data.** We collected MDS assessment data for calendar years 2011 through 2019 to identify long-stay nursing home residents who were aged 65 and older during their nursing home stay.

**Medicare Parts A, B, C, and D data.** We collected prescription drug event records for Medicare Part D claims from 2011 through 2019 for nursing home residents who were aged 65 and older. We also collected Medicare Parts A and B claims data from the National Claims History File; and Part C encounter data.

**PBJ staffing data.** We collected PBJ data for the nursing homes that provide care for the residents in this population.

**First DataBank data.** We collected data from the First DataBank to determine the National Drug Codes (NDCs) that are categorized as psychotropic drugs. For consistency with other OIG reports, we used First DataBank's Enhanced Therapeutic Class (ETC) code to identify psychotropic drugs.

**Qualitative data.** We collected written responses to a structured interview with CMS officials to gain information about CMS's efforts toward monitoring psychotropic 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. The team also engaged a representative from the National Council for Prescription Drug Programs regarding initiatives related to the inclusion of diagnostic information on prescription drug claims.<sup>44</sup>

## Data Analysis

We combined the data collected from the sources listed above to analyze the extent of the use of psychotropic drugs in nursing homes, to identify the number of residents who received a prescription for any of these psychotropic drugs, and to categorize the types of drugs paid for by the Medicare Part D program over this span of time. For the remainder of the report, "residents" refers to long-stay nursing home residents who were aged 65 and older and were Medicare beneficiaries.

**Residents who were prescribed psychotropic drugs.** For each year from 2011 through 2019, we used the data sources described above to identify residents who received psychotropic drugs. We examined all MDS records with an assessment date in the year for any residents. We determined the number of days of each resident's stay in these nursing homes and limited the population to those residents with stays of 101 or more consecutive days within a single calendar year. We then reviewed for this long-stay population all Medicare Part D psychotropic drug claims with a date of service (i.e., date a prescription was filled) during a nursing home stay in the year. We used First DataBank to determine the NDCs for psychotropic drugs. We identified 19 categories of psychotropic drugs that affect brain activities associated with mental processes and behavior. We then used these to identify psychotropic drugs during our analysis of Medicare Part D drug claims. For the nursing homes identified in these MDS records, we also analyzed nursing home staffing information from the PBJ.<sup>45</sup> We used Medicare enrollment data to determine which residents were receiving a Medicare Part D low-income subsidy in the year.<sup>46</sup>

**Residents with schizophrenia.** For each year from 2011 through 2019, we analyzed schizophrenia diagnoses reported in MDS and in Medicare claims. For the residents identified as aged 65 or older for whom there was at least one MDS assessment in the year, we determined the number of those residents for whom there was an MDS-reported diagnosis of schizophrenia. We also determined the number of those residents aged 65 or older who had claims in Parts A or B or encounter data in Part C with a schizophrenia diagnosis.

## Limitations

The results of our analysis rely on the accuracy of the data in CMS's databases. It is possible that some beneficiaries received services that were not included in our analysis (e.g., due to incorrect or incomplete MDS coding; drugs that were not submitted to Medicare), which may lead to an underestimate or overestimate

regarding some information for some beneficiaries. Additionally, our Part D claims analysis allows us to only determine which medications were prescribed and then filled by a pharmacy, not which medications were administered.

## Standards

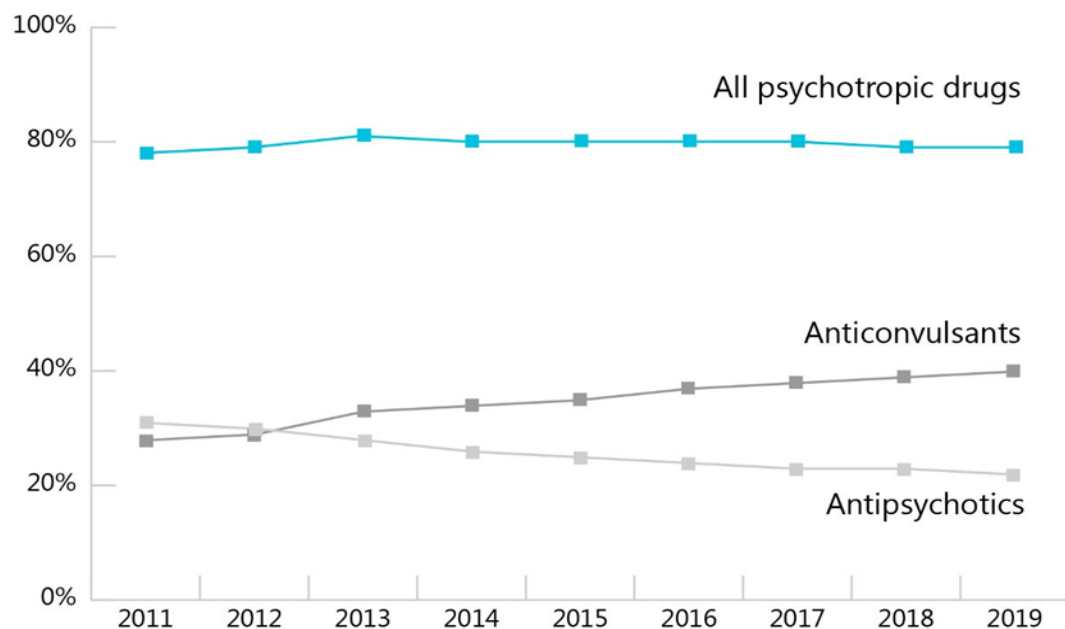
We conducted this study according to the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

# FINDINGS

## Overall psychotropic drug use among nursing home residents was relatively constant from 2011 through 2019 at 80 percent; antipsychotic use declined while use of another category of psychotropic drug—anticonvulsants—increased

From 2011 through 2019, the overall use of psychotropic drugs among nursing home residents remained about constant at about 80 percent. (See endnote 11 for a list of all categories included in the analysis of all psychotropic drugs.) While the use of one category of psychotropic drug—antipsychotics—decreased from 31 percent in 2011 to 22 percent in 2019, the use of another category of psychotropic drug—anticonvulsants—increased. Anticonvulsants showed an increase in use among nursing home residents from 28 percent to 40 percent during the same period. These data demonstrate that overall use of psychotropic drugs did not decrease but rather the use of psychotropic drugs shifted toward a different category. The use of psychotropic drugs in nursing homes can be concerning because of the serious side effects associated with the use of some psychotropic drugs that could include increased risk of death, suicidality, or falls among the elderly.

**Exhibit 1: While CMS focused its efforts on reducing antipsychotic drug use, overall psychotropic drug use remained constant, and anticonvulsant drug use increased among long-stay residents aged 65 and older.**



Source: OIG analysis of MDS and Medicare claims data, 2022. (See endnote 11 for a list of all categories included in the analysis of all psychotropic drugs.)

The focus of CMS's targeted monitoring of antipsychotic drugs likely contributed to a decline in antipsychotic drug use among nursing home residents; however, anticonvulsant drug use increased during this effort. In 2012, following OIG's report, CMS started monitoring antipsychotic drug use in nursing homes, which coincides with the decline in antipsychotic drug use. In 2015, CMS began using the long-stay quality measure that tracks antipsychotic use in nursing homes in its Nursing Home Five-Star Quality Rating System calculations. Antipsychotic drug use continued to decline while anticonvulsant drug use continued to increase after CMS made this change. However, CMS guidance to State surveyors of nursing homes states "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."<sup>47</sup>

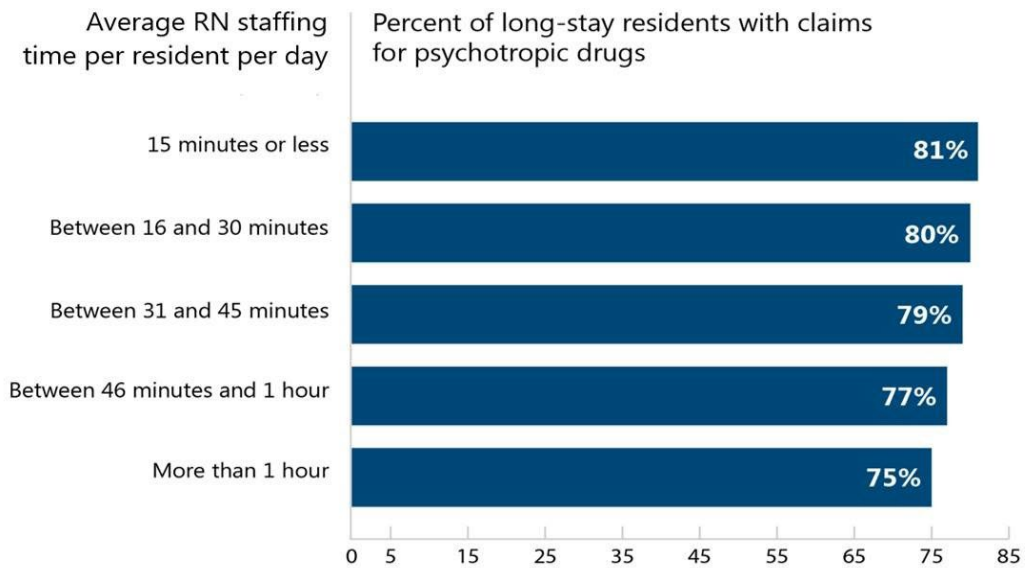
We did not conduct a medical record review for these drug claims to determine whether their use was clinically indicated and cannot assess the appropriateness of the use of these drugs nor determine why they were prescribed.

## Higher use of psychotropic drugs was associated with nursing homes that had certain characteristics in 2019

Using 2019 data sources that are available to CMS, we identified two characteristics that correlate with higher use of psychotropic drugs in nursing homes—staffing and low-income subsidies.

**Nursing homes with lower RN staffing numbers were associated with higher use of psychotropic drugs in 2019.** Using PBJ data that CMS collects, we determined that for the nearly 1,100 nursing homes that had RNs on staff for 15 minutes or less per resident per day, 81 percent of residents had claims for psychotropic drugs in 2019. In contrast, for the nearly 2,000 nursing homes that had RNs on staff for more than 1 hour per resident per day, 75 percent of residents had claims for psychotropic drugs in 2019. See Exhibit 2.

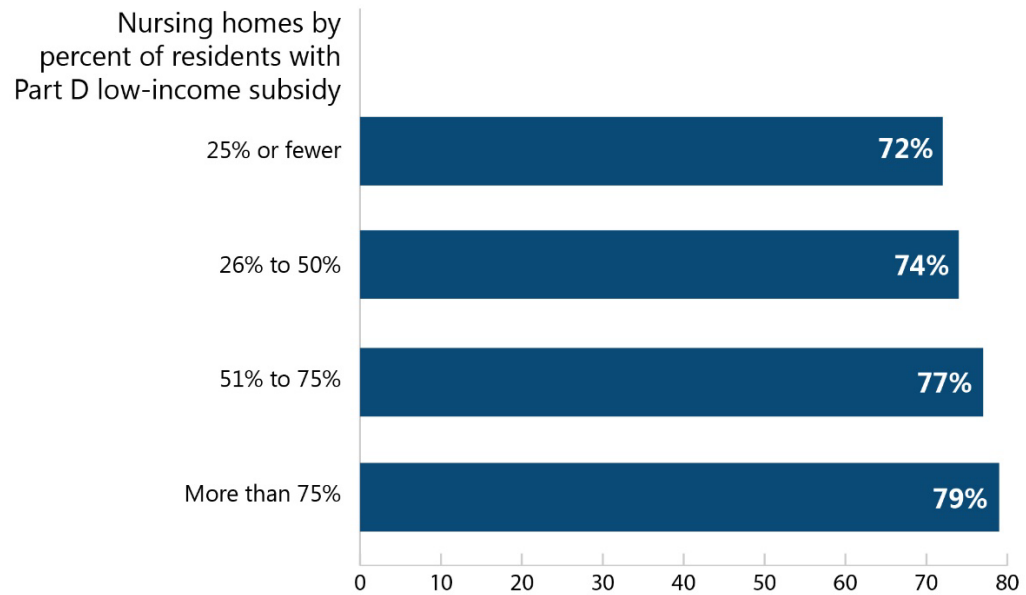
**Exhibit 2: Nursing homes with lower RN staffing numbers were associated with a higher percentage of long-stay residents with claims for psychotropic drugs in 2019.**



Source: OIG analysis of Medicare claims and PBJ data, 2022.

**Nursing homes with higher percentages of residents with low-income subsidies had higher use of psychotropic drugs in 2019.** Using Medicare Part D data, we determined that higher use of psychotropic drugs is associated with nursing homes that serve more residents who receive low-income subsidies in 2019. For instance, the nearly 5,000 nursing homes in which more than 95 percent of residents received a Medicare Part D low-income subsidy had 79 percent of residents with claims for psychotropic drugs in 2019. In contrast, the nearly 550 nursing homes in which 50 percent or fewer residents received a Medicare Part D low-income subsidy had only 73 percent of residents with claims for psychotropic drugs in 2019. See Exhibit 3.

**Exhibit 3: Nursing homes with higher percentages of residents with low-income subsidies have higher percentages of residents with claims for psychotropic drugs in 2019.**



Source: OIG analysis of Medicare claims and enrollment data, 2022.

**From 2015 through 2019, there were increases in both MDS reporting of schizophrenia and the numbers of residents who lacked a corresponding schizophrenia diagnosis in Medicare claims and encounters**

The reporting of residents in the MDS as having schizophrenia increased from 2015 through 2019. After 2015, the number of nursing home residents reported in the MDS as having schizophrenia increased by 35 percent.

Additionally, the number of residents reported in the MDS as having schizophrenia but lacking a corresponding schizophrenia diagnosis in Medicare claims and encounter data increased by 194 percent. In 2015, there were 6,465 residents who were reported in the MDS as having schizophrenia but who lacked a corresponding schizophrenia diagnosis in their

claims for medical visits, treatments, tests, or supplies during 2015 or in the preceding year. By 2019, this number had almost tripled to 19,009 residents reported in the

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There was a **194% increase** in the number of residents reported in the MDS as having schizophrenia but who lacked a corresponding schizophrenia diagnosis in their Medicare claims and encounters (2015–2019).

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MDS as having schizophrenia but who lacked a corresponding schizophrenia diagnosis in their claims during 2019 or the preceding year.

The timing of this increase coincides with CMS's incorporation of the quality measure that tracks antipsychotic use in nursing homes in 2015 into one of its Nursing Home Five-Star Quality Rating System calculations, which impacts the nursing home's rating on Care Compare. The increases in MDS reporting of schizophrenia and the number of residents who lack a corresponding diagnosis in Medicare claims is concerning as schizophrenia is a condition that is excluded from calculation in CMS's quality measure of antipsychotic use.<sup>48</sup> Therefore, any antipsychotic drug use for these residents may not be counted in their nursing homes' quality measure of long-stay antipsychotic drug use.

Additionally, more than 75 percent of these residents had a claim for an antipsychotic drug in 2019 but qualified for exclusion from the antipsychotic measure because of MDS-reported schizophrenia.

Certain nursing homes had particularly high levels of inconsistent reporting. Specifically, 99 nursing homes had 20 percent or more of their residents with this type of MDS reporting that was inconsistent with Medicare claims history. Of these 99 nursing homes, 88 percent were classified as for-profit.<sup>49</sup>

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One Five-Star-rated nursing home reported 36 residents with schizophrenia in the MDS in 2019, even though only 3 of those residents had a Medicare encounter or claim with a schizophrenia diagnosis. Twenty-nine of these residents were prescribed antipsychotics but qualified for exclusion from being calculated in CMS's quality measure for long-stay antipsychotic use.

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## By not collecting a diagnosis on Medicare Part D claims, CMS is limited in its ability to effectively conduct oversight of psychotropic drugs

Without a diagnosis on Medicare Part D claims, CMS is not able to determine the condition for which psychotropic drugs are prescribed without reviewing residents' underlying medical records. This raises two concerns. First, claims data provide no information on why a drug was prescribed. This limits CMS's ability to detect risky prescribing patterns and protect vulnerable residents from inappropriate use. Antipsychotics, for example, are FDA-approved for certain conditions (e.g., schizophrenia). However, antipsychotics also have a boxed warning from the FDA. The boxed warning states that elderly patients with dementia-related psychosis who are treated with these drugs face increased risk of death. Additionally, drugs such as

anticonvulsants are approved to treat conditions such as epilepsy and manage some types of nerve pain but are also sometimes prescribed off-label for other types of pain management. Second, the lack of diagnoses makes it difficult for CMS to determine whether claims meet the payment requirement that drugs be used for medically accepted purposes. Medical record reviews are conducted to evaluate the appropriate uses of psychotropic drugs, but these are costly and time-consuming.

# CONCLUSION AND RECOMMENDATIONS

CMS and the Partnership continue to work to reduce the use of one category of psychotropic drug—antipsychotics—in nursing homes. During our period of review (2011 through 2019) we found that while antipsychotic use declined in nursing homes, the use of another category of psychotropic drug—anticonvulsants—increased. Overall, about 80 percent of Medicare long-stay nursing home residents each year were prescribed some type of psychotropic drug.

Higher use of psychotropic drugs was associated with nursing homes that have certain characteristics. Higher numbers of psychotropic drug use were associated with nursing homes with lower RN staffing numbers and nursing homes with a higher percentage of residents with low-income subsidies.

Additionally, from 2015 through 2019, the number of beneficiaries reported by nursing homes as having schizophrenia—without corresponding claims or encounters that included a schizophrenia diagnosis—increased three-fold. CMS's quality measure for monitoring antipsychotic drug use may not be capturing use for these residents.

Other trends of psychotropic drug use in nursing homes cannot be comprehensively monitored because a diagnosis is not required to be included on Medicare Part D claims. This limits CMS's ability to both fully understand how psychotropic drugs are used for nursing home residents and target oversight of nursing homes with concerning patterns.

There are ways that CMS could use existing data—and collect new data—to monitor the use of psychotropic drugs in nursing homes. We identified three ways that CMS could enhance its monitoring of the use of psychotropic drugs in nursing homes. The use of this data could identify areas of heightened concern and increase CMS's ability to focus efforts on monitoring the use of psychotropic drugs in nursing homes.

## **We recommend that CMS:**

### **Evaluate the use of psychotropic drugs among nursing home residents to determine whether additional action is needed to ensure that use among residents is appropriate**

Given the increased rate of anticonvulsant use we identified and the relatively unchanged overall use of all psychotropic drugs, CMS should monitor the use of psychotropics, and the increased use of anticonvulsants in particular, to determine whether additional action is needed to better safeguard nursing home residents from overuse of any psychotropic drug. CMS may identify other methods of analysis to

ensure that the use of these drugs is appropriate. In addition, CMS should evaluate the impact of completely excluding certain conditions, such as schizophrenia, from calculations in future quality measures. CMS may consider excluding residents with MDS-reported schizophrenia from the quality measure calculation only when the residents have corresponding diagnoses in CMS claims data or other medical documentation.

## **Use data to identify nursing homes or nursing home characteristics that are associated with a higher use of psychotropic drugs and focus oversight on nursing homes in which trends may signal inappropriate use**

CMS should increase its focused oversight on nursing homes that appear inconsistent with peer nursing homes or meet thresholds that warrant a followup. It could accomplish this by establishing mechanisms to detect characteristics, such as low nurse staffing, that correspond with higher rates of psychotropic drug use and target oversight of outlier nursing homes to determine whether they are using these drugs inappropriately.

## **Expand the required data elements on Medicare Part D claims to include a diagnosis code**

The findings of this report reiterate the need for CMS to implement a previous recommendation by OIG: that CMS facilitate access to information necessary to ensure accurate coverage and reimbursement determinations. OIG understands that this would be a long-term investment that would benefit from a multistep implementation plan. As a first step, CMS should develop a pilot program to include a diagnosis code (i.e., reason for the drug) on Medicare Part D claims for psychotropic drugs prescribed to long-stay nursing home residents. CMS could consider partnering with other entities conducting work in this area (e.g., the National Council for Prescription Drug Programs, which recently awarded a grant to The University of Arizona, Department of Pharmacy Practice and Science to demonstrate the impact of including diagnostic information.)

# AGENCY COMMENTS AND OIG RESPONSE

CMS concurred with two recommendations and did not concur with one recommendation in this report. Additionally, CMS provided details on its work to optimize the quality of life for residents in nursing homes by taking actions to reduce antipsychotic overuse.

In response to our first recommendation—for CMS to evaluate the use of psychotropic drugs among nursing home residents to determine whether additional action is needed to ensure that use among residents is appropriate—CMS agreed and stated it is evaluating the use of psychotropic drug use among residents in nursing homes. CMS's evaluation includes the analysis of schizophrenia diagnosis history and prescribing trends. CMS plans to determine what actions, if needed, are appropriate after the evaluation is concluded. We appreciate CMS's continued efforts and encourage CMS to safeguard nursing home residents from the overuse of any psychotropic drug.

In response to our second recommendation—for CMS to use data to identify nursing homes or nursing home characteristics that are associated with a higher use of psychotropic drugs and focus oversight on nursing homes in which trends may signal inappropriate use—CMS agreed and described actions taken in recent years to use data to analyze the use of psychotropics and other drugs that affect brain activity, such as anticonvulsants. These actions include changes to the survey process that specifically target inappropriate use of anticonvulsants, analysis of data to identify nursing homes with a higher rate of diagnosed schizophrenia among residents, and analysis of data to identify any trends or anomalies among nursing home residents, facilities, and prescriber levels. We encourage CMS to include a range of psychotropic drugs in its data analysis to ensure that trends do not shift from highly monitored psychotropic drugs to less monitored psychotropic drugs.

In response to our third recommendation—for CMS to expand the required data elements on Medicare Part D claims to include a diagnosis code—CMS did not concur. CMS stated that it lacks statutory authority to require that prescribers include diagnosis codes on prescriptions, noting that only States can directly mandate prescription requirements. CMS also raised concerns with requiring diagnosis codes on Part D claims. While CMS did not dispute having the authority to do this, it is concerned that without a State mandate that prescribers put the diagnosis code on the original claim, rejected Part D claims could lead to potential delays in receiving medications related to rejected claims. CMS finally stated this change would lead to more burden for prescribers, pharmacies, Part D sponsors, and pharmacy benefit managers. Additionally, CMS believes there are other ways to effectively monitor nursing home compliance. We continue to urge CMS to expand the required data

elements on Medicare Part D claims to include a diagnosis code, seeking statutory authority, as needed. We appreciate the need to maintain timely access to needed drugs for Part D enrollees and ask CMS to take steps to protect access and minimize burden in implementing such a requirement. Without diagnosis codes on Part D claims, CMS is limited to medical record reviews to determine whether drugs are prescribed for medically accepted indications, which are costly, time-consuming, and infeasible to conduct on a large scale. This information is a critical data element to monitor the use of psychotropic drugs in nursing homes. We continue to recommend that CMS work with its Part D sponsors and stakeholders in the medical and pharmaceutical professions to ensure that Part D drugs are only covered when used for medically accepted purposes.

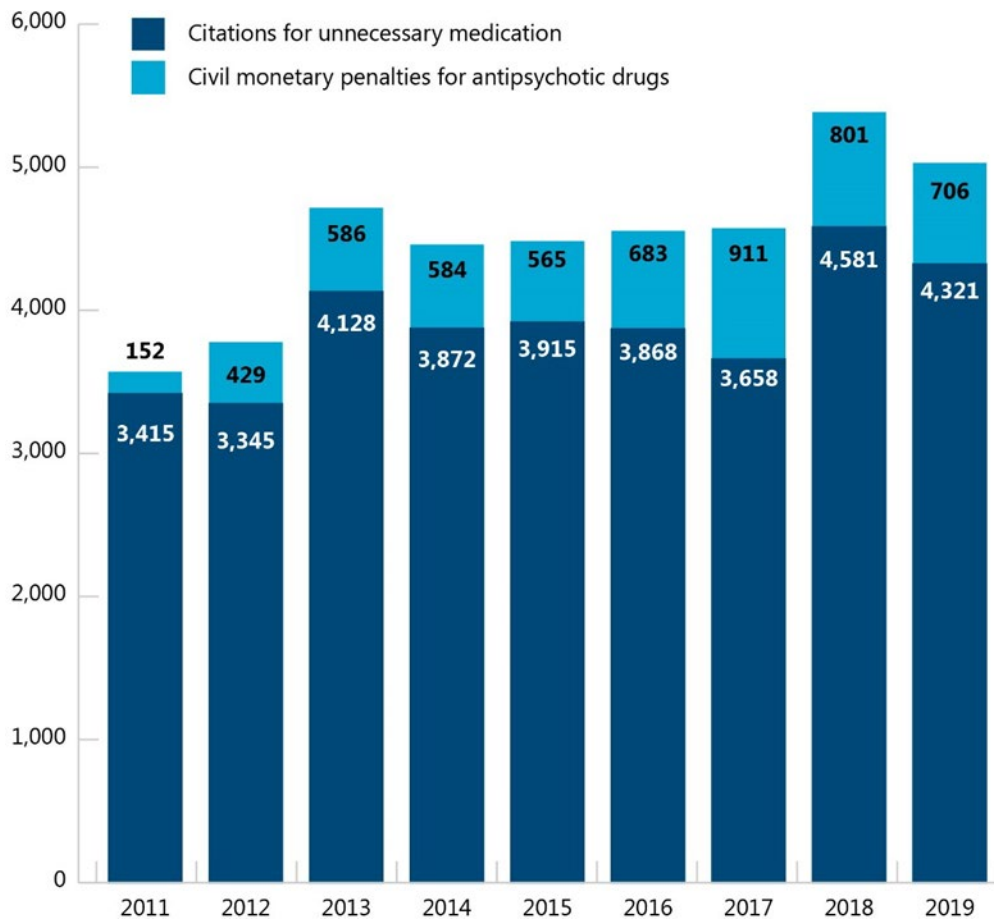
For the full text of CMS's comments, see Appendix C.

# APPENDICES

## Appendix A: CMS Enforcement Actions

CMS increasingly took enforcement actions against nursing homes from 2011 through 2019 for using unnecessary medications in nursing homes. The number of citations issued for the use of unnecessary medications increased from 3,415 citations in 2011 to 4,321 citations in 2019. Also, during this time CMPs issued by CMS to nursing homes for the use of antipsychotic drugs increased. In 2011, there were 152 CMPs issued to nursing homes and in 2019 there were 706 CMPs issued to nursing homes. The increase in citations for unnecessary medications and the increase in CMPs indicates that some nursing homes continued to use psychotropic drugs inappropriately.

**Exhibit 4: CMS enforcement actions related to psychotropic drug use in nursing homes from 2011 through 2019**



Source: OIG analysis of CMS data, 2022.

## Appendix B: Select CMS Regulatory Requirements

42 CFR  
§§483.21(a)(3),  
(b)(1)

**Care planning:** The facility must develop and implement a care plan for each resident that includes the instructions needed to provide effective and person-centered care of the resident. Each resident has the right to participate in choosing treatment options and must be given the opportunity to participate in the development, review, and revision of their care plan. The facility must provide the resident and their representative with a summary of the care plan that includes a summary of the resident's medications.

42 CFR  
§483.40(a)

**Sufficient and competent staffing:** Nursing homes are required to employ sufficient staff to provide care and services in assisting residents to attain or maintain their highest practicable level of physical, mental, and psycho-social well-being. Furthermore, each nursing home must ensure that it has sufficient staff members who possess the basic competencies and skill sets to meet the behavioral health needs of residents. These competencies and skills sets include, but are not limited to, caring for residents with mental and psycho-social disorders, and implementing non-pharmacological interventions.



## Appendix C: Agency Comments

Following this page are the official comments from CMS.



Administrator  
Washington, DC 20201

**Date:** October 11, 2022

**To:** Deputy Inspector General  
Office of Inspector General

**From:** Centers for Medicare & Medicaid Services *Chig B Lad*

**Subject:** Office of Inspector General Draft Report: Long-Term Trends of Psychotropic Drug Use in Nursing Homes (OEI-07-20-00500)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General (OIG) draft report.

CMS takes its role in improving the safety and quality of care in our nation's nursing homes seriously. As such, CMS is leading the Biden-Harris Administration's new efforts to increase accountability for nursing homes. The Administration has laid out 21 initiatives spread across five key strategic goals, including a goal to reinforce safeguards against unnecessary medications and treatments.<sup>1</sup> These initiatives were developed with extensive input from advocates, industry experts, nursing home workers, and – most importantly – residents and their loved ones.

Nursing homes must ensure that residents are free from unnecessary medications (42 CFR 483.45). Since CMS issued the Psychosocial Outcome Severity Guide in Appendix P of the State Operations Manual in 2006,<sup>2</sup> CMS has implemented a number of strategies to reduce the inappropriate use of psychotropic drugs in long-term care settings, as outlined below. Most recently, in June 2022, CMS revised its guidance addressing the inappropriate use of medications not defined as psychotropic drugs but other medications that affect brain activity and can have adverse consequences.<sup>3</sup>

The use of antipsychotic medications has decreased through the National Partnership to Improve Dementia Care in Nursing Homes (the National Partnership), which started in 2012 and is ongoing.<sup>4</sup> Through the National Partnership, CMS collaborates with federal and state agencies, nursing homes, other providers, advocacy groups, and care partners to optimize the quality of care and quality of life for residents in nursing homes by improving care for all residents, especially those with dementia, by reducing the use of antipsychotic medications and enhancing the use of non-pharmacologic approaches and person-centered dementia care practices. There have been notable reductions in the prevalence of antipsychotic medication use in long-stay nursing home residents since the launch of the National Partnership, as indicated by these quality

<sup>1</sup> The White House, [FACT SHEET: Protecting Seniors by Improving Safety and Quality of Care in the Nation's Nursing Homes, February 28, 2022.](#)

<sup>2</sup> CMS Memo S&C-06-09, Nursing Homes – Issuance of Revised Activities Guidance (Tags F248 and F249) as Part of Appendix PP, State Operations Manual, and Training Materials, March 10, 2006

<sup>3</sup> CMS Memo QSO-22-19-NH, [Revised Long-Term Care Surveyor Guidance: Revisions to Surveyor Guidance for Phases 2 & 3, Arbitration Agreement Requirements, Investing Complaints & Facility Reported Incidents, and the Psychosocial Outcome Severity Guide](#), June 29, 2022

<sup>4</sup> CMS Press Release, [CMS Announces Partnership to Improve Dementia Care in Nursing Homes](#), May 30, 2012

measures. Between 2011 and the fourth quarter of 2021, the national prevalence of antipsychotic medication use among long-stay nursing home residents was reduced by 39.1 percent to 14.5 percent nationwide. Success has varied by state and CMS regions, with some states and regions having seen a reduction of greater than 45 percent. While we have seen progress in reducing the prevalence of antipsychotic drug use in nursing homes, CMS and its partners continue to use a variety of interventions to continue these efforts, such as review of stakeholder feedback on the agency's guidance and trends in enforcement; public data reporting; and technical assistance through Quality Improvement Organizations (QIOs) or other quality improvement partners. CMS and its partners will also continue to promote research on improving systems of care in nursing homes, use of individualized and person-centered approaches to care for people with dementia, and inclusion of innovative programs such as telepsychiatry for rural nursing homes.

CMS also shares management of nursing home oversight with State Survey Agencies (SSAs), which conduct onsite surveys to assess compliance with federal requirements and investigate facility complaints. SSAs serve as the front-line responders to address health and safety concerns raised by residents, their families, and facility staff. Psychotropic and other medication use is reviewed on every standard survey and surveys conducted in response to complaints, as appropriate. As with all medications, the indication for any prescribed psychotropic 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 the implementation of person-centered, non-pharmacological approaches to care and consideration of the 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 that 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 antipsychotic drugs, and that are determined in a current survey to be out of substantial compliance with those requirements. CMS and the SSAs continue 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.

Additionally, 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 Quality Rating System. While Care Compare helps consumers, their families, and caregivers compare nursing homes more easily, it also makes public information on antipsychotic use in nursing

homes, which can have a sentinel effect in reducing the unnecessary usage of such medications and provide additional transparency around antipsychotic use.

Separate from the Five-Star Quality Rating System, CMS also uses quality measures to track trends in utilization across the Medicare prescription drug benefit program using Part D claims found in Prescription Drug Event (PDE) data. 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 *APD - for Long-Term Nursing Home Residents*. CMS has provided monthly measure reports to Part D sponsors on the overall APD measure as well as the APD measure specific to the long-term nursing home setting. In addition to PDE and MDS data, the Part D measures are calculated using data from the Common Medicare Environment for enrollment information, Risk Adjustment Processing System data, the Encounter Data Systems, and the Common Working File for diagnoses. Through these reports, CMS has communicated with Part D plan sponsors about their performance on these APD quality measures, including sharing information about specific beneficiaries. Part D plan sponsors who are outliers on each APD measure are encouraged to report to CMS on their plan to reduce inappropriate use.

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.<sup>5</sup> 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: ten percent among Medicare Advantage Prescription Drug Plan contracts and nine percent among stand-alone Prescription Drug Plan contracts.<sup>6</sup>

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 has a national focus related to plan oversight pertaining to the following Part C and Part D program integrity initiatives: identification of program vulnerabilities, data analysis, health plan audits, outreach, education, and law enforcement support, which includes requests for information.<sup>7</sup> CMS has directed the PPI MEDIC to use proactive data analysis in Part D 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.<sup>8</sup> 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 exist.<sup>9</sup>

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<sup>5</sup> 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>.

<sup>6</sup> See Part C and D Performance Data, 2021 Display Measures (ZIP), available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData>.

<sup>7</sup> U.S. Department of Justice & U.S. Department of Health and Human Services, [Health Care Fraud and Abuse Control Program, Annual Report for Fiscal Year 2021](#)

<sup>8</sup> CMS Memo to All Medicare Part D Plan Sponsors, Drug Alert: Nuedexta® - Potential Inappropriate Part D Billing for Non-Medically Accepted Indications

<sup>9</sup> CMS Memo to All Medicare Part D Plan Sponsors, Drug Alert: Nuedexta® - Effect of Prior Authorizations (PA) on Potential Inappropriate Part D Billing for Non-Medically Accepted Indications, August 28, 2019

Through all of these efforts, CMS has worked diligently to optimize the quality of life for residents in 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 that 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**

Evaluate the use of psychotropic drugs among nursing home residents to determine whether additional action is needed to ensure that use among residents is appropriate

### **CMS Response**

CMS concurs with this recommendation. CMS is currently evaluating the use of psychotropic drug use among residents in nursing homes by analyzing schizophrenia diagnosis history and prescribing trends. After the evaluation is concluded, CMS will determine what actions, if needed, are appropriate.

### **OIG Recommendation**

Use data to identify nursing homes or nursing home characteristics that are associated with a higher use of psychotropic drugs and focus oversight on nursing homes in which trends may signal inappropriate use

### **CMS Response**

CMS concurs with this recommendation. CMS is using data to analyze the use of psychotropics and other drugs that affect brain activity, such as anticonvulsants. As stated above, in June 2022, CMS released changes to the survey process and guidance that specifically target inappropriate use of anticonvulsants. At this time, CMS has reviewed and is actively analyzing data to identify nursing homes with a higher rate of diagnosed schizophrenia amongst residents admitted between January 2020 and June 2021 with a new claim of schizophrenia within the last five years. CMS is also reviewing data to identify any possible trends or anomalies among nursing home residents, facilities, and prescriber levels<sup>10</sup>.

### **OIG Recommendation**

Expand the required data elements on Medicare Part D claims to include a diagnosis code

### **CMS Response**

CMS cannot concur with this recommendation. CMS lacks the statutory authority to require that prescribers include diagnosis codes on prescriptions. State laws govern what is required to be included on prescriptions. Additionally, even if CMS had this authority, we would be concerned that requiring diagnosis codes on Part D claims in the absence of state requirements for prescribers to include diagnosis codes on prescriptions could lead to significant access concerns due to potential delays in receiving medications related to rejected claims. This would also lead to more prescriber, pharmacy, Part D sponsor, and pharmacy benefit manager burden to adjudicate CMS-rejected claims because they lack diagnosis codes. Nevertheless, CMS believes there are other ways to effectively monitor nursing home compliance for this vulnerable population, which we are in the process of evaluating, as described above.

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<sup>10</sup> CMS Fact Sheet, [CMS releases prescriber-level Medicare data for first time](#), April 30, 2015

# ACKNOWLEDGMENTS AND CONTACT

## Acknowledgments

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This report was prepared under the direction of Brian Whitley, Regional Inspector General for Evaluation and Inspections in the Kansas City regional office, and Dana Squires and Abbi Warmker, Deputy Regional Inspectors General.

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To obtain additional information concerning this report, contact the Office of Public Affairs at [Public.Affairs@oig.hhs.gov](mailto:Public.Affairs@oig.hhs.gov). OIG reports and other information can be found on the OIG website at [oig.hhs.gov](http://oig.hhs.gov).

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# ENDNOTES

<sup>1</sup> Social Security Act § 1819(b); 42 CFR § Part 483 Subpart B.

<sup>2</sup> 42 CFR § 483.45.

<sup>3</sup> Office of Senator Chuck Grassley, news release, “Congressional Policy Leaders Seek Review Of Psychotropic Prescription Use In Nursing Homes,” April 7, 2020. Accessed at <https://www.grassley.senate.gov/news/news-releases/congressional-policy-leaders-look-for-review-of-psychotropic-prescription-use-in-nursing-homes> on October 25, 2022.

<sup>4</sup> The White House, Office of the Press Secretary, “Fact Sheet: Protecting Seniors by Improving Safety and Quality of Care in the Nation’s Nursing Homes,” February, 2022. Accessed at <https://www.whitehouse.gov/briefing-room/statements-releases/2022/02/28/fact-sheet-protecting-seniors-and-people-with-disabilities-by-improving-safety-and-quality-of-care-in-the-nations-nursing-homes/> on August 16, 2022.

<sup>5</sup> 42 CFR § 483.45(c)(3). CMS, State Operations Manual, “Appendix PP—Guidance to Surveyors for Long Term Care Facilities,” November 2017. Accessed at [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_pp\\_guidelines\\_ltcf.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf) on March 6, 2019.

<sup>6</sup> Medicaid and CHIP Payment and Access Commission, “Use of Psychotropic Medication among Medicaid Beneficiaries,” p. 146, June 2015. Accessed at <https://www.macpac.gov/wp-content/uploads/2015/06/Use-of-Psychotropic-Medications-among-Medicaid-Beneficiaries.pdf> on May 19, 2022.

<sup>7</sup> Marco Mula, “Psychotropic Effects of Anticonvulsants in Patients with Epilepsy,” *Clinical Medicine Insights*, No. 2, 2010, p 286. Accessed at <https://journals.sagepub.com/doi/pdf/10.4137/CMT.S3285> on May 19, 2022.

<sup>8</sup> CMS, State Operations Manual, “Appendix PP—Guidance to Surveyors for Long Term Care Facilities,” November 2017. Accessed at [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_pp\\_guidelines\\_ltcf.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf) on March 6, 2019.

<sup>9</sup> CMS guidance related to psychotropic and antipsychotic medication regulations states that the use of other psychotropic medications should not increase when efforts to decrease antipsychotic medications are being implemented unless the other types of psychotropic medications are clinically indicated. CMS further states that medications that may affect brain activity (including anticonvulsants and mood stabilizers) must be prescribed with a documented clinical indication. CMS, State Operations Manual, “Appendix PP—Guidance to Surveyors for Long Term Care Facilities,” November 2017. Accessed at [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_pp\\_guidelines\\_ltcf.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf) on July 2022.

<sup>10</sup> CMS published guidance effective October 2022 relating to medications that affect brain activity but are not specifically listed as psychotropic medications by CMS. The guidance notes that these medications that affect brain activity are subject to the psychotropic medication requirements if the documented use appears to be a substitution for another psychotropic medication rather than for the original or approved indication. See CMS, memorandum, addressed to State Survey Agency Directors, QSO 22-19-NH, June 2022. Accessed at <https://www.cms.gov/files/document/qso-22-19-nh.pdf-0> on July 20, 2022.

<sup>11</sup> For consistency with other OIG reports, we used First DataBank’s ETC code and identified 19 categories of drugs that met CMS’s description of psychotropic drugs (i.e., any drug that affects brain activities associated with mental processes and behavior). This report uses the following 19 categories to identify Medicare Part D drug claims that represent psychotropic drugs: antianxiety agents; antidepressants; antipsychotics (neuroleptics); bipolar therapy agents; sedative-hypnotics; central nervous system stimulants; migraine therapy; anticonvulsants; antiparkinsonian therapy; movement disorder drug therapy; attention deficit hyperactive disorder therapy; narcolepsy and cataplexy therapy agents; fibromyalgia agents; pseudobulbar affect agents; psychoactive drugs—alternative therapy/recreational use; hypoactive sexual desire disorder treatment agents; benzodiazepines; neuropathic pain therapy; and agents to treat episodic cluster headaches.



- <sup>12</sup> CMS, State Operations Manual, "Appendix PP—Guidance to Surveyors for Long Term Care Facilities," p. 518, November 2017. Accessed at [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_pp\\_guidelines\\_ltcf.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf) on March 6, 2019.
- <sup>13</sup> Anticonvulsants are approved by the FDA to treat seizures and many other medical conditions unrelated to seizure disorders, such as nerve pain. Accessed at <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Pharmacy-Education-Materials/Downloads/ac-adult-factsheet11-14.pdf> on July 11, 2022.
- <sup>14</sup> Boxed warnings are the strictest warnings that can be issued by the FDA. FDA notified health care professionals in 2008 that both conventional and atypical antipsychotics were found to be associated with an increased risk of mortality in elderly patients treated for dementia-related psychosis. At that time, the analyses of 17 placebo-controlled trials that enrolled 5,377 elderly patients with dementia-related behavioral disorders revealed a risk of death among antipsychotic drug-treated patients of between 1.6 and 1.7 times that seen among placebo-treated patients. FDA, "Information for Healthcare Professionals: Conventional Antipsychotics," June 2008. Accessed at <https://wayback.archive-it.org/7993/20170722190727/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124830.htm> on October 26, 2021.
- <sup>15</sup> CMS, "Anticonvulsant Medications: Use in Adults," p. 5, October 2015. Accessed at <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Pharmacy-Education-Materials/Downloads/ac-adult-factsheet11-14.pdf> on March 16, 2022.
- <sup>16</sup> Sheng-Min Wang, Han Changsu, et. al, "Addressing the Side Effects of Contemporary Antidepressant Drugs: A Comprehensive Review," Chonnam Medical Journal, 2018. Accessed at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5972123/pdf/cmj-54-101.pdf> on March 16, 2022.
- <sup>17</sup> CMS, National Partnership to Improve Dementia Care in Nursing Homes. Accessed at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/National-Partnership-to-Improve-Dementia-Care-in-Nursing-Homes?msclkid=8d1644beab7611ecaa3e6f99441aa1d2> on March 28, 2022.
- <sup>18</sup> 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.
- <sup>19</sup> 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 on <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SC-Letter-14-19-Partnership-Interim-Report.pdf> on May 1, 2019.
- <sup>20</sup> Medicaid and CHIP Payment and Access Commission, "Nursing facilities" explains that "States have broad flexibility to determine payments to nursing facilities. Federal rules do not prescribe how nursing facilities should be paid or how much they should be paid, but require that Medicaid payment policies should promote efficiency, economy, quality, access, and safeguard against unnecessary utilization. Under fee-for-service payment arrangements, State Medicaid programs typically pay nursing facilities a daily rate, called a per diem. States often apply a variety of adjustments and incentives to the base payment, and there is considerable variation in rates both within and across States." Accessed at <https://www.macpac.gov/subtopic/nursing-facilities/> on May 1, 2021.
- <sup>21</sup> CMS, memorandum to State Survey Agency Directors S&C: 14-22-NH, "Focused Minimum Data Set (MDS) and Dementia Care Surveys," April 2014. Accessed at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SC-Letter-14-22-Focused-Survey-Pilot.pdf> on July 14, 2022.
- <sup>22</sup> CMS, memorandum to State Survey Agency Directors S&C: QSO-19-07-NH, "Enhanced Oversight and Enforcement of Non-Improving Late Adopters," May 2019. Accessed at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO19-07-NH.pdf> on July 14, 2022.

- <sup>23</sup> CMS has an additional antipsychotic quality measure for short-stay nursing home residents: Percent of Short-Stay Residents Who Newly Received an Antipsychotic Medication. Quality measures can be found at CMS, MDS 3.0 Quality Measures User's Manual. Accessed at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/MDS-30-QM-Users-Manual-V70.pdf> on October 26, 2021.
- <sup>24</sup> CMS, 2016/2017 Nursing Home Action Plan. Accessed at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Downloads/2016-2017-Nursing-Home-Action-Plan.pdf> on October 26, 2021.
- <sup>25</sup> Social Security Act §§ 1819(b)(3)(A)(ii) and (f)(6)(A). 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%20october%202019.pdf> on September 21, 2020.
- <sup>26</sup> 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," May 2015. 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.
- <sup>27</sup> The MDS contains federally mandated self-reports from nursing homes to quantify percentages for the long-stay antipsychotic quality measure. The MDS includes information about whether a resident received any of four categories of psychotropic medications (i.e., antipsychotics, antidepressants, antianxiety medications, and hypnotics).
- <sup>28</sup> Social Security Act §§ 1819(f), (g) and 1919(f), (g). See also CMS, State Operations Manual, "Program Background and Responsibilities," Section 1002. Accessed at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c01pdf.pdf> on December 4, 2020.
- <sup>29</sup> Nursing home surveys are conducted according to survey protocols and Federal requirements to determine whether a citation of noncompliance is appropriate. The survey protocols and interpretive guidelines serve to clarify and/or explain the intent of the regulations. All surveyors are required to use them in assessing compliance with Federal requirements. CMS publishes Critical Element Pathways to guide surveyors as their deficiency assessments of nursing homes are based on violations of the regulations. The survey is based on observations of a nursing home's performance or practices. The Critical Element Pathway for Unnecessary Medications, Psychotropic Medications, and Medication Regimen Review requires surveyors to also assess a nursing home's compliance with each of the regulatory requirements associated with medication management.
- <sup>30</sup> 42 CFR § 483.40 (a). Accessed at <https://www.law.cornell.edu/cfr/text/42/483.40>.
- <sup>31</sup> CMS, State Operations Manual, "Appendix PP—Guidance to Surveyors for Long Term Care Facilities," November 2017. Accessed at [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_pp\\_guidelines\\_ltcf.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf) on March 6, 2019.
- <sup>32</sup> CMS, State Operations Manual, "Appendix PP—Guidance to Surveyors for Long Term Care Facilities," November 2017. Accessed at [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_pp\\_guidelines\\_ltcf.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf) on March 6, 2019.
- <sup>33</sup> CMS, memorandum QSO-18-17-NH. Accessed at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-17-NH.pdf> on April 8, 2021.
- <sup>34</sup> CMS, Medicare Benefit Policy Manual and Prescription Drug Benefit Manual, Chap. 6. Section 1860D-2(e)(4) of the Social Security Act defines a "medically-accepted indication" for a Part D drug by referencing section 1927(k)(6) of the Social Security Act as "any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in compendia as described in 1927(g)(1)(B)(i) of the Act." Furthermore, Ch. 6 § 10.6 of the Medicare Prescription Drug Benefit Manual defines a Part D-covered drug as a drug that may be dispensed only upon a prescription and for a medically accepted indication. Accessed at <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf> on July 9, 2022.

- <sup>35</sup> OIG, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents*, May 2011. Accessed at <https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf> on August 15, 2019.
- <sup>36</sup> OIG, *Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs*, July 2012. Accessed at <https://oig.hhs.gov/oei/reports/oei-07-08-00151.asp> on April 9, 2021.
- <sup>37</sup> OIG, *Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs*, July 2012. Accessed at <https://oig.hhs.gov/oei/reports/oei-07-08-00151.asp> on April 9, 2021.
- <sup>38</sup> CMS, State Operations Manual, “Appendix PP—Guidance to Surveyors for Long Term Care Facilities,” November 2017. Accessed at [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_pp\\_guidelines\\_ltcf.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf) on March 6, 2019.
- <sup>39</sup> OIG, *Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries*, February 2014. Accessed at <http://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf> on December 30, 2020.
- <sup>40</sup> The tool referenced can be found at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/downloads/adverse-drug-event-trigger-tool.pdf>. Accessed on October 13, 2022.
- <sup>41</sup> OIG, *CMS Use of Data on Nursing Home Staffing: Progress and Opportunities To Do More*, March 2021. Accessed at <https://oig.hhs.gov/oei/reports/OEI-04-18-00451.asp> on April 20, 2021. See also HHS OIG Data Brief, *Some Nursing Homes’ Reported Staffing Levels in 2018 Raise Concerns; Consumer Transparency Could Be Increased*, August 2020. Accessed at <https://oig.hhs.gov/oei/reports/OEI-04-18-00450.pdf> on April 20, 2021.
- <sup>42</sup> CMS, memorandum QSO-18-17-NH. Accessed at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/QSO18-17-NH.pdf> on June 15, 2021. Additionally, CMS, Staffing Data Submission Payroll Based Journal (PBJ) informs nursing homes that staffing is “one of the vital components of a nursing home’s ability to provide quality care.” Accessed at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Staffing-Data-Submission-PBJ> on June 15, 2021.
- <sup>43</sup> OIG, *CMS Could Improve the Data It Uses To Monitor Antipsychotic Drugs in Nursing Homes*, May 2021. Accessed at <https://oig.hhs.gov/oei/reports/OEI-07-19-00490.pdf> on October 26, 2021.
- <sup>44</sup> One initiative includes awarding a grant to The University of Arizona, Department of Pharmacy Practice and Science to demonstrate the impact of including diagnostic information on electronic prescriptions.
- <sup>45</sup> For the RN staffing analysis, we included all residents. However, only nursing homes that had matching nurse staffing data from PBJ and nursing homes with at least one long-stay resident were included.
- <sup>46</sup> For the Part D low-income subsidy analysis, we analyzed only long-stay residents and included nursing homes with 10 or more long-stay residents.
- <sup>47</sup> CMS, State Operations Manual, “Appendix PP—Guidance to Surveyors for Long Term Care Facilities,” November 2017. Accessed at [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_pp\\_guidelines\\_ltcf.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf) on July 22, 2021.
- <sup>48</sup> Schizophrenia is typically diagnosed in the late teen years to early thirties and tends to emerge earlier in males (late adolescence to early twenties) than females (early twenties to early thirties). National Institute of Mental Health, *Schizophrenia*, May 2022. Accessed at <https://www.nimh.nih.gov/health/statistics/schizophrenia> on May 2, 2022.
- <sup>49</sup> For this analysis, we included beneficiaries who were aged 65 or older. We only analyzed nursing homes with 10 or more long-stay residents in 2019. Of all the nursing homes that met this criteria, 71 percent were classified as for-profit.