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Nursing Homes' Inappropriate Use of Antipsychotic Drugs Poses a Risk to Residents

HHS Office of Inspector General
HIGHLIGHTS

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Why OIG Did This Review

- Antipsychotic drugs present a risk to nursing home residents, particularly those with dementia. These drugs are not approved to treat dementia, and the Food and Drug Administration (FDA) has warned that they may increase the risk of death for these individuals.
- The inappropriate use of antipsychotic drugs in nursing homes has been a longstanding concern for Congress and others.[1] The drugs can have a sedative effect, raising concerns that nursing homes may use them to control residents' behavior.
- This is the first of a two-part series addressing inappropriate use of antipsychotic drugs in nursing homes.

What OIG Found

OIG's comprehensive review of 40 focused nursing home inspections completed by CMS found alarming instances of inappropriate use of antipsychotic drugs and revealed vulnerabilities in care that have implications for the wider nursing home population beyond these examples. Our review found:

- Nursing homes **gave antipsychotic drugs to residents with dementia** to manage their behavior for the benefit of staff, despite FDA's warning that these drugs may increase the risk of death.
- Even though antipsychotic drugs pose risks to residents' health, nursing homes **did not take required steps** to help protect residents who were given these drugs.
- **Medical directors failed to prevent** inappropriate use of antipsychotic drugs.
- **Nursing home pharmacists failed to identify** medical concerns and did not recommend dose reductions.
- Inadequate nursing home **policies and procedures undermined safeguards** meant to protect residents.

What OIG Recommends

OIG recommends that CMS:

1. Further **develop resources for nursing homes and increase transparency** in order to reduce inappropriate use of antipsychotic drugs and improve dementia care in nursing homes.
2. Take steps to **ensure that nursing home medical directors fulfill their role** in reducing the inappropriate use of antipsychotic drugs.
3. Take steps to **ensure that nursing home pharmacists fulfill their role** in reducing the inappropriate use of antipsychotic drugs.
4. Assist nursing homes to **improve their policies and procedures** pertaining to antipsychotic drug use.

CMS did not explicitly concur or nonconcur with our first and fourth recommendations. CMS nonconcurred with our second and third recommendations. We added clarification to these recommendations based on CMS's comments to the draft and encourage CMS to re-examine its position on concurrence in its Final Management Decision.

Primer on: **Use of Antipsychotic Drugs in Nursing Homes**

The Food and Drug Administration (FDA) **has not approved the use** of antipsychotic drugs to treat dementia. Antipsychotic drugs are used to treat symptoms of psychiatric disorders such as schizophrenia.

In fact, the agency imposed its most serious warning—a **boxed warning**, also known as a black box warning—on the use of antipsychotic drugs by elderly patients **with dementia**.[2] These patients face **an increased risk of death** when treated with these drugs.

Moreover, these drugs can have a sedative effect, raising concerns that they could be used to control behavior.[3]

CMS has placed restrictions on drugs—including antipsychotic drugs—used in nursing homes that participate in Medicare and Medicaid. These requirements include:

- Residents must be **free from chemical restraints** imposed for the purposes of staff convenience instead of treating the residents' medical symptoms.[4]
- Residents must be **free from unnecessary drugs**, such as those used in **excessive dose**, for **excessive duration**, **without adequate monitoring**, or **without adequate clinical indications** for their use.[5]
- Nursing homes must have a documented **clinical rationale** for administering a medication that is based upon an assessment of the resident's condition and is consistent with, among other things, manufacturer's recommendations or clinical practice guidelines, such as the American Psychiatric Association (APA) practice guidelines.[6]
- Residents who are prescribed antipsychotic drugs **must receive gradual dose reductions** and **non-drug interventions** (unless clinically contraindicated) in an effort to discontinue these drugs.[7]
- Residents' **medication regimens** must be **reviewed at least monthly by a pharmacist**, who **identifies irregularities** and makes **recommendations** to the resident's physician. The physician must act on the recommendation or, if they disagree, provide a rationale.[8]

The APA has concluded that there is little benefit to using antipsychotic drugs to treat patients with dementia.[9] It outlines only **narrow circumstances** for such use: when symptoms are **severe, are dangerous, and/or cause significant distress to the patient**. The APA also states that if these drugs are prescribed, it should only be after first-line non-drug interventions have been attempted and at the lowest dose on a short-term basis.[10]

OIG has a **substantial body of work** raising concerns about the use of antipsychotic drugs in nursing homes. Notably, a 2011 OIG report found that the vast majority of these drugs were being prescribed to residents with dementia.[11] Another OIG report found that more than one in five residents were prescribed these drugs in 2019.[12] CMS has also identified antipsychotic drug use in nursing homes as a concern and taken some important steps to address it.[13]

FINDINGS

This issue brief builds on OIG's extensive oversight work related to antipsychotic drugs and provides an in-depth account of practices inside nursing homes. Prior OIG work found that more than one in five residents were given antipsychotic drugs.[14] This issue brief gives a deeper understanding of practices and experiences within nursing homes. Its findings and recommendations can be used to improve resident care and safety and reduce inappropriate use of antipsychotic drugs in nursing homes.

We based this issue brief on an analysis of a purposive sample of onsite inspection reports—known as surveys—that were completed by CMS and focused on antipsychotic drug use in nursing homes. These sampled surveys looked at 40 nursing homes across the country and assessed whether the nursing homes met requirements related to antipsychotic drugs. The surveys are based on surveyors' direct observations; record reviews; and interviews with staff, residents, and family members. Surveys are a critical oversight tool for CMS; they also provide comprehensive accounts of antipsychotic drug use in nursing homes and its effect on residents.

The findings in this issue brief provide an in-depth look into practices in nursing homes that put residents at risk. The examples featured do not represent all nursing homes. However, they reveal vulnerabilities in nursing home care that have implications for the wider nursing home population and must be addressed to improve care and better protect residents.

This issue brief is the first in a two-part series. The companion report addresses nursing homes inappropriately diagnosing residents with schizophrenia to mask the misuse of antipsychotic drugs.[15]

Nursing homes gave antipsychotic drugs to residents with dementia to manage their behavior for the benefit of staff, despite FDA's warning that these drugs may increase the risk of death

Medicare requires that medications, such as antipsychotic drugs, be given to treat residents' medical symptoms and not for staff convenience.[16] FDA has issued its most serious warning against these drugs to treat elderly individuals with dementia, citing that they may increase the risk of death.[17] Despite this, some nursing homes gave antipsychotic drugs to residents with dementia to manage behaviors that posed no risk to themselves or others.[18] Justifications for giving these drugs included quieting a resident for innocuous behaviors, such as signaling a need to use the

bathroom. Some nursing home staff admitted that these drugs were given to help staff, with one nursing home psychiatrist telling a surveyor outright that "[the] medications are more [for the] benefit of [the] staff."

Nursing homes used antipsychotic drugs to limit behaviors that posed little to no risk to residents

At times, residents with dementia received antipsychotic drugs for exhibiting behaviors that the nursing homes themselves acknowledged were not dangerous or distressing to the resident. These drugs were used to address harmless behaviors such as repeatedly asking for help or trying to calm themselves. See text box below for a case in which calming behavior was used as justification for giving a resident antipsychotic drugs.

A nursing home gave antipsychotic drugs to a woman because she carried and cared for baby dolls.

- A nursing home in Pennsylvania gave antipsychotic drugs to an elderly woman who carried dolls and happily spoke about her "babies." She was more than a hundred years old and found comfort in caring for the dolls. The woman was prescribed an antipsychotic drug for this behavior. The nursing home's psychiatrist acknowledged that holding a baby doll was not a delusion that would justify the use of an antipsychotic drug.

Surveyors sometimes determined that the nursing home's use of antipsychotic drugs amounted to a chemical restraint. That is, the nursing home administered a medication that has a sedating effect, and the medication was not given to treat a medical symptom.[19] Medicare requirements state that residents must be free from chemical restraints imposed for the purposes of staff convenience that are not required to treat the residents' medical symptoms.[20] The text box below describes cases in which a nursing home was cited for using chemical restraints.

A nursing home in Virginia used antipsychotic drugs as a chemical restraint to subdue residents who were trying to communicate discomfort or an unmet need.

- A nursing home used antipsychotic drugs to restrain a woman with dementia. Her family noted that she would get upset and make noise at night when there were long delays in answering her call light. The nursing home named nighttime yelling as the reason for giving the woman antipsychotic drugs. In accordance with CMS guidelines, this nursing home was cited for using a chemical restraint.
- In another case, the same nursing home admitted to using a chemical restraint when it gave an antipsychotic drug to a resident who wanted to stay in bed. This resident was regularly forced to go into his wheelchair, and then would try to get back into bed. According to the nursing home, the antipsychotic drug was used to "calm him down."

Nursing homes turned directly to antipsychotic drugs to address behaviors without trying non-drug interventions or addressing possible illness

Medicare requires that nursing homes attempt non-drug interventions, unless contraindicated, before prescribing antipsychotic drugs.[21] Similarly, the American Psychiatric Association calls for non-drug interventions to be attempted first.[22] These interventions are approaches to care that do not involve medications and are used to, among other things, stabilize or improve a resident's mental, physical, and psychosocial well-being.[23]

> **The first approach is always medication…Medication is fastest and easiest.**
>
> – Director of Nursing, explaining how non-drug approaches take more work than giving drugs

However, nursing homes turned to antipsychotic drugs to address behaviors associated with dementia diagnoses without first attempting non-drug interventions. Staff acknowledged that non-drug approaches were more challenging and time-consuming than requesting an antipsychotic drug from a resident's physician. The text box below describes instances in which a nursing home continued to rely on antipsychotic drugs even when it had identified effective non-drug interventions.

A nursing home used antipsychotic drugs in lieu of non-drug approaches that were found effective.

- One nursing home considered a 102-year-old resident as "combative to care" when her brief was being changed. Yet, a nurse who cared for the resident found that simply explaining what was happening to the woman calmed her down and made her cooperative. The nursing staff believed that explaining worked best, adding "I think they started the [an antipsychotic drug] to control her behavior but it doesn't really work."
- Another resident did not like being sprayed by the shower nozzle while being bathed and was much calmer when staff used a cup to pour water on her. This woman was given antipsychotic drugs to manage behaviors, some prompted by shower spraying. The effective and simple non-drug solution of using a cup was not included in the woman's care plan.

CMS instructs nursing homes that decisions about interventions should be guided by key steps, which include evaluating and understanding the origin of the behavior; addressing any underlying environmental stressors; and ruling out underlying physical illness or needs.[24]

> **The staff do not have the man power to deal with behaviors […] He would do fine without the medication.**
>
> – A psychiatrist talking about a resident with dementia receiving monthly antipsychotic drug injections

However, nursing homes used antipsychotic drugs to control behaviors that may have been caused by treatable illnesses. See text box below for instances in which illnesses were discovered and resolved, but the use of antipsychotic drugs did not change.

Nursing homes used antipsychotic drugs to solve problems that were likely caused by treatable illnesses.

- At one nursing home, a psychologist noted that a resident with dementia seemed a little more agitated. In response, the attending physician increased the resident's dosage of antipsychotic drugs. It was then discovered that the man had pneumonia. After treatment in a hospital, he returned to the nursing home much improved, even singing. However, the higher dosage of the antipsychotic drug was not re-evaluated upon his return.
- At another nursing home, a resident was prescribed an antipsychotic drug when she had a urinary tract infection, which can cause delirium. Although the nursing home knew an infection was diagnosed, the nursing home did not re-evaluate or discontinue the antipsychotic drug.

Without a clinical rationale, nursing homes extended the use of antipsychotic drugs to keep residents cooperative

Nursing homes must have a clinical rationale for giving antipsychotic drugs.[25] Medicare also requires that nursing homes document the rationale, which must be based on an assessment of the resident's condition and consistent with manufacturer's recommendations or clinical practice guidelines.[26] Yet, some nursing homes continued to give antipsychotic drugs to residents with dementia to keep them cooperative, without a clinical rationale. Some of these residents were lethargic or sleeping most of the day. In other cases, nursing homes did not evaluate the need for antipsychotic drugs if a resident arrived at the home already taking them, resulting in residents staying on these drugs for prolonged periods. See text box for cases in which nursing homes continued to give antipsychotic drugs to residents without a clinical rationale.

> **He's been 'hanging out' on [an antipsychotic drug] for no good reason.**
>
> – A psychiatrist about a resident with dementia

Some nursing homes gave calm residents antipsychotic drugs.

- Staff at one nursing home in New York described a resident as "never aggressive," yet gave him antipsychotic drugs. This resident was quiet, had no behavioral symptoms directed toward others, did not disrupt his living environment, and stayed in his room. The nursing home could provide no reason why he was given antipsychotic drugs.
- Multiple nurses at a nursing home in Louisiana acknowledged that they gave an 88-year-old resident a second dose of an antipsychotic drug nearly every night before bed. They did so without assessing the resident's behaviors, even though they had been instructed by the resident's physician to give an additional dose only if needed. One nurse admitted that they gave the additional dose because they wanted to "keep it smooth sailing." Resident records revealed no evidence of disruptive behaviors.

Even though antipsychotic drugs pose risks to residents' health, nursing homes did not take required steps to help protect residents who were given these drugs

Medicare requires nursing homes to take several steps when they give antipsychotic drugs to residents. Nursing homes must monitor residents for potential side effects and adverse consequences of antipsychotic drugs, as well as monitor resident behaviors to assess the medication's effectiveness.[27] In addition, nursing homes must administer antipsychotic drugs at the lowest possible dosage for the shortest period of time.[28] They are required to periodically assess the continued necessity of the dose, and attempt to taper or gradually reduce the dose of antipsychotic medications unless that is clinically contraindicated.[29] These requirements are meant to keep residents safe; however, some nursing homes did not meet these requirements when giving antipsychotic drugs to residents.

Nursing homes did not monitor residents with dementia for side effects of antipsychotic drugs even though these residents were at an increased risk of death

Some nursing homes did not effectively monitor side effects of the antipsychotic drugs they were giving residents, as required. The text box below describes cases in which nursing homes' failure to monitor residents could have had severe consequences.

Nursing homes' lack of attention put residents at risk for dangerous drug interactions and side effects.

- Staff at a nursing home in Ohio failed to take appropriate action after getting an alert about a potentially severe drug-to-drug interaction involving the antipsychotic drug the nursing home was giving a resident with dementia. The antipsychotic drug could have interacted with an antibiotic he was taking, which could have resulted in a heart rhythm disorder. This is especially concerning given that the resident was admitted to the nursing home with a slow heart rate.
- At a nursing home in California, staff failed to monitor blood pressure for two residents with dementia who were receiving antipsychotic drugs. A physician ordered weekly monitoring over concerns that these drugs could induce orthostatic hypertension, but the nursing home did not monitor the residents' blood pressures for several months.

Previous OIG work found that preventable, medication-related adverse consequences are a serious concern in nursing homes.[30] An OIG report showed that almost 40 percent of adverse events in nursing homes (i.e., when a resident experiences harm during a skilled stay) were related to medications and 66 percent of all medication-related events were preventable.[31]

Nursing homes failed to ensure that residents were receiving the lowest possible dose of antipsychotic drugs

Some nursing homes failed to take steps to ensure that residents were receiving the lowest possible dose of antipsychotics. In fact, in some situations, physicians appeared to be unaware of their residents' current doses or why the drug was being administered. Residents continued to receive the same amount of antipsychotic drugs without any attempt to decrease the dose, such as in the case below.

A nursing home continued for many months dosages that may have been unnecessarily high.

- A nursing home continued to give an 84-year-old resident the same dose of an antipsychotic drug for 2 years. The nursing home did not attempt a gradual dose reduction during that time, even though the woman did not have any concerning behaviors for the last 7 months of that 2-year span.

Some nursing homes continued to give residents antipsychotic drugs in direct conflict with physician orders

In multiple instances, nursing homes did not follow physicians' orders to discontinue residents' antipsychotic drugs or lower the dosage. These residents continued to receive the drugs, as in the cases in the text box below.

Nursing homes did not follow physicians' orders to discontinue antipsychotic drugs or lower dosages.

- One nursing home in Utah continued to give a resident with dementia an antipsychotic drug multiple times a day for weeks after the medical director ordered it to be stopped.
- At a nursing home in Vermont, a physician ordered a decrease in the dosage of antipsychotic drug given to an 87-year-old resident, but the nursing staff continued to give him the higher dosage for a month after the ordered decrease. The higher dosage was twice what the physician ordered.

Medical directors failed to prevent inappropriate use of antipsychotic drugs

Each nursing home must have a medical director who is responsible for the quality of medical care provided to residents and for overseeing other clinicians in the nursing home.[32] As part of their role, medical directors are responsible for addressing situations in which a clinician is providing care that does not meet clinical standards. For example, medical directors receive recommendations from nursing home pharmacists regarding each resident's medications and are expected to consult with the resident's attending physician if they have concerns about the physician's followup or lack of followup on the recommendations.[33] This would include recommendations for dose reductions of antipsychotic drugs.

As this issue brief's previous findings of inappropriate use of antipsychotic drugs indicate, medical directors fell short in ensuring quality care in nursing homes and failed to properly oversee the care provided. Additional examples specific to medical directors' poor oversight include a physician assistant at one home whom surveyors determined prescribed an antipsychotic drug as a chemical restraint to multiple residents. Surveyors determined that the medical director at this home failed to perform his responsibilities. At another nursing home, records showed that a nurse practitioner repeatedly declined dose reductions for a resident and attributed the decisions to a psychiatrist, but the resident had never seen a psychiatrist and never received psychiatric services. In neither case did the medical director take action.

Medical directors also fell short when providing direct care to residents as their physician—referred to as a resident's attending physician. For example, one medical director—who was the attending physician for most residents in a nursing home in Mississippi—signed monthly order summaries without reviewing them. Another medical director did not attempt gradual dose reductions for multiple residents, despite recommendations to do so from the pharmacist. One of these residents received the same dosage of an antipsychotic drug for about a year and a half in spite of five separate dose reduction recommendations from the pharmacist to the medical director. The medical director provided no rationale for continuing the higher dosage of antipsychotic drugs, despite Medicare's requirement to provide such a rationale. When medical directors provide poor care as attending physicians, it raises questions about how the care they provide is monitored.

In addition, some medical directors were not familiar with key Medicare requirements to protect residents. One medical director admitted that he had not read the requirements for antipsychotic use. Another was not aware that, as medical director, he must provide input on the nursing home's resident care policies.[34]

Nursing home pharmacists failed to identify medical concerns and did not recommend dose reductions

Each nursing home must have a licensed pharmacist who consults on pharmacy services, also called a consultant pharmacist. The pharmacist's job is to help ensure that the medication provided to residents is appropriate.[35] Nursing home pharmacists must review the drug regimen of each resident at least monthly to identify irregularities, including any unnecessary drugs.[36] For example, the pharmacist reviews whether the physician has attempted dose reductions, as required, to reduce or discontinue an antipsychotic drug. If necessary, the pharmacist makes recommendations to the resident's attending physician to address irregularities. The pharmacist also sends the recommendations to the medical director. In turn, the attending physician must review and act on the pharmacist's recommendations or document a rationale if they do not agree with the recommendations.[37] The medical director is expected to follow up with the attending physician when necessary.[38] There is no CMS specific requirement that pharmacists follow up if the physician does not respond to recommendations.

Some pharmacists failed to identify irregularities, such as when residents received antipsychotic drugs without a clear clinical indication. This sometimes happened repeatedly. For example, one pharmacist failed in six separate reviews to flag that a resident was given an antipsychotic drug but did not have a diagnosis or clinically significant symptoms that would warrant the ongoing use of the drug. The nursing home gave this resident the antipsychotic drug for nearly a year, stopping only after the nursing home was inspected.

At times, pharmacists did not recommend antipsychotic drug dose reductions, even when they were past due. For example, a pharmacist did not make a recommendation to lower the dose of an antipsychotic drug that a resident received for more than a year. At one nursing home in New York, a pharmacist did not recommend gradual dose reductions at all, thinking it was not their job to do so.

In some instances, pharmacists did make dose-reduction recommendations, but they went unnoticed or ignored. In one case, a pharmacist recommended a gradual dose reduction of the antipsychotic drug given to a resident with dementia and bipolar disorder. The physician caring for the resident failed to respond to the recommendation and the pharmacist did not follow up. As a result, the resident continued to receive the higher dosage of the antipsychotic drug for an additional eight months after the recommendation was made to reduce it.

Inadequate nursing home policies and procedures undermined safeguards meant to protect residents

Nursing homes need policies and procedures to help them implement key Medicare requirements and ensure that safeguards are in place to protect residents. However,

these policies and procedures were at times lacking, as some nursing homes did not have any while others had outdated ones.

Inadequate policies and procedures can contribute to a failure to implement key CMS requirements, putting residents at risk. For example, some nursing homes did not have procedures in place to monitor behavioral symptoms to evaluate the effectiveness of antipsychotic drugs.[39] At one of these homes, the director of nursing shrugged her shoulders when asked how the home justified prescribing antipsychotics for "behaviors" when there was no procedure in place for staff to monitor behavioral symptoms. Another nursing home did not have a procedure for monitoring dose reductions. The medical director and pharmacist mistakenly thought that the psychiatrist was monitoring dose reductions. As a result, no one was monitoring, and multiple residents with dementia were kept on the same dose of antipsychotics long after they were due for a reduction attempt.

Other nursing homes had policies and procedures that were outdated or lacked critical information. A nursing home in Ohio relied on policies that were developed more than a decade before significant changes were made to the requirements pertaining to antipsychotics and other psychotropic drugs in 2016.[40] Another nursing home's policies did not include time frames for discontinuing medication, and a resident there received antipsychotic drugs for weeks longer than needed. In still another case, a nursing home's policy was missing instructions on how pharmacists should alert physicians about irregularities. As a result, the pharmacist's repeated recommendations to assess the antipsychotic drugs given to a resident with dementia went unnoticed by the attending physician.

> **I wasn't aware the antipsychotic policy was 19 years old. Sounds like we should review policies and procedures.**
>
> – A medical director

Staff responsible for resident care were sometimes unaware of key requirements for antipsychotic drug use. One psychiatrist did not know that antipsychotics had an FDA boxed warning against their use on elderly patients with dementia. A physician at another nursing home acknowledged, "I am not aware of the [F]ederal regulations for antipsychotics." A nurse practitioner at another home did not know the requirements for attempting dose reductions. He did not attempt a dose reduction for two residents who had been receiving antipsychotic drugs for at least a year.

CONCLUSION AND RECOMMENDATIONS

Improving the safety and quality of nursing home care is a top priority for OIG. OIG's past work has raised concerns about antipsychotic use in nursing homes, finding that more than one in five residents were given these drugs.[41] This issue brief builds on that work by providing an in-depth account of nursing home practices related to the use of antipsychotic drugs. To get this more comprehensive picture, we reviewed a purposive sample of 40 focused nursing home inspection reports. Our review found alarming instances of antipsychotic drug use, revealing vulnerabilities in care that have implications for the wider nursing home population beyond the examples highlighted in this issue brief.

We found that nursing homes gave antipsychotic drugs to residents with dementia to manage their behavior for the benefit of staff, despite an FDA warning that these drugs may increase the risk of death for these residents. Even with known risks, nursing homes did not take the required steps to help protect residents. Further, medical directors failed to prevent inappropriate use of antipsychotic drugs and pharmacists failed to identify medical concerns and did not recommend dose reductions. Additionally, inadequate policies and procedures at nursing homes undermined safeguards meant to protect residents.

Over the years, CMS has taken action to reduce the use of antipsychotic drugs in nursing homes. In 2012, CMS launched the National Partnership to Improve Dementia Care in Nursing Homes (the National Partnership) to promote comprehensive dementia care and reduce unnecessary antipsychotic drug use in nursing homes.[42] More recently, CMS has focused its efforts on specific concerns that nursing homes may be misreporting information to obscure their rate of antipsychotic drug use. To address this issue, CMS in 2023 initiated audits of selected nursing homes and in 2022 updated guidance to surveyors regarding when to refer clinicians to State Medical Boards for practices that violate professional standards.[43] CMS also recently revised surveyor guidance related to chemical restraints and antipsychotic drugs. As part of this revision, CMS made clear that surveyors should interview medical directors and consultant pharmacists, among others, to address any concerns that surveyors observe regarding the inappropriate use of antipsychotic drugs.[44]

However, the findings in this report demonstrate that inappropriate use of antipsychotic drugs continues to be a concern that warrants additional action from nursing homes and CMS. A holistic approach is important, as there may be factors in addition to the ones highlighted in this report that have contributed to the inappropriate use of antipsychotic drugs in nursing homes. OIG makes the below recommendations to CMS to bolster efforts to address the inappropriate use of antipsychotic drugs that puts nursing home residents at risk. OIG has also released a companion report that examines nursing homes inappropriately diagnosing residents

to mask the misuse of antipsychotic drugs. See Appendix A for a summary of that issue brief's findings and recommendations.

We recommend that CMS:

Further develop resources for nursing homes and increase transparency in order to reduce inappropriate use of antipsychotic drugs and improve dementia care in nursing homes

CMS should develop additional resources for nursing homes that will help reduce inappropriate antipsychotic drug use and improve dementia care. CMS currently provides resources on these topics to nursing homes as part of the National Partnership, which was developed in 2012. While the Partnership is ongoing, CMS should strengthen this effort. Many of the resources that the Partnership offers are not regularly updated and fall short of providing clear, actionable steps for nursing homes to reduce inappropriate antipsychotic use and improve dementia care. For instance, some website links do not work and some materials provided are more than a decade old.

As part of its efforts, CMS should work with industry associations, professional societies, and other interested parties to identify effective practices and develop resources on the appropriate use of antipsychotic drugs in nursing homes. These efforts could be led or coordinated by CMS's Quality Improvement Organization (QIO) Program. Resources should address non-drug interventions, dose reductions, and other relevant issues identified in the findings of this report. The resources should be easily accessible and provide clear, actionable information. They could include live and on-demand webinars, conferences, documents such as job aids, or other resources that CMS deems appropriate.

CMS should engage with nursing homes to share this information widely, given that nursing homes are responsible for the quality of care they provide. CMS should provide opportunities for nursing homes to ask questions and give feedback. Further, CMS could involve dementia care experts to consult with nursing homes.

In addition, CMS should explore ways to promote transparency and inform the public about the dementia care available in individual nursing homes. This information would be extremely helpful to prospective residents and their loved ones as they make decisions about their care and choose facilities. For instance, CMS might consider sharing publicly the percentage of the nursing home's residents with dementia who are given antipsychotic drugs, as this population faces additional risks from these drugs. Currently, CMS provides the overall percentage of a nursing home's residents who are given antipsychotic drugs, without distinguishing residents with dementia. As CMS continues to work with nursing homes to reduce

antipsychotic drug use and improve dementia care, it may identify other information about the dementia care in individual facilities that would be valuable for consumers.

Take steps to ensure that nursing home medical directors fulfill their role in reducing the inappropriate use of antipsychotic drugs

We found failures by medical directors to prevent inappropriate use of antipsychotic drugs in nursing homes and that some medical directors fell short when providing care directly. Medical directors are responsible for the quality of medical care provided to residents and are critical to identifying and addressing concerns. CMS currently issues a citation against nursing homes when surveyors find that medical directors did not perform their responsibilities in accordance with Medicare requirements.[45] CMS also recently updated its guidance to surveyors on the responsibilities of medical directors.

The findings in this report demonstrate the importance of the medical director's role and the serious consequences that can arise when the medical director does not fulfill this role specific to use of antipsychotic drugs. As such, OIG recommends that CMS take action to strengthen the accountability of medical directors in nursing homes to reduce the inappropriate use of antipsychotic drugs.

CMS should provide education and training so that medical directors better understand their responsibilities and the requirements related to antipsychotic drug use in nursing homes. The education and training should inform medical directors about the consequences, such as resident harm and nursing home citations, that could result when medical directors do not fulfill their role.

CMS should also assess whether additional, specific safeguards should be developed to address the vulnerabilities in oversight that result when the medical director is also the resident's attending physician. Currently, CMS instructs nursing homes to address concerns about this situation.[46] Additional efforts may be warranted, as we found multiple instances of medical directors providing poor care when they were also the resident's attending physician.

Take steps to ensure that nursing home pharmacists fulfill their role in reducing the inappropriate use of antipsychotic drugs

We found that nursing home pharmacists failed to identify medical concerns and did not recommend dose reductions for antipsychotic drugs. The pharmacist's job is to help ensure that the medication provided to residents is appropriate and necessary. Currently, CMS issues a citation against nursing homes when surveyors find that

pharmacists did not perform their responsibilities in accordance with Medicare requirements.[47]

As with medical directors, the findings in this report demonstrate the importance of the nursing home pharmacist's role and the serious consequences that can arise when the pharmacist does not fulfill this role specific to use of antipsychotic drugs. As such, OIG recommends that CMS take action to ensure that nursing home pharmacists fulfill their role in reducing the inappropriate use of antipsychotic drugs.

CMS should provide education and training so that pharmacists better understand their responsibilities and the requirements related to antipsychotic drug use in nursing homes. The education and training should inform pharmacists about the consequences, such as resident harm and nursing home citations, that could result when pharmacists do not fulfill their role.

Assist nursing homes to improve their policies and procedures pertaining to antipsychotic drug use

Policies and procedures help ensure that nursing homes implement key Medicare requirements and put safeguards in place to protect residents. Without adequate policies and procedures, residents may be at risk of poor care. Yet, some nursing homes did not have policies and procedures, while others had outdated ones.

CMS should assist nursing homes to develop clear and comprehensive policies and procedures so that they can better ensure that key Medicare requirements are implemented and that safeguards are in place to protect residents. This effort could be coordinated through CMS's QIO Program and would entail providing general resources to all nursing homes that would assist in the development of clear and comprehensive policies and procedures. Such policies and procedures would outline the appropriate use of antipsychotic drugs and explain proper indications for use, particularly regarding residents with dementia. The policies and procedures would also address dose reductions and monitoring for efficacy and adverse consequences.

CMS should also pay particular attention to nursing home policies and procedures for drug regimen reviews. Specifically, CMS should clarify, within the existing drug regimen review guidance, that policies and procedures for these reviews should include clearly defined roles and responsibilities to address situations in which physicians do not respond to pharmacist recommendations.

When it is warranted and feasible to do so, CMS could also provide individualized assistance to nursing homes that may need additional support to develop and update comprehensive policies and procedures. These nursing homes may include those CMS has identified as having inappropriate antipsychotic drug use or using chemical restraints.

AGENCY COMMENTS AND OIG RESPONSE

CMS stated that its approach to the oversight of nursing homes, including their use of medications, is constantly evolving and that CMS is continuously looking for ways to improve its oversight of the inappropriate use of antipsychotic drugs.

CMS did not explicitly concur or nonconcur with two of our recommendations and nonconcurred with the remaining two. We carefully considered CMS's comments to the draft report and made revisions to the two recommendations with which CMS did not concur. In light of these revisions, we encourage CMS to re-examine its position on concurrence in its Final Management Decision. OIG remains committed to our recommendations and will continue to work with CMS to promote their implementation.

CMS did not explicitly concur or nonconcur with our first recommendation to further develop resources for nursing homes and increase transparency in order to reduce inappropriate use of antipsychotic drugs and improve dementia care in nursing homes. CMS stated that, in November 2024, it published revisions to surveyor guidance on the unnecessary use of psychotropic drugs and noted that Care Compare offers the percentage of residents receiving an antipsychotic drug. Lastly, CMS stated that Quality Improvement Organizations work with nursing homes to reduce the use of antipsychotic medications and requested that OIG close this recommendation.

OIG recognizes CMS's efforts to reduce the use of antipsychotic drugs in nursing homes and that these efforts have spanned years and have led to improvements in nursing home care. The findings in our report demonstrate that more is needed to address underlying problems and promote high-quality care for nursing home residents. As such, we recommended specific actions for CMS to take. These include updating materials and fixing website links provided by the National Partnership, working with industry associations and others to identify effective practices, engaging with nursing homes to share this information widely, and exploring ways to promote transparency and inform the public about dementia care available in individual nursing homes.

CMS nonconcurred with our second and third recommendations to strengthen the accountability of nursing home medical directors and nursing home pharmacists in order to reduce the inappropriate use of antipsychotic drugs. CMS stated that its authority is limited to enforcement action against a nursing home found in noncompliance and that it issues a citation against a nursing home if there is evidence that the medical director or pharmacist is found to not be compliant with Medicare and Medicaid requirements.

OIG recognizes CMS's survey and enforcement authority. Our recommendations are complementary to this work, and we have modified them to focus on ensuring that

nursing home medical directors and pharmacists fulfill their roles. CMS should provide education and training so that medical directors and nursing home pharmacists better understand their responsibilities related to antipsychotic drug use in nursing homes and are informed about the consequences of failing to fulfil their responsibilities. CMS should also assess whether additional, specific safeguards should be developed to address the vulnerabilities in oversight that result when medical directors act as residents' attending physicians. With these clarifications, we encourage CMS to re-examine its position on concurrence in its Final Management Decision.

CMS did not explicitly concur or nonconcur with our fourth recommendation to assist nursing homes to improve their policies pertaining to antipsychotic drug use. CMS stated that it published revisions to surveyor guidance in November 2024 and noted that a lack of funding is the main barrier to implementing individualized assistance to nursing homes, and requested that OIG close this recommendation.

OIG appreciates CMS efforts and further points to the importance of improving nursing home policies for antipsychotic drugs. We recommend specific actions to address the inadequate nursing home policies and procedures discussed in our findings. We have clarified in the recommendation that these actions include providing assistance broadly to all nursing homes and providing individualized assistance when warranted and feasible. CMS should pay particular attention to nursing home policies and procedures for drug regimen reviews and clarify, within existing guidance, that policies and procedures for these reviews should include clearly defined roles and responsibilities to address situations in which physicians do not respond to pharmacist recommendations.

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

METHODOLOGY

We based this issue brief on a review of key documents about requirements for antipsychotic drug use in nursing homes and an analysis of a purposive sample of onsite inspection reports, known as surveys. These surveys assess whether nursing homes meet requirements and are based on surveyors' direct observations; record reviews; and interviews with staff, residents, and family members.

Data Collection and Analysis

Document Review. We reviewed relevant documents related to Medicare requirements for the use of antipsychotic drugs in nursing homes, including CMS's Requirements of Participation and CMS's State Operations Manual, and other guidance and protocols for surveyors. We also reviewed the relevant requirements for nursing home medical directors and consultant pharmacists. For additional context, we reviewed information issued by CMS, including memoranda to surveyors and information from the National Partnership to Improve Dementia Care, as well as other studies and related information.

Sample Selection. We reviewed a sample of surveys focused on dementia care or schizophrenia that CMS conducted from 2018 through 2021.[48] These types of surveys specifically address the use of antipsychotics.[49] We requested from CMS all survey reports focused on dementia care or schizophrenia conducted from 2018 through 2021.[50] We then purposively selected a sample of 40 survey reports for review. We selected the sample using a range of criteria including recency of the survey, type of survey, and citations related to the inappropriate use of antipsychotic drugs.

Survey Report Review. We developed and used a document review tool to review the sampled survey reports. We conducted these reviews to describe and characterize nursing home practices and processes related to the inappropriate use of antipsychotic drugs, and to identify those that put residents at risk. We focused on key areas, including the use of antipsychotic drugs, use of antipsychotic drugs as chemical restraints, non-drug approaches, dose reductions, and monitoring of behaviors and side effects. We also reviewed the survey reports to describe the role of medical directors and consultant pharmacists as well as nursing home policies and procedures about the use of antipsychotic drugs. These survey reports include statements from interviews that the surveyors conducted with staff, residents, and family members. The quotes in this issue brief are taken from these statements.

Limitations

This report is based on a purposive sample of surveys. Therefore, we do not determine the prevalence of inappropriate use of antipsychotic drugs by all nursing

homes. We based our analysis on the information included in the survey reports. We did not independently verify the accuracy of the information in the survey reports.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued in 2020 by the Council of the Inspectors General on Integrity and Efficiency.

APPENDICES

Appendix A: Summary of Findings and Recommendations from Companion Report

Below is the information about the second issue brief in the series. For more information, click the title of the issue brief to be directed to the OIG website.

Nursing Homes Inappropriately Diagnosed Residents with Schizophrenia to Mask the Misuse of Antipsychotic Drugs, OEI-02-23-00201

Our review of nursing home inspections completed by CMS found that:

- Nursing homes inappropriately diagnosed residents with schizophrenia to mask the nursing homes' misuse of antipsychotic drugs and to artificially inflate their star ratings.
- Medical directors made inappropriate schizophrenia diagnoses to justify prescribing antipsychotic drugs.
- Nursing homes also used inappropriate schizophrenia diagnoses to skirt Medicare safeguards intended to protect residents.
- By inappropriately diagnosing schizophrenia, nursing homes compromised residents' care.

We recommended that CMS:

- Build on its efforts to reduce inappropriate schizophrenia diagnoses in nursing homes.
- Expand its use of data to monitor nursing homes' use of schizophrenia diagnoses and target oversight.
- Increase efforts to ensure that nursing home residents and their families are fully informed when antipsychotic drugs are given.

Appendix B: Agency Comments

Following this page are the official comments from CMS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: November 19, 2025

TO: Ann Maxwell
Deputy Inspector General for Evaluations and Inspections

FROM: Dr. Mehmet Oz
Administrator

SUBJECT: Office of Inspector General Draft Report: Nursing Homes' Inappropriate Use of Antipsychotic Drugs Poses a Risk to Residents (OEI-02-23-00200)

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

CMS is charged with developing and enforcing quality and safety standards across the nation's health care system, a responsibility we take seriously. This duty is especially important when it comes to the care provided for people covered by Medicare and Medicaid who live in nursing homes. CMS's approach to the oversight of Medicare and Medicaid-certified nursing homes, including their use of medications, is constantly evolving and CMS is continuously looking for ways to improve our oversight of the inappropriate use of antipsychotic drugs. It is important to highlight that OIG's findings in this report are based on an analysis of sample inspection survey results conducted by CMS and the State Survey Agencies (SAs), which means the CMS survey process effectively identified the unnecessary use of antipsychotic drugs in these cases. As always, when a survey identifies facility non-compliance, the deficiencies are immediately addressed, and thus CMS has already addressed the specific instances OIG highlighted in the report.

CMS has worked diligently to optimize the quality of life for residents in nursing homes by taking actions to reduce the inappropriate use of antipsychotic medications in nursing homes and improve comprehensive care approaches to better address the psychosocial and behavioral health needs of all residents. In 2012, CMS launched the National Partnership to Improve Dementia Care in Nursing Homes to promote comprehensive dementia care and therapeutic interventions for nursing home residents with dementia-related behaviors.[1] The goals of the initiative include a focus on person-centered care and the reduction of unnecessary antipsychotic medication use in nursing homes. CMS began with developing and conducting trainings for nursing home providers, surveyors, and consumers. As part of the initiative, CMS also announced that it was conducting research, raising public awareness, using regulatory oversight, and public reporting to increase transparency. CMS partnered with national organizations to encourage communication

[1] CMS Memo S&C: 12-42-NH, Request to Convey Information: Partnership to Improve Dementia Care in Nursing Homes, August 31, 2012

among the organizations and their members. In July 2012, CMS began public reporting quality measures on the percentage of residents residing 100 days or less that are given an antipsychotic medication, and residents residing 101 days or more that are receiving an antipsychotic medication on Nursing Home Compare (Care Compare) website.[2] The first-year goal of the National Partnership to Improve Dementia Care was to reduce the use of antipsychotic medications by 15 percent nationally, which was achieved after 21 months.[3] CMS announced that by late 2014, nursing homes had achieved a 19.4 percent reduction in antipsychotic drug use.[4] And, in early 2015, CMS announced that the measure of the percentage of residents receiving an antipsychotic medication would be included in the Quality Measures that impact a nursing home's quality rating on the Five-Star Quality Rating System.[5]

Additionally, in 2013, CMS highlighted the problematic use of medications, such as antipsychotics, as part of a larger, growing concern that nursing homes may use medications as a "quick fix" for behavioral symptoms or as a substitute for a holistic approach that involves a thorough assessment of underlying causes of behaviors and individualized, person-centered interventions.[6] To help SAs surveying Medicare and Medicaid-certified nursing homes better assess compliance with federal participation requirements related to nursing home residents with dementia and unnecessary drug use and identify deficiencies, CMS published a comprehensive guidance update in the CMS State Operations Manual Appendix PP in 2013.[7]

To further address the issue, in 2014 CMS piloted a focused dementia care survey program to more thoroughly examine the process for prescribing antipsychotic medication as well as assess compliance with other federal requirements related to dementia care practices in nursing homes. CMS's goal was to gain new insights into surveyor knowledge, skills, attitudes, and ways that the current survey process may be streamlined to more efficiently and accurately identify and cite deficient practice as well as to recognize successful dementia care programs. The focused dementia care survey included detailed reviews of dementia care practices in nursing homes, including reviewing resident-level and organizational processes in nursing homes. CMS also surveyed facility coding practices for the Minimum Data Set, Version 3.0 (MDS 3.0) and evaluated the MDS assessments and associated care planning for residents.[8]

By late 2015, CMS completed the focused dementia care survey pilot and revised the long-term care survey materials and tools based on surveyor feedback and data analysis. In response to feedback from stakeholders and partners of the National Partnership to Improve Dementia Care,

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[2] CMS, Description of Antipsychotic Medication Quality Measures on Nursing Home Compare, PDF, 2012
[3] CMS Memo S&C: 15-26-NH Nursing Home Compare 3.0 – Five Star Quality Rating System – Expanded and Strengthened, February 13, 2015
[4] CMS Memo S&C: 15-31-NH 2014 Final Report & 2015 Expansion Project – CMS Focused Dementia Care Survey Pilot, March 27, 2015
[5] CMS Memo S&C: 15-26-NH Nursing Home Compare 3.0 – Five Star Quality Rating System – Expanded and Strengthened, February 13, 2015
[6] CMS Memo S&C: 13-35-NH Advanced Copy: Dementia Care in Nursing Homes: Clarifications to Appendix P State Operations Manual (SOM) and Appendix PP in the SOM for F309 – Quality of Care and F329 – Unnecessary Drugs, May 24, 2013
[7] Id.
[8] CMS Memo S&C: 14-22-NH Focused Minimum Data Set and Dementia Care Surveys, April 18, 2014

CMS shared the revised material publicly so that all nursing homes can use the tools to assess their own practices in providing resident care.[9]

CMS has continued to provide surveyor trainings, release updated guidance, refine quality measures, and conduct focused dementia care surveys in selected facilities based on available funding. For instance, in 2016, CMS began monitoring the use of antipsychotics overall for residents enrolled in Medicare Part D and began reporting the data publicly in 2018.[10] [11] Between 2011 and the fourth quarter of 2024, the national prevalence of antipsychotic medication use among residents residing in a nursing home for 101 or more days was reduced by 38.4 percent.[12]

CMS thanks OIG for their efforts on this issue and looks forward to working with OIG on this and other issues in the future.

OIG's recommendations and CMS' responses are below.

OIG Recommendation

Further develop resources for nursing homes and increase transparency in order to reduce inappropriate use of antipsychotic drugs and improve dementia care in nursing homes

CMS Response

CMS requests this recommendation be closed as implemented given the recent resources that have been implemented already take a person-centered approach. Specifically, in November 2024, CMS published extensive revisions to guidance on the unnecessary use of psychotropic drugs, which includes any drug that affects brain activities associated with mental process and behavior.[13] CMS provided clear and actionable information that is specific to comprehensive assessments and behavioral (non-pharmacological) interventions, resident rights, gradual dose reduction, and proper documentation. Further, CMS is dedicated to empowering consumers, their families, and their caregivers by giving them the resources they need to make informed decisions. Care Compare offers a wide variety of data related to nursing home quality, including the percentage of residents receiving an antipsychotic drug, presented in a format that allows consumers to fully compare different nursing homes. It is critical to note, however, that Care Compare is designed to help consumers make more informed decisions; CMS expects consumers and their loved ones to visit a nursing home and ask questions before making a decision. To assist with this, CMS revised the "Questions to Ask When You Visit a Nursing Home" document with a list of questions that are important to ask.[14, 15] Included in the extensive questionnaire are a list of specific questions related to caring for residents with dementia.

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[9] CMS Memo S&C: 16-04-NH Focused Dementia Care Survey Tools, November 2015
[10] CMS Memo to All Part D Plan Sponsors, Updates – 2016 Part D Patient Safety and Overutilization Monitoring System Reports, April 6, 2016
[11] CMS Press Release, Medicare Offers Improved Access to High-Quality Health Coverage Choices in 2018, October 11, 2017
[12] Calculations based on CMS Nursing Homes Quality Measure data
[13] CMS Memo QSO-25-07-NH Revised Long-Term Care Surveyor Guidance: Significant revisions to enhance quality and oversight of the LTC survey process, November 18, 2024
[14] CMS-12130, Questions to Ask When You Visit a Nursing Home, November 2022
[15] CMS Guidance, Your Guide to Choosing a Nursing Home, February 2025

Further, within the resources currently allotted, the Quality Innovation Network – Quality Improvement Organizations' (QIN-QIO) work with nursing homes, as appropriate, so that the nursing home can achieve a goal of a 40 percent reduction rate in the use of antipsychotic medications. As of September 2025, the QIN-QIOs are working with almost 7,400 Medicaid and Medicare-certified nursing homes related to antipsychotic medications and adverse drug events.

OIG Recommendation

Strengthen the accountability of nursing home medical directors in order to reduce the inappropriate use of antipsychotic drugs

CMS Response

CMS non-concurs with this recommendation. CMS's authority is limited to surveying for a facility's compliance with Medicare and Medicaid requirements; therefore, CMS's authority is limited to enforcement action against a nursing home found in non-compliance. As OIG reports, CMS issues a citation against a nursing home if there is evidence that the medical director is found to not be compliant with Medicare and Medicaid requirements pertaining to medical director responsibilities. CMS updated the interpretive guidance for F841 (42 C.F.R. § 483.70(g)) in April 2025 to specify that medical director responsibilities should include discussing and intervening with a healthcare practitioner regarding medical care that is inconsistent with standards of care, such as physicians assigning new psychiatric diagnoses and/or prescribing psychotropic medications without following professional standards of practice.[16] Regarding specific medical director accountability, CMS refers cases to the Office of Inspector General and the Department of Justice to pursue civil or criminal action.

OIG Recommendation

Strengthen the accountability of nursing home pharmacists in order to reduce the inappropriate use of antipsychotic drugs

CMS Response

CMS non-concurs with this recommendation. CMS's authority is limited to surveying for a facility's compliance with Medicare and Medicaid requirements; therefore, CMS's authority is limited to enforcement action against a nursing home found in non-compliance. Specifically, federal requirements are not for individual pharmacists; rather, nursing homes provide certain pharmacy services and must meet the requirements related to the provision of those services, including services of a licensed pharmacist. Therefore, if the nursing home's pharmacist is providing services that do not meet federal standards, then the nursing home is held accountable for noncompliance. Regarding specific pharmacist accountability, CMS refers cases to the Office of the Inspector General and the Department of Justice to pursue civil or criminal action.

OIG Recommendation

Assist nursing homes to improve their policies and procedures pertaining to antipsychotic drug use.

[16] CMS Memo QSO-25-14-NH Revised Long-Term Care (LTC) Surveyor Guidance: Significant revisions to enhance quality and oversight of the LTC survey process, pg. 3, March 10, 2025

CMS Response

CMS requests this recommendation be closed as implemented given the extensive guidance revisions CMS published in November 2024 providing, among other things, clear and actionable information related to policies and procedures pertaining to antipsychotic drug use. For example, CMS provides information on comprehensive assessment and behavioral (nonpharmacological) interventions, resident rights, dose and duration, gradual dose reduction, monitoring and adverse consequences, among other topics. CMS also revised the Use of Unnecessary Medications, Chemical Restraints/Psychotropic Medications, and Medication Regiment Review Critical Element Pathway[17] which provide further probing questions if there are concerns.

It is crucial for CMS to note that while OIG encourages CMS to provide individualized assistance to nursing homes, a lack of funding is the main barrier to CMS implementing these types of recommendations. Specifically, the survey and certification budget has been nearly flat funded since 2015. In the FY 2026 Budget Justification of Estimates for Appropriation Committees, CMS stated that the requested increase in the budget will provide the resources to achieve 65 percent completion of mandatory surveys and ten percent of non-statutory surveys across all provider types.[18] CMS currently does not have the resources to carry out a 100 percent completion rate of mandatory surveys, and therefore, CMS does not have the capacity or resources to work individually with the approximately 15,000 Medicare and Medicaid certified nursing homes.

[17] CMS Memo QSO-25-07-NH Revised Long-Term Care Surveyor Guidance: Significant revisions to enhance quality and oversight of the LTC survey process, pg. 870-877, November 18, 2024

[18] HHS, CMS, FY 2026 Justification of Estimates for Appropriations Committees, pg. 4, 2025

ENDNOTES

[1] For example, see National Academies of Sciences, Engineering, and Medicine, *The National Imperative to Improve Nursing Home Quality: Honoring Our Commitment to Residents, Families, and Staff* (Washington, DC: The National Academies Press, Apr. 6, 2022). Accessed at https://doi.org/10.17226/26526 on Mar. 13, 2025. See also Report of the Committee on Ways and Means Majority (WMJ), *Under-Enforced and Over-Prescribed: The Antipsychotic Drug Epidemic Ravaging America's Nursing Homes*, July 2020. Accessed at https://democrats-waysandmeans.house.gov/sites/evo-subsites/democrats-waysandmeans.house.gov/files/documents/WMD%20Nursing%20Home%20Report_Final.pdf on Mar. 31, 2025. In this report, the Ways and Means Committee noted the efforts over the past decade to reduce antipsychotic drug use, but stated that the "high rate of antipsychotics use across our nation's nursing homes shows that many facilities continue to resort to the use of these potentially dangerous drugs as a chemical restraint in lieu of proper staffing—which has the potential to harm hundreds of thousands of patients."

[2] 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. FDA, *Information for Healthcare Professionals: Conventional Antipsychotics*, June 2008. Accessed at https://wayback.archive-it.org/7993/20170722033234/https:/www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm107211.htm on Dec. 10, 2024.

[3] Substance Abuse and Mental Health Services Administration (SAMHSA), *Guidance on Inappropriate Use of Antipsychotics: Older Adults and People with Intellectual and Developmental Disabilities in Community Settings.* Accessed at https://library.samhsa.gov/sites/default/files/pep19-inappuse-br.pdf on Jan. 22, 2025.

[4] Social Security Act § 1819(c)(1)(A)(ii) and §1919(c)(1)(A)(ii); 42 CFR § 483.12(a)(2).

[5] 42 CFR § 483.45(d).

[6] CMS, *State Operations Manual*, Appendix PP, Rev. 229, issued Apr. 25, 2025, F605. In its April 2025 revisions, CMS expanded the definition of "adequate indication for use" to include that drugs should only be prescribed after any other treatments have been deemed clinically contraindicated.

[7] 42 CFR § 483.45(e)(2); CMS, *State Operations Manual,* Appendix PP, Rev. 229, issued Apr. 25, 2025, F605.

[8] 42 CFR § 483.45(c); CMS, *State Operations Manual*, Appendix PP, Rev. 229, issued Apr. 25, 2025, F756.

[9] American Psychiatric Association (APA), *The American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients With Dementia*, pp. 6-7. Accessed at https://psychiatryonline.org/doi/book/10.1176/appi.books.9780890426807 on Sept. 5, 2024.

[10] APA, *The American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients With Dementia*, Statements 5, 6, 8, and 12, pp. 3-4. Accessed at https://psychiatryonline.org/doi/book/10.1176/appi.books.9780890426807 on Sept. 5, 2024.

[11] OIG, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents* (OEI-07-08-00150), May 4, 2011.

[12] OIG, *Long-Term Trends of Psychotropic Drug Use in Nursing Homes* (OEI-07-20-00500), Nov. 14, 2022. This evaluation included nursing home residents who were aged 65 or older and enrolled in Medicare Part D.

[13] For example, in 2012, CMS launched the National Partnership to Improve Dementia Care in Nursing Homes (the National Partnership) to promote comprehensive dementia care and reduce unnecessary antipsychotic drug use in nursing homes. CMS, *Update Report on the* National Partnership to Improve Dementia Care in Nursing Homes (S&C 16-28-NH), June 3, 2016. Accessed at https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/sc-letter-16-28-partnership-update-report.pdf on Sept. 3, 2024. More recently, CMS has focused its efforts on specific concerns that nursing homes may be misreporting information to obscure their rate of antipsychotic drug use. To address this issue, CMS in 2023 initiated audits of selected nursing homes. CMS, *Updates to the Nursing Home Care Compare Website and Five Star Quality Rating System: Adjusting Quality Measure Ratings Based on Erroneous Schizophrenia Coding, and Posting Citations Under Dispute* (QSO-23-05-NH), Jan. 18, 2023. Accessed at https://www.cms.gov/files/document/qso-23-05-nh-adjusting-quality-measure-ratings-based-erroneous-schizophrenia-coding-and-posting.pdf on Aug. 26, 2024.

[14] OIG, *Long-Term Trends of Psychotropic Drug Use in Nursing Homes* (OEI-07-20-00500), Nov. 14, 2022. This evaluation included nursing home residents who were aged 65 or older and enrolled in Medicare Part D.

[15] OIG, *Nursing Homes Inappropriately Diagnosed Residents with Schizophrenia to Mask the Misuse of Antipsychotic Drugs* (OEI-02-23-00201), March 2026.

[16] 42 CFR § 483.10(e)(1). CMS defines convenience as the unnecessary administration of medication that causes (intentionally or unintentionally) a change in a resident's behavior (e.g., sedation) such that the resident is subdued and/or requires less effort from staff. See CMS, *State Operations Manual*, Appendix PP, Rev. 229, issued Apr. 25, 2025, F605. In April 2025, CMS revised the guidance regarding "convenience" to include situations in which medications are used to cause symptoms consistent with sedation and/or require less effort by facility staff to meet the resident's needs. See CMS, *REVISED: Revised Long-Term Care (LTC) Surveyor Guidance: Significant revisions to enhance quality and oversight of the LTC survey process* (QSO-25-14-NH), Mar. 10, 2025. Accessed at https://www.cms.gov/files/document/qso-25-14-nh.pdf on Mar. 12, 2025.

[17] This boxed warning remains for brexpiprazole, which, after the conclusion of our study-review period, FDA approved for the treatment of agitation associated with dementia due to Alzheimer's disease. See FDA, *FDA Approves First Drug to Treat Agitation Symptoms Associated with Dementia due to Alzheimer's Disease*, May 11, 2023. Accessed at https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-treat-agitation-symptoms-associated-dementia-due-alzheimers-disease on Sept. 6, 2024.

[18] Dementia is a serious and debilitating neurological condition characterized by progressive decline in one or more cognitive domains in the brain.

[19] CMS, *State Operations Manual*, Appendix PP, Rev. 229, issued Apr. 25, 2025, F605.

[20] Social Security Act § 1819(c)(1)(A)(ii) and § 1919(c)(1)(A)(ii); 42 CFR § 483.12(a)(2); CMS, *State Operations Manual*, Appendix PP, Rev. 229, issued Apr. 25, 2025, F605.

[21] CMS, *State Operations Manual*, Appendix PP, Rev. 229, issued Apr. 25, 2025, F605. In April 2025, CMS streamlined survey guidance related to the use of antipsychotic medications and chemical restraints. Guidance concerning the unnecessary use of these drugs was located under tag F758, but was incorporated into tag F605 (Chemical Restraint). See CMS, *REVISED: Revised Long-Term Care (LTC) Surveyor Guidance: Significant revisions to enhance quality and oversight of the LTC survey process* (QSO-25-14-NH), Mar. 10, 2025. Accessed at https://www.cms.gov/files/document/qso-25-14-nh.pdf on Mar. 12, 2025.

[22] APA, *The American Psychiatric Association Practice Guideline on the Use of Antipsychotics to Treat Agitation or Psychosis in Patients With Dementia*, Statement 6, p. 3. Accessed at https://psychiatryonline.org/doi/book/10.1176/appi.books.9780890426807 on Sept. 5, 2024.

[23] CMS, *State Operations Manual*, Appendix PP, Rev. 229, issued Apr. 25, 2025, F605.

[24] Ibid.

[25] 42 CFR § 483.45(d)(4); CMS, *State Operations Manual*, Appendix PP, Rev. 229, issued Apr. 25, 2025, F605. In its April 2025 revisions, CMS expanded the definition of "adequate indication for use" to include that drugs should only be prescribed after any other treatments have been deemed clinically contraindicated.

[26] Ibid.

[27] 42 CFR § 483.45(d)(3); CMS, *State Operations Manual*, Appendix PP, Rev. 229, issued Apr. 25, 2025, F605 and F757.

[28] CMS, *State Operations Manual*, Appendix PP, Rev. 229, issued Apr. 25, 2025, F605.

[29] CMS, *State Operations Manual*, Appendix PP, Rev. 229, issued Apr. 25, 2025, F605. See also 42 CFR § 483.45(e)(2). Gradual dose reductions are required as part of an effort to discontinue antipsychotic drugs, unless clinically contraindicated.

[30] OIG, *Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries* (OEI-06-11-00370), Feb. 27, 2014.

[31] Ibid.

[32] 42 CFR § 483.70(g); CMS, *State Operations Manual*, Appendix PP, Rev. 229, issued Apr. 25, 2025, F841. Medical directors are responsible for discussing and intervening, as appropriate, with clinicians regarding medical care that is inconsistent with current standards of care. CMS guidance, effective April 2025, clarifies that this includes situations in which clinicians do not follow accepted standards of practice when prescribing psychotropic drugs, which is a class of drugs that includes antipsychotics. See CMS, *REVISED: Revised Long-Term Care (LTC) Surveyor Guidance: Significant revisions to enhance quality and oversight of the LTC survey process* (QSO-25-14-NH), Mar. 10, 2025. Accessed at https://www.cms.gov/files/document/qso-25-14-nh.pdf on Mar. 12, 2025.

[33] 42 CFR § 483.45(c)(4); *Federal Register*, vol. 81, no. 192 (Oct. 4, 2016), pp. 68688, 68767-68769.

[34] The medical director works with the nursing home to recommend, develop, and approve policies related to resident care. 42 CFR § 483.70(g)(1)-(2); CMS, *State Operations Manual*, Appendix PP, Rev. 229, issued Apr. 25, 2025, F841. Resident-care policies include those related to the resident's physical, mental, and psychosocial well-being. In April 2025, CMS expanded guidance under tag F841 to clarify the medical director's

responsibilities related to the implementation of resident care policies. See CMS, *REVISED: Revised Long-Term Care (LTC) Surveyor Guidance: Significant revisions to enhance quality and oversight of the LTC survey process* (QSO-25-14-NH), Mar. 10, 2025. Accessed at https://www.cms.gov/files/document/qso-25-14-nh.pdf on Mar. 12, 2025.

[35] 42 CFR § 483.45; CMS, *State Operations Manual*, Appendix PP, Rev. 229, issued Apr. 25, 2025, F755 and F756.

[36] 42 CFR § 483.45(c)(1), (2), and (4).

[37] 42 CFR § 483.45(c)(4); CMS, *State Operations Manual*, Appendix PP, Rev. 229, issued Apr. 25, 2025, F756.

[38] *Federal Register*, vol. 81, no. 192 (Oct. 4, 2016), pp. 68688, 68767-68769.

[39] CMS, *State Operations Manual*, Appendix PP, Rev. 229, issued Apr. 25, 2025, F605.

[40] *Federal Register*, vol. 81, no. 192 (Oct. 4, 2016), pp. 68688, 68765-68774.

[41] OIG, *Long-Term Trends of Psychotropic Drug Use in Nursing Homes* (OEI-07-20-00500), Nov. 14, 2022. Other related OIG work includes *CMS Could Improve the Data It Uses To Monitor Antipsychotic Drugs in Nursing Homes* (OEI-07-19-00490), May 3, 2021; *Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs* (OEI-07-08-00151), July 6, 2012; and *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents* (OEI-07-08-00150), May 4, 2011.

[42] CMS, *Update Report on the* National Partnership to Improve Dementia Care in Nursing Homes (S&C 16-28-NH), June 3, 2016. Accessed at https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/sc-letter-16-28-partnership-update-report.pdf on Sept. 3, 2024. CMS launched the National Partnership following the release of OIG work that raised concerns about off-label use of antipsychotic drugs in nursing homes. See OIG, *Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents* (OEI-07-08-00150), May 4, 2011.

[43] CMS, *Updates to the Nursing Home Care Compare Website and Five Star Quality Rating System: Adjusting Quality Measure Ratings Based on Erroneous Schizophrenia Coding, and Posting Citations Under Dispute* (QSO-23-05-NH), Jan. 18, 2023. Accessed at https://www.cms.gov/files/document/qso-23-05-nh-adjusting-quality-measure-ratings-based-erroneous-schizophrenia-coding-and-posting.pdf on Aug. 26, 2024. CMS is conducting audits in response to concerns raised by OIG and others that nursing homes may be inaccurately reporting that residents have schizophrenia, since a schizophrenia diagnosis excludes residents from being counted in CMS's long-stay quality measure on antipsychotic use. For example, see OIG, *Long-Term Trends of Psychotropic Drug Use in Nursing Homes* (OEI-07-20-00500), Nov. 14, 2022. See also CMS, *Revised Long-Term Care Surveyor Guidance: Revisions to Surveyor Guidance for Phases 2 & 3, Arbitration Agreement Requirements, Investigating Complaints & Facility Reported Incidents, and the Psychosocial Outcome Severity Guide* (QSO-22-19-NH), June 29, 2022. Accessed at https://www.cms.gov/files/document/qso-22-19-nh-revised-long-term-care-surveyor-guidance.pdf on Sept. 3, 2024. See also CMS, *State Operations Manual*, Appendix PP, Rev. 229, issued Apr. 25, 2025, F605, F641, and F658.

[44] CMS*, State Operations Manual*, Appendix PP, Rev. 229, issued Apr. 25, 2025, F605.

[45] CMS issues a citation, or deficiency, when it finds that a nursing home failed to meet a participation requirement, such as that related to medical directors. See 42 CFR § 488.301 and 42 CFR § 483.70(g).

[46] CMS*, State Operations Manual*, Appendix PP, Rev. 229, issued Apr. 25, 2025, F841.

[47] See 42 CFR § 488.301 and 42 CFR 483.45(c).

[48] CMS implemented focused schizophrenia surveys from 2016 through 2021 and focused dementia care surveys from 2014 through 2019. We reviewed the most recent available surveys. CMS implemented these surveys in response to concerns that nursing homes may be inaccurately reporting that residents have schizophrenia, since a schizophrenia diagnosis excludes residents from being counted in CMS's quality measure on antipsychotic use. By excluding these residents from the quality measure, nursing homes can hide the true rate of antipsychotic drug use in the nursing home. See OIG, *CMS Could Improve the Data It Uses To Monitor Antipsychotic Drugs in Nursing Homes* (OEI-07-19-00490), May 3, 2021. See also OIG, *Long-Term Trends of Psychotropic Drug Use in Nursing Homes* (OEI-07-20-00500), Nov. 14, 2022. See also CMS, *Updates to the Nursing Home Care Compare Website and Five Star Quality Rating System: Adjusting Quality Measure Ratings Based on Erroneous Schizophrenia Coding, and Posting Citations Under Dispute* (QSO-23-05-NH), Jan. 18, 2023. Accessed at https://www.cms.gov/files/document/qso-23-05-nh-adjusting-quality-measure-ratings-based-erroneous-schizophrenia-coding-and-posting.pdf on Aug. 26, 2024.

[49] We did not review standard and other surveys of nursing homes for this report. Standard surveys assess whether nursing homes meet other requirements pertaining to resident rights, transfer and discharge procedures, and food and nutrition services, for example. See Social Security Act § 1819(g) and Social Security Act § 1919(g); 42 CFR § 488.330. See also CMS, *State Operations Manual*, Appendix PP, Rev. 229, issued Apr. 25, 2025.

[50] CMS provided 22 focused dementia care survey reports and 56 focused schizophrenia survey reports in response to our request.

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