

The Biden Administration and other policymakers are actively discussing nursing facility reform, motivated in part by the death and isolation residents suffered during the COVID pandemic. In this series of briefs, Justice in Aging makes and evaluates several proposed reforms, focusing on proposals' real-world impact on residents.

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SUMMARY

Too many nursing facilities overmedicate residents to sedate them and make them more easily managed. Current initiatives to stop this practice are flawed because they ignore residents' decision-making rights, assuming implicitly that facilities have unilateral discretion to administer medication. But nursing facility residents, like any other person, have "informed consent" rights. The federal government and nursing facilities should revise their policies so that 1) residents receive adequate written information regarding a proposed medication's benefits and risks and 2) medication is administered only with a resident's written consent.

OVERMEDICATION IN NURSING FACILITIES

"Psychotropic" medications affect mental processes and behavior. Psychotropic medications include antipsychotics, antidepressants, anticonvulsants, hypnotics, and anti-anxiety medications, among other medications.\(^1\) While psychotropic medications might provide benefit when used appropriately for certain persons (including some with psychiatric conditions), psychotropics in nursing facilities too frequently are used to sedate residents and make them more easily managed. Psychotropics slow down the brain's ability to function; as a result, they can decrease people's ability to understand their surroundings, negatively affect quality of life, and (particularly in the case of antipsychotics) increase the risk of death.\(^2\)

Overuse of psychotropics has plagued nursing facilities for decades. In 1987, a Congressional committee reported "that psychotropic drugs are being used to manage residents for the convenience of nursing facility staffs in a manner that is wholly inconsistent with high quality care or an adequate quality of life." And today, 35 years later? In November 2022, the Inspector General for the Department of Health and Human Services (HHS) reported that 80 percent of studied nursing facility residents received psychotropic medications. More specifically: 22 percent of residents received antipsychotics, while 40 percent of residents received anticonvulsants. The remainder of the 80 percent received other types of psychotropics. In accord, the Long Term Care Community Coalition released a report the following month that documented "A Decade of Drugging" despite federal initiatives to reduce psychotropic use.

The Inspector General highlighted what can be visualized as a Whac-A-Mole problem in efforts to reduce improper use of antipsychotics (which are the most powerful of the psychotropics). Specifically, federal initiatives to reduce antipsychotic use may be simply shifting residents from antipsychotics to a different psychotropic.⁶ Although antipsychotic use decreased from 31 to 22 percent of residents during the study period (2011-2019), use of anticonvulsants increased from 28 to 40 percent during that same period. And, as mentioned above, 80 percent of residents overall received one type of psychotropic or another.⁷

In another Whac-A-Mole effect, the Inspector General noted significant increases in the identification of schizophrenia, which can be used by nursing facilities to justify antipsychotic use. This justification is relevant primarily for its effect on published quality measures. In 2012, the federal Nursing Home Compare website began publishing facility-specific quality measures for improper antipsychotic use. A facility's measure might report, for example, that the facility administered antipsychotics improperly to 20 percent of its short-stay residents and 28 percent of its long-stay residents; potential residents might choose against facilities with higher percentages. The impact of these quality measures was amplified in 2015, when the Centers for Medicare & Medicaid Services (CMS) incorporated the antipsychotic measures into the algorithm that determines a facility's star rating (from one to five stars).

The intent of the quality measures and star ratings is, of course, to reduce antipsychotic use. But the Inspector General found a significant negative effect as well. Under the measures, antipsychotic use is not counted against a facility if a resident is identified as having schizophrenia, Huntington's Disease or Tourette's Syndrome. After 2015 — when the star ratings algorithm first included antipsychotic use — the number of residents identified as having schizophrenia increased by a full 35 percent. In an even more dramatic post-2015 result, the study found an increase of 194% in residents who lacked a schizophrenia diagnosis but were nonetheless identified as having schizophrenia. Likewise, the New York Times in 2021 found a 70 percent increase in schizophrenia diagnoses in nursing facilities since 2012, leading to schizophrenia now being diagnosed in one of nine residents.

Such facility stratagems make any sense of progress more nebulous. Reduced antipsychotic use is good — but not if reduction comes from substituting other psychotropics or creating false diagnoses.

PAST AND ONGOING REFORM EFFORTS, AND THEIR LIMITATIONS

To be clear, previous and ongoing reform efforts have led to some progress. The Appendix summarizes significant activities and recommendations, including CMS's National Partnership to Improve Dementia Care in Nursing Homes (which began in 2012), multiple recommendations from the HHS Inspector General, and President Biden's

February 2022 reform proposal. Broadly speaking, reform efforts focus on educating health care providers, issuing deficiencies and penalties, publishing quality measures, and related strategies.

But, as detailed in the recent Inspector General's report, psychotropic use remains high. The continuing problem demands reexamining with a critical eye the reform initiatives' theories of change.

Notably, current strategies focus heavily on changing facility behavior. Aside from an Inspector General recommendation relating to care plans, however, none of the reform activities consider a resident's right to make decisions, assuming implicitly that a resident has no agency and no voice. The residents are to be protected, of course, but they are passive, with seemingly little to no influence over medications they receive.

Why have change-facility-behavior strategies fallen short? The focus on facility behavior faces a significant underlying problem: administration of antipsychotics (and other psychotropics) to nursing facility residents is not per se illegal. Antipsychotics are approved by the Food and Drug Administration (FDA) for use by persons with schizophrenia and certain other psychiatric conditions, and can also be prescribed "off-label" in other situations, at a physician's discretion.¹³

This is true even though the FDA has found an increased risk of death when antipsychotics are used to treat behavioral disorders in "elderly patients." In these situations, the FDA merely requires a "black box" warning label to inform pharmacists, physicians and others that the medication is not approved for the treatment of behavioral disorders, and also may increase the risk of death.¹⁴

Like the FDA rules, CMS's nursing facility regulations also rely heavily on physician discretion. If a resident has not previously received a psychotropic, the medication cannot be administered unless it is "necessary to treat a specific condition as diagnosed and documented in the clinical record."15 If a resident already is receiving a psychotropic, the facility must provide "gradual dose reductions, and behavioral intervention, unless clinically contraindicated, in an effort to discontinue" the medication.¹⁶

In addition, the nursing facility regulations provide a right against "chemical restraints," which can be understood as a medication used to control a resident's behavior. Specifically, a resident has a right to be free of "chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms."17 When chemical restraints are employed, "the facility must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints."18

The discretion given to physicians and facilities seriously limits CMS's ability to assess deficiencies or penalties for overmedication. In order to prove a regulatory violation, a surveyor must develop evidence that a resident received an antipsychotic or other psychotropic medication, and the medication was not necessary to treat a diagnosed condition, or was imposed for discipline or convenience. This is not necessarily an easy task, particularly when the resident's physician may be prepared to vouch for a medication's efficacy.

And, if enforcement is stymied, efforts to change facility behavior then may depend on education and persuasion. The worst facilities, however, seem unaffected by appeals to their better nature.

REFORM THROUGH RECOGNIZING RESIDENTS' **DECISION-MAKING RIGHTS**

Medication Administration Procedures

Basic medication procedures apply both inside and outside nursing facilities. Some medications can be obtained over the counter; others require a prescription from a physician or other qualified health care provider. A nurse or other health care provider can administer medication only with the patient's "informed consent." 19

The informed consent process will be familiar to anyone who has ever received a flu shot (for example). Under informed consent protocols, a health care provider gives an explanation of a medication's benefits and potential negative consequences; then, medication is administered only if and after the patient affirmatively consents.

How Medication Administration Procedures Fall Short in **Nursing Facilities**

In a nursing facility, at least two persons must agree on a medication's value: the resident's physician and the resident (or representative). Administration of harmful medications means that some combination of the following is occurring:

- Physicians are making poor decisions;
- Residents are making poor decisions;
- Facilities are administering medication without physician authorization; or
- Facilities are administering medication without residents' informed consent.

Each of these possibilities deserves attention, but this issue brief focuses primarily on the final scenario because evidence suggests that nursing facility residents indeed are being medicated without consent. In California, facilities failed to comply with informed consent requirements in 48 percent of investigated incidents of antipsychotic use.²⁰ Furthermore, as detailed in the Appendix, policy discussions have virtually ignored the informed consent requirement. Additionally, in regard to current practices, the 856-page CMS Surveyor's Guidance tellingly uses the term "informed consent" only nine times ... and seven of those mentions pertain to bed rails. The remaining two mentions of "informed consent" occur in reference to experimental research, and within a discussion of a facility's obligation to provide written materials in a resident's language. 21 By contrast, the Guidance's 31-page discussion of psychotropic medication does not use the term "informed consent" even once.²²

Importance of Recognizing Residents' **Decision-Making Rights**

For multiple reasons, the regulatory system would benefit from increased focus on residents' decision-making rights. The current enforcement system depends

CMS guidance on psychotropics does not say "informed consent" even once.

on surveyors first identifying use of a potentially improper psychotropic, and then unearthing evidence that the medication was not used to treat a diagnosed condition. If, on the other hand, informed consent requirements were honored and enforced, residents and their representatives could address whether a medication was "needed" in deciding whether to give consent, presumably preventing much improper administration of medication in the first instance. If and when residents nonetheless received improper psychotropics—due to the facility violating informed consent requirements, or under other fact patterns—surveyors would retain current authority to impose sanctions.

(Other reform proposals might strengthen FDA guidance and CMS regulations to facilitate enforcement actions against psychotropic misuse.)

Change will require CMS and other stakeholders to recognize current procedures' implicit prejudice. In general, CMS and other stakeholders proceed as if nursing facility residents cannot make personal decisions. Consider the various initiatives to reduce psychotropic use in nursing facilities, as detailed in the Appendix. The proposals largely ignore residents' decision-making rights, implicitly assuming that

With informed consent, residents and representatives could decide up front whether medication was needed.

facilities and/or physicians have authority to impose psychotropics. Consequently, the initiatives call for educating health care professionals, improving data on medications and diagnoses, and similar activities.

A thought experiment illustrates the problem. Assume that the HHS Inspector General has discovered overmedication of hospital patients. Would CMS respond by increasing training of hospital staff, and requiring that medication payment claims include diagnoses? Or would CMS and other parties automatically look to informed consent and patient choice as a key factor in addressing the problem? As a reference point, consider how public policy discussions routinely recognize rights of psychiatric hospital patients to refuse unwanted psychotropics.²³

Notably, federal nursing facility regulations emphasize the primacy of resident's decision-making in other important situations. Most prominently, the resident (or resident's representative) participates within an interdisciplinary team to create the resident's comprehensive care plan.²⁴ Similarly, a resident (or representative) has the "right to be informed in advance, by the physician or other practitioner or professional, of the risks and benefits of proposed care, of treatment and treatment alternatives or treatment options and to choose the alternative or option he or she prefers."²⁵ And consistent with these resident-focused provisions, the regulations were amended in 2016 to add an emphasis on "person-centered care," which "means to focus on the resident as the locus of control and support the resident in making their own choices and having control over their daily lives."²⁶

It is time for CMS and other stakeholders to live up to the declared goal of person-centered care. Like any other adult, a nursing facility resident has the right (potentially through a representative) to decide whether to accept a psychotropic medication. Because that right has been largely ignored, nursing facility residents have been overmedicated for decades. A greater focus on residents' decision-making rights would honor residents' dignity while allowing for more efficient enforcement of the requirement that medication treat a diagnosed need.

Steps to Implement Informed Consent Requirements

Informed consent requirements have previously been asserted to protect nursing facility residents from overmedication. In 2014, for example, a California trial court approved settlement of a case against a nursing facility based on allegations that residents had been medicated with psychotropics without consent.²⁷ On a legislative front,

It's time for CMS and other stakeholders to live up to the declared goal of person-centered care. the California legislature in 2022 enacted legislation formalizing informed consent requirements for psychotropic medications in nursing facilities, including requirements that residents and representatives be informed of any black-box warnings.²⁸

Informed consent requirements also have been proposed at the federal level. During initial development of the federal nursing facility regulations

in 1992, proposed regulations required a nursing facility to "[o]btain the written consent of the resident or the resident's legal representative" for use of psychotropic medication, but this provision was not included in the final regulations.²⁹

Residents must receive adequate written information, with medication administered only with a resident's written consent.

The current problem requires a national solution. To limit misuse of psychotropics, the federal government and nursing facilities should revise policies so that 1) residents receive adequate written information regarding a proposed medication's benefits and risks and 2) medication is administered only with a resident's written consent.

Implementing informed consent procedures undoubtedly will present some challenges. For one, informed consent and drug warnings are generally under

the jurisdiction of the states and the FDA, respectively. Any policy initiatives from CMS would have to consider jurisdictional issues and, as necessary, facilitate collaboration between the various governmental entities.

But implementation of any CMS policy involves challenges, and the challenges referenced above are hardly insoluble. Change is needed now: as discussed, current reform proposals suffer from tunnel vision that ignores residents' decision-making rights. As a first step, CMS and stakeholders should examine how informed consent is being honored (if at all) in nursing facilities currently, and consider how to incorporate informed consent principles into nursing facility operations.

CONCLUSION

Why is psychotropic use so persistently high in nursing facilities? One big reason: CMS, nursing facilities, and other stakeholders are ignoring residents' decision-making rights.

Implicit prejudice against nursing facility residents accounts for the current state of affairs. Persons should not lose their rights when they move into a nursing facility. Consistent with person-centered care principles, residents should never receive psychotropic medication unless and until they receive written notice of benefits and risks, and then consent to the medication in writing.

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APPENDIX

FEDERAL STRATEGIES TO REDUCE **PSYCHOTROPIC USE**

National Partnership to Improve Dementia Care in Nursing Homes

Since 2012, CMS has operated a National Partnership to Improve Dementia Care in Nursing Homes, with a primary focus on reducing antipsychotic use. As originally devised, the Partnership included a variety of activities, including trainings, research, public awareness campaigns, regulatory oversight, and public reporting of facility quality measures. The "Partnership" consisted of envisioned collaboration between stakeholders including federal and state agencies, nursing facilities, provider associations, and consumer advocates.³⁰

Activities from 2012-14

From 2012 to 2014, CMS convened a technical expert panel, worked to develop coalitions in every state, and conducted regular conference calls with states, consumer advocates, and state coalitions. CMS increased outreach to nursing facilities, hospitals, other health care providers, and health care professional associations. Comparable educational efforts were pursued by Quality Improvement Organizations as part of an official scope of work.³¹

During this same period, the Partnership identified facilities that had shown little or no reduction in antipsychotic use; for some of those facilities, outreach included peer-to-peer mentoring on potential structured programs. Similarly, the Partnership targeted such poor performers for informative/encouraging e-mails and letters from state survey agencies, CMS regional offices, or professional organizations.³²

The Partnership also developed a website, along with two toolkits for nurse aides on caring for residents with dementia. Three training videos were developed for state surveyors; in the same vein, CMS revised the Surveyor's Guidance to flag the inappropriateness of antipsychotic use as a "quick fix" for perceived behavioral problems. 33

CMS also began public reporting of facility antipsychotic use on the Nursing Home Compare website, separated into measures for short-stay and long-stay residents. To highlight these quality measures, CMS sent quarterly updates with national and state averages, along with individual facility measures, to leaders of state coalitions, as well as many professional associations.³⁴

Finally, the Partnership supported new or continued research on nursing facility care and antipsychotic use. This included researching the reasons for antipsychotic use, and how and when surveyors issue citations for improper antipsychotic use.35

Activities from 2014-16

As before, CMS supported state coalitions, conducted national conference calls with providers, and distributed training materials for nurse aides. Along with a provider association, CMS maintained a dedicated website for Partnership-developed resources. On the Nursing Home Compare website, the short-stay and long-stay antipsychotic quality measures were incorporated into the algorithm for setting a facility's star rating.³⁶

CMS also developed a Focused Dementia Care Survey to look more closely at how the antipsychotic problem is addressed by inspections and citations.³⁷ These survey protocols include examination of facility processes for dementia care, and how facilities code resident conditions in the Minimum Data Set (MDS) assessment document.³⁸

Activities from 2017 through the Present

Beginning in 2017, CMS refocused the Partnership to address antipsychotic administration in so-called "late adopters" — facilities with persistently high levels of antipsychotic use. CMS expanded oversight and enforcement actions related to antipsychotic use, and conducted "outreach" to corporations with control of a significant number of the late adopters.³⁹

From 2020 into 2022, for understandable reasons, CMS's nursing facility policy initiatives focused largely on responding to COVID-19. As the pandemic receded, in mid-2022, CMS revised the Surveyor's Guidance to direct surveyors' attention to the potential misuse of schizophrenia diagnoses. In a similar vein, the guidance now instructs surveyors that certain medication other than psychotropics should nonetheless be treated as a psychotropic, because that "other" medication affects brain activity and can have adverse consequences. 40

Reports and Recommendations from HHS Inspector General Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents (2011)

In this report, after documenting overuse of antipsychotics in nursing facilities, the Inspector General made three recommendations to CMS on how to reduce improper use of antipsychotics. CMS agreed with two of the recommendations: to assess whether survey and certification processes are adequate to address improper use of antipsychotics, and explore alternative methods of accomplishing the same goal. By beginning the Partnership the following year, CMS arguably addressed each of these recommendations.⁴¹

The Inspector General made a third, similarly broad recommendation — to "[f]acilitate access to information necessary to ensure accurate coverage and reimbursement determinations" — but CMS did not concur. Implementation of this recommendation would require that diagnoses be linked to medication payment transactions but, as CMS argued, diagnoses are not included in prescriptions nor required for pharmacy billing transactions. 42

Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic **Drugs** (2012)

The 2012 report focused on nursing facility care plans. Under federal nursing facility law, an individual resident's care must be based on a care plan developed by a small "team" including nursing facility staff, the resident's physician, the resident (or resident's representative), family members, and others. ⁴³ Care plan development is informed by the MDS assessment of the resident's condition and needs.⁴⁴

The Inspector General found frequent noncompliance with these requirements in relation to antipsychotic use, with three corresponding recommendations. First, the Inspector General recommended that CMS strengthen detection of violations relating to assessments and care plans. For example, CMS could require that facilities document efforts to include residents and family members in care planning. CMS also could target the survey process on a small subsample of residents receiving antipsychotics.⁴⁵

Second, the Inspector General recommended that CMS increase penalties for violations of the assessment and care planning requirements. CMS also could "explore alternative methods," such as incentive programs for physicians, and introduction of quality measures relating to assessments and care plans. 46

Third and finally, the Inspector General recommended that CMS "provide methods" to improve the usefulness of assessments and care plans for residents receiving antipsychotics. Suggested strategies included a task force to develop best practices, greater access to mental health professionals, and staff training on "the importance of care plan interventions."47

CMS concurred with each of the three recommendations, relying primarily on its intention to modify Surveyor's Guidance accordingly. In addition, CMS noted its intention to add the antipsychotic-use quality measure to Nursing Home Compare, and what CMS described as a pre-existing multidisciplinary approach to reducing antipsychotic use.48

CMS Could Improve the Data It Uses to Monitor Antipsychotic Drugs in Nursing Homes (2021)

By using Medicare claims data, the Inspector General found that, of residents with a schizophrenia diagnosis, almost one-third had no evidence of that diagnosis in their Medicare claims history. Accordingly, CMS undercounts antipsychotic use by relying almost exclusively on facility-reported MDS data, rather than incorporating claims data.⁴⁹

Consistent with these findings, the Inspector General recommended that CMS consider using Medicare claims data to improve reporting of antipsychotic use and verify MDS assessments. CMS concurred with both recommendations, although its concurrence related only to a commitment to "consider" the Inspector General's suggestions.50

Long-Term Trends of Psychotropic Drug Use in Nursing Homes (2022)

As discussed above, the Inspector General in this recent report found that reported decreases in antipsychotic use are offset by corresponding negative developments. Specifically, use of other psychotropics is increasing, as are diagnoses of schizophrenia.⁵¹

The Inspector General made three recommendations. First, CMS should consider additional actions to limit inappropriate use of psychotropics. CMS could better monitor anticonvulsant use, and consider using Medicare claims data to identify dubious schizophrenia diagnoses. Second, CMS should increase focused oversight on outlier poor-performing facilities.⁵²

Finally, the Inspector General reiterated a recommendation from its 2011 report: that "CMS facilitate access to information necessary to ensure accurate coverage and reimbursement determinations." As a first step, the Inspector General suggested a pilot program to include a diagnosis code on Medicare claims for psychotropic medications prescribed to nursing facility residents.⁵³

CMS concurred with the first two recommendations, but not the third. In rejecting the third recommendation, CMS stated that the prescription protocols are controlled by state law, and a diagnosis requirement for Medicare claims might lead to more rejected claims, and a concomitant delay in providing Medicare recipients with needed medication.54

President Biden's 2022 Initiative

In February 2022, President Biden announced a nursing facility reform initiative that included a proposal to "reinforce safeguards against unnecessary medications and treatments." The initiative fact sheet cited a "dramatic decrease" in antipsychotic use due to the Partnership, but also reported that "inappropriate diagnoses and prescribing" remained much too common. To address the continuing problem, the initiative commits CMS to "launch a new effort to identify problematic diagnoses and refocus efforts to continue to bring down the inappropriate use of antipsychotic medications."55

ENDNOTES

- 42 C.F.R. § 483.45(c)(3).
- See, e.g., FDA, FDA Public Health Advisory: Deaths with Antipsychotics in Elderly Patients with Behavioral Disturbances (April 11, 2005); Raya Elfadel Kheirbek et al., Association Between Antipsychotics and All-Cause Mortality Among Community-Dwelling Older Adults, J. of Gerontology: Series A, Vol. 74, No. 12, at 1916-21 (Dec. 2019); Human Rights Watch, They Want Docile (2018).
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- 4 HHS OIG, Long-Term Trends of Psychotropic Drug Use in Nursing Homes, OEI-07-20-00500, at 9-10 (Nov. 2022).
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- 42 C.F.R. § 483.45(e)(1).
- 42 C.F.R. § 483.45(e)(2).
- 42 C.F.R. § 483.10(e)(1); see also 42 C.F.R. § 483.12(a)(2) (almost identical language).
- 42 C.F.R. § 483.12(a)(2).
- See, e.g., Cobbs v. Grant, 502 P.2d 1, 11 (Cal. 1972) (right to make health care decision "can be effectively exercised only if the patient possesses adequate information to enable an intelligent choice"); David M. English et al., Tax, Estate & Financial Planning for the Elderly § 14.03.
- California Dep't of Public Health and California Dep't of Health Care Services, Executive Report of Antipsychotic Collaborative, at 6 (May 31, 2012).
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- Id. at F-Tag F757, at 556-86 (accessed Dec. 14, 2022).
- See, e.g., Rennie v. Klein, 462 F. Supp. 1131 (D. N.J. 1978) (right to refuse psychotropic medication in "state mental institution").
- 42 C.F.R. §§ 483.10(c)(2)-(3), 483.21(b).
- 25 42 C.F.R. § 483.10(c)(5).
- 42 C.F.R. § 483.5(b).
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- *Id.*at 19 (April 1, 2014).
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- 43 42 U.S.C. §§ 1395i-3(b)(2)(B), 1396r(b)(2)(B); 42 C.F.R. § 483.21(b).
- 42 U.S.C. §§ 1395i-3(b)(3), 1396r(b)(3); 42 C.F.R. § 483.20.
- HHS OIG, Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs, at 17 (2012).
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- 48 Id. at 19 (2012).
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- 50 *Id.* at 11, 15-18 (May 2021).
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