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Recent OIG Report May Lead to Increased Scrutiny of Antipsychotic Drug Prescriptions in Nursing Facilities

There are many reasons why the Centers for Medicare & Medicaid Services (CMS) may increase its scrutiny of a particular practice in nursing homes, and the survey/enforcement actions that frequently follow. Among the primary origins is a recommendation from the Office of Inspector General (OIG) to CMS after conducting an integrity and efficiency assessment of CMS's administration of a particular area.

This Client Alert will (a) outline how this process generally works from start to finish, and (b) discuss a recent OIG report, its recommendations, and the important implications for nursing home operators.

What is the OIG?

All healthcare providers are aware of the function of CMS and the scope of its oversight authority. However, many may not know much about the OIG.

The OIG is the internal oversight arm of the federal government. Its goal is to audit, investigate, and identify any waste, fraud, abuse, and other forms of inefficiencies across the federal programs. The OIG has 75 branches, each with its own oversight scope and responsibilities. The largest is the OIG for the Department of Health and Human Services (HHS), which is tasked with overseeing HHS's multi-trillion-dollar collection of programs, including CMS.

While CMS has its own review and audit processes to ensure providers and beneficiaries are complying with its rules, the OIG is tasked with oversight of CMS itself and how it is administering its own programs. In essence, the OIG serves as the watchdog of the watchdog.

How The OIG's Oversight Affects Healthcare Providers

The OIG has some direct authority over providers, which mostly takes the form of imposing civil monetary penalties against noncompliant providers and/or excluding them from CMS programs subsequent to an OIG audit. However, the OIG's influence on providers more often comes indirectly, via its recommendations to CMS on how to improve provider compliance and program administration. Specifically, whenever an OIG review uncovers areas of concern, the OIG will submit a report to CMS that includes its factual findings and formal recommendations on the issues identified. This report oftentimes will affect providers, as it frequently encourages CMS to conduct targeted reviews of providers on related compliance issues. This in turn may lead to increased CMS audits of providers, and ultimately enforcement actions for any perceived violations, including prosecutions by the U.S. Department of Justice for more serious violations.

The OIG recently submitted one such report to CMS that may put nursing home operators on notice that targeted reviews of their antipsychotic prescription practices could be coming down the road.[i]

History of Antipsychotics in Nursing Homes

Why the OIG focus on antipsychotics? There's some important history:

In a skilled nursing setting, antipsychotics are intended to control behavioral and psychological symptoms for residents suffering from forms of psychoses. However, antipsychotics can equally control aggression, agitation, irritability, and wandering in residents suffering from a different condition with similar symptoms, such as dementia.

As such, medical staff on the ground at a nursing facility may consider using antipsychotics as an off-label treatment for residents with serious dementia symptoms, and perhaps even as a chemical restraint in particularly extreme situations.

However, this does not come without a cost: the potential severity of antipsychotics' side effects among the elderly led the U.S. Food and Drug Administration (FDA) to institute a "black-box warning" in 2005 for atypical antipsychotics, which the FDA then expanded in 2008 to include all antipsychotic medications.[ii]

Despite the FDA's warning, by 2011, the rate of off-label antipsychotic prescriptions for long-stay nursing facility residents with dementia was 23.9%.[iii] There has even been an informal

consensus in certain medical circles that antipsychotics indeed could be used as a first-line treatment for some individuals with severe forms of dementia.[iv]

Nonetheless, by 2015, given the potential for negative side effects and to discourage off-label use, CMS formally updated its Five Star Quality Rating System to include specific quality assessments of antipsychotic prescription practices for nursing facility residents. Specifically, CMS began utilizing each facility's Minimum Data Set (MDS) to assess the total antipsychotic prescriptions in a facility, and then published these statistics in Care Compare and the Star Rating System. However, CMS excluded from this quality assessment antipsychotic prescriptions for residents with MDS-reported diagnoses of schizophrenia, Huntington's disease, or Tourette's syndrome.[v]

At the start of the year, CMS indicated that they would be increasing their efforts to reduce antipsychotic prescriptions in nursing homes.[vi] The OIG recently reviewed CMS' administration of these quality assessments for antipsychotic prescriptions in nursing homes, and submitted a report to CMS with its findings and recommendations (the "Issue Brief").

The OIG Finds Discrepancies in MDS Data

CMS gauges the level of antipsychotic prescriptions in a nursing facility based on only the self-reported data of the MDS. As part of its review, the OIG utilized corresponding Medicare Part D claims for pharmaceuticals as a second data source to compare against the MDS's data. In so doing, the OIG found that the MDS did not always result in a complete assessment of the number of residents who were prescribed antipsychotic drugs.

Specifically, the OIG found that:

(a) In 2018, 12,091 Part D beneficiaries who were long-stay residents age 65 and older—5% percent of all such beneficiaries—had a Medicare Part D claim for an antipsychotic drug that had not been reported in the MDS;[vii]

(b) There were 98,227 residents age 65 and older whom nursing homes reported as having schizophrenia (a diagnosis that is excluded from CMS's quality assessment of antipsychotic prescriptions for a facility). However, 29,617 (30 percent) of those residents had no record of a schizophrenia diagnosis in any of their 2017 or 2018 Medicare claims history;[viii] and

(c) These discrepancies were concentrated in specific facilities, with 52 homes having greater than 20% of their residents reported with inconsistent data.[ix]

An Innocuous Explanation

The Issue Brief implicitly indicated that innocent reasons may explain some of the discrepancies: CMS calculates the percentage of nursing home residents receiving antipsychotics by reviewing the number of days a resident received an antipsychotic during the 7 days preceding the MDS assessment.

Given the brevity of this 7-day window and the lengthy intervals between MDS assessments, the reporting structure itself could inherently lead to discrepancies in antipsychotic data during a given period.[x]

A Less Innocuous Explanation

However, the Issue Brief also implicitly indicated that another reason may explain these discrepancies, which should raise red flags for nursing home operators: some facilities may still be prescribing antipsychotics for their off-label use to residents who do not actually suffer from a psychosis, perhaps even as a chemical restraint in extreme circumstances. Facilities then may be underreporting the prescriptions and/or inaccurately reporting the residents as schizophrenics on the MDS, each to reduce the level of antipsychotics from the quality assessment. Doing so would avert the harm to the facilities' rating that comes from higher levels of antipsychotic prescriptions.[xi]

The OIG's Recommendation

The Issue Brief recommended that CMS (1) take additional steps to validate the information reported in MDS assessments, and (2) supplement the data it uses to monitor the use of antipsychotic drugs in nursing homes.

Potential CMS Scrutiny and Enforcement

CMS agreed with the OIG's recommendation. As such, CMS may start increasing scrutiny of discrepancies between MDS data and Medicare Part D claims – indications that antipsychotic prescriptions are being underreported. CMS also may start increasing scrutiny of schizophrenia diagnoses and/or antipsychotic prescriptions for residents without a history of schizophrenia – indications that antipsychotics are being mis-prescribed.

Range of Penalties

42 CFR §483.45 governs facilities' compliance obligations for its pharmaceutical practices. This regulation prohibits unnecessary drug prescriptions, including the misuse of antipsychotics. In survey settings, violations could lead to F-Tags 755 (Licensed Pharmacist Consultation), 756 (Drug Regimen Review) 757 (Unnecessary Drugs), and 758 (Psychotropics).[xii] Depending on the severity level for each violation, civil monetary penalties could reach $10,000/day or instance.[xiii] Moreover, inaccurately reported MDS data is subject to a 2% reduction in a facility's APU, and there may be two improper entries at play: underreporting antipsychotic use and misreporting residents as schizophrenics.[xiv]

Notably, effective July 16, 2021, the Biden administration encouraged state survey agencies to resume favoring per-day penalties over per-instance penalties, reversing what had been the Trump administration's policy.[xv] As per-day penalties often apply retrospectively, they tend to yield larger fines than per-instance penalties for the same violations. Consequently, longtime violations – such as ongoing noncompliant drug prescription practices – now may be particularly vulnerable to significant monetary penalties under the new administration.

Furthermore, Medicare Part D covers a drug only if it is used for an FDA-approved use, or supported by a citation in one of the medical compendia relied upon by the Medicaid program.[xvi] Consequently, knowingly submitting a claim for reimbursement of an antipsychotic prescribed for an off-label use, or that was not medically necessary, also may lead to liability under the False Claims Act (FCA).[xvii] Liability under the FCA is between $11,665 to $23,331 for each false claim, plus triple the amount of the government's damages; self-disclosure of an FCA violation under certain conditions may result in not less than double damages.[xviii] Also, risks increase in proportion to the ease with which a *qui tam* claim may be filed under the FCA by a whistleblower, who can receive up to 25% of any government recovery should the government intervene, and up to 30% if the government declines to intervene.[xix]

Bottom Line Takeaways

Provider noncompliance with antipsychotic requirements is on the government's radar, as well as journalists'. The New York Times reported in detail on this very issue recently, and noted that, according to CMS spokeswoman Catherine Howden, CMS is "concerned about this practice" being used to "circumvent" CMS' system of protections. Howden further stated that "[i]t is unacceptable for a facility to inappropriately classify a resident's diagnosis to improve their performance measures," and that CMS "will continue to identify facilities which do so and hold them accountable."[xx]

Given the potential for significant liability, nursing home operators would be well advised to confirm that best practices are being implemented in this area. A good start may be:

1. Ensuring all compliance systems are in place to accurately report all antipsychotic drug use on each MDS;
2. Reminding clinical staff that they must strictly adhere to all compliance criteria when diagnosing residents with schizophrenia;
3. Implementing compliance safeguards to protect against any off-label prescription of antipsychotics, especially as unnecessary chemical restraints for residents; and
4. If needed, self-disclosing to the government any claim for reimbursement for antipsychotics that was not fully compliant with all applicable CMS requirements.

The Firm

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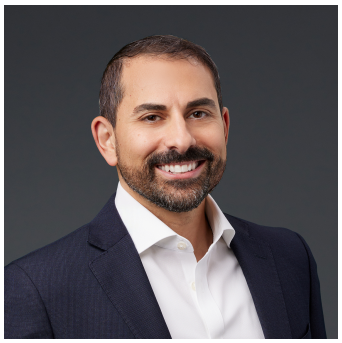
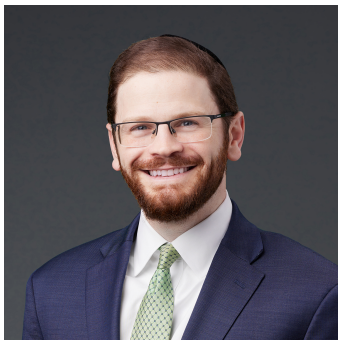


Aharon S. Kaye is the head of the firm's Litigation practice. He regularly represents corporations and individuals in complex civil and criminal cases involving false claims, fraud, tax, antitrust, securities, consumer fraud, health care, Medicare/Medicaid, partnership and business disputes, enforcement and defense of restrictive covenants, disputes arising out of the purchase and sale of businesses and securities, business valuations, and contracts.



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Endnotes

[i] U.S. Department of Health and Human Services, Office of Inspector General, OEI-07-19-00490, CMS COULD IMPROVE THE DATA IT USES TO MONITOR ANTIPSYCHOTIC DRUGS IN NURSING HOMES (May 2021). Available at: https://oig.hhs.gov/oei/reports/OEI-07-19-00490.pdf

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[v] New England Quality Innovation Network-Quality Improvement Organization. Understanding the new MDS 3.0 quality measures: February 2018. Available at: https://healthcarefornewengland.org/wp-content/uploads/QM_Manual_FINAL_022018.pdf

[vi] *See* January 8, 2021 CMS Mission & Priority Document, pp. 35, 41. Available at: https://www.cms.gov/files/document/fy-2021-mpd-admin-info-20-03-all.pdf.

[vii] OEI-07-19-00490, *supra* note 1, at 6.

[viii] *Id*. at 7.

[ix] *Id*. at 7-8.

[x] *Id*. at 6.

[xi] *Id*. at 5, 8, 9.

[xii] *See* State Operations Manual, Appendix PP - Guidance to Surveyors for Long Term Care Facilities (Rev. 173, 11-22-17).

[xiii] 42 CFR § 488.438.

[xiv] CMS, Skilled Nursing Facility Quality Reporting Program Help Desk, Question 1 (2019). Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/SNF-QRP-Quarterly-FAQ-Update-Q1-2019.pdf.

[xv] https://www.cms.gov/files/document/qso-21-20-nh.pdf

[xvi] 42 C.F.R. § 423.100.

[xvii] 31 U.S.C. §§ 3729(a)(1)(A) and (B).

[xviii] 31 U.S.C. §§ 3729(a)(1)(G) and (a)(2), as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990.

[xix] 31 U.S.C. §§ 3730(b) and (d).

[xx] https://www.nytimes.com/2021/09/11/health/nursing-homes-schizophrenia-antipsychotics.html