# PUBLICATION

## Enhancing Compliance in Nursing Facilities: OIG's New Guidance

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The Office of Inspector General (OIG) for the U.S. Department of Health and Human Services (HHS) issued new Nursing Facility Industry Segment-Specific Compliance Program Guidance (Nursing Facility ICPG) for nursing facilities and skilled nursing facilities on November 20, 2024. Factors that have motivated the Nursing Facility ICPG include long-standing challenges around staffing, infection control, emergency preparedness, employee background checks, reporting of adverse events experienced by residents, inappropriate use of medications, and other compliance and quality issues.

The Nursing Facility ICPG is the first industry-specific guidance published since the 2023 General Compliance **Program Guidance** (GCPG), which provided more general guidance to the entire health care compliance community. The Nursing Facility ICPG, together with the GCPG, serves as OIG's updated and centralized source of voluntary compliance program guidance for nursing facilities. This is the first update to OIG's nursing facility guidance since 2008.

The Nursing Facility ICPG describes risk areas for nursing facilities, recommendations and practical considerations for mitigating those risks, and other important information OIG believes nursing facilities should consider when implementing, evaluating, and updating their compliance and quality programs. Nursing facilities can use the Nursing Facility ICPG to help identify their own risks and implement an effective compliance and quality program to reduce those risks. The OIG also notes that the guidelines are not one-size-fits-all and must be tailored to the unique nature of each facility.

The Nursing Facility ICPG should not be considered in isolation but, rather, should be implemented with an eye toward earlier guidance issued by OIG in its 2000 Compliance Program Guidance for Nursing Facilities (the 2000 CPG) and 2008 Supplemental Compliance Program Guidance for Nursing Facilities (the 2008 Supplemental CPG). The Nursing Facility ICPG carries forward certain pertinent risk areas and relevant considerations from the 2000 CPG and 2008 Supplemental CPG. The OIG notes that the absence of a previously identified risk area or consideration in the Nursing Facility ICPG does not signal that a risk no longer exists, has become irrelevant, or is otherwise inapplicable. Rather, OIG further notes that nursing facilities may still wish to address the risk area or consideration in their compliance programs.

#### A Note About Assisted Living Facilities

While the Nursing Facility ICPG is primarily directed at skilled nursing facilities and nursing facilities, the OIG notes that other long term and post-acute care providers such as assisted living facilities should find the ICPG useful. However, the OIG recognizes that these providers may be subject to different laws, rules, and regulations. Accordingly, they may have different or additional risk areas and may need to adopt different compliance strategies. The OIG encourages all long term and post-acute care providers to establish and maintain effective compliance and quality programs.

#### **Key Highlights**

The Nursing Facility ICPG links fraud and abuse compliance, quality assurance, and regulatory adherence, signaling that these together can trigger False Claims Act investigations.

The Nursing Facility ICPG incorporates information and recommendations that are based on the OIG's: (1) findings and observations from decades of work on matters involving nursing facilities including audits, evaluations, investigations, enforcement actions, and monitoring of Corporate Integrity Agreements (CIAs); (2) legal actions initiated and investigated by the OIG and its government partners; (3) current enforcement priorities; and (4) interactions and discussions with owners, operators and leaders of nursing facilities, trade associations, resident advocacy groups, and other industry stakeholders.

The OIG emphasizes that the Nursing Facility ICPG and the GCPG (which provide voluntary, nonbinding guidance) are intended to complement the Compliance Program Requirements of Participation (ROPs) for long term care facilities in 42 CFR 483, Subpart B, which are mandatory for nursing facilities to participate in Medicare and Medicaid programs.

The Nursing Facility ICPG identifies the following key areas of compliance risk for nursing facilities:

## 1. Quality of Care and Quality of Life

Beyond the ROPs, the OIG notes that the failure to provide quality care and promote quality of life poses a risk of fraud and abuse for nursing facilities. When a nursing facility submits a claim to Medicare or Medicaid for reimbursement, the claim submission form includes certifications that the claimed services were provided in compliance with all applicable statutes, regulations, and rules. If a nursing facility fails to meet its obligations regarding the provision of care in accordance with professional standards of quality, or regarding the provision of services in an environment that promotes quality of life, claims for reimbursement may be considered false.

The OIG highlights the following common risk areas for nursing facilities associated with providing quality of care and quality of life for residents:

- Staffing levels, shortages, and competencies;
- Appropriate resident care plans and resident activities;
- Challenges due to demographic changes in the resident profile, higher resident acuity levels, and behavioral health issues;
- Medication management;
- Appropriate use of medications; and
- Resident safety.

Related to these risk areas, the OIG notes that nursing facilities should:

- Ensure regular, specific, and comprehensive training for all members of an organization on requirements of the ROPs relating to providing quality health care and promoting quality of life;
- Consistently, proactively, and continually assess the facility's compliance with the ROPs beyond addressing deficiencies cited in recent surveys relating to a particular ROP;
- Review OIG resources for recommendations about integrating compliance and quality oversight; and
- Monitor the OIG's nursing home featured topic page to remain informed about the OIG's audits, evaluations, and investigations addressing risk areas that are pertinent to the nursing facility industry, and to access reports that include practical recommendations for improving operational efficiencies and preventing fraud, waste, and abuse.

## 2. Medicare and Medicaid Billing Requirements

Ensuring compliance with Medicare and Medicaid billing requirements should be a core function of nursing facility compliance program operations. The OIG emphasizes that submitting a false claim or causing a false

claim to be submitted to a federal health care program may subject an individual, entity, or both to criminal prosecution, civil liability under the False Claims Act or Civil Monetary Penalties Law, and exclusion from participation in federal health care programs, as described in the GCPG. The OIG notes nursing facilities should take proactive measures to ensure compliance with program rules, including conducting regular reviews to ensure billing and coding practices are current and accurate, as well as performing regular internal billing and coding audits. The Nursing Facility ICPG reminds nursing facilities that even if an entity makes an isolated billing error, the entity still has an obligation to repay the overpayment to the government to avoid False Claims Act liability, as explained in the GCPG.

The Nursing Facility ICPG discusses some of the risk areas related to Medicare and Medicaid billing requirements for nursing facilities and recommendations for addressing those risks. It is intended only to assist nursing facilities in evaluating and mitigating their own particular risk areas. The list of risk areas is not exhaustive and includes:

- SNF Prospective Payment System (PPS);
- Value-Based Payment Models and Programs;
- Medicare Advantage and Medicaid Managed Care;
- Medicare Part D; and
- Medicare Health Plan Enrollment for Nursing Facility Residents.

### 3. Federal Anti-Kickback Statute

Nursing facilities must comply with the federal Anti-Kickback Statute at 42 U.S.C. § 1320a-7b(b). Although liability under the federal Anti-Kickback Statute depends in part on a party's intent, the OIG emphasizes it is incumbent on nursing facilities to identify arrangements with referral sources and referral recipients that present a potential for fraud and abuse under the federal Anti-Kickback Statute. The GCPG provides some illustrative questions to consider when attempting to identify problematic arrangements. Those questions – and appropriate follow-up questions – can help nursing facilities identify, address, and avoid potentially problematic arrangements.

The OIG highlights several risk areas for nursing facilities under the federal Anti-Kickback Statute and recommendations for mitigating those risks. Nursing facilities should scrutinize the specific risk areas as part of their risk assessment, internal review, and monitoring processes, considering this new guidance along with continued review of the OIG's 2000 and 2008 guidance, fraud alerts, advisory opinions, and related resources. The Nursing Facility ICPG offers specific guidance in key areas that are useful in evaluating and structuring arrangements to demonstrate compliance. Examples of where arrangements may be problematic are detailed in the ICPG.

The OIG identifies the following risk areas to be evaluated under the federal Anti-Kickback Statute:

- Free (or Below Fair Market Value) Goods and Services.
- Discounts (Price Reductions and Swapping):
  - The OIG notes that discounts should be considered in evaluating vendor contracts and Group Purchasing Organization arrangements. The OIG further notes that most discounts can be structured to meet the safe harbor to the federal Anti-Kickback Statute for discounts and that nursing facilities should structure their discount arrangements to meet the safe harbor whenever possible. To qualify for the safe harbor, the discount must be a reduction in the amount the nursing facility, i.e., the buyer, is charged for an item or service based on an arm's-length transaction. The discount also must be fully and accurately reported on the nursing facility's cost

reports (and in any claims as appropriate) filed with a federal health care program (among other requirements); and

- The OIG also emphasizes its ongoing concern about "swapping" arrangements wherein a nursing facility accepts a low price from a supplier or provider for an item or service covered by the nursing facility's Part A per diem payment in exchange for the nursing facility referring to the supplier or provider other federal health care program business. This can include a supplier charging below cost for items or services for which the nursing facility is responsible under Part A rates in exchange for referrals from the nursing facility to the supplier of Part B business that the supplier can bill directly.
- Arrangements for Services and Supplies.
- Long Term Care Pharmacy and Consultant Pharmacist Arrangements.
- <u>Hospital arrangements.</u> Considering the extensive referral relationships between nursing facilities and hospitals, the OIG notes that nursing facilities should carefully monitor any remuneration exchanged with hospitals to ensure the remuneration is not intended to induce or reward referrals. The OIG notes that payments to expedite admission of hospital patients to a nursing facility potentially pose federal Anti-Kickback Statute concerns, particularly in the following two scenarios: (1) a hospital offers (or a nursing facility solicits) payments to accept a discharged hospital patient; and (2) a hospital offers (or a nursing facility solicits) payments to reserve or hold beds to ensure that the nursing facility has sufficient capacity to accept the hospital's patients when the hospital needs to discharge patients to the nursing facility. Arrangements in connection with facilitated discharges and bed reservation agreements should be evaluated to consider the factors the OIG considers relevant, including whether they are part of a value-based care enterprise.
- Hospice Arrangements.
- Care Coordination and Value-Based Care Arrangements.
- <u>Joint Ventures.</u> The OIG acknowledges that nursing facilities often enter into "joint ventures," i.e., shared enterprises (through equity or by contract) to accomplish specific goals, with other health care entities. While the OIG has long recognized that there may be legitimate reasons to form a joint venture, such as raising necessary investment capital, the OIG emphasizes its longstanding and continuing concerns regarding certain problematic joint venture arrangements, including those entered into by nursing facilities and their ancillary service providers. The ICPG offers examples of problematic arrangements and offers compliance suggestions. This remains an area in which guidance from several sources is helpful, including without limitation, earlier compliance guidance, fraud alerts, advisory opinions, and other resources.

### 4. Other Risk Areas

The OIG describes certain other risk areas that nursing facilities should consider including in their compliance and quality training, risk assessment, internal review, and monitoring processes. Those risk areas include:

• <u>Related-Party Transactions.</u> The OIG expresses concern that nursing facility owners, operators, and private investors participating in related-party transactions may be engaging in "tunneling," i.e., the practice of misrepresenting or hiding profitability by overstating payments for operational expenses that are funneled to related parties. Tunneling in the nursing facility industry typically appears in: (1) real estate transactions when a nursing facility sells its building and land to a commonly owned company or real estate investment trust and then leases the property back at higher than fair market rates; and (2) arrangements for the outsourcing of administrative or management services with commonly owned companies under which the nursing facility pays higher than fair market rates for those services. The OIG notes that tunneling has broad implications for federal health care programs and enrollees if funds from related-party transactions are used to unjustly profit and enrich nursing facility owners, operators, and investors while allocations for resident care decrease.

- Physician Self-Referral Law.
- <u>Anti-Supplementation.</u>
- HIPAA Privacy, Security, and Breach Notification Rules.
- <u>Civil Rights.</u>

#### 5. Other Compliance, Quality, and Resident Safety Considerations

Because the risk areas and recommendations in the Nursing Facility ICPG are not exhaustive, OIG states that nursing facilities should closely review the GCPG and the Nursing Facility ICPG considering their own organizations' risk profile as they work to implement, evaluate, and update compliance program operations.

Expanding on the GCPG's recommendation that entities should incorporate quality and patient safety oversight into their compliance programs, as well as the GCPG's discussion regarding the responsibility of investors and governing bodies to ensure compliance with federal fraud and abuse laws, the OIG identifies in the Nursing Facility ICPG the following compliance, quality, and resident safety considerations for nursing facilities:

- Oversight Role of Responsible Individuals. OIG underscores that nursing facilities may be more successful in achieving compliance and quality objectives when OIG recommends that governing bodies, their members, owners, investors, operators, and executive leadership (collectively, Responsible Individuals) demonstrate their commitment to corporate-level compliance and quality. Responsible Individuals set an appropriate tone for an organization and demonstrate an interest in ensuring the quality of care and quality of life for residents and a supportive working environment for staff. The inclusion of investors as Responsible Individuals is of paramount importance. The OIG recommends that investors and all Responsible Individuals maintain as much of a focus on compliance, quality, and safety performance as on financial and profit indicators. The Nursing Facility ICPG provides specific guidance on available tools that can demonstrate the commitment of Responsible Individuals to compliance.
- <u>Compliance Officer Experience</u>. The OIG notes that nursing facilities should consider recruiting a compliance officer with sufficient experience in managing compliance programs and involvement with quality assurance efforts centered on quality of care, quality of life, and resident safety.
- Role of the Compliance Committee in Supporting Collaboration and Alignment Between Compliance and Quality Functions. The OIG emphasizes that the nursing facility's compliance committees should play a pivotal role in supporting collaboration and alignment between compliance and quality functions at nursing facilities and in assisting compliance officers in overseeing regulatory compliance.
- <u>Competency-Based Training.</u> The OIG stresses that nursing facilities should continually focus on ensuring that training achieves the competencies that are reflected in the regulations and that all staff have the knowledge, skill, and ability to support the delivery of high-quality care and to promote quality of life through the performance of individual job responsibilities.
- <u>Risk Assessment, Internal Review, and Monitoring Processes.</u> The OIG indicates each nursing facility develop and implement a centralized annual risk assessment, internal review, and monitoring process to identify and address risks associated with the nursing facility's participation in federal health care programs, including risk areas discussed in this Nursing Facility ICPG.
- <u>Reporting Requirements.</u> OIG stresses that a nursing facility's compliance and quality programs should coordinate efforts and provide regular comprehensive training to all staff to ensure a high level of integrity and accuracy in compiling and calculating data the facility provides to meet all reporting obligations.

#### **Practical Takeaways**

- Although the Nursing Facility ICPG is considered voluntary, it will likely be considered the minimum standard for nursing facility compliance programs going forward.
- Nursing facilities' compliance teams should review and reference the Nursing Facility ICPG when assessing whether their current program conforms with the OIG's expectations.
- While the Nursing Facility ICPG speaks directly to owners and operators of nursing facilities, it also provides guidance to hospitals and contractors that work with nursing facilities and their patients.
- The updated guidelines reflect the growing commitment by the government to use fraud allegations as a means of addressing what it perceives as sub-quality care.
- This guidance may serve to enable later arguments to soften some relatively high legal thresholds for "worthless services" cases in the various Circuits as well as help bolster *Escobar*-type certification legal theories under the False Claims Act by memorializing agency guidance and understanding, as well as putting owners and operators on notice of such informal interpretation.

For assistance in evaluating and enhancing your current compliance program, developing a compliance program, or for more information on the Nursing Facility ICPG, please contact Howard L. Sollins, Thomas H. Barnard, Mary Grace Griffin, or the Baker Donelson Health Law team member with whom you typically work.