Quality of Care Considerations in OIG's Nursing Facility Compliance Guidance

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In November 2024, the U.S. Department of Health and Human Services' Office of the Inspector General ("OIG") published the long-awaited Industry Segment-Specific Compliance Program Guidance for Nursing Facilities ("Nursing Facility ICPG" or "ICPG"). Of the many compliance risk areas addressed in the ICPG, this article focuses on key takeaways and practical implications from the ICPG's discussion of quality of care as a compliance concern. The guidance, as written, is a voluntary, nonbinding tool to assist facilities in reducing risks related to fraud, waste, and abuse. Experience dictates that the Government may rely on the guidance as binding, and as a basis for investigations and enforcement actions, which underscores the need to understand the ICPG.

The Nursing Facility ICPG is especially important for the "Responsible Individuals" of a nursing facility. Responsible Individuals include governing bodies, their members, owners, operators, and executives. The ICPG emphasizes that investors, where applicable, are also considered Responsible Individuals. The Responsible Individuals of a nursing facility should be aware of the Government's focus on quality of care as a compliance concern and the associated risks under the False Claims Act. A facility's decision to self-report potentially substandard care under the False Claims Act is not as straightforward as the ICPG might suggest, and involvement by experienced counsel in these circumstances is critical.

Investors should especially note that there has been a focus on the "for-profit" impact on quality of care in nursing and other facilities. For example, in 2021, the Massachusetts Attorney General reached a $25 million settlement with private equity firms in a false claims matter based on services provided by unlicensed, unqualified, and improperly supervised staff.[1] More recently, on January 7, 2025, the U.S. Senate Budget Committee issued a scathing report concluding that certain private equity firms' involvement in health care led to poor outcomes and conditions.[2] We expect this to be a continuing area of focus.

It is important to note that the Nursing Facility ICPG is distinct from the Centers for Medicare and Medicaid Services' Requirements of Participation ("ROPs"), which are mandatory for nursing facilities to participate in the Medicare and Medicaid programs. The ICPG is meant to complement the ROPs and the ROPs are mentioned throughout the ICPG.

QUALITY OF CARE AND QUALITY OF LIFE

The ICPG addresses the following topics related to qualify of care: (1) staffing levels and competencies; (2) resident care plans and activities; (3) challenges presented by resident demographics, higher acuity levels, and behavioral health issues; (4) medication management and appropriate use of medications; and (5) resident safety.

Staffing Levels and Competencies

When staffing is so low or training is so deficient that it leads to "grossly" substandard care and poor clinical outcomes, the Government may bring an enforcement action. In recent years, OIG, the Department of Justice, and their state agency partners have focused on quality-of-care issues, including the provision of allegedly substandard or inappropriate care. The underlying theories include that the services rendered were "worthless" under the law or were not provided in compliance with laws applicable to nursing facilities.

Inadequately trained or supervised staff may also lead to allegations of substandard care. According to the ROPs, nursing facilities are required to provide the necessary care and services to attain or maintain the best possible physical, mental, and psychosocial wellbeing of each resident, including ensuring that residents receive treatment and care in accordance with professional standards of practice. The Government's flexibility in enforcing such a vague standard should be of concern to providers.

Related to staffing standards, on May 10, 2024, CMS published a Final Rule that requires each nursing facility to have certain minimum staffing levels to reduce the risk of substandard care. Local laws may require higher staffing levels. These regulations are much more concrete than the ICPG. However, while minimum standards are prescribed by these regulations, the ICPG makes clear that facilities are required to staff their resident population based on resident acuity and the skill of staff needed to care for those residents—which may require staffing hours that exceed those minimums. The ICPG encourages facilities to seek input from employees to help account for any gaps in skill or additional resources needed to appropriately care for residents. Where feasible, routinely assigning the same staff to particular residents may promote quality of resident life.

The ICPG also emphasizes the importance of proper recruitment and retention of nursing leadership, particularly directors of nursing. The guidance recommends that, to improve recruitment and retention efforts, facilities endeavor to offer competitive salary, bonus, and benefits packages, and routine recognition of staff members' outstanding performances. A satisfied workforce can also mitigate the likelihood of personnel issues contributing to lapses in quality care.

Appropriate Resident Care Plans and Resident Activities

The ICPG expresses concerns that nursing facilities are failing to develop, implement, and operationalize sufficient care plans. In addition, significant care plan deviations pose a compliance risk that providers should be aware of, especially where such deviations contribute to resident harm and may lead to substandard care, false claims, and enforcement actions. Continuous resident assessment by nursing staff, as well as physician involvement in and careful documentation of care plan meetings, are important strategies to minimize risk.

Nursing facilities are also required to have an activities program under the ROPs. Facilities should dedicate the necessary resources, including a qualified activities director, for an activities program that appeals to each resident.

Challenges Presented by Resident Demographics, Higher Acuity Levels, and Behavioral Health Issues

Nursing facilities are required by the ROPs to provide person-centered care—regardless of diagnoses or acuity level—for each resident, including residents with behavioral health issues. To help manage changing demographics, the ICPG recommends a system to evaluate the consistent application of internal policies and tools that determine resident admissions. Facilities must ensure they have the resources to provide appropriate services to any particular resident and should assess the current and foreseeable services a potential resident may need.

Medication Management and Appropriate Use of Medications

Medication-related adverse events can pose significant compliance risk, including unnecessary hospitalizations, life-sustaining interventions, and harm to residents. The overuse and off-label use of medications in nursing facilities is a particular concern to the Government and may be ripe for inquiry. Under the ROPs, nursing facilities are required to provide pharmaceutical services to meet the needs of each resident and ensure that residents not at risk of significant medication errors. To minimize medication-related risk, the guidance recommends consistent and comprehensive training by the facility's pharmacist to familiarize all staff involved in resident care with proper medication management practices and documentation requirements.

Facilities should develop a standard interdisciplinary approach to determine why a resident has been prescribed a medication, whether continued use is appropriate, whether the resident has experienced any behavioral changes or other side effects, and whether the resident has been prescribed the fewest number of medications as possible.[3] Human error in the face of standardized practices is a different and more manageable problem than having no practices.

COORDINATING COMPLIANCE AND QUALITY OF CARE FUNCTIONS

The Nursing Facility ICPG urges facilities to recruit compliance officers with experience in both compliance management and quality assurance—particularly in care, safety, and life quality standards. The guidance also suggests that a compliance committee should review instances when resident care falls below professionally recognized standards and consider "whether any failures in care trigger liability under the False Claims Act." While these are valid points of discussion during compliance committee meetings, consulting with counsel under these circumstances is critical, as a facility's decision to self-report potentially substandard care under the False Claims Act is not as straightforward as the ICPG might suggest.

The compliance committee is also encouraged to support collaboration and alignment between compliance and quality functions at nursing facilities. For example, the committee should review data related to care outcomes, staffing levels, resident satisfaction, hotline calls, staffing turnover, and state and federal surveys. The guidance emphasizes the importance of regular evaluations and "active questioning" by Responsible Individuals of the facility's compliance program, quality measures, and staff performance. The guidance, implicitly, and sometimes explicitly, advises that the skilled nursing industry is not a "passive investment." As such, Responsible Individuals must prioritize compliance and quality as much as they would financial performance. Additionally, the guidance recommends that the facility's compliance committee closely coordinate with the facility's Quality Assurance and Performance Improvement (QAPI) program. The guidance suggests that this collaboration may eliminate certain redundancies across compliance and quality initiatives and potentially yield other efficiencies for nursing facilities.

Facilities should strongly consider the Nursing Facility ICPG within the context of their operations and adapt it to their needs. In implementing the guidance's recommendations, facilities can strengthen their operations and mitigate the likelihood of regulatory risk. Providers should also anticipate the Government's over-reliance on the ICPG in forming the basis for regulatory enforcement actions—making early intervention by counsel paramount.

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1 *U.S. ex rel. Martino-Fleming v. South Bay Medical Health Centers, et al.* 15-13065.

2 *See* U.S. Senate Committee on the Budget, "Private Equity in Health Care Shown to Harm Patients, Degrade Care and Drive Hospital Closures", *available at* https://www.budget.senate.gov/ranking-member/newsroom/press/private-equity-in-health-care-shown-to-harm-patients-degrade-care-and-drive-hospital-closures#:~:text=Bipartisan%20Senate%20Budget%20Committee%20investigation,)%20and%20Sheldon%20Whitehouse%20(D%2DR

3 There are a number of compliance concerns around conflicts of interest with pharmacy services that are outside the scope of this article.