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An Overview of HHS-OIG's New Nursing Facility Compliance Program Guidance

Risk Areas, Mitigation Strategies, and Evaluation Considerations

Robert A. Del Giorno, Esq.
David M. Traskey, Esq., CFE
Colleen Pierson, Esq.

December 17, 2024

Agenda

- Risk Area #1: Quality of Care and Quality of Life
- Risk Area #2: Medicare/Medicaid Billing Requirements
- Risk Area #3: Kickbacks
- Risk Area #4: Other Notable Risks
- Evaluation Considerations
- Key Takeaways

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Overview

November 20, 2024: U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), issued **voluntary, non-binding compliance program guidance** to skilled and other nursing facilities (SNF/NFs).

- Serves as industry-specific supplement to OIG's General Compliance Program Guidance (issued 11/6/2023);
- Updates prior SNF/NF compliance guidance issued in 2000 and 2008;
- Addresses compliance risk areas specific to SNF/NFs and how to reduce risks;
- Includes additional embedded guidance document on reimbursement issues; and
- Complements CMS's mandatory requirements of participation.

Why Now?

Compliance Programs and Quality of Care Inextricably Linked

OIG's current expectations include:

- Collaboration/Integration between compliance and quality of care efforts;
- Quality of care and life, resident safety, and related issues require specialized oversight that relate to but go beyond traditional compliance programs; and
- Adoption of proactive (not reactive) systems and processes to detect/prevent legal violations and promote resident safety as well as quality of care and life.

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Risk Area #1: Quality of Care and Quality of Life

SNF/NFs expressly agree to comply with CMS requirements of participation related to standards of care. Failure to provide quality of care, OIG warns, poses a risk of fraud and abuse, including liability under the False Claims Act and CMP law.

Specific Concerns

- Minimum Staffing
- Appropriate Resident Care Plans and Activities
- Changing Resident Profiles
- Medication Management (including proper MDS reporting)
- Resident Safety

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Staffing Levels, Shortages, and Competencies

CMS implemented a minimum staffing rule aimed at reducing the likelihood of residents receiving unsafe or low-quality care.

- While there is a minimum, OIG stresses that higher acuity residents will likely require higher total RN and CNA staffing levels.
- OIG notes that if staffing is so low that it leads to "grossly substandard care and poor clinical outcomes, the Government may prioritize bringing an enforcement action."
- Includes new requirement that SNF/NFs have a **registered nurse onsite 24 hours a day, 7 days a week** to provide direct resident care (with certain exceptions).

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Staffing Levels, Shortages, and Competencies

Mitigation Strategies:

- Hire DON to set the tone for achieving high quality standards;
- Offer competitive compensation packages;
- Invest in ongoing education and training for existing staff; and
- Focus on relationship-based care to both increase quality of life for residents and the quality of work life for staff.

PBJ Data Accuracy

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Appropriate Resident Care Plans and Activities

A comprehensive care plan is a CMS requirement of participation. Plans are required to:

- Provide person-centered care that meets professional standards of quality care;
- Address medical, nursing, and mental/psychosocial needs of residents and include reasonable objectives and timetables;
- Provide residents with activity choices that meet their interest and support physical, mental and psychosocial well-being.

Mitigation Strategies:

- OIG suggests that compliance staff coordinate with clinical staff and others responsible for quality of care;
- Document the care-planning meeting(s); and
- Use rotating activity schedule that contemplates resident preferences.

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Changing Resident Profiles

Greater Longevity = Greater Need for SNF/NFs

- Residents (both younger and older) have increasingly complicated medical needs, including for behavioral health care.

Mitigation Strategies:

- Develop clear admissions standards and facility policies to ensure SNF/NFs' ability to provide high-quality, person-centered care that:
  - Assesses the clinical, social, and behavioral profile of each potential resident;
  - Assesses the facility's ability to provide current and foreseeable services if the resident is admitted; and
  - Assesses facility's capacity, ability, and resources to provided needed service as of the admission date.

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Medication Management

OIG is prioritizing medication safety and minimizing conflicts of interest in pharmaceutical decision-making to:

- Reduce the likelihood of medication-related adverse events; and
- Ensure that pharmaceutical decisions are objective, unbiased, and based on the best interests of residents rather than positively impacting quality measure. (Ex: misreporting of schizophrenia on MDS).

Mitigation Strategies:

- Provide consistent and comprehensive training on medication management and documentation;
- Identify root causes of errors and how to reduce future recurrences;
- Use interdisciplinary team approach to assess appropriateness of prescribed meds; and
- Limit drug switches to licensed prescribers only and ensure remuneration to pharmacies/consultants is FMV and does not consider volume/value of drugs.

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Resident Safety

Safety is an essential component of high-quality care. Proactive monitoring is critical for:

- resident abuse and neglect prevention;
- staff screening,
- emergency preparedness and life safety;
- infection control; and
- facility-initiated discharges.

Mitigation Strategies:

- Develop a safety culture through communication, training and education, and monitoring and remediation;
- Develop and implement standardized recruitment and screening practices;
- Test and evaluate evacuation procedures and have a plan that addresses related physical or mental stress/trauma residents may experience;
- Conduct training that examines prior infection control lapses and evaluates the availability of necessary supplies; and
- Conduct training on inappropriate discharges or transfers, and document permissible reasons.

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Risk Area #2: Medicare/Medicaid Billing Requirements

Common risk areas include, but are not limited to:

- insufficient documentation and duplicate billing;
- false or fraudulent cost reports; and
- compliance with SNF 3-Day Rule and consolidated billing requirements.

Accuracy matters and proactive auditing, training, and monitoring are essential.

- Certain areas warrant "heightened importance" under the Prospective Payment System Patient Driven Payment Model (PPS/PDPM) and ensuring clinical justification;
- Data accuracy is key for Value-Based Payment Models, Medicare Advantage, and Medicaid Managed Care;
- Understand whether the resident in a covered Part A stay to avoid Part D errors; and
- Objective education and the best interests of the resident must guide Medicare health plan enrollment decisions.

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Risk Area #3: Kickbacks

SNF/NFs must comply with the Federal Anti-Kickback Statute (AKS)

One key to understanding AKS compliance is the ability to identify arrangements with referral sources and referral recipients that have the potential for fraud and abuse.

Suspect arrangements include, but are not limited to:

- free (or below FMV) goods and services;
- discounts in the form of price reductions or swapping;
- arrangements for services and supplies between the SNF/NF and physicians or NPPs, or outside suppliers and providers;
- long-term care pharmacy and consultant pharmacist arrangements;
- hospital payments to SNF/NFs to accept discharged patients or reserve or hold beds;
- hospice payments to SNF/NFs that exceed Medicaid service or room/board rates; and
- joint ventures with other health care entities.

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Risk Area #4: Other Notable Risks

Tunneling: misrepresenting or hiding profitability by overstating payments for operational expenses that are funneled to **related parties.** Commonly occurs in:

- Real estate transactions where facility is sold to REIT or commonly held company and leased back at rate in excess of FMV;
- Outsourcing administrative or management services with commonly owned companies with facility paying in excess of FMV for these services.

Physician Self-Referral / "Stark" Law: SNF services covered by the Medicare Part A PPS payment are not "designated health services" (DHS) under Stark. **BUT** –

- SNF/NFs may be considered an entity providing DHS if it provides certain Part B services to enrollees who (1) are in a non-covered Part A stay; or (2) reside in a facility that is not certified as a SNF by Medicare.

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Risk Area #4: Other Notable Risks, cont'd.

Anti-Supplementation: SNF/NFs must accept the applicable Medicare/Medicaid payment and cannot charge an enrollee (or other person) any amount in excess of what must be paid for the covered items/services.

HIPAA Privacy, Security, and Data Breach Notification Rules: Most SNF/NFs are "covered entities" under HIPAA because they are health care providers that conduct certain health care transactions electronically. They may also be or have arrangements with "business associates."

Civil Rights: SNF/NFs must comply with applicable civil rights laws, which prohibit discrimination and require that nursing facilities provide each individual an equal opportunity to participate in Federal health care program activities regardless of certain protected characteristics.

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Evaluation Considerations

Reexamining OIG's 7 Elements of an Effective Compliance Program

- For chain or system SNF/NFs, responsibility for compliance and quality of care should be assigned to a compliance officer at the highest level within the organization.
  - At independent or individual facilities these functions should rest with a facility-level compliance officer who reports directly to the owner, governing body, etc.

- Include **investors** on the list of "Responsible Individuals." They should question whether the facility complies with applicable laws, rules, regulations, requirements, etc.
- Compliance committees should review compliance, quality, and safety data regularly and work to coordinate compliance and QAPI program functions.

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Evaluation Considerations, cont'd.

- Regular risk assessments, internal reviews, and monitoring are crucial to **proactively identify** potential failures and risks to patients.
    - Root cause analyses can identify weaknesses or errors and reduce likelihood of future recurrence.
- Compliance and quality of care functions should coordinate efforts to ensure quality-related reporting requirements are satisfied (i.e., CHOW, cost reports, claims info, MDS resident assessment data, etc).

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Key Takeaways

- OIG's new guidance is not one-size-fits-all or all-inclusive of compliance and quality considerations or risks. **Customize based on organizational experience.**
- **"Responsible Individuals"** set the tone at the top for preventing, detecting, and fixing compliance and quality of care/life issues.
- Ensuring compliance and quality of care/life is a **team effort**; and
- **Proactivity and continuous improvement** are hallmarks of effective programs given that compliance and quality of care/life issues are evolving.

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Robert A. Del Giorno

Partner/Director

516.393.2505 | rdelgiorno@garfunkelwild.com

Robert Del Giorno is the Chair of Garfunkel Wild's Investigations, Audits and Regulatory Compliance Practice Group. Robert's practice includes representation of skilled nursing facilities, laboratories, physicians and other health care industry-related clients (both for profit and not-for-profit) in the area of health care compliance, with a specific focus on fraud and abuse laws. He has particular expertise assisting clients with internal investigations and frequently defends clients in both civil and criminal investigations conducted by federal and state agencies.

Robert has defended local New York hospitals and individual providers in complex, multi-million dollar Federal and New York State False Claims Act cases and has handled a wide variety of other high-profile matters. Robert also represents clients in the health care and early intervention industries with regard to audits conducted by government agencies. In addition, Robert frequently assists clients in developing effective compliance programs, working with them to develop and implement policies tailored to meet their individual needs. Robert frequently consults on a variety of business transactions and arrangements, including asset purchases, financing and factoring agreements, among others. In this regard, Robert conducts due diligence reviews of health care providers in order to help clients identify and understand potential health care compliance risks and liabilities.

Robert started his career with a large corporate law firm in New York City, where he focused on commercial litigation and criminal defense matters. Prior to joining the firm, Robert served as an Assistant District Attorney in the Nassau County District Attorney's Office where he tried numerous cases to verdict. As a member of the Special Victims Bureau, he handled cases involving victims of sex crimes and domestic violence. Many of Robert's cases and trials were covered by the media, including his trial of a man featured on America's Most Wanted.

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David M. Traskey

Partner

202.844.3256 | dtraskey@garfunkelwild.com

David Traskey advises individuals and entities involved in government investigations, guides clients on corporate compliance and governance matters, and litigates civil and white-collar healthcare fraud cases. Prior to joining Garfunkel Wild, David served as Senior Counsel with the United States Department of Health and Human Services (HHS), Office of Inspector General (OIG).

David's unique expertise in health care enforcement and compliance provides clients with specialized insight into federal investigations and enforcement actions based on his knowledge of the government's case identification strategies, its legal theories, and its interpretation of the applicable laws, rules, and regulations. His HHS-OIG experience also allows him to share critical information with clients about the government's corporate governance expectations and compliance best practices.

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Colleen R. Pierson

Associate

518.560.4024 | cpierson@garfunkelwild.com

Colleen R. Pierson joined Garfunkel Wild, P.C. in 2023. Colleen is a member of the firm's Investigations, Audits, and Regulatory Compliance Practice Group. Colleen's practice includes representation of skilled nursing facilities, assisted living facilities, physicians and other health care industry-related clients (both for profit and not-for-profit) in the area of health care compliance, with a specific focus on regulatory compliance, fraud, and abuse laws. She has particular expertise assisting clients with matters before the New York State Department of Health, the New York State Department of Education, and other state agencies. Colleen also serves as Assistant Town Attorney to the Town of Glenville. Colleen brings over a decade of New York State government experience, having worked in several roles for the New York State Legislature and the New York State Division of Budget.

Prior to joining the firm, Colleen was with a Capital District law firm in their Health Law Group where she worked on a wide range of state and federal civil litigations, including Article 78 actions, transactional work, and other advisory services on behalf of skilled nursing facilities, physicians, and assisted living facilities. During her law school career, Colleen continued her work at the New York State Division of Budget in their Legal and Procurement Unit and participated in externships with the Honorable Mae D'Agostino of the United States District Court for the Northern District of New York and the New York State Attorney General's Litigation Bureau.

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Our Offices

Garfunkel Wild

Great Neck, New York

111 Great Neck Road, Suite 600
Great Neck, NY 11021
Tel: 516.393.2200
Fax: 516.466.5964

Albany, New York

677 Broadway, 7th Floor
Albany, NY 12207
Tel: 518.242.7582
Fax: 518.242.7586

New Jersey

411 Hackensack Avenue, 10th Floor
Hackensack, NJ 07601
Tel: 201.883.1030
Fax: 201.883.1031

Connecticut

350 Bedford Street, Suite 406A
Stamford, CT 06901
Tel: 203.316.0483
Fax: 203.316.0493

Florida

401 E Las Olas Boulevard, Suite 1423
Fort Lauderdale, FL 33301
Tel: 754.228.3853
Fax: 754.228.3852

Washington, DC

1717 K Street NW, Suite 900
Washington, DC 20006
Tel: 202.780.3366
Fax: 202.780.3366

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