U.S. Department of Health and Human Services

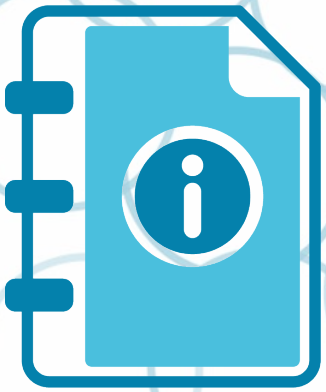
Office of Inspector General

NURSING FACILITY

Industry Segment-Specific Compliance Program Guidance

November 2024

User's Guide



Welcome to OIG's Industry Segment-Specific Compliance Program Guidance for Skilled Nursing Facilities and Nursing Facilities (Nursing Facility ICPG).

In this document, the terms "nursing facility" or "facility" include:

- a skilled nursing facility (SNF) that meets the requirements of section 1819 of the Social Security Act (the Act) (42 U.S.C. § 1395i–3), a nursing facility (NF) that meets the requirements of section 1919 of the Act (42 U.S.C. § 1396r), and a dually certified facility; and
- single facilities, chains, managing and operating companies, and entities that own nursing facilities.

When appropriate, we distinguish between these types of entities.

The Nursing Facility ICPG describes:

- Risk areas for nursing facilities
- Recommendations and practical considerations for mitigating those risks
- Other important information OIG believes nursing facilities should consider when implementing, evaluating, and updating their compliance and quality programs

The Nursing Facility ICPG—together with OIG's General Compliance Program Guidance (GCPG) that applies to all individuals and entities involved in the health care industry—serves as OIG's updated and centralized source of voluntary compliance program guidance for nursing facilities. Nursing facilities can use the ICPG to help identify their own risks and implement an effective compliance and quality program to reduce those risks.

These resources are not one-size-fits-all, comprehensive, or all-inclusive of compliance and quality considerations or risks for nursing facilities. They are not binding on any individual or entity. Of note, OIG uses the word "should" in the Nursing Facility ICPG and GCPG to present voluntary, nonbinding guidance. This means that the documents do not create any new obligations or standards for any individual or entity.

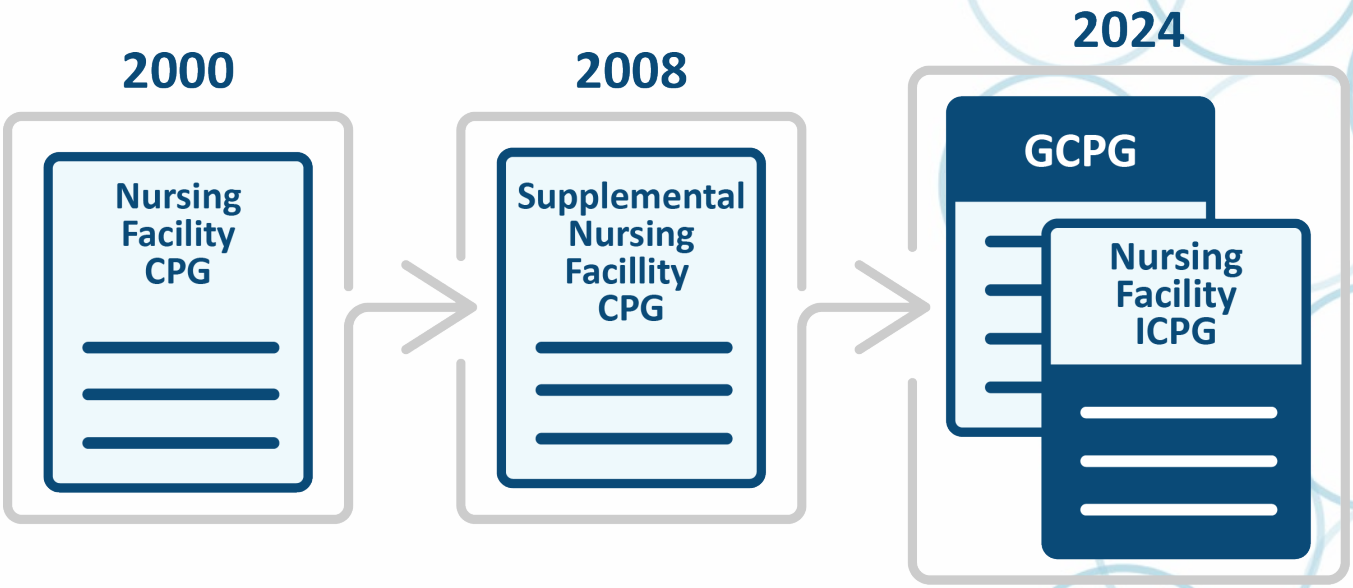
GCPG

- Key Federal authorities for entities engaged in health care business
- Seven elements of a compliance program
- Adaptations for small and large entities
- Other compliance considerations
- OIG processes and resources

Nursing Facility ICPG

- Tailored to compliance risk areas for the nursing facility industry segment
- Compliance measures that the nursing facility industry can take to reduce risk

The Nursing Facility ICPG updates prior 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). We have carried forward certain pertinent risk areas and relevant considerations from the 2000 CPG and 2008 Supplemental CPG in this document. 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. Nursing facilities may still wish to address the risk area or consideration in their compliance programs. The 2000 CPG and 2008 Supplemental CPG will continue to be available on our website as archived resources.



The Nursing Facility ICPG's detailed table of contents allows the user to directly access specific topics of interest. Many sections contain hyperlinks to the GCPG, OIG's resources, laws and regulations, other Internet locations with useful information, or related topics within the ICPG or the Nursing Facility ICPG Supplement: Reimbursement Overview (the Reimbursement Supplement). The Nursing Facility ICPG contains some terms that are hyperlinked to a definition.

Long-term and post-acute care providers other than SNFs or NFs, such as assisted living facilities, should find the Nursing Facility ICPG useful. However, we recognize 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. We encourage all long-term and post-acute care providers to establish and maintain effective compliance and quality programs

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I. Introduction

Improving the quality of care and safety of residents within nursing facilities is a top priority for OIG. Quality of care and safety are matters of critical importance for residents, their loved ones, and the nursing facility workforce. The Nursing Facility ICPG—together with the GCPG—addresses the Government and private industry's shared goals of reducing fraud, waste, and abuse; promoting cost-effective and quality care; enhancing the effectiveness of providers' operations; and propelling improvements in compliance, quality of care, and resident safety within nursing facilities. The Nursing Facility ICPG and GCPG provide resources for the nursing facility industry and interested stakeholders as they seek to meet these goals.

Compliance and Quality. OIG includes references to both compliance programs and quality programs throughout the Nursing Facility ICPG to emphasize their inextricable link and the need for nursing facility compliance programs to include quality considerations within the scope of their daily oversight. Specifically, this guidance reflects OIG's position that there should be collaboration and integration of efforts between compliance and quality programs to monitor nursing facilities' compliance with laws and regulations that govern health and safety standards, resident care, and quality of life—areas that may extend beyond traditional compliance program oversight and require clinical or other specialized expertise and assessment. The Nursing Facility ICPG includes recommendations for nursing facilities to implement compliance and quality programs at the highest corporate level of a system or chain (when applicable) to ensure a consistent approach to monitoring, assessment, and remediation across all nursing facilities within the system or chain.

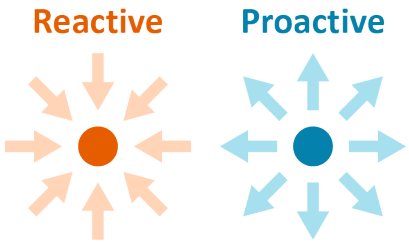
This Nursing Facility ICPG incorporates information and recommendations that are based on our: (1) findings and observations from OIG's decades of work on matters involving nursing facilities including audits, evaluations, investigations, enforcement actions, and monitoring of Corporate Integrity Agreements (CIAs); (2) legal actions initiated and investigated by 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.

A. Application of the Nursing Facility ICPG

We encourage nursing facilities to use the Nursing Facility ICPG as a guide in identifying their own risk areas and in implementing, evaluating, and updating their compliance and quality programs to mitigate these risk areas. As nursing facilities reflect on how to apply the Nursing Facility ICPG to their own operations, OIG recognizes the following important considerations:

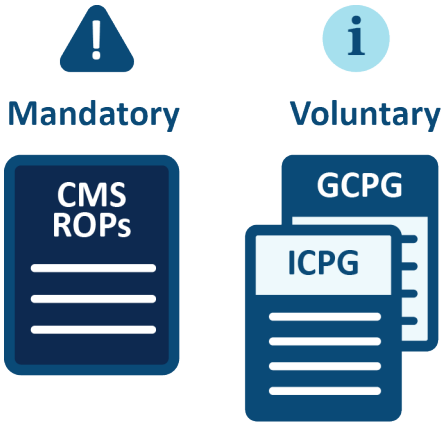
- Many nursing facilities and their staff are dedicated to providing high-quality, compassionate, and cost-effective care to residents. However, many nursing facilities experience substantial challenges in doing so, at times because of matters that may fall outside their control. This ICPG is not intended to add burdens to an industry segment already facing substantial challenges but rather to offer recommendations that may help alleviate or overcome some of those challenges.

- Due to resource and time constraints, nursing facilities often operate in a reactive mode while directing their attention to preparing for an impending survey or addressing deficiencies cited in their most recent survey results. Through this guidance, we encourage facilities to be proactive in establishing systems and processes that will reliably detect and prevent legal violations and promote quality of care and quality of life for residents. In doing so, better survey results may follow.



- Under the Centers for Medicare & Medicaid Services (CMS) requirements of participation for nursing facilities in the Medicare and Medicaid programs (Requirements of Participation or ROPs),[1] operating organizations for nursing facilities are required to operate a compliance and ethics program that effectively prevents and detects criminal, civil, and administrative violations and promotes quality of care (the Compliance Program ROPs).[2] Certain required elements of the Compliance Program ROPs are similar to the voluntary seven elements of a compliance program described by OIG in the GCPG

- Since the implementation of the Compliance Program ROPs in 2019, nursing facilities may have exerted substantial efforts to ensure that they meet and are ready to be surveyed for compliance with these Compliance Program ROPs. **We emphasize that the Nursing Facility ICPG and the GCPG (which provide voluntary, nonbinding guidance) are intended to complement the Compliance Program ROPs (which are mandatory for nursing facilities to participate in the Medicare and Medicaid programs).** The Compliance Program ROPs provide the minimum requirements for compliance program structure and operation. The recommendations and practical considerations in the Nursing Facility ICPG and GCPG—if incorporated by nursing facilities—could help facilitate compliance with the Compliance Program ROPs, as well as facilitate compliance with other statutory and regulatory obligations.



[1] 42 C.F.R. Part 483, Subpart B.

[2] *See* section 1128I(b) of the Act, 42 U.S.C. § 1320a-7j(b); 42 C.F.R. § 483.85; 42 C.F.R. § 483.95(f); *see also* State Operations Manual, Appendix PP, F895 and F946.

B. Motivating Factors

Factors that have motivated the Nursing Facility ICPG include:

- OIG's work relating to nursing facilities has uncovered widespread, chronic challenges that providers face in maintaining compliance and quality programs that are effective in ensuring safe, high-quality care for residents. This work has raised concerns regarding issues such as staffing levels, infection control, emergency preparedness, background checks for employees, reporting of adverse events experienced by residents, inappropriate use of medications, and other compliance and quality issues. OIG believes that the Nursing Facility ICPG may lead to more nursing facilities maintaining compliance and quality programs that are effective in ensuring safe, high-quality care for residents so that these issues can be more effectively mitigated through the industry's voluntary self-monitoring efforts.
- Existing vulnerabilities within the nursing facility industry were exacerbated by the COVID-19 pandemic. Poor infection control, inadequate staffing levels, and other longstanding issues in nursing facilities contributed to their resident populations experiencing greater levels of infection, hospitalization, and death from COVID-19 than the general population.[3] Through this guidance, OIG encourages nursing facilities to develop and maintain compliance and quality programs that are equipped to protect the health and safety of residents in the normal course and in the event of a future public health emergency.
- There is an enhanced and coordinated effort by OIG, CMS, the Department of Justice (DOJ), and other law enforcement partners to pursue nursing facilities that provide grossly substandard care or subject residents to dangerous or unhealthy living conditions. OIG believes that the Nursing Facility ICPG may help nursing facilities proactively detect, assess, and remediate these quality and safety concerns before residents are harmed and before these concerns give rise to an enforcement action.
- Since OIG last published compliance program guidance for nursing facilities in 2008, there have been significant changes in the nursing facility industry, including changes in business practices and the way nursing facilities receive reimbursement for services. Through this Nursing Facility ICPG, OIG seeks to improve the usefulness, timeliness, accessibility, and usability of our compliance program guidance for nursing facilities.

[3] *See, e.g.*, Linda Simoni-Wastila et al., *Staffing and Protective Equipment Access Mitigated COVID-19 Penetration and Spread in US Nursing Homes During the Third Surge*, 22 JAMDA 2504 (Dec. 2021); OIG, COVID-19 Had a Devastating Impact on Medicare Beneficiaries in Nursing Homes During 2020, OEI-02-20-00490 (June 2021); OIG, Lessons Learned During the Pandemic Can Help Improve Care in Nursing Homes, OEI-02-20-00492 (Feb. 2024).

SECTION II
Compliance Risk Areas and Recommendations for Mitigation

II. Compliance Risk Areas and Recommendations for Mitigation

This section describes key areas that pose potential risks of noncompliance with Federal fraud and abuse authorities and Federal health care program requirements for nursing facilities and provides recommendations that may help nursing facilities mitigate these risks.

This section addresses the following key areas of compliance risk for nursing facilities:

A. Quality of care and quality of life

B. Medicare and Medicaid billing requirements

C. Federal anti-kickback statute

D. Other risk areas (related-party transactions; physician self-referral law; anti-supplementation; Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security, and Breach Notification Rules; and civil rights)

DISCLAIMER

This section is not intended to address all potential risk areas for nursing facilities. Rather, nursing facilities should use this section as a guide in identifying their own risk areas and in implementing, evaluating, and updating their compliance and quality programs to mitigate these risk areas. This section presents neither detailed nor comprehensive summaries of lawful or unlawful activities. It is not a substitute for consulting with CMS, a facility's Medicare Administrative Contractor, a State Medicaid agency, or other relevant State agencies or health plans with respect to the application and interpretation of payment rules, coverage criteria, licensure, and other rules, regulations, or policies, which are subject to change.

A. Quality of Care and Quality of Life

A nursing facility serves as both the location in which residents receive medically necessary health care services and a home for residents during the duration of care. It is the essential function of nursing facilities to provide quality of care and quality of life for residents. To participate in and receive payments under the Medicare and Medicaid programs, a nursing facility expressly agrees to

comply with rules and regulations relating to standards of care.[4] Under the ROPs, nursing facilities must (among other things):

- provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident and ensure that residents receive treatment and care in accordance with professional standards of practice;[5]
- provide care in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident;[6] and
- have a Quality Assurance and Performance Improvement (QAPI) program that focuses on indicators of the outcomes of care and quality of life.[7]

Beyond the ROPs, 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.

Examples of quality and related safety concerns that can lead to submission of false claims include:

- providing medically unnecessary or grossly substandard services;
- housing residents in unacceptable or dangerous living conditions;
- failing to provide residents with activities; and
- failing to provide residents with needed psychiatric care.

Nursing facilities that fail to make the provision of quality care and resident safety a priority, and consequently fail to deliver care that meets or exceeds professionally recognized standards or provide an acceptable and safe living environment, risk harming residents and may become the target of Government enforcement efforts. 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, revocation of

[4] *See* 42 C.F.R. § 483.1(b).
[5] *See, e.g.*, 42 C.F.R. § 483.24; 42 C.F.R. § 483.25; *see also, e.g.*, section 1819(b) of the Act, 42 U.S.C. § 1395i-3(b); section 1919(b) of the Act, 42 U.S.C § 1396r(b).
[6] 42 C.F.R. § 483.10(a)(1).
[7] 42 C.F.R. § 483.75.

Medicare enrollment and termination of Medicare and Medicaid certification, and exclusion from participation in Federal health care programs, as described in the GCPG.

OIG and DOJ, often with Medicaid Fraud Control Units and other State agency partners, have increasingly used substandard quality of care as the basis for investigations and enforcement actions. When DOJ and OIG enter into settlements with nursing facilities to resolve quality-of-care allegations, OIG has entered into Quality of Care CIAs to ensure that reliable systems and processes are implemented to improve compliance, quality, and safety performance.

Quality as a Compliance Concern. Referring to quality as a compliance concern does not mean that compliance officers or lawyers should be directing clinical care at nursing facilities. Rather, it means that a nursing facility's compliance leadership should be working closely with clinical leadership to consider resident care and safety-related concerns as part of a compliance program's oversight responsibility. A nursing facility's compliance staff should coordinate with quality staff (e.g., clinical staff and other personnel responsible for quality of care) in assessing the effectiveness, reliability, and thoroughness of internal quality control systems that are in place to promote high quality of care and resident safety. By more closely aligning compliance and quality functions, facilities may be better positioned to comply with the ROPs related to quality of care and quality of life. Alignment of these functions may also achieve efficiencies in preventing, mitigating, and correcting violations of other Federal health care program requirements and fraud and abuse laws.

In the sections below, we highlight some common risk areas for nursing facilities associated with providing quality of care and quality of life for residents, as well as recommendations for mitigating those risk areas. Related to all these risk areas, 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 the following OIG resources for recommendations about integrating compliance and quality oversight:
    - the GCPG's discussion regarding incorporating quality and patient safety considerations within compliance programs;
    - Practical Guidance for Health Care Governing Boards on Compliance Oversight, which references the importance of cooperation and collaboration between compliance and quality improvement functions, and the responsibilities of boards of directors that extend to oversight of quality outcomes and improvement;

- Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors, which has a question-and-answer section on compliance and quality that entities and their boards of directors may find useful;
- Driving for Quality in Long-Term Care: A Board of Directors Dashboard, which has guidance about developing a quality dashboard to monitor quality performance, as well as increasing accountability for quality outcomes;
- Quality of Care CIAs, which include comprehensive compliance and quality assurance requirements that nursing facilities may consider implementing for their own organizations (as described in the GCPG); and

- monitor OIG's nursing home featured topic page to remain informed about 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.

1. Staffing Levels, Shortages, and Competencies

Nursing facility staffing is a vital component to providing quality care, as research has clearly correlated staffing shortages and turnover with substandard care.[8] Nursing facilities persistently operate in an environment of staffing shortages, high staff turnover, and workforce burnout, all of which exacerbate the challenges associated with attracting, training, and retaining an adequate and qualified workforce.[9] High turnover rates among nurse aides, who provide most of the direct care in nursing facilities, often result in residents frequently receiving care from new staff or agency staff who lack experience with and knowledge of individual residents and their needs.

Under the ROPs, nursing facilities are required to have sufficient staff with the appropriate competencies and skills to provide services to assure resident safety and attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.[10] The acuity level of the resident population will affect the number and skill level of staff needed to meet this required level of care. In its final rule published on May 10, 2024 (the CMS Final Rule),[11] CMS established a staffing "floor" requiring nursing facilities to maintain certain minimum nurse staffing levels with the aim to reduce the risk of residents receiving unsafe, low-quality care.[12] As CMS stated in the CMS Final Rule, if the acuity needs of residents in a facility require a higher level of care, a higher total

[8] *See, e.g.*, Karen Shen et al., *Health Care Staff Turnover and Quality of Care at Nursing Homes*, 183 JAMA Internal Medicine 1247 (2023).
[9] *See, e.g.*, Cheryl Heiks & Nicole Sabine, *Long Term Care and Skilled Nursing Facilities*, 8 Delaware Journal of Public Health 144 (2022).
[10] *See, e.g.*, 42 C.F.R. §§ 483.35(a) (nursing services), 483.40(a) (behavioral health services), 483.60(a) (food and nutrition services).
[11] Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting, 89 Fed. Reg. 40,876 (May 10, 2024).
[12] 42 C.F.R. § 483.35(b); 89 Fed. Reg. at 40,877.

registered nurse and nurse aide staffing level will likely be required.[13] Also, nursing facilities under the CMS Final Rule are required to have a registered nurse onsite 24 hours a day, 7 days a week who is available to provide direct resident care (with certain exceptions).[14]

Staffing and the Facility-Wide Assessment. CMS requires each nursing facility to conduct and document a facility-wide assessment to determine the resources that are necessary to competently care for residents on a daily basis and during emergencies. Facility-wide assessments must be reviewed and updated annually and when necessary to address changes in the resident population or facility.[15] Under the CMS Final Rule, nursing facilities are required to continue performing an annual facility-wide assessment of resources necessary for routine and emergency care for residents and to adjust nurse staffing to meet the acuity needs of residents.[16] A facility-wide staffing needs assessment should take into consideration evidence-based, data-driven methods to identify care needs, required skill sets, and staff competencies to address care needs. Nursing facilities should encourage the input and involvement of facility employees (including direct care staff, management, and leadership) in every assessment so that these employees have the opportunity to share perspectives on any skill or competency gaps, or needed resources, that impact a facility's ability to appropriately care for the resident population at any given time.

In addition to CMS requirements, a failure to maintain adequate staffing levels or to sufficiently train or supervise staff to provide medical, nursing, and related services for residents based on the acuity level of the facility residents may leave a nursing facility vulnerable to allegations of substandard care, the provision of worthless services, and the submission of false claims in violation of the False Claims Act. When staffing is so low that it leads to grossly substandard care and poor clinical outcomes, the Government may prioritize bringing an enforcement action.

Because staffing in nursing facilities has an obvious and substantial impact on the quality of care and outcomes residents experience, increasing registered nurse and overall nurse staffing is a priority throughout the nursing facility industry. Achieving staffing goals may require a multifaceted, strategic approach that addresses nursing leadership, recruitment, retention, and overall staffing management.

The following may be helpful considerations to address staffing needs or gaps:

- **Nursing Leadership.** Nursing facilities and industry stakeholders have reported to OIG that recruiting and retaining nursing leadership, namely a director of nursing, may be important not only for achieving a high standard of quality within a facility but also for setting the tone for other nursing staff who contribute to clinical, quality, and safety improvement initiatives at the facility.

[13] 89 Fed. Reg. at 40,877.
[14] 42 C.F.R. § 483.35(c).
[15] 42 C.F.R. § 483.71.
[16] 42 C.F.R. §§ 483.71(a), 483.71(c); *see also* 89 Fed. Reg. at 40,912.

A nursing facility might consider hiring a director of nursing who has an education and competency in geriatric nursing or other specialty tailored to the resident population's particular health needs, as well as experience in other areas including management, compliance, regulatory standards, and professional development.

- **Recruitment.** Nursing facilities and industry stakeholders have reported to OIG that offering competitive salary, bonus, and benefits packages (e.g., comprehensive health insurance, paid time off, and mental health and wellness programs) and rewarding current employees for recommending qualified candidates (all as consistent with applicable laws) may improve recruiting efforts. Nursing facilities and industry stakeholders have also recommended engagement in community outreach and partnerships with local educational institutions to promote careers in the nursing facility sector and to establish direct routes for new graduates to obtain employment.
- **Retention.** Nursing facilities and industry stakeholders have also suggested that regular recognition of staff members' outstanding performance, especially by providing them with the opportunity to share their own strategies and best practices in effectuating their job responsibilities, can help with staff retention. Furthermore, nursing facilities and industry stakeholders have reported to OIG that investing in ongoing education and training programs not only enhances the skills of existing staff but also engenders employee loyalty and improves morale. Developing career ladders that give nursing staff opportunities for advancement may increase retention and improve job performance and care quality.
- **Staffing Management.**
  - Nursing facilities and industry stakeholders have reported to OIG that a continual assessment of staff members' abilities to manage their responsibilities effectively, and to ensure that they have the necessary tools to support their job functions, may translate into higher levels of job satisfaction, which may result in improving the quality of care. Nursing facilities and industry stakeholders have also suggested to OIG that nursing facilities should invest in necessary technologies, including maximizing the usability and functionality of electronic health record systems, to improve efficiencies and allow nursing staff to have more time to devote to resident care and interaction.
  - Nursing facilities and industry stakeholders have reported to OIG the importance of creating a high level of relationship-based care. This may be achieved by consistently assigning the same staff to care for specific residents, which supports person-centered care. When staff members are consistently assigned, they may become more familiar with residents under their care, better understand their clinical and psychosocial needs, and more efficiently address those needs. Consistency in assigning staff also alleviates the need for nursing staff, residents, families, or guardians to repeatedly train based on those needs. It may foster an environment in which both the quality of resident life and the quality of employee work life improves within the nursing facility.[17]

[17] *See* National Academies of Sciences, Engineering, and Medicine, The National Imperative to Improve Nursing Home Quality: Honoring Our Commitment to Residents, Families, and Staff (2022).

Implementing some or a combination of these strategies tailored to the specific needs of the nursing facility may contribute to an increase in staffing levels, positive retention rates, and an overall improvement in quality of care.

2. Appropriate Resident Care Plans and Resident Activities

Developing and implementing appropriate, individualized resident care plans and creating meaningful and enriching activities may contribute substantially to high-quality, individualized, and person-centered care. In addition to complying with regulatory requirements, efforts to improve these practices may have a demonstrable effect on quality of care and quality of life for residents in a nursing facility.

a. Appropriate Resident Care Plans

Developing and implementing reliable processes to consistently identify and address changes in resident conditions is an essential feature of the provision of quality care to residents. The ROPs require nursing facilities to develop and implement a comprehensive care plan for residents that: (1) provides effective and person-centered care for residents that meets professional standards of quality care; (2) addresses the medical, nursing, and mental and psychosocial needs of residents and includes reasonable objectives and timetables; and (3) provides an ongoing program to support residents in their choice of activities designed to meet interest and support physical, mental and psychosocial well-being.[18] The ROPs also require nursing facilities to ensure that care planning includes all disciplines involved in a resident's care.[19]

Nevertheless, OIG's work has revealed that resident care plans often did not meet Medicare requirements or reflect residents' actual care needs and that services often were not provided in accordance with care plans.[20] Based on information gathered through its enforcement work and monitoring of nursing facilities that operate under Quality of Care CIAs, OIG has continuing concerns that nursing facilities are failing to develop and implement sufficient care plans. These failures impact residents' care, well-being, and safety and may lead to the provision of substandard care, submission of false claims, and Government enforcement actions.

[18] *See* 42 C.F.R. § 483.21; 42 C.F.R. § 483.24; *see also* section 1819(b)(2) of the Act, 42 U.S.C. § 1395i-3(b)(2); section 1919(b)(2) of the Act, 42 U.S.C. § 1396r(b)(2).

[19] *See* 42 C.F.R. § 483.20(k)(2)(ii).

[20] OIG, Skilled Nursing Facilities Often Fail to Meet Care Planning and Discharge Planning Requirements, OEI-02-09-00201 (Feb. 2013); *see also* OIG, Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs, OEI-07-08-00151 (July 2012).

Nursing facilities have reported to OIG the following strategies to mitigate the risks associated with ineffective or inadequate care planning and to realize the potential benefits of effective care planning:

- developing policies and providing training to encourage open communication in care planning meetings between direct care providers and interdisciplinary team members so that care plans may reflect all clinical assessments by an entire team;
- documenting the care-planning meeting, which may help standardize the care-planning process. Documentation should include notes about discussions and meeting durations, particularly discussions reflecting the preferences of residents, family members, and guardians; and
- organizing meetings for facilities to promote physician engagement and supervision of each resident's care and to discuss care plans for specific residents. Physicians should be provided advance notice of such meetings. Facilities in conjunction with attending physicians should evaluate how best to ensure physician participation—whether by consultations and post-meeting debriefings or by virtual or in-person attendance at meetings—with a focus on serving the best interests of residents and complying with applicable regulations.

Nursing staff should continuously assess resident conditions, behavior, and overall well-being while giving special consideration to the early detection of changes in physical or mental condition. Effective communication channels between different health care team members should be established, including the regular sharing of observations and insights regarding residents.

b. Resident Activities

Engagement in socially and cognitively enriching activities is an essential contributing factor in residents' quality of life and well-being in a nursing facility. Activities provide needed social interaction and build relationships among residents. They promote a sense of community, stimulate cognitive abilities, and contribute to maintaining and improving physical health and mental alertness. Activities also add much-needed variety, distraction, and entertainment, create comforting and reassuring routines, and reduce feelings of isolation and levels of stress, depression, and anxiety. Nursing facilities are required to have an activities program under the ROPs.[21]

Through OIG's monitoring of Quality of Care CIAs with nursing facilities, we have found that certain activity programs stood out because their leadership teams made concerted efforts to value the quality of activities as much as the quality of care provided to residents. Notably, these facilities developed activities programs that take into consideration the varied interests and capabilities of all residents, creating a sense of community, vibrancy, and engagement.

[21] 42 C.F.R. § 483.24(c).

To maintain a robust activities program, nursing facilities should:

- maintain staff in adequate numbers and with the requisite skill level to make activity programs a realistic possibility;
- dedicate the necessary resources for an activities program that consistently appeals to the specific and unique abilities, interests (past and present), and preferences of the residents living in a facility, and regularly encourage high rates of attendance across activities;
- provide the activity director (who is a qualified therapeutic recreation specialist or an activities professional meeting the standards under the applicable ROP)[22] with the discretion and authority to develop and implement a rotating schedule of stimulating social, physical, cognitive, and creative activities for residents; and
- explore options for appropriate, person-centered activities by including staff, residents, families, guardians, caregivers, and community members, and continually solicit ideas for enlivening and meaningful experiences that residents may enjoy.

3. Challenges Due to Demographic Changes in the Resident Profile, Higher Resident Acuity Levels, and Behavioral Health Issues

The demographic composition of residents in nursing facilities has undergone significant change over the years. Among other factors, the aging of the Baby Boom generation coupled with medical advances extending life expectancies have increased demand for nursing facility services. Nursing facilities are admitting not only residents who are older than the historical, average age of a nursing facility resident but also residents who are younger than average. These residents often have conditions of higher acuity, require higher-level nursing care, or exhibit behavioral health disorders that pose specific challenges for nursing facilities to address, primarily in providing the specialized care and resources these residents need. Amid these changing demographics, nursing facilities may face unique challenges in providing services for their resident populations.

Nursing facilities are required by the ROPs to, among other things, provide comprehensive, person-centered care—regardless of diagnoses or acuity level—for each resident, including residents with behavioral health disorders.[23]

Facilities also are required to review and update the facility-wide assessment (under which a nursing facility determines which resources are necessary to care for residents competently) at least annually and "whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment."[24] As an example of when the facility-wide assessment should be reviewed and updated, CMS explains that "if the facility decides to admit residents with

[22] 42 C.F.R. § 483.24(c)(2).
[23] *See, e.g.*, 42 C.F.R. § 483.20; 42 C.F.R. § 483.21; 42 C.F.R. § 483.20(k); 42 C.F.R. § 483.40.
[24] 42 C.F.R. § 483.71.

care needs who were previously not admitted, . . . the facility assessment must be reviewed and updated to address how the facility staff, resources, physical environment, etc., meet the needs of those residents and any areas requiring attention, such as any training or supplies required to provide care."[25] More information about CMS requirements for facility-wide assessments is found here.

Recommendations for Managing Changing Resident Demographics

- Develop a system to evaluate the consistent application of internal policies and assessment tools that determine resident admission decisions. A consistent application of clear admissions standards and facility policies will help facilities provide appropriate, high-quality, comprehensive, person-centered, and interdisciplinary, team-based care.
- Before admitting each potential new resident:
  - obtain for each potential resident all clinical, social, and behavioral information including background, diagnoses, and other qualitative information to assist in the admission determination process;
  - identify and thoroughly consider the current and foreseeable services that the potential resident would need and the facility's ability to secure and maintain those services if the resident were admitted; and
  - ensure that the facility has the capacity, ability, and resources to provide services to the potential resident as of the admission date. If the facility decides to admit the potential new resident, the facility should promptly identify and address any necessary changes to meet the needs of the resident, such as conducting new staff training or obtaining necessary equipment and supplies, in addition to updating the facility-wide assessment and other requirements under the ROPs.

4. Medication Management

Medication management efforts are critical to minimizing the adverse events that can result from inappropriate prescribing, over-prescribing, and drug interactions. Consequences of poor medication management and medication-related adverse events can include prolonged nursing facility stays, hospitalizations, life-sustaining interventions, permanent harm to residents, and premature death.

Under the ROPs, nursing facilities are required to provide "pharmaceutical services (including procedures that assure accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident,"[26] and to ensure that residents are free of any

[25] State Operations Manual, Appendix PP, F838.
[26] 42 C.F.R. § 483.45(a).

significant medication errors.[27] The ROPs also require that nursing facilities employ or obtain the services of a licensed pharmacist to provide "consultation on all aspects of the provision of pharmacy services in the facility . . . ."[28] Furthermore, each resident's drug regimen must be reviewed at least once a month by a licensed pharmacist.[29]

To facilitate medication safety, a nursing facility should consider:

- offering consistent and comprehensive training by the facility's consultant pharmacist to familiarize all staff involved in resident care with proper medication management practices and documentation requirements; and
- developing and implementing a review process to identify the incidence and frequency of medication errors, determine root causes of those errors, and develop or modify policies and training initiatives to prevent recurrences.

Consultant pharmacists, who specialize in the medication needs specific to nursing facility residents, can help identify, evaluate, and address medication issues, which may improve resident care, reduce hospital admissions, and enhance quality of life.

5. Appropriate Use of Medications

a. Adequate Indication of Necessary Use

Under the ROPs, a nursing facility is required to ensure that each resident's drug regimen is free from unnecessary drugs.[30] With respect to psychotropic drugs, the ROPs require nursing facilities to ensure that: (1) residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific, diagnosed condition; and (2) residents who use psychotropic drugs receive gradual dose reductions and behavior interventions (unless clinically contraindicated) in an effort to discontinue these drugs.[31] Furthermore, the ROPs prohibit nursing facilities from using any chemical restraints for "purposes of discipline or convenience and that are not required to treat the resident's medical symptoms."[32]

[27] 42 C.F.R. § 483.45(f)(2).
[28] 42 C.F.R. § 483.45(b)(1).
[29] 42 C.F.R. § 483.45(c).
[30] 42 C.F.R. § 483.45(d).
[31] 42 C.F.R. § 483.45(e).
[32] 42 C.F.R. § 483.12(a)(2); 42 C.F.R. § 483.10(e)(1).

OIG has reviewed the high utilization of psychotropic, antipsychotic, and anticonvulsant drugs for nursing facility residents and the inappropriate use by nursing facilities of these drugs for off-label conditions. The prescription of psychotropic medications for potentially inappropriate uses raises concerns about whether they are a means of chemical restraint.[33] OIG has noted higher rates of psychotropic drug use at nursing facilities with lower ratios of registered nurse staff to residents and at nursing facilities with higher percentages of residents with low-income subsidies. The prevalence of these medications in nursing facilities is of particular concern given the medications' risk of serious side effects. Antipsychotics and many anticonvulsants contain boxed warnings by the Food and Drug Administration regarding potential life-threatening adverse reactions.

Furthermore, OIG's work has raised concerns that nursing facilities may be misreporting schizophrenia on the Minimum Data Set (MDS) to inappropriately impact CMS's quality measure on antipsychotic use. CMS excludes from this measure any residents with particular diagnoses, including schizophrenia (with the presumption that antipsychotic use for such residents would not be inappropriate).[34]

Under the leadership of a nursing facility's medical director, who is responsible for coordinating medical care and implementing resident care policies,[35] nursing facilities should consider encouraging collaboration among attending physicians, consultant pharmacists, and other resident care providers to mitigate the risk of inappropriate use of medications.

Mitigation strategies should include:

- developing standardized practices that result in an interdisciplinary team 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 from the medication, whether certain medication use should be discontinued, and whether the resident has been prescribed the least number of medications as possible;
- requiring consistent documentation of the appropriate use of medication (e.g., documenting specific symptoms, conditions, or behaviors that the medication is prescribed to treat), its safety and efficacy, and ongoing efforts to monitor the appropriateness of the medication;
- establishing defined communication channels for staff and care providers to raise medication questions and concerns and for leadership to promptly respond to them;
- reviewing protocols to routinely evaluate the adequacy and effectiveness of written standards, staff training programs, documentation practices, and internal review procedures; and

[33] *See* OIG, Long-Term Trends of Psychotropic Drug Use in Nursing Homes, OEI-07-20-00500 (Nov. 2022).
[34] *See* OIG, Long-Term Trends of Psychotropic Drug Use in Nursing Homes, OEI-07-20-00500 (Nov. 2022). For more information about the MDS, see the Reimbursement Supplement.
[35] *See* 42 C.F.R. § 483.70(g).

- ensuring that medication management practices are consistently applied and that risks associated with inappropriate, unnecessary medication use are mitigated.

Nursing facility compliance and quality programs also should continually develop and provide training to all staff that reinforces the critical importance of integrity and accuracy in compiling and reporting resident assessment data in the MDS. Misstatements on the MDS could form the basis of an enforcement action.

b. Minimizing Conflicts of Interest

In all cases, pharmaceutical decisions for nursing facility residents should be objective, unbiased, and in the best interests of residents. The determination of clinical efficacy and appropriateness of a particular drug for a resident should precede, and be paramount to, cost considerations. Potential or real conflicts of interest (e.g., a nursing facility's consultant pharmacist being affiliated with a drug company or long-term care pharmacy) could lead to risks of overprescribing and inappropriate prescribing. Also, depending on the facts and circumstances, conflicts of interests in pharmaceutical decision making may violate the Federal anti-kickback statute, discussed below.

- **Consultant pharmacists** typically provide managerial aspects of nursing facility resident medications including drug regimen reviews and other medication management tasks. Depending on formularies and other State law and payor requirements, consultant pharmacists may make recommendations about particular drugs for a resident.
- **Long-term care pharmacies** typically provide operational aspects of resident medications including the ordering, receipt, storage, packaging, and administering of drugs. Depending on pharmaceutical manufacturer purchasing agreements and other factors, long-term care pharmacies may prefer that nursing facility customers and residents use some drugs over others.

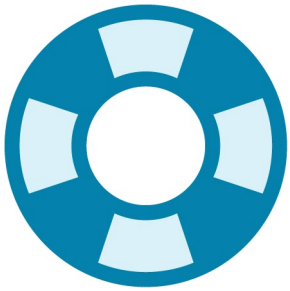
To minimize the potential for a conflict of interest to impact pharmaceutical decisions, nursing facilities should:

- consider having separate contracts for consultant pharmacist services and for long-term care pharmacy services;
- consider requiring consultant pharmacists and long-term care pharmacies to disclose any affiliations that may pose a potential conflict of interest;
- ensure that remuneration to consultant pharmacists and to long-term care pharmacies is:
  - consistent with fair market value; and
  - not structured in any manner that reflects the volume or value of drugs prescribed for, or administered to, residents;
- adopt and implement policies and procedures clearly stating that:

- all prescribing decisions must be based on the best interests of the individual resident; and
- drug switches may only be made upon authorization of an attending physician, medical director, or other licensed prescriber (except in certain limited circumstances, when permitted by State law, e.g., permissible generic substitutions or changes allowed under a collaborative practice agreement between a physician and a pharmacist); and

- monitor drug records for patterns that may indicate inappropriate drug switching, steering, or overprescribing.

6. Resident Safety



Nursing facility resident safety is an essential component of high-quality care, particularly given the large number of residents who have mobility limitations and chronic medical or behavioral conditions. Nursing facilities should develop a safety culture that includes the development of robust communication systems, continual monitoring of quality and safety events, processes to promptly remediate those events, and training and education initiatives covering these elements. Below, we highlight some key resident safety risks and recommendations for mitigating those risks.

a. Resident Abuse and Neglect

Resident abuse and neglect—including resident-on-resident abuse, abuse and neglect by staff, and injuries from unknown sources—is an increasing concern within nursing facilities.[36] Under the ROPs, nursing facility residents have a right to be free from abuse and neglect.[37] Among other requirements in the ROPs, nursing facilities must: (1) develop and implement written policies and procedures to prohibit and prevent the mistreatment, neglect, and abuse of residents;[38] and (2) ensure that incidents involving allegations of mistreatment, neglect, and abuse, as well as injuries from an unknown source, are reported immediately through established procedures to the administrator of the facility and to other officials, including the State Survey Agency, in accordance with State law.[39]

A proactive approach to mitigating resident safety risks through continual monitoring of adverse events and quality of care issues should be the driving force behind

[36] For an overview of research relating to resident abuse and neglect, see World Health Organization, Abuse of Older People (June 15, 2024).
[37] 42 C.F.R. § 483.12.
[38] 42 C.F.R. § 483.12(b).
[39] 42 C.F.R. § 483.12(c).

nursing facilities' resident safety programs. Proactive monitoring may prevent harm before it occurs.

Nursing facilities and industry stakeholders have reported to OIG the importance of implementing a resident safety program that includes the following components, which, taken together, may help to mitigate or eliminate instances of resident harm.

	Recommendations for a Resident Safety Program
Communication Systems	• Develop a safety culture by clearly communicating and promoting safety initiatives, encouraging leadership to foster resident trust in facility staff, and incentivizing and recognizing staff who not only adhere to safety standards but also report safety concerns. • Maintain a confidential reporting mechanism that is publicized to staff, contractors, residents, family members, guardians, visitors, and others in multiple ways to enable the confidential reporting—without fear of retaliation or reprisal—of any threats, abuse, mistreatment, and other safety concerns directly to senior facility staff who have the authority to take immediate corrective action. • Ensure effective communication systems to facilitate the immediate reporting of resident harm to a facility administrator and other officials, including the State Survey Agency, as required by law. • Create and foster a transparent environment in which quality and safety concerns, measures, and review findings are freely and in a timely manner shared with staff.
Training and Education	• Promote resident safety education (e.g., through training, posters, pamphlets, and signage) for everyone in contact with nursing facility residents, including health care professionals, administrative and custodial staff, family, guardians, friends, visiting therapists, volunteers, and community members. • Develop practical training for staff to understand what may constitute an adverse event, substandard care, close call, or hazardous condition that may lead to resident harm. • Use identified safety lapses or failures as learning opportunities. • Develop specialized presentations and trainings regarding how to recognize the warning signs of neglect or abuse.

	• Inform residents about how to self-report mistreatment by other residents or staff, encourage that reporting, and regularly assess residents' comprehension of those reporting systems.
Monitoring and Remediation	• Develop robust systems and processes to proactively monitor adverse events and quality-of-care issues. • Regularly evaluate systems and processes to determine the potential for their failure, whether there may be a consequence of resident harm from any failure, and the need for changes, improvements, or training to mitigate risk of any failure. • Define specific corrective action and a timeline to complete all remedial efforts. Track progress against deadlines and confirm completion of all remedial efforts to prevent recurrence.

b. Staff Screening

Nursing facility staff—including those providing direct care and those in administrative roles or support roles—are entrusted with residents' well-being. Under the ROPs, nursing facilities cannot employ or otherwise engage individuals "found guilty of abuse, neglect, exploitation, misappropriation of property, or mistreatment by a court of law," or individuals with "a finding entered into [a] State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property."[40] Although no background screening can provide nursing facilities with absolute assurance that a job applicant or contractor will not commit resident abuse or neglect in the future, nursing facilities should nonetheless conduct comprehensive background screenings to protect their residents, including checking OIG's List of Excluded Individuals and Entities to confirm the exclusion status of a prospective employee or contractor. If a nursing facility submits a claim to a Federal health care program for an item or service furnished by an individual or entity that is excluded from participation in Federal health care programs, payment for that claim results in an overpayment, as described in the GCPG.

The following are recommendations for nursing facilities to conduct effective staff screening, ensure they provide residents with qualified and skilled caregivers according to Federal and State requirements, and ensure that residents are protected to the greatest extent possible.

- Develop and implement standardized recruitment and screening practices to ensure that prospective and existing employees have appropriate training, education, and certification and that they maintain all requisite qualifications, licensing, and skills.

[40] 42 C.F.R. § 483.12(a)(3).

- In each background screening process, include a comprehensive examination of a prospective employee's criminal record for each State in which the person has worked or resided to ensure that no disqualifying offenses have been committed.
- Conduct monthly screening of employees, including verification of licensure as applicable, and conduct recurring background checks of non-licensed employees.
- Consider appropriate training for human resources personnel on the effects of exclusion.
- Review the GCPG's discussion regarding additional screening recommendations to prevent hiring or contracting with excluded persons.

c. Emergency Preparedness and Life Safety

Natural disasters and public health emergency events often have significant implications for nursing facilities, given that residents are often elderly or have medical conditions that make them particularly vulnerable during any disruptions in care. Residents and their families or guardians rely on nursing facilities to plan and execute appropriate procedures during emergency events. Moreover, residents and their families or guardians rely on facilities to ensure that they meet life safety codes and that critical facility systems such as furnaces, water heaters, kitchen equipment, generators, sprinkler and alarm systems, and elevators are properly installed, tested, and maintained. The ROPs set forth specific requirements for establishing and maintaining an emergency preparedness program, including the minimum elements that the program must have.[41] Nursing facilities are responsible for ensuring that facilities are free from hazards and that emergency plans, including fire evacuation and disaster preparedness plans, are updated and tested regularly.[42]

Nevertheless, prior OIG work found that many nursing facilities that often met the CMS requirements for emergency planning failed to follow their own plans or apply sufficient efforts to ensure the safety and well-being of residents.[43] Nursing facilities should continually assess whether they are dedicating the necessary resources to planning, preparing, and implementing effective responses to a wide array of natural and public health emergencies to protect residents from harm while also ensuring that residents are cared for during and after an emergency. Nursing facilities should also ensure that the State and local community response network is aware that the nursing facility houses vulnerable residents who will be high priority for evacuation in a natural disaster and that the network places the facility at the top of the priority list for power restoration. Regular staff training and resident education focusing on a facility's emergency response program and conducting drills as appropriate for reinforcement is recommended.

[41] 42 C.F.R. § 483.73.

[42] 42 C.F.R. § 483.90.

[43] *See, e.g.*, OIG, Nursing Homes Reported Wide-Ranging Challenges Preparing for Public Health Emergencies and Natural Disasters, OEI-06-22-00100 (Sept. 2023).

With respect to emergencies that require the evacuation of residents, nursing facilities and industry stakeholders have reported to OIG the importance of ensuring that policies, systems, and protocols are regularly tested and evaluated through simulating lapses in a facility's ability to provide continual care for residents who may be frail, have mobility issues, have multiple medical conditions, or experience difficulty in adapting to new surroundings. Simulations may also be developed to test the flexibility of a nursing facility's evacuation procedures to accommodate last-minute, unexpected, or changed circumstances. If nursing facilities contract with a transportation company for emergency transportation services, they should ensure that those companies have adequate capacity to timely and safely transport their residents during emergencies or natural disasters that may affect a large geographic area.

Nursing facilities and industry stakeholders have cited to OIG the importance of including in their emergency preparedness plans post-evacuation procedures to address the physical and mental stress and trauma that residents may experience and that may lead to negative health outcomes. The OIG Resources for Emergency Preparedness and Response website includes toolkits for nursing facilities with key insights and lessons learned from OIG evaluations and audits of community emergency preparedness and response efforts relating to outbreaks, natural disasters, and other events.

d. Infection Control

An effective infection prevention and control program (IPCP) should be a priority for nursing facilities given residents' increased susceptibility and exposure to infection.[44] The ROPs include specific requirements for establishing and maintaining an IPCP designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections. The ROPs set forth the minimum elements an IPCP must include.[45] OIG learned in its evaluations of the COVID-19 pandemic that nursing facilities experienced challenges in implementing their infection control practices and quarantine procedures to effectively protect the health and safety of nursing facility residents and staff.

OIG has found from its monitoring of nursing facilities operating under CIAs that the following recommendations may facilitate improvement of IPCPs:

- consider retaining independent consultants to identify and help address shortcomings in infection control processes;
- consider maintaining at least one dedicated, full-time infection preventionist on staff for larger facilities;

[44] *See* OIG, Certain For-Profit Nursing Homes May Not Have Complied with Federal Requirements Regarding the Infection Preventionist Program, A-01-22-00001 (Aug. 2024).
[45] 42 C.F.R. § 483.80.

- conduct regular and intensive staff training, including lessons learned from prior lapses in the facility's infection control program, and provide staff with the free online infection prevention and control training offered by the Centers for Disease Control and Prevention; and
- implement a system to periodically evaluate whether sufficient and necessary supplies (e.g., personal protective equipment and point-of-care testing kits) are available and address any shortages.

e. Facility-Initiated Discharges

An inappropriate transfer or discharge of a resident initiated by a nursing facility can create an unsafe and traumatic experience for the resident and their family or guardians. According to data from the National Ombudsman Reporting System, State ombudsman programs that are charged with resolving problems for nursing facility residents have reported receiving more complaints about discharge and eviction than any other category of complaints.[46]

OIG has identified a high rate of inappropriate facility-initiated discharges of residents with behaviors that endangered them or others in a facility.[47] We acknowledge the challenges that nursing facilities face in caring for residents with mental health disorders while also recognizing that it is not advisable for nursing facilities to admit residents for whom they do not have the capacity to provide safe and effective care that addresses their disorders and behaviors.

Under the ROPs, nursing facilities may only transfer or discharge a resident if one of the following justifications can be demonstrated by the facility:

- The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met at the facility.
- The transfer or discharge is appropriate because the resident's health has improved sufficiently so that the resident no longer needs services provided by the facility.
- The safety of individuals in the facility is endangered due to the clinical or behavioral status of the resident.
- The health of individuals in the facility would otherwise be endangered.
- The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility (subject to certain caveats).
- The facility ceases to operate.[48]

[46] OIG, Facility-Initiated Discharges in Nursing Homes Require Further Attention, OEI-01-18-00250 (Nov. 2021).
[47] OIG, Nursing Home Residents with Endangering Behaviors and Mental Health Disorders May Be Vulnerable to Facility-Initiated Discharges, OEI-01-18-00252 (Mar. 2024).
[48] 42 C.F.R. § 483.15(c).

CMS regulations require nursing facilities to provide and document sufficient preparation and orientation to residents to ensure a safe and orderly transfer or discharge from the facility. CMS regulations also require nursing facilities to send all facility-initiated discharge notices to a resident and a representative of the State ombudsman at least 30 days in advance of a discharge.[49] State ombudsman offices have reported that untimely, incomplete, and inaccurate facility-initiated discharge notices submitted by nursing facilities present challenges to their ability to address facility-initiated discharges and any associated resident complaints.[50]

Because of the risks that inappropriate facility-initiated discharges pose to nursing facility residents, OIG recommends nursing facilities ensure that facility staff are trained on what constitutes an inappropriate transfer and discharge that violates Federal regulations. Facility staff should also be trained on the specific set of criteria that must be met under the ROPs prior to discharging or transferring residents and on State requirements for facility-initiated discharge notices, with an emphasis on the importance of submitting timely, complete, and accurate notices for all facility-initiated discharges.[51]

OIG recommends that the following processes be developed, when feasible, should a facility arrive at a determination that one or several of the permissible reasons for transfer or discharge under the ROPs (described above) exist:

- confirm that the resident, family members, and guardians have been informed about the specific location of any new recommended facility and its availability, as well as the appropriateness of services at the facility that will be tailored to the needs of the resident;
- facilitate scheduling of a predischarge site visit to the new facility as part of the orientation process, not only for the resident but also family members and guardians, so that there may be assurance of the resident's continuing care;
- work closely with the new facility to provide all information about the resident's care needs, living preferences, and behavioral habits, as well as a catalog of personal items and belongings, so that the resident's transition may be more comfortable and less stressful;
- prior to discharging a resident to their home, ensure that the resident's needs can be met in the home; and
- confirm that the discharge is not to a homeless shelter or an unsafe environment.

[49] 42 C.F.R. § 483.15(c).

[50] OIG, Facility-Initiated Discharges in Nursing Homes Require Further Attention, OEI-01-18-00250 (Nov. 2021).

[51] *See* OIG, Concerns Remain About Safeguards To Protect Residents During Facility-Initiated Discharges From Nursing Homes, OEI-01-18-00251 (Mar. 2024).

B. Medicare and Medicaid Billing Requirements

Ensuring compliance with Medicare and Medicaid billing requirements should be a core function of nursing facility compliance program operations. 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. 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. Even if an entity makes an isolated billing error, that entity still has an obligation to repay the overpayment to the Government to avoid False Claims Act liability, as explained in the GCPG.

In this section, we discuss some of the risk areas related to Medicare and Medicaid billing requirements for nursing facilities and recommendations for addressing those risks. This list of risk areas is not exhaustive. It is intended only to assist facilities in evaluating and mitigating their own particular risk areas. As context for this discussion, see the Reimbursement Supplement, which provides an overview of Medicare and Medicaid reimbursement for nursing facilities. Certain terms used but not defined in this section are hyperlinked to a definition in the Reimbursement Supplement.

1. SNF Prospective Payment System (PPS)

Common and longstanding risks associated with claim preparation and submission under the SNF PPS include duplicate billing, insufficient documentation, and false or fraudulent cost reports. They also include compliance with requirements such as the SNF 3-Day Rule and consolidated billing. Nursing facilities should continue to be vigilant with respect to these important risk areas.

PDPM, which is the current SNF PPS case-mix classification system, changes the way residents are classified into payment groups as compared to the prior case-mix classification system, which was called RUG-IV. However, **PDPM does not change any of the coverage criteria or documentation requirements for services to be covered under the SNF PPS. More importantly, PDPM does not change the care needs of a nursing facility resident. These care needs should always be the primary driver of care decisions, including the type, duration, and intensity of services, including, but not limited to, therapy services.**

	Recommendations to Promote Compliance With SNF PPS Billing Requirements
Policies and procedures	• Develop and maintain policies and procedures that incorporate the following areas of heightened importance under PDPM: ○ resident assessments; ○ care planning; ○ tracking of resident progress and outcomes; ○ proper documentation of the services provided (including, but not limited to, therapy services); and ○ appropriate coding of resident characteristics.
Training and education	• Ensure that clinical and billing staff fully understand the requirements for billing Medicare under the SNF PPS, including the relatively new requirements under the PDPM case-mix classification system and all other requirements (e.g., the SNF 3-Day Rule and consolidated billing). ○ Implement competency-based training for: - areas of heightened importance under PDPM described above; and - lessons derived from the facility's auditing and monitoring activities.
Reviews and audits	• Confirm that coding accurately reflects residents' characteristics and comorbidities. • Confirm that services provided to residents are individualized, skilled, and medically necessary and that coding of services reflects services as rendered. • Periodically assess the adequacy of therapy services—the provision of the appropriate services for the specific care need—to ensure that therapy management does not result in underutilization. • Refer to OIG, CMS, Medicare Administrative Contractor, Recovery Audit Contractor, and other external audits to identify and mitigate additional risks.

2. Value-Based Payment Models and Programs

Value-based payment models and programs (including the SNF VBP Program under the SNF PPS and other accountable care and value-based payment models and programs) generally focus on accountability for quality and total cost of care. Payments that encompass performance measures such as quality and total cost of care may increase the risk of gaming of data to qualify for performance-based payments. Thus, nursing facility compliance programs should include in auditing, monitoring, and training initiatives an emphasis on the importance of data accuracy.

For recommendations regarding reducing fraud and abuse risks under the Federal anti-kickback statute related to care coordination and value-based care arrangements, see below.

3. Medicare Advantage and Medicaid Managed Care

Nursing facilities must ensure the accuracy of claims they submit to managed care plans to avoid causing the plans to submit false claims to a Federal health care program. For example, if a managed care plan passes its financial risk to a nursing facility through a capitated payment arrangement, the nursing facility should ensure that it is not stinting on care provided to residents enrolled in the plan or discriminating against more costly residents enrolled in the plan.

4. Medicare Part D

Because prescriptions are generally covered by the Part A SNF PPS (or the Medicare Advantage plan that provides the Part A benefits) when an individual is in a covered Part A stay, nursing facilities need to ensure that they do not bill MA-PD plans or PDPs for prescriptions to be covered by Part D when an individual is in a covered Part A stay.[52]

5. Medicare Health Plan Enrollment for Nursing Facility Residents

Nursing facilities that educate residents regarding Medicare health plans or assist residents with plan enrollment decisions should mitigate the risk that these efforts will lead to inappropriate steering to a particular plan or enrollment decision. To mitigate this risk, nursing facilities should implement reliable processes to ensure that they:

- provide complete and objective information and remain neutral regarding plans available to residents;

[52] *See* OIG, Medicare Part D Paid Millions for Drugs for Which Payment Was Available Under the Medicare Part A Skilled Nursing Facility Benefit, A-09-21-03008 (Oct. 2024).

- do not accept any remuneration from any individual or entity to influence a resident to select a particular plan;
- comply with health plan policies and Medicare regulations related to marketing and enrollment activities (described in the Reimbursement Supplement);
- to the extent that a resident or a resident's representative requests assistance from the nursing facility with changing the resident's Medicare health plan coverage, take specific steps outlined by CMS to help ensure that changes to the coverage comply with Medicare regulations regarding health plan enrollment and disenrollment and the ROPs regarding resident rights; and
- always act in the best interests of the resident.

C. Federal Anti-Kickback Statute

Nursing facilities must comply with the Federal anti-kickback statute,[53] which is described in the GCPG.

Although liability under the Federal anti-kickback statute depends in part on a party's intent, 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.

In this section, we use the term **"referral"** to include the full range of activities—including referring, arranging for, purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering—that fall within the scope of the Federal anti-kickback statute. It is possible for a Federal health care program enrollee to self-refer to a facility and for another referral source (such as a physician or hospital discharge planner) to arrange for and recommend (among other things) that the enrollee be admitted to a facility.

Nursing facilities obtain referrals of Federal health care program business from (among others): physicians and other health care professionals; hospitals and hospital discharge planners; hospices; home health agencies; other nursing facilities; health plans; and Federal health care program enrollees who self-refer to a facility.

Nursing facilities refer residents to, or order items or services from (among others): hospices; durable medical equipment (DME) suppliers; ambulance providers; laboratories; diagnostic testing facilities; long-term care pharmacies; hospitals; physicians; other nursing facilities; and physical, occupational, and speech therapists.

[53] Section 1128B(b) of the Act, 42 U.S.C. § 1320a-7b(b).

All referral relationships call for **vigilance** under the Federal anti-kickback statute.

When nursing facilities identify an arrangement that implicates the Federal anti-kickback statute, we recommend that, whenever possible, they structure the arrangement to meet all conditions set forth in a statutory exception or regulatory safe harbor to the Federal anti-kickback statute. However, compliance with an exception or safe harbor is voluntary. Arrangements that may implicate the statute and that do not fit into an exception or safe harbor should be evaluated for compliance with the statute based on the totality of the facts and circumstances, including the intent of the parties.

The following safe harbors are most relevant to nursing facilities:

- Investment interests (42 C.F.R. § 1001.952(a))
- Space rental (42 C.F.R. § 1001.952(b))
- Equipment rental (42 C.F.R. § 1001.952(c))
- Personal services and management contracts and outcomes-based payment arrangements (42 C.F.R. § 1001.952(d))
- Discounts (42 C.F.R. § 1001.952(h))
- Employees (42 C.F.R. § 1001.952(i))
- Managed care and risk-sharing arrangements (42 C.F.R. §§ 1001.952(m), (t), and (u))
- Electronic health records items and services (42 C.F.R. § 1001.952(y))
- Local transportation (42 C.F.R. § 1001.952(bb))
- Care coordination and value-based arrangements (42 C.F.R. § 1001.952(ee), (ff), and (gg))
- Arrangements for patient engagement and support to improve quality, health outcomes, and efficiency (42 C.F.R. § 1001.952(hh))
- CMS-sponsored model arrangements and CMS-sponsored model patient incentives (42 C.F.R. § 1001.952(ii))
- Cybersecurity technology and related services (42 C.F.R. § 1001.952(jj))

The discussion below highlights several risk areas for nursing facilities under the Federal anti-kickback statute and recommendations for mitigating those risks. Nursing facilities should scrutinize the listed risk areas as part of their risk assessment, internal review, and monitoring processes.

DISCLAIMER

This list of risk areas is not exhaustive. It is intended only to assist nursing facilities in evaluating and mitigating their own particular risk areas. The propriety of any arrangement can only be determined after a detailed examination of the relevant facts and circumstances. Arrangements similar to those discussed in the risk areas below are not necessarily illegal and could possibly be structured to fit in a safe harbor.

1. Free (or Below Fair Market Value) Goods and Services

OIG has longstanding and continuing concerns about the provision of free (or below fair market value) goods or services to an existing or potential referral source because there is a substantial risk that such goods or services may be used as a vehicle to disguise an unlawful payment to induce or reward referrals of Federal health care program business. The provision of free (or below fair market value) goods or services that have independent value to the recipient or that the recipient would otherwise have to provide at the recipient's own expense confers a benefit to the recipient, which may constitute prohibited remuneration under the Federal anti-kickback statute.

The following are examples of goods and services arrangements between nursing facilities and referral sources or recipients that, when provided for free (or below fair market value), could be used as a vehicle to disguise an unlawful payment for referrals of Federal health care program business. **Nursing facilities should scrutinize these arrangements to ensure they are not unlawful payments for referrals:**

- Consultant pharmacist services, medication management, or supplies offered by a long-term care pharmacy
- Infection control, chart review, or other services offered by laboratories or other suppliers or providers
- Equipment, computers, or software applications offered by a hospital, long-term care pharmacy, or laboratory
- DME or supplies offered by DME suppliers for residents covered by the SNF Part A benefit
- A laboratory phlebotomist providing administrative services that have independent value to the nursing facility
- A hospice registered nurse providing nursing services to nonhospice patients
- A hospital registered nurse providing nursing services to nonhospital patients
- A nursing facility providing free (or below fair market value) items or services to hospital discharge planners (such as free meals or tickets to sporting events)
- A nursing facility providing free (or below fair market value) items or services to Federal health care program enrollees and their family members or guardians (such as gift cards or waiving any applicable copayments)

Providing free (or below fair market value) goods and services—or anything else of value—to a Federal health care program enrollee could implicate the Federal anti-kickback statute, if done with the requisite intent to induce or reward the enrollee's self-referral to the facility. It also could implicate the Beneficiary Inducements CMP, which is described in the GCPG. Nursing facilities are expected to compete for consumers through the quality of care and quality of life they provide—not through offering or paying unlawful inducements.

2. Discounts

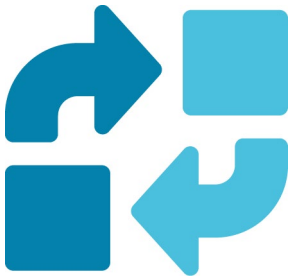
a. Price Reductions

Nursing facilities routinely purchase items and services from third parties that are reimbursable under Federal health care programs. If the supplier or provider of such items or services offers items, services, or both to a nursing facility at a discounted price, the discount is a form of remuneration that may implicate the Federal anti-kickback statute.

Most discount arrangements can be structured to meet the safe harbor to the Federal anti-kickback statute for discounts.[54] Nursing facilities should ensure that their discount arrangements are structured to meet this safe harbor whenever possible. To qualify for this 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).

Some nursing facilities purchase products through group purchasing organizations (GPOs) to which they belong. Any discounts received from vendors who sell products through a GPO contract should be properly disclosed and accurately reported on a nursing facility's cost reports.[55]

b. Swapping



In negotiating arrangements with suppliers and providers, a nursing facility should be careful that there is no link, explicit or implicit, between discounts (or free items and services) offered or solicited for business payable by the nursing facility and the nursing facility's referral of business billable by the supplier or provider directly to a Federal health care program. For example, a nursing facility should not engage in a "swapping" arrangement by accepting 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, such as Part B business excluded from consolidated billing, that the supplier or provider can bill directly to a Federal health care program.

Regardless of the size of the discount, "swapping" arrangements are not protected by the discount safe harbor and may violate the Federal anti-kickback statute. Nursing facility arrangements with

[54] 42 C.F.R. § 1001.952(h).
[55] Although there is a safe harbor for administrative fees paid by a vendor to a GPO, that safe harbor does not protect discounts provided by a vendor to a purchaser of products, such as a nursing facility. *See* 42 C.F.R. § 1001.952(j).

laboratories, DME suppliers, long-term care pharmacies, and ambulance providers are examples of arrangements that may be prone to "swapping" concerns.

Nursing facilities should carefully evaluate whether an improper connection exists between a discount (or free items and services) offered to a nursing facility and referrals of Federal health care program business billed by a supplier or provider. Examples of suspect arrangements include:

- below-cost arrangements or arrangements at prices below prices offered by a supplier or provider to other customers with similar volumes of business but without Federal health care program referrals; and
- discounts (or free items and services) coupled with exclusive provider agreements and discounts or other pricing schemes made in conjunction with explicit or implicit agreements to refer other facility business.

3. Arrangements for Services and Supplies

Often a kickback or other illegal remuneration is disguised as an otherwise legitimate payment or is hidden in a business arrangement that appears, on its face, to be appropriate. Nursing facilities should be mindful of this risk in their arrangements for services and supplies. In particular:

- **Physician and Nonphysician Practitioner Services.** Nursing facilities arrange for physicians (and potentially nonphysician practitioners) to provide medical director, quality assurance, and other services. These physicians and nonphysician practitioners may be in a position to refer Federal health care program patients for admission at the facility, admit patients to the facility, certify or recertify patients' need for skilled services, or order items and services that are billable separately by the facility. Physician and nonphysician practitioner arrangements need to be carefully monitored to ensure that they are not vehicles for paying for referrals.
- **Services and Supplies from Outside Suppliers and Providers.** Nursing facilities often arrange for certain services and supplies to be provided to residents by outside suppliers and providers such as pharmacies; laboratories; DME suppliers; ambulance providers; parenteral and enteral nutrition suppliers; diagnostic testing facilities; rehabilitation companies; and physical, occupational, and speech therapists. These relationships need to be carefully monitored to ensure that they are not vehicles for disguising payments from suppliers and providers to a nursing facility to influence the nursing facility to refer Federal health care program business to the suppliers and providers, or vice versa.

Recommendations to Mitigate Fraud and Abuse Risks Under the Federal Anti-Kickback Statute

The following are steps that nursing facilities should take to mitigate the risk of fraud and abuse under the Federal anti-kickback statute for arrangements that implicate the statute.

- Whenever possible, structure their arrangements to meet all conditions set forth in a safe harbor, which would protect the applicable arrangement from sanctions under the Federal anti-kickback statute. When an arrangement is structured to meet a safe harbor, nursing facilities should periodically review the arrangement to ensure that all conditions of the safe harbor continue to be met—including not just the written agreement documenting the arrangement (if any) but how the arrangement is actually conducted.
- Ensure that:
  - there is a legitimate need for the services or supplies under the applicable arrangement;
  - they have not engaged more physicians or service providers than necessary for legitimate business purposes (e.g., the nursing facility does not have more medical directors than needed);
  - services or supplies are actually provided;
  - compensation is commensurate with the skill level and experience reasonably necessary to perform the services;
  - compensation is at fair market value in an arm's-length transaction; and
  - the arrangement is not related in any manner to the volume or value of Federal health care program business.
- Document the factors that mitigate the risk of fraud and abuse in the arrangement before payment to the provider of supplies or services.
- Maintain contemporaneous documentation of the arrangement, including, for example, time logs or other accounts of services or supplies rendered.
- Monitor the arrangement to ensure it continues to be consistent with any features intended to mitigate fraud and abuse.
- Implement the recommendations in the GCPG regarding financial arrangements tracking.

4. Long-Term Care Pharmacy and Consultant Pharmacist Arrangements

The Federal anti-kickback statute prohibits a nursing facility from knowingly and willfully soliciting or receiving anything of value from a pharmacy or pharmaceutical manufacturer to influence the choice of a drug or switch a resident from one drug to another (when the drug is payable under a Federal health care program). Nursing facilities should educate all staff and contractors involved in prescribing, administering, and managing pharmaceuticals about this prohibition.

Nursing facilities generally should not accept free (or below fair market value) goods or services from a long-term care pharmacy, such as free supplies or free services of the pharmacy's consultant pharmacist, because this could be a vehicle to disguise an unlawful payment for referrals of Federal health care program business. As with other arrangements, nursing facilities should implement the Recommendations to Mitigate Fraud and Abuse Risks in their arrangements with consultant pharmacists and long-term care pharmacies.

When a nursing facility's consultant pharmacist is affiliated with a long-term care pharmacy, the nursing facility should ensure that the pharmacy is not offering or paying anything of value to induce the pharmacist to make particular recommendations about a resident's drug regimen. Taking steps to minimize the potential for a conflict of interest to impact pharmaceutical decisions, described above, may help mitigate risks of fraud and abuse under the Federal anti-kickback statute.

5. Hospital Arrangements

a. General

Hospitals and hospital discharge planners frequently make referrals of Federal health care program business to nursing facilities, and nursing facilities frequently make referrals of Federal health care program business to hospitals. In light of the extensive referral relationships between nursing facilities and hospitals, nursing facilities should carefully monitor any remuneration exchanged with hospitals to ensure the remuneration is not intended to induce or reward referrals.

Examples of suspect arrangements include when a nursing facility:

- refers patients to a hospital to induce the hospital to refer patients to the facility;
- provides:
  - free items or services for hospital discharge planners;
  - "charity care" to certain patients as a favor to the hospital; and
- solicits or receives from a hospital:
  - goods or services for free (or below fair market value);
  - nurses or other staff for free (or below fair market value) to provide services at the facility on behalf of facility residents; and
  - monetary payments to expedite a facility's admission of hospital patients (discussed below).

As with other arrangements, nursing facilities should implement the Recommendations to Mitigate Fraud and Abuse Risks in their arrangements with hospitals.

b. Payments to Expedite Admission of Hospital Patients to a Nursing Facility

Hospitals often face significant challenges with obtaining timely acceptance of admissions from nursing and other post-acute care facilities for hospital patients who need to be discharged from the hospital and admitted to the facility. Hospitals sometimes offer or pay, and nursing facilities sometimes solicit or receive, payments to expedite the nursing facility's admission of these hospital patients.

While there are multiple permutations of this fact pattern, below we discuss the Federal anti-kickback statute implications in 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.

i. Payments to Accept a Discharged Patient

If a hospital offers or pays remuneration to a nursing facility—or a nursing facility solicits or receives remuneration from a hospital—in connection with the nursing facility's acceptance of a Federal health care program patient discharged from the hospital, the Federal anti-kickback statute may be implicated. For example, a hospital might offer to supplement payments a nursing facility receives from a payor for services the facility will provide to a former hospital patient. In exchange, the nursing facility might agree to expedite admission of the former hospital patient to the facility and thereby enable the hospital to have more rapid bed turnover than it otherwise would. There is no safe harbor protection available under the Federal anti-kickback statute in this scenario. These arrangements present risks of fraud and abuse under the Federal anti-kickback statute because they may lead to interference with clinical decision making, steering, and unfair competition.

> If a hospital (or any other source) supplements payments that a nursing facility receives from Medicare or Medicaid, this potentially implicates other laws, including Medicare and Medicaid anti-supplementation provisions, described below.

However, some arrangements related to the timely discharging of patients to nursing facilities could be structured to meet a safe harbor, which would protect the applicable arrangement from sanctions under the Federal anti-kickback statute. For example, a hospital and a nursing facility that are part of a value-based enterprise could structure the provision of the hospital's staff to the nursing facility to alleviate the facility's staffing concerns consistent with the conditions of an applicable safe harbor, such as the safe harbor for care coordination arrangements to improve quality, health outcomes, and efficiency.[56]

[56] 42 C.F.R. § 1001.952(ee).

ii. Payments to Reserve or Hold Beds

Sometimes hospitals enter into reserved bed arrangements with nursing facilities to receive guaranteed or priority placement for their discharged patients. These arrangements must comply with CMS requirements.[57] Under some reserved bed arrangements, hospitals provide remuneration to nursing facilities to keep certain beds available and open. These arrangements can be structured in a way that complies with the Federal anti-kickback statute. But these arrangements could violate the Federal anti-kickback statute if one purpose of the remuneration is to induce referrals of Federal health care program business from the nursing facility to the hospital. Payments should not be determined in any manner that reflects the volume or value of existing or potential referrals of Federal health care program business from the nursing facility to the hospital.

Examples of some reserved bed payments that may give rise to an inference that the arrangement is connected to referrals include:

- payments that result in double-dipping by the nursing facility (e.g., payments for beds that are occupied and for which the facility is already receiving reimbursement);
- payments for more beds than the hospital legitimately needs; and
- excessive payments (e.g., payments that exceed a nursing facility's actual costs of holding a bed or the actual revenues a facility reasonably stands to forfeit by holding a bed given the facility's occupancy rate and patient acuity mix).

Reserved bed arrangements should be entered into only when there is a bona fide need to have the arrangement in place. Reserved bed arrangements should serve the limited purpose of securing needed beds, not future referrals. Nursing facilities should be mindful that conditioning the offer of reserved beds specifically on referrals of Federal health care program enrollees by the hospital to the nursing facility would raise concerns under the Federal anti-kickback statute, even if no payment is made.

6. Hospice Arrangements

A nursing facility may arrange for the provision of hospice services at the nursing facility for a resident if the resident meets the hospice eligibility criteria and elects the hospice benefit.[58] Nursing facilities should be mindful that requesting or accepting remuneration from a hospice may subject both parties to liability under the Federal anti-kickback statute if the remuneration might influence the nursing facility's decision to do business with a hospice or otherwise induce Federal health care program referrals between the parties. Furthermore, under certain circumstances, a nursing facility

[57] *See, e.g.*, Provider Reimbursement Manual, Ch. 21, § 2105.3(D).
[58] *See* 42 C.F.R. § 483.70(n)(1).

that knowingly refers patients for hospice services who do not qualify for the hospice benefit may be liable for the submission of false claims.

Hospice Background Information. Medicare hospice eligibility criteria are found at 42 C.F.R. § 418.20. Hospices themselves must generally furnish substantially all of a core hospice service. Hospices are permitted to furnish noncore services under arrangements with other providers or suppliers, including nursing facilities.[59] For Medicaid patients, the State will pay the hospice at least 95 percent of the State's Medicaid daily nursing facility rate, and the hospice is then responsible for paying the nursing facility for the enrollee's room and board.[60] The Medicare reimbursement rate for routine hospice services provided in a nursing facility does not include room and board expenses, so payment for room and board may be the responsibility of the patient.[61]

Examples of suspect arrangements include when a nursing facility:

- refers patients to a hospice to induce the hospice to refer patients to the facility; and
- solicits or receives from a hospice:
  - goods or services for free (or below fair market value);
  - nurses or other staff for free (or below fair market value) to provide services at the facility for nonhospice patients; and
  - monetary payments for:
    - room and board for a resident in excess of what the nursing facility would have received directly from Medicaid if the patient had not been enrolled in hospice (any additional payment must represent the fair market value of additional services actually provided to that patient that are not included in the Medicaid daily rate);
    - additional services for a resident that are included in the Medicaid room and board payment to the hospice;
    - additional services for a resident that are not included in the Medicaid room and board payment (at a rate that is above fair market value); and
    - a nursing facility providing hospice services to a hospice's patients (at a rate that is above fair market value).

As with other arrangements, nursing facilities should implement the Recommendations to Mitigate Fraud and Abuse Risks in arrangements with hospices.

[59] *See* 42 C.F.R. § 418.64.
[60] *See* section 1902(a)(13)(B) of the Act, 42 U.S.C. § 1396a(a)(13)(B).
[61] *See* Medicare Benefit Policy Manual, Ch. 9, § 20.3.

7. Care Coordination and Value-Based Care Arrangements

Nursing facilities can participate in, or be affiliated with, various CMS and State Medicaid program value-based payment models and programs, as well as care coordination and value-based care arrangements with other health care entities outside these models and programs, as described in the Reimbursement Supplement. Care coordination and value-based care arrangements (whether or not part of a CMS or State Medicaid model or program) are often focused on the coordination of patient care among providers and across care settings, such as between a hospital and a nursing facility.

Care coordination often naturally involves referrals across care settings, including referrals of Federal health care program business. For this reason, remuneration exchanged between a nursing facility and another entity as part of a value-based arrangement may implicate the Federal anti-kickback statute.

As with other arrangements, nursing facilities should implement the Recommendations to Mitigate Fraud and Abuse Risks in their value-based arrangements. In particular, nursing facilities that are part of a value-based enterprise and nursing facilities that participate in a CMS-sponsored model could structure their arrangements consistent with the conditions of one of the safe harbors finalized in OIG's 2020 final rule.[62] These safe harbors were designed to remove potential barriers preventing effective coordination and management of patient care and delivery of value-based care, while at the same time protecting against abusive arrangements. In an effort to remove regulatory barriers to value-based care, the safe harbors finalized in OIG's 2020 final rule may not include some of the standard safe harbor elements, such as fair market value. Other safe harbors may be available to certain value-based arrangements as well.

8. Joint Ventures

Nursing facilities often enter into "joint ventures"—shared enterprises (through equity or by contract) to accomplish specific goals—with other health care entities. OIG has long recognized that "there may be legitimate reasons to form a joint venture, such as raising necessary investment capital."[63] Indeed, joint ventures may offer benefits to joint venture participants, Federal health care programs, and Federal health care program enrollees, such as expanding access to services for enrollees, facilitating shared knowledge among participants, and expanding value-based care arrangements by allowing participants to spread financial risk. However, OIG has longstanding and

[62] Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77,684 (Dec. 2, 2020). The safe harbors finalized in this final rule include, for example, the safe harbors at 42 C.F.R. §§ 1001.952(ee), (ff), (gg), (hh) and (ii).
[63] OIG, Special Fraud Alert: Joint Venture Arrangements (1989), *reprinted in* 59 Fed. Reg. 65,372, 65,373 (Dec. 19, 1994).

continuing concerns regarding certain problematic joint venture arrangements,[64] including those entered into by nursing facilities and their ancillary service providers.

A problematic joint venture could arise in the nursing facility setting, for example, through the following set of facts:

- A contract therapy services company (Therapy Company) that provides therapy staffing for rehabilitation programs in nursing facilities enters into a joint venture with a nursing facility (Facility) for which it provides contract therapy services.
- The joint venture entity that they collectively own (Newco) then provides the same contract therapy services to Facility that Therapy Company previously provided to Facility, and Facility directs its referrals for therapy services (including therapy services reimbursable by a Federal health care program) to Newco instead of to Therapy Company.
- Facility does not participate in the operation of Newco. Instead, Therapy Company manages Newco and supplies it with inventory, employees, space, billing, and other services.

In this example, Facility would receive the profits of Newco as remuneration for its Federal health care program referrals to Newco. One purpose of such an arrangement could be to permit Therapy Company to do indirectly what it cannot do directly: pay Facility a share of the profits from Facility's referrals to Therapy Company for therapy services that are reimbursable under a Federal health care program. Depending on the facts and circumstances, such an arrangement could generate prohibited remuneration under the Federal anti-kickback statute.

Compliance Recommendations for Joint Ventures

- Exercise caution when considering and entering into joint ventures;
- Ensure that a joint venture is entered into for a legitimate purpose and that it does not exhibit attributes of problematic joint ventures that OIG has identified;
- Depending on the facts and circumstances, structure joint venture arrangements to meet the conditions of one of the following safe harbors:
  - small entity investments;[65]
  - care coordination arrangements to improve quality, health outcomes, and efficiency;[66]
  - value-based arrangements with substantial downside financial risk;[67] or
  - value-based arrangements with full financial risk.[68]

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[64] *See, e.g.*, OIG, Special Fraud Alert: Joint Venture Arrangements (1989), *reprinted in* 59 Fed. Reg. 65,372, 65,373 (Dec. 19, 1994); OIG, Special Advisory Bulletin: Contractual Joint Ventures (2003).
[65] 42 C.F.R. § 1001.952(a)(2).
[66] 42 C.F.R. § 1001.952(ee).
[67] 42 C.F.R. § 1001.952(ff).
[68] 42 C.F.R. § 1001.952(gg).

- As with other arrangements, implement the Recommendations to Mitigate Fraud and Abuse Risks in joint venture arrangements.

D. Other Risk Areas

This section describes certain other risk areas that nursing facilities should consider including in their compliance and quality training, risk assessment, internal review, and monitoring processes.

1. Related-Party Transactions

CMS requires nursing facilities to identify related parties and report all payments made to those related parties on the facility's Medicare cost report.[69] Under Medicare, the cost of services, facilities, and supplies furnished to a provider by an organization related to that provider by common ownership or control may be included in the allowable cost of the provider in an amount equal to the related organization's cost. The cost, however, must not exceed the price of comparable services, facilities, and supplies that could be purchased elsewhere. Medicare requires that the reported amount be the lower of either the actual cost to the related organization or the market price for comparable services, facilities, or supplies, thereby removing any incentive to realize profits through these transactions.[70] CMS publishes Facility Affiliation Data, which includes information about individuals or entities that have an ownership stake in, or operational control over, nursing facilities.

OIG is concerned that nursing facility owners, operators, and private investors participating in related-party transactions may be engaging in "tunneling"—the practice of misrepresenting or hiding profitability by overstating payments for operational expenses that are funneled to related parties.[71] 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.[72] This conduct 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.

[69] 42 C.F.R. § 413.17.
[70] 42 C.F.R. § 413.17.
[71] Ashvin Gandhi & Andrew Olenski, National Bureau of Economic Research, Tunneling and Hidden Profits in Health Care 3 (Sept. 2024) (explaining that "estimates suggest that in 2019, 68% of the [nursing home] industry's profits were hidden through markups on related party transactions"); *see also* The National Consumer Voice for Quality Long-Term Care, Where Do the Billions of Dollars Go? A Look at Nursing Home Related Party Transactions (2023).
[72] Ashvin Gandhi & Andrew Olenski, National Bureau of Economic Research, Tunneling and Hidden Profits in Health Care 2 (Sept. 2024).

Recommendations to Mitigate Risks of Related-Party Transactions

- Routinely audit financial data to ensure the nursing facility is reporting related-party costs in accordance with Federal regulations.
- Ensure that related-party transactions are:
  - at fair market value;
  - of quality comparable to or greater than competing services provided by entities that are not commonly owned or controlled; and
  - chosen based primarily on the well-being of residents and not solely on the profit interests of owners, operators, and investors.

2. Physician Self-Referral Law

The Federal physician self-referral law (PSL),[73] often referred to as the "Stark law," is described in the GCPG. SNF services covered by the Medicare Part A PPS payment are not designated health services (DHS) for purposes of the PSL.[74] Nursing facilities, however, may perform or bill for services other than SNF services covered by the Medicare Part A PPS payment—such as services covered by Medicare Part B furnished to enrollees who are in a non-covered Part A stay or who reside in a nursing facility (or part thereof) that is not certified as a SNF by Medicare. When the services are DHS for purposes of the PSL (e.g., laboratory services; physical therapy, occupational therapy, and outpatient speech-language pathology services), the nursing facility is considered an entity that furnishes DHS (DHS entity).

Nursing facilities that are DHS entities should:

- review all financial relationships with:[75]
  - physicians who may refer or order DHS furnished by the nursing facility, such as attending physicians and physicians who are nursing facility owners, investors, medical directors, or consultants; and
  - immediate family members of such referring physicians; and
- ensure that these financial relationships satisfy all requirements of an applicable PSL exception. If they do not, then DHS referrals from the physicians to the facility are prohibited. Implementing recommendations in the GCPG regarding financial arrangements tracking may help support compliance with the requirements of applicable PSL exceptions.

[73] Section 1877 of the Act, 42 U.S.C. § 1395nn. *See generally* 42 C.F.R. Part 411, Subpart J.
[74] *See* 42 C.F.R. § 411.351 (defining "designated health services").
[75] Financial relationships under the PSL include both ownership interests and compensation arrangements. *See* 42 C.F.R. § 411.354 (defining "financial relationship," "ownership interest," and "compensation arrangement").

3. Anti-Supplementation

If another entity (such as a hospital) supplements payments that a nursing facility receives from Medicare or Medicaid, this potentially implicates other laws including the Federal anti-kickback statute, described above.

Nursing facilities must accept the applicable Medicare or Medicaid payment (including any enrollee coinsurance or copayments authorized under those programs), respectively, for covered items and services as the complete payment. Nursing facilities may not charge a Medicare or Medicaid enrollee, or another person in lieu of the enrollee, any amount in addition to what is otherwise required to be paid for covered items and services under Medicare or Medicaid (i.e., a cost-sharing amount).[76]

4. HIPAA Privacy, Security, and Breach Notification Rules

The HIPAA Privacy, Security, and Breach Notification Rules are described in the GCPG. Most nursing facilities are "covered entities" under HIPAA because they are health care providers that conduct certain health care transactions electronically. Nursing facilities also routinely have arrangements with "business associates" under HIPAA and may themselves be business associates to other covered entities.

In addition to requirements imposed under HIPAA, nursing facilities are or may be subject to other privacy-related rules, such as: (1) the confidentiality of substance use disorder patient records at 42 C.F.R. Part 2 and (2) the ROPs regarding the privacy and confidentiality of residents' personal and medical records (42 C.F.R. § 483.10(h) and 42 C.F.R. § 483.70(h)) and resident right of access to personal and medical records (e.g., 42 C.F.R. § 483.10(g)(2)).

5. Civil Rights

Nursing facilities 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.[77] For example:

- Individuals with disabilities have the right to receive services in the most integrated setting appropriate to their needs.[78] The unnecessary segregation of people with disabilities, which may

[76] *See* section 1866(a) of the Act, 42 U.S.C. § 1395cc(a); section 1128B(d) of the Act, 42 U.S.C. § 1320a-7b(d); 42 C.F.R. § 447.15; 42 C.F.R. § 483.10(f)(11); 42 C.F.R. § 483.15(a)(4); 42 C.F.R. § 489.20.
[77] *See, e.g.*, 42 C.F.R. § 483.70(c); *see also, e.g.*, section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. § 18116. For further information, *see* Laws and Regulations Enforced by OCR.
[78] *See* 45 C.F.R. § 84.76(b); *see also* Community Living and Olmstead.

include requiring them to live in a nursing facility, is a form of unlawful discrimination.[79] As part of the MDS, nursing facilities are obligated to ask residents at least on a quarterly basis if they want to live in the community and to make referrals to appropriate community agencies to help individuals transition successfully into the community.[80]

- An individual receiving medication to treat substance use disorder is protected under Federal civil rights laws that protect persons with disabilities in active treatment and recovery.[81] These laws prohibit nursing facilities from discriminating against individuals in active treatment and recovery in their admissions policies.
- Nursing facilities must take reasonable steps to provide meaningful access to limited English proficiency individuals in federally funded health programs and activities. Meaningful access may require the provision of services and translated materials.[82] Nursing facilities that receive financial assistance from HHS must take appropriate steps to ensure that communications with people with disabilities are as effective as communications with others. This may include furnishing appropriate auxiliary aids and services, such as sign language interpreters.[83]

[79] *See* 45 C.F.R. § 84.76; 45 C.F.R. § 92.207(b)(6).
[80] *See* HHS Office for Civil Rights, Guidance and Resources for Long Term Care Facilities: Using the Minimum Data Set to Facilitate Opportunities to Live in the Most Integrated Setting (May 20, 2016).
[81] *See, e.g.*, section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. § 18116; section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794.
[82] *See* section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. § 18116; *see also* Section 1557: Ensuring Meaningful Access for Individuals with Limited English Proficiency.
[83] 45 C.F.R. § 84.77(a)(1); 45 C.F.R. § 84.77(b).

SECTION III
Other Compliance, Quality, and Resident Safety Considerations

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III. Other Compliance, Quality, and Resident Safety Considerations

The GCPG discusses the seven elements of an effective compliance program that are applicable to the broad spectrum of organizations and entities involved in health care delivery, as well as applicable tips for general compliance program implementation. Across the discussion of risk areas in this Nursing Facility ICPG, some sections include recommendations that nursing facilities should consider when implementing those seven elements of a compliance program (and these sections may reference some, but not all, of those elements). Other sections do not include specific recommendations. Because the risk areas and recommendations in the Nursing Facility ICPG are not exhaustive, nursing facilities should closely review the GCPG and the Nursing Facility ICPG in light of their own organizations' risk profile as they work to implement, evaluate, and update compliance program operations.

With respect to nursing facilities in particular, OIG recommends that:

- **For nursing facilities that are part of a system or chain, the highest level of the corporation or management organization should develop, implement, support, and monitor compliance and quality programs to ensure a systematic and consistent approach to compliance and quality oversight. Responsibility for corporate compliance should be assigned to a compliance officer at the highest level of a corporation or management organization.** A corporate-level compliance and quality function should oversee and evaluate the extent to which each nursing facility within the system or chain operates consistently under all compliance and quality standards and protocols and adheres to all laws, regulations, and rules.
- Individual nursing facilities that are independent and not owned or operated by a corporate or management entity should ensure that responsibility for corporate compliance rests with a facility-level compliance officer who reports directly to the owner, governing body (e.g., board of directors), chief executive officer, or some combination thereof.

The inclusion of investors in the term "Responsible Individuals" is of paramount importance.

Also, OIG recommends that governing bodies, their members, owners, investors, operators, and executive leadership (Responsible Individuals) demonstrate their commitment to this corporate-level compliance and quality function as described more fully in this section. **The inclusion of investors in the term "Responsible Individuals" is of paramount importance.** 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.

As a result of OIG's enforcement work and monitoring of Quality of Care CIAs, we believe investors in the nursing facility sector should be actively questioning whether the operating and management companies in their investment portfolios are: (1) complying with Federal health care program requirements and fraud and abuse laws; (2) dedicating the necessary resources to the organization's compliance and quality programs; (3) providing high quality care; and (4) creating a safe and comfortable living environment for all residents. Studies have shown that nursing facilities owned by private equity companies, real estate investment trusts, or other for-profit investment firms had significantly reduced staffing and lower quality ratings.[84]

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 following are specific recommendations that should be considered by nursing facilities.

A. Oversight Role of Responsible Individuals

Nursing facilities may be more successful in achieving compliance and quality objectives when Responsible Individuals set an appropriate tone for an organization and demonstrate interest in ensuring quality of care and quality of life for residents and a supportive working environment for staff. **Responsible Individuals of nursing facilities should demonstrate a formal commitment to compliance, quality, and resident safety that is apparent to employees, caregivers, and residents and their families or guardians. Consistent communication from the highest levels of the organization that high-quality resident care takes priority over profit margins will translate into quality of care being a priority throughout the entire organization. This commitment can be realized when Responsible Individuals become engaged in compliance, quality, and resident safety matters by, for example, evaluating the adequacy and effectiveness of a nursing facility's system of internal controls, quality assurance monitoring, and resident care.**

Responsible Individuals should focus on the needs of residents in their facilities and support all efforts to ensure that those needs are being fully addressed by quality and safety initiatives. Furthermore, Responsible Individuals should conduct periodic meetings with facility leadership, the compliance

[84] *See, e.g.*, HHS Office of the Assistant Secretary for Planning and Evaluation, Trends in Ownership Structures of U.S. Nursing Homes and the Relationship with Facility Traits and Quality of Care (2013–2022) (Nov. 15, 2023); *see also* Robert I. Field et al., *Private Equity in Healthcare: Barbarians at the Gate?*, 15 Drexel Law Review 821 (2023); Atul Gupta et al., National Bureau of Economic Research, Owner Incentives and Performance in Healthcare: Private Equity Investment in Nursing Homes (Aug. 2023).

officer, and the compliance committee. In these meetings, Responsible Individuals should require the compliance committee to present unfiltered information from the committee's review of specific compliance, quality, and safety data. Further, Responsible Individuals should champion a corporate culture of transparency and the candid reporting of concerns—a corporate environment in which issues may be discussed, evaluated, and remediated through a structured and collaborative compliance and quality improvement process.

Responsible Individuals Should Regularly Review and Assess:

- The nursing facility's compliance program, including, but not limited to, the performance of the compliance officer, administrator, director of nursing, and compliance committee;
- The adequacy of the nursing facility's system of internal controls, quality assurance monitoring, and resident care, including resident outcome data;
- The timeliness and thoroughness of the nursing facility's responses to State, Federal, internal, and external reports of quality of care and resident safety problems;
- The status of remedial efforts developed in response to identified problems; and
- The facility's adoption and implementation of policies, procedures, and practices designed to comply with Federal health care program requirements, regulations, and professionally recognized standards of resident care.

Finally, Responsible Individuals should consider adopting a resolution or charter summarizing their: (1) review and oversight of the allocation of all necessary resources to support the nursing facility's compliance, quality, and safety initiatives, including expenditures for staffing, infrastructure, equipment, and capital resources for physical plant improvements; and (2) support for the compliance officer and the compliance and quality programs to ensure that the nursing facility adheres to regulatory requirements and professionally recognized standards of care.

B. Compliance Officer Experience

Nursing facilities should consider recruiting a compliance officer with sufficient experience with managing compliance programs and involvement with quality assurance efforts centered on quality of care, quality of life, and resident safety. Individuals with both compliance and quality assurance experience will be better positioned to monitor and address compliance with regulations and Federal health care program requirements, adherence to professionally recognized standards of care, and remedial efforts to address noncompliance or failures of care.

C. Role of the Compliance Committee in Supporting Collaboration and Alignment Between Compliance and Quality Functions

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. Compliance committees should support compliance and clinical leadership in developing, implementing, and maintaining strong lines of communication and information exchange through regular reviews of facility-wide or chain-wide (as applicable) compliance, quality, and safety data, such as the data listed below.

Compliance, Quality, and Safety Data That Should Be Regularly Reviewed by Compliance Committees

- Resident, family, guardian, and staff complaints
- Resident, family, guardian, and staff satisfaction surveys and any other internal surveys
- Staffing turnover and exit interview reports
- State and Federal surveys (conducted by CMS and its agents, The Joint Commission, and other private agencies)
- Resident outcomes and care delivery
- Events reporting
- Staffing and nursing hours reports
- Hotline calls
- Disclosure logs
- CMS quality indicators measuring nursing facility performance, and the underlying data provided by the facility to support those measures
- Financial indicators

Compliance committee members should also identify and contribute to coordinated objectives to improve compliance and quality by, for example, developing training efforts and ensuring that regular internal quality audits and reviews are conducted. After an internal review, a compliance committee should ensure that results and findings from those reviews were received and assist the compliance officer in determining whether any Federal and State statutes, regulations, or directives have been violated. A compliance committee should also review instances when resident care falls below professionally recognized standards and consider whether any failures in care trigger liability under the False Claims Act and Civil Monetary Penalties Law and should be self-reported.

Nursing facilities should consider coordinating the compliance committee's work with the facility's QAPI program. In this way, efforts to comply with the ROPs and to address the functions of the nursing facility's QAPI program may be coordinated to facilitate compliance with all minimum requirements, while also improving the quality of care provided to residents. This collaborative effort may also eliminate any redundancies in responsibilities across compliance and quality initiatives and may yield other efficiencies and cost savings for nursing facilities.

In addition to appointing a compliance committee at the corporate level, nursing facility chains should consider regional or facility-level staff to support and assist the compliance committee, depending on the size of the organization.

D. Competency-Based Training

Nursing facilities should continually focus on ensuring that training achieves the competencies that are reflected in the ROPs 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 performance of individual job responsibilities. The compliance officer and compliance committee should regularly assess the competency and training needs within the nursing facility and work together to develop a training needs assessment and training plan. An important component of the training needs assessment is asking nursing facility staff for opinions about perceived and actual training needs. Furthermore, current nursing facility staff, as well as exiting staff, should be asked for reactions to completed training sessions and whether the sessions were useful and productive. Post-training job performance should also be evaluated to determine the overall impact and effectiveness of training.

This information should help the compliance officer and compliance committee identify training gaps and make necessary modifications to the training plan. Nursing facilities should also regularly consider whether training remains dynamic (not exclusively online and computer-based) and provides staff with the ability to demonstrate skills that are covered in training modules. Also, training should be developed and provided in response to identified instances of noncompliance with the ROPs. In nursing facilities with high employee turnover or changing resident demographics, a more frequent evaluation of staff training needs may be more critical.

With respect to the training schedule, nursing facilities should offer new employees comprehensive training as soon as possible after being hired. Appropriate training for temporary employees should be provided by a facility before they are assigned responsibility for resident care. Educational efforts should also be extended to physicians, independent contractors, and significant vendors.

The Training and Education section of the GCPG describes the importance of a training plan that addresses concerns or knowledge gaps identified through audits, investigations, and the risk assessment process. OIG recommends that nursing facilities provide training in response to all risks identified in the Nursing Facility ICPG. We have highlighted training requirements in various sections of this guidance to suggest where more targeted or intensive training efforts may be needed. Notwithstanding the absence of a specific training recommendation in any section of the Nursing Facility ICPG, OIG considers training to be an essential compliance and quality program element to address and remediate risk.

E. Risk Assessment, Internal Review, and Monitoring Processes

Each nursing facility should 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.

For nursing facility chains, these processes should be developed at the highest level of the organization and implemented under a consistent and standardized approach across every facility within the chain. OIG also recommends that nursing facility chains conduct regular site visits to facilities. These site visits should include Responsible Individuals, including corporate or regional leadership. Risk assessment, auditing, and monitoring policies should be developed to enable a consistent approach for corporate and regional leadership to identify areas of noncompliance or concern, monitor facilities, and work directly with facility leadership to remediate problems. Priority should be placed on high-risk areas as determined through chain-wide or facility-based data collection activities and the results of previous reviews.

Nursing facilities should regularly evaluate their risk assessment, internal review, and monitoring processes to determine the potential for failure of those processes, and the consequences of any failure on staff and on the safety and well-being of residents. If the risk of a process failure is high, immediate efforts should be directed toward developing any necessary changes to mitigate that risk. Staff should be included in developing any process modifications, as appropriate, and retraining on revised processes should highlight the remedial intent behind all changes.

As noted in the GCPG, the compliance committee should be responsible for implementing and overseeing the risk assessment, internal review, and monitoring processes. Leveraging facility and chain-wide data and analytics may assist corporate and regional leadership in effectuating a risk assessment, auditing, and monitoring protocol, particularly in measuring clinical performance and assessing improvements in care planning and health outcomes.

Even when a nursing facility or a group of facilities are owned, operated, or managed by a larger corporate entity, regular auditing and monitoring of the compliance activities of a single facility should be a key feature in any annual review. Appropriate reports on audit findings should be periodically provided and explained to Responsible Individuals.

F. Reporting Requirements

Nursing facilities operate under extensive Federal and State reporting requirements that have been implemented in an effort to improve the quality and safety of service delivery and hold nursing facilities accountable for the care they provide residents. Among these quality-related reporting requirements, nursing facilities must report:

- certain ownership, management, and control interests, including certain ownership interests held by private equity companies and real estate investment trusts, pursuant to CMS's regulations governing Medicare enrollment, renewal, reactivation, revalidation, change of ownership, and change of enrollment;[85]
- information required for the Medicare cost report, including, but not limited to, related-party costs;[86]
- claims-based information;
- resident assessment data in the MDS;
- direct care staffing information through the PBJ system (as described in the Reimbursement Supplement); and
- certain quality data for the SNF QRP (as described in the Reimbursement Supplement).

Nursing facility 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.

We recommend that nursing facility compliance and quality programs develop and establish:

- clear and comprehensible procedures that guide staff involved in all relevant functions through appropriate reporting practices designed to achieve consistency and continuity in reporting, including, but not limited to, reporting resident assessment data in the MDS;
- direct communication channels for staff to request and obtain clarity from relevant facility leaders if questions regarding documentation and reporting requirements arise;
- periodic audits and reviews of documentation and reporting practices to determine instances of noncompliance with reporting obligations; and
- systematic analyses of the root cause of errors in data, or incomplete and inaccurate reporting, and remediation protocols to address weaknesses in systems or procedures that led to compliance failures.

[85] *See* 42 C.F.R Part 424; 42 C.F.R Part 455; *see also* Medicare and Medicaid Programs; Disclosures of Ownership and Additional Disclosable Parties Information for Skilled Nursing Facilities and Nursing Facilities; Medicare Providers' and Suppliers' Disclosure of Private Equity Companies and Real Estate Investment Trusts, 88 Fed. Reg. 80,141 (Nov. 17, 2023).
[86] 42 C.F.R. § 413.17.

Responsible Individuals should consider reporting obligations a priority and demonstrate for their organizations a heightened interest in ensuring that all reporting from their nursing facilities is complete, accurate, and timely. Responsible Individuals should actively question the information reported by facilities, drill down on the underlying data as needed, and ensure that methods of validating information (e.g., through internal audits, external consultant reviews, and surveys conducted by outside vendors) are used at least periodically. Furthermore, there should be an expectation by employees who work within reporting functions that Responsible Individuals may routinely call upon them to answer questions about the substance of, or processes behind, all facility reporting. OIG also recommends that Responsible Individuals work to identify patterns within their facilities' reporting and identify opportunities to improve chain-wide or facility-wide compliance and quality initiatives.

Above all, Responsible Individuals should set the tone for their respective organizations by elevating the integrity of their reporting to Government agencies, and the functioning of their compliance and quality programs, to the same level of attention that financial viability commands.

SECTION IV
Conclusion

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IV. Conclusion

The Nursing Facility ICPG—together with the GCPG—provides an updated and centralized resource to advance the nursing facility industry's voluntary compliance and quality efforts to prevent fraud, waste, abuse, and substandard care. It provides a compilation of guidelines that nursing facilities should consider when implementing, evaluating, and updating their compliance and quality programs. OIG recognizes that many nursing facilities and their staff are dedicated to providing high-quality, compassionate, and cost-effective care to residents. The recommendations and practical considerations in the Nursing Facility ICPG—if implemented by nursing facilities—may further the goals of ensuring that residents receive high-quality, dignified care, while operating in compliance with all requirements and industry standards.

Because compliance is an evolving discipline, OIG may update this Nursing Facility ICPG periodically to address newly identified risk areas and compliance and quality measures, ensure timely and meaningful guidance from OIG, and respond to stakeholder feedback.

OIG welcomes written and specific feedback from the health care community and other stakeholders in connection with the GCPG and the Nursing Facility ICPG. We have designated an email inbox at Compliance@oig.hhs.gov to which any such written and specific feedback can be submitted.

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