Saint Louis University Journal of Health Law & Policy

Volume 18
Issue 2 *Nursing Homes, Health Justice, and Health Equity*

Article 5

2025

The Intersection of Regulation, Quality Care Delivery, and Ethics and Compliance: Look Carefully Before Crossing!

David R. Hoffman
dhoffman@dhoffmanassoc.com

Ilene Warner-Maron
aldengeriatrics@gmail.com

THE INTERSECTION OF REGULATION, QUALITY CARE DELIVERY, AND ETHICS AND COMPLIANCE: LOOK CAREFULLY BEFORE CROSSING!

DAVID R. HOFFMAN* AND ILENE WARNER-MARON**

ABSTRACT

Quality and compliant care delivery in nursing homes remains elusive. Four main interests are currently misaligned, thereby putting nursing home residents at risk of harm. Without a clearly defined commitment to quality and compliant care and alignment of these interests, nursing home residents will remain vulnerable to severe harm.

The first key interest concerns nursing home ownership and management. Currently, over seventy percent of nursing homes are owned by for-profit entities. Previous ownership models, including non-profit, religious-based, and county-owned facilities, have largely closed or transitioned to for-profit entities. The shift in ownership significantly impacts quality and compliant care delivery. Unfortunately, the consolidation of ownership has not led to improvements in care quality.

The next interest relates to the regulatory system governing nursing homes. This paper will briefly review the history of regulation and enforcement activity (or lack thereof), its effectiveness in terms of focus and uniformity, and its impact on quality and compliant care delivery and resident protection. While increased regulation is a common response to complaints about quality, improvements in care delivery are rarely driven solely by regulation. The inspection process is highly subjective and often overlooks major health and safety issues, significantly affecting residents' quality of care and life.

The third main interest is the nursing home's operations, particularly in terms of staffing. This includes the numbers of nursing employees, their education, competencies, recruitment, and turnover. Multiple studies have demonstrated the relationship between quality of care and the sufficiency of nursing staff. A lack of a sufficient number of competent staff in nursing homes

* JD, FCPP, Practice Professor of Law, Thomas R. Kline School of Law, and President, David Hoffman & Associates, PC, a national health care compliance consulting firm.

** Ph.D., RN, Assistant Clinical Professor Department of Geriatrics and Palliative Medicine, Philadelphia College of Osteopathic Medicine.

has been shown to increase the risk of harm, including falls, pressure injuries, elopements, medication errors, and other serious adverse outcomes.

The fourth key interest concerns nursing home residents and their families. As individuals transition from a home or hospital setting, they and their families often have reasonable expectations regarding care delivery but lack the knowledge or power to select a quality facility. Hospital discharge planners are often unfamiliar with the recommended nursing home, placing uninformed consumers at risk. The incentive to discharge hospitalized patients "sicker and quicker" forces families to accept a transfer to the first available bed. Although it would be highly beneficial for consumers to be knowledgeable regarding the continuum of older adult services (adult day care, Home and Community-Based Services through the Area Agency on Aging, home health care, and hospice), many are unaware of these alternatives to skilled nursing facility (SNF) placement. Planning for the future, including having knowledge of area SNFs, is often neglected until a healthcare crisis arises, requiring hospitalization and post-acute admission. Additionally, the Medicare.gov website, designed to improve consumer behavior through the "Five Star" rating process, remains underutilized by older adults and their families.

This paper proposes changes to the regulatory system, emphasizing important systemic issues that identify care failures. It will suggest enhanced protocols for consumer education and discuss how effective ethics and compliance programs can improve staff performance, increase resident safety, and enhance quality care delivery. The paper will use case examples focusing on pressure injuries as a mechanism to identify and remediate care delivery failures from both an internal and external quality assurance and performance improvement perspective.

I. INTRODUCTION

Healthcare organizations in the United States are among the most highly regulated industries, primarily due to the significant impact on individuals receiving services and the potential for life-threatening consequences. Nursing facilities, in particular, are subject to a complex web of federal, state, and local regulations, as well as requirements imposed by the Occupational Safety and Health Administration (OSHA). This intricate regulatory framework positions nursing facilities as the most regulated healthcare providers.[1] To date, there are 220 federal regulations specifically for nursing homes, forming the foundation for regulatory compliance in this sector.[2]

Despite the sheer number of regulations and the high degree of oversight in nursing facilities, issues of quality, competency, and ethical considerations remain significant concerns for stakeholders.[3] The industry faces numerous challenges, including the aftermath of natural disasters, the disproportionate impact of virulent infectious diseases on older adults, increased malpractice litigation, the admission of non-traditional residents with serious mental illnesses[4] and substance use disorders, and staffing mandates. These factors have highlighted the need for interventions to improve the quality of care. Therefore, examining the regulatory system and reviewing effective compliance and ethics programs are crucial in increasing nursing home residents' safety and quality of care.

II. THE NURSING HOME REGULATORY SYSTEM

In 1984, after almost a decade of litigation brought to address the "deplorable conditions at many nursing homes," the Tenth Circuit Court of Appeals addressed the issue of whether the Secretary of the U.S. Department of Health and Human Services (HHS) has a statutory duty under the Medicaid Act to "develop and implement a system of nursing home review and enforcement which focuses on and ensures high-quality patient care."[5]

The Court held that "[t]he Secretary has a duty to promulgate regulations which will enable her to be informed as to whether the nursing facilities receiving federal Medicaid funds are actually providing high-quality medical

1. For purposes of this article, nursing facilities shall include a skilled nursing facility (SNF), a nursing facility (NF), a dually eligible certified facility, and single facilities and chains.

2. 42 C.F.R. § 483 (2025).

3. Angela Perone, *Reframe, Reform and Transform: Policy Approaches to Improve Nursing Home Quality in the United States*, 6 INNOVATION AGING 397, 397 (2022).

4. Serious mental illness is defined as a mental, behavioral, or emotional disorder resulting in serious functional impairment, which substantially interferes with or limits one or more major life activities. *Mental Illness*, NAT'L INST. MENTAL HEALTH, https://www.nimh.nih.gov/health/statistics/mental-illness (Sept. 2024). The burden of mental illnesses is particularly concentrated among those who experience disability due to SMI. *Id.*

5. *In re* The Estate of Michael Patrick Smith v. Heckler, 747 F.2d 583, 585 (10th Cir. 1984).

care. This conclusion is fully supported by the statute and its legislative history."[6] Tragically, over forty years later, this mandate remains unfulfilled.

In 1986, the Institute of Medicine (IOM) issued a groundbreaking report on the care the nursing home industry provided.[7] The report noted that:

> The implicit goal of the regulatory system is to ensure that any person requiring nursing home care be able to enter any certified nursing home and receive appropriate care, be treated with courtesy, and enjoy continued civil and legal rights. This happens in many nursing homes in all parts of this country. But in many government-certified nursing homes, individuals who are admitted receive very inadequate—sometimes shockingly deficient—care that is likely to hasten the deterioration of their physical, mental, and emotional health.[8]

In response to the IOM's findings, Congress enacted the Nursing Home Reform Act (NHRA) as part of the Omnibus Budget Reconciliation Act of 1987 (OBRA).[9] The NHRA, an important and consequential civil rights act, and its regulations (known as Requirements of Participation) require nursing facilities to support residents' needs and preferences and promote and maintain a high quality of life for their physical, mental, and psychosocial well-being.[10] The NHRA also establishes a Resident's Bill of Rights, governing the minimum requirements that nursing home facilities must adhere to in delivering care to residents.[11] The statute further states, "[a] skilled nursing home facility must care for its residents in such a manner and in such an environment that will promote maintenance or enhancement of the quality of life of each resident."[12]

The NHRA mandates that state and federal governments share responsibility in certifying and ensuring compliance of nursing homes.[13] States must conduct

6. *Id.* at 591.

7. INST. OF MED., IMPROVING THE QUALITY OF CARE IN NURSING HOMES 1 (1986) (ebook).

8. *Id.* at 2.

9. A skilled nursing facility (SNF) must meet the requirements of section 1819 of the Social Security Act, 42 U.S.C. § 1395i–3; a nursing facility must meet the requirements of section 1919 of the Social Security Act, 42 U.S.C. § 1396r. The NHRA's legal requirements are the same for both entities.

10. 42 U.S.C. §§ 1395i-3(b)(1)(B)(2), (c)(1)(A)(v).

11. 42 U.S.C. § 1395i-3(c).

12. 42 U.S.C. § 1395i-3(b)(1)(A). Importantly, residents have the right to be treated with respect, be free from abuse and neglect, be free from restraints, participate in activities, be free from discrimination, have the right to privacy and confidentiality, and have the right to review survey results to name a few. The Residents' Bill of Right also provides residents with rights to encourage their involvement in their own care to include the right to be fully informed about their health in a language that is understood, to be fully informed about their medical condition and exercise informed consent, participate in the development of an individualized care plan, and choose their attending physician. 42 U.S.C. § 1395i-3 (c)(1)(A).

13. 42 U.S.C. § 1395i-3(g)(1); *Nursing Homes*, CMS.GOV, https://www.cms.gov/medicare/health-safety-standards/quality-safety-oversight-general-information/nursing-homes (Dec. 23, 2024) ("The State is responsible for certifying a skilled nursing facility's or nursing facility's compliance or noncompliance, except in the case of State-operated facilities. However, the State's

unannounced surveys at irregular intervals at least once every fifteen months.[14] These inspections include interviews with family members and staff about the residents' daily experiences and outcomes.[15] Noncompliant nursing homes are subject to various remedies designed to address the specific nature of their deficiencies.[16] These remedies include a denial of payment following a finding of noncompliance, a directed plan of correction in response to cited deficiency, a temporary ban on admitting new residents, appointment of a temporary manager to run the nursing facility, and even the possibility of terminating the provider agreement, forcing the closure of the nursing home. [17] The implementation of the patient care and services survey process[18] and the passage of the NHRA shifted the focus on how to evaluate quality care. Rather than assessing the nursing facility's capability of providing quality care through existing policies and procedures, staff credentials, and appropriate equipment, the regulatory focus correctly became whether the care provided to the residents resulted in appropriate clinical outcomes. At its core,

> The purpose of regulation is to assure that products and services are safe and meet certain standards for minimum acceptable quality. A standard economic justification for why nursing home care needs regulation is that regulations can help address market failures, such as consumers' difficulty in accessing, monitoring, and responding to information about quality of care.[19]

The nature and vulnerability of nursing home residents necessitates the need for government oversight and protection. Typically, these residents require

certification for a skilled nursing facility is subject to CMS' approval. 'Certification of compliance' means that a facility's compliance with Federal participation requirements is ascertained. In addition to certifying a facility's compliance or noncompliance, the State recommends appropriate enforcement actions to the State Medicaid agency for Medicaid and to the appropriate CMS Location for Medicare. The CMS Location determines a facility's eligibility to participate in the Medicare program based on the State's certification of compliance and a facility's compliance with civil rights requirements.").

14. 42 U.S.C. § 1395i-3(g)(2)(A)(iii)(I).

15. CTRS. FOR MEDICARE & MEDICAID SERVS., STATE OPERATIONS MANUAL app., § 483.10(a)-(b)(1)&(2) (2024) [hereinafter STATE OPERATIONS MANUAL] ("Surveyors shall make frequent observations on different shifts, units, floors or neighborhoods to watch interactions between and among residents and staff. If there are concerns that staff or others are not treating a resident with dignity or respect or are attempting to limit a resident's autonomy or freedom of choice, follow-up as appropriate by interviewing the resident, family, or resident representative.").

16. *Id.* ch. 7.

17. *See* Malcom J. Harkins, *The Broken Promise of OBRA '87: The Failure to Validate the Survey Protocol*, 8 ST. LOUIS U. J. HEALTH L. & POL'Y 89, 99-100 (2014) (providing a thorough analysis of the history of nursing home regulation and flaws in the survey process).

18. Thomas G. Morford, *Nursing Home Regulation: History and Expectations*, 1988 HEALTH CARE FIN. REV. SUPP. 129, 130 (1988).

19. NAT'L ACAD. OF SCIS., ENG'G, & MED., THE NATIONAL IMPERATIVE TO IMPROVE NURSING HOME QUALITY: HONORING OUR COMMITMENT TO RESIDENTS, FAMILIES, AND STAFF 399 (2022) [hereinafter THE NATIONAL IMPERATIVE].

assistance with activities of daily living (ADLs), such as bathing, grooming, transferring in and out of bed, bed mobility, eating, dressing, and using the bathroom. However, the nursing facility population is evolving to include younger adults with serious mental illness and substance use disorders. Research conducted by the Gerontological Society of America shows that "Nationally, about 40% of [long-stay] residents on Medicaid under 65 years of age and 20% aged 65 years or greater have [a serious mental illness] (SMI) diagnosis such as schizophrenia or bipolar disorder."[20] With this changing nursing home population, the challenges of delivering care are exacerbated by the lack of knowledge and understanding of behavioral health concerns.

While the need for intense scrutiny of provider conduct in nursing homes is apparent, there are two primary regulation approaches: deterrence and compliance. These approaches significantly impact the relationship between the regulators and the regulated entity, as well as the effectiveness of the enforcement system.

> Deterrence regulators see the organizations they regulate as "amoral calculators," out to get what they can and willing to break the rules if they need to and can get away with it. As a result, their approach to regulation is formal, legalistic, punitive, and sanction-oriented. In contrast, compliance regulators see organizations as fundamentally good, well-intentioned, and likely to comply with regulations if they can. Their approach to regulation is generally more informal, supportive, and developmental, and they use sanctions only as a last resort.[21]

A third approach argues for "responsive" or "smart" regulation, which "combines some of the benefits of both deterrence and compliance regulation. The main principle of responsive regulation is that regulatory methods and approaches should be adapted in response to the behavior of individual regulated organizations."[22]

20. Dylan J. Jester et al., *Quality Concerns in Nursing Homes That Serve Large Proportions of Residents With Serious Mental Illness*, 60 THE GERONTOLOGIST 1312, 1312 (2020); *see also* Benjamin H. Han et al., *Trends in Inpatient Discharges with Drug or Alcohol Admission Diagnoses to a Skilled Nursing Facility Among Older Adults, New York City 2008–2014.,* HARM REDUCTION J., Dec. 2020, at 1, 5.

21. Kieran Walshe, *Regulating U.S. Nursing Homes: Are We Learning From Experience?*, HEALTH AFFS., Nov.-Dec. 2001, at 128, 133. Deterrence regulation has been described as "adversarial legalism" and asserted that it has high costs, a divisive and corrosive effect on relationships between organizations, and few compensating benefits. REGULATORY ENCOUNTERS: MULTINATIONAL CORPORATIONS AND AMERICAN ADVERSARIAL LEGALISM 4 (Robert A. Kagan & Lee Axelrad eds., 2000).

22. *Id.* at 134.

CMS has identified the nursing home regulatory system as "compliance regulation."[23] As noted in the enforcement regulations:

> The nursing home reform regulation establishes several expectations. The first is that providers remain in substantial compliance with Medicare/Medicaid program requirements as well as State law. The regulation emphasizes the need for continued, rather than cyclical compliance. The enforcement process mandates that policies and procedures be established to remedy deficient practices and to ensure that correction is lasting; specifically, that facilities take the initiative and responsibility for continuously monitoring their own performance to sustain compliance. Measures such as the requirements for an acceptable plan of correction emphasize the ability to achieve and maintain compliance leading to improved quality of care.
>
> The second expectation is that all deficiencies will be addressed promptly. The standard for program participation mandated by the regulation is substantial compliance.
>
> The third expectation is that residents will receive the care and services they need to meet their highest practicable level of functioning. The process detailed in these sections provides incentives for the continued compliance needed to enable residents to reach these goals.[24]

The nursing home regulatory system has evolved to focus on quality care delivery and greater attention to residents' rights.[25] The notion that a record review was sufficient to evaluate care delivery has been replaced by direct observation of care by the nursing home surveyors, along with the recognition that residents can offer crucial insights into the care they actually receive.[26]

In practice, what specific nursing home provider behaviors are regulated? Is it poor care delivery leading to adverse resident outcomes or technical violations of the numerous regulatory requirements? As it turns out, deficiency citations for facility noncompliance with regulations is neither standardized nor uniform across the country.[27] For example, the citations for "Immediate Jeopardy" are one such area where state survey agencies have treated facilities disparately.[28]

23. STATE OPERATIONS MANUAL, *supra* note 15, ch.7, § 7000.

24. *Id.* "Substantial compliance" means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm. Substantial compliance constitutes compliance with participation requirements. 42 C.F.R. § 488.301 (2025).

25. Morford, *supra* note 18, at 130; THE NATIONAL IMPERATIVE, *supra* note 19, at 186.

26. STATE OPERATIONS MANUAL, *supra* note 15, app., § 483.20(b)(1)-(2)(i)&(iii).

27. Harkins, *supra* note 17, at 115.

28. In order to address deficiency citation consistency, CMS issued guidance on November 21, 2024, revising the requirements for citing Immediate Jeopardy (IJ). Memorandum from the Dep't of Health & Hum. Servs. on Revisions to Appendix Q, Guidance on Immediate Jeopardy to State Surv. Agency Dirs. These changes include changing a potential for serious harm to a likelihood (reasonable expectation) that such harm will occur if not corrected. *Id.* Next, culpability has been removed as a requirement. *Id.* Psychosocial harm can be used as a basis to cite IJ by using

The tendency to add regulations to address actual or potential adverse outcomes of care and services has resulted in a plethora of rules. However, compliance with these multiple layers of regulations has not been realized, as there is no clear link between regulations alone and the quality of care provided to the residents.

A key to enhancing the regulatory framework's effectiveness lies in aligning regulatory requirements and regulators' objectives with interventions that will effectively modify the regulated industry's behavior.

"For nursing homes, the pressures of the marketplace are not well aligned with the objectives of regulation. While nursing home regulation attempts to promote high quality of care, the market does not seem to reward nursing homes that provide such care."[29]

Regulatory misalignment begins with the fact that consumers cannot effectively compare the quality of nursing facilities. In our experience, this issue primarily arises because hospitalized patients are often transferred to nursing facilities based on bed availability rather than the facility's capacity to meet their specific needs.[30] For example, an older adult who suffers a fall resulting in a fractured hip undergoes surgical correction and is then transferred to a nursing facility for rehabilitation. Consumer power is restricted to patients and their families who are aware of the Medicare.gov website, know about nursing facilities in their communities, or have the privilege to visit potential nursing facilities prior to transfer. The consumer education piece through the well-intentioned "five-star rating system" does not provide sufficient knowledge about nursing home quality, given the overwhelming pressure that families routinely face when determining that nursing home care is appropriate for their loved one.

Imminent discharge from the hospital, often driven by payment pressures[31] coupled with a limited list of one or two nursing home facilities willing to accept

a reasonable person standard. "The reasonable person approach considers how a reasonable person in the recipient's position would be impacted by the noncompliance (i.e. consider if a reasonable person in a similar situation could be expected to experience a serious psychosocial adverse outcome as a result of the same noncompliance). *Id.* Finally, there are no automatic IJ citations. *Id.*

29. Walshe, *supra* note 21, at 139 (citation omitted).

30. *See also* Taylor Bucy & Dori Cross, *Information Sharing to Support Care Transitions for Patients with Complex Mental Health and Social Needs*, 71 J. AM. GERIATRIC SOC'Y 1963, 1963-73 (2024). Given the changing resident population entering nursing facilities, it is important that accurate and timely information be provided from the hospital to the nursing facility. See *id.*

31. Beginning in 1984, the Centers for Medicare and Medicaid (CMS) implemented a hospital payment system that not only affected acute care but had a significant impact on post-acute providers, including nursing facilities. Prior to 1984, hospitals received payments based on a bill that was submitted retrospectively. After 1987, under the new payment system, Diagnosis Related Groups (DRGs), hospitals were reimbursed on a prospective basis. As a result, hospitals maximize their payments by discharging patients at the earliest possible point in their treatment, often to

the patient and the failure of hospital discharge planners to fulfill their regulatorily mandated role as patient advocates,[32] conspires to defeat the goal of having an informed consent-type process for nursing home admission purposes. Our experience has shown a process more akin to a nursing home "E-Bay," where facilities bid on patients for admission instead of patients and their representatives selecting a nursing home based on quality care delivery. Rarely have we heard of discharge planners providing quality measurement data to patients and their families as part of the discharge planning process. The lack of consumer participation in the discharge process, the patient's unfamiliarity with home and community-based services, and the lack of knowledge about the quality of services provided by a particular nursing facility, often results in an inappropriate discharge plan to a nursing facility that may not be able to meet the individual's needs.

Moreover, financial pressures from low Medicaid reimbursement rates contribute to regulatory misalignment. A recent study found that, of the 13,285 facilities reviewed, forty percent reported that their Medicaid per diem payments covered only eighty percent or less of their estimated daily Medicaid costs, and only eight percent of nursing facilities in the study received Medicaid payments that exceeded their cost.[33] However, the dispute over the impact of Medicaid reimbursement on *profitability* remains a hotly contested issue.[34] To that end, we support the efforts of several states that

nursing facilities with the first available bed. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., DESIGN AND DEVELOPMENT OF THE DIAGNOSIS RELATED GROUP (DRG) (2019).

32. In 2019, CMS issued final regulations pertaining to the hospital discharge process. 42 C.F.R § 482.43. Importantly, these regulations included the following provision: "**The hospital must assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The hospital must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences."** (emphasis added). 42 C.F.R. § 482.43 (a)(8).

33. MIAMI UNIV., UNIV. OF MASS. BOS. & RTI INT'L, OFF. OF THE ASSISTANT SEC'Y FOR PLAN. AND EVALUATION, ASSESSING MEDICAID PAYMENT RATES AND COSTS OF CARING FOR THE MEDICAID POPULATION RESIDING IN NURSING HOMES 1, 14 (2024) ("Using data for the latest pre-pandemic period (2019), we found that Medicaid payment rates for the average or median nursing home covered about 82 cents per every dollar of costs that nursing homes reported incurring in caring for Medicaid residents.") Of note, the HHS-OIG issued a report that identified the need for a better understanding of how nursing facilities allocate costs and the impact of ownership and financing structures on spending, quality of care, and other aspects of nursing home performance. HHS OFF. OF INSPECTOR GEN., OFF. OF AUDIT SERVS., SOME SELECTED SKILLED NURSING FACILITIES DID NOT COMPLY WITH MEDICARE REQUIREMENTS FOR REPORTING RELATED-PARTY COSTS (2024).

34. Charlene Harrington et al., *United States' Nursing Home Finances: Spending, Profitability, and Capital Structure*, 2023 INT'L J. SOC. DETERMINANTS HEALTH & HEALTH SERVS. 133, 131–42 (2023).

have passed legislation requiring a percentage of nursing home revenues to be allocated to direct care services, with limitations on administrative costs, property costs, and profits.

A nursing facility's financial stability directly impacts its ability to improve the quality of care its residents receive through various ways: (1) increasing staffing and supplies, (2) investing in the skills of its staff, (3) utilizing equipment and electronic health records (EHRs), (4) implementing innovative delivery of dialysis, respiratory, and wound treatments, (5) providing support and education in caring for individuals with serious mental health needs and substance use disorders, and (6) coordinating services between the facility and community providers. These initiatives benefit from adequate reimbursement from the various payers of nursing home care.[35]

CMS has identified "considerable evidence" of the relationship between nursing home staffing and quality of care, stating, "Nursing home staffing has a significant impact on the quality of care that residents receive."[36] The CMS Staffing Study 3, among other research, found a clear association between nursing home staffing ratios and quality of care.[37] There is also a growing body of evidence linking staff turnover and resident outcomes, with higher turnover associated with poorer quality of care.[38] It is our experience that investing in staff through increased salaries and fringe benefits, supportive programs, an in-house CNA training program, and the offering of internal and external role-related educational opportunities that increase competencies has a positive impact on reducing staff turnover.

So, how do we achieve alignment? It may require offering financial and regulatory incentives to facilities that demonstrate consistent, validated, and verifiable high levels of quality care. The preconditions for incentives would include, at a minimum, validating a nursing facility's Quality Assurance and Performance Improvement (QAPI) Program and its ethics and compliance

35. Zee Johnson, *Report Reveals how Medicaid Payments Stack Up Against Nursing Homes' Cost of Care*, MCKNIGHT'S LONG-TERM CARE NEWS (Oct. 16, 2024), https://www.mcknights.com/news/report-reveals-how-medicaid-payments-stack-up-against-nursing-homes-cost-of-care/.

36. *Nursing Home Staffing Campaign*, CMS.GOV, https://www.cms.gov/medicare/health-safety-standards/quality-safety-oversight-general-information/nursing-home-staffing-campaign (Jan. 14, 2025).

37. WHITE ET AL., ABT ASSOCIATES, NURSING HOME STAFFING REPORT: COMPREHENSIVE REPORT 11-12 (2023). ("Higher nurse staffing levels in nursing homes are associated with improved resident care outcomes such as reducing pressure ulcers, emergency department visits, rehospitalizations, and outbreaks and deaths related to COVID-19. Increased staffing levels can be particularly beneficial to vulnerable sub-populations in nursing homes (e.g., residents with dementia or Alzheimer's disease) and for particular quality outcomes (e.g., antipsychotic use, obesity rates, severity of depressive symptoms).") (citations omitted).

38. *See, e.g.*, Qing Zheng et al., *Association Between Staff Turnover and Nursing Home Quality—Evidence from Payroll—Based Journal Data*, 70 J. AM. GERIATRICS SOC'Y 2508, 2514 (2022).

program. Data reported to government entities must be accurate, especially as it pertains to staffing and care outcomes. Any change in nursing home leadership, i.e., Nursing Home Administrator and/or Director of Nursing, would need to be reported immediately to the regulators for review. Finally, any misrepresentation of data would lead to stipulated financial penalties for noncompliance and removal of the incentives offered to the nursing facility.

Achievement of alignment also demands that residents and their families and representatives have a greater say in the regulatory landscape. All too often, complaints made by families to the survey agency are investigated at some point, yet are found to be unsubstantiated because the surveyors did not uncover the alleged noncompliant conduct.[39] This response to family and, in some instances, long-term care ombudsman acting as advocates on behalf of residents, is unacceptable.

Moreover, state survey agencies (SSAs) must be provided with sufficient resources to address their severe staffing shortages, high turnover rates, and the resulting inexperienced workforce to best protect the health and safety of the residents. Put simply, there are not enough state surveyors to enforce the regulations and protect residents. An investigation by the Senate Special Committee on Aging found the nursing home oversight system to be in crisis.[40] Staffing shortages are alarmingly high, with thirty-two state survey agencies experiencing vacancy rates of twenty percent or higher, including nine with vacancy rates of fifty percent or higher.[41] High turnover rates result in less experienced surveyors filling these roles, potentially leading to less effective surveys.[42] Ironically, the nursing home regulatory system faces the same type of staff shortages as the nursing home industry, highlighting the barriers to a successful system that protects residents and assures compliance.[43]

39. U.S. GEN. ACCT. OFF., GAO/HEHS-99-80, NURSING HOMES: COMPLAINT INVESTIGATION PROCESSES OFTEN INADEQUATE TO PROTECT RESIDENTS 2, 12 (1999). *See also* THE NATIONAL IMPERATIVE, *supra* note 19, at 412-14 (indicating where data from 2016-2018 evidenced that high priority complaints were not investigated in a timely manner).

40. MAJORITY STAFF OF S. SPECIAL COMM. ON AGING, 118TH CONG., UNINSPECTED AND NEGLECTED: NURSING HOME INSPECTION AGENCIES ARE SEVERELY UNDERSTAFFED, PUTTING RESIDENTS AT RISK 1 (2023).

41. *Id.*

42. *Id.* at 5.

43. CMS has agreed to perform thorough evaluations of State Survey Agencies' (SAs) performance through the State Performance Standard System (SPSS) to ensure that States' corrective action plans and other remedial efforts are "focus[ed] on making the remedies specific and outcome oriented." Christi A. Grimm, Office of Inspector General, CMS Should Take Further Action to Address States With Poor Performance in Conducting Nursing Home Surveys 18 (2022). Failure by the SAs to be in substantial compliance with performance metrics should be addressed through education followed by progressive enforcement actions including the use of financial penalties. *Id.* at 4, 19. OIG update on its website confirmed CMS' implementation of the OIG's monitoring recommendation. *CMS Should Take Further Action to Address States With Poor*

III. THE EXPECTATION OF CONTINUED COMPLIANCE

How should nursing home regulators ensure "continued compliance" once noncompliance has been identified and cited? One practical approach is to assess the number, type, and circumstances under which a resident develops pressure injuries (bedsores). This assessment can be used as a proxy to examine a facility's adherence to regulatory requirements and ability to provide quality care to its residents.

The development of "avoidable"[44] pressure injuries are associated with several risk factors, many of which are within the nursing facility's control. These factors include inadequate incontinence care, poor protein-calorie intake, deficiencies in turning/repositioning, inadequate support surfaces for the bed and/or chair to reduce pressure, improper skin assessment, the lack of appropriate treatment modalities, the absence of care planning, inadequate infection prevention, the lack of appropriate staff education and supervision, and the failure to provide wound care treatments as ordered.[45]

From an administrative perspective, recruiting and retaining sufficiently proficient nursing staff, a Registered Dietitian, and a competent Medical Director is essential in implementing effective wound prevention and treatment interventions. Based on current literature from the National Pressure Injury Advisory Panel (NPIAP), policies are devised and implemented to ensure that services are provided within the standard of care.[46] Thus, quality can be determined by closely examining the care provided to individuals with pressure injuries.

When surveyors cite a nursing facility for a deficiency related to pressure injuries, a mandatory Root Cause Analysis (RCA) should be performed to identify system failures. Instead, it has been our experience that nursing facilities and the survey process fail to remediate the underlying issues that caused the deficiency. The typical response by nursing facilities is to promise to educate their staff and audit the care for only a short period of time to achieve compliance. For example, when a facility has been cited for non-compliant

Performance in Conducting Nursing Home Surveys, HHS-OIG (Jan. 14, 2022), https://oig.hhs.gov/reports/all/2022/cms-should-take-further-action-to-address-states-with-poor-performance-in-conducting-nursing-home-surveys/ ("**22-E-06-009.01 to CMS - Closed Implemented**, *Closed on 09/20/2024*").

44. STATE OPERATIONS MANUAL, *supra* note 15, app., § 483.25(b)(1) ("Avoidable" is defined as a "resident developed a pressure injury and that the facility did not do one or more of the following: evaluate the resident's clinical condition and risk factors; define and implement interventions that are consistent with resident needs, resident goals, and professional standards of practice; monitor and evaluate the impact of the interventions; or revise the interventions as appropriate.").

45. *Id.* (providing facilities with clear guidance on pressure injury prevention, development, and treatment).

46. *Guidelines & Standards*, NPIAP, https://npiap.com/ (last visited May 12, 2025).

wound care, the facility's typical plan of correction (POC) is to educate staff on pressure injuries (quick staff in-service) and audit wound care for several weeks. But has education effectively ensured competent pressure injury prevention and appropriate treatment? What exactly is the purpose of these care audits, and is the methodology appropriate? While state surveyors and CMS routinely accept these interventions, the "educate and audit" remedy alone does not assure the government and, more importantly, the resident population that compliance has been achieved and will be maintained.

Nursing facility staff should perform RCAs to determine what system failures may have contributed to the development and/or progression of the wound(s). However, it has been our experience that the RCA process performed by nursing facility staff does not follow best practices and instead offers minimal value in analyzing why a pressure injury developed. The Pennsylvania Patient Safety Authority has published valuable resources to assist providers in performing meaningful RCAs.[47] For a POC to be accepted by the government, nursing facilities must be required to conduct thorough RCAs when residents suffer actual harm (G level and above deficiencies) due to noncompliant conduct.[48]

Based on the foregoing, we propose the following changes to the regulatory system:

(1) Require that Root Cause Analyses be submitted as part of a nursing facility's plan of correction for all deficiencies cited at G level and above.

(2) Regulators should expand the use of directed plans of corrections[49] as a primary remedy while working collaboratively with nursing facilities to incorporate education and monitoring components that provide specific metrics for achieving and maintaining compliance.

47. *See Patient Safety Topic: Root Cause Analysis*, PATIENT SAFETY AUTH., https://patientsafety.pa.gov/pst/Pages/Root_Cause_Analysis/hm.aspx?t=tools (last visited Mar. 22, 2025).

48. *Nursing Home Enforcement – Frequently Asked Questions*, CMS.GOV, https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationenforcement/downloads/nh-enforcement-faq.pdf (last visited May 12, 2025) (explaining that the survey enforcement process includes the scope and severity of a deficiency for noncompliance with regulatory requirements. The severity of a deficiency has multiple levels, with Level 3 (G and above) constituting "Actual harm that is not immediate jeopardy: Noncompliance with the requirements that results in actual harm to residents or employees that is not immediate jeopardy.").

49. STATE OPERATIONS MANUAL, *supra* note 15, ch. 7, § 7500 ("A directed plan of correction is a plan that the State or the CMS Location, or the temporary manager, develops to require a facility to take action within specified time frames."). Use of a directed plan of correction (POC) should depend on causes identified by the state, regional office, or temporary manager. *Id.* A directed POC differs from a traditional POC in that the state, not the facility, develops the POC. STATE OPERATIONS MANUAL, *supra* note 15, ch. 3, § 3006.2A. Achieving compliance is the facility's responsibility. *Id.* If it fails to do so, the state may impose another alternative sanction(s) until the facility achieves substantial compliance. *Id.*

(3) Mandate certifications from the Governing Body of the nursing facility, the Nursing Home Administrator, the Director of Nursing, and the Ethics and Compliance Officer, affirming that all promised actions identified in a plan of correction and a directed plan of correction have been completed.

(4) Provide state survey agencies with the necessary resources to oversee the nursing home industry in accordance with federal and state law.

(5) The nursing home regulatory system must ensure that thorough investigations of all complaints made to licensing and certifying agencies, long-term care ombudsmen, Area Agencies on Aging, and other groups occur promptly, regardless of the source of the complaint. Substantiation of a complaint made by third parties to the SSA must be based on the underlying facts that evidence noncompliant conduct, regardless of whether noncompliance was directly observed by state surveyors or not.

IV. THE PURSUIT OF QUALITY

There has been a significant focus on ensuring quality care delivery in nursing facilities, as evidenced by the enactment of the NHRA and the creation of a regulatory framework aimed at improving quality and compliant care delivery. One area that has recently garnered attention is the transparency of nursing facility ownership.[50]

Traditionally, healthcare institutions have been non-profit, religious-based organizations fulfilling particular missions from their parent organizations. However, as of December 2024, the CMS database identified 14,827 licensed nursing facilities, with seventy-two percent being for-profit entities.[51] Not-for-profit nursing facilities represent twenty-one percent of all licensed providers.[52] Government-operated facilities have steadily decreased as county governments sell or convert operations in favor of for-profit entities. Currently, only about six percent of all licensed skilled facilities are operated by government entities.[53] Despite this movement toward consolidation of ownership, the growth of large providers, and economies of scale, improvements in the quality of care have not been realized.[54]

50. Shelby Grebbin, *CMS Issues Final Rule for Transparency in Ownership of Nursing Homes*, SKILLED NURSING NEWS (Nov. 15, 2023), https://skillednursingnews.com/2023/11/updated-cms-issues-final-rule-for-transparency-in-ownership-of-nursing-homes/ (highlighting that particular focus has been placed on private equity ownership of nursing of nursing facilities).

51. Jenny Yang, *Distribution of Nursing Homes in the United States from 2003 to 2024, By Ownership Type*, STATISTA (Dec. 11, 2024), https://www.statista.com/statistics/716813/distribution-of-nursing-homes-in-us-by-ownership-type/.

52. *Id.*

53. *Id.*

54. *See* Robert I. Field, Barry Furrow, David R. Hoffman, Kevin Lownds & Hilary Pearsall, *Private Equity in Health Care: Barbarians at the Gate?*, 15 DREXEL L. REV. 821, 823 (2023) (analyzing private equity ownership's negative impact on nursing home care delivery and exploring

The reimbursement structure has contributed to the growth of large chains in the United States. Private pay residents and Medicare reimbursements are significantly higher than Medicaid payments, resulting in competition among nursing facilities for residents yielding maximum reimbursement.[55] Higher reimbursement levels allow for more competitive wages, increased staffing levels, and improved care quality. However, for-profit facilities are accountable to their stockholders and may be less likely to raise wages or staffing above the minimum levels mandated by federal and state requirements.[56]

Over the past forty years, intricately related policy and regulation issues have significantly impacted nursing facility quality. The NHRA overhauled the assessment, care planning, documentation, and delivery of care while focusing on reimbursing skilled services for up to the first 100 days of a resident's admission.[57] High levels of nursing, physical therapy, occupational therapy, and speech therapy lead to increased reimbursement. However, we have observed on multiple occasions that once skilled services are no longer justified, either due to functional limitations or the number of days in a facility, residents may still require skilled services that are no longer provided, resulting in the loss of previous functional gains.

Since the onset of COVID-19, increased oversight by CMS and contracted states' Health Departments has focused on addressing infection control issues. The deaths of over 200,000 skilled nursing facility (SNF) residents and staff[58] have caused a re-examination of structural and financial factors. This scrutiny revealed that nearly half of the total COVID-19 deaths in the U.S. occurred among the 0.4% of people residing in nursing facilities.[59] A number of these deaths occurred as a consequence of the mandates requiring nursing facilities to accept transfers of patients with COVID-19 from hospitals to allow hospitals to meet the demand of acutely infected patients.[60] This decision led to the spread of the virus among a vulnerable population of older adults with impaired immune function. Simultaneously, these facilities struggled with inadequate

theories of liability under the Federal False Claims Act for holding these owners accountable for the submission of false or fraudulent claims based on regulatory violations).

55. Charlene Harrington et al., *Nurse Staffing Levels and Medicaid Reimbursement Rates in Nursing Facilities,* 42 HEALTH SERVS. RSCH. 1105, 1106 (2007).

56. *Id.* at 1108. Is it time to consider a public utility model of regulation for the nursing home industry?

57. *SNF Care Past 100 Days*, MEDICARE INTERACTIVE, https://www.medicareinteractive.org/get-answers/medicare-covered-services/skilled-nursing-facility-snf-services/snf-care-past-100-days (Mar. 31, 2025).

58. Priya Chidambaram, *Over 200,000 Residents and Staff in Long-Term Care Facilities Have Died From COVID-19*, KFF (Feb. 3, 2022), https://www.kff.org/policy-watch/over-200000-residents-and-staff-in-long-term-care-facilities-have-died-from-covid-19/.

59. James S. Goodwin & Huiwen Xu, *COVID-19 in Nursing Homes—Learning the Hard Way*, 184 JAMA INTERNAL MED. 808, 808 (2024).

60. *Id.*

quarantine measures, insufficient personal protective equipment (PPE), a lack of proper education and protocols, and staffing shortages. Prohibiting families and other visitors from entering the facilities failed to prevent the spread of COVID-19, as employees were a significant vector for the virus. Many employees with little or no sick leave were compelled to continue working despite COVID-19 symptoms.[61] Facilities with larger staff numbers and beds reported higher COVID-19 cases in 2020.[62] The model of having a significant number of beds for economies of scale contributed to the increased number of cases in these nursing facilities.

On April 19, 2024, CMS released a fact sheet stating, "the Centers for Medicare and Medicaid Services (CMS) affirmed its commitment to hold nursing homes accountable for providing safe and high-quality care" by mandating specific total nursing per patient day staffing levels of 3.48, registered nurse (RN) staffing of 0.55 hours per day and certified nursing assistant (CNAs) of 2.45 hours of direct care for each resident per day.[63] These mandates were intended to supplement the regulation that facilities provide sufficient staff to meet the residents' needs as required by individualized care plans. The CMS staffing guidelines also acknowledged "the increasing medical complexity and acuity of health conditions that require substantial resources and care provided or supervised by an RN."[64] In response to the staffing mandates, the nursing home industry filed suit and on April 7, 2025, a federal District Court Judge located in the Northern District of Texas granted summary judgment in favor of the American Health Care Association (and others) and vacated the requirement that nursing facilities have a registered nurse (RN) onsite twenty-four hours per day, seven days a week available to provide direct resident care, and the three separate minimum staffing standards noted above.[65] On June 18, 2025, a second federal District Court Judge located in Iowa agreed and struck down the staffing rule.[66] Given that the DOJ has appealed the Texas case, the fate of the validity of CMS' mandatory staffing requirements will remain at issue for the foreseeable future.

61. *Id.* at 809.

62. Brian E. McGarry et al., *Larger Nursing Home Staff Size Linked to Higher Number Of COVID-19 Cases In 2020*, 40 HEALTH AFFS. 1261, 1264 (2021).

63. *Medicare and Medicaid Programs: Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting Final Rule (CMS 3442-F)*, CMS.GOV (Apr. 22, 2024), https://www.cms.gov/newsroom/fact-sheets/medicare-and-medicaid-programs-minimum-staffing-standards-long-term-care-facilities-and-medicaid-0. At the time of writing this article, both houses of Congress have introduced legislation to rescind the mandatory staffing regulations.

64. *Id.*

65. Am. Health Care Ass'n, v. Kennedy, Jr., No. 2:24-CV-00114-Z-BR (N.D. Tex. April 7, 2025).

66. Kansas v. Becerra, No. C24-110-LTS-KEM (N.D. Iowa June 18, 2025).

Nursing facilities often provide care to three distinct populations of residents: (1) those with unstable housing, (2) those recovering from acute illnesses or surgery, and (3) those who require ongoing nursing care. Farber and Shah argue that only the latter group requires care in a nursing facility.[67] They advocate that repairing the social safety nets for the unhoused and those with serious mental health issues, including those with substance use disorder, would provide a more appropriate setting for most of these individuals. Moreover, they contend that since Medicare incentivizes nursing facilities to admit hospitalized patients for short-term rehabilitation, these individuals would be better served in a setting exclusively devoted to their recovery.[68] Restricting admittance to older adults who require long-term services would allow nursing facilities to focus on providing specialized services for chronic physical and cognitive conditions, as well as terminal illnesses. Farber and Shah dispute the idea that nursing facilities should cater to a widely divergent population rather than focusing on the chronic care needs of older adults.[69]

In an effort to strengthen consumers' ability to identify quality nursing facilities, CMS enhanced its Nursing Home Compare public reporting site in December 2008, including a set of quality ratings for each nursing home participating in Medicare or Medicaid.[70] The ratings take the form of several "star" ratings based on inspections, staffing, and quality measures.[71] However, quality indicators from a surveyor's perspective may differ significantly from a resident's. Quality indicators are generated from the Minimum Data Set (MDS), a federally mandated data collection process also used for care planning and reimbursement.[72] The Medicare "Five Star" rating system[73] was created to help consumers access information about the facility's health inspections, staffing, and quality measures, enabling them to make an informed placement decision. Staffing data is reported directly to CMS via the payroll-based journal (PBJ) process, while quality indicators are derived from input in the MDS.[74]

Examples of short-term quality indicators include re-hospitalization, emergency room visits, the initiation of new psychotropic agents, new or

67. Jeffrey I. Farber & Nirav R. Shah, *We Need to Rethink Nursing Homes,* 39 J. OF GEN. INTERNAL MED. 2106, 2106 (2024).

68. *Id.*

69. *Id.*

70. *Find & Compare Providers Near You*, MEDICARE.GOV, https://www.medicare.gov/care-compare/ (last visited Mar. 22, 2025).

71. CTRS. FOR MEDICARE & MEDICAID SERVS., DESIGN FOR *CARE COMPARE* NURSING HOME FIVE-STAR QUALITY RATING SYSTEM: TECHNICAL USERS' GUIDE 4-5 (2025) [hereinafter 5 STAR RATING GUIDE].

72. *Fact Sheet, Nursing Home Compare Five-Star Quality Rating System*, CMS.GOV, https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcomplianc/downloads/consumerfactsheet.pdf (last visited Mar. 22, 2025).

73. *Find & Compare Providers Near You*, *supra* note 70.

74. 5 STAR RATING GUIDE, *supra* note 71, at 4-5.

worsening pressure injuries, the percentage of residents and staff who received flu vaccinations, the percent of staff vaccinated against COVID, the review of medications by a pharmacist, falls, the percentage of residents who had care plans devised to meet the physical needs, and the improvement of their status at discharge.[75] Several of these quality indicators are federal requirements, such as the pharmacist review and the development of care plans.[76]

Long-term quality indicators also include re-hospitalizations, emergency room visits, and restraints, as well as falls with major injuries, urinary tract infections, the use of catheters, worsening wound status, weight loss, depression, and antianxiety medication use.[77] Residents, on the other hand, may value a stable workforce, the quality of food, the attentiveness of the staff, and the cleanliness of the environment—factors that are not considered in the 5-star rating system.[78]

A. Facility-Level Staff

The education, support, supervision, and reimbursement of a workforce capable of providing quality care to older adults in nursing facilities depend on several factors. These factors include the availability of staff, the perceived benefits of working in this setting, the pay scale of employees, the alignment of residents' needs with staff's skills, the degree of autonomy the staff can exert, and the quality of support provided by ownership. Nursing facility employees skilled in caring for and treating residents with cognitive and physical diseases associated with aging may lack experience in caring for residents with serious mental illnesses, substance use disorders, or those who are younger with health issues not specifically associated with aging.

Supervising and working collaboratively with an interdisciplinary care team may require additional education and support, as well as strategies for managing complex family dynamics and society's negative views on older adults and their caregivers. Staying abreast of new medications, advances in diagnostics and

75. *Id.* at 19.

76. Social Security Act § 1888(e)(6)(B)(i), cross-referencing §§ 1899B(b)-(d); *Quality Measures*, CMS.GOV (Dec. 23, 2024), www.cms.gov/medicare/quality/nursing-home-improvement/quality-measures.

77. 5 STAR RATING GUIDE, *supra* note 71, at 18-19.

78. *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-23-105312, NURSING HOMES: CMS OFFERS USEFUL INFORMATION ON WEBSITE AND IT CONSIDERING ADDITIONAL STEPS TO ASSESS UNDERLYING DATA 20 (2023) (finding that "the nursing home quality information the Centers for Medicare & Medicaid Services (CMS) provides on Care Compare—which was developed to assist consumers in selecting a nursing home—at least partially aligns with 11 of 15 characteristics of understandability and relevancy for an effective transparency tool […] These characteristics include providing descriptions of key differences in clinical quality of care, enabling consumers to customize information, and comparing multiple nursing homes. However, GAO also found Care Compare did not align with four of the characteristics"). Importantly, some of the information is not updated in a timely fashion and is more than 2 years old. *Id.* at 18.

treatment regimens, preventive care, and emerging trends in the care of residents require additional support and attention to decrease staff turnover. We have frequently observed nursing facilities focusing on recruiting employees while neglecting the importance of staff retention, resulting in increased turnover, higher recruitment costs, and decreased employee satisfaction.

When discussing how specific types and numbers of nursing staff impact quality outcomes, the general consensus is that more staff members improve residents' quality of care. Interestingly, using a sample size of 15,790 nursing homes (11,261 participants) from 2017-2019 to avoid COVID-19-related issues, Dana Mukamel, PhD and her colleagues examined the relationship of nursing staff to measures of short-term quality, such as rehospitalization, emergency room visits (which did not involve hospital admittance), and the number of hospitalizations and emergency room visits per 1000 long-stay resident days.[79] Additionally, the study analyzed long-term resident quality measurements, such as pressure injuries, psychotropic medication usage, the increased need for assistance with activities of daily living (ADLs), and a decline in mobility, as well as short-term residents whose functioning did not improve and who received new prescriptions for antipsychotic agents were examined.[80]

Notably, the researchers found that increased levels of CNA staff lowered the residents' use of antipsychotic medications, whereas higher levels of RN actually increased this negative quality indicator.[81] An additional finding noted that increasing the number of CNAs was associated with increased emergency room visits and hospitalizations. With regard to the development of pressure injuries, a major quality of care issue, increasing CNA staffing did not decrease the development of these wounds. This was indeed a surprising finding, as CNAs are chiefly responsible for repositioning, incontinence care, and assistance with eating. However, Mukamel concluded, "A possible explanation for this may be related to the fact that prevention and treatment of pressure injuries require assessment and identification of risks and development of appropriately matched care plans. For higher risk residents, this can be complex and require more than [one] intervention." The complexity of pressure injury prevention appeared to be more dependent upon multiple licensed nurse interventions than the provision of care by CNAs. Indeed, the sheer number of CNAs, LPN/LVNs, or RNs alone

79. Dana B. Mukamel et al., *The Relationship Between Nursing Home Staffing and Health Outcomes Revisited*, J. AM. MED. DIRS. ASS'N., Aug. 2024, at 1, 2-3.

80. *Id.*

81. *Id.* at 4. The study authors note that increased prescribing of antipsychotics "might relate to RNs' role directly communicating behavioral concerns to the prescribing provider and that RNs may initiate the request for antipsychotic orders." *Id.* at 4-5. It has been our experience that antipsychotic medications are often prescribed without following the extensive regulatory requirements prior to the administration of these potentially dangerous drugs to residents. The need for regulatory compliance oversight of medication administration as part of a facility's ethics and compliance program is critically important.

is likely not to guide facilities in developing appropriate staffing strategies; rather, a full understanding of the needs and characteristics of the individual residents may prove more beneficial in promoting quality care.

Bowblis and Roberts argue that evidence is needed to determine what type of nursing staff (Certified Nursing Assistants, Licensed Practical/Vocational Nurses, or Registered Nurses) or non-nursing staff provide the highest quality care while being cost-effective.[82] The authors concluded, "*the least expensive strategy to improve deficiency outcomes involves increasing social service staff and/or activities staff*."[83] This conclusion is based on the impact of quality of life and quality of care on SNF residents, which impacted the quality measures reported on Medicare.gov and the deficiency citations identified by surveyors.

B. Families/Residents

The inclusion of residents and families as stakeholders in the assessment of quality care in nursing facilities cannot be overstated. There is a general lack of understanding among families and residents regarding how much Medicare will reimburse for a nursing facility admission and how much an individual will need to apply for Medicaid for long-term care. Many families first learn that fee-for-service Medicare will only cover up to one hundred days of care if, and only if, the resident's condition requires the skills and services of a licensed nurse or therapist following a minimum of a three-day inpatient hospital stay.[84] Individuals watching daytime television may be inundated with commercials from plaintiffs' attorneys promoting that pressure injuries and falls are always preventable in this setting. Families may feel apprehensive or guilty about their inability to care for their loved ones in the community, yet have no option but nursing facility placement due to work and family commitments. Engaging residents and family members in care conferences and council meetings, as well as establishing mechanisms for effective communication of issues as they arise, are fundamental to the provision of quality care.

Although CMS has developed the Medicare.gov website that allows consumers to compare the inspections, staffing, and quality measures of SNFs across the country, the specific types of short-term and long-term quality measures defined by CMS may not reflect what residents or their families would consider quality care.[85] For example, reporting the percentage of SNF residents who received influenza vaccinations may be of value to CMS but may not provide insight into quality for prospective residents. Nonetheless, multiple

82. *Id.* at 275.

83. Dana B. Mukamel et al., *supra* note 79, at 282.

84. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., SKILLED NURSING FACILITY 3-DAY RULE BILLING 2 (2024).

85. *Find & Compare Providers Near You*, *supra* note 70.

researchers have identified that having a vehicle for the public reporting of quality does affect quality outcomes.[86]

To ensure quality care is provided to nursing facility residents, a reassessment of the financial, structural, ownership, management, and employment-related issues is required. Since poor quality care in these facilities has been associated with low nursing staffing levels, particularly RNs,[87] efforts must be directed towards building the integrity of the workforce through salary increases and considering the impact on the other stakeholders in this industry.

V. ETHICS AND COMPLIANCE PROGRAMS: THE CROSSING GUARD THAT ASSISTS IN PROTECTING RESIDENTS

Federal law and the Requirements of Participation for nursing facilities mandate the implementation of effective ethics and compliance programs to ensure continued compliance and quality care delivery.[88] The Affordable Care

86. *See, e.g.*, John R. Bowblis & Amy Restorick Roberts, *Cost-Effective Adjustments to Nursing Home Staffing to Improve Quality*, 77 MED. CARE RSCH. AND REV. 274, 274 (2020).

87. Charlene Harrington et al., *United States' Nursing Home Finances: Spending, Profitability, and Capital Structure*, 54 INT'L. J. SOC. DETERMINANTS HEALTH & HEALTH SERVS. 131, 131 (2024).

88. Social Security Act § 1128I, 42 U.S.C. § 1320a-7j(b). In a draft chapter addressing the compliance obligations of providers and suppliers, Malcolm J. Harkins, Professor of Practice, Center for Health Law Studies, St. Louis University School of Law, has observed that the ACA provision mandating that all other providers and suppliers have an effective compliance program as a condition of enrollment in federal health care payment programs, 42 U.S.C. § 1395cc(j)(9), is similar, in some respects, to the ACA provisions mandating nursing facility compliance programs. For example, by making the existence of an effective compliance program a condition of participation for all providers and suppliers, the ACA ties a provider or supplier's Medicare and Medicaid cash flow to adoption of an effective compliance plan. In addition, although enforcement mechanisms and potential penalties are not as well developed as those available to enforce nursing facility compliance, whether a provider or supplier has an effective compliance program will be determined by federal and state inspectors in real-time using active monitoring during regular and routine assessments of provider and supplier operations. However, the differences between the ACA's nursing facility requirements and the compliance program requirements for all other providers and suppliers are significant. For one thing, the provisions applicable to providers and suppliers, other than nursing facilities, are open-ended and not prescriptive. Instead, the ACA requires the Secretary of the Department of Health and Human Services to develop regulations specifying the "core elements" of compliance programs that must be adopted by providers and suppliers other than nursing facilities. Although the requirements are to be developed in conjunction with the Office of Inspector General, the statute provides the Secretary no substantive guidance with respect to the components of such core elements. Further, although the ACA provisions applicable to nursing facilities are sufficiently detailed so as to be self-implementing, the provisions applicable to all other providers and suppliers contain no detail, and do not require providers and suppliers to do anything until the Secretary adopts regulations implementing the statute. Further, the nursing facility provisions required action by a date certain, but the ACA provisions applicable to other providers and suppliers allow the Secretary to determine which health care industry segments should be subjected to compliance program regulations and leave the timing of such

Act (ACA) mandated that nursing facilities enact ethics and compliance programs by March 23, 2013.[89] This mandate was sufficiently detailed to be self-implementing. Specifically, the nursing facility provisions required action by a specific date, while the ACA provisions applicable to other healthcare providers and suppliers allowed the Secretary to determine which healthcare industry segments should be subjected to compliance program regulations and left the time of such regulations up to the Secretary.[90] The ACA nursing facility compliance provisions were sufficiently detailed to provide clear instruction on program development. The importance and urgency of the need to implement the nursing facility compliance and ethics program provide a reasonable explanation for the different approaches. This need was grounded in the concern that the existing regulatory system was not protecting nursing home residents sufficiently and that a mandate for internal action by nursing facilities was, therefore, instituted. Unfortunately, the ACA's mandate did not trigger enforcement activity by nursing facility regulators.

In response to the ACA mandate, nursing facilities created ethics and compliance programs, but the "effectiveness" of these programs was not evaluated by regulators. As of November 28, 2019, nursing homes are required, by regulation, to establish ethics and compliance programs that not only address the prevention and detection of legal violations but also promote quality of care.[91] The purpose and effect of this regulatory requirement is to make clear that nursing facilities bear primary responsibility for regulatory compliance and that, from our perspective, the current regulatory system of repairing non-compliance is insufficient. The current system, which allows for quality of care and quality of life violations to occur and then be remedied in a timely manner, has failed to protect nursing home residents and ensure sustained quality care delivery. The objectives of the existing nursing home regulatory system, which aim for continual compliance, have not been achieved. Therefore, nursing homes must develop and implement their own internal system to address regulatory compliance through an effective ethics and compliance program as a Requirement of Participation, punishable for noncompliance as a violation of the Federal False Claims Act.[92]

regulations up to the Secretary. Thus, despite that the statute was adopted in 2013, the Secretary has not yet proposed compliance regulations for providers and suppliers other than nursing homes. A copy of the draft is in the possession of the author.

89. Patient Protection and Affordable Care Act § 6102, 42 U.S.C. § 1320a-7j(b)(1).

90. Patient Protection and Affordable Care Act § 6401, 42 U.S.C. § 1395cc(j).

91. 42 C.F.R. § 483.85(a)(1).

92. 31 U.S.C. §§ 3729–3733 (2010).

Specifically:

42 CFR § 483.85 Compliance and ethics program.

(a) ***Definitions.*** For purposes of this section, the following definitions apply:

Compliance and ethics program means, with respect to a facility, a program of the operating organization that—

(1) Has been reasonably designed, implemented, and enforced so that it is likely to be effective in preventing and detecting criminal, civil, and administrative violations under the Act and in promoting quality of care; and

(2) Includes, at a minimum, the required components specified in paragraph (c) of this section.[93]

93. 42 C.F.R. § 483.85(c) ("***Required components for all facilities.*** The operating organization for each facility must develop, implement, and maintain an effective compliance and ethics program that contains, at a minimum, the following components:

(1) Established written compliance and ethics standards, policies, and procedures to follow that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under the Act and promote quality of care, which include, but are not limited to, the designation of an appropriate compliance and ethics program contact to which individuals may report suspected violations, as well as an alternate method of reporting suspected violations anonymously without fear of retribution; and disciplinary standards that set out the consequences for committing violations for the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles.

(2) Assignment of specific individuals within the **high-level personnel of the operating organization with the overall responsibility to oversee compliance with the operating organization's compliance and ethics program's standards, policies, and procedures,** such as, but not limited to, the chief executive officer (CEO), members of the board of directors, or directors of major divisions in the operating organization.(emphasis added).

(3) Sufficient resources and authority to the specific individuals designated in paragraph (c)(2) of this section to reasonably assure compliance with such standards, policies, and procedures.

(4) Due care not to delegate substantial discretionary authority to individuals who the operating organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under the Social Security Act.

(5) The facility takes steps to effectively communicate the standards, policies, and procedures in the operating organization's compliance and ethics program to the operating organization's entire staff; individuals providing services under a contractual arrangement; and volunteers, consistent with the volunteers' expected roles. Requirements include, but are not limited to, mandatory participation in training as set forth at § 483.95(f) or orientation programs, or disseminating information that explains in a practical manner what is required under the program.

(6) The facility takes reasonable steps to achieve compliance with the program's standards, policies, and procedures. Such steps include, but are not limited to, utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under the Act by any of the operating organization's staff, individuals providing services under a contractual arrangement, or volunteers, having in place and publicizing a reporting

Implementing an effective compliance and ethics program has been elusive for many different types of healthcare providers, particularly nursing facilities. On November 20, 2024, the HHS Office of Inspector General (OIG) published its Nursing Facility Industry Segment- Specific Compliance Program Guidance (Nursing Facility ICPG) to update its previous guidance.[94] Nursing facilities have been a priority for both compliance guidance and government fraud enforcement actions for many years, yet systemic failures in care delivery remain an issue.[95] Notably, the OIG notes that the Nursing Facility ICPG emphasizes the "inextricable link" between quality care delivery and nursing facility compliance initiatives.[96]

But what is the link between quality care delivery and compliance? "Fraudulent conduct has now been defined to include the provision of grossly substandard care and therefore, compliance programs are not just about billing, but must also address integrating care delivery in order to ensure that care is rendered in such a fashion as to support claims submitted to the government for payment." [97] The Nursing Facility ICPG notes that:

> 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

system whereby any of these individuals could report violations by others anonymously within the operating organization without fear of retribution, and having a process for ensuring the integrity of any reported data.

(7) Consistent enforcement of the operating organization's standards, policies, and procedures through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect and report a violation to the compliance and ethics program contact identified in the operating organization's compliance and ethics program.

(8) After a violation is detected, the operating organization must ensure that all reasonable steps identified in its program are taken to respond appropriately to the violation and to prevent further similar violations, including any necessary modification to the operating organization's program to prevent and detect criminal, civil, and administrative violations under the Act.").

94. U.S. DEP'T HEALTH & HUM. SERVS. OFF., OF INSPECTOR GEN., NURSING FACILITY INDUSTRY SEGMENT-SPECIFIC COMPLIANCE PROGRAM GUIDANCE 3 (2024) [hereinafter ICPG], https://oig.hhs.gov/documents/compliance/10038/nursing-facility-icpg.pdf.

95. OFF. OF INSPECTOR GEN., SEMIANNUAL REPORT TO CONGRESS APR. 1, 2022–SEPT. 30, 2022, at 2 (2022), https://oig.hhs.gov/documents/sar/1253/OIG-SAR-FALL-2022-Complete%20 Report.pdf ("My top priority is propelling meaningful improvement in the quality and safety of care in the more than 15,000 Medicare- and Medicaid-certified nursing homes.") (statement of Christi A. Grimm, HHS-Inspector General).

96. ICPG, *supra* note 94, at 6.

97. David R. Hoffman, *Failing to Care: How Effective Compliance Prevents Institutional Elder Neglect*, MARQ. ELDER'S ADVISOR, Aug. 2012, at 1, 12-13.

> 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.[98]

Adhering to the recently enacted Facility Assessment regulation[99] provides a link between compliance and quality care delivery:

> The facility must conduct and document a facility-wide assessment to determine what resources are necessary to care for its residents competently during both day-to-day operations (including nights and weekends) and emergencies. The facility must review and update that assessment, as necessary, and at least annually. The facility must also review and update this assessment whenever there is, or the facility plans for, any change that would require a substantial modification to any part of this assessment.[100]

This assessment process should not be limited to an annual basis; it must be done (to some extent) on a daily basis as it pertains to the necessary resources to care for residents. As noted in the Preamble relating to the Facility Assessments regulation:

> The facility assessment is the foundation for LTC facilities to assess their resident population and determine the direct care staffing and other resources, to provide the required care to their residents. The facility assessment must be conducted and developed with the intent of using it to inform decision making, especially about staffing decisions.[101]

Beyond quality care delivery, Facility Assessments play an important role in performing risk assessments required by an effective ethics and compliance program. For these reasons, we recommend that nursing facilities, as part of their compliance monitoring function under their ethics and compliance programs, perform focused Facility Assessments on a *monthly* basis.

Is every medication administration error a compliance matter? Does every nursing home resident fall require an investigation by the compliance and ethics officer? The key to answering these questions is understanding the fundamental elements of an ethics and compliance program, which will aid in designing an effective program. Additionally, a robust incident/event reporting system, supervised by the compliance department, will link quality care delivery to compliance.[102]

98. ICPG, *supra* note 94, at 6.

99. 42 C.F.R. § 483.71.

100. 42 C.F.R. § 483.71.

101. Medicare and Medicaid Programs; Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting, 89 Fed. Reg. 40876, 40909 (proposed May 10, 2024) (to be codified at 42 C.F.R. pt. 483).

102. Carl Macrae, *The Problem with Incident Reporting*, 25 BMJ QUALITY & SAFETY 71, 74 (2016), https://qualitysafety.bmj.com/content/qhc/25/2/71.full.pdf ("The core functions of an

The creation of compliance and ethics programs is grounded in the Federal Sentencing Guidelines for Organizations.[103] The purpose of these guidelines is to establish baseline structural requirements to help organizations comply with the law. In the event of non-compliant conduct rising to criminality, they ensure that the wrongdoer was a rogue employee and that the organization is not fundamentally corrupt. In that event, the program is evaluated for possible financial benefit to an organization prosecuted for fraud.[104] More importantly, the design of an effective ethics and compliance program must create an environment where employees feel comfortable reporting compliance concerns within the organization, thereby effectively creating a "culture of compliance."[105]

Creating a culture of compliance in the nursing facility setting is especially challenging, given the regulatory pressures identified previously. For example, allegations of abuse must be reported in a timely manner both internally to leadership and externally to law enforcement agencies, older adult protective services agencies, regulators, and possibly other agencies. Nursing facility staff must conduct a thorough internal investigation, and state regulators will evaluate the investigation and impose appropriate sanctions when warranted. To address abuse promptly and protect the alleged victim and all other residents in the nursing facility, an effective incident reporting system, free from intimidation and retaliation, must be in place.

That is why it is imperative to have a reporting system grounded in doing the right thing for the right reasons rather than a "gotcha" program where fear reigns supreme. A law enforcement model of compliance program design, i.e., establishing rules coupled with rigid enforcement, will create an environment that may be hostile to effective internal reporting of mistakes, accidents, or other actions that may unintentionally harm residents.

incident reporting system are twofold. One is to use incidents to identify and prioritize which aspects of a healthcare system and its underlying risks need to be examined more closely. The other is to organize broader investigation and improvement activities to understand and address those risks. These active processes of investigation, inquiry, and improvement underpin learning.") (citation omitted).

103. U.S. SENT'G COMM'N, U.S. SENTENCING GUIDELINES MANUAL § 8B2.1.

104. *Id.* at § 8C2.5(f)(1) ("If the offense occurred even though the organization had in place at the time of the offense an effective compliance and ethics program, as provided in §8B2.1 (Effective Compliance and Ethics Program), subtract **3** points.").

105. U.S. DEP'T HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN., GENERAL COMPLIANCE PROGRAM GUIDANCE 33 (2023). The seven (7) elements of a compliance program are (1) Written Policies and Procedures, (2) Compliance Leadership and Oversight, (3) Training and Education, (4) Effective Lines of Communication with the Compliance Officer and Disclosure Program, (5) Enforcing Standards: Consequences and Incentives, (6) Risk Assessment, Auditing and Monitoring and (7) Responding to Detected Offenses and Developing Corrective Action Initiatives. *Id.* at 32. Board of Director and Governing Body oversight and active engagement in ensuring that the program is effective is another critically important element. *Id.* at 34, 43-44.

Additionally, the relationship between leadership and front-line employees may be unintentionally negatively impacted, with the Chief Ethics and Compliance Officer viewed as the corporate cop. A rules-based system *alone* may instill fear of disciplinary sanctions, leading to a lack of reporting of crucial compliance-related issues.

Instead, an ethics-dominant approach to compliance is more valuable because it asks employees to do the right things for the right reasons, reducing the pressure to act in a non-compliant fashion. Interviews with nursing facility staff have evidenced the desire to do the right thing in delivering care to residents; however, barriers such as a lack of necessary resources and support to achieve their goals have been identified. From our perspective, these failures constitute a reportable compliance issue, as quality care delivery is paramount. Moreover, staff who come forward to their supervisors and the compliance department should be rewarded for bringing care concerns or possible billing irregularities to the leadership's attention. Therefore, the message of compliance is one of individual responsibility and accountability, with a laser focus on resident safety and satisfaction. This approach to compliance is not merely a noble goal but is the essence of the nursing facility's compliance mandate.

To ensure the compliance message gains traction and fosters a culture of compliance, communication must start at the top of the organization, from ownership to the Governing Body, the C-suite, mid-level management, and frontline staff. All nursing facility personnel should be aware that owners and corporate executives must attend educational compliance sessions, as they are bound by the same Code of Conduct/Code of Ethics as everyone else in the organization.[106] These ethics and compliance educational sessions should include in-person gatherings rather than solely being conducted online. Interactive sessions incorporating role-playing and hypothetical scenarios are important in evaluating understandings and competencies associated with defining and reporting compliance matters.

When reviewing the guidance provided to surveyors for evaluation of compliance with the compliance and ethics program regulation, Appendix PP states the following:

> INVESTIGATIVE PROCEDURES
>
> When concerns regarding the compliance and ethics program are identified, use the applicable probes below to assist with investigating and determining compliance.
>
> PROBES
>
> • Does the operating organization have written standards, policies and procedures for the compliance and ethics program that are reasonably capable

106. *See* J. Paul McNulty et al., *What an Effective Corporate Compliance Program Should Look Like*, 9 J. L. ECON. & POL'Y 375, 383 (2013).

> of reducing the possibility of criminal, civil and administrative violations under the Act?
>
> • Interview high-level personnel designated to oversee the organization's compliance and ethics program about their involvement in the program.
>
> Determine:
>
> o how the facility uses monitoring and auditing systems to detect criminal, civil, and administrative violations by staff;
>
> o if they are aware of the potential violation under investigation and what was their response.
>
> • Ask staff if:
>
> o they are aware of the facility's compliance and ethics program;
>
> o there is a method for staff to anonymously report suspected violations;
>
> o they are confident in reporting compliance matters without fear of retaliation.
>
> • When reports or reasonable suspicions of violations are identified, did the organization take prompt action to respond to the violation and prevent future occurrences, including enforcement of program standards, policies and procedures through disciplinary mechanisms, if appropriate?
>
> • Did the operating organization delegate substantial discretionary authority to an individual it knew or should have known through due diligence, had a propensity to engage in criminal, civil and/or administrative violations?
>
> • Does the operating organization review the program annually and as needed, in response to organization, facility and/or regulatory changes?
>
> • If the operating organization has five or more facilities, have a compliance officer and a facility-based compliance liaison been designated and is mandatory annual training conducted.[107]

These probes are a good starting point for evaluating the effectiveness of an ethics and compliance program, but much more is required. What triggers a concern regarding a nursing facility's compliance and ethics program? Instead, a review of this program should be included in every survey. While policies and procedures are important, a full understanding and effective implementation of the ethics and compliance program are also essential. What metrics are to be applied when analyzing whether high-level personnel are adequately overseeing the ethics and compliance program?

The Department of Justice (DOJ) issued Compliance Effectiveness Guidance, which has evolved over time to focus more on ethics.[108] We will discuss some of the reporting systems and incentives for compliance detailed in the guidance.

107. STATE OPERATIONS MANUAL, *supra* note 15, § 483.85(e).

108. U.S. DEP'T JUST. CRIM. DIV., EVALUATION OF CORPORATE COMPLIANCE PROGRAMS 11 (2024).

First, the DOJ guidance regarding reporting provides the following:

> Effectiveness of the Reporting Mechanism – Does the company have an anonymous reporting mechanism and, if not, why not? How is the reporting mechanism publicized to the company's employees and other third parties? Has it been used? Does the company test whether employees are aware of the hotline and feel comfortable using it? Does the company encourage and incentivize reporting of potential misconduct or violation of company policy? Conversely, does the company use practices that tend to chill such reporting? How does the company assess employees' willingness to report misconduct? How has the company assessed the seriousness of the allegations it received? Has the compliance function had full access to reporting and investigative information?[109]
>
> *********
>
> What insights can be taken from the management of a company's hotline that provide indicia of its compliance culture or its management of hotline reports? …. Has the company undertaken a root cause analysis into areas where certain conduct is comparatively over or under-reported? What is the average time for completion of investigations into hotline reports and how are investigations that are addressed inconsistently managed by the responsible department?[110]

These inquiries get to the heart of the company's effectiveness in implementing its reporting mechanism. We have found that while nursing facility employees are typically aware of a compliance hotline, they often lack clarity on what constitutes a compliance issue that requires reporting.

Another major area that has received limited attention is how to incentivize personnel to comply with an ethics and compliance program. Organizations are known to discipline employees for violations of the Code of Conduct or a policy/protocol, but what about creating a culture that rewards compliance-related activities? Interestingly, the DOJ has addressed this issue in several different ways. The guidance states:

> Compensation structures that clearly and effectively impose financial penalties for misconduct can deter risky behavior and foster a culture of compliance. At the same time, providing positive incentives, such as promotions, rewards, and bonuses for improving and developing a compliance program or demonstrating ethical leadership, can drive compliance. Prosecutors should examine whether a company has made working on compliance a means of career advancement, offered opportunities for managers and employees to serve as a compliance "champion", or made compliance a significant metric for management bonuses.[111]

109. *Id.* at 7.
110. *Id.* at 16.
111. *Id.* at 15.

Next, the DOJ guidance also suggests that companies ask important questions surrounding senior-level compensation and tie this area of inquiry into the effectiveness of an ethics and compliance program.

> **Financial Incentive System** – Has the company considered the impact of its financial rewards and other incentives on compliance? Has the company evaluated whether commercial targets are achievable if the business operates within a compliant and ethical manner? What role does the compliance function have in designing and awarding financial incentives at senior levels of the organization? **How does the company incentivize compliance and ethical behavior?** What percentage of executive compensation is structured to encourage enduring ethical business objectives? Are the terms of bonus and deferred compensation subject to cancellation or recoupment, to the extent available under applicable law, in the event that non-compliant or unethical behavior is exposed before or after the award was issued? Does the company have a policy for recouping compensation that has been paid, where there has been misconduct? Have there been specific examples of actions taken (e.g., promotions or awards denied, compensation recouped or deferred compensation cancelled) as a result of compliance and ethics considerations? (emphasis added)[112]

Who should take the lead on this critical inquiry? Compliance is a top-down program and, as such, a nursing facility's Board of Directors and/or Governing Body, in conjunction with the Chief Ethics and Compliance Officer, should work collaboratively to obtain the answers to these questions. Importantly, action steps must be taken to align financial incentives with ethical and compliant conduct. For example, if a Nursing Home Administrator (NHA) is pressured to admit residents based on financial incentives, regardless of the facility's known inability to meet residents' needs, this misalignment may lead to resident harm and must be rectified in a timely fashion by the Chief Ethics and Compliance Officer and Compliance Committee.

Finally, a culture of compliance may mean many different things to nursing facility owners, senior leadership, and staff. From our perspective, a culture of compliance is one of responsibility and accountability at all levels of a nursing facility, from ownership down.

> Culture of Compliance – How and how often does the company measure its culture of compliance? How does the company's hiring and incentive structure reinforce its commitment to ethical culture? Does the company seek input from all levels of employees to determine whether they perceive senior and middle management's commitment to compliance? What steps has the company taken in response to its measurement of the compliance culture?[113]

112. *Id.* at 15-16.

113. U.S. DEP'T JUST. CRIM. DIV., *supra* note 108, at 18.

To evaluate a nursing facility's culture of compliance, several foundational steps must be taken:

> (1) Survey all staff (anonymously) regarding what constitutes a compliance or ethics issue such that reporting to the Compliance Department should occur;
>
> (2) Based on the staff survey results, develop an educational program for all staff and ownership/leadership on what constitutes a compliance or ethics issue that should be reported to the Compliance Department and explain the investigation and remediation process. The program should be delivered in person to facilitate discussion;
>
> (3) Use hypotheticals during the hiring process to inquire into ethical considerations facing nursing facility personnel and evaluate whether an applicant meets the facility's standards and culture;
>
> (4) Perform a Root Cause Analysis on substantiated noncompliant or unethical conduct in order to prevent recurrence; and
>
> (5) Ensure that the nursing facility's Code of Conduct is written in a way that clearly reflects the mission and values of the organization and stresses that a violation of the Code is a compliance matter.

While federal prosecutors have additional questions to consider when evaluating an ethics and compliance program, nursing home regulators should evaluate all the factors set forth in this section and demand strict proof of actions taken in order to comply with the regulatory requirement for an effective ethics and compliance program. By doing so, regulators would significantly contribute to ensuring that a nursing facility's ethics and compliance program protects residents.

Finally, the proposed compliance message and program design presented in this article align with the notion that an effective ethics and compliance program should create a culture of compliance. This culture will encourage more compliant conduct and promote quality care delivery to residents. The program must:

> (1) promote an ethical environment by rewarding staff who report compliance concerns in a timely manner;
>
> (2) create a team approach to delivering care to residents;
>
> (3) mandate a reporting mechanism that does not lead to purely punitive responses;
>
> (4) ensure that staff are educated on how to perform timely investigations that are clearly documented, including thorough and accurate incident/event reports;
>
> (5) develop a protocol for compliance department review of incident/event reports;
>
> (6) use the findings from incident/event and compliance investigations for quality assurance and performance improvement (QAPI) purposes;

(7) provide meaningful compliance education to all owners, leadership, and front-line staff on laws, regulations, and best practices associated with nursing facility care;

(8) create a culture of compliance by shifting the focus from blame alone to a full understanding of what caused the noncompliant conduct; and

(9) provide meaningful remedies to avoid the recurrence of non-compliant conduct, including the involvement in a full evaluation of the competencies associated with quality care delivery.

If nursing facilities implement such a program, the intersection of regulation, quality care, and compliance will be significantly enhanced, leading to a much safer environment for residents.

VI. CONCLUSION

Nursing facility residents remain at risk of harm despite attempts by legislators and regulators to ensure compliance with the multitude of rules governing the long-term care industry. The enforcement of these regulations by increasingly under-staffed and under-resourced state survey agencies, which have been ineffective in protecting residents and have failed to produce the intended result of the Nursing Home Reform Act, i.e., care delivery that meets individualized resident needs and the provision of meaningful quality of life initiatives. Nursing home ownership and management models, staffing shortages, the continued aftermath of COVID-19, and reimbursement concerns have contributed to this failure to protect residents. This is an opportunity for Congress and federal regulators to take steps to reform a system that is broken and fails at the most basic levels to incentivize quality care.

The design and implementation of an effective ethics and compliance program offers a mechanism that will reasonably ensure compliance not only with regulatory requirements but will facilitate positive impacts on the delivery of quality care and the provision of therapeutic recreation activities that enhance residents' quality of life. The mandate for such a program to be implemented by nursing facilities has been in effect for well over a decade. At this point, the failure to enact and evaluate the elements of this critically important program, as discussed in Part V, may subject nursing facilities to fraud claims actionable under the federal False Claims Act based on the knowing failure to comply with legal and regulatory requirements. Therefore, it is imperative that nursing facility owners and operators commit the resources necessary to fulfill the compliance mandate, thereby creating a culture of compliance whereby nursing facility owners and all staff are responsible and accountable for the health, safety, and well-being of their residents.