

RISK AND COMPLIANCE PRACTICES FOR NURSING FACILITIES

Carey F. Kalmowitz, Esq.
Wachler & Associates, P.C.
(248) 544-0888
www.wachler.com

Walter S. Wheeler, Esq.
Walter Wheeler Associates, PLC
517-347-8937
www.walterwheeler.com

INTRODUCTION

On March 16, 2000, the United States Department of Health and Human Services Office of Inspector General (the "**OIG**") published its first "Compliance Program Guidance" for Nursing Facilities" (the "**Guidance**" or "**2000 Guidance**").¹ The Guidance comprised a set of voluntary recommendations for nursing facility programs that encourage compliance with applicable federal regulations. Although the recommendations were not enforceable operating standards, they contained practical advice which, if implemented, would mitigate the regulatory scrutiny to which a nursing facility likely would be subject. Since the publication of the original Guidance in 2000, there have been significant changes to the regulatory enforcement environment, the federal payment system for nursing facility services, and a heightened focus on quality of care, an issue that the Guidance addressed, albeit not with the emphasis currently accorded to the issue.

On September 30, 2008, the OIG published further recommendations in its *Supplemental Compliance Program Guidance for Nursing Facilities* (the "**Supplemental Guidance**" or "**2008 Guidance**"). The Supplemental Guidance reflects the above-noted transformations in the way nursing facilities deliver, and receive reimbursement for, health care services, as well as the intensification of federal enforcement activity and increased concerns about quality of care in nursing facilities. Together, the original and supplemental guidelines identify risk areas that will assist to nursing facilities to evaluate and refine their current compliance program, or develop a new program.

This article reviews the Supplemental Guidance with an emphasis on the areas of risk identified by the OIG, the need for compliance programs in nursing facilities, and the recommendations for reducing risks. This article also will discuss certain practical steps which, while not specifically addressed in the 2008 Guidance, can substantially increase the likelihood of a nursing facility remaining compliant, especially if adopted as part of a comprehensive compliance plan that also incorporates the OIG's recommendations.

The 2008 *Supplemental Compliance Program Guidance* contains five major sections:

1. Overview of the Compliance Program Guidance Process
2. Overview of the Medicare/Medicaid Reimbursement System
3. Fraud and Abuse Risk Areas

¹ See 65 FR 14289 (March 16, 2000), "Publication of the OIG Compliance Program Guidance for Nursing Facilities" (2000 Nursing Facility CPG), available at <http://oig.hhs.gov/authorities/docs/cpgnf.pdf>

4. Other Compliance Considerations -- Including the Importance of an Ethical Culture and Regular Review of Compliance Program Effectiveness
5. Self-Reporting Violations of Criminal, Civil or Administrative Law

COMPLIANCE PROGRAM GUIDANCE.

Both the 2000 Guidance and the 2008 Guidance are intended to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. The fact that the OIG has published compliance guidance for nursing facilities does not, by itself, suggest that the OIG views compliance problems to be more acute among nursing facility providers; rather, the 2000 and 2008 Guidance each is part of a series of compliance program guidance that the OIG has issued for hospitals, hospices, ambulance suppliers, durable medical equipment suppliers, physicians, pharmaceutical companies and a number of other segments of the health care industry.

The areas of fraud and abuse risk addressed by the OIG are supplemental to federal certification and state licensure compliance risks. The Supplemental Guidance states: "Together with our law enforcement partners, we have used, with increasing frequency, federal civil fraud remedies to address cases involving poor quality of care, including troubling failure of care on a systemic level in some organizations. To promote compliance and prevent fraud and abuse, OIG is supplementing the 2000 Nursing Facility CPG (Compliance Program Guidance) with specific risk areas related to quality of care, claims submissions, the (Medicare and Medicaid) Antikickback Statute (the "**Anti-Kickback Statute**"), and other emerging areas."

In general, the purpose of a compliance program is to reduce fraud and abuse, with the associated benefit of enhancing health care providers' operations, improving the quality of health care services, and reducing their overall cost. On this point, the 2008 Guidance provides: "Compliance programs help nursing facilities fulfill their legal duty to provide quality care; to refrain from submitting false or inaccurate claims or cost information to the Federal health care programs; and to avoid engaging in other illegal practices."

An effective compliance program demonstrates a nursing facility's good faith effort to comply with applicable statutes, regulations, and other federal health care program requirements, and may significantly reduce the risk of unlawful conduct and corresponding sanctions. Note that there is no one-size-fits-all compliance program that will have the same efficacy for all nursing facilities. Although, as identified in the 2000 and 2008 Guidance and discussed in this article, there are certain principles that should be incorporated into any plan, any truly effective plan will evaluate the particular risk areas of a specific nursing facility's operations and formulate a plan in response to those needs.

REIMBURSEMENT SYSTEM OVERVIEW

The Supplemental Guidance provides a detailed overview of the current reimbursement system for nursing facilities to provide a context for the risk analysis. From a compliance perspective, the fact that SNFs are reimbursed under a consolidated billing requirement (*i.e.*, the prospective payment system) triggers a number of potential risks. For example, because ancillary services, such as therapy, are included within the composite rate, SNFs have a financial incentive to reduce the level of medically necessary therapy services furnished to residents since there is no supplemental reimbursement for such services. In addition, as a result of the reimbursement system, certain nursing facilities have entered into unlawful "swapping" arrangements by which they refer business to providers or suppliers for services outside the consolidated rate (*i.e.*, that the outside provider or supplier can bill to the federal government) in exchange for that provider

or supplier providing the nursing facility with items or services included within the composite rate at below fair market value rates.

FRAUD AND ABUSE RISK AREAS

Several fraud and abuse risk areas are particularly relevant to the nursing facility industry. The nursing facility's compliance program should carefully evaluate these risk areas and, in coordination with health care legal counsel, identify those to which they have potential exposure. The primary areas of fraud and abuse risk identified by the 2008 Guidance include:

- Quality of Care
- Submission of Accurate Claims
- The Federal Anti-Kickback Statute
- Other Compliance Considerations

Quality of Care

Inadequate staffing, insufficient training and education, lack of oversight, or other factors often lead to a failure of nursing facilities to deliver quality care, resulting in a risk of harm to residents that, in turn, involves licensing and certification issues. When this failure is systemic and acute, a nursing facility also potentially may be subject to a number of federal authorities and state laws addressing false and fraudulent claims made to the government. Criminal, civil and administrative sanctions may result. This approach (*i.e.*, charging nursing facility with violations of false claims statutes on the basis of substandard resident care) has been applied with increasing frequency in recent years. To reduce potential liability risks under several key federal fraud and abuse statutes and regulations, the OIG recommends that, as a foundation for understanding quality of care issues, the key staff and members of a nursing facility understand the Medicare Conditions of Participation for Nursing Facilities. Additional considerations include sufficient staffing, comprehensive resident care plans, medication management, appropriate use of psychotropic medications, and resident safety. To reduce risk, the Supplemental Guidance emphasizes:

- A nursing facility must provide sufficient levels of trained, competent staff to attain and maintain the highest practicable physical, mental, and psychosocial well-being of its residents. In connection with this obligation, nursing facilities should evaluate whether staff patterns are sufficient to meet patient needs.
- A comprehensive, interdisciplinary care plan must be developed for each resident. A physician must be involved in both the development of the plan, and the care of that resident.
- Nursing facilities must demonstrate proper medication management, which includes education of staff on medication management, and ensuring that pharmacist consultants are not receiving improper kickbacks based on the volume or value of drugs prescribed to residents.
- The appropriate use of psychotropic medications must be ensured through the careful monitoring, documentation, and review of resident use of psychotropic drugs.
- Nursing facilities must ensure resident safety, protecting against abuse and neglect from both staff and other residents. The 2008 Guidance states that education, internal reporting systems, monitoring, comprehensive staff screening, communication of a firm commitment to resident safety, and other steps can help protect residents.

Submission of Accurate Claims

The need for accurate reimbursement claim submissions is a second risk area addressed by the 2008 Guidance. Facilities are advised to regularly review the accuracy of all reported data. Four primary sub-areas of risk exist: proper reporting of resident case-mix, therapy services, screening for excluded individuals, and restorative and personal care services.

- Nursing facilities must ensure that they are not improperly upcoding resident Resource Utilization Group (“**RUG**”) assignments. Assessment, reporting, and evaluation of resident case-mix data is a significant and common risk area. Inappropriately elevating the resource intensity of care required by the resident (*i.e.*, in the form of upcoding the RUG), in effect, causes the federal government to pay for a level of care in excess of that which the facility in fact will be providing, and can result in risks for the facility under the false claims statutes.
- Facilities must also ensure that they are providing medically appropriate physical, occupational, and speech therapy services. The OIG found, for example, improper instances of inflating RUG classifications, over-utilization of fee-for-service therapy covered by Part B under consolidated billing, and stinting on therapy services covered by the Part A Prospective Payment System, each of which can result in submission of false claims.
- Pre-employment screening of new employees and periodic screening of existing employees is an essential means of identifying excluded individuals. Employing an excluded individual can subject a facility to penalties under the civil monetary penalties statute.
- If a nursing facility fails to provide necessary restorative and personal care services, it risks violating the fraud and abuse laws for billing for services not rendered as claimed. Facilities should implement procedures to ensure that the quality and amount of services are delivered appropriately.

The Anti-Kickback Statute

Nursing facilities must evaluate numerous factors when contemplating entry into contractual arrangements with referral sources when the arrangements do not fit within one of the safe harbors to the Anti-Kickback Statute. Six specific areas of risk are identified by the OIG: free goods and services, services contracts, discounts, swapping, hospices, and reserved bed arrangements.

- If a facility provides a good or service of independent value to residents at no cost, for the purpose of generating referrals, the facility may be in violation of offering remuneration with the intent to generate business payable by a federal program. This is the hallmark of a violation under the Anti-Kickback Statute. Some examples include supplies offered by a pharmacy, or a hospice nurse providing nursing services for non-hospice residents.
- Facilities can minimize risk of disguised kickbacks in physician and non-physician service contracts by reviewing arrangements for legitimate need, the actual provision and complete documentation of services, compensation at fair-market value in an arm’s-length transaction, and the severing of any correlation between compensation, on one hand, and the volume or value of federal healthcare program businesses, on the other. To completely eliminate the risk, facilities should endeavor to structure services arrangements to comply with the personal services and management contract safe harbor (to the extent reasonably practicable). In those cases where, for one or more reasons, it is not possible to fit expressly within the safe harbor, the arrangement

nonetheless should be structured in a manner that conforms as closely as possible to the terms of an applicable safe harbor.

- While the Anti-Kickback Statute contains an exception for discounts, any discounts must be based on the reduced price of a good or service and in an arm's-length transaction. Discounts must be fully disclosed on cost reports and claims.
- Nursing facilities must not accept a reduced price from a supplier or provider in exchange for the facility referring other federal healthcare program business for which the supplier can bill Medicare or Medicaid. Such swapping arrangements are expressly not protected by the discount safe harbor.
- Facilities should ensure that requesting or accepting benefits from a hospice does not influence the facility's decision to do business with that hospice. For example, a hospice might offer free or below-market goods or services (e.g., when a hospice nurse provides services for non-hospice patients) to induce a facility to refer patients to the hospice. This and other related practices are suspect under the Anti-Kickback Statute.
- If a hospital pays to reserve a bed in a nursing facility, with even one purpose being the potential inducement of referrals to the hospital, this would pose a clear risk under the Anti-Kickback Statute. Reserved bed payments must be for the sole purpose of securing needed beds.

Other Risk Areas

Additional areas of risk identified in the Supplemental Guidance include: physician self-referrals (including, in particular, Section 1877 of the Social Security Act commonly known as the "**Stark Law**"), anti-supplementation, Medicare Part D, and Health Insurance Portability and Accountability Act ("**HIPAA**") Privacy and Security Rules.

- Nursing facility services, by themselves, are not "**designated health services**" (or "**DHS**") for the purposes of Stark Law (and, thus, arrangements involving solely nursing facility services do not implicate the Stark Law); nonetheless, certain services (*e.g.*, laboratory services) sometimes offered by the facility are DHS and, as a result, are covered by the Stark Law. Facilities must be conversant with Stark Law, and review all financial relationships with physicians who refer or order DHS, to ensure compliance with Stark. Facilities should pay attention, in particular, to physicians who are owners, investors, medical directors, or consultants to the facility.
- Nursing facilities are prohibited from charging residents (or their families) for covered services in excess of the Medicare or Medicaid amount.
- Facilities must ensure that they provide beneficiary freedom of choice when choosing a Part D plan, a right guaranteed under federal law. Nursing facilities cannot coach or steer the selection of a plan, and must guard against a pharmacy who services the nursing facility from engaging in this practice.
- Nursing facilities must design policies and procedures that ensure the privacy and confidentiality of protected health information, as required under the HIPAA Privacy Rule and HIPAA Security Rule.

OTHER COMPLIANCE CONSIDERATIONS

Ethical Culture

The 2000 Nursing Facility Guidance stressed the importance for a nursing facility to have an organizational culture that promotes compliance. OIG commends nursing facilities that have adopted a code of conduct that details the fundamental principles, values, and framework for action within the organization, and that articulates the organization's commitment to compliance. OIG encourages those facilities that have not yet adopted codes of conduct to do so. Additionally,

a nursing facility's leadership should foster an organizational culture that values, and even rewards, the prevention, detection, and resolution of quality of care and compliance problems. Good compliance practices may include the development of a mechanism, such as a "dashboard."² Further information and resources about quality of care dashboards are available on the OIG Web site.³ When communication tools such as dashboards are properly implemented and include quality of care information, the directors and senior officers can, among other things:

- Demonstrate a commitment to quality of care and foster an organization-wide culture that values quality of care;
- Improve the facility's quality of care through increased awareness of and involvement in the oversight of quality of care issues; and
- Track and trend quality of care data (*e.g.*, state agency survey results, outcome care and delivery data, and staff retention and turnover data) to identify potential quality of care problems, identify areas in which the organization is providing high quality of care, and measure progress on quality of care initiatives.

OIG views the use of dashboards, and similar tools, as a helpful compliance practice that can lead to improved quality of care and assist the board members and senior officers in fulfilling, respectively, their oversight and management responsibilities.

Regular Review of Compliance Program Effectiveness

Nursing facilities should regularly review the implementation and execution of their compliance program systems and structures – typically on an annual basis. The assessment should include an evaluation of the overall success of the program, as well as each of the basic elements of a compliance program individually, which include:

- Designation of a compliance officer and compliance committee;
- Development of compliance policies and procedures, including standards of conduct;
- Developing open lines of communication;
- Appropriate training and teaching;
- Internal monitoring and auditing;
- Response to detected deficiencies; and
- Enforcement of disciplinary standards.

Nursing facilities seeking guidance for establishing and evaluating their compliance operations should review the 2000 Guidance, which discusses in detail the fundamental elements of a compliance program.⁴

Other issues a nursing facility may want to evaluate are whether there has been an allocation of adequate resources to compliance initiatives; whether there is a reasonable timetable for

² Much like the dashboard of a car, a "dashboard" is an instrument that provides the recipient with a user-friendly (*i.e.*, presented in an appropriate context) snapshot of the key pieces of information needed by the recipient to oversee and manage effectively the operation of an organization and forestall potential problems, while avoiding information overload.

³ *See, e.g.*, OIG, "Driving for Quality in Long-Term Care: A Board of Director's Dashboard – Government-Industry Roundtable," available on the OIG Web site at: <http://oig.hhs.gov/fraud/docs/complianceguidance/Roundtable013007.pdf>

⁴ 2000 Nursing Facility CPG, *supra* note 1, at 14289.

implementation of the compliance measures; whether the compliance officer and compliance committee have been vested with sufficient autonomy, authority, and accountability to implement and enforce appropriate compliance measures; and whether compensation structures create undue pressure to pursue profit over compliance.

Most importantly, nursing facilities should recognize that the development of a compliance program (or, in the case of facilities with existing programs, the refinement of such program), by itself, does not suffice. In other words, there must be an ongoing commitment, reinforced on a regular and continuous basis, to implementing the provisions of the compliance program – with a view toward elevating the quality of care at the facility and reducing the facility’s regulatory risks.

SELF-REPORTING

If the compliance officer, compliance committee, or a member of senior management discovers credible evidence of misconduct from any source and, after a reasonable inquiry, believes that the misconduct may violate criminal, civil, or administrative law, the nursing facility should promptly report the existence of the misconduct to the appropriate federal and state authorities.⁵ The reporting should occur within a reasonable period, but not longer than 60 days,⁶ after determining that there is credible evidence of a violation.⁷ Prompt voluntary reporting will demonstrate the nursing facility’s good faith and willingness to work with governmental authorities to correct and remedy the problem. In addition, prompt reporting of misconduct will be considered a mitigating factor by OIG in determining administrative sanctions (*e.g.*, penalties, assessments, and exclusion) if the reporting nursing facility becomes the subject of an OIG investigation.⁸

To encourage providers to make voluntary disclosures to OIG, OIG published the Provider Self-Disclosure Protocol.⁹ When reporting to the government, a nursing facility should provide all

⁵ Appropriate Federal and State authorities include OIG, CMS, the Criminal and Civil Divisions of the Department of Justice and the U.S. Attorney in relevant districts.

⁶ To qualify for the “not less than double damages” provision of the False Claims Act, the provider must provide the report to the Government within 30 days after the date when the provider first obtained the information. 31 U.S.C. 3729(a).

⁷ Some violations may be so serious that they warrant immediate notification to governmental authorities prior to, or simultaneous with, commencing an internal investigation. By way of example, OIG believes a provider should immediately report misconduct that: (i) is a clear violation of administrative, civil, or criminal laws; (ii) poses an imminent danger to a patient’s safety; (iii) has a significant adverse effect on the quality of care provided to Federal health care program beneficiaries; or (iv) indicates evidence of a systemic failure to comply with applicable laws or an existing corporate integrity agreement, regardless of the financial impact on Federal health care programs.

⁸ OIG has published criteria setting forth those factors that OIG takes into consideration in determining whether it is appropriate to exclude an individual or entity from program participation pursuant to section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)) for violations of various fraud and abuse laws. *See* 62 FR 67392 (December 24, 1997), “Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act.

⁹ For details regarding the Provider Self-Disclosure Protocol, including timeframes and required information, see 63 FR 58399 (October 30, 1998), “Publication of the OIG’s Provider Self-Disclosure Protocol,” available at <http://oig.hhs.gov/authorities/docs/selfdisclosure.pdf>. *See also* OIG’s April 15, 2008, Open Letter to Health Care Providers, available at <http://oig.hhs.gov/fraud/docs/openletters/OpenLetter4-15-08.pdf> and OIG’s April 24, 2006, Open Letter

relevant information regarding the alleged violation of applicable federal or state law(s) and the potential financial or other impact of the alleged violation. The compliance officer, under advice of legal counsel and with guidance from governmental authorities, may be requested to continue to investigate the reported violation. Once the investigation is completed, and especially if the investigation ultimately reveals that criminal, civil, or administrative violations have occurred, the compliance officer should notify the appropriate governmental authority of the outcome of the investigation. This notification should include a description of the impact of the alleged violation on the applicable Federal health care programs or their beneficiaries. Note, however, that the decision as to whether or not a facility should self-report typically is complex since an initial determination needs to be made whether the conduct is more accurately characterized as a billing error (for which repayment can be made, without the requirement to self-disclose), or whether the conduct rises to a level that self-disclosure is the appropriate course of action.

Summary

A critical element of a nursing facility's compliance program is the establishment of a culture of compliance, and a formal commitment to an ethical culture and compliance that begins with senior management and, in turn, permeates all levels of the organization. Nursing facilities should establish clear policies and procedures to ensure compliance, and should regularly review, revise, and build on this compliance program. Further, as noted above, there must be an emphasis on continually implementing the principles of the compliance program. It is our sense that, by investing in compliance, a nursing facility can simultaneously take steps to elevate the quality of health care services furnished to residents, while it also mitigates the risks of regulatory violations (that can result in penalties and other sanctions, including closure of the facility). In light of the heightened scrutiny to which nursing facilities are subject in the current enforcement climate, with significant resources being deployed to find violations, prudence dictates that nursing facilities, in turn, attach a commensurate degree of attention to these risks.

to Health Care Providers, available at
<http://oig.hhs.gov/fraud/docs/openletters/Open%20Letter%20to%20Providers%202006.pdf>