How to Stay Afloat: Nursing Facilities Must Prepare For Compliance Program Requirements

Peter M. Mellette, Esquire
Crews & Hancock, P.L.C.

I. INTRODUCTION

On March 16, 2000 the Office of Inspector General of the Department of Health and Human Services ("OIG") published its final compliance program guidance for nursing facilities. This guidance was no surprise; it followed similar provider regulations and guidance given by HCFA and OIG over a period of years, including the draft OIG guidance given three and a half (3½) months previously. The final OIG guidance notes in several places that it is intended to provide a blueprint for "voluntary" compliance by nursing facilities. Although the OIG notice uses the word "voluntary," the OIG's published guidance should become the mandatory standard by which the regulatory compliance of all nursing facilities will be judged in the future.

To prepare for continued Medicare and Medicaid program participation, nursing facilities need to review their facility compliance with regulatory requirements at both the state and federal levels. The OIG notes that nursing facilities can use elements of OIG guidance to establish a compliance program regardless of nursing facility staff size, revenues, location, or organizational structure. The OIG also notes that regardless of these factors, every nursing facility should strive to implement the policies and procedures set forth in the OIG compliance notice.

The OIG guidance sets high standards for all nursing facilities. According to the OIG, each nursing facility may use the guidance as a beginning model to enhance quality of care, improve operational functions, and reduce fraud and abuse. By building upon the OIG guidance and implementing a compliance program, the nursing facility has the chance to develop effective internal controls to assure compliance with state and federal statutes, regulations, and program guidance.

According to the OIG, the advantages of a compliance program are clear. A successful compliance program gives the nursing facility a more accurate assessment of employee and contractor behavior and increases the likelihood of identifying and preventing unlawful and unethical behavior. It may also allow the nursing facility to demonstrate to employees and the outside community that the nursing facility is responsive to employee and resident concerns and has the ability to investigate those concerns thoroughly and promptly. In establishing a working compliance program, the nursing facility may also detect billing and quality of care issues early on and avoid or minimize exposure to criminal sanctions, civil damages, and civil monetary penalties. Additionally, an effective compliance program may also be a mitigating factor in any penalties assessed.

II. REGULATORY COMPLIANCE IS NOT NEW: OLD WINE/NEW BOTTLES

Nursing facilities have faced regulatory compliance obligations and issues for years. The underlying state licensure requirements for operation of nursing facilities have to be met in order to obtain a license each year. See Virginia Code §32.1-123 et seq. In addition, Medicare and Medicaid certification requirements must be met as a condition of payment for services provided to nursing facility residents. See 42 C.F.R. Part 483. In most nursing facilities, Medicaid beneficiaries alone constitute over two thirds (2/3) of nursing facility residents. Therefore, at a minimum, each nursing facility compliance program should seek to satisfy these licensure and certification requirements to enhance the likelihood of regulatory compliance and payment for most nursing facility services.

Regulatory compliance and payment are not assured any more. Quality of care estimates based on state surveys reveal extensive noncompliance with resident needs. Nursing facility reimbursement is likewise based now upon a resident's assessment and needs, rather than a fixed per diem rate plus ancillary costs. Accordingly, rules governing resident assessment, care planning, and billing have become complex and present traps for the unwary. Many changes are occurring in nursing facility payments from Medicare, Medicaid, and other payors due to the development of
prospective payment systems for Medicare nursing facility residents and anticipated changes in the formula for Medicaid payments as well.

Over the last few years, nursing facilities are receiving greater scrutiny for billing errors. In addition, many facilities are routinely subject to civil monetary penalties for quality of care and resident rights violations. These errors and penalties also attract the attention of certain residents and families. Plaintiffs’ attorneys representing residents and their family members in lawsuits filed in many parts of the United States have obtained large verdicts, resulting in the potential loss of affordable nursing facility insurance, and even nursing facility care, in many areas. These are all issues facing nursing facilities as they continue to operate in Virginia.

The OIG's civil penalties have become a source of federal funding for further investigations. Based on recently published data, the OIG received, as a result of settlements and actual cash payments, over $490,000,000 in recovered billings and fines from all providers in Fiscal Year 1999 alone.

A primary reason for having a compliance program in place is to address quality of care and billing issues and to avoid criminal and civil penalties. Under a recent U.S. Supreme Court decision, the Department of Justice's and OIG's pursuit of both criminal and civil penalties will not constitute double jeopardy, so the OIG can pursue nursing facilities under criminal and civil law for the same violation. Even without criminal prosecution or civil monetary fines, the specter of exclusion from Medicare, Medicaid, and other federal health care programs should motivate nursing facilities to undertake compliance efforts to minimize their legal liability for non-compliance.

III. THE SEVEN STEP PLAN - READ THE LABEL

The OIG nursing facility compliance program identifies seven (7) basic compliance elements common to all of the OIG compliance plans for health care providers. The OIG copied these from the federal sentencing guidelines. The seven (7) steps or elements include:

1) the development and distribution of written standards of conduct, as well as written policies, procedures and protocols that promote the nursing facility's commitment to compliance to employees, contractors, residents, and others;

2) the designation of a compliance officer and, where appropriate, a compliance committee, charged with developing, operating, and monitoring the compliance program, and maintaining a direct reporting relationship to the nursing facility owner or corporate CEO;

3) the implementation of routine education and training programs for all affected employees;

4) an assurance that effective lines of communication between the compliance officer and all employees exist, whether by use of hotlines or other reporting measures, to allow employee reporting of potential non-compliance observed by employees without breach of confidentiality;

5) the establishment of a schedule of periodic audits to monitor compliance and identify any problem areas;

6) the development of procedures for criminal background and provider checks on all employees and contractors; and

7) a process for addressing complaints on a timely basis. These procedures provide the essential first steps for nursing facilities seeking to develop compliance programs.

IV. RISK AREAS - THE MESSAGE IN THE BOTTLE

The OIG guidance designates several substantive risk areas for consideration in developing a corporate compliance plan. These risk areas, which are discussed briefly below, include quality of nursing facility care; resident rights and consent; billing and payment rules; state and federal fraud and abuse law compliance; and employment practice compliance.

A. QUALITY OF CARE

Quality of care is a risk area that does not appear in any significant form in other OIG corporate compliance guidance for health care providers. The OIG's nursing facility compliance guidance, however, focuses on assuring facility compliance with the Omnibus Budget Reconciliation Act of 1987 requirements for nursing facilities, with the implementing regulations, and with the state operations manual provisions enacted in 1995. To the OIG, maintenance of quality care means that no "substandard care" will be provided to nursing facility residents. While the HCFA standard for substandard quality of care and poor performer designations do not equate to the OIG substandard care test, a nursing facility's systemic, repeated failure to comply with the HCFA quality of care standards can be the basis for an OIG finding of substandard care. Repeated failures to meet OBRA survey guidelines, including poor and inappropriate treatment of pressure ulcers, dehydration, malnutrition, incontinence, and behavioral problems; the failure to provide sufficient staff or monitoring for resident care, drug use, therapy services, on activities; or where residents are subjected to abuse, neglect, mistreatment, and the facility fails to make reports of such
abuse and neglect, are all potential substandard quality of care issues. In the above instances, which follow the HCFA quality indicators and quality initiative studies, a nursing facility may not only find itself subject to civil monetary penalties and other remedies for poor quality care, it may also find itself subject to OIG investigation for non-compliance and potential prosecution under the False Claims Act. The OIG may view submission of a claim for which substandard services were provided as a "false claim." Therefore, in order to minimize the risks in the quality of care area, a nursing facility should consider not billing Medicare or Medicaid in instances where repeated non-compliance may exist and should adopt compliance policies and procedures to ensure that quality of care standards are met on a going forward basis.

**B. RESIDENTS' RIGHTS**

Residents' rights are also a unique area of risk for nursing facilities under the OIG guidelines. The OIG expects nursing facilities to protect residents from abuse and inappropriate use of restraints. The OIG also requires that nursing facilities assure resident privacy, obtain resident participation in care decisions, and safeguard resident assets. While these requirements are not new to nursing facilities, most nursing facilities prior to the OIG guidance did not consider resident rights issues to be the basis for False Claims Act liability; however, like the quality of care issues, the OIG may view services rendered which do not protect residents' rights as services for which a facility cannot submit a legitimate claim. Therefore, nursing facilities will need to be vigilant in this area and take steps to ensure that residents maintain a quality of life which includes non-discriminatory caregiving, preservation of individual dignity, and to the extent possible, personal autonomy. Integration of appropriate policies and procedures as part of a comprehensive compliance program will help nursing facilities achieve these goals.

**C. BILLING**

Another risk area for nursing facilities is the area of billing and cost reporting. While Medicare certified skilled nursing facilities no longer bill Medicare for the reasonable cost of services and are subject instead to payment based on resource utilization groups ("RUGs"), RUGs billing based on the resident's assessment by a clinical staff are still subject to upcoding and other false claim abuse. Moreover, because of consolidated billing, there is a significant risk of duplicate billing by nursing facility suppliers for a service that the supplier used to bill for directly but now must bill the nursing facility. Often the supplier may be unaware of the possible duplicate bill. The Virginia Department of Medical Assistance Services, which administers the Medicaid program in Virginia, is also moving to a RUGs-based system. Similar issues will arise with Medicaid payment in the future as cost based systems are phased out and replaced with prospective, all inclusive payment rates.

Other billing risk areas include failure to obtain necessary certifications and other false or inaccurate billings. Faulty billing practices can have serious consequences. The OIG expects nursing facilities to have systems in place to monitor coding practices and claims submissions and to detect and correct inaccurate/unnecessary billing. Where such systems do not exist, the erroneous bills may become the basis for False Claims Act liability, with monetary penalties of up to $10,000 per claim and treble damages. As a result, it has become crucial for nursing facilities to hire skilled, competent persons to code and bill for Medicare and Medicaid claims, to perform internal audits to ensure proper billing procedures are being followed, and to develop policies and procedures which encourage proper billing and provide for prompt repayment of any funds erroneously billed and received by the nursing facility.

**D. KICKBACKS, INDUCEMENTS AND SELF-REFERRALS**

An additional risk area involves the avoidance of kickbacks and other inducements to provide additional or unnecessary services. The OIG lists specific arrangements that are vulnerable to abuse and risk violating the federal anti-kickback statute, the federal physician self-referral prohibition and possibly other federal and state laws. These arrangements include:

- Routine waivers of coinsurance and deductibles.
- Agreements between nursing facilities and hospitals, home health agencies and hospices.
- Acceptance or giving of gifts and gratuities.
- Conditioning admission on third party guarantees.
- Soliciting payments for services covered by Medicaid.
- Certain arrangements with physicians.
- Certain arrangements with vendors.
- Allowing access to medical records in exchange for items of value.
- Joint ventures.
A specific arrangement raised by the OIG are "swapping" contracts where a Medicare Part A supplier gives a facility discounted rates in exchange for referrals of the lucrative Medicare Part B business. The OIG recently reiterated its suspicion of such arrangements in a letter dated April 20, 2000 from D. McCarty Thornton, Chief Counsel to the Inspector General. In responding to a letter regarding these "swapping" arrangements and the perceived lack of enforcement by the OIG, Mr. Thornton states, "Providers that mistake the absence of visible enforcement as a green light to engage in [swapping] arrangements do so at their own jeopardy." With this ominous warning, each nursing facility should ensure that employees are aware of potential kickback liability raised by "swapping" arrangements and the other arrangements listed as OIG risk areas.

E. EMPLOYEE/VENDOR SCREENING

Employee/vendor screening is also an important risk area identified by the OIG. Nursing facilities should follow state law requirements for doing background checks, including checks of the Central Criminal Record Exchange, on all nursing facility employees. Nursing facilities should also insure that there is a mechanism in place to check the criminal backgrounds of all temporary employees engaged by nurse staffing agencies. Any evidence of abuse and neglect of residents by prospective, current or temporary employees should be addressed swiftly. Questions concerning eligibility for hiring or engagement as an employee or independent contractor should always be resolved in favor of resident protection.

The nursing facility should also check the OIG's List of Excluded Individuals/Entities (LEIE) to ensure that no employees or independent contractors have been suspended, excluded or otherwise restricted from participation in any federal health care program. The list should be checked prior to employment of individuals or engagement of individuals or entities and periodically thereafter. Any individual or entity who is suspended, excluded or otherwise restricted from such program participation should be terminated. Facilities should include appropriate automatic termination provisions in all employment and independent vendor contracts.

V. DEMONSTRATING COMPLIANCE - DON'T LOSE THE CORK

To demonstrate compliance with the above risk areas, a nursing facility needs to document that it has appropriately cared for, billed for, and retained sufficient eligible employees to care for residents. The OIG guidance anticipates that facilities will have systems in place to maintain and monitor the accuracy of such documentation. In addition to correspondence, in service training lists, and medical/billing records, a log of oral inquiries between the nursing facility and third parties (including the Medicare Intermediary) is also an important means to document compliance efforts. Along with documentation, nursing facilities must be vigilant with regard to disclosure issues. The OIG expects that medical record privacy laws and security laws will be scrupulously followed in connection with compliance efforts.

The OIG nursing home compliance guidance anticipates that nursing facilities will approach compliance in different ways. However, the OIG expects that the development of a compliance program will create a culture of compliance within the nursing facility based on written policies, procedures and protocols, and a code of conduct applicable to all employees. Such information also needs to be distributed to vendors, independent contractors, and other suppliers, so that they may conform their conduct to the program requirements. Moreover, active employee participation in a provider's compliance program should become an element of employee performance evaluations.

The OIG corporate compliance guidance stresses that every nursing facility should have a compliance officer who oversees and manages the compliance program. That person must be a high level management official, with direct access to and support by the owner or other governing body. The individual compliance officer should have both opportunity to report on compliance issues and have sufficient funding to perform compliance functions. While some of these functions may already be performed by existing nursing facility staff, and therefore shifting of existing tasks may be possible, the nursing facility is likely to bear some additional costs for audits, in service training, etc. that are not currently funded. Hiring a compliance officer to set up the necessary procedures and systems to implement the compliance plan may be the most difficult hurdle for nursing facilities working on an already tight budget. However, nursing facilities may be able to draw from current personnel resources and existing policies and procedures as they begin their compliance efforts and them call upon outside consultants and legal counsel on an as needed basis to assist with policy review, implementation and designing of procedures and assistance with investigations.

The OIG also recommends that a compliance committee be established with persons to assist the compliance officer with development and ongoing implementation of the compliance program. The compliance committee should be comprised of individuals from each key area of the nursing facility who have specialized knowledge of the various risk areas discussed above.

According to the OIG, education and training on general and specific compliance issues be offered, whenever needed, but no less than annually to employees, corporate officers, and health care professionals associated
with the nursing facility. Such education and training (i.e.,
in-services) should include not only the corporate
compliance requirements in each risk area but also the
availability of communication vehicles, such as hotlines, to
report concerns. There should also be follow up
monitoring by the compliance officer and external
evaluators of compliance with the compliance program to
help determine its effectiveness. Nursing facilities should
publicize their disciplinary guidelines so that non-
compliance is viewed as a bases for discipline, including
in severe cases, termination. Finally, there should be an
overall assessment of the effectiveness of a nursing
facility's compliance program on at least an annual basis.
The use of quality indicators, rejected billings, complaints,
and other criteria can also provide good measures of a
nursing facility's compliance.

VI. CONCLUSION

The OIG compliance guidance for nursing
facilities is yet another step in the federal government's
efforts to get all health care providers to comply with the
law. While this guidance is "voluntary," statements within
the guidance indicate that a basic minimum standard must
be met and documented. A nursing facility's compliance
with the seven (7) program elements, its ability to
document its compliance, and its systematic, periodic
review of potential risk areas will be important in avoiding
future liability and, in turn, ensuring the viability of the
nursing facility today and for years to come.

**Peter Mellette** is a Member of the law firm of Crews &
Hancock, P.L.C. and represents health care providers,
including hospitals, nursing homes, pharmacies,
treatment centers, physicians, and other licensed health
care practitioners. Mr. Mellette advises clients on
certificate of public need projects, licensure issues,
third-party payor certifications, Medicare and Medicaid
payment disputes, regulatory compliance, and other
development and operational issues affecting provider
services. He has successfully represented facilities and
practitioners on development issues and in payment
disputes before state and federal courts and at
administrative hearings. He has also sought redress from
adverse actions by peer review organizations and
licensing agencies in both administrative and judicial
appeals. Mr. Mellette is a graduate of T.C. Williams
School of Law, University of Richmond and Dartmouth
College and is admitted to practice in Virginia federal
and state courts. He can be reached at
pmellette@crewshancock.com.