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OIG Updates Compliance Guidance for Nursing Facilities October 2008

The Office of Inspector General (OIG) of the U.S. Department of Health and Human Services issued a compliance program guidance supplement for nursing facilities late in September 2008. According to the OIG, the new voluntary guidance is designed to help nursing facilities develop compliance programs that address major Medicare and Medicaid fraud and abuse problems related to poor quality of care, billing Federal health care programs, and kickbacks.

The OIG originally published a Compliance Program Guidance for nursing facilities in 2000. According to the OIG, the new supplement reflects input from public comments received on a draft document published in April 2008.

A significant goal of the supplemental guidance, according to the OIG, is to encourage quality of care in nursing facilities. It addresses areas such as staffing, resident care plans, medication management, appropriate use of psychotropic medications, and resident safety. It emphasizes the importance of submitting accurate claims and discusses issues related to reporting resident case-mix data, therapy services, screening for excluded individuals and entities, and restorative and personal care services. The guidance also urges nursing facilities to consider the risks of improper kickback payments associated with their business arrangements including those involving free goods and services, as well as those with physicians and suppliers.

This article focuses on only some of the elements found in the supplemental guidance. It, and the entire supplement, should be shared with the compliance officer, senior management and the board of directors of each nursing facility that participates in any Federal health care program. The supplement can be found on the web at:

http://www.oig.hhs.gov/fraud/docs/complianceguidance/nhg_fr.pdf

Quality care

Among other things the supplemental guidance indicates that those nursing facilities that fail to deliver quality care may find themselves a subject of a false claim investigation.

Training

The guidance recommends that nursing facilities should familiarize themselves with 42 CFR part 483 (part 483), which sets forth the principal requirements for nursing facility participation in the Medicare and Medicaid programs. The guidance says that targeted training for care providers, managers, administrative staff, officers, and directors on the requirements of part 483 will help nursing facilities ensure that they are fulfilling their obligation to provide quality health care.

Moreover, the guidance indicates that the requirement to deliver quality health care is a continuing obligation for nursing facilities. As regulations change, so too should the training. Therefore, the guidance explains, a simple one-time employee orientation on the need to deliver quality health care will not be enough.

Clearly, documentation of every training session should be maintained.

Staffing

According to the guidance, some facilities systematically failed to provide staff in sufficient numbers and with appropriate clinical expertise to serve their residents. The guidance goes on to recognize that while there is a complex relationship between staff ratios and competency, and quality of care, there is a correlation between substandard care and staff turnover, staff shortages, and insufficient training.

The guidance recommends that nursing facilities assess their staffing patterns regularly to evaluate whether they have sufficient staff members who are competent to care for the unique acuity levels of their residents.

The guidance suggests that staffing patterns may be assessed by considering resident case-mix, staff skill levels, staff-to-resident ratios, staff turnover, staffing schedules, disciplinary records, payroll records, timesheets, and adverse event reports (e.g. falls or adverse drug events), as well as interviews with staff, residents, and resident families or legal guardians.

While the guidance recommends that nursing facilities assess their staffing patterns by considering the above stated criteria, it does not offer clear and objective measurement tools. Nevertheless, it is evident that the assessments should be performed regularly and they should be documented.

Submission of accurate claims

Examples of false or fraudulent claims include claims for items not provided or not provided as claimed, claims for services that are not medically necessary, and claims when there has been a failure of care. In this regard, the guidance provides specific risk factors associated with SNFs.

Upcoding

The guidance states that upcoding of resident RUG assignments is known to be a risk factor, and points to an OIG report issued in 2006 that found that 22 percent of claims were upcoded.

The guidance indicates that an effective compliance program will include training of responsible staff to ensure that persons collecting the coding data and those charged with analyzing and responding to the data are knowledgeable about the purpose and utility of the data.

It goes on to suggest that internal and external periodic validations of coding data may be useful.

Therapy services

The guidance also points out that therapy services can pose another risk factor that could lead to the submission of inaccurate claims. For example, the improper utilization of therapy services could inflate the severity of RUG classifications that could generate unwarranted reimbursement.

The guidance advises SNFs to develop policies and procedures to ensure that residents are receiving medically appropriate therapy services. The guidance provides some examples: ensuring that therapy contractors provide complete and contemporaneous documentation of each resident's services; regular and periodic reconciliations of the physicians' orders to services actually provided; interviews with the residents and family members to be sure services are delivered; and assessments of the continued medical necessity for services during resident care planning meetings at which the attending physician attends.

Again, the performance of the procedures outlined above should be documented.

Screening for excluded individuals and entities

The supplemental guidance outlines the rules and penalties associated with employing or contracting with excluded individuals and entities. In general, the rules prohibit payments under Medicare or Medicaid for items or services furnished by an excluded individual or entity.

The guidance recommends various procedures to ensure compliance. Among others, a nursing facility that relies upon third-party agencies to provide temporary or contract staffing should consider including provisions in its contracts that require the vendors to screen staff against certain government lists. The lists include:

- OIG's List of Excluded Individuals /Entities available at www.oig.hhs.gov
- U.S. General Services administration's Excluded Parties List System available at www.epls.gov

For the benefit of Connecticut nursing facilities, the Department of Social Services also recommends the screening of another list maintained by DSS. However, to review the list one must first go to the DSS home page at <http://www.ct.gov/dss/site/default.asp> and in the DSS search box, type Administrative Actions List and click the "GO" button. Alternatively, one can go to the Medical Audits Division of DSS at <http://www.ct.gov/dss/cwp/view.asp?a=2349&q=304852> and scroll down to the link for the "Administrative Actions List."

Federal anti-kickback statute

The guidance provides an extensive overview of the Federal anti-kickback statute which places constraints on business arrangements related to items and services reimbursable by Federal health care programs including Medicare and Medicaid. The statute is a criminal prohibition against remuneration made purposefully to induce or reward the referral or generation of Federal health program business.

Although liability under the anti-kickback statute ultimately turns on a party's intent, the guidance points out that it is possible to identify arrangements or practices that may present a significant potential for abuse. In this regard, the guidance suggests a number of useful inquiries including but not limited to:

- Does the nursing facility (or its affiliates or representatives) provide anything of value to persons or entities in a position to influence or generate Federal health care program business for the nursing facility (or its affiliates) directly or indirectly?
- Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making?
- Does the arrangement or practice have a potential to increase the risk of overutilization or inappropriate utilization?
- Does the arrangement or practice raise patient safety or quality of care concerns?

The guidance indicates that an affirmative answer to any of these questions is a "red flag" signaling an arrangement or practice that may be particularly susceptible to fraud and abuse.

If a nursing facility has identified "problematic arrangements or practices" the guidance indicates that it can take steps to lessen or eliminate a risk of a violation, by utilizing relevant "safe-harbors." The safe-harbors are contained in statute and corresponding regulations. However, the guidance cautions that to receive protection, an arrangement must "fit squarely" in a safe harbor. While failure to comply with a safe harbor does not mean an arrangement is illegal, the guidance recommends that nursing facilities structure arrangements to fit in a safe harbor whenever possible.

The guidance discusses several known areas of potential risk under the anti-kickback statute and suggests they should be scrutinized by nursing facilities. These include but are not limited to the following:

- Free goods and services
 - Pharmaceutical consultant services, medication management, or supplies offered by a pharmacy

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- Infection control, chart review, or other services offered by laboratories or other suppliers
- Equipment, computers, or software applications that have independent value to the nursing facility
- DME or supplies offered by DME suppliers for patients covered by SNF Part A benefit
- Service contracts
 - Arrangements where there is a provision or receipt of goods or services at below fair market value
 - Arrangement with a referring physician who may order items and services that result in an increased RUG or that are billable separately by the nursing facility
- Discounts
 - Price reductions – Vendor discounts are encouraged as long as the discount is in the form of a price reduction
 - Swapping – Nursing facilities should not, for example, engage in arrangements by accepting a low price from a supplier or provider on an items or service covered by the nursing facility's Part A per diem payment in exchange for the nursing facility referring to the supplier or provider other Federal health care program business, such a Part B business excluded from consolidated billing, that the supplier or provider can bill directly to a Federal health care program
- Hospices
 - Arrangements where the hospice offers free goods or goods at below fair market value to induce the nursing facility to refer patients to the hospice
 - Arrangements where the hospice pays the nursing facility an amount in excess of the amount that would be payable to the nursing facility from Medicaid

Other compliance considerations

The guidance discusses a number of other elements nursing facilities should consider in their compliance programs. Among these, the guidance cites the need for an *ethical culture that promotes compliance*. The OIG encourages all nursing facilities to adopt a code of conduct that details fundamental compliance principles and the organization's commitment to compliance.

As part of that culture, the guidance suggests that nursing facilities develop a "dashboard" designed to communicate appropriate compliance and performance-related information to a nursing facility's board of directors and senior officers.

The guidance suggests that nursing facilities should refer to "Driving for Quality in Long-Term Care: A Board of Directors Dashboard" available at:

<http://oig.hhs.gov/fraud/docs/complianceguidance/Roundtable013007.pdf>. Moreover, to determine the effectiveness of a nursing facility's compliance program, the OIG suggests annual reviews. Each review should include an evaluation of the success of the nursing facility's compliance program.

In addition the guidance suggests that nursing facilities evaluate whether there has been an allocation of adequate resources to compliance initiatives; 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.

Self-reporting

The supplemental guidance reiterates the OIG's policies on the self-reporting of "evidence of misconduct" by nursing facilities. The OIG expects prompt voluntary reporting because it will demonstrate the nursing facility's good faith and willingness to work with federal and state authorities to correct and remedy problems. The guidance also points out that prompt reporting of misconduct will be considered a mitigating factor by OIG in determining administrative sanctions.

We believe that it is important to mention some of the content expressed in footnotes to the OIG's supplemental guidance.

When the OIG mentions "federal and state authorities" it means the following:

- Office of Inspector General
- Centers for Medicare and Medicaid
- The Department of Justice
- The US Attorney in relevant districts
- The Food and Drug Administration
- The Department's Office for Civil Rights
- The Federal Trade Commission
- The Drug Enforcement Administration
- The Federal Bureau of Investigation
- The State Medicaid Fraud Control Unit
- The Defense Criminal Investigative Services
- The Department of Veterans Affairs
- The Health Resources and Services Administration
- The Office of Personnel Management

With regard to sanctions, to qualify for the "not less than double damages" provision of the False Claims Act, OIG indicates that the provider must provide the report to the government within 30 days after the date when the provider first obtained the information of the misconduct. However, some violations may be so serious that they warrant immediate notification to governmental authorities prior to, or simultaneous with, commencing an internal investigation. For example, the OIG believes a provider should immediately report misconduct that:

- Is a clear violation of administrative, civil, or criminal laws, Poses an imminent danger to a patient's safety,
- Has a significant adverse effect on the quality of care provided to Federal health care program beneficiaries, or
- Indicates evidence of a systemic failure to comply with applicable laws or an existing corporate integrity agreement, regardless of financial impact on Federal health care programs.

The OIG published the Provider Self-Disclosure Protocol to guide providers on voluntary disclosures. The Protocol may be found on the web at:

<http://www.oig.hhs.gov/authorities/docs/selfdisclosure.pdf>

While the decision to follow the OIG's suggested Protocol rests with the provider, the OIG indicates that making full disclosure to the investigative agency at an early stage generally benefits the provider.

However, though the Protocol offers detailed information about the form and content of disclosures, it is important to note that according to the OIG there are several considerations that should influence the decision to follow the Protocol. For example, a provider that uncovers an ongoing fraud scheme within its organization should immediately contact the OIG, but should not follow the Protocol's suggested steps to investigate or quantify the scope of the problem. If the provider follows the Protocol in this type of situation without prior consultation with the OIG, there is a substantial risk that the government's subsequent investigation will be compromised.

If the nursing facility decides to report the misconduct, the Protocol offers significant information about what should be disclosed, the certification that must accompany the disclosure, the internal investigation, the internal financial assessment, and how alleged overpayments should be treated. It seems safe to presume that the reporting entity should read the Protocol, consult with qualified counsel and work closely with OIG to ensure that its guidelines have been followed.

Needless to say the disclosing entity's conscientious cooperation during the entire investigative process is important. The OIG indicates that the lack of cooperation by the nursing facility will be an aggravating factor when the OIG makes its assessment. And the intentional submission of false information or the omission of relevant information will be cause for the OIG to refer the matter to the Department of Justice or other agencies and such action could result in criminal sanctions.

Conclusion

Clearly, the OIG means business. Compliance plans should not be taken lightly. Fraud and abuse rules are complex and the penalties for noncompliance can be painful and personal.

The Supplemental Compliance Program Guidance for Nursing Facilities appears to respond to the government's focus on quality of care. While voluntary, the guidance is clearly a warning.

Although the supplement applies to nursing facilities, other providers may wish to take note of the OIG's message.

The government has and will continue to use fraud remedies to resolve cases of poor quality of care.

If you have questions you may contact Vincent Ruocco, LLC, CPA at 203.932.2931.

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