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OIG Issues Supplemental Compliance Program Guidance for Nursing Facilities

On September 30, 2008, the United States Department of Health and Human Services Office of Inspector General (“OIG”) published Supplemental Compliance Program Guidance for Nursing Facilities (“CPG”). The CPG is available on the OIG’s web site at http://www.oig.hhs.gov/fraud/docs/complianceguidance/nhg_fr.pdf.

In the CPG, the OIG details fraud and abuse risks that nursing home compliance programs should address. The CPG also offers recommendations for the establishment of a proper ethical and compliance culture, for the assessment of the effectiveness of compliance programs, and for proper self-reporting protocols. We recommend that all nursing facilities review the CPG and use it to measure and evaluate existing compliance programs. To assist in that effort, this Advisory discusses the evolution of the CPG, summarizes its contents, and provides a list of suggested action items for consideration.

I. BACKGROUND

For the last ten years, the OIG has encouraged implementation of voluntary compliance programs for the health care industry by periodically issuing voluntary compliance program guidance particular to the various health care providers and organizations. In March 2000, the OIG published its first CPG for nursing facilities and introduced seven basic elements expected of a compliance program.¹ Many nursing facilities have employed the seminal CPG as a framework for their compliance programs.

The OIG issued the 2008 CPG in response to: (1) changes in the nursing home industry since 2000; (2) evolving compliance enforcement concerns; and (3) the OIG’s increased focus on quality of care. According to the OIG, the new CPG is designed as a “roadmap for updating or refining” compliance programs instituted pursuant to the original compliance program guidance. It is meant to supplement, not replace, the 2000 guidance.

II. IMPLEMENTING THE SUPPLEMENTAL COMPLIANCE PROGRAM GUIDANCE

A. Benefits

The 2008 CPG catalogues the benefits of a comprehensive compliance program for nursing homes to include:

- *Enhancing the quality of care delivered to nursing home residents.* An effective compliance program will help ensure that appropriate services are provided and that residents receive only quality services.
- *Encouraging employees to report potential problems, leading to early detection and correction of unlawful practices.* The risk of False Claims Act liability and the imposition of sanctions, such as monetary penalties or exclusion, can be significantly reduced by early detection and remediation.
- *Creating a culture of honest and responsible conduct where compliance, integrity, and the delivery of quality care are prioritized.* The nursing facility’s reputation will be enhanced by demonstrating a commitment to these values, thereby improving its image in

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the community and its market competitiveness.

- *Preventing unnecessary government spending and financial loss to the facility.* By avoiding costly billing or payment errors, auditing will help protect taxpayer dollars as well as facility funds.

B. No “One Size Fits All” Model

The CPG recognizes that “[s]ome nursing facilities are small and may have limited resources to devote to compliance measures; others are affiliated with well-established, large multi-facility organizations with a widely dispersed work force and significant resources to devote to compliance.” Acknowledging that there is no “one size fits all” model program, the OIG encourages “each facility to adapt the objectives and principles underlying [the] guidance to its own particular circumstances.” Once a facility identifies its weakness or vulnerability, it should tailor its compliance program accordingly.

C. Deficit Reduction Act Obligation

Although compliance programs are encouraged by the OIG, their implementation is strictly voluntary. The Deficit Reduction Act of 2005 (the “DRA”) and related Connecticut regulations, however, make certain compliance components mandatory. The DRA requires that providers receiving \$5 million or more in annual Medicaid payments implement specific compliance program policies directed to preventing fraud and false claims. More particularly, the DRA requires that:

- compliance programs include: reference to state and federal false claims acts; the rights of employees to be protected as whistleblowers; and, the entity’s policies and procedures for detecting and preventing fraud, waste, and abuse;²

- the employee handbook contain a description of the facility’s written compliance policy and that the compliance policy be readily available to employees; and
- the facility’s written compliance policy be disseminated to any contractors or agents of the facility e.g. billing contractors, therapy contractors, any contractor providing items or services reimbursable by Medicaid, any contractor engaged to monitor health care, and the medical director.

The DRA does not impose penalties on providers that fail to meet these basic requirements, but they are conditions of participation in the Medicaid program.

In 2007, the Connecticut Department of Social Services (“DSS”) issued regulations that mirror the DRA’s requirements. That same year, DSS also issued a Provider Bulletin instructing nursing facilities that meet the \$5 million DRA threshold that they must submit an affidavit to DSS attesting that the organization has satisfied the DRA’s requirements. See, Regulations of Connecticut State Agencies §§ 17b-262-770 et seq.; DSS Provider Bulletin 2007-41, available at http://www.ctmedicalprogram.com/bulletin/pb07_41.pdf.

III. FRAUD AND ABUSE RISK AREAS

The CPG highlights and updates three areas of risk for fraud and abuse, and suggests other areas that should be addressed in nursing home compliance programs.

A. Quality of Care

Quality of care in nursing homes is an OIG priority. A recent OIG Memorandum describing the nature and extent of nursing home deficiencies from 2005 to 2007, reports that 91% of

nursing homes surveyed were cited for deficiencies.³ Government authorities have employed the federal False Claims Act and Civil Monetary Penalties Law as tools in addressing substandard quality of care. Indeed, the new CPG states: “[i]n cases that involved failure of care on a systemic and widespread basis, the nursing facility may be liable for submitting false claims for reimbursement to the Government under the Federal False Claims Act, the Civil Monetary Penalties Law (CMPL), or other authorities that address false and fraudulent claims or statements made to the Government.” The OIG telegraphs its enforcement priorities in the 2008 CPG when it states: “Nursing facilities that fail to make quality a priority, and consequently fail to deliver quality health care, risk becoming the target of governmental investigation.”

The CPG highlights “common risk areas” associated with delivery of quality health care to nursing facility residents:

- *Sufficient staffing:* Nursing facilities should assess staffing patterns regularly to evaluate whether sufficient staff is available to care for the resident population and to meet the federal requirement for “sufficient staffing necessary to attain or maintain the highest practicable physical, mental, and psychosocial well-being of residents.” The OIG stresses the need to focus on staffing numbers and staff competency, acknowledging that “[n]o single staffing model will suit every facility.” According to the OIG, “[i]mportant considerations for assessing staffing models include, among others, resident case-mix, staff skill levels, staff-to-resident ratios, staff turnover, staffing schedules, disciplinary records, payroll records, timesheets, and adverse event reports . . . as well as interviews with staff, residents, and residents’ family or legal guardians.”
- *Comprehensive care plans:* Care plans should be developed using a comprehensive approach and an interdisciplinary team. The OIG flags attending physician involvement as a “risk area” and cautions that nursing facilities must have policies and procedures to ensure that physicians appropriately supervise each resident’s care.
- *Medication management:* Facilities should implement policies and procedures for maintaining accurate drug records and tracking medications. The OIG advises that “the facility’s consulting pharmacist is an important resource for development of policies and procedures, training and quality assurance efforts related to medications.” The OIG references OBRA requirements, including that the consulting pharmacist review the drug regimen of each resident at least monthly.
- *Appropriate use of psychotropic medication:* The OIG identifies the inappropriate use of psychotropic medications for chemical restraint for discipline or for convenience and prescribing unnecessary drugs as possible areas of abuse. The CPG recommends training on appropriate monitoring and documentation practices for all drugs, as well as auditing drug regimens and resident care plans.
- *Resident safety:* Resident safety should be addressed through staff training, staff screening, promotion of confidential reporting mechanisms, and 24/7 coverage. The OIG also underscores resident-to-resident abuse of an area of concern meriting targeted training and monitoring.

B. Submission of Accurate Claims

The submission of false or fraudulent claims is the area most commonly associated with fraud and abuse. According to the OIG, the dangers of duplicate billing, insufficient documentation, and false cost reports addressed in the 2000 CPG are now considered “relatively well understood by the industry.” The 2008 CPG observes that as reimbursement systems have evolved, the “OIG has uncovered other types of fraudulent transactions related to the provision of health care services to residents of nursing facilities reimbursed by Medicare and Medicaid.” The most recent CPG urges vigilance in the following areas:

- *Proper reporting of resident case mix:* Facilities should conduct training to ensure that Resource Utilization Group (RUG) assignments are not improperly upcoded. The OIG recommends that periodic internal and external validation reviews be conducted to ensure the accuracy of data reported to the government.
- *Therapy services:* Concerns here include therapy services to inflate RUG classifications, overutilization of therapy services billed on a fee-for-service basis to Part B, and “stinting on therapy services provided to patients covered by the Part A PPS payment.” To ensure that residents are receiving appropriate therapy services, the OIG recommends that facilities require therapy contractors to “provide complete and contemporaneous documentation of each resident’s services,” and that facilities conduct regular reviews of the resident’s medical chart to compare the physician’s orders to the services provided. The OIG also recommends regularly assessing the continued

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medical necessity of therapy services during resident care plan meetings.

- *Screening for excluded individuals and entities:* Prospective owners, officers, directors, employees, contractors, and agents should be screened against the OIG's List of Excluded Individuals or Entities, available at http://www.oig.hhs.gov/fraud/exclusions/exclusions_list.asp, and the U.S. General Services Administration's Excluded Parties List System, available at <https://www.epls.gov/>. Screening should be done on an ongoing basis. The list of excluded individuals in Connecticut is available at <http://www.ct.gov/dss/cwp/view.asp?a=2349&q=310706>. Policies should also provide procedures for periodically screening current owners, officers, directors, employees, contractors and agents; training of human resources personnel on the effects of exclusion; and removal of excluded individuals.
- *Restorative personal care services:* Billing federal health care programs for restorative and personal care services where the services were either "deficient or, in some cases, not provided" is an area of concern. The OIG warns that billing for services such as ambulation, fall prevention, incontinence management, bathing, dressing, and grooming activities will not be reimbursed by Medicare if they are so "wholly deficient that they amounted to no services at all." Nursing facilities should ensure that these services are in fact delivered to residents and that they are of appropriate quality through: (1) resident and staff interviews; (2) medical record reviews; (3) consultation with the attending physician, medical

director, and consulting pharmacist; and (4) direct observation.

C. The Federal Anti-Kickback Statute

The federal Anti-Kickback Statute prohibits kickbacks to physicians and other referral sources in exchange for referrals of items or services reimbursable under Medicare, Medicaid, or any other federal or state health care program. Criminal penalties may include fines of up to \$25,000 and imprisonment up to 5 years. Civil penalties include exclusion from participation in federal and state health care programs, civil monetary penalties of \$50,000 per violation, and three times the amount of remuneration paid. Since nursing homes constantly "make and receive referrals of Federal health care program business," the OIG strongly warns about possible compliance problems in this area.

A transaction may be immunized from liability under the Anti-Kickback Statute if it fits squarely within a regulatory safe harbor. Common safe harbors utilized in the nursing home context are the personal services and management contracts safe harbor, 42 CFR § 10001.952(c), the discount safe harbor, 42 CFR § 1001.952(h), and the employee safe harbor, 42 CFR § 1001.952(i). Failure to fit within one of the safe harbors does not render the transaction per se illegal; the intent of the parties, as well as the totality of the facts and circumstances, are generally considered.

Nursing facilities should consult the questions presented in the Anti-Kickback section of the CPG in order to identify transactions that may violate the Anti-Kickback Statute. The CPG also describes relevant factors to consider when analyzing a potentially problematic

transaction, including the nature of the relationship between the parties; how the participants were selected; how remuneration was determined; the value of the remuneration; the nature of the items or services provided; the potential federal program impact; potential conflicts of interest; and how the arrangement was documented.

According to the OIG, the following arrangements are “suspect practices” because they present a heightened risk for violation of the Anti-Kickback Statute in the nursing home context:

- *Arrangements for free goods and services.* The OIG has “a longstanding concern about the provision of free goods or services to an existing or potential referral source” since “there is a substantial risk that free goods or services may be used as a vehicle to disguise or confer an unlawful payment for referrals of Federal health care program business.” Whenever a nursing facility gives or receives free goods or services to or from another entity with the intent to induce referrals, the Anti-Kickback Statute is implicated. Examples of suspect free goods or services include pharmaceutical consultant services or supplies; laboratory services such as chart review or infection control; durable medical equipment; nursing care provided by a hospice nurse or a hospital nurse; or administrative services.
- *Service contracts.* Service contracts with suppliers and providers may be “vehicles to disguise kickbacks from the suppliers and providers to the nursing facility to influence the nursing facility to refer Federal health care program business to

the suppliers and providers.” Contracts between nursing homes and physicians may induce physicians to refer patients to the nursing home or to increase facility revenue by ordering items or services that the facility may bill for separately or that will result in increased reimbursement to the facility. The OIG recommends that these transactions comply with the personal services and management contracts safe harbor.⁴ At the very least, all service contracts should be written in advance, based on a legitimate need, and provide compensation set at fair market value that is unrelated to the value or volume of referrals. The OIG expressed specific concern that pharmacy decisions could be “tainted” by kickbacks, citing as an example the situation in which a consulting pharmacist faces a potential conflict of interest in making recommendations about a resident’s drug regimen when a drug prescribed is not on the pharmacy’s formulary. Nursing facilities should make it clear that all prescribing decisions should be based on the best interests of the patient. In addition, drug records should be monitored for suspicious patterns and staff should be educated about opportunities for abuse in this area.

- *Discounts from providers and suppliers.* Nursing facilities should verify that any discounts received from suppliers or providers meet the requirements of the discount safe harbor, codified at 42 CFR § 1001.952(h). Furthermore, all discounts must be properly disclosed and accurately reflected on cost reports. The OIG specifically cautions about the practice of “swapping,” whereby a facility accepts a low price from a

supplier on an item or service covered by Part A, in exchange for the facility’s referral of Part B business, (which the supplier or provider can bill to a Federal health care program directly) which is not protected by the discount safe harbor.

- *Hospice services provided in the nursing facility.* Arrangements between nursing facilities and hospices are particularly vulnerable to fraud and abuse under the Anti-Kickback Statute and are a priority for the OIG.⁵ In fact, the OIG’s 2009 Work Plan lists one single item on its agenda for hospice: hospice services provided to nursing home residents. Compliance with the personal services and management contracts safe harbor is again recommended whenever possible. According to the OIG, impermissible remuneration from hospices to nursing homes include: “free nursing service for non-hospice patients; additional room and board payments; or inflated payments for providing hospice services to the hospice’s patients.”

The CPG also lists the following “suspicious practices:”

- Hospice referrals of patients to nursing facilities in exchange for nursing facility referrals to the hospice;
- A hospice providing the nursing facility with staff for free;
- A hospice offering the nursing facility goods without charge or below market value;
- A hospice paying the nursing facility for services that Medicare considers part of its room and board payment to the hospice;
- A hospice paying a nursing facility above market value for other services;

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- A hospice paying room and board in excess of what the nursing facility would receive directly from Medicaid had the patient not been enrolled in hospice; or
- A hospice providing free or below market value care to nursing facility patients, for whom the nursing facility is receiving Medicare payment under the SNF benefit, with the expectation that after the patient exhausts the SNF benefit, the patient will elect the hospice benefit and receive services from the hospice.
- *Reserved bed arrangements with hospital.* On occasion, nursing homes enter into arrangements whereby the facility receives payment from a hospital and in return, provides guaranteed or priority placement for discharged hospital patients. The OIG warns that “[t]hese arrangements could be problematic under the Anti-Kickback Statute if one purpose of the remuneration is to induce referrals of federal health care program business from the nursing facility to the hospital.” Reserved bed arrangements may also sometimes disguise clearly fraudulent transactions, such as when a nursing home accepts payment from the hospital to reserve beds but then occupies those beds; when the hospital pays for more beds than it needs to reserve; or when the hospital pays the nursing facility excessively for the reserved beds.

Nursing facilities in Connecticut must comply with the Connecticut waiting list regulations governing hospital bed reservations. These regulations permit nursing homes to enter into reserved bed arrangements with hospitals only under certain specified conditions. See Regulations of Connecticut State Agencies § 17-311-209.

D. Other Compliance Issues

- *Physician self-referral law (the “Stark Act”):* Nursing facilities should ensure that contracts with physicians comply with the Stark Act. The Stark Act prohibits physicians from referring patients for certain “designated health services” provided by organizations with which the physician has a financial arrangement. The Stark Act contains several exceptions, however, including an exception for personal services agreements such as an agreement between a nursing facility and its medical director. To satisfy the exception, the agreement must meet several enumerated requirements. To guard against violations, nursing homes should require that all physician agreements be in writing, that all payments made to physicians represent fair market value, and that the agreements cover only time periods during which services were provided. The OIG additionally recommends that nursing facilities pay “particular attention to their relationships with attending physicians, who treat residents and with physicians who are nursing home facility owners, investors, medical directors, or consultants.”
- *Anti-supplementation:* Medicare or Medicaid beneficiaries should not be charged any amount in addition to what is otherwise required to be paid under Medicare or Medicaid.
- *Medicare Part D:* Nursing facilities should be careful not to frustrate a resident’s freedom of choice in selecting a Part D prescription plan and should make efforts to provide residents with complete and objective information about all available plans.
- *HIPAA privacy and security rules:* HIPAA took effect after the OIG released its original CPG and therefore,

was not included in the original guidance. Most facilities are already familiar with HIPAA and have effective policies and procedures in place. The OIG reminds nursing facilities that HIPAA compliance should remain a priority.

IV. AN ETHICAL CULTURE AND COMPLIANCE PROGRAM ASSESSMENT

Beyond technical compliance policies and procedures, the OIG stresses the importance of creating an ethical culture, “that values compliance from the top down and fosters compliance from the top up.” The nursing home’s leadership should encourage compliance efforts and develop effective communication mechanisms between staff and leadership about compliance and performance related matters.

The OIG specifically recommends the use of a “dashboard,” which is a instrument that provides a “user-friendly . . . snapshot of key pieces of information needed . . . to oversee and manage effectively the operation of an organization and forestall potential problems, while avoiding information overload.” The OIG directs facilities to its website to learn more about dashboards, at <http://www.oig.hhs.gov/fraud/docs/complianceguidance/Roundtable013007.pdf>.

Furthermore, the OIG recommends that nursing facilities assess their compliance programs annually to determine if compliance measures are being implemented as planned and whether they are effective. Education, communication, training and audits are essential tools in implementing and assessing the effectiveness of compliance initiatives. The OIG urges facilities to review the 2000 CPG for Nursing Facilities for guidance concerning the basic elements of

a compliance program. Nursing facilities may access quality of care corporate integrity agreements entered in to by the OIG and parties settling specific matters to view compliance measures that have been approved by the OIG at http://www.oig.hhs.gov/fraud/cia/cia_list.asp.

V. SELF-REPORTING

The OIG advises that providers must report issues to the appropriate authorities if “credible evidence” shows that a problem may exist and the facility determines, after a “reasonable inquiry,” that a violation of law may have occurred. In those circumstances, the facility should report the issue promptly (which the OIG defines as within 60 days). The OIG encourages voluntary self-reporting through its self-disclosure protocol.⁶ In a recent Open Letter to Health Care Providers dated April 15, 2008, the OIG stated that it “generally will not require the provider to enter into a Corporate Integrity Agreement or Certification of Compliance” when the provider provides a “complete and informative” self-disclosure.⁷ According to the OIG, self-reporting not only “demonstrates the nursing facility’s good faith and willingness to work with governmental authorities to correct and remedy the problem,” but also will be considered “a mitigating factor by OIG in determining administrative penalties if the reporting nursing facility becomes the subject of an OIG investigation.”

VI. ACTION STEPS

The CPG’s 17 pages of small print and 139 footnotes may be overwhelming for nursing facility compliance officers who often shoulder other duties. It does, however, provide an opportunity for

facilities to reexamine and update compliance policies and procedures. Here are five steps that nursing facilities should consider in response to the new CPG:

- **Review the fraud and abuse risk areas identified by the OIG and assess how your facility measures up in practice. Consider incorporating specific suggestions into your existing practices and procedures based on the CPG.**
- **Review your facility’s current compliance program policies and procedures to make sure that the risk areas identified by the OIG are adequately addressed.**
- **Meet with the facility’s leadership to discuss improving the ethical culture and the lines of communication.**
- **Educate your Board of Directors about the facility’s compliance program and the Board’s responsibilities under the program. Make sure that the Board of Directors, or a designated Board committee, receives regular updates from the compliance officer about the compliance program and that they are informed of any significant issues that arise.**
- **Institute a yearly review of your compliance program to assess compliance program effectiveness.**

¹ The CPG issued in March 2000 is available at <http://www.oig.hhs.gov/authorities/docs/cpgnf.pdf>.

² Although Connecticut has no direct state equivalent to the federal False Claims Act, it does have laws that address fraudulent health care claims.

³ Memorandum Report: “Trends in Nursing Home Deficiencies and Complaints,” OEI-02-08-00140, September 18, 2008, available at <http://www.oig.hhs.gov/oei/reports/oei-02-08-00140.pdf>.

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⁴ The personal services and management contracts safe harbor, 42 CFR § 10001.952(c), requires that:

1. The agreement be set out in writing and signed by the parties;
2. The agreement cover all of the services that the agent provides to the principle for the term of the agreement and specifies the services to be provided by the agent;
3. If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic, or part time basis, rather than on a full time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals;
4. The term of the agreement is for at least one year;
5. The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms length transactions and is not determined in a manner that takes into account the value or volume of referrals;
6. The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law; and
7. The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purposes of those services.

⁵ See, The OIG's Special Fraud Alert on Nursing Home Arrangements with Hospices, available at <http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/hospice.pdf>; The OIG's Compliance Program Guidance for Hospices, 64 Federal Register 54031.

⁶ Provider Self-Disclosure Protocol, 63 Federal Register 58399 (October 30, 1998).

⁷ Open Letter to Health Care providers, April 15, 2008, available at <http://www.oig.hhs.gov/fraud/docs/openletters/OpenLetter4-15-08.pdf>. See also Open Letter to Health Care Providers, April 24, 2006, available at <http://www.oig.hhs.gov/fraud/docs/openletters/Open%20Letter%20to%20Providers%202006.pdf>.

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