

HEALTH CARE ALERT

April 29, 2008

OIG HEIGHTENS FOCUS ON NURSING FACILITY COMPLIANCE

KUTAK ROCK HOSTS SUMMER SEMINAR ON IMPLEMENTING AN EFFECTIVE COMPLIANCE PLAN

Taking an aggressive step toward increased scrutiny of nursing facility compliance, on April 16, 2008, the Office of Inspector General of the United States Department of Health and Human Services (“OIG”) published its “Draft Supplemental Compliance Program Guidance for Nursing Facilities.” Intended to expand upon the existing Compliance Program Guidance for Nursing Facilities issued in 2000, OIG recommends that providers consider both the original and new compliance program guidance (“CPG”) in seeking to comply with applicable law and avoid civil, criminal and administrative sanctions. The supplemental CPG elaborates upon specific fraud and abuse risk areas identified in the original CPG and identifies additional risk areas that should be addressed by written policies and procedures as part of a compliance plan. Providers seeking to adopt strategies to avoid regulatory risk and to better understand their obligations in light of the OIG's new pronouncements should carefully evaluate the new guidance and should consider attending Kutak Rock's June 20, 2008 Nursing Facility Compliance Seminar in Denver, Colorado.¹

The CPG places all providers on notice of OIG's recommendations on how to enhance legal compliance. Compliance programs are critical tools for nursing facilities to use in avoiding catastrophic legal risks, and assist nursing facilities in fulfilling their legal duty to provide quality care, to avoid the submission of false or inaccurate claim or cost information to Federal health care programs, and to avoid other illegal practices. Although the OIG's guidance is not legally binding, nursing facilities that substantially follow the CPG can reduce the risk of engaging in unlawful conduct and reduce the legal exposure they may suffer when a violation of law nevertheless occurs. The OIG recognizes that differences exist among nursing facilities and therefore encourages nursing facilities to focus compliance efforts on areas of potential concern or risk that are most likely to affect their organizations, while striving to accomplish the objectives and principles underlying all of the suggested compliance policies and procedures. Accordingly, the OIG recommends using the CPG as a starting point to conduct a legal review of particular practices and to develop or refine policies and procedures to reduce or eliminate potential risk. The OIG will treat harshly those providers which ignore the CPG, or fail to integrate recommended compliance processes into the provider's everyday business.

The supplemental CPG strongly suggests that the OIG intends to scrutinize nursing facilities with resident care-related regulatory violations for potential false claims liability in connection

¹ [Click here for the Agenda and Registration Form](#)

with billings submitted for the care of those residents, as well as other care-related documentation that could impact a facility's reimbursement (e.g., Minimum Data Sets and care plans). In addition, the supplemental CPG indicates ongoing concerns related to arrangements between nursing facilities and vendors that provide goods or services that are paid for, in whole or in part, by Federal health care programs.

The OIG is currently soliciting comments regarding this draft supplemental CPG. The deadline for submitting comments is 5:00 p.m. June 2, 2008.

Supplemental Compliance Program Guidance

The supplemental CPG elaborates on specific fraud and abuse risk areas the OIG believes nursing facilities should address in order to ensure compliance and targets three main areas of concern, including (1) quality of care, (2) submission of accurate claims, and (3) the Federal anti-kickback statute. These issues present potential liability issues under several key Federal fraud and abuse statutes and regulations.

To participate in the Medicare and Medicaid programs, CMS requires that nursing facilities meet the principal requirements set forth in 42 C.F.R. 483 (Requirements for States and Long Term Care Facilities), which delineates requirements for residents' rights, quality of care, resident behavior and facility practices, resident assessment, and physician and pharmacy services, among other things. The OIG emphasizes that key members of the organization should understand these requirements and should ensure the provision of targeted training to care providers, managers, administrative staff, and officers and directors to ensure compliance.

Nursing facilities that fail to provide quality health care risk becoming the target of governmental investigations. Issues respecting the delivery of quality health care frequently arise in OIG enforcement cases under the False Claims Act ("FCA"). The FCA is the government's most effective tool to combat health care fraud. Claims may be brought under the FCA by the government or by private individuals who have direct knowledge of the fraud (known as "qui tam" relators). The theory for prosecution under the FCA is that the provision of inadequate care to Medicare and Medicaid beneficiaries and subsequent seeking of reimbursement for those services equates to health care fraud. Many statutes and regulations impose standards for quality of care or safety as preconditions to participation in Federal programs and form the basis for liability under this theory. State laws are also relevant in quality of care issues under the FCA with respect to the payment of Medicaid claims, because Medicaid claims are considered claims presented to the federal government.

The FCA states that "any person who knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval is liable to the United States Government." Violating the FCA can expose nursing facilities to civil penalties of not less than \$5,000 and not more than \$10,000 plus three times the damages that the government sustains as a result of the fraudulent act.

Quality of Care

In quality of care claims brought under the FCA, the underlying theory is that the government is being billed for services that were, in effect, never rendered. This may happen in two ways. When a provider submits a request for reimbursement to a federally funded program, the provider is said to implicitly or explicitly certify that it has complied with applicable standards of care. In this type of case, quality of care standards must generally be a condition of payment under the program. Another type of case involves that of “worthless services.” Worthless services may exist in the performance of services that are so deficient that they are the practical equivalent of no performance at all. Claims submitted for worthless services are false claims because they equate to submitting claims for services that were not rendered.

These theories have met with varying levels of success depending on the jurisdiction. The Eighth Circuit—which includes Arkansas, Iowa, Minnesota, Missouri, Nebraska, North Dakota and South Dakota—recently upheld a “worthless services” claim in Missouri where the government alleged that the nursing home should have known that it was providing insufficient care because it received complaints from staff, residents, surveyors and family members. Other circuits—including the Second, Ninth and Tenth Circuits—have taken more narrow approaches, finding liability only where payment is expressly conditioned upon regulatory compliance or where a false certification actually influenced the government’s decision to pay. Providers should be cognizant of these differences in assessing potential compliance risks for their organizations. Kutak Rock’s June 20 seminar will include in-depth discussion of these theories and their implications.

The original CPG stated that nursing facilities should, *at a minimum*, make efforts to analyze annual state agency surveys, Federal validation surveys and complaint surveys to detect and address deficiencies cited therein and ensure adherence to Medicare requirements. In the supplemental CPG, the OIG specifically identified several common quality of care risk areas including sufficient staffing, comprehensive care plans, appropriate use of psychotropic medications, medication management, and resident safety. All of these areas present risks for liability under the FCA and should be addressed by written policies and procedures as part of a broader compliance effort. Each of these issues will be addressed in detail at the June 20 seminar, but are briefly summarized below.

Sufficient Staffing. The original CPG cited inadequate staffing levels or insufficiently trained or supervised staff as a quality of care risk area and noted basic Federal requirements for physician supervision of patient care, registered nurse services, and applicable State-mandated staffing levels. Federal law requires nursing facilities to provide staffing sufficient to “attain or maintain the highest practicable physical, mental, and psychosocial well-being of residents.” Research demonstrates that substandard care bears relation to staff shortages and insufficient training. The supplemental CPG stresses that nursing facilities must assess the unique circumstances of their organizations in order to determine an appropriate staffing model and should regularly assess staffing patterns to ensure they have sufficient, competent staff. The supplemental CPG delineates specific considerations for ensuring these obligations are met, and states that the methods used to assess staffing should provide an accurate measurement of “on-the-floor” staff rather than “on-paper” staff.

Comprehensive Care Plans. In the original CPG the OIG recognized that the standard for ensuring that care and services permit residents to “attain or maintain the highest practicable physical, mental, and psychosocial well-being” may not lend itself to an easy, objective determination. Medicare and Medicaid regulations require nursing facilities to develop comprehensive resident care plans that address each resident’s medical, nursing, mental and psychosocial needs, and ensure reasonable objectives and timetables. Plans that do not encompass all disciplines of a resident’s care may be insufficient and therefore jeopardize residents’ well-being and may result in inadequate or medically unnecessary care, or medically inappropriate services. In the supplemental CPG, the OIG suggests nursing facilities take basic steps to reduce these risks by including the full clinical team, and potentially the resident or residents’ family members or legal guardians, in resident care planning.

Appropriate Use of Psychotropic Medications. Federal regulations and professional standards require facilities to ensure the appropriate use of psychotropic medications. The original CPG identified inappropriate prescribing, administering and monitoring of prescription drug usage as a quality of care risk area. In the supplemental CPG, the OIG expands upon those issues to identify two inherent risks: (1) potential violations of the prohibition of the inappropriate use of chemical restraints and (2) potential violations of the requirement to avoid unnecessary drug usage. Facilities may not use medication as a means of chemical restraint for “purposes of discipline or convenience” or for reasons unrelated to treating the resident’s medical symptoms. Additionally, regimens must be free from unnecessary drugs. The OIG suggests that facilities take compliance measures such as educating care providers and auditing drug regimen reviews and resident care plans to ensure drug usage is indicated and appropriate.

Medication Management. Medication management was not explicitly addressed in the original CPG and appears to be an emerging area of concern. In the supplemental CPG the OIG expands upon the need to ensure the appropriate use of psychotropic medications and emphasizes that the Social Security Act requires nursing facilities to provide “pharmaceutical services ... to meet the need of each resident.” Failing to properly manage these services can jeopardize resident safety. Proper medication management processes can promote compliance as can training and monitoring staff (including consultant staff) involved in prescribing, administering and managing pharmaceuticals. Additionally, staff should receive education on the legal prohibition against improper kickbacks that may taint pharmaceutical decisions. Prescribing must be based on the clinical efficacy and appropriateness of medications and not cost considerations. Purchasing agreements and consultant pharmacist contracts present risks under the Federal anti-kickback statute and compliance measures should be taken to monitor prescribing practices and consultant pharmacist compensation in order to avoid liability.

Resident Safety. The original CPG suggested that nursing facilities should address the following risk areas related to resident safety as part of a compliance plan: (1) discriminatory admission or improper denial of access to care; (2) verbal, mental, or physical abuse, corporal punishment and involuntary seclusion; (3) inappropriate use of physical or chemical restraints; (4) failure to ensure residents have personal privacy and access to personal records upon request and that the privacy and confidentiality of those records are protected; (5) denial of a resident’s right to participate in care and treatment decisions; and (6) failure to safeguard residents’ financial affairs. The OIG also highlighted the obligation placed upon nursing facilities to self-

report resident abuse as a condition of participation in Medicare. Nursing facilities are required by state and federal laws to implement policies and procedures that ensure protection of the legal right of residents to be free from abuse and neglect, and to thoroughly investigate and report incidents. The OIG cites to specific concerns in the supplemental CPG respecting harm caused by staff and fellow residents. An effective compliance program requires an internal commitment to eliminating resident abuse and should put into place confidential reporting and specialized training measures for staff that interact with residents on a regular basis. Resident-on-resident abuse can be addressed by targeted education and proper screening and assessment of residents. Nursing facilities should also make reasonable efforts to ensure a competent workforce that will maintain resident safety. The OIG has suggested measures to accomplish this, including screening prospective employee's criminal records in all states in which they have worked or lived and verifying licensure, education, certifications and training for care providers. Many states require these checks for all professional care providers and Federal regulations require nursing facilities to check their state nurse aide registry in addition to every state nurse aide registry believed to include information on the individual to ensure competency.

Submission of Accurate Claims

Nursing facilities are prohibited from submitting false or fraudulent claims. This includes claims for items not provided or not provided as claimed, claims for services that are not medically necessary, and claims for which there has been a failure of care. Submitting or causing the submission of such claims presents the risk of criminal prosecution, civil penalties and exclusion from participation in Federal health care programs. Although many common risk areas are relatively well-understood in the industry, the OIG believes that the following types of fraudulent transactions have increasingly become apparent with the evolution of reimbursement systems.

SNF Resident Case-Mix Reporting. The OIG has identified several instances in which SNFs improperly upcoded resident RUG assignments. In 2006, the OIG found that 22% of claims were upcoded, resulting in \$542 million in potential overpayments. Resident assessments must be comprehensive and accurate to ensure that residents are classified into the correct RUG. The OIG has identified the assessment, reporting, and evaluation of resident case-mix data as a significant risk area for SNFs. Failure to ensure accurate reporting could result in misrepresentation of resident status, false claims submission and potential enforcement actions. To reduce the risk of improper upcoding, the OIG suggests that certain training measures be implemented alongside internal and external periodic validations.

Therapy Services. The original CPG cited the failure to provide appropriate therapy services as a quality of care issue, specifically as it relates to the provision of medically unnecessary services. The OIG also emphasized the need ensure that financial pressures resulting from introduction of the prospective payments system do not result in underutilization of medically necessary services. The OIG identifies certain circumstances in the supplemental CPG that may result in the submission of false claims related to the provision of physical, occupational, and speech therapy services, including: (1) improper utilization of therapy services to inflate the severity of RUG classifications and obtain additional reimbursement; (2) overutilization of therapy services billed on a fee-for-service basis to Part B under consolidated

billing; and (3) stinting on therapy services provided to patients covered by the Part A PPS payment. Additionally, the provision of unnecessary therapy services or too few therapy services may expose residents to risk of physical injury and result in failure of care problems. The OIG strongly recommends that nursing facilities adopt policies, procedures and measures to ensure residents receive medically appropriate therapy services.

Screening for Excluded Individuals and Entities. In the supplemental CPG, the OIG reiterates the critical importance of screening employees and non-employee personnel in order to ensure the integrity of a nursing facility's workforce and the safety and welfare of its residents. Items or services furnished by excluded individuals or entities are not eligible for reimbursement under Federal health care programs. Any person who arranges or contracts with an excluded individual or entity may be subject to civil monetary penalties if the person knows or should know of the excluded status. The OIG recommends that nursing facilities take steps screen prospective owners, officers, directors, employees, contractors, and agents to ensure they are not excluded prior to entering into any agreement or relationship, and periodically thereafter. Nursing facilities that utilize contract or temporary staffing agencies are counseled to consider contractually requiring such agencies to screen their staff against the OIG's List of Excluded Individuals/Entities prior to determining that they are eligible to work at the facility. Facility policies and procedures should address pre-employment screenings, including a requirement that prospective employees disclose excluded status as part of the application process. Facility policies should also require removal of excluded individuals or entities from involvement with any aspects of the facility's operations related to Federal health care programs.

Restorative Personal Care Services. The original CPG highlighted quality of care issues surrounding the responsibility of nursing facilities to ensure that treatment and services are appropriate and sufficient to meet best practice guidelines concerning residents' clinical conditions, including pressure ulcers, dehydration, malnutrition, bladder incontinence, and mental or psychosocial problems. Additionally, the original CPG stated that nursing facilities should provide appropriate services to assist residents with activities of daily living and ongoing activities programs to meet the individual needs of all residents. The supplemental CPG discusses these services in the context of accurate claims submission and states that nursing facilities should have comprehensive procedures in place to ensure the provision of *quality* necessary restorative and personal care services. Restorative and personal care services should enable residents to "attain and maintain their highest practicable level of functioning." According to the OIG, payments received from Federal health care programs for services that are not provided or are "so wholly deficient" that they amount to no care at all could subject nursing facilities to liability under fraud and abuse statutes and regulations for billing for services not rendered as claimed. This issue may also present potential liability under the FCA.

The Federal Anti-Kickback Statute

The federal anti-kickback statute strictly prohibits, in broad terms, the knowing and willful solicitation, receipt, payment, or offer of payment of anything of value for the purpose of influencing the referral of any item or service covered under a federal health care program. Specifically, the law states that it is illegal for any person to solicit, offer, or receive anything of value in exchange for purchasing, ordering, leasing, or arranging for, recommending, or inducing

the purchasing, ordering, or leasing of any item or service that may be reimbursed under a federal health care program. This prohibition is applicable if any one purpose of the arrangement is to induce or reward the referral or recommendation of business, even if otherwise lawful purposes underlie the arrangement.

Compliance with the anti-kickback statute is a precondition to payment under Medicare and other Federal health care programs. Violation of the anti-kickback statute is a felony offense and subjects those in violation to hefty fines and/or potential imprisonment, automatic exclusion from Federal health care programs, and civil monetary penalties. These remedies may be applicable individually to all of those involved in a given arrangement. Liability under the FCA may also arise if an anti-kickback statute violation results in the submission of a claim for payment under a Federal health care program.

The anti-kickback statute provides for detailed “safe harbors” that protect certain arrangements. When arrangements fall squarely within one of the safe-harbors, individuals are immunized from criminal and civil prosecution under the statute for payment and business practices that would otherwise be prohibited. The OIG identified eight safe harbors in the supplemental CPG that are of most relevance to nursing facilities. Arrangements with referral sources and referral recipients should be structured to fit within a safe harbor whenever possible.

Nursing facilities receive and/or generate a variety of referrals that may implicate the anti-kickback statute. Certain of these referrals may present a significant potential for abuse. Nursing facilities should be mindful of anti-kickback issues when structuring and reviewing arrangements, should take steps to identify potential kickback risks, and should develop policies and procedures to identify and address problematic arrangements and eliminate or curtail the risk for an anti-kickback violation. In both the original and supplemental CPG, the OIG identified several known areas of potential abuse under the anti-kickback statute that nursing facilities should closely scrutinize. The supplemental CPG elaborates on several of those areas in greater detail.

Free Goods and Services. Providing goods or services to an existing or potential referral source presents risks under the anti-kickback statute. The original CPG identified the routine waiver of coinsurance or deductible amounts without a good faith determination that the resident is in financial need, or absent reasonable efforts to collect the cost-sharing amount, as a significant risk area. Additionally, the OIG emphasized the risk inherent in soliciting, accepting or offering any gift or gratuity of more than nominal value to or from residents, potential referral sources, and other individuals and entities with which the nursing facility has a business relationship. The supplemental CPG stresses that the OIG has issued warnings stating that the provision of goods or services that have independent value to the recipient (or that the recipient would otherwise have to provide at its own expense) may constitute an illegal inducement. For example, certain arrangements involving pharmaceutical consultant services, registered nurses provided by hospitals, or DME or supplies offered by DME suppliers for patients covered by the SNF Part A benefit warrant careful scrutiny.

Service Contracts. The original CPG identified joint ventures with entities supplying goods or services as a potential risk area. Providing or receiving goods or services at other than fair-market value presents a risk under the anti-kickback statute. Kickbacks may be hidden in seemingly appropriate business arrangements. Examples of situations that present the potential for abuse include those in which nursing facilities arrange for outside suppliers and providers to serve residents. Arrangements with physicians should also be closely monitored to ensure compliance. The OIG elaborates on the need to review financial arrangements in the supplemental CPG and recommends that nursing facilities conduct periodic review of contractor, staff, and physician arrangements to ensure (1) there is a legitimate need for the services or supplies; (2) the services or supplies are actually provided and adequately documented; (3) the compensation is at fair-market value in an arm's length transaction; and (4) the arrangement is not related in any manner to the volume or value of Federal health care program business. If possible, these arrangements should be structured to fit within the personal services and management contracts safe harbor.

Discounts. Certain discounts in the price of a product or service are permitted under an exception in the anti-kickback statute. Such discounts, including rebates, must be properly disclosed, accurately reflected by nursing facility cost reports, and filed with a Federal program when appropriate. Discounts received from vendors selling products under a group purchasing organization contract must likewise be disclosed and reported.

The original CPG identified "swapping" as a potential risk area. The supplemental CPG elaborates on this risk area and explains that discounts obtained from suppliers and providers on items and services the nursing facilities purchase for their own account may constitute improper "swapping" arrangements under the anti-kickback statute. Examples of arrangements that are prone to "swapping" problems include those with clinical laboratories, DME suppliers, and ambulance providers. In negotiating arrangements with providers and suppliers, nursing facilities must ensure that there is no link of any kind between the price offered to a nursing facility "for items or services that the nursing facility pays for out-of-pocket and referrals of Federal business for which the supplier or provider can bill a Federal health care program."

Hospices. Nursing facilities arranging for the provision of hospice services in the nursing facility may be at risk of violating the anti-kickback statute. For example, liability could arise if the nursing facility requests or accepts remuneration from a hospice that could affect the nursing facility's decision to do business with the hospice. The OIG highlights several suspect practices relating to hospice care arrangements that may implicate the anti-kickback statute in the supplemental CPG and states that such arrangements should be structured to fit in a safe harbor.

Reserved Bed Arrangements. The OIG has identified several potentially problematic reserved bed arrangements. Although nursing facilities are permitted to enter into reserved bed arrangements, certain limitations exist. These arrangements should be structured in such a way that the payment only serves to secure needed beds and not as a payment to induce future referrals from the nursing facility to the hospital.

Other Risk Areas

The OIG also expressed concern about other risk areas such as physician self-referrals, anti-supplementation, Medicare Part D, and HIPAA privacy and security regulations. The following summarizes highlights of the OIG's concerns with respect to these issues.

The Stark Law. Nursing facilities should be familiar with the prohibition on physician self-referrals under the Stark law. Under the Stark law, entities furnishing designated health services ("DHS") may not submit or receive payment from Medicare for claims for DHS if the referral comes from a physician with whom the entity has a prohibited financial relationship. Stark is a strict liability law and violations may result in a required refunding of prohibited payments, and, in cases of knowing violations, civil monetary penalties and exclusion from Federal health care programs. Knowing violations of Stark may also subject individuals and entities to liability under the FCA.

Although nursing facility services (including SNF services under the Part A PPS system) are not DHS for purposes of Stark, laboratory services and physical and occupational therapy services are among the DHS covered by the statute. Therefore, nursing facilities that bill Part B for those services, or other DHS under consolidated billing rules, are subject to Stark and should review financial relationships with physicians who refer or order such services to ensure compliance.

Stark does provide for statutory and regulatory exceptions for many types of arrangements. The actual relationship between the parties, and not merely the paperwork, must fit squarely within an exception to avoid liability. Unlike the voluntary safe harbors provided for under the anti-kickback statute, compliance with Stark exceptions is mandatory. Nursing facilities should ensure that all arrangements with physicians fit into an exception and should implement systematic measures to protect against violations.

Anti-Supplementation. Nursing facilities must accept applicable Medicare or Medicaid payments for covered items or services as complete payment and are prohibited from imposing a charge on another party for services already covered by Medicare or Medicaid. Such an imposition is considered a "supplemental payment," which is precluded by Medicare provider agreements and applicable Medicaid regulations.

Medicare Part D. Medicare beneficiaries, including those that reside in nursing facilities, have the right to choose a Part D plan for voluntary prescription drug coverage. Nursing facilities must avoid acting in ways that may frustrate this freedom of choice. The OIG has stated that nursing facilities should not "require, request, coach or steer" a resident's decision to select or change a plan or "knowingly and/or willingly allow the pharmacy servicing the nursing home" to do so.

HIPAA Privacy and Security Rules. The supplemental CPG expounds upon requirements set forth in the original CPG with respect to the documentation and retention of records. As of April 14, 2003, nursing facilities conducting electronic transactions governed by HIPAA must comply with the HIPAA Privacy Rule. The Privacy Rule generally addresses the

use and disclosure of personally identifiable health information (“protected health information” or “PHI”) by covered entities. Additionally, the Privacy Rule addresses individuals’ privacy rights to understand and control the use of their health information, and requires disclosure of PHI under certain circumstances. Nursing facilities that are covered entities must also be in compliance with the HIPAA Security Rule. The HIPAA Security Rule requires covered entities to implement a series of administrative, technical, and physical security safeguards to protect the confidentiality of electronic PHI. Nursing facilities should have policies and procedures in place to ensure compliance with all applicable provisions of the Privacy and Security Rules.

This publication is intended to notify our clients and friends of current events and provide general information about health care issues. It is not intended, nor should it be used, as legal advice. For in-depth information about how to minimize your nursing facility’s compliance risks, please attend our June 20, 2008 seminar in Denver, Colorado or, if you desire legal advice related to this guidance, contact your regular Kutak Rock LLP attorney or any member of our Health Care Practice Group, including those identified below:

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