



OIG'S SUPPLEMENTAL COMPLIANCE PROGRAM GUIDANCE FOR NURSING FACILITIES

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On September 30, 2008, the Office of the Inspector General of the Department of Health and Human Services (OIG) reviewed Supplemental Compliance Program Guidance for Nursing Facilities (Supplemental CPG-NF).¹ The Supplemental CPG-NF builds on, and does not replace, the original CPG for nursing facilities issued on March 16, 2000.² Quality of care is one of the primary focuses of the Supplemental CPG-NF.

The Supplemental CPG-NF also provides guidance related to fraud and abuse risk areas such as the submission of accurate claims, the federal

Anti-Kickback Statute, physician self-referrals, supplemental payments, Medicare Part D, and the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules.

All health care providers should review the Supplemental CPG-NF, especially the section regarding quality of care. We have seen an increased focus on quality-of-care issues in the media, with False Claims Act litigation and with various reports, such as the Institute of Medicine's report *To Err is Human* and the OIG and American Health Lawyers Association's

¹ 73 Fed. Reg. 56832 (Sept. 30, 2008).

² 65 Fed. Reg. 14289 (Mar. 16, 2000).

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(AHLA's) white paper, "Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors."³ In the original CPG for nursing homes, OIG focused on quality-of-care issues, but not as extensively as it did in the recently issued Supplemental CPG-NF. The Supplemental CPG-NF provides a good template for all health care providers to expand their own compliance program and to get ahead of the curve as quality initiatives continue to develop in the enforcement context. Health care providers can no longer view quality as an elusive concept that is entirely subjective. The Supplemental CPG-NF provides concrete examples for nursing facilities to enhance the standard of care they provide to residents. Consequently, with the new supplement, OIG provides clarity regarding necessary operational components for a compliance program focused on quality. The growing emphasis on quality in health care is something that continues to gain momentum.

OIG COMPLIANCE PROGRAM GUIDANCE

In 1998, in an effort to combat fraud and abuse and to prevent the submission of erroneous claims, OIG began to develop and publish CPGs. The CPGs are focused on a variety of health care sectors, including hospitals; nursing facilities; clinical laboratories; home health agencies; third-party billing companies; ambulance suppliers; the durable medical equipment, prosthetics, orthotics, and supply industry; physicians; and pharmaceutical companies. As time passed, significant changes occurred in some industries, which in turn spurred OIG to issue supplemental CPGs. In the Supplemental CPG-NF, OIG stated that it issued supplemental guidance because of the "significant changes in the way nursing facilities deliver, and receive reimbursement for, health care services, as well as significant changes in the Federal enforcement environment and increased concerns about quality of care in nursing facilities, which continues to be a high priority of OIG."

CPGs are not mandatory, nor are they exhaustive. In fact, in the Supplemental CPG-NF, OIG acknowledges that there is not a "one size fits all" approach to compliance. However, given the growing focus on compliance initiatives, it is a

useful exercise for members of the health care industry to review the OIG CPGs, regardless of the health care sector to which the CPG is addressed. The CPGs are a good source of information to help foster, expand, and audit a health care provider's own compliance program.

KEY FOCUS AREAS

Nursing facilities should spend time reviewing the Supplemental CPG-NF and adapting new and revised processes as necessary. Other health care providers should not ignore this supplement. Instead, they should use it as a tool to understand the trends in the government's expectations related to compliance—especially quality of care.

QUALITY OF CARE

The first fraud and abuse risk area that OIG addresses in the supplement deals with quality of care. In an extensive discussion of quality, OIG sets forth guidance related to staffing, comprehensive resident care plans, medication management, appropriate use of psychotropic medications, and resident safety. OIG verifies that quality-of-care issues will continue to be a national focus. OIG states that nursing facilities should familiarize themselves with the guidelines in the Code of Federal Regulations regarding Medicare and Medicaid Conditions of Participation, recognize the inter-relatedness of quality-of-care issues with other risk areas in the Supplemental CPG-NF, and develop appropriate training programs.

In terms of staffing, OIG emphasizes the need for nursing facilities to assess staffing patterns and to regularly evaluate staff members' competencies relevant to residents' needs. For example, nursing facilities should review staffing models, resident case mix, staff skill levels, staff-to-resident ratios, and adverse event reports. In addition, OIG advises nursing facilities to interview staff, residents, and residents' family members or legal guardians to gain additional insight into the facility's staffing models.

³ Institute of Medicine, *To Err is Human*, available at <http://www.iom.edu/?id=12735> (all web sites herein last visited Jan. 30, 2009); Office of the Inspector General & AHLA, "Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors," available at <http://oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFinal%209-4-07.pdf>.

OIG also emphasizes the need for nursing facilities to ensure that the comprehensive care plan for each resident, which the Medicare and Medicaid regulations require, reflects that resident's needs and is developed via an interdisciplinary and comprehensive approach. There should be physician involvement in the development and maintenance of a comprehensive resident care plan.

OIG then discusses the need for nursing facilities to have processes in place that focus on medication management, including an emphasis on patient safety, minimal adverse drug interactions, and addressing irregularities in residents' drug regimens. In order to operationalize some of these changes, OIG recommends that nursing facilities develop policies and procedures and provide training to staff who are involved in the pharmaceutical care of residents. The Centers for Medicare and Medicaid Services' (CMS's) regulations require nursing facilities to consult with licensed pharmacists regarding the provision of pharmacy services; it is pivotal for nursing facilities to work with consultant pharmacists regarding proper medication management.

In addition to the focus on medication management, OIG urges nursing facilities to be mindful of and to develop processes to protect against inappropriate use of psychotropic medications as chemical restraints, as well as unnecessary drug usage. All members of a resident's care team, including the attending physicians, the medical director, the consultant pharmacist, and other care providers, should ensure that there is adequate indication for, and carefully monitor a resident's use of, psychotropic drugs.

Finally, with respect to quality of care, OIG focuses on the need for nursing facilities to develop practices and policies that promote resident safety. Nursing facilities should implement policies and procedures to prevent, investigate, and respond to issues related to potential resident abuse. OIG emphasizes that an important aspect of promoting resident safety is developing a mechanism by which people can make confidential reports and creating a culture in which people know they are free from retaliation if they do file a report. In addition, nursing facilities should be aware of problematic resident-to-resident interactions and respond to aggressive behavior and abuse. Nursing facilities should also have proper safeguards in place to screen residents

and staff members with backgrounds that might increase the risk for resident abuse.

SUBMISSION OF ACCURATE CLAIMS

In the next section of the Supplemental CPG-NF, OIG emphasizes the risks of False Claims Act litigation and possible exclusion from Medicare and Medicaid programs that an individual or entity may face from the submission of false claims. OIG acknowledges that there were previous historical risk areas associated with duplicate billing, insufficient documentation, and false or fraudulent cost reports. It then states that as reimbursement systems have changed, additional claims risk areas have appeared. These areas include proper reporting of resident case mix, the provision of therapy services, pre-employment screening for excluded individuals, and appropriate use of restorative and personal care services. For example, nursing facilities should be aware of improperly upcoding resident Resource Utilization Group (RUG) assignments, which can lead to the submission of false claims.

THE FEDERAL ANTI-KICKBACK STATUTE

OIG uses the Supplemental CPG-NF to discuss the Anti-Kickback Statute and the safe harbors that are especially relevant to nursing facilities. OIG identifies potential high-risk areas for nursing facilities related to the Anti-Kickback Statute, including risks associated with providing free goods and services, services contracts, discounts, swapping, hospices, and reserved bed arrangements.

For example, with respect to hospices, OIG discusses the risk inherent in a nursing facility's receipt of remuneration from a hospice organization if such remuneration might influence the nursing facility's decision to do business with that hospice. The risk areas OIG identifies with respect to the federal Anti-Kickback Statute and hospices include a hospice offering free services or goods below fair market value, a hospice providing staff at its expense to the nursing facility, or a hospice paying amounts above fair market value for additional services that Medicaid does not consider to be included in the room and board payment made to the nursing facility.

OTHER RISK AREAS

In a section titled “Other Risk Areas,” OIG discusses risks associated with physician self-referrals, supplemental payments, and Medicare Part D.

Regarding risks with physician self-referrals, OIG urges nursing facilities to review the Stark laws and to focus their attention on the relationships that the nursing facility has with physicians who treat residents and physicians who are nursing facility owners, investors, medical directors, or consultants. Second, nursing facilities may not charge a Medicare beneficiary (or someone in lieu of the beneficiary) an amount that would be considered an additional amount to what is paid under Medicare or Medicaid. OIG urges nursing facilities to be mindful of this condition and not to accept supplemental payments, including cash and free or discounted services and items, just because the nursing facility considers the Medicare or Medicaid payment inadequate. Finally, with respect to Medicare Part D, nursing facilities should develop appropriate safeguards to ensure that Medicare beneficiaries have the freedom to choose whichever Medicare Part D plan they wish. Nursing facilities can ensure freedom of choice by providing residents with objective and complete information about all available plans.

HIPAA PRIVACY AND SECURITY RULES

The final risk area OIG discusses in the Supplemental CPG-NF focuses on HIPAA privacy and security rules. Nursing facilities should review the privacy and security rules and determine whether they are compliant and where potential risk areas exist. Nursing facilities should pay particular attention to protected health information (PHI) within their organizations to ensure that confidentiality is maintained, as well as the standards for use and disclosure of such PHI.

ADDITIONAL EMPHASIS

OIG also emphasizes some general compliance concepts at the end of the Supplemental CPG-NF. For example, a nursing facility should take necessary steps to have an “ethical culture” that “values compliance from the top down and fosters compliance from the bottom up.” In addition, OIG encourages nursing facilities to review their compliance programs and to maintain appropriate self-reporting programs.

INCREASED CLARITY LEADS TO GREATER EXPECTATIONS

OIG has made a dramatic move in its extensive focus on quality in the Supplemental CPG-NF. OIG thoroughly discusses quality risks as the first fraud and abuse risk area; however, OIG does not stop there. Quality is a central theme in the entire Supplemental CPG-NF. For example, with respect to its discussion on the need for an ethical culture, OIG states that “[f]irst, and foremost, a nursing facility’s leadership should foster an organizational culture that values, and even rewards, the prevention, detection, and resolution of quality of care and compliance problems.” OIG then discusses the use of a quality dashboard, which can help demonstrate a commitment to quality, improve quality through awareness and oversight, and track and trend quality-related data.⁴

The Supplemental CPG-NF was not the first CPG to focus on quality of care. The original CPG for nursing facilities, issued in 2000, briefly discussed quality. Also, in the Supplemental CPG for Hospitals issued in 2005, OIG discussed the need for hospitals to review quality of care throughout their organizations and with their medical staff.⁵ In the Supplemental CPG for Hospitals, OIG directed hospitals to the Medicare Conditions of Participation, including the condition of participation related to quality assessments and performance improvement programs. However, OIG’s recent focus on quality-of-care issues in the Supplemental CPG-NF is more detailed and expansive compared to the quality discussion in the Supplemental CPG for Hospitals.

⁴ OIG refers to the OIG and Health Care Compliance Association report titled “Driving for Quality in Long-Term Care: A Board of Directors Dashboard,” available at <http://www.oig.hhs.gov/fraud/docs/complianceguidance/Roundtable013007.pdf>.

⁵ 70 Fed. Reg. 4858, 4870 (Jan. 31, 2005).

Can we expect a similar, heavily quality-focused Supplemental CPG for Hospitals? Quality in health care will be a central theme in future OIG initiatives and government activities. In August 2006, President Bush issued an executive order requiring federal agencies to promote quality in health care organizations and to improve the transparency of measurements used to assess the quality of care provided by health care providers.⁶ In the 2008 OIG Work Plan, CMS stated that it will continue to review quality of care in nursing homes and other settings.⁷

The nursing home industry has paved the way for many quality initiatives; therefore, it would be beneficial for all health care providers to pay particular attention to the quality-of-care discussion in the Supplemental CPG-NF. Many of the recommendations that OIG sets forth for nursing facilities can be adopted in other health care settings. Quality is no longer a vague concept. The Supplemental CPG-NF provides concrete examples of ways nursing facilities can enhance compliance programs and develop quality initiatives. The clarity provided by OIG does not stand in a vacuum. Other health care providers may find direction regarding the ways to implement quality initiatives and focus areas related to quality. Nursing facilities have tools to enhance their quality programs. Now that OIG has done its job in detailing quality implementation, nursing facilities will be expected to take action. Hospitals and other health care providers are not immune to similar quality demands.

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⁶ Exec. Order No. 13410, 71 Fed. Reg. 51089 (Aug. 29, 2006).

⁷ Centers for Medicare & Medicaid Services 2008 Work Plan, available at http://www.oig.hhs.gov/publications/docs/workplan/2008/Work__Plan__FY__2008.pdf.

