# Draft Supplemental Compliance Program Guidance for Nursing Facilities

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On April 16, 2008, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) published Draft OIG Supplemental Compliance Program Guidance for Nursing Facilities.[1] With quality of care the first risk area identified, the draft supplemental guidance is part of a series of recent government efforts focused on improving quality of care at skilled nursing and long-term care facilities. In November, 2007, the Centers for Medicare and Medicaid Services (CMS) unveiled a list of the poorest performing nursing facilities nationwide, dubbed Special Focus Facilities (SFF).[2] CMS has kept the list current, and on April 24, 2008, began identifying those poor performing SFFs on its Nursing Home Compare Website.[3] The draft supplemental guidance also follows the joint OIG-HCCA roundtable report, Driving for Quality in Long-Term Care: A Board of Directors Dashboard, released January 31, 2008.[4] Daniel Levinson, HHS Inspector General, announced the draft supplemental guidance in his speech at the HCCA 2008 Compliance Institute in New Orleans, with a final version to be published in the Fall. The OIG comment period on the draft guidance closed June 2, 2008.

## Background

The OIG first published a compliance program guidance for nursing facilities on March 16, 2000.[5] The original guidance addressed the fundamentals of establishing an effective compliance program in the nursing industry. Since the publication of the original guidance, the OIG recognized that there have been significant changes in the way nursing facilities deliver, and are reimbursed for, health care services. Although the original guidance included quality of care as a risk area, recent significant changes to the regulatory enforcement environment and increased concerns regarding quality of care in nursing facilities prompted a greater, renewed emphasis on quality in the draft supplemental guidance.

The draft guidance contains new compliance recommendations and an expanded discussion of risk areas. When drafting the supplemental guidance, the OIG considered "Medicare and Medicaid nursing facility payment systems and regulations, evolving industry practices, current enforcement priorities (including the government's heightened focus on quality of care), and lessons learned in the area of nursing facility compliance."[6] When published, the final supplemental guidance will "provide voluntary guidelines to assist nursing facilities in identifying significant risk areas and in evaluating and, as necessary, refining ongoing compliance efforts."[7]

Because the draft guidance supplements, rather than replaces, the original guidance, the two documents "collectively offer a set of guidelines that nursing facilities should consider when developing and implementing a new compliance program or evaluating an existing one."[8]

The draft supplemental guidance is partitioned into five sections. The first two offer a background overview of the compliance program guidance process and the Medicare/Medicaid reimbursement system. The third section covers several fraud and abuse risk areas relevant to nursing facilities. In the fourth section, the OIG offers recommendations for establishing an ethical culture and assessing and improving existing compliance programs. Section five lists steps a nursing facility should take if it discovers credible evidence of misconduct.

## Fraud and abuse risk areas

By identifying current, relevant risk areas, the draft supplemental guidance should assist nursing facilities in their efforts to "identify areas of their operations that present potential risks of liability under several key federal fraud and abuse statutes and regulations."[9] The OIG stresses that each facility should carefully examine these risk areas and identify those that potentially affect it.

### Quality of care

Although it is a priority for nursing facilities,

a significant number fail to deliver quality health care. Whether this failure is the result of inadequate staffing, insufficient training and education, or lack of oversight, the result is often the same: residents risk harm. In cases where the care failure is systemic and widespread, a facility may be liable for submitting false claims for reimbursement under the False Claims Act, the Civil Monetary Penalties law, a variety of additional federal authorities that address false and fraudulent claims or statements made to the government, and similar state laws, including criminal, civil, and administrative sanctions.[10] As a starting point on quality of care issues, facilities should familiarize themselves with the principal nursing facility Medicare Conditions of Participation.[11] The OIG states "it is essential that key members of the [nursing] organization understand these requirements and support their facility's commitment to compliance with these regulations."[12] The five sub-areas on quality of care identified in the draft supplemental guidance are:

**Sufficient staffing.** A critical factor in quality care is to provide enough trained, competent staff to care for residents. Federal law requires a facility to provide sufficient staffing necessary to attain or maintain the highest practicable physical, mental, and psychosocial well-being of its residents.[13] Many state laws, including California, require specific, higher nursing staff ratios. OIG strongly encourages facilities to assess their staffing patterns regularly to evaluate skill levels, staff-to-resident ratios, turnover, schedules, disciplinary records, payroll, timesheets, adverse event reports, and resident and family feedback.[14]

**Comprehensive resident care plans.** Medicare and Medicaid regulations require facilities to develop a comprehensive care plan for each resident.[15] OIG states that a comprehensive care plan is "essential to reducing risk."[16] Facilities should ensure that care planning includes all disciplines involved in the resident's care, designing an interdisciplinary and comprehensive approach to developing care plans.[17] The attending physician should participate in the development of the care plan and facilities should ensure that the physician actually supervises each resident's care.[18]

**Appropriate use of psychotropic medications.** OIG identified this risk area as a violation of the prohibition against inappropriate use of chemical restraints[19] and a violation of the requirement to avoid unnecessary drug usage.[20] Facilities should ensure that medications are only used with adequate indication and should carefully monitor, document, and review resident use of psychotropic drugs. Educating caregivers and auditing drug regimen reviews is an important part of reducing risk in this area.[21]

**Medication management.** Facilities must "provide pharmaceutical services to meet the needs of each resident" and should be mindful of potential quality-of-care problems when implementing policies and procedures on proper medication management.[22] Consultant pharmacists, though required by CMS regulations, may create a conflict of interest if a resident is prescribed a drug not preferred by the pharmacy.[23] Facilities can reduce risk by educating staff on medication management and improper pharmacy kickbacks. Facilities should review the total compensation paid to consultant pharmacists to ensure it is not structured in a way that reflects the volume or value of particular drugs prescribed or administered to residents.

**Resident safety.** OIG suggests several steps that facilities may take to protect residents from abuse and neglect, a right protected by federal (and often state) law.[24] Facilities can promote resident safety through internal, confidential reporting systems; hotlines; posters; and by communicating a clear commitment to protecting from retaliation those people who make reports. Because residents also suffer harm at the hands of other residents, a heightened awareness and monitoring of resident interaction is crucial. Facilities should perform comprehensive staff screening for criminal records, exclusions, and other information on staff—both prior to employment and periodically for current staff.

**Submission of accurate claims**

Accurate claim submission is another risk area identified in the draft supplemental guidance. OIG identified four sub-areas:

**Proper reporting of resident case-mix.** OIG mentioned instances where skilled nursing facilities improperly upcoded resident Resource Utilization Group (RUG) assignments.[25] Assessment, reporting, and evaluation of resident case-mix data is a significant risk area. Particularly as enforcement activity increases scrutiny of quality reporting data, facilities are "well-advised to review such data regularly to ensure its accuracy and to identify and address potential quality-of-care issues."[26]

**Therapy services.** Physical, occupational and speech therapy services continue to be a risk area for facilities, including inflated RUG classifications, over-utilization of fee-for-service therapy billed to Part B under consolidated billing, and stinting on therapy services covered by the Part A Prospective Payment System (PPS) payment. These practices may result in the submission of false claims and OIG advises facilities to develop policies and procedures to ensure that residents receive medically appropriate therapy services.

**Screening for excluded individuals.** Pre-employment screening and periodic screening of existing employees is an important

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part of reducing risk. The draft guidance reminds facilities that exclusion does not automatically end; it remains in effect until OIG reinstates the excluded individual.

**Restorative and personal care services.** Facilities that fail to provide necessary restorative and personal care services risk billing for services not rendered as claimed, and can face risk under fraud and abuse laws. OIG strongly encourages facilities to implement comprehensive procedures to ensure that appropriate quality and amount of services are actually delivered to residents. Interviews, observations, and a contemporaneous documenting requirement can all assist in reducing risk in this area.

**The federal Anti-kickback Statute**

The Anti-kickback Statute remains a significant risk area for nursing facilities. The draft supplemental guidance devoted over four pages to the issue, discussing the statute generally, the eight safe harbors most relevant to nursing facilities, and listing a number of factors/questions facilities should consider when evaluating contractual arrangements. The factors are the traditional aspects of most anti-kickback analysis, the overall message being that facilities should evaluate potentially problematic arrangements with referral sources and recipients who do not fit into a safe harbor. OIG identified five sub-areas:

**Free goods and services.** When a facility provides goods and services that have an independent value to the recipient or that the recipient would otherwise needed to provide at its own expense, a benefit is conferred. If one purpose of the conferred benefit is to generate referrals, it may constitute prohibited remuneration under the Anti-kickback Statute. OIG highlighted certain examples of this risk area, including but not limited to: supplies or consulting services offered by a pharmacy or laboratory; computers and software with an independent value to the facility; durable medical equipment (DME) supplies for patients covered by Part A; and a hospice nurse providing nursing services for non-hospice residents.[27]

**Services contracts.** To minimize the risk of disguised kickbacks in physician and non-physician services contracts, a facility should periodically review arrangements to ensure: (1) a legitimate need for services or supplies; (2) services or supplies were actually provided and documented; (3) 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.[28] To eliminate risk, OIG advises facilities to structure their services arrangements to comply with the personal services and management contracts safe harbor whenever possible.[29]

**Discounts.** Although the Anti-kickback statute contains an exception for discounts, to qualify for it the discount must be in the form of a reduction in the price of the good or service based on an arm's-length transaction.[30] OIG cautions that all discounts, including rebates, should be properly disclosed on cost reports and claims, as appropriate. OIG also stressed that the safe harbor for administrative fees paid by a vendor to a group purchasing organization does not protect discounts provided by a vendor to purchasers of products.[31]

**Swapping.** OIG stated that facilities should not engage in "swapping" arrangements by accepting a low price from a supplier or provider on an item or service covered by the Part A per diem, in exchange for the facility referring other federal health care program business, such as Part B business excluded from consolidated billing, for which the supplier can directly bill Medicare or Medicaid.[32] Facility arrangements particularly prone to "swapping" problems include those with clinical laboratories, DME suppliers and ambulance providers. Such "swapping" arrangements, the OIG stated, implicate the Anti-kickback statute and are not protected by the discount safe harbor.

**Hospices.** Facilities should be aware that requesting or accepting benefits from a hospice may subject the facility and the hospice to liability under the Anti-kickback Statute if those benefits might influence the facility's decision to do business with the hospice.[33] OIG identified a number of hospice-related practices that are suspect under the Anti-kickback statute. Among those practices are: a hospice offering free or below-market goods (or referring patients) to induce the facility to refer patients to the hospice; a hospice paying room-and-board payments in excess of what the facility would have received directly from Medicaid; and a hospice providing staff at its own expense to the nursing facility.

**Reserved bed arrangements.** Payments from a hospital to a nursing facility to reserve beds may pose a risk under the Anti-kickback Statute if one purpose of the arrangement is to induce referrals to the hospital.[34] OIG offered examples of potentially problematic arrangements, including: payments above the actual costs to the facility of holding an empty bed; payments for lost opportunity costs calculated based on a facility's revenues for an occupied bed; and payments for more beds than the hospital legitimately needs. Payments, OIG stated, should be for the limited purpose of securing needed beds, not future referrals.

**Other risk areas**

The draft supplemental guidance grouped

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three additional risk areas under a single heading relevant to nursing facilities:

**Physician self-referrals.** Nursing facilities should familiarize themselves with the current Stark laws and prohibited physician financial relationships.[35] OIG explained that nursing facility services are not designated health services (DHS) for purposes of Stark.[36] However, nursing facilities frequently use laboratory, physical therapy, and occupational therapy services, and those services are among the DHS covered by Stark.[37] Accordingly, OIG advises facilities to review all financial relationships with physicians who refer or order DHS to ensure compliance with Stark. Facilities should pay particular attention to relationships with attending physicians and physicians who are owners, investors, medical directors, or consultants to the facility.

**Anti-supplementation.** Medicare Conditions of Participation prohibit a facility from charging a beneficiary (or someone else in lieu of the beneficiary) for covered services in excess of the Medicare or Medicaid amount.[38] Seeking supplemental payments from residents (or their families) is a risk area for nursing facilities because the supplemental payment would be a prohibited charge imposed for services already covered by Medicare or Medicaid. Facilities should carefully ensure residents and their families are not billed for such charges.

**Medicare Part D:** Beneficiary freedom of choice when choosing a Part D plan is guaranteed by federal law.[39] Facilities must be particularly careful, the OIG advised, not to frustrate a beneficiary's freedom of choice when choosing a Part D plan.[40] CMS has stated that "[u]nder no circumstances should a nursing home require, request, coach or steer any resident to select or change a plan for any reason," nor should it "knowingly and/or willingly allow the pharmacy servicing the nursing home" to do the same.[41]

**HIPAA Privacy and Security Rule**

The last risk area identified in the draft supplemental guidance addresses the HIPAA Privacy Rule and the HIPAA Security Rule. The Privacy Rule protects against the disclosure of patient protected health information (PHI), and the Security Rule specifies the administrative, technical, and physical safeguards to ensure confidentiality of PHI. Under both rules, covered nursing facilities have a certain amount of flexibility to design their own privacy policies and procedures. OIG urges facilities to verify compliance with all applicable Privacy and Security Rule provisions, including standards for use and disclosure of protected health information, both with and without patient authorization.

## Other compliance considerations

Key to the success of any compliance program is establishing a tone at the top and a culture of compliance. Section IV of the draft supplemental guidance discusses the importance of an ethical culture and a formal commitment to compliance by the nursing facility's governing body and senior management. Although compliance programs should be scaled according to each facility's particular needs, size, and resources, every program must be afforded appropriate resources. A program should be structured to communicate across departments and overcome the silos of communication that frequently occur in large organizations. A clear statement of policies and procedures is the core of a compliance program, but OIG recommends facilities also develop a general statement of ethical and compliance principles. A compliance program charter and code of conduct, signed and approved by the governing body, is important to give the program sufficient authority, autonomy, and resources to implement compliance measures.

Closely tied with the written compliance materials is the need for assessment of the compliance program's effectiveness.[42] Facilities should regularly review, revise, and build their compliance program and may look to the original nursing facility compliance program guidance for details on the elements of an effective compliance program.[43] OIG also recommends that facilities develop a mechanism to communicate with decision makers, such as a dashboard, designed to easily convey compliance and performance-related information to a facility's governing body.[44]

## Self-reporting

Section V of the draft supplemental guidance addresses self-reporting requirements. If the compliance officer, compliance committee, or a member of senior management discovers credible evidence of misconduct from any source and, after a reasonable inquiry, believes that the misconduct may violate criminal, civil, or administrative law, the facility should promptly report the misconduct to the appropriate federal and state authorities.[45] The reporting should occur within a reasonable period of time, and no longer than 60 days after determining that there is credible evidence of a violation.[46] Some situations may be so serious that immediate reporting may be warranted.[47]

Prompt, voluntary reporting demonstrates a facility's good faith efforts to cooperate with OIG and is considered a mitigating factor when determining administrative sanctions, if the reporting facility becomes the subject of an OIG investigation.[48] Facilities should carefully review the OIG's Provider Self-Disclosure Protocol,[49] particularly in light of OIG's April 15, 2008 Open Letter stating that providers who resolve fraud matters using the protocol generally will no longer be required to enter into Corporate Integrity Agreements.[50]

## Most recent efforts

The draft supplemental compliance program guidance is the most recent of several government efforts to improve the quality of care in nursing homes. Other activities include: the joint OIG-HCCA roundtable report, Driving for Quality in Long-Term Care: A Board of Directors Dashboard; developing new, more stringent systems for criminal background checks on facility workers and applicants; an unprecedented focus on preventing severe pressure ulcers in residents; reducing the use of restraints; considering resident feedback and emotional satisfaction; and refining the survey process, identified in the CMS 2008 Action Plan for (Further Improvement of) Nursing Home Quality.[51]

CMS' Nursing Home Value-Based Purchasing Demonstration seeks to establish a fundamental change in the way nursing providers are reimbursed for care. Under the program, CMS will assess a nursing home's performance based on selected measures of quality of care.[52] The cost savings from the anticipated quality improvements would be shared with nursing homes that either improve quality or maintain exceptionally high quality of care.[53] The Demonstration, scheduled to begin in 2008 will include approximately 300 facilities and will ensure financial investments to improve quality will see reimbursement methods that discern the difference between excellent, good, mediocre, and poor quality.[54]

## Nursing facilities can take action now

Nursing facilities should consider themselves on the front line of quality enforcement and must evaluate whether they have sufficiently integrated quality-of-care review into their operations and compliance programs. Facilities can review the original and draft supplemental compliance program guidance, visit the Nursing Home Compare Website, and track the Value-Based Purchasing Demonstration. When developing a quality-of-care compliance program for a nursing facility, it is essential to use an interdisciplinary approach incorporating the administration, attending physician, nurses, various specialist therapists, and, as necessary, legal counsel.

A nursing facility can start immediately to reduce the risk of an adverse enforcement action. The first step in the process is to educate the governing body and senior management on quality-of-care issues and get their participation and commitment. Then, the compliance officer should gather together the key personnel in the organization (senior leadership, quality, risk, legal, compliance, etc.) and perform an assessment of the organization's compliance efforts. A nursing facility can establish internal quality controls and identify areas of potential quality breakdowns through an external audit for quality of care and legal risks. Such an audit, performed under the attorney-client privilege by skilled healthcare counsel, can reveal to a nursing facility its current legal exposure, based on quality of care factors, and direct the facility to revise its structure and operations accordingly.

## Conclusion

As OIG stressed, it is imperative for nursing facilities to establish and maintain effective compliance programs, foster a culture of ethical compliance, and make an organization-wide commitment to delivering quality health care. The draft supplemental compliance program guidance reflects how quality of care should be a primary concern of nursing facilities. Investments in quality of care can give a nursing facility an operational advantage, increased reputation in the community, minimize litigation exposure, and reduce the risk of enforcement actions based on poor quality.

1 73 Fed. Reg. 20680-96 (April 16, 2008).
2 See CMS Press Release, "CMS Publishes National List of Poor-Performing Nursing Homes, Key Tool for Families Seeking Quality Care" (November 29, 2007).
3 www.medicare.gov/NHCompare
4 See www.oig.hhs.gov/fraud/docs/complianceguidance/Roundtable013007.pdf.
5 65 Fed. Reg. 14289 (March 16, 2000).
6 Note 1, supra, at p. 20680.
7 Id.
8 Id.
9 Note 1, supra, at p. 20683.
10 Id.; 31 U.S.C. 3729-33 (False Claims Act); 42 U.S.C. 1320a-7a (civil monetary penalties); 42 U.S.C. 1320a-7b(c) (false statements or representations with respect to condition or operation of institutions; 18 U.S.C. 287 (false or fraudulent claims); 18 U.S.C. 1001 (statements or entries generally); 18 U.S.C. 1035 (false statements relating to health care matters); 18 U.S.C. 1347 (health care fraud); 18 U.S.C. 1516 (obstruction of a Federal audit)
11 42 C.F.R. part 483.
12 Note 1, supra, at p. 20684.
13 42 U.S.C. 1395i-3(b)(4)(A), 1396r(b)(4)(A).
14 Note 1, supra, at p. 20684.
15 42 C.F.R. 483.20(k).
16 Note 1, supra, at p. 20684-5.
17 42 C.F.R. 483.20(k)(2)(ii).
18 42 C.F.R. 483.20(k)(2)(ii), 483.40(a).
19 42 C.F.R. 483.13(a).
20 42 C.F.R. 483.25.
21 42 C.F.R. 483.60(c).
22 42 U.S.C. 1395i-3(b)(4)(A)(iii).
23 42 C.F.R. 483.60(b)(1).
24 42 U.S.C. 1351i-3, 1396r; 42 C.F.R. 483.10.
25 Note 1, supra, at p. 20687.
26 Id.
27 Note 1, supra, at p. 20690.
28 Note 1, supra, at p. 20691.
29 42 C.F.R. 1001.952(b).
30 Note 1, supra, at p. 20691; 42 C.F.R. 1001.952(h).
31 42 C.F.R. 1001.952(d).
32 Note 1, supra, at p. 20691.
33 Note 1, supra, at p. 20692.
34 Id.
35 42 U.S.C. 1395nn.
36 Note 1, supra, at p. 20693.
37 Id.; see also 66 Fed. Reg. 856, 923 (January 4, 2001).
38 42 U.S.C. 1395cc(a); 42 CFR 447.15, 483.12(d)(3), 489.20.
39 42 U.S.C. 1395w-101.
40 Note 1, supra, at p. 20694.
41 See CMS Survey and Certification Group's May 11, 2006 letter to State Survey Agency Directors, www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter06-16.pdf.
42 Note 1, supra, at p. 20695.
43 65 Fed. Reg. 14289 (March 16, 2000).
44 See www.oig.hhs.gov/fraud/docs/complianceguidance/Roundtable013007.pdf.
45 Note 1, supra, at p. 20695.
46 Id.; 31 U.S.C. 3729(a).
47 Note 1, supra, at p. 20695 (footnote No. 134).
48 Id.; see 62 Fed. Reg. 67392 (December 24, 1997).
49 See 63 Fed. Reg. 58399 (October 30, 1996); see also, www.oig.hhs.gov/authorities/docs/selfdisclosure.pdf.
50 www.oig.hhs.gov/fraud/docs/openletters/OpenLetter4-15-08.pdf.
51 www.cms.hhs.gov/CertificationandComplianc/Downloads/2008NHActionPlan.pdf.
52 Note 51, supra.
53 Note 51, supra.
54 Note 51, supra.