

# HEALTH LAW

## Update

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

### Focusing the Lens: OIG Issues Supplemental Compliance Program Guidance for Nursing Facilities

October 31, 2008

On September 30, 2008, the Office of Inspector General for the Department of Health and Human Services ("OIG") released the final Supplemental Compliance Program Guidance for Nursing Facilities (the "Supplemental Compliance Guidance").<sup>1</sup> The Supplemental Compliance Guidance augments the original OIG Compliance Program for Nursing Facilities which was released on March 16, 2000 (the "Compliance Guidance").<sup>2</sup>

#### **Background**

Beginning in 1998, the OIG turned its focus to preventing the submission of erroneous claims and combating fraud and abuse in Federal health care programs through voluntary compliance efforts. As a result, the OIG began developing compliance program guidelines for the health care industry and its various segments. Through the implementation of the compliance program guidelines, the OIG aims to encourage the development and use of internal controls by health care providers to better ensure adherence to applicable statutes, regulations and program requirements.

In 2000, the OIG released the original Compliance Guidance for nursing homes, which included the seven elements of a comprehensive compliance program such as developing and distributing written policies and procedures, designating a compliance officer and a compliance committee, and conducting effective training and education.<sup>3</sup>

Since the OIG originally published the Compliance Guidance, significant changes have taken place in the nursing home industry that alter the manner in which nursing services

<sup>1</sup> OIG Supplemental Compliance Program Guidance for Nursing Facilities, 73 Fed. Reg. 56832 (September 30, 2008).

<sup>2</sup> OIG Compliance Program Guidance for Nursing Facilities, 65 Fed. Reg. 14289 (March 16, 2000).

<sup>3</sup> For complete list of the seven components of a compliance plan see *supra* note 2.

are provided and reimbursed and that also heighten scrutiny of quality of care at nursing facilities. These changes have correspondingly shaped Federal enforcement in this area. In response to these changes, on April 16, 2008, the OIG released a Draft OIG Supplemental Compliance Program Guidance for Nursing Facilities (the "Draft Supplemental Guidance").<sup>4</sup>

During the notice and comment period for the Draft Supplemental Guidance, the OIG received comments from trade associations who sought clarification on the role of consultant pharmacists in assisting with appropriate medication management, the role of physicians in the compliance process, and various other contractual issues.<sup>5</sup> Responses to these questions are addressed in the final version of the Supplemental Compliance Guidance.

### **Fraud and Abuse Risks**

The final Supplemental Compliance Guidance addresses current fraud and abuse concerns for the enforcement community, including issues relating to quality of care, submission of accurate claims, violations of the Federal anti-kickback statute, and various additional risks including potential Stark law violations.

#### Quality of Care

The Supplemental Compliance Guidance recommends that nursing facilities make quality a priority and highlights the following risk areas associated with the delivery of quality healthcare to nursing facility residents.

- *Conditions of Participation:* The OIG emphasizes the importance of an organization's key members understanding regulations that govern participation in the Medicare and Medicaid programs. Specifically, the OIG recommends focused training for care providers, managers, administrative staff, officers, and directors in order to assist with delivering the necessary quality of care. Such training, in the OIG's view, should be ongoing and should continue after the "orientation" period.<sup>6</sup>
- *Sufficient Staffing:* Facilities that have systematically failed to provide adequate staffing levels to serve their residents are high on the OIG's radar screen. The OIG recommends that facilities continually monitor staffing patterns to ensure there is a sufficient number of staff with the level of competence necessary to handle the acuity levels of their residents.

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<sup>4</sup> Draft OIG Supplemental Compliance Program Guidance for Nursing Facilities, 73 Fed. Reg. 20680 (April 16, 2008).

<sup>5</sup> *Supra* note 1 at 56833. Several commentators also suggested legislative or policy change which was outside the scope of OIG's authority. In addition, the OIG specifically requested in the Draft Supplemental Guidance comments relating to specific measures of compliance program effectiveness tailored to nursing facilities. The OIG, however, did not receive any response to this call for comments; therefore they were not addressed in the final Compliance Guidance.

<sup>6</sup> *Supra* note 1 at 56836, fn 34.

- *Comprehensive Resident Care Plans:* Prior OIG reports have revealed that a significant number of resident care plans fail to address the residents' actual care needs.<sup>7</sup> The Supplemental Compliance Guidance, therefore, recommends an interdisciplinary approach to developing comprehensive resident care plans by including all disciplines involved in the resident's care. The OIG warns that failure to include the full clinical team in the planning process may increase the risk of providing inadequate care and medically unnecessary or inappropriate services. The Supplemental Compliance Guidance includes examples of how facilities can ensure an interdisciplinary and comprehensive approach to care planning, such as appropriate scheduling of meetings to accommodate the full interdisciplinary team and completing all clinical assessments before the meeting is convened.<sup>8</sup>

Another risk area identified by the Supplemental Compliance Guidance is the involvement (or lack thereof) of attending physicians in the resident care planning process. Although specific regulations govern the responsibilities of attending physicians in nursing facilities, the OIG emphasizes that nursing facilities also have an important role to play in ensuring appropriate physician supervision of resident care. The Supplemental Compliance Guidance recommends that nursing facilities meet with physicians to determine how best to involve them in the care planning process.<sup>9</sup>

- *Medication Management:* Failure of facilities to appropriately manage pharmaceutical services is another area that the OIG worries may seriously jeopardize resident safety. To avoid this risk, the Supplemental Compliance Guidance recommends that nursing facilities have in place proper medication management processes, including appropriate training of staff involved in pharmaceutical care, and that any irregularities in drug regimes be identified and dealt with promptly. The Supplemental Compliance Guidance also emphasizes the importance of the nursing facility and its consultant pharmacist working together to achieve proper medication management.
- *Appropriate Use of Psychotropic Medications:* Another risk area to which nursing facilities are especially vulnerable is inappropriate use of psychotropic medications, specifically the inappropriate use of chemical restraints and unnecessary drug usage. Nursing facilities should carefully monitor, document and review the use of each resident's psychotropic drugs. This process should be a collaborative effort involving the attending physician, medical director, consultant pharmacist and other providers

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<sup>7</sup> *Supra* note 1 at 56837.

<sup>8</sup> *Supra* note 1 at 56837. Other examples provided by the OIG include opening lines of communication between direct care providers and interdisciplinary team members, involving the resident and the residents' family members or legal guardian, and documenting the length and content of each meeting.

<sup>9</sup> *Supra* note 1 at 56837. The OIG provides examples of how to include attending physicians in the care planning process, which include scheduling meetings to discuss a particular resident's care plan, developing policies and procedures to facilitate participation by physicians who may not be physically present at the nursing facility on a daily basis, ensuring that physicians are required to attend and participate in such meetings, and improving communication with physicians by providing advance notice of care planning meetings.

involved in resident care. The Supplemental Compliance Guidance provides examples of useful compliance measures to address this risk, including educating providers on the monitoring and documentation process.

- *Resident Safety*: Since nursing facilities are legally bound to provide services free from any form of abuse or neglect, the Supplemental Compliance Guidance includes a discussion on the need to prevent harm caused to residents by staff or other residents. To promote resident safety, an effective compliance program should include policies and procedures to prevent, investigate, and respond to potential resident abuse resulting from staff, other residents, and unknown causes of abuse.<sup>10</sup> The OIG describes confidential reporting as a key component to an effective resident safety program and recommends that facilities encourage reporting through various means such as posters, brochures, online resources, and a reporting hotline.

To avoid resident-to-resident abuse, the OIG recommends targeted education relating to such abuse, thorough resident assessments, comprehensive care plans, periodic resident assessments, and proper staffing assignments. In order to avoid staff abuse of residents, the OIG recommends that an effective recruitment, screening, and training process be implemented by facilities to ensure that appropriate staff are retained. In addition, criminal background checks, verification of education, licensing, certifications, and a search of the appropriate state nursing aide registry should be conducted.

### Submission of Accurate Claims

With respect to the submission of accurate claims, the Supplemental Compliance Guidance identifies the following areas of concern and provides nursing facilities with protective measures to guard against the submission of inaccurate claims relating to these services.

- *Proper Reporting of Resident Case Mix by SNFs*: The OIG has become aware of instances in which skilled nursing facilities have improperly upcoded resident resource utilization group ("RUG") assignments. The OIG recommends an effective compliance program involve appropriate training of staff collecting resident case-mix data to ensure the accuracy of such data. In addition, as federal authorities continue to scrutinize quality-reporting data, nursing facilities should review this data on a regular basis to ensure accuracy and to manage any potential quality of care issues.<sup>11</sup>
- *Therapy Services*: A risk of false claims can result from the following practices: (i) the improper utilization of therapy services to inflate the severity of RUG classifications and obtain additional reimbursement; (ii) overutilization of therapy services billed on a fee-for-service basis to Part B under consolidated billing; and (iii) stinting on therapy services provided to patients covered by Part A.<sup>12</sup> Aside from the

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<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> *Supra* note 1 at 56840.

potential false claims liability, the potential health risk from the over- or under-utilization of therapy services exists because of the frailty of many residents. Therefore, the OIG strongly recommends that nursing facilities develop policies, procedures, and measures to ensure that residents are actually receiving medically necessary therapy services.<sup>13</sup>

- *Excluded Individuals and Entities:* The Supplemental Compliance Guidance observes that facilities should appropriately screen all potential owners, officers, directors, employees, contractors and agents to prevent hiring or contracting with an excluded person.<sup>14</sup> Furthermore, nursing facilities should ensure that they have measures in place to remove excluded individuals or entities.<sup>15</sup>
- *Restorative and Personal Care Services:* According to the Supplemental Compliance Guidance, the OIG has become aware of instances in which payment from Federal healthcare programs has been made for restorative and personal care services, even though such services were either not provided or were grossly unsatisfactory. Nursing facilities that fail to provide adequate restorative and personal care services run the risk of billing for services not rendered, leading to potential liability under fraud and abuse statutes and regulations.<sup>16</sup>

#### The Federal Anti-Kickback Statute

In the Supplemental Compliance Guidance, the OIG discusses the following known potential risks under the Federal anti-kickback statute (the "Anti-Kickback Statute").

- *Free Goods and Services:* Historically, the OIG has been concerned about the provision of free goods or services to an existing or potential referral source.<sup>17</sup> Examples include suspect arrangements involving free goods and services, such as pharmaceutical consultant services, medication management or supplies offered by a pharmacy, and equipment, computers or other software that have independent value to the nursing facility.<sup>18</sup>
- *Service Contracts:* In order to minimize the risk of violating the Anti-Kickback Statute in connection with contracts for non-physician services and supplies, the OIG suggests that nursing facilities periodically review these arrangements to confirm that (i) there is a legitimate need for such services or supplies; (ii) the services or supplies are actually provided and adequately documented; (iii) the compensation is at fair-market value in an arm's-length transaction; and (iv) the arrangement is not related in

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<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

<sup>17</sup> *Supra* note 1 at 56842.

<sup>18</sup> *Supra* note 1 at 56842. Other suspect arrangements include infection control; chart review or other services offered by laboratories or other suppliers; DME or supplies offered by DME suppliers for patients covered by the SNF Part A benefit; laboratory phlebotomist providing administrative services; hospice nurse providing nursing services for non-hospice patients; and registered nurse provided by a hospital.

any manner to the volume or value of Federal health care program business.<sup>19</sup> In addition, to minimize risk, nursing facilities should structure service arrangements to comply with the personal services and management contracts safe harbor, if possible.<sup>20</sup> Nursing facilities should also adopt policies and procedures to minimize the risk that decisions relating to pharmaceuticals are not tainted by kickbacks.<sup>21</sup>

With respect to physician services, the Supplemental Compliance Guidance advises that nursing facilities continue to monitor relationships involving physicians to ensure that they are not a means by which physicians are paid for referrals. Nursing facilities should monitor physician arrangements according to the same four criteria discussed above with regards to non-physician services. In addition, the OIG suggests that nursing facilities maintain contemporaneous documentation of the arrangement, including, for example, the compensation terms, time logs, and the basis for determining compensation. With respect to medical directorships, the OIG recommends that nursing facilities continually monitor the number of medical directors on staff to ensure it does not exceed what is required from a legitimate business standpoint. As with non-physician contracts, the OIG suggests that nursing facilities structure services arrangements with physicians to comply with the personal services and management contracts safe harbor whenever possible.

- *Discounts:* Nursing facilities should ensure that all discounts, including those received under a group purchasing organization ("GPO") contract, are properly disclosed and accurately reflected in their cost reports. In addition, the OIG warns nursing facilities against "swapping" by accepting the benefit of a lower price from a supplier or provider on an item that is covered by the facility's Part A per diem payment in exchange for referrals by the facility to the supplier or provider, such as for Part B business excluded from consolidated billing.
- *Hospices:* Under certain circumstances, nursing facilities may arrange for the provision of hospice services in the nursing facility. Therefore, nursing facilities should be aware of certain practices involving hospices that may be considered suspect under the Anti-Kickback Statute. These practices include a hospice providing free goods or goods below fair market value and a hospice paying room and board payments to a nursing facility in excess of what the nursing facility would have received directly from Medicaid had the patient not been enrolled in hospice.<sup>22</sup>
- *Reserved Bed Arrangements:* The OIG advises nursing facilities to monitor arrangements whereby hospitals provide remuneration to keep certain beds available for the hospital's patients, which may pose a risk under the Anti-Kickback Statute. The OIG provides examples of potentially problematic arrangements, such as paying

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<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> *Supra* note 1 at 56845. Further examples of suspect practices are provided at this citation. Also, the OIG recommends reviewing the OIG's Special Fraud Alert on Nursing Home Arrangements with Hospices, March 1998, for further guidance, available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/hospice.pdf>.

more than the actual cost to the nursing facility of holding an empty bed and paying for more beds than the hospital legitimately needs.<sup>23</sup> Reserved bed arrangements must be entered into only when there is a bona fide need to have the arrangement in place, not to secure future referrals.

### Other Risk Areas

The Supplemental Compliance Guidance addresses additional risk areas that nursing facilities should be aware of when drafting a compliance program, including:

- *Stark Law*: Although nursing services (including skilled nursing facility services covered by the Part A prospective payment system) are not designated health services ("DHS") for purposes of the federal physician self-referral statute (known as the "Stark Law"), nursing facilities that bill Part B for any DHS services pursuant to the consolidated billing rules are DHS entities and, therefore, must comply with the Stark Law. The OIG recommends that nursing facilities review closely their relationships with attending physicians who treat residents and with physicians who are nursing facility owners, investors, medical directors, or consultants. In addition, nursing facilities should enter into appropriate written arrangements with physicians, document reasonableness and fair market value for such services, and track non-monetary compensation (such as free parking or gifts) provided to such physicians.
- *Anti-Supplementation*: Nursing facilities must accept the applicable Medicare or Medicaid rate for covered payments and services. Supplemental payment is in violation of the nursing facilities' provider agreements.<sup>24</sup>
- *Medicare Part D*: Nursing facilities must not infringe on their residents' freedom of choice in selecting a Part D plan.<sup>25</sup>

### Other Compliance Considerations

The Supplemental Compliance Guidance emphasizes the importance of an organization promoting a culture of compliance.<sup>26</sup> Nursing facilities should adopt a code of conduct that articulates the organization's commitment to compliance.<sup>27</sup> The OIG also suggests the development of a "dashboard,"<sup>28</sup> which communicates to the board of directors and senior officers important compliance- and performance-based information.<sup>29</sup> The OIG

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<sup>23</sup> *Supra* note 1 at 56845. For example, nursing facilities may be billing for laboratory services, physical therapy services, occupation therapy services, among other DHS.

<sup>24</sup> *Supra* note 1 at 56486.

<sup>25</sup> *Supra* note 1 at 56487.

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> In footnote 131 of the Compliance Guidance, the OIG describes the "dashboard" as "an instrument that provides the recipient with a user-friendly (i.e., presented in an appropriate context) snapshot of the key pieces of information needed by the recipient to oversee and manage effectively the operation of an organization and forestall potential problems, while avoiding information overload."

<sup>29</sup> *Supra* note 1 at 56487.

believes that the dashboard, when used effectively, can be an effective tool for the implementation of the compliance program.

Nursing facilities should periodically review their compliance programs.<sup>30</sup> The Supplemental Compliance Guidance recommends that the review include an evaluation of the overall success of the program as well as the basic elements of a compliance program. The Supplemental Compliance Guidance also suggests reviewing quality of care corporate integrity agreements entered into between OIG and parties settling specific matters.<sup>31</sup>

### **Self-Reporting**

The OIG recommends to nursing facilities that if the compliance officer, compliance committee, or a member of the senior management discovers misconduct in the organization from a credible source, the nursing facility should report this misconduct to the appropriate Federal and State authority no later than sixty days after determining a violation has occurred.<sup>32</sup> The OIG advises that prompt reporting can provide evidence of good faith on the part of the nursing facility and display a commitment to working with governmental authorities to rectify the problem. Prompt reporting apparently will be considered as a mitigating factor by the OIG in determining administrative sanctions if an OIG investigation is pursued. To encourage providers to self-disclose, the OIG published the provider self-disclosure protocol in 1998<sup>33</sup> and released further refinements to the protocol in 2006<sup>34</sup> and 2008<sup>35</sup>. When reporting to the government, a nursing facility should, according to the Supplemental Compliance Guidance, provide relevant information regarding the alleged violations of the applicable federal and state law(s) and the potential financial or other impact of the alleged violation.

### **Conclusion**

In the Supplemental Compliance Guidance, the OIG reiterates the importance of nursing facilities establishing and maintaining effective compliance programs, especially "in today's environment of increased scrutiny of corporate conduct and increasingly large expenditures for health care."<sup>36</sup> The Supplemental Compliance Guidance provides nursing facilities with additional guidance on how to operate an effective compliance program and to ensure the highest quality of care is provided to its residents.

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<sup>30</sup> *Supra* note 1 at 56488. OIG states this is typically conducted on an annual basis.

<sup>31</sup> *Supra* note 1 at 56488. Other recommendations include evaluating whether there has been an allocation of adequate resources to compliance initiatives; whether there is a reasonable timetable for implementation of the compliance measures; whether the compliance officer and compliance committee have been vested with sufficient autonomy, authority, and accountability to implement and enforce appropriate compliance measures; and whether compensation structures create undue pressure to pursue profit over compliance.

<sup>32</sup> *Supra* note 1 at 56848.

<sup>33</sup> "Provider Self Disclosure Protocol," 63 Fed. Reg. 58399 (Oct. 30, 1998).

<sup>34</sup> "Open Letter to Health Care Providers," (Apr. 24, 2006) *available at* <http://oig.hhs.gov/fraud/docs/openletters/Open%20Letter%20to%20Providers%202006.pdf>

<sup>35</sup> "Open Letter to Health Care Providers," (Apr. 15, 2008) *available at* <http://oig.hhs.gov/fraud/docs/openletters/OpenLetter4-15-08.pdf>

<sup>36</sup> *Supra* note 1 at 56848.

If you should have any questions on the topics raised in this *Health Law Update*, please contact any of the attorneys in our Healthcare Industry Practice Area listed below.

### Bass, Berry & Sims Healthcare Attorneys

**H. Stanford Adams, Jr.**  
(615) 742-7775  
[sadams@bassberry.com](mailto:sadams@bassberry.com)

**Philip F. Berg**  
(615) 742-7908  
[pberg@bassberry.com](mailto:pberg@bassberry.com)

**Valere B. Fulwider**  
(615) 742-7742  
[vfulwider@bassberry.com](mailto:vfulwider@bassberry.com)

**Anna Grizzle**  
(615) 742-7732  
[agrizzle@bassberry.com](mailto:agrizzle@bassberry.com)

**Clevonne M. Jacobs**  
(615) 742-7769  
[vjacobs@bassberry.com](mailto:vjacobs@bassberry.com)

**David King**  
(615) 742-7890  
[dking@bassberry.com](mailto:dking@bassberry.com)

**T. Scott Noonan, Co-Chair**  
(615) 742-6273  
[snoonan@bassberry.com](mailto:snoonan@bassberry.com)

**Cynthia Y. Reisz**  
(615) 742-6283  
[creisz@bassberry.com](mailto:creisz@bassberry.com)

**Catherine J.B. Sloan**  
(615) 742-7789  
[csloan@bassberry.com](mailto:csloan@bassberry.com)

**Elizabeth S. Warren**  
(615) 742-7719  
[ewarren@bassberry.com](mailto:ewarren@bassberry.com)

**Kevin L. Alonso**  
(615) 742-7913  
[kalonso@bassberry.com](mailto:kalonso@bassberry.com)

**Krista Thornton Cooper**  
(615) 742-7734  
[kcooper@bassberry.com](mailto:kcooper@bassberry.com)

**Nesrin E. Garan**  
(615) 742-7861  
[ngaran@bassberry.com](mailto:ngaran@bassberry.com)

**Elisa E. Harris**  
(615) 742-6553  
[eharris@bassberry.com](mailto:eharris@bassberry.com)

**J. James Jenkins, Jr.**  
(615) 742-6236  
[jjenkins@bassberry.com](mailto:jjenkins@bassberry.com)

**Leslie Maclellan**  
(615) 742-7818  
[lmaclellan@bassberry.com](mailto:lmaclellan@bassberry.com)

**Brenda N. Phillips**  
(615) 742-6237  
[bnphillips@bassberry.com](mailto:bnphillips@bassberry.com)

**Brian D. Roark**  
(615) 742-7753  
[broark@bassberry.com](mailto:broark@bassberry.com)

**Danielle M. Sloane**  
(615) 742-7763  
[dsloane@bassberry.com](mailto:dsloane@bassberry.com)

**Douglas M. Wolford**  
(615) 742-7917  
[dwolford@bassberry.com](mailto:dwolford@bassberry.com)

**H. Lee Barfield, II**  
(615) 742-6202  
[lbarfield@bassberry.com](mailto:lbarfield@bassberry.com)

**Mary Beth Fortugno**  
(615) 742-7739  
[mfortugno@bassberry.com](mailto:mfortugno@bassberry.com)

**Pooneh Ghiassi**  
(615) 742-7782  
[pghiassi@bassberry.com](mailto:pghiassi@bassberry.com)

**Angela Humphreys**  
(615) 742-7852  
[ahumphreys@bassberry.com](mailto:ahumphreys@bassberry.com)

**Seth A. Killingbeck**  
(615) 742-7707  
[skillingbeck@bassberry.com](mailto:skillingbeck@bassberry.com)

**Claire F. Miley**  
(615) 742-7847  
[cmiley@bassberry.com](mailto:cmiley@bassberry.com)

**Shannon Pinkston**  
(615) 742-7727  
[spinkston@bassberry.com](mailto:spinkston@bassberry.com)

**Scott B. Shanker**  
(901) 543-5932  
[sshanker@bassberry.com](mailto:sshanker@bassberry.com)

**Leigh Walton, Co-Chair**  
(615) 742-6201  
[lwalton@bassberry.com](mailto:lwalton@bassberry.com)

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315 Deaderick Street • Suite 2700 • Nashville, TN 37238-3001 • (615) 742-6200

The Tower at Peabody Place • 100 Peabody Place, Suite 900 • Memphis, TN 38103-3672 • (901) 543-5900

1700 Riverview Tower • 900 S. Gay Street • Knoxville, TN 37902 • (865) 521-6200