June 2, 2008

The Honorable Daniel R. Levinson  
Office of Inspector General  
U.S. Department of Health and Human Services  
Attention: OIG-126-PN  
Room 5246  
Cohen Building  
330 Independence Ave., SW  
Washington, DC 20201  

Re: Draft OIG Supplemental Compliance Program Guidance for Nursing Facilities

Honorable Daniel R. Levinson:

The American Health Care Association (AHCA) appreciates the opportunity to comment on the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG) Draft OIG Supplemental Compliance Program Guidance for Nursing Facilities (Draft Supplemental Guidance) (73 Federal Register 20680 [April 16, 2008]). AHCA represents more than 10,000, non-profit and proprietary facilities dedicated to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to more than 1.5 million or our nation’s frail, elderly and disabled citizens who are in nursing facilities (NF), assisted living residences, subacute centers and homes for persons with mental retardation and developmental disabilities. The vast majority of AHCA’s member providers participate in the Medicare and/or Medicaid programs. Accordingly, AHCA and its members have a direct interest in OIG’s efforts to revise and update the current compliance guidance for nursing facilities (NFs).

AHCA’s Commitment to Quality:

AHCA is proud to play a continued and active role in improving the quality of care in NFs. Long before the words quality and transparency were the catch words of the federal government and their oversight of healthcare, they were truly the compass for AHCA and its member facilities. Our Association’s long-held mission clearly states, “our goal is to provide a spectrum of patient/resident-centered care and services which nurture not only the individual’s health, but their lives as well, by preserving their connections with extended family and friends, and promoting their dignity, respect, independence, and choice.”

AHCA has been working diligently to change the national debate from merely regulatory compliance to quality of care in long term care (LTC) settings. We have been actively engaged in a broad range of activities which seek to enhance the overall performance and excellence of not only NFs, but the entire LTC profession.

In recent years, the Online Survey, Certification and Reporting (OSCAR) data tracked by the Centers for Medicare & Medicaid Services (CMS) clearly points to improvements in patient outcomes, increases in overall direct care staffing levels and significant decreases in quality of care survey deficiencies in our nation’s NFs.
AHCA also recognizes the vital link between patient and family satisfaction, and has urged all of its member facilities to conduct such assessments for more than a decade. In recent years, we have encouraged facilities to use a nationally-recognized company, My InnerView (MIV), to conduct consumer and staff satisfaction surveys to establish a national database for benchmarking and trend analysis. In May 2008, MIV released its third independent NF survey that indicates up to 82 percent of consumers (patients and their families) report that their satisfaction is either "excellent" or "good," and that they would recommend the NF to others. As well, 70 percent of NF employees said they were satisfied with their facility — up 2 percent from last year.

Positive trends related to quality are also evidenced by profession-based initiatives including the Quality First and the Advancing Excellence in America’s Nursing Homes campaigns — both of which are having a significant impact on the quality of care and quality of life for the frail, elderly and disabled citizens who require nursing facility care. Quality First, established in 2002, set forth seven core principles that reflect LTC providers’ commitment to continuous quality improvement, leadership and transparency.

AHCA also is a founding partner of the Advancing Excellence in America’s Nursing Homes campaign, which is a coordinated initiative among providers, caregivers, consumers, government and others that promote quality around eight measurable goals. This campaign takes a step further than previous initiatives. It not only measures outcomes, but it establishes numerical targets and benchmarks. It also promotes best practices and evidence-based processes that have been proven to enhance patient care and quality of life.

AHCA members also participated in the recent Health Care Compliance Association (HCCA) and the OIG Roundtable, Driving for Quality in Long-Term Care: A Board of Directors Dashboard. The Roundtable provided AHCA members a great opportunity to educate both the federal government and other stakeholders on our profession’s current quality improvement efforts and initiatives, and to reevaluate LTC company quality dashboards already implemented and utilized by some of AHCA member facilities.

In sum, the increased focus on resident-centered care, actual care outcomes, increased transparency and public disclosure, enhanced stakeholder collaboration and the dissemination of best practices models of care delivery is moving the LTC profession in the right direction. AHCA remains committed to its long-standing practices and programs which seek to improve the quality of care for our nation’s most frail, elderly and disabled who require LTC services, and enhance the quality of life for patients and caregivers alike.

**General Comments:**

As stated in our February 25, 2008, comments to the OIG re: Solicitation of Information and Recommendations for Revising the Compliance Program Guidance for Nursing Facilities, AHCA commends the OIG for detailing the benefits of a compliance program, and appreciates the OIG’s attempts in the Draft Supplemental Guidance to better articulate the parameters for how the agency determines the effectiveness of a NF’s compliance program (i.e., demonstrating the NF’s commitment to honest and responsible corporate conduct; increasing the likelihood of preventing unlawful and unethical behavior, or identifying and correcting such behavior at an early stage; encouraging employees and others to report potential problems, etc.)
We are also pleased that “OIG recognizes the complexities of the nursing facility industry and the differences among facilities;” and that the agency “does not intend this supplemental guidance to be a ‘one-size-fits-all guidance.’” Instead, “OIG strongly encourages nursing facilities to identify and focus their compliance efforts on those areas of potential concern or risk that are most relevant to their organizations.” We take these statements as implying that NFs may undertake elements of the compliance program on a phased in basis as is practical and consistent with the organization’s overall goals and the availability of limited resources.

We are concerned; however, that despite the OIG’s insistence that the Draft Supplemental Guidance “will provide voluntary guidelines to assist nursing facilities, in identifying significant risk areas and in evaluating and…refining ongoing compliance efforts,” it actually expands the current survey, certification and enforcement standards outlined in the Omnibus Budget Reconciliation Act of 1987 (OBRA’87) and CMS’ respective State Operation Manuals (SOMs) absent rulemaking, and allows the OIG to enforce these new standards, not through the CMS survey process, but through OIG investigation. Specifically, many of the “suggestions” listed under III. Fraud and Abuse Risk Areas extend the current requirements, blurring the lines between the NFs responsibility to implement appropriate policies/procedures, and the OIG’s suggestion to create a system of checks and balances that comprises an effective compliance program. Further, we are confused by the fact that many of the items discussed under IV. Other Compliance Considerations seem to offer only the most basic and fundamental principles underlying the design and implementation of a compliance program, and it is difficult to understand how this information supplements or changes the original Corporate Compliance Guidance for NFs first published in 2000.

Specific Comments:

III. Fraud and Abuse Risk Areas:

Quality of Care: AHCA believes that NFs must have the flexibility to continue to address quality of care issues through their quality assessment and assurance committees, by the management and clinical professionals most qualified and best equipped to identify and address resident care. The OIG continues to rely on the comprehensive survey, certification and enforcement scheme, mandated by OBRA ’87 that, for the most part, everyone agrees is flawed, to identify instances of poor quality of care in nursing facilities. Today, we know far more about promoting quality, and we have better tools with which to measure it than we did twenty years ago. We need to intelligently work together to change the regulatory process to allow and encourage us to use what we have learned—to place quality over process, care over procedure and most importantly, put patients at the forefront. We must revamp the system to ensure that the quality of life of the residents is emphasized, consistent with the intent of OBRA ’87. Maybe it’s time to think about using other quality indicators beyond just survey, such as the Quality First/Advancing Excellence trending data on restraints, pain, pressure ulcers, etc.?

1. Sufficient Staffing: AHCA has long recognized that the provision of high quality LTC and services is dependent upon a stable, well-trained workforce. However, America’s LTC system is currently suffering from a chronic supply and demand problem when it comes to our labor force. Addressing both of these challenges is the only real means to sustain the provision of high quality LTC. While efforts to recruit
and train new qualified LTC workers are costly, our profession has been aggressively pursuing nurses and caregivers.

AHCA agrees with the OIG’s assertion that “NFs...[must] assess their staffing patterns...to evaluate whether they have sufficient staff who are competent to care for the unique acuity levels of their residents.” AHCA supports the creation of an aggregate optimal staffing standard. We offer these guiding principles for the creation and maintenance of NF staffing standards:
(a) Any standard enacted by legislation or adopted by regulation must impact all patients regardless of payor source. Specifically, for the purpose of the legislative discussions—any staffing standard cannot be “Medicare specific.”
(b) States must fully fund any staffing standard in their Medicaid reimbursement methodologies.
(c) AHCA supports a fully funded aggregate optimal staffing standard to provide quality care for our patients.
(d) The Administration and the Congress must join providers in a national crusade to recruit, retain and train thousands of Certified Nursing Assistants (CNA) for the LTC profession.
(e) The profession and policy makers must work together to develop dependable and defensible data collection systems to establish appropriate staffing standards and to monitor them.

2. Comprehensive Resident Care Plans: We agree that the current Medicare/Medicaid regulations require NFs to develop a comprehensive care plan for each resident, but the OIG’s “suggestions” in the Draft Supplemental Guidance far exceed the current federal standards. Further, OBRA’87 mandates that NFs use the Resident Assessment Instrument (RAI) to identify residents’ strengths, weaknesses, preferences and needs in key areas of functioning. The minimum data set (MDS) also is a component of the RAI, which contains a standardized set of essential clinical and functional status measures. Triggers from the MDS identify conditions for additional evaluation, through the use of the Resident Assessment Protocols (RAPs), which lead to the development of the resident’s individual care plan. AHCA is concerned that the OIG is using the RAPs for comprehensive care planning when there are currently no plans to update the RAPs in tandem with the updated MDS 3.0, that will be implemented in 2009.

3. Appropriate Use of Psychotropic Medications: AHCA believes that the OIG must look at the use of psychotropic medications across all health care settings, and not just focus on the use of psychotropic medication use in NFs. It is important that the OIG recognize that changes in medications occurring in the hospital setting can greatly impact the geriatric patient in the nursing home.

5. Resident Safety:
   (c) Staff Screening: AHCA wants to remind the OIG that the LTC profession needs the tools and access to critical data to be able to undertake diligent compliance activities in the most comprehensive and efficient means possible. In this regard, AHCA believes that
the OIG must work with the CMS, other federal agencies and LTC providers, as necessary, to adopt or seek legislation to establish a:

i. national registry (or multi-state access to state registries) of certified nurse aides so that employers can determine whether a prospective applicant has been involved anywhere with documented resident neglect, abuse or misappropriation of resident property; and

ii. nationwide criminal background check system for health care workers and provide funding for and reimbursement for use of that system.

A. Submission of Accurate Claims:

1. Proper Reporting of Resident Case-Mix by SNFs: The Resource Utilization Groups (RUGs) flow from the MDS and drive the Medicare reimbursement to NFs under the Prospective Payment System (PPS). NF residents are initially assigned to major categories of RUGs, and then further classified into minor RUG categories, based on the MDS assessment. According to an OIG report, Nursing Home Resident Assessment: Resource Utilization Groups (OEI-02-99-00041), the OIG states that “46 percent of the residents [in] the nursing home coded the resident in a RUG that was higher than our reviewer. For the remaining 30 percent, the nursing home coded the residents in a RUG that was lower than our reviewer. We tested the potential effect on reimbursement; it was not statistically significant.” If the OIG is going to review for “upcoding,” it must also review for “undercoding.”

3. Screening for Excluded Individuals and Entities: AHCA believes that the OIG should update and provide more specific information on the OIG’s Exclusion program in the revised guidance. Since the original compliance guidance was released, there have been some reoccurring problems such as difficulties: 1) tracking nurses; 2) tracking corporations unless you know the exact spelling and formal company name; or 3) incorporating the various state lists with the federal OIG list. It would be helpful to give more detailed information and guidance in this area; perhaps modeled on the specific guidance in the OIG Special Advisory on the effect of federal exclusion, particularly with regard to those licensed/certified individuals who have resolved state sanctions but remain ineligible for federal reinstatement.

4. Restorative and Personal Care Services: AHCA believes that this is another area that the OIG needs to consider looking at transition of care issues from one setting of care to another to really understand what conditions the resident actually has on admission and how those conditions are being addressed.

B. The Federal Anti-Kickback Statute:

5. Reserved Bed Arrangements: In the original Corporate Compliance Guidance for NFs, Footnote 70, the OIG refers to bed reservation agreements. Clearly, these agreements need to be at fair market value (FMV). However, the Draft Supplemental Guidance has more specific language that would prevent the NF from holding a bed at the FMV rate. If this is the case, what would be the incentive for a NF to hold a bed? If the bed reservation agreement is needed
because the local hospital needs beds but the facility is otherwise full, why would the NF be prevented from charging a FMV rate?

IV. Self-Reporting: The OIG released its recent Open Letter to Health Care Providers, which states that “A provider’s submission of a complete and informative disclosure, quick response to OIG’s requests for further information, and performance of an accurate audit are indications that the provider has adopted effective compliance measures.” Further, “providers who disclose in good faith, fully cooperate with OIG, and provide requested information in a timely manner will generally not be required to enter into Corporate Integrity or Certification of Compliance Agreements with OIG.” AHCA is optimistic that the OIG will make good on it’s promise that in instances of voluntary disclosure, the agency will acknowledge “good faith efforts,” and these efforts will be recognized in reduced or eliminated sanctions and penalties, including foregoing of the imposition of a Corporate Integrity Agreement (CIA) or Certification of Compliance Agreement.

Again, we appreciate the opportunity to provide these comments regarding the OIG’s Draft OIG Supplemental Compliance Program Guidance for Nursing Facilities. If you should need any additional information or materials, please feel free to contact me directly.

Sincerely,

Bruce Yarwood
AHCA, President and CEO