



Testimony before the

Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives

**“In the Hands of Strangers:
Are Nursing Home Safeguards
Working?”**

Testimony of
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Good morning, Chairman Stupak and distinguished members of the Committee. I am Lewis Morris, Chief Counsel to the Inspector General of the Department of Health and Human Services. I appreciate the opportunity to appear before you today to discuss our work related to nursing home quality issues. The Office of Inspector General (OIG) shares your commitment to ensuring the well-being of nursing home residents and the proper oversight of programs designed to serve this vulnerable population. I look forward to discussing with you today some of the ways OIG seeks to fulfill these goals.

A large portion of OIG's work in the area of nursing homes is aimed at identifying and recommending methods to reduce inappropriate payments, close programmatic loopholes, and evaluate payment and pricing methods to ensure that Medicare and Medicaid receive value for program expenditures. Ensuring that nursing homes receive appropriate payment for quality services not only promotes the interest of taxpayers, but also protects nursing home residents. Fraudulently billed services drain the Medicare and Medicaid program funds, as well as residents' personal savings in the form of excessive copayments and deductibles.

In addition to promoting financial integrity, Inspector General Daniel Levinson has made improving the quality of care a top priority for OIG, because behind every claim for reimbursement is a program beneficiary. In particular, OIG has long been concerned with the quality of care rendered in nursing facilities. OIG's efforts to improve quality of care in nursing homes involve three strategies: (1) the evaluation of the systems used to oversee quality of care, (2) the investigation and prosecution of cases of egregiously substandard care, and (3) the provision of guidance to the long term care industry in order to encourage program compliance and high quality care.

In my testimony today, I will describe the studies, enforcement actions, initiatives, and Government-industry collaboration that OIG has undertaken to identify ways to improve the quality of care provided to our beneficiaries. I will conclude my testimony by offering several recommendations that we believe will advance this objective.

OIG's Assessment of the Programs and Systems for Ensuring Quality of Care

Nursing homes have been a particular focus for OIG over the past decade because of the increasing number of beneficiaries living in long-term care facilities and the unique vulnerabilities associated with this population. Nursing home residents not only rely on facilities to provide them with proper medical care, but also depend on them to provide the basic life necessities, such as proper nutrition, safe living environments, and any assistance with their

activities of daily living. Unfortunately not all nursing homes consistently provide the level and amount of care, support, and assistance necessary to adequately promote and sustain their residents' health and quality of life.

The oversight and regulation of nursing homes that participate in the Medicare and Medicaid programs are primarily the responsibility of the Centers for Medicare & Medicaid Services (CMS) and State agencies through their survey and certification efforts. However, OIG work has determined that CMS and State mechanisms to identify and correct quality-of-care problems in nursing homes do not always function as designed. In addition, OIG has identified shortcomings in the methods used by nursing homes to screen prospective employees to ensure that potentially abusive care workers are not hired. Such shortcomings can result in quality-of-care problems not being detected timely, the continued Government payment to poorly performing nursing homes, and the hiring of staff with a history of mistreating residents.

Effectiveness of CMS and State Oversight of Nursing Homes

CMS establishes quality-of-care standards and conditions of participation for the Medicare and Medicaid programs. Through a system of periodic facility inspections and individual complaint investigations, CMS and the State agencies assess nursing home performance and determine whether to certify, or recertify, facilities for participation in Medicare and Medicaid. As part of this process, surveyors identify whether facilities are falling short in certain quality-of-care measures, such as providing proper treatment to prevent or treat pressure sores, appropriate treatment for mental or psychosocial functioning, adequate supervision and/or devices to prevent accidents, proper nutrition and fluid intake, and appropriate levels and types of medication. Nursing facility standard surveys are required by statute to be conducted at least every 15 months, and the statewide average interval between surveys of facilities cannot exceed 12 months.

When facilities are found to be out of compliance for designated time periods or have deficiencies that put residents in immediate jeopardy, States are required to refer the case to CMS for enforcement action. In particularly egregious cases of noncompliance, enforcement actions are mandatory. Such actions can include corrective action plans, civil monetary penalties (CMP), required changes in management, denial of payment for new admissions, or termination of a facility's Medicare and/or Medicaid contract. OIG reviews of the use of these processes indicate that CMS and States do not always effectively or fully use existing tools and authorities to identify, monitor, or bring back into compliance nursing homes that do not meet required quality standards.

For instance, both OIG and Government Accountability Office (GAO) work identified inaccurate and inconsistent deficiency citations as well as delayed responses to complaints. To illustrate, in a March 2003 report, OIG reviewed trends in survey and certification deficiencies, as well as the effectiveness and consistency of the survey and certification process. This work identified inconsistencies in the manner in which deficiencies were cited by the various State survey agencies. These inconsistencies resulted from variations in survey focus, unclear guidelines, lack of a common review process for draft survey reports, and high turnover of surveyor staff. In a 2007 report, GAO found that State surveys sometimes understate the extent of serious care

problems that cause actual harm or place residents in immediate jeopardy, that there continued to be significant variation across States in their citation of these types of deficiencies, and that there continue to be weaknesses in Federal oversight of State survey activities.

OIG has also assessed the implementation of States' oversight of abuse- and neglect-reporting requirements. The Omnibus Budget Reconciliation Act of 1987 requires States to provide timely reviews of complaints and to promptly investigate allegations of neglect, abuse, and misappropriation of resident property. In a July 2006 evaluation, OIG found that State agencies did not investigate some of the most serious nursing home complaints within the required timeframe and that CMS's oversight of nursing home complaint investigations is limited. CMS has since updated the State Performance Standard, which it uses to hold State agencies accountable for the timeliness of their complaint investigations, to make the timeframe consistent with the 10-day requirement in its "State Operations Manual."

When facilities are found to be out of compliance with quality standards, CMPs are an important element of an effective enforcement strategy, especially in cases when nursing homes are out of compliance for designated time periods or have deficiencies that put residents in immediate jeopardy. Unfortunately, this tool has not been used to its full potential. For example, in an April 2005 report, OIG found that although \$81.7 million in CMPs were imposed during 2000 and 2001, CMS had collected only \$34.6 million (42 percent) by the end of 2002. The unpaid portion included reductions resulting from compromises with nursing homes waiving their right to appeal, settlements and reductions resulting from appeals, payment delays caused by appeals or bankruptcy proceedings, and nonpayment of collectible CMPs. We found that CMS did not utilize the full dollar range allowed for CMPs and that impositions were frequently at the lower end of the allowed ranges. Low imposition rates and slow and/or difficult collection efforts may minimize the coercive remedial effect that CMPs ultimately have on noncompliant facilities.

Denying payment for new admissions is another powerful tool that CMS can use to protect beneficiaries while bringing nursing homes into compliance. CMS must impose this sanction, or a more severe penalty, on homes that remain out of compliance with Federal standards for more than 3 months or when three consecutive surveys detect substandard quality of care. When properly implemented, the sanction works to divert new patients to more suitable facilities until such time as the deficient nursing home improves. OIG recently completed a study that found processing errors in nearly three quarters of the instances in which CMS attempted to impose the sanction on substandard nursing facilities. In rooting out the cause of these errors, we identified numerous communication breakdowns between CMS and the contractors that process Medicare claims. We proposed several solutions to improve communication and accountability, and CMS indicated that it will implement changes to ensure more effective use of this remedy.

In the most egregious cases, termination of the nursing home may be the only effective means of protecting nursing home residents from danger. When a facility either fails to correct an immediate jeopardy situation, an instance involving actual or potential for death or serious injury, or fails for two successive surveys to correct deficiencies that involve any level of actual harm to residents, termination from the Federal health care programs is mandatory. In a report issued in May 2006, OIG found that for the majority of cases requiring mandatory termination of

nursing facilities, CMS failed to apply this sanction because of both late case referrals by States and CMS staff's reluctance to impose this severe remedy. Significantly, OIG found that all of the facilities that failed to implement the termination remedy in a timely manner were subsequently cited for noncompliance that was serious enough to require referral to CMS for enforcement action. Ten of the 29 facilities that CMS failed to terminate were cited with immediate jeopardy deficiencies and 1 facility was cited with an immediate jeopardy deficiency four times in consecutive years. Fourteen of the 29 facilities reviewed had deficiencies that were sufficiently serious to warrant referral to CMS for enforcement in three or more subsequent surveys. To address these problems, CMS has committed to taking a number of actions, including implementing both case- and incident-tracking systems, which should help to ensure that enforcement actions are properly taken when warranted and implemented more timely.

Moving forward, OIG is continuing its oversight reviews of issues such as the use of antipsychotic drugs in nursing homes, the appropriateness of psychotherapy services provided to Medicare beneficiaries in nursing homes, the impact of transitioning into Part D on nursing home residents' ability to obtain needed drugs, the nature and extent of survey and certification deficiencies in nursing homes and patterns of repeated noncompliance with Federal quality standards, and whether States are correctly applying civil monetary funds to programs that protect the health or property of nursing home residents.

Nursing Home Screening of Employees

Residents of nursing homes have a right to live in safe and secure environments, free from abuse at the hands of their caregivers. OIG has found, however, that States and nursing facilities currently depend on a patchwork of data sources to identify persons posing possible threats of elder abuse in nursing homes and to minimize and prevent such abuse.

For instance, nursing homes should screen their staff and prospective staff against the OIG's List of Excluded Individuals and Entities (LEIE). Under a congressional mandate (sections 1128 and 1156 of the Social Security Act), OIG established a program to exclude individuals and entities affected by these authorities. Once a person is excluded, Federal health care programs will not pay for items or services furnished by that person. Screening staff against the LEIE helps ensure that a nursing home does not employ an excluded person and that it does not bill Federal health care programs for any excluded person's work.

Exclusions related to quality of care arise in the following situations; therefore, checking against the LEIE will help nursing facilities to ensure that the following types of individuals are not employed:

- OIG must exclude any person convicted of an offense related to the abuse or neglect of a patient in connection with the delivery of health care;
- OIG may exclude any person whose license to practice health care has been revoked or suspended for reasons bearing on the person's professional competence or professional performance;

- OIG may exclude any person who has furnished items or services to patients: (1) that are substantially in excess of the needs of such patients or (2) that fail to meet professionally recognized standards of care; and
- OIG may exclude anyone who has caused the submission of false or fraudulent claims to a Federal health care program.¹

In addition to using the LEIE, nursing facilities should screen prospective nurse aides and other nonlicensed direct care staff through the use of the State nurse aide registries. Federal regulations prohibit facilities from employing individuals who have been found guilty by a court of law or who have had findings entered into the registry for abuse, neglect, or mistreatment of residents or misappropriation of their property. Each State is required to establish and maintain a registry of nurse aides, which includes information on any finding by the State certification agency of abuse, neglect, or misappropriation of property belonging to the elderly.

In a July 2005 report, OIG found that although most facilities check their State nurse aide registries prior to employing an individual, they do not routinely check registries in other States, thereby potentially jeopardizing the safety of their residents. Additionally, while most States require criminal background checks, the scope of these checks varies widely. Although some of the nursing facilities in our sample conducted more comprehensive checks than required by their State laws, about half of the background checks performed were limited in scope, e.g., limited to one State. Additionally, in a February 2005 report, OIG examined the accuracy of nurse aide registries maintained by States and found that some States failed to adequately update registries with information on substantiated adverse findings against nurse aides. In fact, some individuals with criminal records in one State were certified in other States and therefore still able to have access to residents.

Without accurate nurse aide registry information, nursing homes may inadvertently hire aides who have committed criminal offenses, such as abuse, neglect, and theft, which place residents at considerable risk. To reduce the potential risk to residents, OIG recommended that CMS seek legislative authority to create a national nurse aide registry and to consider developing a Federal requirement for comprehensive criminal background checks.

Pursuant to section 307 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, CMS implemented a seven-State criminal background check pilot program. The purpose of this pilot is to determine effective and efficient methods for conducting State and national background checks and searches of relevant registries for screening prospective direct care employees in nursing homes and other long-term care facilities. Funding for the program ended in September 2007 and an evaluation of the pilot is expected to be completed in the near future.

¹ This provision parallels the False Claims Act and is implicated in any case in which the Government is asserting a failure-of-care theory in a civil case.

OIG Quality-of-Care Investigations and Enforcement

As previously described, the survey and certification process provides several mechanisms for the identification of quality-of-care deficiencies and the enforcement of nursing home standards through the use of remedies such as corrective action plans, CMPs, suspension of intake of new Medicare and Medicaid patients, and required changes in management. However, in some cases, the quality of care is so deplorable that these types of remedies are not sufficient. In such instances, the Department of Justice (DOJ), OIG, State Medicaid Fraud Control Units (MFCU), and other law enforcement partners have used the criminal and civil fraud statutes to pursue cases of substandard care. Under the False Claims Act, the Government is authorized to collect substantial penalties against anyone who has knowingly caused the submission of false or fraudulent claims to the Federal Government.

The predominant criminal and civil fraud theories—medically unnecessary services and “failure of care”—rely on the submission of a claim for reimbursement to the Government to establish jurisdiction over the provider. The first theory is based on the fact that Medicare and Medicaid cover only costs that are reasonable and necessary for the diagnosis or treatment of illness or injury. When medically unnecessary services are provided and billed to Federal health care programs, the claims are fraudulent, the patient is unnecessarily exposed to risks of a medical procedure, and the Federal health care programs incur needless costs. The second theory of liability involves the provision of care that is so deficient that it amounts to no care at all. This theory derives from the concept commonly applied in the financial fraud context, which subjects providers to liability for billing Government programs for services that were not actually rendered as claimed. The Government has pursued this civil cause of action only in cases that involve systemic and widespread problems of quality or significant harm to patients.

Prosecuting Providers of Substandard Care

Pursuant to the Deficit Reduction Act of 2005, OIG has heightened its collaborative efforts with State and local law enforcement entities. For example, in 2007, OIG worked 534 cases jointly with State MFCUs. We also continue our close work with DOJ pursuing failure-of-care cases under the Federal False Claims Act. For example, during 2007, we settled cases with two nursing home chains resulting in quality-of-care CIAs covering all of the facilities within those chains. Both cases involved OIG attorneys and special agents, Assistant United States Attorneys, trial attorneys from DOJ, and attorneys and investigators from State MFCUs. This level of coordination has become the standard for quality-of-care work.

The 2007 settlement with Ciena Healthcare Management, Inc., a provider of management services to 32 skilled nursing facilities located throughout the State of Michigan, provides a recent example of a failure-of-care case. In this case, the United States and the State of Michigan alleged that the defendants violated the False Claims Act by submitting claims to Medicare and Medicaid for services at four Ciena facilities that failed to meet the following resident needs: (1) resident nutrition and hydration, (2) assessment and evaluation, (3) care planning and nursing interventions, (4) medication management, (5) fall prevention and management, and (6) pressure ulcer care. Under the settlement agreement, the defendants agreed

to pay the United States \$1.25 million and enter into a chain-wide quality-of-care Corporate Integrity Agreement (CIA) that covers all 32 Ciena facilities.²

In another example, in 2005, the Government settled a False Claims Act case with Life Care of Lawrenceville, a Georgia nursing home, for \$2.5 million. Many of the problems at Life Care of Lawrenceville were related to chronic understaffing. Among the examples of poor care alleged by the Government, a resident on coumadin, a blood-thinning medication, died of toxic poisoning because the facility staff failed to check his blood-clotting times. Another resident allegedly fell four times during her 4-month stay and fractured and refractured her hip. Still another resident allegedly developed maggots in her mouth and died of larvae infestation because the facility staff failed to provide basic oral hygiene care. Life Care and OIG entered into a quality-of-care CIA for the Lawrenceville facility.

To further illustrate, Federal prosecutors in Missouri charged American Healthcare Management (AHM), a long-term care facility management company, its Chief Executive Officer, and three nursing homes with criminal conspiracy and health care fraud based on their imposition of budgetary constraints that prevented the facilities from providing adequate care to residents. The investigation found that numerous residents suffered from dehydration and malnutrition, went for extended periods of time without cleaning or bathing, and contracted preventable pressure sores. In 2005, the corporate defendants were convicted and fined, entered into a False Claims Act settlement of \$1.25 million, and agreed to be excluded. The primary owner was convicted of a false statement misdemeanor offense, was sentenced to 2 months incarceration, and agreed to be excluded for 20 years. Finally, in February 2007, AHM's former CEO was sentenced to 18 months of incarceration and fined \$29,000.

In a final example, Ronald Reagan Atrium Nursing Home, a Pennsylvania nursing home, and its owner/operator were convicted in 2007 of health care fraud and false statements after a 6-week trial in which evidence showed that employees were directed to falsify medical records to conceal the nursing home's deficiencies. As a result of the scheme, the nursing home billed Medicare and Medicaid for services provided to residents, most of whom suffered from Alzheimer's disease, that either were not provided or were substandard. The nursing home, which is now closed, was ordered to pay a \$490,000 fine. The owner/operator was sentenced to 5 years in prison and ordered to pay a \$50,000 fine. The investigation also revealed, that although the nursing home claimed that it did not have the ability to pay food and pharmaceutical vendors, it donated \$1 million to another nonprofit company, which, in turn, paid the owner/operator an exorbitant salary.

Excluding Caregivers and Owners

Exclusion actions fall under two broad categories: (1) derivative (based on an action by another Government agency or tribunal) and (2) affirmative (initiated independently by OIG). OIG uses these exclusion authorities to build upon and supplement enforcement actions taken by States, CMS, and DOJ. To provide protection to Federal health care program beneficiaries, OIG imposes derivative exclusions of persons who have been convicted of patient abuse or neglect or

² Quality-of-care CIAs are described in further detail on page 11 of this statement.

who have lost medical, nursing, or other health care licenses for reasons related to abuse or neglect of patients or professional competence. In fiscal year 2006, OIG excluded 295 persons based on convictions of patient abuse or neglect and 1,867 persons based on revocation or loss of health care licenses.

In addition to imposing these large numbers of derivative exclusions, OIG initiates affirmative exclusions to address serious quality-of-care problems that have not been addressed through other enforcement actions. As part of this affirmative strategy, we can exclude direct caregivers who pose a risk to patients, the owners and managers who are responsible for allowing the abuse of patients or provision of substandard care, as well as entities that have demonstrable, systemic poor quality of care. For example, OIG excluded a nursing home owner for causing the provision of substandard care in his facilities as a result of providing insufficient staffing and financial support. Because the owner was not a licensed health care professional (or nursing home administrator), the exclusion was the most effective way to bar him from involvement in Federal health care programs.

Establishing Accountability

In investigating and resolving cases such as those described above, law enforcement often struggles to determine who in the organization's management should be held responsible for the egregiously poor care. Federal and State law enforcement have therefore resorted to resource intensive and time-consuming investigative and auditing techniques to determine the roles and responsibilities of various management companies that are affiliated with a single nursing facility.

Establishing accountability is a challenge, in part, because of the sometimes Byzantine structures that are intentionally constructed around the long-term care facilities. The Service Employees International Union has reported, and OIG's law enforcement experiences confirm, a growing trend in the corporate restructuring of nursing home chains and other long-term care facilities to obfuscate the ownership and control of nursing homes. We have seen a variety of methods that have been used to hide the true owners that often involve the following steps: (1) creating a holding corporation to own the entire chain of nursing homes; (2) creating limited liability companies (LLCs) to manage the operations of the individual homes; (3) creating LLCs for the real estate holdings (the facility and the grounds), usually referred to as Real Estate Investment Trusts (REITs); and (4) creating an affiliated corporation to lease all of the properties from the REITs and then sublease those properties to the facility-specific entity, usually an LLC, which operates the individual homes.

The entity that acts as the facility operator does not own any assets and is authorized to use the facility under a sublease. The operating entity usually contracts with a management or administrative services company to perform the day-to-day operations of the facility. During ongoing investigations of nursing homes for the provision of substandard care, OIG has encountered nursing facilities that have as many as 17 LLCs that play a role in the operations of the facility. Such complex structures dilute accountability, greatly complicate law enforcement investigations, and delay implementation of essential corrective actions required to protect residents.

OIG Efforts To Promote and Ensure Quality of Care in Nursing Homes

The numerous oversight mechanisms used by States and CMS are primarily designed to identify and correct quality-of-care problems after they have occurred. By themselves, these mechanisms are insufficient to ensure that nursing home residents receive proper care. OIG has therefore undertaken numerous initiatives and worked closely with the nursing home industry to identify additional strategies to promote and ensure quality of care.

Encouraging Adoption of Voluntary Compliance Programs

OIG frequently provides nonbinding guidance to health care providers regarding how to establish systems and controls to promote and monitor compliance with Federal health care program requirements. Much of this voluntary guidance focuses on the importance of providing high quality health care to patients. The suggestions made in these compliance program guidances (CPG) are not mandatory, nor should they be construed as model compliance programs. Rather they offer a set of guidelines that providers should consider when developing and implementing new compliance programs or evaluating existing ones.

OIG originally published a CPG for nursing facilities in 2000, in which we provided guidance and resources to assist nursing home providers to voluntarily build systems of care and oversight. Since that time, there have been significant changes in the way nursing facilities deliver, and are reimbursed for, health care services, as well as significant changes in the Federal enforcement environment and increased concerns about quality of care in nursing facilities. In response to these developments, in April 2008, OIG published draft supplemental compliance program guidance for nursing facilities. We are currently soliciting public comments on this draft.

The draft supplemental nursing home CPG addresses major Medicare and Medicaid fraud and abuse risk areas, including quality of care, accurate claims submission, and kickbacks. The supplemental CPG focuses particular attention on such quality of care risks as inadequate staffing, poor care plan development, inappropriate use of psychotropic medications, lack of proper medication management, and resident neglect and abuse. Examples of measures that improve resident care that could be incorporated into compliance programs include:

- Regular assessment of staffing patterns to evaluate whether the facility has sufficient staff who are competent to care for the unique acuity levels of its residents;
- Policies and procedures designed to ensure an interdisciplinary and comprehensive approach to developing care plans. These can include requiring such things as completing all clinical assessments before interdisciplinary team meetings are convened, opening lines of communication between direct care providers and interdisciplinary team members, involving the resident and the residents' family members or legal guardian in discussions, and including the attending physician in the development of the resident's care plan;

- Requirements to ensure that there is an adequate indication for the use of psychotropic medication and to ensure the careful monitoring, documentation, and review of each resident's use of psychotropic drugs;
- Commitment to robust training and monitoring on a regular basis of all staff involved in prescribing, administering, and managing pharmaceuticals, and implementation of policies for maintaining accurate drug records and tracking medications; and
- Policies and procedures to prevent, investigate, and respond to instances of potential resident abuse, neglect, or mistreatment resulting from staff-on-resident abuse and neglect, and resident-on-resident abuse, including a method for staff, contractors, residents, family members, visitors and others to confidentially report any instances of abuse.

Encouraging Boards of Directors' Involvement in Compliance and Quality of Care

With a new focus on quality and patient safety, oversight of quality is a core fiduciary responsibility of health care organization boards of directors. In exercising his or her fiduciary duties, a governing board member of a health care entity can be expected to exercise general supervision and oversight of quality of care and patient safety issues. Because the support of the organization's leadership is essential to the success of any compliance program, OIG has worked collaboratively with health care industry groups to develop resources for boards of directors, including several recent efforts focusing on the role of the board in the oversight of compliance and quality of care.

In 2003, OIG and the American Health Lawyers Association (AHLA) produced a resource guide that highlighted the role that health care boards of directors can play in promoting effective compliance programs within their organizations. Another resource, published in 2004, considered the role of the general counsel in promoting an organization's compliance efforts. Most recently, in September of 2007, OIG and AHLA issued the third publication in this series, entitled "Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors." This document explores the role of health care boards of directors in responding to emerging issues related to promoting improved quality of care and patient safety. In it, we describe how compliance departments can play an integral role in aiding boards in fulfilling their oversight and decision-making obligations relating to quality-of-care issues. Some examples of possible measures that can be undertaken to strengthen the board's understanding of, and commitment to, quality of care include: (1) educating the board on emerging legal and compliance issues related to quality of care, (2) briefing the board on existing compliance systems equipped to respond to legal and regulatory quality-of-care developments, and (3) employing compliance mechanisms to implement board initiatives that seek to monitor or improve quality of care.

To further awareness of corporate responsibility and health care quality, in December 2007, OIG co-sponsored a roundtable with the Health Care Compliance Association called, "Driving for Quality in Long-Term Care: A Board of Directors Dashboard." The roundtable was an opportunity to bring together a diverse and knowledgeable group of long-term care industry and

Government representatives to generate ideas about how to effectively involve boards of directors in the oversight of quality of care in nursing homes. The participants represented a wide spectrum of long-term care organizations and professionals, including not-for-profit and for-profit organizations, multi-facility and single facility organizations, nationally and locally based organizations, clinicians, administrators, compliance officers, outside and corporate counsel, and monitors involved in OIG quality-of-care CIAs. Another goal of the roundtable was to identify information that could be included on a “Quality of Care Dashboard,” a matrix, used by boards of directors as a tool for monitoring the organization’s quality-of-care data.

Although it was not the purpose of the roundtable to reach consensus regarding best practices, a number of themes ran through the discussions. For example, participants consistently stated that boards of directors can demonstrate their commitment to quality resident care by establishing a forum for board-level discussions about quality; quality outcome data can help the board assess the actual performance of the organization on identified quality-of-care standards; and, where quality of care problems are identified, the response needs to be coordinated, with board oversight, to properly address the underlying cause of the problem.

Imposing Corporate Integrity Agreements

As part of the resolution of False Claims Act cases, OIG often agrees to not exclude a defendant in exchange for the defendant entering into a CIA with OIG. A CIA is a contract that imposes systems, monitoring, and reporting requirements on providers. Like all of OIG’s CIAs, quality-of-care CIAs are designed to compel the strengthening of existing, or the development of, internal systems of quality assurance and communication within the monitored organization. CIAs are typically entered into for 5-year terms; the intention is that systems will be reformed and staff competence dramatically improved during the first 3 years and that the monitored organization will demonstrate that it can maintain compliance during the last 2 years.

Quality-of-care CIAs typically include the following eight key components:

1. An independent quality monitor authorized with unfettered access to facilities, staff, residents, documents, and management at every level of the organization;
2. A compliance officer who oversees all compliance systems and coordinates with OIG and the monitor;
3. Policies and procedures with an interdisciplinary focus;
4. Competency-based training requirements;
5. Internal audit functions that should continue beyond the CIA;
6. A Quality Assurance Committee (including clinical leadership and the compliance officer) to oversee clinical improvement and compliance issues throughout the organization;
7. A system of reporting information within the organization without fear of retaliation; and
8. Requirements that the organization report certain events, such as significant overpayments or serious quality-of-care problems, to the Monitor and OIG within specific timeframes.

If the entity fails to comply with the CIA, OIG may impose stipulated monetary penalties. In addition, certain violations (e.g., failing to report reportable events or to pay the independent monitor in a timely manner) may result in a breach of contract, for which exclusion of some or all of the organization may result.

The appointment of an independent quality monitor has been essential to the success of CIAs and the nursing homes' development of systems of care and oversight. The monitor is selected by OIG, or by the monitored entity with OIG's approval, sets its own budget, and is paid for by the monitored entity. These independent quality monitors effectively build upon and complement the actions of State surveyors. By using State survey results and other quality-related data, such as Quality Indicators/Quality Measures derived from the Minimum Data Set, the monitors proactively identify any quality problems or systems issues that could lead to quality problems.

The success of these quality CIAs also has been a result of their access to an array of quality-of-care data. The use of a national, historical database that integrates a variety of quality measures allows the monitors to effectively compare the quality of care provided among facilities in the same corporation and to compare the quality of care in facilities from different nursing home chains. This analysis allows the monitors to track improvements or deterioration in the entity under the CIA over time and to identify areas needing a stronger focus and more resources. In consultation with the provider, the monitor recommends enhancements to systems and controls to improve quality of care. If the monitor makes a recommendation to the monitored entity, the entity must either implement the recommendation or explain to OIG its reason for failing to do so.

Over the last 7 years, many nursing home chains and individual health care facilities have agreed to operate under CIAs with independent quality monitors. Since 2002, over 1,300 health care facilities, mostly nursing homes, have operated for some period of time under quality-of-care CIAs. OIG currently has 11 CIAs with nursing homes and psychiatric facilities (or chains) with independent quality monitor requirements. These 11 CIAs cover operations in about 400 long-term care and psychiatric facilities across the country.

Conclusion and Suggestions To Promote Improved Quality of Care in Nursing Homes

Our extensive work has determined that the current mechanisms used to detect, monitor, and correct quality-of-care problems in nursing homes are insufficient. The procedural inefficiencies, communication breakdowns, inconsistent citing of deficiencies and application of remedies mean that consumers have no guarantee that the nursing home in which they place a family member provides good care or that it thoroughly screens its staff. Additionally, the program administrative oversight and enforcement systems are designed largely to identify poor care after it has already occurred. While these approaches can help to correct existing problems, they are insufficient by themselves to prevent these problems from occurring. In spite of existing oversight mechanisms, we continue to see examples of horrific treatment of nursing home residents.

Ultimately the responsibility rests with the nursing homes, and their owners and boards of directors to do everything possible to ensure that the residents in their facilities consistently receive the best possible care. I have described a number of initiatives that OIG has undertaken with the nursing home industry to promote and ensure quality of care. However, more must be done. I offer the following suggestions for consideration.

1. Improve screening of all nursing home staff by creating a nationwide centralized database that includes information from OIG's exclusions database, State nurse aide registries, and disciplinary actions by State licensing boards.

Given the dependence of nursing home residents on the nursing facility staff for their health and well-being, it is vital that providers have access to the most complete personal background information possible, including data currently residing in OIG's exclusions database and the multiple employee databases. Without this information, there is a significant risk that potentially abusive caretakers will be employed to care for this vulnerable population. With so many different sources of information, however, it can be administratively difficult and costly for a provider to ensure that it has effectively screened all of its prospective employees against all of the relevant databases. For this reason, we recommend that consideration be given to the creation of a single database that aggregates the various Federal and State sources of adverse information about direct patient access employees. We recognize that although the initial startup efforts would be resource intensive, in the long run nursing homes and other health care providers would have access to a cost-effective means of conducting a more comprehensive background check on prospective or re-check of current employees. One possible method to ensure stable funding for the continued maintenance of the centralized database would be to require that nursing homes and other potential employers check these data prior to hiring direct care staff, along with charging a user fee for access to this information. The results of the CMS criminal background check pilot program should also help to inform how such a database could be constructed and utilized.

2. Create a demonstration project to establish mandatory compliance programs for selected nursing homes.

OIG believes that the implementation of a comprehensive compliance program in nursing facilities can help achieve the goals of reducing fraud and abuse, enhancing operational functions and transparency, improving the quality of health care services, and decreasing the cost of health care. The implementation of a compliance program may not entirely eliminate fraud from the operations of a nursing facility, nor will it completely remove the specter of poor care and resident abuse. However, in our experience, an effective compliance program can significantly reduce the risk of unlawful or improper conduct. For example, nursing homes that have operated under CIAs typically report significant improvements in internal financial controls and care delivery systems. Simply put, effective compliance systems can promote improvements in quality of care. Additionally, the widespread implementation of compliance programs levels the playing field for the majority of health care organizations, which are honest and law-abiding.

A number of different approaches can be taken to achieve this objective. For example, New York now requires providers that participate in its Medicaid program to adopt effective compliance programs, designed to be compatible with the providers' characteristics. The Department of Veteran Affairs (VA) also has a robust compliance and business integrity program (CBI) for its health care systems. Although the focus of the compliance initiative is on the VA's own facilities and its employees, the CBI requires VA's independent contractors to receive formal training on compliance awareness, as well as job-specific training for physicians, clinicians, and anyone involved in the revenue cycle, either through the contractor or at the facility.

OIG suggests that the Congress work with CMS to establish and provide resources for several demonstration projects to explore different approaches to the implementation of compliance programs in nursing homes. As an example, one project could concentrate on the "special focus" facilities identified by CMS and, where appropriate, on corporations that have more than one special focus facility with a history of severe deficiencies. These nursing homes have already been identified as needing significant improvement in their quality infrastructure and would be an ideal testing ground of mandatory compliance programs. An additional demonstration project could use the nursing home's existing quality assurance committee as the starting point for building a compliance program. Such projects will help identify "best practices" and refocus the priorities of facilities that have in the past placed profit over resident care.

3. Enhance the quality-of-care data made available to the nursing home industry and the public.

Currently, CMS offers consumers and the nursing home industry a good base of information on the quality of nursing homes, primarily through its Nursing Home Compare Web site. Nursing Home Compare includes four categories of information: (1) inspection results, including deficiencies identified by Medicare certification surveys and complaint investigations; (2) facility characteristics, such as number of beds and type of ownership; (3) nursing home staffing levels; and (4) quality measures which are based on the clinical and functional status of a nursing home's residents. Information included in Nursing Home Compare can be used by consumers to select and monitor performance in nursing homes and by providers to serve as the basis for quality improvement efforts. Additionally, last month, CMS announced that it had enhanced Nursing Home Compare to identify the nursing facilities that are or have been on the CMS Special Focus Facility List. We commend this change. However, we believe that more can be done to provide critical data to the industry to enable it to better police itself. Furthermore, we believe that consumers need more detailed information about the operation of a nursing home chain or its regional components to make an educated choice about where to seek nursing care.

As described earlier, the quality monitors' oversight of corporations and individual providers under CIAs demonstrate the value and potential of using a combination of resident assessment data and survey-based performance measures to provide richer and more detailed information that corporations can use to better identify quality-related risk areas and to focus their quality improvement efforts. Until now these vital quality improvement data have been available only

to those corporations that have entered into quality of care CIAs with OIG. We believe that quality improvement in all nursing facilities can be enhanced well beyond their current capabilities by providing similar trended, comparative resident-level performance measures that would allow facilities to “gauge” how they compare in providing quality care related to other facilities. Every corporation that OIG has monitored has indicated that its facilities have regularly used this information and have expressed concern that this comparative information is not available to them after the CIA had ended.

This concludes my statement. Thank you for the opportunity to testify today. I would be pleased to answer your questions.