Statement of Dara Corrigan Acting Principal Deputy Inspector General U. S. Department of Health and Human Services Before the Senate Finance Committee July 17, 2003

Good morning Mr. Chairman and Members of the Committee. I am pleased to have this opportunity to speak to you about quality of nursing home care -- a subject of intense, continuing interest to the Office of Inspector General.

As you know, we have been working in this field for a number of years, covering all aspects of Medicare and Medicaid nursing home services, focusing our audits, evaluations, investigations, and legal attention on issues relating to funding, access, and quality oversight. In fact, it was almost exactly four years ago (March, 1999) our office testified before you, Mr. Chairman, and other members of the Senate Aging Committee, advising you of our concerns about deficiencies in nursing home care and weaknesses in the survey and certification process. We made numerous recommendations to improve nursing home care, which addressed the survey and certification system, the ombudsman program, resident abuse safeguards, care guidelines, and access to information for family members of nursing home residents.

Since that hearing, we have continued our work, completing studies on resident assessments, services for seriously mentally ill persons residing in nursing homes, the use of psychotropic drugs as chemical restraints, standards for nurse aid training, the efficacy of quality oversight committees, the role of medical directors, and adequacy of psychosocial services. Most recently, we repeated the earlier study of the survey and certification process and of trends in nursing home deficiency rates, which served as a general barometer for the measurement of care, as discussed in our earlier testimony.

You have asked for our current assessment of nursing homes, based on the entire body of our work. In response, I would say that while we see glimmers of progress, we still have serious concerns about the quality of living conditions and care in nursing homes.

Following is a more detailed description of our findings, recommendations, and enforcement actions. We have divided our analysis into two broad sections: conditions in nursing homes, and oversight and quality assurance systems.

CONDITIONS IN NURSING HOMES

Much of the information we have about conditions in nursing homes is derived from oversight, care planning, and protection systems that are discussed in the second half of this testimony. Among them are the survey and certification system (the state-based quality oversight mechanism for nursing homes based on on-site visits by independent, professional teams, the Minimum Data Set (MDS) (used in connection with assessments of the care needs of individual nursing home residents), and the ombudsman complaint system, one of several venues through which residents or their families can register their concerns about the safety and quality of conditions in the facilities and receive assistance from an independent advocate to get their problems resolved.

We used several approaches to analyze this information. First, we examined data from *all* of these systems, assessing the consistency among them. Second, we emphasized *trends* rather then absolute values so we could assess general directions over time. Finally, we sought other, corroborating evidence, such as complaints received by long-term care ombudsmen and opinions of survey and certification officials who are in a position to know what is going on and whose judgment is informed by their experience and expertise.

We also based our evaluation on our in-depth studies of assessment systems used to identify the needs of and develop plans of care for nursing home residents. On a selected basis, we sampled residents' records and assessments and subjected them to independent review by medical experts. We also sent our own teams to nursing homes to examine specific aspects of care.

In addition, we compared our data and findings to those obtained by the General Accounting Office (GAO), which are also being presented at this hearing. Our information and analysis is consistent with GAO's. We supplemented their findings by identifying those factors that lead to the kinds of critical care problems identified in their report and attempted to identify steps that can be taken to avoid the occurrence of these problems. Here is what we found.

Overall Increase in Nursing Home Deficiencies

General Rates of Increase. All Medicare and/or Medicaid participating nursing homes must be certified as meeting certain Federal requirements. Certification is achieved through routine facility surveys, which the Centers for Medicaid and Medicaid Services (CMS) contracts with States to perform. Nursing homes are subject to unannounced standard surveys no later than 15 months after the date of the previous standard survey. If, during the standard survey, a nursing home is found to have provided substandard quality of care, an additional extended survey is conducted within two weeks. Nursing home surveys are typically conducted by a team of surveyors, with a team leader assigned to manage the process while on site. The survey team also conducts various pre-survey tasks, such as reviewing existing program data, before going to the facility.

When a nursing home fails to meet a specific requirement, the facility receives a deficiency citation. These deficiencies are categorized into 1 of 17 major areas, such as quality of care and physical environment. A total of 190 deficiencies with different tag numbers can be cited. Surveyors also determine a scope and severity level for each deficiency. Scope indicates how widespread the deficiency is, while severity indicates potential for harm. Survey data are entered into the Online Survey and Certification Reporting System.

We compared the deficiencies cited by surveyors in 2001 and compared them to the citations in 1998. We found that the overall number of survey and certification deficiencies went up, both in the aggregate and in the number of deficiencies per nursing home.

Quality of Care. We found that 78 percent of nursing homes received at least one deficiency in three categories related to quality of care. This is an 8-percentage point increase since 1998. These categories of deficiencies are – Quality of Care (covering 25 deficiencies), Quality of Life (covering 19 deficiencies), and Resident Behavior and Facility Practices (covering six deficiencies). Deficiencies in each of these categories rose 9.1, 9.0, and 5.3 percent respectively. Some examples of deficiencies in these categories that we found in the survey and certification reports we reviewed are:

- A resident reported that a nurse aide tied a sheet around the resident's neck and kept pulling it tighter; this resident had redness around his neck as a result. A review of the aide's file indicated that she had seven prior incidents of resident mistreatment.
- Two residents were admitted to a nursing home each with stage II or III pressure sores. Each developed stage IV pressure sores -- one within 24 hours.
- One resident who did not eat or drink and showed signs of dehydration continued to receive diuretics for 10 days. This resident was transferred to a hospital where he died.

Resident Assessments and Care Plans. Of particular concern is the category that showed the greatest overall increase--resident assessment. Resident assessments are required to be conducted by inter-disciplinary teams comprised of nursing home staff when individuals first enter the facilities and at other prescribed intervals. These routine assessments may trigger additional, more specific assessment protocols depending on clinical and functional conditions observed. Such protocols in turn provide the framework for developing care plans to address the needs of the residents. These protocols relate to such things as pressure ulcers, dehydration and fluid maintenance, delirium, dementia, urinary incontinence and indwelling catheter, psychosocial wellbeing, mood state, behavior symptoms, falls, nutrition, feeding tubes, dental care, psychotropic drug use, physical restraints, visual function, communication, and functional abilities for activities of daily living. If resident assessments are not done or are not performed correctly, residents with conditions such as these may not receive the care they need.

In 2001, 50.1 percent of nursing homes had at least one deficiency related to resident assessments. This is an increase of 11.6 percentage points since 1998. This is significant because the resident assessment is the foundation for care planning for residents. Without reliable assessments, residents' needs cannot be appropriately addressed and they may therefore not get the care they need.

In reviewing survey reports for our inspection work, we have noted a number of resident assessment deficiencies that have resulted in actual or potential harm. For example, a large, suburban California nursing home failed to develop comprehensive care plans for 7 of 31 sampled residents. One resident suffered with severe pain, but had no pain management plan; another at risk for weight loss actually lost weight because diet was not addressed in the plan; and the plan for a third resident with a history of falling did not identify approaches to prevent further falls. Other examples of resident assessment deficiencies include a Down's syndrome resident with a history of wandering and resistance to care; the staff simply acknowledged that these behaviors were ongoing problems, but they were not addressed in the care plan. At another facility, a resident whose care plan did not address his violent behavior had to be transferred to another facility after he assaulted another resident.

Our inspection reports note vulnerabilities in the resident assessment process. In 2001, we released a report on the nursing home resident assessment processes, including the use of the Minimum Data Set. In this inspection, we sampled medical records and had them reviewed by medical experts to assess the accuracy of the resident assessments and the appropriateness of additional assessment protocols required by conditions found in the initial review. They found that 17 percent of assessment data fields contained errors and 25 percent of the additional assessment protocols triggered by the initial assessments were questionable. Furthermore, 25 percent of the protocols which were completed did not have associated care plans.

In that same year, we examined the independent physical and mental evaluations that are required for Medicaid beneficiaries with serious mental illnesses who were in nursing homes. We focused on younger patients, those under 65. We found that only 41 percent of the required evaluations were conducted, as were only 29 percent of required reassessments.

Additionally, in March of this year we released a report on psychosocial services in nursing homes. In it we reported that 10 percent of residents missed one or more required assessments and that 39 percent of residents with psychosocial needs had inadequate care plans. Furthermore, we found that 46 percent of those with care plans did not receive all planned services.

Further evidence of shortcomings in resident assessment comes from the state ombudsman reporting system whose data show a 70 percent increase since 1996 in complaints related to care plans and assessments.

Other Deficiencies. Deficiencies in other categories also increased. These include pharmacy services (21.1 percent of nursing homes had at least one deficiency in this category in 2001, an increase of 7.9 percentage points since 1998), infection control (20.7 percent, up 5.1 percentage points), physical environment (25.8 percent, up 5.1 percentage points), and residents' rights (29 percent, up 3.7 percentage points).

Decrease in Consecutive Deficiencies. We did find some signs of improvement. One indicator of nursing home care is whether a nursing home has "actual harm" or "immediate jeopardy" deficiencies in consecutive standard surveys. In 2001, 7 percent of the nursing homes had repeat deficiencies of this severity. We analyzed deficiency data going back to 1998 and found that this represents a decline from 11.5 percent in 1999.

Other Evidence Corroborating Deficiency Trends

Ombudsman Complaints. Data from the National Ombudsman Reporting System show that between 1996 and 2000 the total number of complaints have risen 28 percent to 186,000. This translates to 102 complaints per 1,000 beds -- a 30 percent increase.

The characteristics of these complaints, however, did not change significantly over time. The top 12 categories, which account for one-third of all complaints, remained the same. Accidents and request for assistance remained the top two most common complaints. In addition, personal hygiene, medication administration and symptoms unattended, complaints categorized under resident care, also remained in the top 12 categories between 1996 and 2000. These types of complaints may include unexplained bruises, unanswered requests for assistance, a resident not bathed in a timely manner, medications not given, and failure to provide services to a resident's changed condition. Staff turnover, while not one of the top 12, did show the greatest increase at over 200 percent.

State Survey Staff. To gain further insight into the state of care in nursing homes, we surveyed all State Survey and Certification Directors in all States and the District of Columbia, and interviewed a purposive sample of 32 surveyors. With regard to the trend in the quality of care, 45 percent of Directors believe it has remained the same, but 27 percent believe it has in fact declined over the past 3 years. Similarly, 34 percent of front line surveyors believe quality of care has remained the same, while the same number believes quality has declined. On the other hand, 19 of 32 of nursing home administrators we interviewed reported that the quality of care has improved over the past 3 years. The others believe it has remained the same or declined.

OVERSIGHT AND QUALITY ASSURANCE SYSTEMS

As noted in the previous section on conditions in nursing homes, most of the data we use to monitor the quality of life and care is derived from systems whose primary purpose is to provide oversight and enforce compliance with quality of life and care requirements, to plan and care for residents, and to protect them when things go wrong. The following is a discussion of the major oversight and quality assurance systems.

Survey and Certification Process

Inconsistencies in the Citing of Deficiencies. We found many inconsistencies in the citation of deficiencies at all levels -- among States, between Federal and State reviews, and even among individual survey reports. Such inconsistencies can weaken the efficacy of the survey and certification process. Residents receiving inadequate care or living in

substandard conditions may not be protected as a result of the failure to cite the deficiencies.

The inconsistencies could also open deficiency citations to legal challenges. This in turn might make surveyors and State administrators wary of citing deficiencies even when they are clearly justified. As a result, the entire process can be encumbered with administrative delays and expenses resulting from preparing and responding to appeals, remedies delayed or foregone, and residents' needs untended.

In our most recent study of survey and certification deficiencies, we found wide variance in individual State-level deficiency data. In 2001, for example, one-third of the nursing homes in Virginia were deficiency-free while none in Nevada were. In five States almost a quarter or more of homes were deficiency-free; in 12 other States, 5 percent or less were. The national average for deficiency-free nursing homes was 11 percent in 2001. The rate of deficiencies per nursing home also varied. This ranged from a high of 11.2 deficiencies per nursing home in California to a low of 2.9 in Vermont. Nationally, the average deficiency rate in 2001 was 6.2 deficiencies per nursing home.

Differences Between Federal and State Surveys. Federal oversight surveys, conducted by the Centers for Medicare and Medicaid Services on a sample of State surveys, provide additional evidence of the inconsistency in the application of deficiency standards. Furthermore, the inconsistency between Federal and State surveys runs overwhelmingly in one direction—Federal survey teams find larger numbers of, and more serious, deficiencies than State teams. In 166 comparative surveys conducted in 2002, Federal surveyors found 1303 deficiencies compared to 851 identified by State surveyors. Federal surveyors found deficiencies involving actual harm or immediate jeopardy to residents in 24 percent of facilities, while for State surveyors, this number was only 13 percent. Overall, Federal and State surveyors cited the same deficiency only 124 times.

Reasons for Inconsistencies. There are many possible explanations for these inconsistencies. Presumably, they reflect variations in the conditions of nursing homes. However, a greater number of citations may also reflect more intense efforts to identify and correct deficiencies rather than a greater incidence of them. Or, they may reflect longstanding practices that have varied from State to State or region to region over many years. In order to gain a greater understanding of the underlying causes, we reviewed documentation for 310 different deficiencies from 135 survey reports. We also interviewed 32 surveyors in eight States, and gathered information from all 50 State agency directors and the District of Columbia concerning the way each conduct surveys. Based on our review, we identified four factors that contribute to variability in citing deficiencies across States.

Differences in Focus. We found considerable variation in the overall focus of State surveys. For example, the degree to which surveys emphasize enforcement aspects of the survey versus consultative aspects varies among States and from year to year. Thirty-six State agency directors said that their State's survey process is only somewhat consistent

in this regard, acknowledging that the difference between enforcement and consultative focus affects the scope of the review.

During our on-site visits to the six sample States, we observed such differences in focus by survey teams. In one State, surveyors used a more consultative approach in making specific recommendations to the nursing home staff about treatment protocols for an individual resident. This approach contrasted with a more enforcement approach we observed in another State survey, where very little dialogue occurred between the survey team and nursing home staff.

Regarding the consultative approach, both GAO and our office note instances where surveyors fail to cite deficiencies. In five of the six surveys we observed, we noted that surveyors did not always cite deficiencies for problems they identified. This would occur, for example, if the nursing home said they were aware of the problem and were addressing it.

The 51 State agency directors we surveyed also cited several other factors affecting the focus of nursing home surveys. These included the political climate, the strength of the nursing home lobby, and changing Federal and State regulations.

Lastly, 21 States have their own specific criteria governing nursing home surveys that may affect the focus of their Federal surveys. These State criteria most commonly include nursing home staffing ratios and State life safety codes. In 14 of these States, the criteria have changed over the past 3 years. Differences in these criteria among the States also accounts for some of the inconsistencies we found.

Lack of Clarity in Guidelines. We found that surveyors occasionally had difficulty interpreting deficiency guidelines. Twenty-three State agency directors and 17 of 32 sampled surveyors reported that some groups of deficiencies are inherently more vulnerable to inconsistent citation than others. They said deficiencies that are categorized under "quality of life" are most vulnerable due to the lack of clarity in and complexity of the Federal guidelines. They believe this fosters a subjective interpretation, thereby contributing to inconsistent citation among surveyors.

We reviewed the State Operations Manual's "quality of life" and "quality of care" categories and found some of the guidance to be confusing. For example, guidance for tag F250 (social services) offers 14 examples of medically related social services, six types of unmet needs, and 10 conditions to which the nursing home must respond with social services. Some of the definitions for these tags are general and subjective. While the guidance does offer numerous examples of specific scenarios that can be cited under each deficiency tag, in some cases the broad range of examples can be confusing. We also noted that for certain deficiencies, surveyors are directed to refer to more than one deficiency category or tag for the same issue, without explicit direction as to whether to cite under multiple tags when the facility is found to be out of compliance.

Differences in the Way Draft Survey Reports Are Processed. States use different review processes for draft survey reports. In 42 States, all draft survey reports had supervisory reviews in 2001, but not in the remaining eight. Only 18 States conducted reviews when reports changed significantly from draft to final. Thirty-one States had internal quality assurance teams and two States developed continuous quality improvement teams, while17 States had both.

These inconsistencies in States' review processes are reflected in the wide variation in revisions made to draft deficiency reports. State agencies report that an average of 5 percent of deficiencies are removed from draft survey reports before they become final. However, this removal rate ranges from 25 percent in one State to 0 percent in three other States. Further, State agencies report that an average of 6 percent of scope and severity determinations are downgraded from draft surveyors' reports before they become final. This ranges from 38 percent of deficiencies downgraded in one State to 0 downgraded in two other States. In addition, the States with lower deficiency rates removed more deficiencies, on average, from draft survey reports than States with higher rates.

Turnover of Surveyor Staff. We also learned that staff turnover influences survey results. Virtually every State survey director reported that it is very or somewhat difficult to replace survey staff when they leave. Thirty-one said that registered nurses are the most difficult to replace. Based on our survey data, we determined that nationally, surveyors work an average of only 6.5 years for the State agency and that State survey directors have held their jobs on average for only 6.4 years.

On all our visits to the six States, surveyors told us that finding and retaining staff was problematic. They also expressed concern that high staff turnover impacts the consistency of the survey process, since a high proportion of newer staff detracts from the continuity of surveyors' experience. In fact, in one nursing home that we visited the survey team members all had less that two years experience, and two had been on the job for only a few months. We observed that these surveyors were uncertain about what problems to cite and spent several hours debating which deficiency tags to cite.

Based on our study, we recommended that the Centers for Medicare and Medicaid Services continue to improve its guidance to State agencies on citing deficiencies by providing guidelines that are both clear and explicit, and work with the States to develop a common review process for draft survey reports.

The Federal False Claims Act As An Enforcement Tool

The survey and certification process provides several mechanisms for enforcement of nursing home standards. These include corrective action plans, civil monetary penalties, suspension of intake of new Medicare and Medicaid patients, required changes in management, and even de-certification. In some cases, the quality of care is so deficient that remedies under the survey and certification process are not sufficient. If resident care is so poor that it effectively represents a failure to provide care, the Federal False Claims Act can be invoked. In essence, this would amount to a charge that the Federal

Government had been billed for services not rendered. More than 20 nursing home cases have been settled based on the False Claims Act since 1996.

A hallmark of all of these settlements is the imposition of substantial quality of care obligations upon the facilities and the requirement the facilities pay for independent monitors. Depending upon the jurisdiction in which the case arose, these requirements are contained either in the body of the settlement agreement or in separate corporate integrity agreements with the OIG. Following are some recent examples of settled cases.

- **Poor Care and Abrupt Closure.** A nursing home company agreed to resolve its liability under the False Claims Act in a case involving allegations that two nursing homes owned by the company had failed to provide adequate nutrition, hydration, pressure ulcer prevention and treatment, dental care, and safety monitoring to its residents. During the course of the government's investigation, both nursing homes closed abruptly and all of the residents were transferred to other facilities with little advance notice. As part of the settlement, the company agreed to fund a study of the effect of transfer trauma on residents.
- Infection, Pressure Ulcers, and More. A nursing home agreed to implement specific protocols, standards of care and compliance policies to resolve its liability for failing to provide appropriate care to one of its residents. The resident developed an infection and pressure ulcer due to a lack of care. The investigation also revealed facility-wide problems with respect to staffing, nutrition monitoring, pressure ulcer care, and treatment planning. The settlement required the facility to pay for an outside monitor selected by the government and to fund special "quality of care/quality of life" projects.
- Death and Cover-up. The allegations in this case involved deficiencies with respect to admission assessments, pressure ulcer care, monitoring of residents' hydration, medication administration, and pain management. The investigative focus of the case was on the facility's failure to properly treat one particular resident that died as a result of medication errors that were then covered-up. The nursing home agreed to implement specific protocols, standards of care and compliance policies to resolve its liability. The nursing home also agreed to pay for an outside monitor selected by the government. A nurse, who falsified records in the cover-up attempt, pled guilty to making false Statements and received a 10-month prison sentence.
- Infested Wounds. Another nursing home agreed to enter into a 3-year comprehensive corporate integrity agreement that included the appointment of a monitor. The allegations involved multiple findings of residents with maggot infested wounds, substandard catheter care, and significant staffing shortages. The damage aspect of the case focused on two patients whose care was particularly egregious.

Perspectives on Using the False Claims Act for Nursing Home Cases. As the terms of these particular settlement agreements reflect, our first priority is to ensure nursing home residents receive the care they need. We work closely with the Department of Justice on these settlements in order to achieve a balance between recovering a fair amount of dollars for restitution and damages, and establishing systematic changes in the way the nursing homes provide care. It is a very difficult balance because we do not want to take dollars away from the nursing home that would otherwise be spent on patient care. As part of that collaboration, last year the OIG sponsored a 1 1/2 day conference on nursing home quality of care. During the conference, nearly 100 Federal prosecutors and investigators explored ways to effectively use our enforcement tools, including the False Claims Act, corporate integrity agreements, and program exclusions, to improve the quality of care residents receive.

We will continue to investigate cases of care failure and resident harm for which application of the False Claims Act may be appropriate and to work with the Department of Justice, CMS, State officials, and others to resolve them expeditiously.

Resident Assessment Needs to Be Performed and Improved

I have already described inadequacies of the assessment processes related to the Minimum Data Set and stemming from special requirements for residents with serious mental illness and psychosocial service needs. Several additional Office of Inspector General reports shed more light on this subject. They are listed in an attachment to this testimony and can be readily accessed on the Internet.

In our reports on this topic, we have recommended that the Centers for Medicare and Medicaid Services more clearly define the MDS elements; work with the nursing home industry to enhance MDS training; and focus on psychosocial services as part of resident assessment oversight. With regard to Medicaid, we recommended they ensure the completion of the required assessments for residents with severe mental illness and require State Medicaid agencies to work with State mental health agencies on community based treatment alternatives.

Quality Assurance Programs Also Need Attention

Through our studies, the Office of Inspector General has also examined other systems mandated by the Omnibus Reconciliation Act of 1987 to assure that residents receive appropriate care in nursing homes. Our reports cover such topics as training requirements for nurse aides; the role of medical directors; and the efficacy of quality assurance committees. In general, we found that the most fundamental requirements were being met: aides were receiving the required training; medical directors were assigned to nursing homes and were working to provide general oversight of residents' medical care; quality assurance committees were appointed and met regularly to advise on nursing home conditions and care; and psychotropic drugs were generally not being used as chemical restraints.

However, all of these programs could benefit from improvements. Training standards need to be modernized; the practice of medical directors would be enhanced if more specific standards and clearer expectations were developed for them; quality assurance committees could make better use of available information to inform their deliberations; and psychotropic drugs may still be over-utilized and need to be subjected to stronger drug utilization review procedures. The relevant reports and their Internet addresses are listed in the attachment.

LOOKING AHEAD

In light of the findings cited above and based on our work over the last several years, I recommend a three-pronged strategy to improve the quality of living conditions and care in nursing homes:

- Strengthen the enforcement system, especially the survey and certification process. This includes improving the reliability of deficiency citations though clearer definition and report processing standards; following up on repeat offenders; and working to investigate, and resolve complaints expeditiously.
- Make sure that patient assessments are performed, that they are accurate, and that care plans are prepared and followed.
- Establish continuous improvement programs for quality assurance infrastructures such as those relating to nurse aide training, medial directors, drug utilization review, quality assurance committees, long-term care ombudsmen, and quality of care information for residents and their families.

CMS has already taken steps in this regard. I refer to their initiatives over the last several years related to such things as the scheduling and conduct of surveys, resident assessment, performance measures, and publication on the Internet of information about quality of care in each and every nursing home. It is critical for CMS to follow through on its plans to improve all these systems in a timely manner.

Improving nursing home services will also require the combined efforts, over many years, of all stakeholders -- the residents and their families, the nursing home industry, health care professionals, Medicare and Medicaid program administrators, and State quality assurance organizations.

CONCLUSION

Much has been done, but much still remains to improve conditions in nursing homes and guarantee that the improvements take hold. The Office of Inspector General will continue to do its part through its evaluations, audits, investigations, and legal services. We hope our contributions are constructive.