United States General Accounting Office

GAO

Report to Congressional Committees

July 2002

MEDICARE HOME HEALTH AGENCIES

Weakesses in Federal and State Oversight Mask Potential Quality Issues

GAO-02-382

Report Documentation Page

Report Date	Report Type	Dates Covered (from... to)
00Jul2002	N/A	-

Title and Subtitle MEDICARE HOME HEALTH AGENCIES: Weaknesses in Federal and State Oversight Mask Potential Quality Issues	**Contract Number**
	Grant Number
	Program Element Number
Author(s)	**Project Number**
	Task Number
	Work Unit Number
Performing Organization Name(s) and Address(es) U.S. General Accounting Office 441 G Street NW, Room LM Washington, D.C. 20548	**Performing Organization Report Number** GAO-02-382
Sponsoring/Monitoring Agency Name(s) and Address(es)	**Sponsor/Monitor's Acronym(s)**
	Sponsor/Monitor's Report Number(s)
Distribution/Availability Statement Approved for public release, distribution unlimited	
Supplementary Notes	
Abstract see report	
Subject Terms	
Report Classification unclassified	**Classification of this page** unclassified
Classification of Abstract unclassified	**Limitation of Abstract** SAR
Number of Pages 105	

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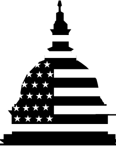
Abbreviations

CMS	Centers for Medicare and Medicaid Services
COP	condition of participation
HCFA	Health Care Financing Administration
HHA	home health agency
LPN	licensed practical nurse
LVN	licensed vocational nurse
OASIS	outcomes and assessment information set
OBRA	Omnibus Budget Reconciliation Act of 1987
OSCAR	On-Line Survey, Certification, and Reporting system
RN	registered nurse



United States General Accounting Office
Washington, DC 20548

July 19, 2002

Congressional Committees

Home health agencies (HHA) play an important role in the U.S. health care system—allowing individuals who are unable to leave home without great difficulty to receive certain medical or therapeutic care in their own homes. In 2000, Medicare, the federal health care program for elderly and disabled Americans, covered home health services for 2.5 million beneficiaries at a cost of $8.7 billion.[1] The approximately 6,900 HHAs that serve Medicare beneficiaries must meet federal requirements, known as conditions of participation (COP), intended to ensure that, among other things, HHAs have the appropriate staff, are following the plan of care specified by a physician, maintain medical records to document the care provided, and periodically reassess each patient's condition. To verify compliance with these and other requirements, the federal government contracts with states to periodically conduct an inspection, known as a standard survey, at each HHA. The survey includes a review of a sample of medical records and interviews with patients in their homes. If an HHA fails to meet a Medicare COP—a serious deficiency that adversely affects (harms) or has the potential to adversely affect (potential to harm) patients—it can be terminated from the program.[2] Oversight of HHAs has become even more important since the implementation of a new prospective payment system in October 2000 that encourages HHAs to provide care more efficiently but also provides an incentive to reduce services in order to increase net revenues.

In 1997, we reported on serious shortcomings in both HHA surveys and the survey process that resulted in the failure to detect and exclude HHAs

[1]Medicaid, the joint federal-state health care program for low-income individuals, also covers home health services. In fiscal year 1999, the most current year for which data were available, about 800,000 Medicaid recipients were served by HHAs at a cost of $2.2 billion.

[2]Although HHAs are surveyed to determine if they meet Medicare COPs, HHAs may serve a mixture of Medicare, Medicaid, and private pay patients. The medical record and patient visit samples may include individuals from any payer group. Thus, Medicare quality standards protect not only Medicare beneficiaries but other home health users as well.

with quality problems.[3] First, HHAs obtained approval to serve Medicare beneficiaries too easily. The requirements to become a Medicare HHA were minimal, and surveys done at an HHA's start-up provided little assurance that the HHA was capable of furnishing high-quality care. Second, periodic state surveys failed to assess HHAs against all COPs and did not cover care provided by branch offices—satellite locations that operate under the supervision of a "parent" HHA approved to participate in Medicare. Third, few HHAs were terminated from Medicare when serious deficiencies were uncovered. Because the federal government had not implemented additional, statutorily authorized sanctions, such as civil monetary penalties, terminating an HHA from Medicare was the only available sanction for HHAs with serious deficiencies. Termination, however, rarely occurred because HHAs are given an opportunity to return to compliance after a deficiency is identified. Several recommendations we made have not been implemented, including ensuring that all HHAs are periodically assessed against all COPs and implementing additional sanction options.

In December 2000, the Congress directed that we assess quality-related aspects of HHAs, including the operation of branch offices.[4] To do so, we addressed four questions: (1) what is known about the quality of care provided by HHAs, (2) is the current survey process adequate to identify quality-of-care problems at both parent and branch offices, (3) are state investigations of complaints made against HHAs effective in protecting patients, and (4) is federal oversight of state survey activities and enforcement efforts adequate? To answer these questions, we analyzed information from the On-Line Survey, Certification, and Reporting system (OSCAR), a federal database that tracks the results of state HHA surveys; visited survey agencies in California and Texas, states with the largest numbers of HHAs; surveyed 12 additional states in order to evaluate their survey and complaint processes; reviewed a sample of 96 survey reports from the 34 states that cited deficiencies in certain quality-related COPs or associated standards;[5] and reviewed a sample of 93 complaints from our

[3]U.S. General Accounting Office, *Medicare Home Health Agencies: Certification Process Ineffective in Excluding Problem Agencies*, GAO/HEHS-98-29 (Washington, D.C.: Dec. 16, 1997).

[4]Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554, Appendix F, § 506, 114 Stat. 2763A-463, 2763A-531.

[5]The District of Columbia is included as one of the 34 states that cited deficiencies in certain quality-related COPs or associated standards. In this report, we generally refer to the District of Columbia as a state.

14-state sample. We also interviewed officials at the Centers for Medicare and Medicaid Services (CMS), an agency within the Department of Health and Human Services, and surveyed CMS's 10 regional offices about inspection requirements and federal oversight activities.[6] CMS administers Medicare and oversees the contracts with state survey agencies. We reviewed statutory requirements and CMS regulations regarding HHA surveys. We performed our work from January 2001 through June 2002 in accordance with generally accepted government auditing standards. (App. I presents a detailed discussion of our scope and methodology.)

Results in Brief

Although HHA surveys conducted nationwide since 1998 identified a small proportion of HHAs with serious, COP-level deficiencies, there is evidence suggesting that the extent of serious care problems may be understated and that situations endangering the health and well-being of home health patients may occur more often than documented. Over two-thirds of all HHAs nationwide with documented serious, COP-level deficiencies were located in just two states, which conducted 16 percent of the surveys nationwide. In 14 states, no COP-level deficiencies were identified during the approximately 40-month period we reviewed. In contrast with these state survey results, reports compiled from HHA data on adverse events—situations that raise a flag about the quality of care provided—showed little such variation in their occurrence across states. Adding uncertainty to the status of quality, states are not required to routinely survey branch offices, which constitute about one-quarter of all HHA service locations. Our analysis of a sample of HHA surveys showed that, when deficiencies were documented in quality-of-care COPs, surveyors identified serious care problems that harmed patients or had the potential to do so. For example, instances with the potential to harm patients included the failure to monitor the blood sugar levels of patients with diabetes, not informing the physician of abnormal vital signs, or not checking for potential adverse drug reactions or duplicate prescriptions. Instances in which we concluded that a patient was likely harmed included the lack of interventions to treat worsening pressure sores and failure to notify the physician of a circulation blockage that resulted in the loss of a patient's leg.

[6] Until June 2001, CMS was known as the Health Care Financing Administration (HCFA). In this report, we continue to refer to HCFA when our findings apply to the organizational structure and operations associated with that name.

Shortcomings in the survey process and inconsistencies in how states conduct surveys make it difficult to assess the quality of care delivered and may mask potential problems. For example, although consistent with CMS requirements, surveys routinely exclude about half of the 15 COPs from review, including the COP for skilled nursing services, and rely on small samples of clinical records and patient visits that may be inadequate to make determinations about the quality of care provided or the prevalence of quality problems. Inconsistencies in how the surveys are conducted magnify survey process shortcomings and help explain some of the variability in survey findings. For example, states we reviewed did not consistently categorize problems of similar severity as COP-level deficiencies, thus underreporting severe quality problems. State surveyors generally lacked clear criteria and tools to help them decide when to cite a COP-level deficiency. Moreover, 20 states did not survey all COPs when at least one COP-level deficiency was identified; 20 percent of HHAs nationwide with COP-level deficiencies on recent surveys had not received on-site revisits as required; and about half of HHAs that are required to have annual surveys—such as HHAs with less than 3 years in the Medicare program and those with documented COP-level deficiencies—did not receive them with that frequency. The ability of states to survey all HHAs as required—whether that means every 3 years or less often because of other considerations—may be compromised by the recent reduction in federal funding for HHA surveys.

The complaint intake and investigation practices in the 14 states we reviewed frequently had weaknesses. The ability to lodge complaints about an HHA—whether by patients, family members, or the caregivers themselves—and to have them resolved in a timely manner is an important aspect of protecting patient health and safety, especially if an HHA is surveyed only once every 3 years or for patients served by branch offices that generally receive little scrutiny. However, states' complaint hotlines and filing procedures sometimes placed burdens on complainants that could discourage them from filing their complaints, such as hotlines that were not advertised, identified, or used exclusively as complaint hotlines or that did not enable callers to leave a message. In our opinion, based on the allegations presented, about one-fourth of the complaints we reviewed to determine if they were appropriately prioritized appear to have been assigned too low a priority, thus delaying a timely response to potentially serious care problems. In addition, 5 of the 14 states we reviewed had management information systems that were insufficient for the state and CMS to properly monitor complaint investigations during 2000. For example, the systems in several states did not include the assigned investigation's priority or a key date, such as the date a complaint was

received or investigated, which is vital to determining the timeliness of the state's investigation. Two of the five states indicated that they have since improved their information systems to better track the timeliness of complaint investigations.

CMS oversight of HHAs has been too limited to identify the problems we found in the survey process and with state performance. CMS does not review state compliance with certain requirements for conducting HHA surveys, such as whether HHAs with COP-level deficiencies are surveyed annually rather than every 3 years or whether minimum patient visit and medical record review samples are adhered to. Moreover, CMS is not statutorily required to conduct federal monitoring surveys that would better enable it to evaluate state performance in conducting HHA surveys, as it is required to do for nursing homes; consequently, few are done. Although CMS plans to take some steps to improve oversight, regional offices told us that they lack the staff to devote to this effort. Shortcomings in the OSCAR data system also impair effective oversight, such as limited data on branch offices and inconsistent data entry by states. To enforce compliance with federal quality requirements, termination from the Medicare program remains the only sanction CMS uses. The Congress mandated implementation of alternative, intermediate sanctions for noncompliant HHAs by 1989—13 years ago; CMS has yet to implement such sanctions and has set no firm time frame for doing so. In our previous work, we found that the threat of termination often had little effect on HHAs' continuing compliance with quality requirements because it is rarely carried out. In practice, HHAs often are able to slip in and out of compliance repeatedly without any adverse effects on their participation in the Medicare program.

We are suggesting that the Congress consider providing CMS a new deadline to implement intermediate sanctions for HHAs that do not comply with federal quality requirements and requiring CMS to conduct federal monitoring surveys of state survey agencies in order to better assess state performance in ensuring that HHAs provide quality care to public beneficiaries. We are also making recommendations to the Administrator of CMS to (1) strengthen the survey process, (2) better ensure that the complaint process is accessible and responsive to allegations of serious quality problems, and (3) improve federal oversight of state compliance with statutory, regulatory, and other CMS requirements. CMS concurred with all of our recommendations.

Background

Medicare's home health benefit includes skilled nursing and home health aide services, physical and occupational therapy, speech pathology services, medical social services, and the provision of certain medical supplies and equipment. To qualify for services, beneficiaries must be confined to their homes; have a plan of care signed by a physician; and need intermittent skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample), physical therapy, speech-language pathology services, or have a continuing need for occupational therapy services. Intermittent means that the skilled care is either provided or needed fewer than 7 days each week, or less than 8 hours of each day for periods of 21 days or less, with extensions in exceptional circumstances when the need for additional care is finite and predictable.

HHAs may serve Medicare beneficiaries from a parent office or expand their coverage by delivering services from affiliated branches or subunits. Branch locations provide services in the same geographic area as the parent and share administration, supervision, and services with the parent. Subunits are semiautonomous entities and provide services in a geographic area different from the parent HHA. To participate in Medicare, parent offices as well as subunits must generally serve a minimum of 10 patients prior to undergoing an initial survey that certifies compliance with Medicare COPs. In other words, a subunit must meet the Medicare COPs independent of its parent office. In contrast, a branch location is not subject to an initial survey. In approving a branch location, CMS requires a parent HHA to demonstrate that it provides adequate day-to-day supervision to prove that the branch is not autonomous and should not independently meet Medicare COPs. As of mid-2001, there were approximately 6,900 HHAs and subunits and approximately 2,600 separate branch offices, for a total of about 9,500 service locations.[7] Sixty-eight percent of HHAs were freestanding agencies (not associated with a hospital), and nearly 50 percent were for-profit.

CMS and its 10 regional offices are responsible for overseeing the quality of care delivered by HHAs. CMS fulfills this responsibility by contracting with states to examine compliance with Medicare requirements, known as COPs, through periodic surveys generally conducted every 12 to 36

[7]About 3 percent of the 6,900 HHAs were subunits.

months, depending on an HHA's compliance history.[8] Focusing on care processes, Medicare's 15 COPs cover broad areas such as patient rights, adherence to the physician-prescribed patient plan of care, the provision and supervision of skilled nursing and home health aide services, and the maintenance of medical records. All but two COPs are further subdivided into more detailed standards. For example, the "skilled nursing services" COP covers the duties of both a registered nurse and a licensed practical nurse as further defined by 15 specific standards.[9]

Two of the 15 COPs, added in 1999, cover patient assessments using the Outcome and Assessment Information Set (OASIS). OASIS is used to collect standardized information on patient conditions in order to monitor changes over time and help identify potential quality-of-care problems. In general, assessments are required no less frequently than at the start of care, every 60 days following admission, and when the patient is discharged by the HHA. HHAs were required to begin collecting and reporting OASIS data in July 1999. OASIS data are also an integral part of the new HHA prospective payment system implemented in October 2000, which provides HHAs a fixed, predetermined payment for each 60-day "episode of care." The amount of the payment is adjusted for the severity of the patient's condition using OASIS data. While encouraging efficiency, the new prospective payment system also provides HHAs an incentive to reduce services in order to increase net revenues. Prior to October 1997, HHAs were paid on the basis of their costs, up to preestablished per-visit limits. There were no incentives to control the volume of services delivered, and as a result, HHAs could enhance their revenues by providing more beneficiaries with more visits.[10]

[8]Alternatively, HHAs may elect to be surveyed and accredited by either the Joint Commission on the Accreditation of Healthcare Organizations or the Community Health Accreditation Program. HHAs that are surveyed according to the CMS-prescribed survey frequency by either of these accrediting bodies and pass their surveys are "deemed" to meet Medicare COPs.

[9]COPs are composed of numerous standards. The most basic standards are listed under their associated COPs in the *Code of Federal Regulations* (42 C.F.R. §§ 484.10– 484.55). Other more detailed standards are published in CMS's *State Operations Manual*.

[10]From October 1, 1997, until the implementation of the new prospective payment system in October 2000, HHAs were paid under an interim payment system, which incorporated tighter per-visit cost limits than were previously in place and subjected each agency to an annual Medicare revenue cap. See U.S. General Accounting Office, *Medicare Home Health Care: Prospective Payment System Could Reverse Recent Declines in Spending*, GAO/HEHS-00-176 (Washington, D.C.: Sept. 8, 2000).

According to CMS requirements, state surveyors must routinely conduct a "standard survey" to test compliance with about half of the 15 COPs (see app. II).[11] CMS deems these COPs to be those most closely associated with the quality of care provided by HHAs. If an HHA is found to be out of compliance with at least one of these COPs, surveyors are required to extend the standard survey and review the remaining COPs. Typically, state surveyors are registered nurses. CMS offers a basic course that focuses on HHA regulations and survey methodology but it is not mandatory for HHA surveyors to take this course.[12] However, every surveyor must complete one of the basic training courses, such as the course on surveying nursing homes, end-stage renal facilities, or hospitals. In addition to focusing on the regulations specific to a provider, each of these courses also covers generic skills such as observation, interviewing, and documentation.

The core of the statutorily defined standard survey is the review of a case-mix stratified sample of patient medical records and visits to patients' homes to validate the record review.[13] The medical record review includes determining whether the HHA has a current and appropriate plan of care for each patient as ordered by the patient's physician, whether the ordered care and services are provided and coordinated by the personnel who furnish them, and whether the patient's physician is notified of changes in medical condition. The visit to the patient's home is to ensure the patient is receiving the physician-ordered treatment in accordance with the plan of care and that the care is provided in accordance with Medicare health and safety standards.[14] The number of records reviewed and patients visited is based on the number of unduplicated skilled care patients served

[11]During a standard survey, only one of the standards—coordination of patient services—associated with the COP "organization, services, and administration," is examined.

[12]In contrast, it is a statutory requirement for nursing home surveyors to successfully complete a training and testing program that specifically focuses on nursing homes.

[13]Stratified means that the patients selected for the sample are grouped on the basis of the primary admitting diagnosis for which they are receiving care from the HHA. Case-mix means that the sample includes patients receiving care services from different types of HHA care providers—nurses, therapists, social workers, and home health aides.

[14]Home visits conducted by a state surveyor require a patient's consent. The HHA usually obtains the permission and schedules the home visits. If a patient chooses not to participate, the surveyor substitutes another patient from the sample.

by an HHA in the 12 months prior to the survey.[15] For example, an HHA with fewer than 150 patients would have a minimum of 3 to 5 record reviews with patient home visits, while an HHA with 1,251 or more patients would have 25 or more. Because home health patients reside in their own homes and care delivery is not as readily observable, detecting quality-of-care deficiencies—both individual and systemic—is more challenging than it is for nursing home residents. For example, HHA surveyors are typically in each patient's home for less than an hour to interview the patient and, if possible, to observe care delivery by HHA personnel; in contrast, a nursing home survey lasts several days, giving surveyors a significant opportunity to observe the delivery of care and identify the quality-of-care concerns of a number of residents over a longer period of time.

When HHAs fail to meet Medicare quality requirements, surveyors are required to cite deficiencies of either COPs or standards or both. According to CMS's guidance, COP-level deficiencies are more serious and reflect the existence of a significant problem that "adversely affects or has the potential to adversely affect patients"—that is, harms patients or has the potential to do so.[16] CMS guidance does not specifically define a standard-level deficiency. When a deficiency is cited, HHAs must submit a plan of correction. CMS requires state surveyors to confirm that HHAs with a COP-level deficiency have returned to compliance by making on-site revisits.

By statute, each HHA must be surveyed at least once every 36 months, with CMS requirements determining the exact survey frequency based on an HHA's compliance history and other factors. Generally, CMS requires an HHA without COP-level deficiencies to be surveyed once every 3 years. In contrast, CMS requires annual surveys if HHAs have participated in Medicare for fewer than 3 years; have had a recent change in ownership; have had a COP-level deficiency within the last 24 months; have been reviewed by a state, regional, or national fraud and abuse initiative; or have had a complaint survey with any deficiency citations since the last

[15]To determine unduplicated skilled care admissions, HHA patients who are admitted and discharged and then readmitted during the 12 months prior to the survey are counted only once.

[16]CMS guidance directs surveyors to take several factors into consideration when making judgments about an HHA's compliance with COPs: the effect or potential effect on the patient, the degree of severity, the frequency of occurrence, and the impact on the delivery of services.

standard survey. This variable 12- to 36-month survey schedule was implemented in 1996 to focus survey resources on HHAs with compliance problems.[17] The results of HHA surveys are tracked in CMS's OSCAR database, which permits federal monitoring of state survey activities.

State survey agencies are required to conduct timely investigations of reported complaints, and to operate a home health hotline for individuals to register complaints against HHAs. For complaints that involve a possible immediate and serious threat, states must conduct complaint investigations within 2 working days. Additional time frames for investigating other complaints may be set at each state's discretion. A complaint investigation can trigger a standard survey if surveyors find situations that warrant further review.

HHAs that are out of compliance with one or more COPs can be terminated from the Medicare program and thus lose the right to serve Medicare beneficiaries. Termination is the only federal sanction available because CMS has not implemented other sanctions as directed by the Congress in 1987. When a COP-level deficiency poses an "immediate and serious threat" to a patient's health and safety, HHAs are placed on an accelerated 23-day termination timetable; in less serious situations, CMS uses a 90-day termination timetable. HHAs can avoid termination by implementing plans of correction that bring them back into compliance with Medicare's COPs. HHAs with one or more standard-level deficiencies—as opposed to having a COP-level deficiency—are not subject to termination but must submit an acceptable plan of correction. In states that license HHAs, other state-specific enforcement actions, including revoking an HHA's operating license or assessing monetary penalties, may be available.

[17]Prior to 1996, HHAs were surveyed approximately every 12 months. In making the case for a more flexible survey schedule, HCFA noted that such frequent state surveys found few serious deficiencies.

Limited Number of Identified Deficiencies May Understate Prevalence of Serious Care Problems, Creating Uncertainty About Overall Quality

Although the results of HHA surveys conducted since 1998 indicated that few agencies had serious quality problems, the prevalence of reported COP-level deficiencies varied dramatically across states, suggesting that such problems may be understated in many states. In contrast, analysis of adverse events recorded in OASIS data collected by HHAs—incidents that raise a flag about the quality of care delivered—showed they occurred with little variation across states. Thus, problems endangering the well-being of patients may be occurring with greater regularity than state surveys indicate. Moreover, CMS does not require states to routinely survey branch offices, which constitute about one-quarter of HHA service locations, adding to the uncertainty about the status of HHA quality. Our review of 80 surveys that cited quality-of-care related COP deficiencies, including 25 from the two states citing the majority of COP deficiencies, indicated that surveyors had documented serious care problems that either harmed patients or had the potential to do so.[18] The deficiencies often represented a basic failure to follow the patient's plan of care, notify the doctor of important changes in the patient's condition, or take appropriate precautions with medications.

Wide Variability in Citing Deficiencies Questions Credibility of State Surveys

The most recent HHA surveys showed that only about 6 percent of HHAs nationwide had COP-level deficiencies—situations that harm or have the potential to harm patients.[19] However, the skewed findings of COP-level deficiencies in a small number of states, despite more consistent indications of potential care problems across all states, suggest that states may not be identifying all COP-level deficiencies, resulting in a likely understatement of serious care problems. Furthermore, the fact that branch offices are not required to be routinely surveyed limits knowledge

[18]As discussed later in this report, we reviewed 16 additional surveys that cited three or more standards associated with certain quality of care COPs but not the COP itself. Overall, we reviewed 96 survey reports.

[19]We analyzed HHA surveys conducted after March 31, 1998, and entered into OSCAR by August 17, 2001, excluding about 600 HHAs (almost 9 percent) whose most recent survey was older than April 1, 1998, and thus may not reflect the current quality of care. Since HHAs are required to be surveyed at least once every 3 years, we worked with CMS regional offices as well as states to understand why about 9 percent of active HHAs had surveys more than 3 years old. We learned that either the survey results had not been entered into OSCAR, the HHA had been terminated, the HHA was deemed by other entities to meet Medicare COPs, or the HHA only served Medicaid recipients (66 of 6,905 HHAs in OSCAR as of August 17, 2001). No survey results would be expected or required in the latter three instances. With the exception of California HHAs, most agencies appear to have been surveyed at least once every 3 years.

about the quality of care they provide. Branches account for about one-quarter of HHA operating locations nationwide, and in five states branches are more numerous than parent HHAs. (App. III shows the number of branch offices as a percentage of all HHA operating locations for each state.) Moreover, the number of branches may be significantly greater than the number identified by CMS.[20] In addition, states lack a way of separately recording the results of any branch office surveys because branches operate under their parents' provider numbers.

California and Texas accounted for over two-thirds of documented COP-level deficiencies nationwide, suggesting that states have disparate survey practices that may not consistently capture the actual status of quality.[21] While these two states represented less than one-fifth of the nation's HHAs with current surveys, they identified 261 of the 368 HHAs with COP-level deficiencies.[22] The remaining 107 HHAs with COP-level deficiencies were spread across 35 states, states that accounted for almost 70 percent of HHAs with current surveys. Finally, as of August 2001, 14 states had cited no COP deficiencies since March 31, 1998. (App. IV shows the number of HHAs cited with COP-level deficiencies in each state.)

In contrast with the variable citation of COP-level deficiencies nationwide, our analysis of OASIS adverse events reports showed significantly less

[20]On the basis of a survey conducted by CMS's Denver regional office, the number of HHA branches may be understated. The survey identified 127 branch offices in the Denver region, compared with the 58 identified in OSCAR.

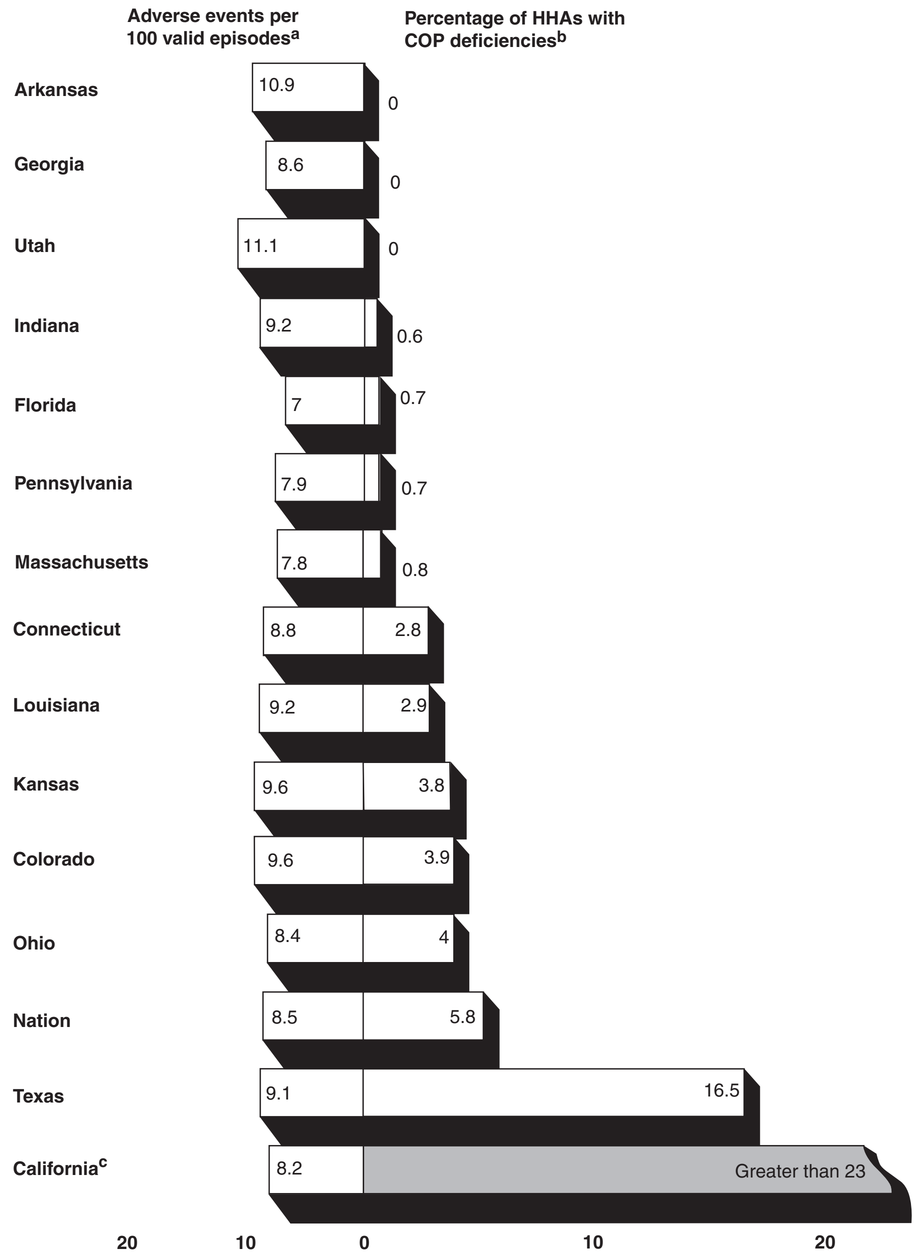
[21]The results of California's HHA surveys likely overstate the proportion of all agencies with COP-level deficiencies in the state. Over the approximately 40-month period we analyzed, the state only surveyed 39 percent of its active HHAs, assigning a higher priority to surveying HHAs with a poor performance record. As a result of this focus, 58 percent of the HHAs surveyed had COP-level deficiencies. However, if the 61 percent of the state's HHAs that were not surveyed had no COP-level deficiencies, the statewide estimate of HHAs with COP-level deficiencies would be 23 percent. Nationwide, 91 percent of active HHAs had a survey during the period we analyzed.

[22]California and Texas also identified 916 of the 1,103 COP deficiencies cited nationwide.

interstate variation.[23] While the range in the percentage of HHAs with COP-level deficiencies is wide—from none in Arkansas, Georgia, and Utah to at least 23 percent in California—the range of adverse events per 100 valid episodes is much narrower, from 7 to 11.1 percent. Figure 1 compares the percentage of surveys with COP-level deficiencies and adverse events per 100 valid episodes for our sample of 14 states (see app. IV for other states). California and Texas cited COP-level deficiencies at a significantly higher proportion of the HHAs they surveyed than did most other states, but for adverse events reports, both states were close to the national average of 8.5 adverse events per 100 valid episodes. Arkansas and Utah, which cited no COP-level deficiencies, were among the states with the highest number of adverse events per 100 valid episodes—10.9 and 11.1, respectively.

[23]Adverse events reports provide numeric warning signs of potential quality-of-care problems at HHAs. Adverse events reports tally the number of problematic situations in 13 areas of care, including deteriorating wound status, development of urinary tract infections, and an increase in the number of pressure sores. These reports are compiled from OASIS data submitted by HHAs for patients with "valid episodes" of care, meaning there was a start- and end-of-care assessment and the data have passed a variety of quality tests. These reports were developed as a tool to help state survey agencies target specific patient cases or HHAs for review and do not necessarily indicate poor care, which can only be validated through record reviews and patient visits during an on-site survey.

Figure 1: Adverse Events per 100 Valid Episodes of Care, Compared with Percentage of HHAs with COP-Level Deficiencies in GAO Sample States



[a]A valid episode includes data that are for patients who have received a start- and end-of-care assessment and that have passed a variety of quality tests. Data are based on HHAs reporting OASIS data during calendar year 2000.

[b]Data include active HHAs with a current survey in OSCAR conducted after March 31, 1998, and entered into the database by August 17, 2001, totaling 91 percent of active HHAs.

[c]Focusing on surveying HHAs with a poor performance record, California surveyed only 39 percent of its active HHAs over the approximately 40-month period we analyzed and documented that 58 percent of those surveyed had COP-level deficiencies. However, assuming that no COP-level deficiencies existed in the 61 percent of HHAs not surveyed, the overall estimate of California HHAs with COP-level deficiencies would be 23 percent.

Source: GAO analysis of OSCAR data and CMS analysis of OASIS adverse events.

State Surveys Document Potentially Serious Quality-of-Care Problems

To assess the severity of the problems identified during HHA surveys, we reviewed 80 surveys that documented at least one of five quality-of-care related COP deficiencies. (Table 1 describes the five COPs and associated standards.)[24] These surveys—containing 132 quality-of-care related COP deficiencies—documented serious care delivery problems, the majority of which had the potential to harm patients.

[24]According to OSCAR data, surveys in 32 states conducted since December 31, 1999, and entered into OSCAR as of August 17, 2001, documented at least one of these quality-related COP deficiencies. We reviewed all such COP deficiencies in surveys from 30 states but randomly selected 25 surveys from California and Texas, the 2 states citing the majority of deficiencies in these five COPs.

Table 1: Five COPs and Associated Standards Related to Quality of Care That Were Frequently Cited in Surveys

COP	Associated standards
Acceptance of patients, plan of care, and medical supervision	• Care follows written plan • Plan covers all pertinent diagnoses • Doctor alerted about need to alter plan of care • Drugs and treatments administered per doctor's orders
Skilled nursing services	• Skilled services administered per plan of care • Nurse regularly reevaluates patient's nursing needs • Nurse prepares clinical notes and informs physician of changes in patient's condition
Home health aide services	• Aides must have written care instructions prepared by nurse • Nurse visits patient once every 2 weeks
Medical records	• Medical records maintained
Comprehensive assessment of patients	• Drug regimen is reviewed for duplicative medications and potential adverse reactions

Note: The COPs included on a standard survey are those most closely associated with quality of care, according to a CMS official (see app. II, table 8). However, skilled nursing services is not one of these COPs. For our analysis, we based our selection of COPs on input obtained from CMS regional offices and officials at state survey agencies in our sample states. These 5 quality-of-care related COPs and 11 associated standards were among those most frequently cited on current surveys. Each of these COPs has numerous related standards, but many of them are cited infrequently. In commenting on a draft of this report, CMS suggested that since the standard survey focuses on patient care and those COPs that support patient care, it was appropriate to exclude skilled nursing services because it focuses on the duties of the registered nurse (RN), RN oversight, and supervision of the licensed practical nurse. However, the home health aide services COP also focuses on duties, oversight, and supervision but is included in a standard survey. Our sample states and CMS regional offices generally identified skilled nursing services as a critical quality-of-care COP. In addition, it is the most frequently cited home health COP.

Source: Medicare COPs for HHAs.

Our analysis showed that the examples provided to support 93 percent of the 132 COP-level deficiency citations demonstrated serious quality-of-care problems with either the potential for or likely patient harm. However, we found that the documentation for these COP-level deficiencies described relatively few instances of likely patient harm.[25] On the basis of the information in the survey reports, we were usually unable to determine whether there was no harm or it was simply not documented. The deficiencies often represented a basic failure to follow the patient's

[25]Unlike nursing home surveys, which base their determination of the seriousness of a deficiency on its scope and severity and whether actual harm has occurred to the resident, HHA deficiencies are not categorized according to whether the patient has been harmed. As a result, our review specifically focused on identifying instances where patients were likely harmed as a result of poor-quality care.

plan of care, notify the doctor of important changes in the patient's condition, or take appropriate precautions with medications (see table 2). Consistent with the focus of surveys on care processes rather than outcomes, the potential for harm was frequently shown, but only a relatively small number of the COP deficiencies documented whether likely patient harm had resulted. Overall, the 132 COP deficiencies we reviewed in the 80 state survey reports demonstrated likely harm to 22 patients in 16 of the surveys. Appendix V contains abstracts of these 22 instances, including the lack of interventions to treat worsening pressure sores and failure to notify the physician of a circulation blockage that resulted in the loss of a leg.

Table 2: Typical COP-Level Quality-of-Care Problems Documented during State HHA Surveys

Problem	Example
HHA not following patient's plan of care	• Not monitoring blood sugar level of patients with diabetes • Not regularly weighing patients with congestive heart failure • Not promptly following physician's orders to test the ability of blood to clot in patients taking a blood-thinning medication • Not providing appropriate treatment for patients with pressure sores or surgical incisions • Not providing all of the prescribed skilled nursing, home health aide, or physical therapy visits
Physician not informed of significant changes in patient's condition	• Physician not informed about abnormal vital signs—blood pressure, respiratory difficulty, or temperature—whether or not ordered to do so by the plan of care • Physician not informed when high or low blood sugar readings are found for diabetic patients, whether or not ordered to do so by the plan of care • Physician not promptly informed about symptoms suggesting infected pressure sores, urinary tract infections, congestive heart failure, respiratory diseases, and declining circulation in the limbs • Physician not informed of observed psycho-social problems, such as depression or inability to pay for ordered medications
HHA not taking appropriate precautions with patient's medications	• Nurse did not assess patient for potential adverse reactions or duplicate prescriptions • Nurse provided incorrect dosage • Nurse did not administer medication at the ordered frequency • Nurse unaware that patient was not taking medications • Medical record unclear about which medications the patient was taking, the dosage, or the frequency ordered

Source: GAO analysis of 80 state surveys conducted since December 31, 1999.

In 7 percent of the 132 COP-level deficiencies we reviewed, surveyors demonstrated that HHAs were not following the Medicare COPs, but the documentation for problems cited in those standards we examined did not indicate a potential for serious or immediate harm to patients. Most of these deficiencies involved the failure to meet medical record or patient assessment documentation requirements, and they were frequently systemic in nature. For example, surveyors in one state cited a new HHA for a COP-deficiency related to medical records because the HHA had not assigned numbers to the medical records of the 14 patients it had served up to that time or completed discharge summaries for any of its 7

discharged patients. Another state cited an HHA with this same deficiency because of an undated physician's signature on care plans for four patients and the lack of a physician's signature or date on the care plan for one other patient. Finally, two states cited HHAs for failing to meet the COP related to patient assessment because the HHAs consistently performed separate OASIS and patient assessments instead of integrating them as required.

Weaknesses in Survey Process and Inconsistencies in How States Conduct Surveys Mask Potential Quality Problems

Shortcomings in the HHA survey process as well as inconsistencies in how states conduct surveys make it difficult to assess the quality of care provided. Although CMS now requires surveyors to use reports generated from OASIS data to help identify patients for whom quality of care may be a concern when selecting medical record and patient visit samples, this change is not sufficient to address more fundamental shortcomings in the survey process. For instance, standard surveys exclude about half of the 15 COPs and rely on very small samples of clinical records and patient visits to adequately assess quality of care. In addition, the surveyors lack clear criteria and tools to help them decide when to cite a COP-level deficiency, and guidance on when to survey branch offices is unclear. Inconsistencies in how states conduct surveys magnify these weaknesses and help explain some of the variability in survey findings. For example, states did not consistently categorize problems of similar severity as COP-level deficiencies, providing evidence that quality-of-care problems may be understated. Three of the states we assessed used nursing home surveyors for HHA surveys who were inexperienced with the HHA survey process. In addition, based on our analysis of OSCAR data, states did not always comply with federal survey requirements, such as reviewing the required number of medical records and visiting the minimum number of patients. Furthermore, HHAs new to the Medicare program and those with serious deficiencies frequently were not surveyed annually as required. The ability of states to survey these and other HHAs as required may be compromised by the reduction in federal funding for HHA surveys.

Recent Changes Have Not Fundamentally Altered the Process Focus of HHA Surveys, nor Have They Addressed Other Serious Weaknesses

Although CMS now requires surveyors to use reports generated from OASIS data to focus survey activities on patients for whom quality of care may be a concern, this change has not fundamentally altered the survey's reliance on process requirements to evaluate HHA performance. CMS also has not addressed some of the serious weaknesses in the survey process we identified in our 1997 report, such as not surveying HHAs against all COPs and inadequate oversight of HHA branch offices.

Surveys Remain Essentially Process-Oriented despite Use of OASIS Data during Surveys

Consistent with provisions of the Omnibus Budget Reconciliation Act of 1987 (OBRA), CMS has taken incremental steps from 1991 through 2001 to broaden the focus of surveys beyond a test of compliance with process requirements by including an evaluation of the kind of care being provided and the effect of that care on the beneficiaries being served.[26] In 1991, HCFA implemented a revised survey process using indicators of medical, nursing, and rehabilitative care to determine the quality and scope of patient care services provided by an HHA. Nevertheless, a 1994 study commissioned by HCFA to evaluate the 1991 changes concluded that HHA surveys continued to emphasize care processes over patient outcomes.[27] While determining compliance with standard care processes is an important aspect of measuring quality of care, determining patient outcomes is also vital because it identifies the impact of poor care processes. However, the design of the HHA survey still allows surveyors to cite a deficiency without addressing the patient outcome because the COPs focus on care processes (see app. II, table 8). In contrast, the design of the nursing home survey process allows surveyors not only to examine compliance with care processes but also to identify the outcomes of care delivered.[28] (See app. II, table 9, for examples of outcome measures used in nursing home surveys.)

While HCFA had proposed revising the COPs against which HHAs are evaluated, it gave introduction of OASIS a higher priority. HCFA issued proposed rules in 1997 to revise the home health COPs and to require HHAs to begin collecting and reporting OASIS data. Revising the COPs was intended to eliminate unnecessary process requirements and focus on the health status impact of the treatment furnished by an HHA. For example, the proposed changes would likely require a review of skilled nursing services during standard surveys. Similarly, OASIS was intended to have HHAs collect standardized patient information that could be used

[26] Pub. L. No. 100-203, §§ 4021, 4022 (1987). Other key changes mandated by OBRA 1987 were (1) strengthening the rules governing participation in Medicare to require, for instance, that HHAs hire only trained and competent home health aides; (2) requiring state or local agencies to maintain toll-free complaint hotlines; and (3) expanding sanctions to include options such as civil monetary penalties so that termination is not the only sanction available for HHAs that fail to meet federal requirements.

[27] Robert E. Schlenker and others, *Home Health Agency Assessment Process Evaluation Project: Final Report* (Denver, Colo.: University of Colorado Health Sciences Center, Center for Health Policy Research, Dec. 1994).

[28] In 1990, responding to provisions in OBRA 1987, HCFA implemented a revised, more outcome oriented, nursing home survey process.

to monitor changes in patients' conditions and to link any changes to the care provided by an HHA. Although the issuance of revised COPs has been delayed until mid-2003, new OASIS COPs—requiring HHAs to collect and report OASIS data on most patients—were implemented during 1999.[29]

With the availability of OASIS data, HCFA began requiring state surveyors to access and review certain reports before conducting HHA surveys: (1) patient characteristics, (2) adverse events, (3) health care services utilization, and (4) improvement and stabilization of health status. These reports are intended to assist surveyors in targeting potential quality-of-care problems during the on-site survey and identifying individuals or types of patients to be included in the case-mix stratified sample.[30] While worthwhile, the use of these reports has not fundamentally altered surveys, which continue to focus on care processes.

Weaknesses in Other Federal Survey Requirements Are Not Being Addressed

Despite CMS's focus on revising the home health COPs and adding OASIS, other shortcomings in the survey process have not been addressed, including (1) exclusion of some COPs during routine surveys, (2) insufficient sample sizes to adequately detect quality-of-care problems, (3) lack of clear criteria or tools to categorize the severity of deficiencies, and (4) lack of sufficiently detailed requirements regarding surveys of branch offices.

HHAs Not Surveyed against All COPs. HHAs may participate in the Medicare program without ever undergoing a survey that examines their compliance with all COPs.[31] During 2000, 92 percent of HHA surveys did not include a review of all 15 COPs. Without such a review, CMS has no assurance that an HHA is fully complying with Medicare health and safety requirements. In particular, the skilled nursing COP is not one of the COPs included in a standard survey, even though the need for skilled nursing

[29]The HHA standard survey was altered at this time to include two of the three new OASIS COPs. The urgency of adopting the OASIS COPs was due to the impending implementation of the HHA prospective payment system in October 2000. Under this new payment system, OASIS data are used to adjust payments on the basis of the care needs of patients.

[30]CMS awarded a 33-month contract in September 2001 to formalize the use of OASIS data during HHA surveys. The objective is to develop protocols for using OASIS and other existing data to help target on-site survey activities, define protocols for off-site monitoring of OASIS data collection and transmission requirements, and incorporate new quality and performance measures into HHA surveys.

[31]Surveyors are required to examine all COPs only when a COP-level deficiency is found during a standard survey, which examines about half of the 15 COPs.

care is one of the eligibility requirements for Medicare beneficiaries to receive home health services.[32] According to CMS, initial surveys of HHAs—unlike surveys of nursing homes, critical access hospitals, intermediate care facilities for the mentally retarded, hospices, and kidney dialysis facilities—do not automatically assess compliance with all COPs. Moreover, HHAs are one of the few such providers for which surveyors do not automatically examine all COPs during subsequent surveys.[33] In 1997, we recommended that HCFA establish targeting criteria for selecting HHAs to survey for compliance with all COPs—to periodically ensure that all HHAs fully comply with Medicare safety and health requirements. HCFA responded that its targeting criteria were adequate. We continue to believe that the agency should require states to periodically review HHAs' compliance with all COPs, since over 40 percent of recently cited COP-level deficiencies involved conditions that are not routinely examined during a standard survey.[34]

Insufficient Sample Size. HCFA's 1994 evaluation of the survey process concluded that the number of medical records reviewed with and without home visits was too small to detect the prevalence of quality-of-care problems at HHAs. A change in the sample selection procedure introduced since 1994, however, has generally further reduced home health survey

[32]The proposed COP revisions, published in 1997 but still not implemented, would likely require a review of skilled nursing services during standard surveys.

[33]While HCFA eliminated the distinction between conditions and standards for nursing homes, it still exists for HHAs. Thus, nursing homes are assessed against all of the 190 federal requirements, while in general HHAs are only routinely assessed against a subset of the 177 federal requirements—about half of the COPs and the associated standards.

[34]These data reflect surveys conducted since March 31, 1998, and entered into OSCAR as of August 17, 2001.

sample sizes.[35] Currently, survey sample sizes are based on the number of unduplicated skilled care admissions from all payer sources during the 12 months preceding a survey. Depending on the number of unduplicated skilled care admissions, surveyors must review a minimum of 11 to 40 records and interview a minimum of 3 to 25 patients in their homes.[36] The nursing home survey sample size, on the other hand, is considerably larger.[37] For example, a nursing home surveyor must review 30 records for 400 patients, while an HHA surveyor inspecting a similarly sized HHA would need to review a minimum of 15 records. Reviewing a valid and representative sample of medical records and conducting patient visits is important because these activities allow surveyors to identify the nature and prevalence of quality-of-care concerns, including whether treatment is consistent with the plan of care. Small sample sizes reduce the ability of surveyors to generalize their findings to other patients at an HHA or determine whether quality-of-care problems are isolated or widespread.

[35]Since 1994, the criteria for determining the sample size universe have changed from all skilled care admissions per HHA to unduplicated skilled care admissions—generally decreasing record reviews and patient visits because the universe is now smaller. Using unduplicated skilled care admissions, an HHA patient who is admitted and discharged and then readmitted is counted only once. For example, an HHA with 800 *duplicated* skilled care admissions requires a records review with home visits of a minimum of 7 to 10 patients. The same HHA may have 550 *unduplicated* admissions—requiring a review of a minimum of 5 to 7 patients. This change may not have affected very large HHAs because the sample size requirements remain the same for admissions greater than 1,251. Another change implemented during 1998 expanded the number of patients used to determine the sample size for home visits from only Medicare or Medicaid skilled care patients to all skilled care clients—regardless of payer source. Because the universe may have become larger and there was no corresponding increase in the sample size for very large HHAs, this change effectively decreased the likelihood that a quality-of-care problem would surface during a survey.

[36]Surveyors may review more than the minimum number of patients outlined if they need more information to assess compliance with Medicare COPs. For HHAs with unduplicated skilled care admissions greater than 1,250 per year, surveyors may limit the review to 10 to 12 patient visits if (1) they find no quality-of-care problems, (2) there has been no change of ownership or management since the previous survey, and (3) no COPs were cited on the previous survey. If a quality-of-care problem is detected anytime during the survey, all of the patient visits from the original sample must be completed.

[37]We previously identified weaknesses in the nursing home survey sampling methodology that resulted in surveyors missing significant care problems. In response, HFCA undertook a series of initiatives to address these weaknesses, including instructing surveyors to increase the sample size in areas of particular concern. See U.S. General Accounting Office, *Nursing Homes: Sustained Efforts Are Essential to Realize Potential of the Quality Initiatives*, GAO/HEHS-00-197 (Washington, D.C.: Sept. 28, 2000).

Limited Criteria or Tools to Help Categorize the Severity of Deficiencies. Federal guidance to surveyors about when to cite a COP-level deficiency is limited, and surveyors lack tools to help categorize deficiencies when they are found. CMS guidance for surveyors states that an incident with little or no effect on the delivery of patient services does not warrant a deficiency citation. On the other hand, a COP-level deficiency may be cited if, in a surveyor's judgment, the deficiency constitutes a significant or a serious problem that adversely affects, or has the potential to adversely affect, patients.[38]

Vague Requirements for Surveying Branch Offices. Despite the fact that branch offices represent about one-quarter of all HHA locations, CMS guidance on surveying branches is vague.[39] In 1997, we recommended that HHA branch locations be "periodically surveyed."[40] CMS instructed states as of April 2001 that (1) branch locations should be periodically included in or replace the unannounced standard survey of a parent HHA, (2) standard surveys should be routinely conducted at a branch location when that location serves more patients than the parent, and (3) all locations of an HHA should be visited during the survey whenever possible. Officials in CMS regional offices told us that no additional guidance was provided to states for defining the terms "periodically," "included in," or "routinely." Furthermore, according to CMS, some state surveyors currently lack a systematic way of determining the number of patients served by a parent HHA or its branch offices prior to the actual survey.

[38]Nursing home surveyors have an additional tool to help them categorize deficiencies that is not available to home health surveyors. Beginning in 1995, nursing home surveyors were required to begin using a standardized framework to categorize quality-of-care problems identified during either standard surveys or complaint investigations. As a result, nursing home quality-of-care problems are now classified in 1 of 12 categories according to their scope (the number of patients potentially or actually affected) and their severity. This nursing home severity assessment distinguishes between (1) care that actually caused harm versus care that had the potential to cause harm and (2) the potential for minimal harm and the potential for more than minimal harm. Recognizing that the inconsistent application of the scope and severity deficiency criteria contributed to the variability across states in the documentation of deficiencies during nursing home surveys, CMS is developing improved nursing home surveyor guidance.

[39]CMS regional offices must approve an HHA's request to open a branch office. However, there is no requirement to visit a branch location to ensure that the parent office is providing adequate day-to-day supervision and that the branch location is complying with Medicare requirements if this information can be ascertained by reviewing HHA records.

[40]GAO/HEHS-98-29.

Inconsistencies in How States Conduct Surveys Help Explain Interstate Variability in Citing Deficiencies

Inconsistencies in how states conduct surveys may amplify shortcomings in the survey process and help explain some of the variability in survey findings we noted across states. Based on our work with the 14 sample states and analysis of national OSCAR data, we found that surveyors in certain states (1) inconsistently categorized quality-of-care deficiencies, (2) lacked appropriate training and experience, (3) failed to cite deficiencies because they viewed their role as advisory rather than as one of oversight of HHAs, and (4) did not consistently follow CMS requirements regarding significant elements of the survey process.

Inconsistent Categorization of Quality-of-Care Deficiencies

Georgia and Massachusetts, 2 of our 14 sample states, reported no COP-level quality-of-care deficiencies in surveys conducted since December 31, 1999, and entered into OSCAR as of August 17, 2001.[41] In reviewing documented standard-level deficiencies in these two states, we noted six examples in 5 of 16 surveys where patients were exposed to likely harm, but no COP-level deficiency was cited. (See app. VI.) In other states, we found that deficiencies of this severity were often cited at the COP level. (See app. V.)

Such survey inconsistencies across states probably result in an understatement of quality problems. For example, Massachusetts cited standard-level deficiencies for a case in which a patient on a blood-thinning medication died after the HHA failed to ensure that the patient received regular tests to measure blood clotting time, as ordered by the physician. In commenting on a draft of this report, a Massachusetts official said that only standard-level deficiencies were cited in this case because, in the professional judgment of the surveyors, the HHA had implemented systemic changes to correct the problem prior to their arrival at the HHA. We continue to believe that the likely patient harm we identified in this and another Massachusetts survey warranted the citation of COP-level deficiency. Moreover, we found cases in other states where COP-level deficiencies were cited for outcomes of similar or lesser severity. For example, Nevada cited an HHA with a COP-level deficiency for waiting 9 days before informing the physician of a patient's nausea, vomiting, and diarrhea. This patient was admitted to the hospital for weakness, inability to eat, and dehydration. In another case, Texas cited an HHA with a COP-

[41] In addition to reviewing all quality-of-care related COP deficiencies from 30 states, plus a random sample of all deficiencies from California and Texas, we reviewed all surveys from Massachusetts and Georgia that cited 3 or more of 11 associated standards but not the COP itself during this period. We selected these two states because they were already part of our 14 state sample.

level deficiency at the level of “immediate jeopardy” for failing to report the patient’s worsening pressure sore and pulmonary status to the physician, and failing to ensure that the physician’s orders for tests were fully implemented. As a result, this patient’s pressure sore worsened and became infected and the pneumonia was not treated for 2 months. (See app. V.)

Inadequate Surveyor Training and Experience

In Florida, Kansas, and Louisiana, we found that a substantial number of surveyors assigned to conduct HHA surveys during 2000 had neither (1) taken the basic HHA training course offered by CMS nor (2) acquired substantial on-the-job experience by conducting HHA surveys (see table 3).[42] In contrast, surveyors in Arkansas, California’s Los Angeles county district office, and Texas have generally taken CMS’s HHA training course. According to a CMS official, attendance at a basic training course is mandatory for HHA surveyors, but the course does not have to be the basic HHA training course.[43] In general, officials in Florida, Kansas, and Louisiana said that the limited number of surveyors who had graduated from the course was the result of the course being offered infrequently, the limited number of slots available to a state, surveyor turnover, and the amount of training resources. However, a Texas official told us that the state sent 30 new surveyors to basic HHA training in 2000 and 2001 because it sees national training as an investment that helps ensure consistency across surveys. Texas, we were told, pushed for more slots at each of these courses. Florida and Louisiana officials indicated that their respective CMS regional offices allocated fewer HHA training slots than were requested. According to a CMS headquarters training official, regional offices should be working with headquarters to accommodate state needs. A state official also emphasized that, like Texas, Louisiana valued national training. Finally, Florida, Kansas, and Louisiana all pointed out that they provide state-level training to HHA surveyors, which may include on-site mentoring by experienced staff.

[42]For this analysis, we focused on several states from our 14-state sample that had different policies for assigning HHA surveyors. Surveyors in Kansas and Louisiana survey both nursing homes and HHAs. Florida surveyors focus on HHAs, hospices, and other facility types but may also be asked to survey nursing homes if they have the prior experience and training. Texas and Arkansas have a dedicated group of surveyors for HHAs and hospices. Similarly, surveyors in California’s Los Angeles county district office, who survey about 40 percent of the state’s HHAs, focus on HHAs, hospices, and related provider types.

[43]The basic training courses were developed with the objective of training surveyors. Each course addresses the principles of documenting deficiencies and the use of survey protocols. However, the underlying regulations as well as important aspects of the survey process differ by provider type.

As shown in table 3, Florida, Kansas, and Louisiana gave little opportunity for surveyors to develop their HHA survey skills because they generally assigned a large number of surveyors relative to the number of HHAs being inspected, resulting in many surveyors conducting few surveys. For example, Louisiana assigned 74 surveyors to inspect 125 HHAs—a ratio of less than 2 HHAs per surveyor. From 18 percent to 32 percent of surveyors in these states conducted only one survey during 2000 and about half or more conducted no more than three. A Kansas official attributed the assignment of a large number of surveyors to having less experienced surveyors assist experienced surveyors and to providing less experienced surveyors on-the-job training before receiving more formal HHA training. In contrast, Arkansas, which had 36 percent more HHAs than Kansas, surveyed HHAs in 2000 with 6 surveyors compared with the 27 used by Kansas. Three of Arkansas' six dedicated HHA surveyors inspected from 16 to 28 HHAs during 2000; the remaining three surveyors only conducted from 7 to 10 surveys each because they were only employed part of the year. According to a CMS official, surveyors who do a limited number of HHA surveys each year would lack a cohesive comprehension of the regulations. In addition, ensuring consistency across surveys is very difficult if surveyors have limited on-the-job experience.

Table 3: Selected Characteristics of Surveyors in Florida, Kansas, and Louisiana Who Conducted HHA Surveys in 2000

State	Number of HHA surveys during 2000	Number of individual surveyors assigned to HHA surveys	Percentage of surveyors: Who had conducted 1-3 HHA surveys	Percentage of surveyors: Who had conducted 10 or more HHA surveys	Percentage of surveyors: Who had or have since attended CMS HHA training[a]
Florida	171	73	60	6	8
Kansas	94	27	48	11	41
Louisiana	125	74	60	1	7[b]

[a]Some surveyors attended CMS HHA training after they conducted HHA surveys in 2000.

[b]Louisiana was unable to provide training information on 21 surveyors who were no longer employed by the state survey agency.

Source: GAO analysis of OSCAR and state training data.

Surveyors Advising, Not Overseeing, HHAs

Although the objective of HHA surveys is to examine compliance with federal health and safety requirements, officials in several states acknowledged that surveyors previously considered or continued to view their roles as educating and consulting with rather than overseeing HHAs—practices that are contrary to CMS policy. For example, an official

with Colorado's survey agency explained the state's small number of COP deficiencies by noting that both top management and two surveyors advocated educating providers about HHA regulations but not citing deficiencies when they were found. A June 2001 Colorado State Auditor's report found additional problems with state HHA surveys including inconsistent and inadequate deficiency citations, poor documentation of survey results, and failure to follow federal guidance on sample sizes.[44] According to the Colorado survey agency official, a change in top management in late 2000, along with surveyor retirement and retraining, has resulted in more deficiency and COP citations. Since July 2000, surveyors have found deficiencies at 78 percent of surveyed HHAs, compared with 15 percent of HHAs surveyed in 1999.[45]

Arkansas officials told us that until recently HHA surveyors did not cite deficiencies when the problem appeared to be inadequate documentation of services required by patients' care plans because surveyors viewed their role as educational. From 1997 through 2000, Arkansas surveyors cited no COP-level deficiencies, and 93 percent of the state's HHA surveys found no deficiencies of either COPs or standards. According to a state survey agency official, a change in management has resulted in a reversal of this practice and Arkansas HHA surveyors are now citing deficiencies when they find inadequate documentation of services. This official told us that 43 of 62 surveys conducted from October 2001 through May 2002 cited deficiencies, including two HHAs with COP-level deficiencies. We noted that other states do cite deficiencies for inadequate documentation. Thus, our review of 96 recent surveys from 34 states demonstrated that deficiencies were frequently cited because of the inadequate documentation of services (see app. V). Without such documentation, determining whether patients received physician-ordered services would depend on agency staff's recall.

Survey Requirements Not Consistently Followed

Many states did not consistently follow CMS requirements when COP violations were found during surveys. Fifteen percent of surveys conducted nationally during 2000 that identified COP-level deficiencies did

[44]Report of the Colorado State Auditor, *Home and Community Based Services and Home Health Services* (Denver, Colo.: State of Colorado, June 2001).

[45]Several years ago, Idaho officials identified a problem similar to Colorado's. Idaho survey agency officials told us that surveyors either left or were trained after managers discovered that surveyors consulted with HHA staff on the problems they identified but did not cite deficiencies. After training, the number of COP-level deficiencies jumped from 3 in 1997 to 31 in 1998 and 25 in 1999.

not include a review of all COPs, even though surveyors are required to expand a survey and examine all COPs when they find at least one COP-level deficiency. Specifically, 19 of 20 states did not extend 25 of the 85 surveys that had COP-level deficiencies, while Texas, the 20th state, did not extend 21 of 95. In addition, surveyors did not always conduct on-site revisits to ensure that the COP deficiencies identified had been corrected. We found that 20 percent of HHAs nationwide with at least one COP-level deficiency on surveys since January 2000 had not received on-site revisits as required.[46]

Based on our analysis of OSCAR data, states did not consistently review the minimum sample of medical records and patient visits, exacerbating the problem noted earlier of sample sizes that are already too small to adequately identify the prevalence of quality-of-care problems. Overall, six of the states we reviewed failed to meet minimum sampling requirements during 2000 for patient visits and record reviews 23 percent and 24 percent of the time, respectively (see table 4). Furthermore, while CMS requires sample sizes to fall within specified ranges, for example, a minimum of 5 to 7 patient visits for an HHA with 150 to 750 unduplicated admissions, state surveyors almost never chose to review the highest number in this range.

[46]Of the 86 surveys nationwide with COP-level deficiency citations that did not receive on-site revisits, most were in Texas and California (48 and 10, respectively)—the two states with the highest level of such citations.

Table 4: Surveys from Six States with Insufficient Medical Record Reviews and Patient Visits during 2000

State	Number of surveys	Percentage of surveys with insufficient patient visits[a]	Percentage of surveys with insufficient records reviewed
Arkansas	64	8	9
Colorado[b]	71	39	39
Connecticut	27	4	N/A
Louisiana	125	25	24
Ohio	156	13	13
Texas	454	27	28
Total	**897**	**23**	**24**

Note: We were unable to analyze sample sizes for the remaining eight states we reviewed—California, Florida, Georgia, Indiana, Kansas, Massachusetts, Pennsylvania, and Utah—because the data they entered in OSCAR were inconsistent with CMS guidance used to determine sample sizes. For example, some states said they entered the number of unduplicated admissions since the previous standard survey, which could have been up to 3 years earlier. CMS guidance calls for basing the sample size on unduplicated admissions during a recent 12-month period. When HHA survey frequency changed from an average of every 12 months to a maximum interval of once every 3 years, CMS did not update the form used to record unduplicated admissions, which still refers to the last survey. In addition, some states told us that they entered both skilled and unskilled unduplicated admissions, while CMS guidance requires the use of skilled unduplicated admissions when determining sample sizes.

[a]If the surveyor is unable to draw the required sample size for home visits, CMS requires an increase in the number of records reviewed by one for each home visit not made. Our analysis took into account this possibility. In addition, our analysis excluded initial surveys of HHAs, which only require two patient visits.

[b]The analysis for Colorado may underestimate the percentage of surveys with insufficient patient visits and records reviewed. A Colorado official told us that one of the state's HHA surveyors was only considering Medicare and Medicaid patients when determining appropriate sample sizes for surveys—not all payer sources, as is required.

Source: GAO analysis of OSCAR data.

In addition, because CMS's April 2001 guidance for states to periodically include branch offices in their standard surveys is vague, state interpretations of the new requirement have varied. For example, 6 of the 14 states in our sample told us that the requirement could be satisfied by including patients served by branches in their clinical records review when conducting surveys at parent locations. Likewise, five states said the new guidance does not require them to physically visit the branch location during routine surveys, and half stated they do not plan to conduct standard surveys at branches. Texas, on the other hand, recently initiated

agency surveys at branch offices instead of at parent locations.[47] Having done so, the state found more serious deficiencies, including 13 COP violations, at the 13 branches surveyed than it did at the respective parent locations during previous surveys. CMS officials in the San Francisco and Seattle regions said that the new federal requirement to periodically survey branches does not change what the states in their regions have been doing because they have been surveying branch locations for many years.

Finally, about half of the HHAs nationwide that are required to have annual surveys are actually surveyed less frequently. Such HHAs would include those in the Medicare program for fewer than 3 years, with a change of ownership since the previous survey, with a COP-level deficiency cited within 24 months of their most recent survey, or with a complaint deficiency citation since the previous survey (see table 5). By reviewing these providers more frequently, states can ensure that problematic HHAs and those lacking experience or a consistent quality-of-care track record will receive extra scrutiny. In addition, CMS requires that states survey 5 percent of their HHAs that qualify for surveys every 36 months within 16 to 20 months of their prior survey. Based on information entered into OSCAR, it appears that states are generally not conducting these surveys at all. According to CMS, the objective of this 16- to 20-month survey cycle is to reduce the predictability of 3-year surveys and to provide intermittent scrutiny of at least a small number of HHAs that fall into this category.

[47]Texas plans to continue to vary surveys between parent and branch locations—to reduce the predictability of where surveys will be conducted.

Table 5: HHAs Nationwide Not Receiving Required Annual Survey Since January 1, 1998

Category requiring annual survey	Number of HHAs in category	HHAs not surveyed annually	
		Number	Percentage
Medicare-certified for less than 3 years	709	380[a]	54
Change in ownership since previous survey	182	46[b]	25
COP deficiencies cited within 24 months of most recent survey	460	185[c]	40
Complaint survey with deficiency citation since previous survey	599	312[d]	52
Nation[e]	**1,756**	**865**	**49**

Note: Information as of August 17, 2001, for HHAs with a current survey as of January 1, 1998, or later. Our analysis examined surveys conducted since January 1998 because during 1996 HCFA implemented an annual survey requirement for HHAs meeting the criteria shown in this table. Our analysis does not consider the annual survey requirement for HHAs reviewed by a state, regional, or national fraud and abuse initiative because CMS does not have a way to track this information. With the exception of national totals, an HHA may be included in more than one category. (See app. I for additional details on our methodology.)

[a]The majority of surveys occurred more than 5 months after the time period had passed.

[b]The majority of surveys occurred more than 4 months after the time period had passed.

[c]The majority of surveys occurred more than 2 months after the time period had passed.

[d]The majority of surveys occurred more than 7 months after the time period had passed.

[e]National totals represent an unduplicated count of HHAs that may have required annual surveys for more than one reason.

Source: GAO analysis of OSCAR data.

Cut in HHA Survey Funding Could Undermine States' Ability to Conduct All Required Surveys

Reduced funding for HHA surveys could undermine the statutory and other requirements to inspect all HHAs at least once every 3 years and certain HHAs more frequently. Although CMS requires HHAs with a good survey track record to be surveyed every 3 years, some must be surveyed annually, such as those with COP-level deficiencies and those with 3 or fewer years in the Medicare program and thus little practical experience in providing home health services. Because some states must survey more than one-third of their HHAs annually, they may be unable to survey the remaining HHAs at least once every 3 years. Moreover, states electing to periodically survey branch offices as well as the parent HHA face an increased survey workload.

From fiscal years 2000 through 2002, federal funding of state HHA surveys has been reduced by 20 percent from $31.9 million to $25.4 million. While CMS estimated that the number of standard surveys would fall from about 5,000 in fiscal year 2001 to about 2,500 in fiscal year 2002, the new funding level would still be sufficient to survey each HHA on average once every 3 years rather than every 2 years, as provided for in earlier budgets.[48] But basing funding of state HHA surveys on a 3-year average is inconsistent with the variable survey schedule implemented in 1996, in which certain HHAs are specifically required to be surveyed annually. Under that schedule, 11 states must survey more than one-third of their HHAs annually because of recent COP citations or other factors (see table 6). Four of the 11 states—California, Delaware, Maine, and Nevada—must survey over half of their HHAs annually.

Table 6: States Required to Survey More than One-Third of HHAs Annually

	HHAs requiring annual surveys	
State	**Number**	**Percentage**
California	413	73
Connecticut	34	41
Delaware	11	69
Florida	102	36
Idaho	25	48
Maine	20	56
Michigan	70	36
Nevada	19	53
Texas	399	48
Wisconsin	47	36
Wyoming	14	37

Source: GAO analysis of OSCAR data.

[48]In general, CMS officials told us that they view the new OASIS data as partially addressing the program implications of shrinking survey funds. CMS intends to transition to a system that targets HHAs for more frequent surveys based, in part, on an off-site review of OASIS data. On that basis, HHAs with good outcomes would be surveyed less frequently.

Some States' HHA Complaint Investigation Practices May Not Ensure Protection of Patients

Despite the importance of the complaint process in responding to concerns and problems with patient health and safety, complaint investigation practices in the 14 states we reviewed frequently had weaknesses that undermined their effectiveness. An effective state complaint investigation process is important because state surveyors will not otherwise be aware of potentially harmful situations that arise between surveys, especially concerning complaints filed directly with an HHA, a practice encouraged by some states. Yet some states in our sample used practices that could discourage the filing of complaints with the state. In addition, we believe that roughly one-fourth of the complaints we analyzed to determine if they were appropriately prioritized were assigned a lower priority for investigation than the alleged problems appeared to warrant. Inappropriately delaying the investigation of complaints alleging serious quality problems may prolong a condition that places patients at risk of harm. Furthermore, 5 of the 14 states did not have management information systems capable of providing necessary information to adequately monitor complaint investigations in 2000, but 2 states indicated that they have since improved their systems.

Some States' Procedures and Practices Could Discourage the Filing of Complaints

Our review of states' procedures for handling HHA complaints found practices in some states that could discourage individuals from filing complaints. These practices included not publicizing the existence of the toll-free telephone numbers for filing complaints, limiting access to such toll-free telephone numbers to in-state residents, making it difficult to reach state hotline staff by telephone to file a complaint, and requiring complaints to be submitted in writing. Our prior work on nursing home complaints concluded that the process of filing a complaint should not place an unnecessary burden on a complainant.[49] An easy-to-use complaint process should include a toll-free telephone number that is easy to access and use and that permits the complainant to leave a recorded message when state staff are unavailable. In addition, a user-friendly hotline would accept complaints verbally and not expect or require complaints to be submitted in writing.

In 1987, federal legislation directed that each state establish a toll-free telephone number, or "hotline," to provide the public information about

[49] U.S. General Accounting Office, *Nursing Homes: Complaint Investigation Processes Often Inadequate to Protect Residents*, GAO/HEHS-99-80 (Washington, D.C.: Mar. 22, 1999).

HHAs in the state and to receive complaints against HHAs.[50] According to CMS, the hotline requirement was added because home health patients are homebound, may have little contact with anyone except the HHA's staff, and may therefore be vulnerable to poor care or abuse. Under such circumstances, a hotline gives patients a direct link to the state for filing complaints—a link that is also available to family members, neighbors, and even HHA personnel.

While each of the 14 states we contacted maintains a hotline, as required, publicity about its availability is limited. The only CMS requirement with respect to publicizing the hotline is that an HHA inform each new patient that the state maintains a hotline for filing complaints and make the patient aware of the telephone number.[51] There is no requirement for states to publicize the number to the general public, and officials from 3 of the 14 states we contacted indicated that they do not publicize the number at all. Officials from 6 of the 14 states indicated that they list the number in local telephone books or show it on their Web site.

The hotlines in 5 of the 14 states contacted are toll-free only for calls made from within the state. To file a complaint from outside one of these states, a complainant must pay for the call. This could present a difficulty not only for family members who live in another state but also for patients who live in one state but are served by an HHA located in an adjacent state. Officials from two of the five states indicated that the states chose to limit the hotline to in-state calls because of cost.[52] According to CMS, the toll-free hotlines in about half the states and territories do not accept out-of-state calls.

Although hotlines should be easy to use, callers in some states may find using them confusing or may even find the hotlines unresponsive. When we called the hotlines in our 14 sample states, we identified situations that

[50]See OBRA 1987, section 4025, which requires states to operate a complaint hotline.

[51]Failure to do so was one of the 25 most frequently cited standard-level deficiencies from 1997 through 2000.

[52]CMS funds the costs for each state's hotline out of the Medicare survey and certification budget.

could frustrate complainants, especially patients who may be elderly and in poor health.[53] The following are examples of such situations:

- Hotlines in eight states did not clearly indicate in their telephone messages that the caller had reached the number for filing a complaint against an HHA. For example, when we contacted the Florida hotline in September 2001, Florida's message indicated that we had reached the state survey agency and then asked us to select from six menu options. If the correct option was selected, the next message provided three more options from which to select. At no time did Florida's recorded message specifically indicate that any of the options were for filing a complaint or for using the complaint hotline. In commenting on a draft of this report, a state official indicated that in January 2002 the state changed the menu options and the message to provide up-front notice that the caller had reached the state's HHA complaint hotline. While Massachusetts also used a menu system, it specifically identified the number for the caller to press to file a complaint.

- Six states use their hotlines for multiple purposes. Although this practice is not prohibited, it could confuse callers. Connecticut's toll-free number, for example, is a referral line for all types of health care questions. Kansas uses its hotline for complaints against any state-licensed provider, while Indiana uses its hotline for providing HHA and hospice information. Ohio uses its toll-free number for information about all state health facilities, and the wide range of calls it receives on this number include calls about animal cruelty concerns. Where hotlines are used for multiple purposes, it is important that clear instructions are provided so that callers can be sure they have reached the proper number.

- Reaching state staff or leaving a voice message at the hotline was a problem in five states. For example, Florida and Kansas have no voice mail capability, requiring complainants to call only during business hours. A Kansas official noted that only 40 HHA complaints were received in all of 2000, suggesting that the lack of voice mail was not causing a problem. On the contrary, a voice mail capability that makes it easier to reach state officials could result in an increase in complaints. In three other states, it was difficult either to have a call returned or to leave a message. For example, we called the Pennsylvania hotline after business hours four

[53] In California, we called the complaint hotline for Los Angeles, one of about 18 state district offices responsible for surveys of Medicare providers, including HHAs. Los Angeles has the largest concentration of HHAs in the state.

times over several days in September 2001 and again in April 2002 and the voice mail activated only once. A Pennsylvania official expressed concern about our finding but indicated that system tests showed no equipment problems. As Florida noted, CMS does not require states to have a voice mail capability.

Of the 14 states contacted, only Connecticut has a policy that "Complaints made to the Department must be in writing; however, staff must be flexible regarding the needs of some individuals." Only one of eight complaints we reviewed from Connecticut did not include a written letter from the complainant. A Connecticut official indicated that the state "encourages" complaints in writing but never requires a letter if it is a hardship to the complainant. Similarly, Massachusetts encourages complainants to follow up their telephone call with a letter or a fax. As we noted in our prior work on nursing homes, requiring complaints to be put in writing may place an unnecessary burden on the complainant and limit the number of complaints received.

Many Complaints Alleging Possible Harm to HHA Patients Are Not Categorized for Prompt Investigation

Of 79 complaints we examined that states placed in low-priority investigation categories, about one-fourth, in our opinion, appeared to be inappropriately prioritized.[54] Delaying the initiation of an investigation could delay the identification of serious problems at HHAs and postpone needed corrections. Furthermore, delayed investigations of complaints could prolong periods in which a patient's health and safety are at risk. With some notable exceptions, the 14 states we contacted generally investigated their complaints within the time frames they assigned. Finally, since many complaints are filed directly with an HHA rather than the state, and the interval between standard surveys can be up to 3 years, there may be a gap in state oversight of complaints against HHAs.

The state survey agency ascertains the potential seriousness of each complaint it receives in order to determine how quickly it should be investigated. CMS requires that complaints representing a potential immediate and serious threat to a patient be investigated within 2

[54]We asked the 14 states we reviewed to identify all complaints filed against each HHA in the state during 2000. We then asked 12 states to provide the complete investigation files for 93 complaints against HHAs that, in general, had no deficiencies on their standard survey. We excluded California and Texas from this analysis due to the volume of complaints in those states. States categorized 79 of the 93 complaints we obtained in other than 2-day or 10-day investigation categories.

workdays of receipt.[55] For all other complaints, states are permitted to establish their own investigation time frames.[56] Officials in 9 of the 14 states we contacted said they have a requirement that complaints alleging harm to a patient be investigated within 10 days of receipt. Complaint investigation categories for less serious complaints vary by state but often include 30-day, 60-day, and 90-day time frames as well as a category that does not require investigation until the HHA's next scheduled survey.

As demonstrated in table 7, states placed few of the complaints they received in 2000 in the 2-day or 10-day investigation time frames—with the exception of Florida, which placed 68 percent of the complaints it received in one of these two categories.

[55] Although the federal requirement is 2 workdays, some states told us that they have a stricter requirement. For instance, Florida requires such complaints to be investigated within 24 hours, while Kansas requires an on-site investigation the same day the complaint is received.

[56] In 1999, HCFA instructed states to investigate complaints alleging actual harm against nursing home residents within 10 working days of the day the complaint is received, but it did not extend this requirement to similar complaints filed against HHAs.

Table 7: Complaints Received in 2000 Categorized as Potential Immediate and Serious Threat or Potential Actual Harm

State	Number of HHAs (as of Dec. 2000)	Number of complaints received in 2000	Number of complaints categorized for investigation in 2 days	Number of complaints categorized for investigation in 10 days[a]	Percentage of all complaints categorized as 2-day or 10-day
Arkansas	182	3	0	0	0
California	573	360	29	Category not used	8
Colorado	131	63	0	7	11
Connecticut[b]	81	44	Not available	Not available	Not available
Florida	302	141	16	80	68
Georgia[c]	98	25	Not available	Not available	Not available
Indiana	173	63	0	Category not used	0
Kansas	137	40	6	2	20
Louisiana	248	133	2	5	5
Massachusetts[d]	125	63	0	0	0
Ohio	349	70	0	2	3
Pennsylvania	311	56	0	Category not used	0
Texas	811	717	17	21	5
Utah	42	21	2	Category not used	10

[a]Officials in nine states told us that state regulations require some complaints to be investigated in 10 days.

[b]Connecticut uses "classes" to which it does not assign specific investigation time frames. According to state policy, Class 1 requires an immediate investigation, which generally equates to an immediate and serious threat. All Connecticut complaints in 2000 were placed in Class 2, which represents quality-of-care or quality-of-life complaints. Class 3 is for complaints against HHAs whose next survey is "in the near future." Connecticut is revising its complaint policies to be more specific and to more closely reflect CMS's complaint time frames.

[c]Georgia was unable to provide summary information about complaint categories for 2000 but began collecting such data during 2001.

[d]Massachusetts began implementing a new complaint prioritization system in 2002. In the first 5 months of 2002, 23 of 26 complaints were prioritized for investigation in 10 days or less.

Because the infrequent use of high-priority investigation time frames in some states raised a question as to whether complaints were appropriately categorized, we reviewed the 79 complaints in our sample that states placed in categories other than the 2-day or 10-day categories. In our opinion, 21 of the 79 complaints alleged potential serious care issues and should have been placed in a category requiring investigation within at

least 10 days.[57] Three examples follow. (App. VII includes other examples of these complaints.)

- A Colorado complaint alleged that the HHA was not providing proper wound care and indicated that the HHA aide's failure to correctly change the patient's bandage caused the patient to require surgery for the wound. The complaint also alleged that the HHA was not providing this patient with physical therapy services as required. The state categorized this complaint as a 60-day complaint. It contacted the HHA by telephone the day after receiving the complaint and requested the patient's medical record, which the state received 19 days later. The state also requested medical records from the hospital but did not receive them for 78 days.

- A Kansas complaint alleged that an HHA nurse, while providing wound care for a patient who had recently had heart bypass surgery, failed to report signs of wound infection to the physician. It also alleged that at the patient's scheduled 3-week checkup, the physician found that the wound was infected to the bone and that the patient was readmitted to the hospital where the entire chest incision had to be redone. The state categorized this complaint as a 60-day complaint and investigated it in 72 days. Kansas officials did not agree with our judgment that an earlier time frame was warranted, commenting that the state had a well-developed complaint policy and procedure that is utilized in complaint intake and investigations. We continue to believe that the seriousness of the allegation—including rehospitalization of the patient—warranted investigation within 10 days.

- An Ohio complaint alleged that by using the wrong syringe, an HHA nurse gave 4 times the amount of quick-acting insulin ordered by the physician to a diabetic patient whose blood sugar was severely elevated. The nurse was supposed to remain with the patient for 2 hours to monitor the patient's response but left after 1 hour and 40 minutes. The patient then became ill, weak, and pale and called the physician, who told the patient to drink orange juice to reduce the insulin level. Ohio categorized this complaint as a 30-day complaint (30 working days) and investigated it in 16 working days (24 calendar days).

[57] While some of these complaints could represent a potential immediate threat to a patient and thus require investigation within 2 days, our analysis did not attempt to distinguish between 2-day and 10-day complaints.

In reviewing the 79 complaints, we also found that state agencies sometimes did not gather or document sufficient information from the complainant to determine the correct investigation time frame. For instance, one complaint in Georgia alleged that a patient was not given physical therapy as ordered. It added that a therapist from the HHA that came to the house to evaluate the patient for therapy was rude and told the family that they would have to provide the therapy themselves. There was no documentation in the complaint file to indicate that the state staff that received this complaint probed for further information about the condition or the needs of the patient. This complaint was placed in the next-on-site-investigation category and was not investigated for 182 days.[58] A complaint in Indiana alleged that the HHA did not provide a substitute aide when the regular aide was on vacation and also did not keep a list of the patient's medications. The complaint file did not indicate that the state employee who took the complaint information probed for other information, such as how long the patient went without services or whether the HHA's failure to keep a list of the patient's medications resulted in the patient's not receiving necessary medications. The state placed this complaint in the 90-day investigation category but investigated it in 32 days.

With some notable exceptions, most of the 14 states we contacted generally investigated complaints within the investigation time frames they assigned.[59] Among the exceptions was California, which did not timely investigate 10 of the 29 complaints it placed in the 2-day category, and Texas, which as of April 2001 had not investigated 56 of the 118 complaints that it received in 2000 and placed in its 45-day investigation category.

As discussed earlier, the interval between standard surveys of an HHA can be lengthy—often up to 3 years. This could present a gap in state oversight with respect to complaints, since they may be filed directly with an HHA rather than with the state. Colorado, for instance, encourages HHAs to ensure that patients and others direct complaints to the HHA before

[58]The "next-on-site" category generally means that the complaint will be investigated during the HHA's next standard survey.

[59]As discussed later, Colorado, Massachusetts, Florida, Georgia, and Louisiana could not provide sufficient information for us to determine the timeliness of their complaint investigations. For example, in 2000, Georgia did not track complaint priorities, which is critical to assessing timeliness of investigations, but began doing so in 2001.

contacting the state.[60] Furthermore, our review of one standard survey of a Connecticut HHA showed that the HHA received 23 complaints during a 6-month period in 2000, while the state agency received no complaints against this HHA for the entire year. Although states review HHA practices for investigating complaints during a standard survey, the state agency may be unaware of the volume, seriousness, and disposition of complaints filed directly with the HHA during the sometimes lengthy interval between standard surveys.

Adequacy of Management Information Systems for Monitoring Complaint Investigations Varies across States

Five of the 14 states we contacted lacked adequate information systems necessary to effectively manage and track complaint investigations. Two of these states, Florida and Georgia, told us that since 2000 they have improved their complaint tracking systems. An effective complaint reporting system is an important element of both state and CMS efforts to ensure the adequacy of complaint investigations, including the categorization and investigation status of each complaint.

We asked each of the 14 states we contacted to identify all complaints filed against each Medicare-certified HHA during 2000. For each complaint, we asked the state to provide information identifying (1) the investigation category (for example, 2-day, 10-day, or 30-day) that the complaint was assigned, (2) the date each complaint was received, and (3) the date each complaint was investigated. Louisiana officials told us that information on either the date a complaint was received or the date it was investigated was not available in any state reports.[61] Colorado's system does not track the date an HHA was contacted to investigate a complaint but instead tracks the dates that a complaint investigation was started and completed. However, the start date may represent only the date some action was taken on the complaint, such as when the state recontacted the complainant for further information or clarification. Massachusetts'

[60]Colorado sends a standardized cover letter to an HHA after the state investigates a complaint filed against it. The letter tells the HHA that 52 percent of individuals who file a complaint to the survey agency against an HHA in the state have not first identified their concerns to the HHA and requests the HHA to ensure that its patients are comfortable in expressing concerns to the HHA.

[61]A Louisiana official told us that the state monitors investigation timeliness manually and conducts spot audits to determine compliance with the assigned investigation time frames. In contrast, states with automated complaint data systems could conduct routine and comprehensive monitoring of the timeliness of investigations. Although state comments on a draft of this report indicated that timeliness information was available, such information was not provided after two requests.

system could not identify the investigation category, the dates of investigation, or the investigation results of the 29 complaints that the state categorized as off-site investigations.[62] Since 2000, Florida and Georgia have made improvements to their systems that allow them to track the timeliness of complaint investigations. Thus, Florida now includes in its database the date a complaint investigation was initiated and Georgia assigns each complaint an investigation priority.

Federal Oversight for HHA Surveys and Available Sanctions Are Too Limited

CMS oversight of the HHA survey process has been too limited to identify and address the weaknesses and inconsistencies we identified in the survey process and in states' performance of surveys. Although the home health prospective payment system introduced in October 2000 encourages HHAs to provide care more efficiently, it also provides the incentive to reduce services in order to increase net revenues.[63] The potential associated adverse effect on the level and quality of care thus makes appropriate oversight even more important. CMS regional offices do not routinely review whether states are complying with key statutory, regulatory, or other requirements, such as performing annual surveys of HHAs with COP-level deficiencies and ensuring that sample sizes of clinical records and patients meet minimum federal standards. Although CMS intends to improve state accountability, its plans are limited, and officials in most CMS regional offices told us that they lacked sufficient staff to improve oversight. In addition, CMS is not required to conduct federal monitoring surveys, as it is statutorily required to do for nursing

[62]Of the 63 complaints filed against HHAs in Massachusetts in 2000, the state could provide investigation dates for only 9. The remaining complaints were classified as either off-site investigations (29), referred to other agencies (6), reviewed and filed (13), or other miscellaneous categories (6). Acknowledging the lack of certain data on off-site investigations, a Massachusetts official indicated that the state policy is to begin off-site investigations by the next business day and that a narrative field in the database contains dated progress notes on such investigations.

[63]Under the new prospective payment system, HHAs receive a single payment, adjusted for the severity of the patient's condition, to deliver home health services over a 60-day period. We have expressed concern that the 60-day episode payment creates incentives to lower the intensity or cost of services in the episodes, by shortening visit lengths or by reducing the number of visits provided within the episode. See U.S. General Accounting Office, *Medicare Home Health Care: Prospective Payment System Will Need Refinement as Data Become* Available, GAO/HEHS-00-9 (Washington, D.C.: Apr. 7, 2000). We recently reported that HHAs are providing fewer visits per episode than the estimates used to develop the new payment system. See U.S. General Accounting Office, *Medicare Home Health Care: Payments to Home Health Agencies Are Considerably Higher than Costs*, GAO-02-663 (Washington, D.C.: May 6, 2002).

homes, which would help it to evaluate the effectiveness of states in fulfilling their contractual responsibility to oversee HHAs. Consequently, few are done. Even if oversight improved, shortcomings in OSCAR and inconsistent data entry by states would require attention in order to optimize federal monitoring. To enforce compliance with COPs, CMS uses just one sanction—termination from the Medicare program—which carries little deterrent effect for noncompliant HHAs. Our prior HHA work and this analysis showed that the threat of termination effects only temporary compliance, and HHAs may slip back into noncompliance until their next survey. Although the Congress mandated implementation of intermediate sanctions—short of termination—for HHAs by April 1, 1989, CMS has not established them and has no concrete time frame for doing so.

CMS Oversight of State HHA Surveys Is Too Limited to Address Inconsistencies

CMS oversight of state HHA surveys has been too limited to identify and address the inconsistencies in the survey process we have cited. For example, CMS has not applied to HHA survey activities the types of oversight tools it uses to monitor state nursing home surveys. Periodic analysis of OSCAR data to monitor state survey activities is now routine for state nursing home inspections but not for HHA surveys. In 2000, the agency began requiring its 10 regional offices to prepare and review 18 reports to track state nursing home surveys.[64] These reports, in standard format, allow comparisons within and across states and regions to help surface problems and identify the need for intervention. Because CMS does not use OSCAR to monitor state compliance with HHA survey requirements, it was unaware of significant issues and inconsistencies that we identified by analyzing OSCAR data. State survey weaknesses we found include the following:

- Surveyors used less than the minimum number of medical records and patient visits to determine the scope and nature of quality-of-care problems.
- Surveyors failed to expand standard surveys, when a COP-level deficiency was identified, beyond the COPs typically examined.

[64]Examples of reports that track state activities include reports of OSCAR data entry timeliness (quarterly), tallies of state surveys that find homes deficiency-free (semiannually), and analysis of the most frequently cited deficiencies by states (annually). Some of the tracking reports look at regional office performance to ensure consistency across the 10 CMS regions. See GAO/HEHS-00-197, p. 39.

- Surveyors did not verify that COP-level deficiencies were corrected through required on-site HHA revisits.
- HHAs falling into categories requiring annual surveys did not receive them within that time period.

CMS officials generally were unaware of the variability in the extent to which states cited deficiencies, as shown by OSCAR, and were unable to offer insights as to the underlying causes. Officials also did not know that six states had cited no COP-level deficiencies for 4 years in a row, or that Texas and California accounted for more than two-thirds of all COP-level deficiencies identified on current surveys nationwide over the approximately 40-month period we analyzed.

To improve oversight, CMS officials told us they will begin to apply the concept of performance standards—adopted for nursing homes in 2000—to HHA surveys in fiscal year 2002.[65] However, the three home health performance standards CMS chose to apply do not focus on critical issues that require more immediate attention, such as ensuring that HHAs with COP-level deficiencies are surveyed annually and that states do not assign an inappropriately low investigation category to complaints, resulting in investigations that are not timely. The three home health standards CMS selected require that (1) all HHAs are surveyed at least every 36 months, (2) the appropriate HHA termination time frames are followed,[66] and (3) state survey expenditures are substantiated.

Even if CMS used OSCAR to monitor state survey agency compliance with statutory, regulatory, and other requirements, our analysis identified current OSCAR data shortcomings that need to be addressed. For example, it is difficult to use OSCAR to determine whether HHAs are being surveyed at least once every 36 months because the database includes

[65]In 2000, HCFA directed its 10 regional offices to assess state compliance with seven nursing home performance standards covering state survey conduct and timing, deficiency documentation, complaint investigations, and OSCAR data entry. Some of these reviews are conducted by regional offices on-site at the state survey agency. HCFA developed state performance standards in response to our finding that federal oversight of state survey activities was inadequate. See U.S. General Accounting Office, *Nursing Home Care: Enhanced HCFA Oversight of State Programs Would Better Ensure Quality*, GAO/HEHS-00-6 (Washington, D.C.: Nov. 4, 1999).

[66]The two termination deadlines to be monitored are whether (1) a 23-day termination process is adhered to in 95 percent of cases when an HHA has an immediate and serious threat to patient health and safety and (2) a 90-day termination process is adhered to in 95 percent of state survey agencies' determinations when an HHA has a COP-level deficiency.

HHAs no longer participating in Medicare, and states do not always enter survey results into OSCAR. We found that such problems produced incorrect information for about one-fourth of California's HHAs. For example, OSCAR indicated that 129 California HHAs had not been surveyed, when in fact the HHAs had ceased participation or had been surveyed. Similarly, improper state entry of unduplicated admissions of patients receiving skilled services—numbers used by surveyors to determine correct HHA survey sample sizes—means that OSCAR cannot be used to monitor the medical record and patient visit sample sizes in certain states. Furthermore, because an HHA branch office does not have a provider number different from its parent's, it is impossible to use OSCAR to identify branch locations surveyed in lieu of their parent office.[67] CMS also lacks data to routinely monitor the home health survey training and experience of the personnel states assign to survey HHAs.[68]

CMS is not required to conduct federal monitoring surveys to assess how effectively states meet federal standards for surveying HHAs. Federal monitoring surveys are statutorily mandated for nursing homes. During a monitoring survey, federal surveyors either resurvey a nursing home soon after the state completes its survey (known as a comparative survey) or observe and coach state surveyors while the survey is being conducted (known as an observational survey).[69] Federal monitoring surveys must be conducted annually in at least 5 percent of nursing homes in each state—a

[67]Effective April 15, 2001, HCFA began requiring that (1) branch locations be periodically included in or replace the survey of the parent HHA and (2) surveys be conducted at a branch when it serves more patients than the parent HHA.

[68]CMS officials told us that they awarded a contract in September 2001 to establish an automated training database to track individual surveyors' CMS training, professional licensing, and certification. This database does not address the need to ensure that appropriately trained surveyors with HHA inspection experience are assigned to conduct HHA surveys.

[69]During an observational survey, one or more federal surveyors accompany a state survey team, observe the team conducting the survey, provide immediate feedback, and later may rate the team's performance. The presence of federal surveyors during observational surveys can influence the conduct of state surveyors who, because they are aware of being observed, may be more attentive to the survey tasks than they are normally. During a comparative survey, a federal survey team conducts a complete, independent survey of a nursing home in order to compare and contrast its findings with those of the state survey team. Our analysis of 157 nursing home comparative surveys conducted from late 1998 through early 2000 found that federal surveyors identified more serious deficiencies than the state surveyors 70 percent of the time. See GAO/HEHS-00-197.

total of about 850 surveys.[70] Although the majority of federal nursing home surveys are observational, regional offices conduct one to three comparative surveys in each state annually—depending on the number of nursing homes.

CMS officials told us that they encourage the regional offices to conduct HHA monitoring surveys, but only 132 were actually undertaken from 1997 through 2000. Over this same 4-year period, states conducted over 18,000 HHA surveys. The bulk of federal monitoring surveys were completed in 1997 or 1998—only 10 were conducted during 2000. Furthermore, 91 percent of the federal HHA surveys were observational or training rather than comparative. In our nursing home work, we have recommended increased reliance on comparative surveys as a way to assess state performance, because such surveys are the only oversight tool that furnishes an independent measure whereby deficiency results can be compared with those of the states to determine the adequacy of state survey agency performance.[71] When asked about the small proportion of comparative HHA surveys, 7 of the 10 regions said that they do not have adequate staff to conduct comparative HHA surveys, which are more time-consuming than observational surveys. For example, CMS's Seattle office stated it has dedicated only 0.4 full-time-equivalent staff to oversee the region's 190 HHAs, including conducting federal monitoring surveys and state agency training, OASIS support, certification, and state survey agency monitoring. Because few comparative surveys were conducted and the regional offices often lacked documentation of their findings, we did not attempt to analyze the results.

CMS explained its lack of focus on HHA oversight by noting the emphasis since 1998 on monitoring nursing home surveys and its attempt to enhance HHA oversight through OASIS. Monitoring HHA quality through patient-focused OASIS data, however, is no substitute for CMS and regional office activities that would ensure state compliance with statutory and regulatory requirements for HHA surveys. For example, OASIS data do not indicate whether HHAs with COP-level deficiencies are being surveyed more frequently, as required. Regional offices said they lacked sufficient staff to increase oversight of HHA surveys, and CMS officials

[70]A minimum of five reviews must be conducted in each state each year, even if this brings the total number of required reviews to more than 5 percent.

[71]GAO/HEHS-00-6.

acknowledged that it is a challenge to meet all of the demands placed upon CMS staff.

CMS Has Not Implemented the Full Array of Federal Sanction Options

Although OBRA 1987 required the implementation of additional home health sanctions by April 1, 1989, termination from the Medicare program remains the only federal sanction that CMS uses. Termination is an all or nothing option reserved for HHAs that fail to return to compliance after a COP-level deficiency is cited.[72] Officials in all but two CMS regional offices stated that termination is an effective option, not because HHAs are actually terminated but because most HHAs return to compliance before the termination process is effected. However, an HHA can avoid termination by taking short-term corrective action to show compliance at the surveyor's revisit, thus stopping the termination process. The HHA may then revert to noncompliance until the next survey, take corrective action again, and so on, remaining certified almost indefinitely. Our analysis of OSCAR data identified 86 active HHAs nationwide with the same COP-level quality-of-care deficiency on consecutive surveys.[73] While over half occurred on the two most recent surveys, 9 of the 86 had the same quality-of-care COP cited on three of four surveys. Nearly 84 percent of the recurring COP-level deficiencies involved the same two quality-of-care deficiencies: (1) lack of a physician-prescribed plan of care that was followed and periodically reviewed and (2) failure to provide skilled nursing services in accordance with the plan of care. Despite the recurrence of the same quality-of-care problems, these 86 HHAs still participate in the Medicare program.[74]

[72]Before being terminated from the Medicare program, HHAs have up to 90 days to return to compliance but HHAs can be terminated more quickly if the deficiency is immediate and serious. Thus, if an HHA fails to return to compliance with one or more COPs for 90 days after the state survey, it is required to be terminated. However, if surveyors identify a deficiency that results in an immediate and serious situation, termination is required to take place in 23 days. See GAO/HEHS-98-29.

[73]OSCAR maintains data on up to the last four surveys for each HHA. Our analysis considered the survey results for all active HHAs entered into OSCAR as of August 17, 2001. The majority of the 86 HHAs with consecutive deficiencies in the same COP were located in California (25) and Texas (40).

[74]We reviewed three other COP-level quality-of-care deficiencies. The remaining 16 percent of consecutively cited quality-of-care deficiencies involved requirements related to the provision of home health aide services and the maintenance of clinical records to facilitate effective, efficient, and coordinated care. The COP requiring OASIS standardized assessments was not cited on consecutive surveys, probably because it was only implemented in July 1999.

Our analysis also suggests that the actual termination of an HHA can be a time-consuming process reaching beyond the 23-calendar-day termination period that CMS sets for immediate and serious threat situations—even if a patient has been seriously harmed. According to CMS regions, seven HHAs were terminated from 1997 through 2000 when surveys or complaint investigations found immediate and serious threats to patients. Texas officials also brought to our attention an immediate and serious threat termination from 2001. Six of the eight terminations were not completed in the expedited time frame of 23 calendar days required by CMS. Although four of the six were terminated within 37 days, the other two terminations exceeded the 23-day period by over twice the allowed time—periods ranging from 52 days to about 9 months. The 52-day termination was initiated by a substantiated complaint investigation involving a patient who was hospitalized for 2 days for accelerated hypertension. The Texas HHA failed to monitor whether the patient took the prescribed hypertension medication, failed to inform the patient's physician of elevated blood pressure readings, and failed to realize the patient had missed three cardiologist visits for lack of transportation. Appendix VIII describes the 9-month chronology of a Texas HHA placed on a 23-day termination track as a result of an immediate and serious threat involving a patient with pressure sores so serious that bone was visible through the open wound. Factors that contributed to the time required to terminate this HHA included (1) a court order postponing termination and (2) the delayed participation of a federal surveyor in a resurvey that validated the continued existence of an immediate and serious threat. The CMS regional office indicated that it had taken corrective action to prevent this type of delay from occurring in future serious and immediate threat terminations. For the few HHAs involuntarily terminated, 3 of the 10 CMS regions volunteered that they lacked the ability to cross-check earlier HHA information, such as owner names, against a new application, to determine if an HHA was later readmitted to Medicare or reapplied under a new name or location.

CMS has set no specific time frame for establishing less severe intermediate sanctions as required by OBRA 1987, which include civil monetary penalties, suspension of all or part of an HHA's Medicare payments, and appointment of temporary management to oversee an HHA during its efforts to return to compliance. HCFA stated in 1997 that it wanted to gain experience with intermediate sanctions for skilled nursing homes, which became effective in July 1995, before it implemented them for HHAs. In October 2001, CMS told us that it intended to coordinate the introduction of HHA intermediate sanctions with planned, but yet unscheduled, changes to the Medicare home health COPs.

The difficulty of actually terminating an HHA underscores the value of other, less drastic sanctions. Intermediate sanctions, such as those implemented in 1995 for nursing homes, provide state survey agencies and regional offices with additional tools short of termination to help ensure compliance with Medicare COPs.[75] For HHAs with standard-level deficiencies only, even if they are repeated and involve significant patient care issues, such as inadequate prescription drug monitoring, there is no federal sanction. Four CMS regional offices generally supported having intermediate sanctions implemented. With only the termination sanction available, seven states in our sample indicated difficulties in ensuring HHA compliance including (1) lack of assurance an HHA will follow its plan of correction after a resurvey, (2) the lengthy termination process that allows HHAs to correct their compliance problems, and (3) the fact that HHAs move in and out of compliance because they can fix problems regardless of how often they have occurred in the past.

Conclusions

Although CMS contracts with states to enforce federal quality standards through surveys and complaint investigations, it does not adequately ensure that HHAs safeguard the well-being of patients by providing quality care. Thorough state surveys and investigations are critical, given the isolation and potential vulnerability of patients who receive care in their homes. The introduction of the home health prospective payment system makes state and federal oversight even more important because, in addition to encouraging efficiency, it also provides incentives for HHAs to decrease services in order to increase net revenues. As now performed, state survey activities are insufficient to adequately determine whether problems exist and how extensive they are—a situation that could be exacerbated by the reduced funding for HHA surveys. According to CMS officials, fiscal year 2002 funding is adequate for states to survey one-third of HHAs annually, but at least 11 states must survey more than one-third of their HHAs each year, raising a question about whether reduced funding may undermine the goal of inspecting all HHAs at least once every 3 years. Moreover, CMS oversight of state activities is too limited to identify the significant problems we have reported. Weaknesses in current state and federal HHA oversight that mask the status of the quality of care provided include:

[75]Nursing home intermediate sanctions include civil monetary penalties, denial of Medicare and Medicaid payments for new patient admissions, and appointment of temporary management until compliance is achieved.

- likely underreporting of serious care problems, as suggested by skewed findings of COP-level deficiencies in a small number of states, despite more consistent indications of potential care problems across all states based on adverse events reports;
- a survey process that gives surveyors vague criteria for surveying branches and identifying COP-level deficiencies; does not require HHAs to be surveyed periodically against all COPs, including compliance with the skilled nursing COP; and uses patient visit and medical record samples that are inadequate to detect the prevalence of quality-of-care problems;
- inconsistencies in the conduct of surveys nationwide that magnify shortcomings in the survey process, such as uneven adherence to the required minimum sample sizes across states, inadequate surveyor training or on-the-job experience, and failure to survey HHAs with COP-level deficiencies as frequently as required;
- a complaint process that does not compensate for survey weaknesses because it may discourage the submission of complaints in some states; does not ensure that serious complaints are promptly investigated; and often lacks tracking systems that would enable states to monitor complaints and enable the federal government to evaluate states' responsiveness;
- limited use of federal oversight tools to monitor state performance, including measuring state survey activities against performance standards; routinely analyzing data on state survey results; and performing federal monitoring surveys, such as comparative surveys that allow federal surveyors to judge the adequacy of a recently completed state survey, as is required for nursing home surveys; and
- a single sanction that is too limited to prevent a cycle of recurring noncompliance for some HHAs.

Matters for Congressional Consideration

Given the significant delay in implementing intermediate sanctions for HHAs, the Congress should consider giving CMS a new deadline for issuing the necessary implementing regulations.

To better ensure that state surveys comply with statutory, regulatory, and other CMS requirements, the Congress should consider requiring CMS to conduct federal monitoring surveys of HHAs, with priority given to comparative surveys.

Recommendations for Executive Action

To strengthen the ability of the HHA survey process to identify and address problems that affect the quality of care, we recommend that the Administrator of CMS

- develop more specific branch oversight criteria and procedures for states and assign unique identification numbers for each HHA branch office to enable CMS to track survey results and facilitate its own branch oversight.
- develop more specific guidance and training for distinguishing between COP-level and lesser deficiencies and for improving the consistency across states in documenting deficiencies.
- improve the adequacy of the sampling process, such as increasing the size of the sample of medical records and patient visits, to better determine the prevalence of quality-of-care problems.
- ensure that resources are adequate for states to fully comply with the requirement to survey all HHAs at least once every 36 months and certain HHAs more frequently.

To ensure that the complaint process adequately addresses quality-of-care problems, we recommend that the Administrator

- ensure that states eliminate barriers to filing complaints by improving the accessibility and effectiveness of hotlines and by not requiring complaints to be filed in writing.
- monitor states' responsiveness to complaints, including developing assurances that serious allegations are promptly investigated and resolved.
- provide technical assistance to states as appropriate to develop consistently effective complaint tracking systems.

To ensure that states comply with home health statutory, regulatory, and other CMS requirements designed to protect patient health and safety, we recommend that the Administrator

- adopt comprehensive state performance standards for HHAs, such as holding states accountable for (1) performing HHA surveys based on CMS's variable 12- to 36-month survey schedule and (2) improving the timeliness and reliability of states' OSCAR data entry.
- use OSCAR and other means to monitor and assess state survey performance on an ongoing basis.

Agency Comments and Our Evaluation

We provided a draft of this report to CMS and the 14 states included in the scope of our work for their review and comment. (See app. IX for CMS's comments.) CMS concurred with all of our recommendations and indicated that it was already taking steps to implement them. CMS did not comment on our Matters for Congressional Consideration concerning the need for a new deadline to implement intermediate sanctions or the expansion of federal monitoring surveys to include state HHA surveys—with priority given to comparative surveys.

In its comments, CMS elaborated on the initiatives already under way to address shortcomings in state HHA surveys and the survey process that would respond to our recommendations. However, CMS generally did not specify implementation time frames. We believe that timely implementation of these recommendation is integral to better ensuring the quality-of-care provided by HHAs. As our report points out, several key initiatives have encountered significant implementation delays, suggesting the importance of a clear sense of priorities and accountability for deadlines. For example, CMS still has not implemented intermediate HHA sanctions as directed by the Congress in 1987. In response to OBRA 1987, the agency proposed revised COPs in 1997 to achieve a more outcome-oriented survey process but currently projects that the final COPs will not be issued until mid-2003. As a result, the home health COPs still lack patient-specific outcomes to help measure the quality of care. In its comments, CMS cited a study initiated in 1999 to evaluate the nursing home complaint process, a study whose findings could be applied to complaint systems for other provider types, such as HHAs. After almost 3 years, however, the study is currently undergoing CMS review with no specific time frames to implement the report's recommendations. The 33-month contract awarded in October 2001 to develop improved survey protocols to measure HHA quality of care and promote consistency in the survey process will not be implemented for several years. While we recognize that the implementation of some initiatives legitimately requires planning, research, and testing, we also believe that improving HHA surveys and oversight requires establishing clear priorities and concrete implementation timetables.

CMS oversight of state survey activities is one area that need not wait for additional research or study. Yet, CMS commented that its development of a new HHA oversight program would hinge on a contract to be awarded by October 2002 to inventory and determine the utility of data in monitoring state survey activities. We believe that CMS could take immediate steps, using existing data, to hold states accountable for HHA survey requirements—such as those covering survey frequency, patient visit and

record review samples, and extended surveys. CMS has already enhanced oversight of state compliance with nursing home survey requirements by periodically analyzing OSCAR data and undertaking both on- and off-site measurement of state performance against specific standards. Additional study is not needed to extend of this approach to HHA oversight, such as ensuring that HHAs with COP-level deficiencies are surveyed annually and that states do not assign an inappropriately low investigation category to HHA complaints, resulting in investigations that are not timely and that may reduce the likelihood of substantiating allegations.

CMS commented that the national HHA survey budget—which is based on states' historical costs of conducting surveys—adequately supported the current estimated workload. However, we found that states often were not conducting the number of required surveys, which would then understate actual funding requirements. In addition, CMS indicated the current funding levels are sufficient to allow surveys of one-third of HHAs annually, but we found that 11 states must survey a greater proportion each year. CMS acknowledged the need for additional resources to address other shortcomings in the survey process, such as (1) changing its policies to include a review of all COPs on certain surveys, (2) routinely requiring surveys of branch offices, and (3) developing policies and procedures for actively and regularly monitoring compliance with CMS survey requirements. California and Kansas officials also commented that additional CMS funding was needed to improve state oversight and compliance with CMS requirements, and California acknowledged that the priority assigned to nursing home surveys was a contributing factor to delays involving HHA surveys. CMS commented that it will be a challenge to ensure that adequate resources are available and proposed addressing some survey process shortcomings by using OASIS data to more efficiently focus resources on branch offices with poor outcomes or by increasing sample sizes at HHAs with poor outcomes.

Kansas commented that we had overstated the need for on-site surveys of branch offices, concluding that it would be a waste of valuable survey time. In contrast, Indiana emphasized the importance of adequate branch oversight, commenting that it had developed a state database to monitor branch offices. Our point was that because states are not required to routinely survey branch offices, there is limited knowledge about the quality of care provided by branch offices. Moreover, states lack a way of separately recording the results of branch office surveys because branches operate under their parents' provider numbers. CMS concurred and indicated it is taking steps to improve oversight of branch offices.

CMS, in its technical comments, and Florida indicated that our comparison of COP-level deficiencies cited during surveys and adverse events reports was inappropriate, that is, not an "apples-to-apples" comparison. As our report stated, we recognized that adverse event reports were developed as a tool to help state survey agencies target specific cases for HHA review and that they do not necessarily result in COP-level deficiencies, which are documented through record reviews and patient visits during on-site surveys. The purpose of this comparative analysis was to illustrate the wide variability in state citations of COP-level deficiencies in contrast to the more consistent indications through OASIS adverse events reports of potential care problems across all states. The greater variability among states in documented COP-level deficiencies indicated to us a likely understatement of serious care problems. We also presented other evidence to support this conclusion, such as examples in several states where surveyors did not document deficiencies because they viewed themselves as advisors, and examples of quality-of-care deficiencies in two states that were cited at the standard level, while other states cited problems of similar severity as COP-level deficiencies.

Massachusetts clarified its rationale for documenting certain deficiencies at the standard level rather than at the COP level as states with similar deficiencies had done, which we described in appendix VI. The state commented that standard-level deficiencies were cited because, in the professional judgment of the surveyors, the outcome was not severe enough to warrant a COP-level deficiency, the deficiencies were not widespread, the deficiencies had been corrected prior to a follow-up visit, or the HHA had implemented systemic changes to correct the problem prior to the surveyor's arrival at the HHA. We continue to believe that the likely patient harm in the two Massachusetts surveys was at least as severe as deficiencies cited at the COP-level in other states. The first survey included deficiencies that resulted in the death of one patient, and, for another patient, a week's delay in treating an infected wound. The second survey included deficiencies that resulted in a patient's developing a new pressure sore and in not being assessed for physical therapy to achieve the maximum potential for walking. Furthermore, any judgment on how widespread a problem may or may not be is only one of several criteria for determining whether a COP-level deficiency is warranted. We believe that Massachusetts' comments reinforce our finding that subjectivity in documenting similar problems can—and does—result in understatement of COP-level deficiencies.

CMS and 10 states also provided technical comments, which we incorporated as appropriate.[76]

We are sending copies of this report to the Secretary of Health and Human Services and to the Administrator, Centers for Medicare and Medicaid Services. We also will make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at http://www.gao.gov.

Please contact me at (202) 512-7118 or Walter Ochinko at (202) 512-7157 if you have questions about this report. Staff acknowledgments are listed in appendix X.

Kathryn G. Allen
Director, Health Care—Medicaid and
Private Health Insurance Issues

[76]We received comments from officials in Arkansas, California, Connecticut, Florida, Georgia, Indiana, Kansas, Louisiana, Massachusetts, and Pennsylvania.

List of Committees

The Honorable Max Baucus
Chairman
The Honorable Charles E. Grassley
Ranking Minority Member
Committee on Finance
United States Senate

The Honorable Bill Thomas
Chairman
The Honorable Charles B. Rangel
Ranking Minority Member
Committee on Ways and Means
House of Representatives

The Honorable W.J. "Billy" Tauzin
Chairman
The Honorable John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

Appendix I: Scope and Methodology

To assess the quality of care provided by HHAs, we analyzed survey results and compliance with federal requirements using CMS's On-Line Survey, Certification, and Reporting (OSCAR) system. Although OSCAR data indicated that there were 6,905 active HHAs on August 17, 2001, we focused our review on the 6,318 most recent surveys conducted since March 31,1998, and entered into OSCAR as of August 17, 2001. We chose this approximately 40-month time frame because, according to federal requirements, all HHAs should have been surveyed at least once every 36 months, and the additional 4-1/2 months allowed time for states to enter the survey results in OSCAR. If an HHA was surveyed more than once since March 31, 1998, we only included the results of the most current survey in our analysis. Our analysis excluded the results of the most recent surveys for 587 HHAs conducted before April 1, 1998, because the majority of these surveys were conducted in 1996 or earlier and therefore may not accurately reflect the current quality of these HHAs.

Our assessment nationwide of HHA compliance with the annual federal survey frequency requirements included surveys of active HHAs conducted on or after January 1, 1998, and entered into OSCAR as of August 17, 2001. This date was chosen to allow for implementation of the variable survey cycle, which requires certain categories of HHAs to be surveyed more frequently, such as agencies that have COP-level deficiencies within 24 months of their current survey. For those HHAs that had two surveys and a triggering event requiring an annual survey (such as a change in ownership since the previous standard survey), compliance with the annual survey requirement was determined by (1) calculating whether the elapsed time between the current survey and the previous survey or triggering event was greater than 13 months[1] or (2) calculating whether the elapsed time since the current survey or triggering event was greater than 13 months (allowing an additional 2-1/2 months for states to enter the survey results into OSCAR). For those HHAs that had only one survey on or after January 1, 1998, and a triggering event requiring an annual survey, compliance was determined by calculating whether the elapsed time since the current survey or triggering event was greater than 13 months (again, allowing an additional 2-1/2 months for states to enter the survey results into OSCAR).

To ensure the accuracy and completeness of the OSCAR data used in our analysis, we worked with CMS regional offices and states from April

[1]CMS interprets "annual" as less than 13 months.

through September 2001 to determine why active HHAs had current surveys more than 3 years old—the 587 HHA surveys we excluded from our analysis of HHA quality. We learned that either the more recent survey results had not been entered into OSCAR, the HHA had been terminated, the HHA was deemed by other entities to meet Medicare COPs, or the HHA only served Medicaid recipients (66 of 6,905 HHAs in OSCAR as of August 17, 2001). No survey results would be expected or required in the last three instances. One state, California, accounted for the majority of HHAs with current surveys that were over 3 years old.[2] The CMS regional office told us that during this time, the state had assigned a higher priority to conducting nursing home surveys than to conducting HHA surveys.

To assess state survey activities, we reviewed operations in 14 states. We conducted fieldwork in California and Texas, states that have the largest number of HHAs. We met with state officials and surveyors to discuss survey activities at both parent and branch offices, the complaint intake and referral process, and enforcement activities. In Texas, we also observed an HHA survey and complaint investigation. We used a structured survey to collect information about HHA survey activities and processes in 12 other states from diverse geographic regions—Arkansas, Colorado, Connecticut, Florida, Georgia, Indiana, Kansas, Louisiana, Massachusetts, Ohio, Pennsylvania, and Utah. We selected these states because OSCAR data showed that they had consistently cited no, or very few, COP-level deficiencies since 1998.

To analyze the nature and severity of COP-level quality-of-care deficiencies, we reviewed 132 COP deficiencies from 80 HHA surveys conducted by 32 states since December 31, 1999, and entered into OSCAR as of August 17, 2001. These surveys contained at least one of five quality-of-care-related COP deficiencies and cited deficiencies in at least 1 of 11

[2]OSCAR data show that 39 percent of California's 565 HHAs were surveyed and the results entered into the database between March 31, 1998, and August 17, 2001—suggesting that about 60 percent of the state's HHAs had not been surveyed in 3 years or more. At our request, CMS's San Francisco regional office worked with the state to verify the number of surveys conducted. Regional office officials informed us that 89 HHAs had been surveyed, and the survey results for most of these agencies should have been entered into OSCAR by August 17, 2001. As of March 2002, many of these surveys had still not been entered into OSCAR. Forty additional HHAs had been terminated but were still listed in the database as active. Seventeen HHAs were "deemed" to meet Medicare COPs as a result of surveys by either the Joint Commission on the Accreditation of Healthcare Organizations or the Community Health Accreditation Program. Finally, 18 HHAs only serve Medicaid recipients. The results of surveys of deemed HHAs are not entered into OSCAR, and states have the option of entering Medicaid-only HHA survey results.

associated standards. The five COPs included acceptance of patients, plan of care, and medical supervision; skilled nursing services; home health aide services; clinical records; and comprehensive assessment of patients. According to officials from the states in our sample, these COPs were the most closely associated with quality of care. Overall, 32 states cited at least one of the five COPs, and 19 states cited none. We reviewed all applicable surveys from 30 states that cited at least one of the five COPs but randomly selected 25 surveys from California and Texas because of the large number of such COP-level deficiencies documented. To determine whether states were consistent in citing COP-level deficiencies, we also reviewed 16 surveys from Massachusetts and Georgia that cited deficiencies in 3 or more of the 11 associated standards—but not the COP—and abstracted those cases that seemed comparable in severity to cases other states cited at the COP level. We selected Massachusetts and Georgia from the 19 states that cited no deficiencies in any of the five quality-related COPs because they were included in our 14-state sample. A registered nurse on our staff with home health experience reviewed our assessment of surveys for clinical accuracy and significance.

To test the adequacy of states' complaint investigation procedures, we asked each of our 14 sample states to identify all complaints filed against each HHA in the state during 2000, including the investigation priority, when the investigation was started and completed, and whether the complaint was substantiated. We selected a sample of 93 complaint investigation files to review. In general, these complaints were filed against HHAs that had no deficiencies on their standard surveys in 2000. A registered nurse on our staff with home health experience reviewed our analysis of these 93 complaints for clinical accuracy and significance. We also assessed the operation of the complaint hotlines in all 14 states by contacting them both during and after business hours.

To analyze the training and experience of state HHA surveyors, we extracted surveyor identification numbers from OSCAR for all HHA surveys conducted in 2000 by Florida, Kansas, and Louisiana. We selected these states because they were part of our 14-state sample and their surveyors are or can be used to inspect both nursing homes and HHAs. We limited our analysis to these three states because of its time-consuming nature—unlike survey results, it is not possible to produce OSCAR analytical reports on the assignment or training of surveyors. OSCAR data allowed us to determine how many individuals had participated in HHA surveys and the number of HHA surveys they had conducted. We then asked state officials to indicate whether these surveyors had attended CMS's basic HHA training course. We also contacted Arkansas, California,

and Texas—states with surveyors who focus on HHAs or on HHAs and related provider types and who do not conduct nursing home surveys—to determine whether the surveyors had generally attended CMS's basic HHA training course.

To determine the adequacy of federal oversight efforts, we interviewed officials at CMS headquarters and in selected regional offices. We reviewed statutory requirements, CMS regulations, and policy guidance regarding HHA survey activities. Using a structured survey, we collected more detailed data from CMS's 10 regional offices on their states' HHA inspection activities and their own oversight and enforcement efforts. We also interviewed CMS officials about the federal budgeting process for state HHA survey activities and reviewed budget trends since 1997.

Appendix II: Medicare COPs for HHAs and Selected Nursing Home Quality-of-Care Requirements

Table 8 lists the 15 Medicare COPs for HHAs. The first group of COPs contains COPs required to be reviewed on a standard survey, and the remaining COPs must be reviewed if any one of the initial COPs is cited as a deficiency. To contrast the COPs with the nursing home requirements, table 9 lists nine selected quality-of-care requirements reviewed during nursing home surveys. These tables illustrate the differences in orientation between the HHA and nursing home survey processes: the HHA COPs, while addressing broad process-related requirements, do not focus on outcomes as do some nursing home requirements.

Table 8: HHA Medicare COPs

COP	Description
COPs reviewed during a standard survey	
1. Patient rights	HHA must inform, protect, and promote the rights of patients, including the right to participate in planning their care and treatment, to have person and property respected, to have medical record confidentiality, to be informed of payment liability, and to be informed of complaint hotline availability.
2. Compliance with laws and accepted professional standards	HHA must comply with all federal, state, and local laws and regulations, including licensure; disclose all persons with ownership or control interest in HHA; and comply with accepted professional standards established by federal and state regulatory bodies and national organizations, boards, and councils.
3. Organization, services, and administration[a]	HHA must have a governing body to operate the agency, an administrator, a supervising physician or registered nurse, personnel policies, and written contracts for personnel providing services on a per hour or per visit basis. HHA coordinates patient services and has an annual operating budget and capital expenditure plan.
Standard—Coordination of patient services	All personnel providing patient services coordinate efforts effectively and support objectives in each patient's plan of care. Clinical records or case conference minutes establish effective coordination of patient care. HHA sends a written report to the physician for each patient every 60 days.
4. Acceptance of patients, plan of care, and medical supervision	HHA must have and follow physician-prescribed plan of care for each patient, alert physician to any changes necessary to alter plan, and periodically review plan.
5. Home health aide services	HHA must select, train, and supervise home health aides qualified to carry out patient care in a safe, effective, and efficient manner; conduct, document, and evaluate aide training to ensure competency; and provide supervision by a registered nurse.
6. Medical records	Medical records must provide current, organized, and clearly written synopses of each patient's treatment, including services provided for HHA by arrangement or contract. The records should facilitate effective, efficient, and coordinated care and be retained and protected from unauthorized access.
7. Release of patient-identifiable OASIS information	HHA and any agent acting on its behalf must ensure confidentiality of all patient-identifiable information contained in clinical records, including OASIS data, and may not release patient-identifiable information to the public.
8. Comprehensive assessment of patients	Each patient must have a comprehensive assessment accurately reflecting the patient's current health status with information that may be used to demonstrate progress toward achievement of desired outcomes that is periodically updated and incorporates use of OASIS reporting items.

COP	Description
Additional COPs reviewed if a deficiency in one of above COPs is cited during survey	
9. Group of professional personnel	HHA must have professional personnel, including at least one physician and registered nurse, and personnel of other appropriate disciplines, to establish and review HHA's policies regarding patient services and to advise on and evaluate its programs. At least one member of the group is neither an owner nor an employee of the agency.
10. Skilled nursing services	HHA must provide services by or under the supervision of a registered nurse in accordance with the patient's plan of care; registered nurse and licensed practical nurse duties are specified.
11. Therapy services (physical, occupational, speech)	HHA must ensure that therapy services are provided directly or under arrangement by a qualified therapist or supervised assistant in accordance with the patient's plan of care.
12. Medical social services	If HHA offers medical social services, they must be provided by a qualified social worker or supervised assistant in accordance with the patient's plan of care.
13. Qualifying to provide outpatient therapy services	If HHA provides outpatient physical therapy or speech pathology services, it must meet all conditions of participation and meet additional health and safety requirements.
14. Evaluation of HHA's program	HHA must have written policies to require at least an annual evaluation of its program by its group of professionals, HHA staff, and consumers, or by outside professionals and consumers. The evaluation includes a review of policies, administration, and clinical records.
15. Reporting of OASIS information	HHA must encode accurate data and transmit in standard format to CMS.

[a]During a standard survey of about half of the 15 COPs, only one of the standards associated with this COP is examined. That standard is described here.

Source: Medicare's *State Operations Manual*.

Table 9: Selected Quality-of-Care Requirements Reviewed during Nursing Home Surveys and the Expected Resident Outcomes

Nursing home requirement	Description of expected resident outcome
Activities of daily living (such as bathing, dressing, eating, and toileting)	A resident's abilities in activities of daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that diminution was unavoidable.
Pressure sores	A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable.
Catheterization	A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary.
Range of motion	A resident who enters the facility without a limited range of motion does not experience reduction in range of motion unless the resident's clinical condition demonstrates that a reduction in range of motion is unavoidable.
Mental problems	A resident does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors unless the resident's clinical condition demonstrates that such a pattern is unavoidable.
Tube feeding	A resident who has been able to eat enough alone or with assistance is not fed by naso-gastric tube unless the resident's clinical condition demonstrates that the use of a naso-gastric tube was unavoidable.
Nutrition	A resident maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible.
Antipsychotic drugs	A resident who has not used antipsychotic drugs is not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the resident's medical record.
Medication errors	Residents are free from significant medication errors that cause them discomfort or jeopardize their health and safety.

Source: Medicare's *State Operations Manual.*

Appendix III: Branch Offices as a Percentage of Total HHA Operating Locations

Table 10 shows branch offices in each state as a percentage of total HHA operating locations, that is, parent, subunit, and branch offices.

Table 10: Branch Offices as a Percentage of Total HHA Operating Locations

State	Branch offices as a percentage of total HHA operating locations	Branch offices	Parent and subunit HHAs	Total HHA operating locations
South Carolina	59	109	75	184
Mississippi	57	80	61	141
Vermont	55	16	13	29
Tennessee	53	165	148	313
Utah	52	46	42	88
Georgia	49	91	96	187
Kentucky	44	88	111	199
Maine	42	26	36	62
Delaware	41	11	16	27
Connecticut	40	54	82	136
Idaho	38	32	52	84
Oklahoma	36	107	190	297
Pennsylvania	36	175	313	488
North Dakota	34	18	35	53
Washington	33	30	61	91
Florida	30	125	285	410
Nebraska	30	29	67	96
Virginia	30	66	156	222
Michigan	30	82	194	276
Massachusetts	29	52	125	177
Wisconsin	28	51	129	180
South Dakota	27	17	46	63
Nevada	27	13	36	49
Missouri	26	59	164	223
Kansas	26	48	134	182
Rhode Island	26	8	23	31
New York	26	73	211	284
New Jersey	25	18	54	72
Alabama	25	47	142	189
Minnesota	25	80	242	322
Indiana	24	52	167	219
District of Columbia	23	5	17	22
Texas	21	213	825	1,038
Louisiana	20	61	244	305
Ohio	19	80	344	424
North Carolina	18	35	163	198

State	Branch offices as a percentage of total HHA operating locations	Branch offices	Parent and subunit HHAs	Total HHA operating locations
Maryland	17	11	54	65
New Hampshire	17	7	35	42
California	16	111	565	676
Illinois	16	54	279	333
Colorado	16	24	130	154
Iowa	15	32	179	211
Arizona	14	10	64	74
Montana	12	7	52	59
Arkansas	10	20	182	202
New Mexico	10	7	66	73
Oregon	8	5	61	66
West Virginia	7	5	71	76
Alaska	6	1	16	17
Wyoming	5	2	38	40
Hawaii	0	0	14	14
Total	**27**	**2,558**	**6,905**	**9,463**

Note: Data are as of August 17, 2001.

Source: GAO analysis of OSCAR data.

Appendix IV: HHAs Current Survey Results Compared with Adverse Events Episodes for All States

Table 11 expands the comparison of current survey results and adverse events from our 14 sample states (see fig. 1) and shows the number of HHAs with COP-level deficiencies cited by each state for the approximately 40-month period we analyzed.

Table 11: Comparison of HHA Survey Results and Adverse Events Reports

State	Percentage of HHAs with COP-level deficiencies[a]	Adverse events per 100 valid episodes[b]	Number of HHAs with COP-level deficiencies	Number of HHAs with current surveys[c]
North Dakota	0	7.7	0	35
Delaware	0	8.3	0	16
Rhode Island	0	8.4	0	22
Georgia	0	8.6	0	96
South Dakota	0	8.8	0	46
North Carolina	0	9.2	0	158
Montana	0	9.2	0	50
Washington	0	9.4	0	61
Iowa	0	9.5	0	179
New Hampshire	0	9.8	0	34
Hawaii	0	10.0	0	12
Vermont	0	10.3	0	12
Arkansas	0	10.9	0	182
Utah	0	11.1	0	39
Indiana	0.6	9.2	1	162
Florida	0.7	7.0	2	279
Pennsylvania	0.7	7.9	2	286
Alabama	0.7	9.2	1	142
Massachusetts	0.8	7.8	1	122
Wisconsin	0.8	9.0	1	127
Minnesota	0.8	9.5	2	237
Virginia	1.3	9.5	2	150
South Carolina	1.4	9.6	1	74
New York	1.5	7.7	3	201
West Virginia	1.5	9.2	1	67
Mississippi	1.6	9.0	1	61
Kentucky	1.9	8.4	2	106
Missouri	1.9	8.4	3	158
New Jersey	2.3	7.5	1	44
Connecticut	2.8	8.8	2	71
Tennessee	2.8	8.9	4	144
Maine	2.9	9.2	1	35
Louisiana	2.9	9.2	7	241
Illinois	3.0	8.0	8	266

State	Percentage of HHAs with COP-level deficiencies[a]	Adverse events per 100 valid episodes[b]	Number of HHAs with COP-level deficiencies	Number of HHAs with current surveys[c]
Nebraska	3.0	8.4	2	67
Arizona	3.2	8.7	2	63
Oregon	3.3	10.6	2	61
Michigan	3.4	8.6	5	149
New Mexico	3.5	10.0	2	57
Kansas	3.8	9.6	5	133
Colorado	3.9	9.6	5	129
Ohio	4.0	8.4	13	326
Maryland	4.2	8.6	2	48
Wyoming	5.3	9.6	2	38
Oklahoma	5.4	9.3	10	185
Nevada	5.6	8.0	2	36
Nation	**5.8**	**8.5**	**368**	**6,318**
Alaska	6.3	9.6	1	16
District of Columbia	6.7	10.3	1	15
Idaho	13.5	10.2	7	52
Texas	16.5	9.1	133	806
California[d]	Greater than 23	8.2	128	222

[a]Includes active HHAs with a current survey in OSCAR that was conducted since March 31, 1998, and entered into the database by August 17, 2001, totaling 91 percent of active HHAs. The remaining 9 percent of surveys were not in the system because states failed to enter the survey results, HHAs had been terminated but were still classified as active, HHAs were deemed by other entities to meet Medicare COPs, or HHAs only served Medicaid recipients (66 of 6,905 HHAs in OSCAR as of August 17, 2001). No survey results would be expected or required in the last three instances.

[b]A valid episode includes data on patients who have received a start- and end-of-care assessment. This information is based on HHAs reporting OASIS data during calendar year 2000.

[c]As of August 2001.

[d]Focusing on surveying HHAs with a poor performance record, California surveyed only 39 percent of its active HHAs over the approximately 40-month period we analyzed and documented that 58 percent of those surveyed had COP-level deficiencies. However, assuming that no COP-level deficiencies existed in the 61 percent of HHAs not surveyed, the overall estimate of California HHAs with COP-level deficiencies would be 23 percent.

Source: GAO analysis of OSCAR data and CMS analysis of OASIS adverse events.

Appendix V: Documented Examples of Likely Harm from 80 HHA Surveys

We reviewed 80 surveys with a total of 132 quality-of-care related COP-level deficiencies to identify instances where it appeared likely that a patient was harmed as a result of poor quality care provided by the HHA.[1] For the vast majority of COP-level deficiencies, the documentation in the survey reports supported the *potential* for harm to patients. However, in 16 of the 80 surveys that contained sufficient documentation for us to draw a conclusion about patient harm, we determined that 22 patients were likely to have been harmed. Although a COP-level deficiency can be cited for a situation that harms or has the potential to harm patients, the survey reports do not explicitly state the level of harm reflected in the patient examples. From the information in the survey reports, we were unable in other cases to determine if there was no harm or if it was simply not documented. Table 12 contains abstracts from those 16 surveys describing the patient's condition, the plan of care ordered by the physician, deficiencies in the care provided by the HHA, and the likely patient harm. The information contained in the table is drawn from the surveyors' descriptions of the deficiencies found.

[1]Appendix I describes our methodology for selecting the 80 surveys, and table 1 lists the five quality-of-care related COPs and 11 associated standards.

Table 12: Documented Examples of Likely Harm from Quality-of-Care Related COP Deficiencies for 80 HHA Surveys

State and date of survey	COP cited	Patient description	Plan of care	Deficiencies in care provided by HHA	Likely patient harm
California Nov. 2000	Skilled nursing services[a]	42-year-old with multiple sclerosis has painful pressure sores on buttocks and lower back.	Doctor's order: Vicodan for pain relief prior to wound care; observe/assess pain level and response to wound care (one stage III and two stage II pressure sores).[b]	Registered nurse (RN) did not (1) assess patient's pain or (2) provide medication ordered for relief for pain during wound care; patient confirmed he had pain and did not receive medication prior to the wound care treatment. HHA said patient did not receive regular assessments and evaluations of his pain levels and response to treatments.	Patient suffered unrelieved pain during home care of wounds; progress or lack of progress was not assessed.
California Apr. 2001	Skilled nursing services	Patient with diagnosis of diabetes has existing lower-back pressure sores and is at risk for further skin breakdown.	Assess skin integrity; prevent formation of new pressure sores; use Duoderm (protective dressing) on right and left heels as needed for skin breakdown.	During eight visits over a 12-day period, RN (1) did not assess patient's skin integrity and (2) took no action to prevent further deterioration of skin. Surveyor noted and reported additional pressure sores on heel during visit to patient's home.	Patient developed a new pressure sore on heel of left foot.
Colorado June 2000	Skilled nursing services	Quadriplegic patient with pressure sore on left elbow.	Skilled care plan: wound care for existing pressure sore. Patient also receiving custodial care from home health aides directly employed by patient.	(1) Care plan did not provide interventions for prevention of new sores, wound healing, or infection control, (2) custodial caregivers frequently did not come to patient's home to provide care, and (3) RN did not notify physician, did not file a 62-day summary describing patient's decline, and did not coordinate care provided by custodial caregivers.	Patient's condition worsened over 5 months: elbow pressure sore became infected and patient developed four more pressure sores. Patient was hospitalized in fifth month for intravenous antibiotic treatment of antibiotic-resistant pressure sore on elbow and for surgical intervention for all five pressure sores.

State and date of survey	COP cited	Patient description	Plan of care	Deficiencies in care provided by HHA	Likely patient harm
Colorado July 2000	Acceptance, plan of care, medical supervision	Patient admitted to home care with diagnosis of insulin-dependent diabetes, open wound of hip, spinal cord injury, and quadriplegia.	(1) Administer insulin on a sliding scale per physician order, depending on degree of blood sugar elevation. (2) COP requires that RN assess patient response. RN to supervise licensed practical nurse (LPN) care.[c]	LPN (1) provided insulin on the basis of a nondocumented change in the medical order, (2) did not accurately record the amount of insulin administered, (3) did not provide the dose of insulin ordered by physician according to the sliding scale based on patient blood sugar level, and (4) did not adequately or accurately document patient's blood sugar levels or the amount of insulin administered over a 6-day period. RN did not (1) determine the appropriateness of care provided by the LPN or (2) revisit the patient to assess the plan of care.	Four days following the period of inadequate documentation by the LPN, patient was admitted to the emergency room with mental confusion, stupor, elevated blood sugar, and changes in urinary output.
Colorado Dec. 2000	COP not cited. Standard cited was under skilled nursing services	Patient with osteoporosis, muscle/ligament disorder, backache, depressive disorder, and congestive heart failure admitted to home care for pain assessment and management.	(1) Visit patient twice a week, (2) assess pain and manage it, and (3) medicate for pain.	Nurse did not assess or manage patient's complaint of terrible pain and confusion about pain medications.	Patient readmitted to hospital within 1 week for pain management.
Connecticut Jan. 2001	Acceptance, plan of care, medical supervision	Patient with cerebral palsy, who is blind and unable to speak, admitted to home care for physical therapy to relieve contractures of the thigh muscles.	(1) Resume walking, with or without walker, as tolerated by patient, and (2) COPs require that RN assess progress and report changes in patient's condition to physician.	Therapists and nurse supervisor did not (1) adequately assess source of patient's pain, initially during therapy and following a fall in which patient's knee cracked audibly; (2) used poor judgment in ascribing patient's cries of pain to temper tantrums; and (3) failed to keep physician informed of patient's progress and behavior.	On a routine visit to the physician 42 days after falling, the patient was found to have a fractured femur.

State and date of survey	COP cited	Patient description	Plan of care	Deficiencies in care provided by HHA	Likely patient harm
Idaho Nov. 2000	Skilled nursing services	Patient with poor leg circulation has pressure sore on foot.	RN to (1) assess foot pressure sore and (2) notify physician of changes in condition.	RN (1) noted patient had pain in affected foot, as well as fever, and (2) did not notify physician of change in condition.	Patient's condition worsened and hospitalization was required.
Kentucky June 2001	Skilled nursing services	Patient had triple coronary artery bypass surgery, admitted to home care for dressing changes, incision care of right leg, and monitoring of right foot pulse (pedal pulse).	COP requires evaluation of patient status and notification of physician of changes in patient's status that may affect the plan of care. COP also requires that RN supervise LPN.	RN did not adequately supervise LPN or assess patient's complaint of pain on day 1. LPN did not record or report patient's increase in pain on day 2 and loss of pulse in foot, decrease in temperature, and change in color in patient's right foot to RN or physician on day 3. RN did not record or call the physician about the changes in the patient's leg.	Patient called physician on day 4, underwent emergency surgery to remove a blood clot from leg, and was subsequently admitted to the hospital intensive care unit. Patient was at high risk of losing her leg, according to physician.
Louisiana Feb. 2001	Skilled nursing services	47-year-old patient admitted to home care services with multiple diagnoses including hypertensive heart disease, chest pain, and prolonged depression.	COP requires evaluation of patient status, notifying of physician of changes in patient's status that might affect the plan of care, and referral of patient's psychosocial issues to appropriate professionals. COP also requires that RN supervise LPN.	(1) RN did not assess patient's depression and concerns about paying for medications, (2) RN did not report changes in patient's condition to appropriate professionals, and (3) supervisory RN did not review care.	Patient was depressed, in total despair, and expressed suicidal thoughts. Patient told surveyor that she was extremely depressed, was unable to function, and did not want to live. She said she had no money for medications, and had no more mental health visits left on her Medicaid card. Surveyor noted that for 11 cases reviewed at the HHA, this case was 1 of 8 cases for which the RN had not reevaluated the nursing needs of the patient.

State and date of survey	COP cited	Patient description	Plan of care	Deficiencies in care provided by HHA	Likely patient harm
New York Nov. 2000	Skilled nursing services	Patient with pressure sore on right foot.	COP requires RN to (1) assess, monitor, record, treat, and prevent progression of disease; (2) inform physician of patient health status and needs; and (3) ensure that the plan of care includes safety measures to protect against injury.	RN did not (1) consistently assess, monitor, or record status of pressure sore; (2) record preventative actions; (3) explore or record cause of multiple cigarette burns on patient's chest; (4) consistently record continued treatment for pressure sores; (5) notify physician of patient status; or (6) assess or manage pain or oxycodone use.	After 3 months of home care, this patient's condition had deteriorated. Patient (1) had multiple pressure sores on toes, heels, and hip; (2) had several infected pressure sores; (3) exhibited multiple and unexplained cigarette burns on the chest; (4) developed bone infection resulting in amputation of ulcerated fifth toe on right foot; (5) had constant, unmanaged pain; and (6) had laceration of feet from unsafe bath chair.
New York Nov. 2000	Skilled nursing services	Patient admitted to home care with an impaired circulation ulcer and two pressure sores that were not healing.	COP requires RN to (1) assess, monitor, record, treat, and prevent development of infection and new pressure sores and (2) notify physician of patient response to treatment.	Record showed no indication of (1) assessment, monitoring, treatment, or prevention of infection and new pressure sores or (2) any communication with the physician.	At 21-day follow-up nurse assessment, patient had not made progress in healing of the impaired circulation ulcer or the two pressure sores.
Nevada Sept. 2000	Acceptance, plan of care, medical supervision	Patient admitted to home care with bilateral toe amputation, open wound of toe, renal failure, depression, and hypertension.	COP requires professional staff to promptly alert physician to any changes suggesting the need to alter the plan of care.	RN did not notify the physician of the patient's deteriorating condition related to nausea, vomiting, and diarrhea that began on the 16th day following admission to home care and continued for 9 days, until patient was hospitalized.	Patient was admitted to hospital with weakness, inability to eat, and dehydration. Surveyor stated, "Agency staff failed to promptly alert physician to changes in the patient's status."

State and date of survey	COP cited	Patient description	Plan of care	Deficiencies in care provided by HHA	Likely patient harm
Oklahoma Oct. 2000	Skilled nursing services	Patient admitted to home care with diagnosis of diabetes and postbypass surgery of the major arteries to improve leg circulation.	COP requires regular evaluation of patient status and notification of physician about changes in patient status and need to change the plan of care. Nursing practice guidelines for diabetic patients with lower extremity circulation problems include assessment of both legs and feet for adequacy of circulation, presence of pain, and changes in skin color and integrity.	RN did not regularly evaluate the pulses in both feet; did not assess and regularly measure the surgical wounds of the right leg; did not regularly reevaluate the skin condition of either foot and the development of sores, severe pain, and dead tissue on the toes on right foot; and did not regularly reevaluate the development of brown-black drainage of the surgical wound of the right leg, right groin, and right ankle. The RN failed to adequately record the deterioration of both legs. The RN did not coordinate the patient's care with other RNs and the LPN or coordinate the orders for medical care between two physicians, and did not report the LPN's assessment of severe pain or the progressive decline of the patient's condition.	On the 45th day of care, the physician told the LPN he was scheduling the patient for amputation of the left leg after the LPN told him that the patient had severe pain in the infected left leg. According to the surveyor, there was no previous mention of a problem with the patient's left leg in the medical record. All previous references were to the right leg.
Texas May 2000	Skilled nursing services Agency cited at immediate jeopardy level.	81-year-old patient admitted to home care with urinary incontinence and pressure sores on lower back, both feet, and both hips.	RN to (1) administer wound care for pressure sores; (2) notify physician of swelling around pressure sores, skin breakdown, increase in size of sores, changes in odors or drainage or of diastolic blood pressure of less than 50; and (3) have patient return to emergency room if foot pain increases or signs of infection are present.	RN did not notify physician for 2 days of increased foot swelling, change in color of toes and heel, and diminished pulses. When physician was notified, patient was sent to emergency room. During the 12 days after patient's return from emergency room visit, RN failed to notify physician of changes in patient's condition, which included severe pain, increased infection, loss of pulse in both	Three weeks after admission to home care, patient was admitted to the hospital for above-the-knee amputations of both legs. When RN was asked why he had failed to notify the physician of changes in the patient, the RN responded that the physician had been notified by the 60-Day Physician Summary, which was mailed to the physician's office 12 days after the

State and date of survey	COP cited	Patient description	Plan of care	Deficiencies in care provided by HHA	Likely patient harm
				feet, suspected gangrene, urinary tract infection, and systemic infection.	emergency room visit.
Texas May 2000	Skilled nursing services	85-year-old patient admitted to home care for care of an abdominal incision.	RN to (1) provide wound care and observation and note complications and (2) notify physician of signs of infection, increased drainage, redness, unrelieved pain, skin breakdown, and falls or injury.	RN did not report to physician that wound was open and separated during the first visit.	Patient admitted to hospital on second day of care with wound dehiscence (opening of a surgical wound, often through the muscle layers), requiring a 22-day stay.
Texas Aug. 2000	Acceptance, plan of care, medical supervision Agency cited at immediate jeopardy level.	Patient with diagnosis of two pressure sores, emphysema, and fracture of spine, admitted to in-home care for monitoring of respiratory status.	Nurse to (1) monitor patient's vital signs (pulse, respiration, and blood pressure) on every visit and (2) report respiration greater than 30 or less than 16 and pulse rate of greater than 105 or less than 56.	(1) RN inconsistently documented patient's respiration rate and (2) failed to report the patient's deteriorating respiratory status and mental confusion to the physician over a period of 1 month, even when she knew the patient was dying (she documented talking to patient's wife about admission to hospice).	Patient was admitted to hospital and died. Surveyor stated "the RN failed to notify the physician about the progressively deteriorating condition of the patient that ultimately resulted in death."
Texas Aug. 2000	Acceptance, plan of care, medical supervision Agency cited at immediate jeopardy level.	Patient with diagnosis of emphysema admitted to home care for monitoring.	Physician ordered one skilled nursing visit per week for 3 weeks, then every other week.	RN (1) visited patient once during the first week but did not visit during the second or third weeks and (2) did not report to physician the patient's increased respiratory distress and failure to respond to increased medication.	Patient was admitted to the hospital during week 3 with congestive heart failure and pneumonia, and died 3 days later. Surveyor stated that the failure of the RN to initiate changes in the plan of care and notify the physician of changes in patient condition resulted in the patient's hospitalization and death.

State and date of survey	COP cited	Patient description	Plan of care	Deficiencies in care provided by HHA	Likely patient harm
Texas	Acceptance, plan of care, medical supervision	Patient with coronary occlusion, gastritis, peripheral vascular disease, and insulin-dependent diabetes was admitted to home care for monitoring.	Assess all of patient's systems and report any abnormalities to physician.	RN did not report patient's complaint of nausea, vomiting, and headache, which persisted over 48 hours, to physician.	Patient admitted to hospital with dehydration after more than 48 hours of persistent nausea and vomiting.
Texas Aug. 2000	Acceptance, plan of care, medical supervision	Patient with hypertension admitted to home care for monitoring. Weight at beginning of 1-month period was 152 lbs.	Plan included monitoring of weight.	(1) RN did not weigh patient for 1 month, (2) RN failed to report patient's poor nutritional intake or weight loss to physician, and (3) plan of care was not signed by physician or RN.	Patient had an unplanned 17-lb. weight loss within 1 month (more than 11 percent of patient's body weight), and nutritional status was poor.
Texas Dec. 2000	Acceptance, plan of care, medical supervision Agency cited at immediate jeopardy level.	74-year-old patient admitted to home care with pressure sore on back, emphysema, and anemia.	Physician orders were to (1) assess lung and chest sounds for cardiac and pulmonary distress, congestion, and infection; (2) assess for complications and notify physician of changes; (3) have chest X ray and take sputum culture; and (4) take wound culture.	(1) RN did not consistently assess and record lung sounds, did not report worsening of pulmonary status to physician, and inconsistently reported status of pressure sore on back; (2) RN did not obtain chest X ray; and (3) the results of wound culture were misplaced. Patient remained untreated for pneumonia until surveyor noted patient's condition, 2 months after first unsuccessful treatment of pneumonia symptoms.	Patient developed a pseudomonas pneumonia (untreated for 2 months); the pressure sore on back increased in size and depth and was infected with staphylococcus aureus.
Texas May 2001	Acceptance, plan of care, medical supervision Skilled nursing services	Patient admitted to home care with diagnoses of seizure disorder, diabetes, shortness of breath, hypertension, and depression.	(1) Prior to hospitalization, plan of care called for weighing patient during each visit. Patient was transferred to hospital for gall bladder surgery. Patient was able to walk with a cane and stand on scale before surgery. Plan of care resumed after patient was	After resumption of care, (1) RN noted at beginning and end of a 1-month period that patient was unable to stand or walk to be weighed and had abdominal pain and (2) RN did not notify physician that patient was unable to stand or that patient was having pain.	The patient was unable to walk after 1 month of care, and was having pain. Patient was not assessed for ability to walk and referred for evaluation. The cause of this patient's change in condition went unexplored and untreated for 1 month.

State and date of survey	COP cited	Patient description	Plan of care	Deficiencies in care provided by HHA	Likely patient harm
			readmitted to home care. (2) COP requires RN to report changes in patient's condition to physician and assess potential for rehabilitation to overcome functional limitations.		
Texas May 2001	Skilled nursing services Agency cited at the immediate jeopardy level.	Patient admitted to home care with adult-onset diabetes and pressure sores on lower back and limb.	COP requires (1) RN to assess, monitor, record, treat, and prevent development of infection and new pressure sores; (2) RN to notify physician of patient response to treatment; (3) LPN to report patient status to RN; and (4) RN to supervise LPN, evaluate patient, and report to physician.	(1) RN did not supervise LPN or evaluate patient's pressure sores and (2) RN and LPN did not communicate with the physician.	Patient's pressure sore on foot increased in size and depth and became infected over a period of 5 weeks. Patient was admitted to the hospital and his leg was amputated below the knee.

[a]Skilled nursing services refers to services provided by a registered nurse (RN) or a licensed practical/vocational nurse (LPN/LVN).

[b]Stages of pressure sore formation are I—skin of involved area is reddened; II—upper layer of skin is involved and may be blistered or abraded; III—skin has an open sore, involving all layers of skin down to underlying connective tissue; and IV—tissue surrounding sore has died and may extend to muscle and bone and involve infection.

[c]For instances in which surveyors did not record or incompletely recorded the plan of care, we used the requirements of the COPs as criteria for what the HHA personnel should have done.

Source: GAO review of a sample of 80 state survey reports. See app. I for a description of how this sample was selected.

Appendix VI: Inconsistencies between States in Deficiency Levels Cited in HHA Surveys

Table 13 describes standard-level deficiencies cited in Georgia and Massachusetts HHA surveys that resulted in likely harm to patients. We selected these 2 states for review because they were part of our 14-state sample and did not cite any of the 5 quality-of-care COPs that we examined but did cite 3 or more of the 11 standards associated with those COPs. These deficiencies appear at least as serious as deficiencies cited at the COP-level in other states (see app. V) and indicate that serious quality problems are likely understated. Because the state agency cited only standards but did not cite the COPs from which the standards were drawn, the only available sanction, that of termination, could not be used even if the HHA failed to correct the deficiencies.

In commenting on a draft of this report, Massachusetts noted that in the professional judgment of its surveyors, the care deficiencies summarized in table 13 did not warrant COP-level deficiencies either because the outcome was not severe enough to warrant a COP-level deficiency, the deficiencies were not widespread, the deficiencies had been corrected prior to a follow-up visit, or the HHA had implemented systemic changes to correct the problem prior to the surveyor's arrival at the HHA. We continue to believe that the likely patient harm in the two Massachusetts surveys was at least as severe as deficiencies cited at the COP-level in other states. The first survey included deficiencies that resulted in the death of one patient, and, for another patient, a week's delay in treating an infected wound. The second survey included deficiencies that resulted in a patient's developing a new pressure sore and in not being assessed for physical therapy to achieve the maximum potential for walking. Furthermore, any judgment on how widespread a problem may or may not be is only one of several criteria for determining whether a COP-level deficiency is warranted. We believe that Massachusetts' comments reinforce our finding that subjectivity in documenting similar deficiencies can—and does—result in understatement of COP-level deficiencies.

Table 13: Examples of Standard-Level Deficiencies in Georgia and Massachusetts Similar to COP-Level Deficiencies in Other States

State and survey date	Standard(s) cited	Patient description	Plan of care	Deficiencies in care provided by HHA	Likely patient harm
Georgia Nov. 2000	Duties of RN: prepares clinical notes, coordinates services, and informs physician and others of patient's condition and needs. Assignment and duties of the home health aide: include provision of hands-on care.	Patient with an indwelling urinary bladder catheter (Foley).	Standards require the RN to (1) furnish those services that require specialized nursing skills (Foley catheter care), (2) record and report changes in patient condition to physician, and (3) supervise other nursing personnel who provide care.[a]	(1) Home health aide did not provide proper hygienic care in bathing patient and attending to Foley catheter, (2) RN did not supervise the aide, and (3) RN did not notify the physician of the development of bladder infection.	Patient had a painful, untreated bladder infection for 1 week.
Georgia Dec. 2000	Duties of RN: prepares clinical and progress notes, coordinates services, and informs physician and others of patient's condition and needs.	Patient with diabetes admitted to home care.	Standards require RN to regularly evaluate patient's nursing needs and inform the physician of changes in the patient's condition and needs (for example, adherence to diet and exercise, monitoring blood sugar).	RN (1) did not adequately assess patient's dietary history, (2) did not refer patient to social worker and dietician for problems including inability to pay for food and instruction in proper meal planning, and (3) did not report to physician blood sugar levels that ranged from 219 to over 500 (normal level ranges from 70 to 110).	With a reading greater than 500, patient's blood sugar level was dangerously elevated.
Georgia Feb. 2001	Duties of RN: initiates appropriate preventive or rehabilitative nursing procedures. Clinical records: contain drugs, dietary, treatment, and activity orders; signed and dated clinical progress notes; and summary reports sent to physician.	Patient with diabetes.	(1) Assess status of patient's diabetes and (2) record and notify physician of progress and changes in patient status.	(1) During 13 of 17 visits, RN did not assess and record patient's blood sugar levels, which were initially assessed as highly unstable; and (2) RN did not notify the physician of blood sugar fluctuations, elevations of blood sugar greater than 300, or the need for treatment alterations.	Patient was admitted to the emergency room for treatment of unstable blood sugar levels that ranged from 47 to 410 (normal range: 70 to 110).

State and survey date	Standard(s) cited	Patient description	Plan of care	Deficiencies in care provided by HHA	Likely patient harm
Massachusetts Feb. 2001	Coordination of patient services: agency coordinates care provided by personnel as required by the plan of care. Plan of care: includes medications, treatments, and services provided. Periodic review of plan of care: staff notify physician of changes in condition that suggest a need to alter the care plan. Drug regimen review: RN must provide a comprehensive review of all medications, including adverse effects and noncompliance with drug therapy.	Post-heart attack patient with diabetes and asthma.	(1) Perform tests for blood-clotting (prothrombin) time, blood chemistries, and digoxin (drug used for congestive heart failure) level; (2) patient's medications included Coumadin (blood thinner), aspirin (blood thinner), and digoxin (makes the heartbeat stronger and slower); and (3) instruct patient on purpose, action, dose, and side effects of Coumadin.	(1) Agency failed to establish liaison with laboratory services required for obtaining and analyzing blood samples; (2) RN did not obtain ordered laboratory services, and laboratory tests were never done; (3) RN failed to notify the physician of inability to obtain laboratory services; (4) after reviewing the use of Coumadin with the patient, RN did not question or halt the use of blood thinners that were administered without performing physician-requested laboratory tests; and (5) RN continued patient on blood thinners and heart medication without monitoring effects, such as potential bleeding and potassium imbalance, through laboratory tests.	Patient was admitted to the hospital and died. The state surveyor said that "there was no coordination between the nurse, clinical supervisor, physician, and medical insurer agency . . . to ensure that this client received the ordered laboratory tests for monitoring the prothrombin levels . . ." that would have prevented the patient's hospitalization and subsequent death.
Massachusetts Feb. 2001	Periodic review of plan of care: notify physician of condition and changes requiring change in plan of care.	Patient with poor circulation in legs, surgical wounds of the leg, and hypertension.	(1) Skilled nursing 5-7 times per week for 3 weeks, then 1-3 times for 6 weeks, and (2) physical therapy.	Seven different nurses (over 1week) did not notify physician of (1) patient complaint of pain and swelling in affected leg and (2) green drainage from groin wound.	Patient suffered pain and developed a wound infection that physician subsequently ordered treated with antibiotics.

State and survey date	Standard(s) cited	Patient description	Plan of care	Deficiencies in care provided by HHA	Likely patient harm
Massachusetts Feb. 2001	Compliance with professional standards: agency staff must comply with accepted professional standards and principles that apply to professionals furnishing services in an agency. Duties of RN: regularly reevaluates the patient's nursing needs. Drug regimen review: review of all medications patient currently uses.	Wheelchair-bound paraplegic patient with pressure sores on lower back and left buttock.	RN to (1) assess patient's skilled care needs and (2) provide wound care 2 to 3 times a week. Standards also provide that RN notify physician of changes in patient's condition and need for additional services and review the medication profile. Standards provide that plan of care is to be developed in consultation with agency staff and is to cover types of services, equipment required, rehabilitation potential of patient, functional limitations, activities permitted, and safety measures to be taken to protect against injury.	RN (1) did not adequately assess the patient's need for physical therapy and nutritional consultations; (2) did not properly irrigate wound and change the dressing; (3) did not assess patient's safety needs and permitted him to ride a stationary bicycle with open sores on his buttocks and lower back; (4) did not reassess patient's needs for physical therapy and safety when patient indicated he was walking, using the wheelchair for support; (5) did not assess patient's nutritional risk status or obtain a consultation with a dietician, although patient was noticeably thin; and (6) did not review patient's medication profile.	Patient developed an additional pressure sore on left buttock. Patient's physical rehabilitation to achieve maximum potential for walking was unnecessarily delayed.

[a]For instances in which surveyors did not record or incompletely recorded the plan of care, we used the requirements of the COPs as criteria for what the HHA personnel should have done.

Source: GAO review of a sample of state survey reports. See app. I for a description of the methodology used to select this sample.

Appendix VII: Complaints to Which States Assigned Questionable Investigation Time Frames

CMS has only one requirement for initiating complaint investigations against HHAs—complaints that represent a potential immediate and serious threat to a patient must be investigated within 2 workdays of receipt. Nine of the 14 states we contacted have established a state requirement that complaints alleging harm (but which do not rise to the level of immediate and serious threat) be investigated in 10 days or less. For less serious complaints—those not rising to the level of either immediate and serious threat or harm—states have established lower-priority investigation categories such as 30-day, 45-day, 60-day, and "next-on-site" (which generally means the complaint will be investigated during the HHA's next standard survey, which could be imminent or in the distant future).

The states placed 79 of the 93 complaints we reviewed in one of these lower-priority investigation categories—that is, beyond 10 days. In reviewing the 79 complaints, we determined that 21 appeared to present potential harm to the patient and required more immediate investigation. Our analysis showed that in some instances a complaint was investigated more quickly than the assigned category. However, we believe that the category assigned implied that the complaint was a low priority for investigation. Three of these examples were discussed earlier in this report. The remaining 18 examples are summarized in table 14. In commenting on a draft of this report, Pennsylvania indicated a willingness to establish a 10-day complaint investigation category if CMS increased funding. Currently, the state prioritizes HHA complaints for investigation in either 2 days or 56 days. Likewise, a Connecticut official indicated that CMS did not provide sufficient resources for the state to complete its complaint workload.

Table 14: Complaints Assigned Questionable Investigation Time Frames

State	Summary of allegation(s)	State's assigned investigation time frame[a]	Actual number of days to investigate
Arkansas	The patient was released from hospital to home with an intravenous line in place and could not take anything by mouth. The day before the patient was discharged from the hospital, the family contacted the HHA and made arrangements for HHA staff to visit the patient at 1:00 p.m. on the day he arrived home. HHA staff did not appear for this scheduled visit. The patient's daughter then called the HHA and was told that staff were too busy and no one could be there until the next day. This meant that the patient would go without fluids for over 24 hours. The HHA tried to describe to the daughter (by telephone) how to connect the patient's intravenous system, but a part of the system was missing. The HHA said the staff could do nothing more at that time and told the daughter that arrangements for the HHA to visit should have been made sooner.	45 working days	29 working days (43 calendar days)
Colorado	The family of a ventilator-dependent patient complained that the patient was to receive 98 hours of LPN care per week, but the patient had gone weeks at a time without it. The HHA had sent out staff lacking experience with the care of ventilator-dependent patients.	Next-on-site	2 working days (2 calendar days)
Colorado	The patient had elevated blood glucose levels, and the HHA failed to inform the doctor of a change in condition. The patient also received incorrect doses of insulin.	60 working days	114 working days (163 calendar days)
Connecticut	Complainant alleged that an HHA aide struck the patient on two occasions.	Medium	9 days
Connecticut	Complainant alleged that "numerous problems put the patients at risk for potential serious mistakes": doctors' orders are late, aides do not receive orientation or supervision, notes about patient care are not filed for weeks, medical sheets are not updated in the patients' charts, visits are being missed, and sudden departure of staff is leaving patients at risk.	Medium	24 days
Connecticut	A physician complained that the HHA had failed to properly treat a patient's pressure sore that had reached an advance stage, requiring immediate surgery. The physician also charged that the HHA had failed to communicate the worsening of the sore to the patient's primary care physician and that an HHA nurse acted unethically by telling the patient that surgery ordered by the doctor was unnecessary.	Medium	21 days
Connecticut	On the first day of service, the home health aide took the patient outside in a wheelchair. Both the aide and patient fell. The patient was not visibly hurt, but HHA came and took the aide to be checked, leaving the patient with no aide for days.	Medium	24 days
Connecticut	The aide left the 13-year-old patient, who suffers from cancer and cerebral palsy and is also confined to a wheelchair, alone with a juvenile friend before the patient's mother returned home.	Medium	7 days
Florida	The patient, who is an RN, complained that the HHA's nurse used a blood pressure cuff to pump intravenous antibiotics more quickly instead of using an electronic pump designed specifically to regulate the flow of intravenous solutions (an inappropriate and potentially dangerous substitution). The complainant also alleged that the nurse used an unsterile technique to change the patient's dressings, did not take the patient's vital signs, and did not check her laboratory blood tests. When the patient complained to the HHA, it discharged her "because she is a registered nurse."	30 to 90 days	13 days

State	Summary of allegation(s)	State's assigned investigation time frame[a]	Actual number of days to investigate
Georgia	A diabetic patient who had recently had leg surgery and had a wound on his foot complained that the skilled nurse was not making visits to clean and dress the wound every day as ordered. He noted that this had been an ongoing problem.	Next-on-site	186 days
Indiana	Two separate complaints made similar allegations, including that (1) the HHA has no Director of Nurses; (2) the agency receptionist (rather than a medical professional) is doing the in-service training; (3) clerical staff are doing employee background checks; (4) staff members are performing work they are unqualified to do (for example, LPNs are auditing patients' records); (5) patients are not receiving all the visits they are supposed to receive, but their records are fraudulently prepared to show that they are; and (6) the HHA is charging home health aide service rates for homemaking services.	90 days	125 days
Indiana	Allegation indicated that patient may have been discharged, without written notice, from the HHA, due to wound care and long-term care needs.	90 days	58 days
Indiana	The complaint made numerous allegations against a patient's nurse, including charges that the nurse (1) stole the patient's medication and prescription, thus preventing the patient from obtaining needed refills, and (2) overdosed the patient with sleeping pills, which resulted in a hospital visit to determine whether the patient had suffered a stroke. It also cited newspaper reports indicating that this same nurse had previously been caught stealing a prescription pad and writing prescriptions for herself, her husband, and others. Finally, the complaint alleged that the patient had a very difficult time finding another agency after she was given a 5-day notice that the HHA would no longer provide services.	90 days	14 days
Kansas	After receiving care from both an HHA and a private caregiver (simultaneously), a patient was admitted to a nursing home. Upon admission, the nursing home discovered that she was recovering from two black eyes and also had fresh bruises, skin tears, and old scars. The patient's daughter then filed a complaint against the HHA, saying that when she raised a concern about the private caregiver, the HHA's nurse defended her and did not look into the daughter's concerns. The HHA's nurse told the daughter that she was not aware of the bruises and skin tears and said that the patient's black eyes had occurred because whenever the private caregiver moved the patient, the patient's face bumped the private caregiver's shoulder. The daughter contended that the HHA should have done a skin/body assessment for other wounds.	60 days	19 days
Louisiana	A former employee of the HHA made 11 allegations about the HHA's failure to provide services to patients, including charges that the HHA failed to (1) administer medication as required, (2) perform required laboratory tests, (3) inform the physician of significant changes in patients' conditions, and (4) ensure that RNs were supervising LPNs.	30 days	15 days
Ohio	The complainant alleged that the patient was supposed to have her burn dressings changed two times a day to prevent infection, but the dressings had not been changed for 2 consecutive days.	30 working days	20 working days (29 calendar days)
Pennsylvania	The HHA told the state survey agency that a patient's mother called the HHA to allege that the HHA's physical therapist had abused the patient, her 29-year-old daughter. The HHA suspended the therapist pending an investigation.	56 days	27 days

State	Summary of allegation(s)	State's assigned investigation time frame[a]	Actual number of days to investigate
Pennsylvania	The complainant alleged that the HHA gave 12 patients a substance used to detect tuberculosis or exposure to tuberculosis instead of flu shots.	56 days	14 days

[a]Arkansas, Colorado, and Ohio use working days as a basis for categorizing complaints. For these states, the table identifies both the number of working days and the number of calendar days that passed before the complaint was investigated. Georgia, Florida, Indiana, Kansas, and Pennsylvania use calendar days and, for these states, information is presented in calendar days. Louisiana uses calendar days for its 30-day investigation priority (but working days for 2- and 10-day complaints). Connecticut prioritizes each complaint into one of three classes but does not attach specific time frames to any of the classes. Class 1 complaints equate to immediate jeopardy complaints and must be investigated within 2 days per federal requirements (although Connecticut's policy identifies these complaints as requiring "immediate action or response"). Class 2 complaints (referred to as "medium" in the table) are complaints that have an impact on the quality of care or quality of life provided to patients. Class 3 complaints are issues that do not directly affect the care of the patient.

Source: State HHA complaint files.

Appendix VIII: Termination Chronology of an HHA Cited for Immediate and Serious Threat to Patients

This appendix describes the 9-month process—from September 28, 2000, through July 1, 2001—of terminating an HHA that was under an expedited 23-day termination process because of surveys finding immediate and serious threats to patients. We selected this case to illustrate the difficulty associated with expeditiously terminating an HHA from participating in Medicare. Factors that contributed to the time required to terminate this HHA included (1) a court order postponing termination and (2) the delayed participation of a federal surveyor in a resurvey that validated the continued presence of an immediate and serious threat. According to the CMS regional office, corrective action was subsequently taken to prevent this type of delay from occurring in any future serious and immediate threat terminations.

On September 28, 2000, less than a year following an ownership change, three separate complaints against the HHA's branch office were investigated.[1] The investigation was expanded into a state standard survey of the HHA's Medicare conditions of participation. During a home visit to a 99-year-old patient, who was the subject of one of the complaints, the state surveyor discovered an immediate and serious threat to the patient as well as potential harm to other patients. The patient was taken to the emergency room and subsequently admitted to the hospital, where she died 9 days later. At the completion of the survey, the state surveyor recommended (1) immediate termination from the Medicare certification program, with immediate suspension of the HHA's state license and the imposition of state administrative penalties,[2] and (2) initiation by the HCFA regional office of a 23-day termination process to expire on November 7, 2000.[3]

In November 2000, the federal district court granted the HHA a temporary restraining order to postpone termination from the Medicare program by HCFA. Before the order expired, the state survey agency conducted a

[1]The HHA had participated in the Medicare program since 1987 and had no COP-level deficiencies cited on its three prior surveys conducted in 1995, 1998, and 1999. In December 1999, the state approved a change of ownership application for the HHA, and a new state license was issued.

[2]Three of the states in our 14-state sample do not license HHAs and would have been unable to invoke state regulatory authority to revoke an HHA's license. An additional six states nationally do not license HHAs.

[3]Under the HCFA 23-day termination process, the HHA should have been terminated on October 22. However, the HCFA regional office letter dated October 17 informed the HHA that it would be terminated on November 7.

resurvey and again found the HHA out of compliance with several conditions and standards and in an immediate and serious threat situation. The state survey agency and HCFA regional office disagreed about whether the November survey had identified an immediate and serious threat. The state asked the HCFA regional office to have a federal surveyor resurvey the HHA. The third resurvey—with a federal surveyor participating—was conducted 4 months later in April 2001. Again the HHA was out of compliance with several conditions and standards, and an immediate and serious threat to a patient was found. Following the April resurvey, the HHA agreed to withdraw from the Medicare program, on July 1, 2001, and its state license was revoked that day.

Table 15 provides a detailed timeline of the patient's treatment provided by the HHA, the state surveys conducted, and the actions taken by the state and CMS's Dallas regional office.

Table 15: HHA Termination Chronology

Date	Action
HHA care from August 10 through September 28, 2000	
August 2	Patient first admitted to HHA following a surgical repair of a fractured right femur. On August 4, patient was transferred to the hospital with decreased appetite, abdominal discomfort, confusion, and sluggishness.
August 10	Readmitted to HHA with diagnoses of dehydration and low blood pressure. The RN noted three stage II pressure sores, a leg brace, and bowel and bladder incontinence. The physical therapist noted, “knee brace is poorly fitted.” Posthospital orders state “clean wound on right buttock with saline, pat dry and cover wound with a protective dressing.”
August 18	RN noted right buttock pressure sore had increased in length and width.
August 20	LVN noted sore now involved both buttocks, with large, dark red, irritated areas and medium amount of yellow/bloody drainage.
August 22	Patient seen by physician (office visit) who ordered changes to patient’s wound care and discontinued protective dressing, leaving wound open to the air.
August 24	RN noted sores increasing in size, with pink and white tissue.
August 25	RN noted four pressure sores; RN noted abrasions of right knee and top of right foot at area of brace openings.
August 26	LVN noted that skin of lower back was scraped.
September 2	Physician ordered use of wet dressing followed by dry dressings for wound care.
September 5	RN noted wound with blackened dead tissue located at left upper end of thighbone area. Did not notify physician.
September 6	RN noted new wound on left upper back. Did not notify physician.
September 7	RN noted patient had an egg crate mattress instead of an alternating pressure mattress that was requested September 1, 2000. RN left message with physician’s office about the need for alternating pressure mattress but did not follow up.
September 8	On recertification documentation, RN noted that patient had difficulty swallowing, dehydration, bowel and bladder incontinence, and was eating poorly; the buttock pressure sore was 14 inches long and 8 inches wide; three other sores’ measurements were also noted. Physician was not notified.
September 11	Doctor ordered wet to dry dressing wound care increased to twice a day.
September 15	RN noted large area of blackened dead tissue—1½ to 2 inches—in buttock/lower-back area with small amount of thick tan drainage with slight odor. RN was unable to contact physician.
September 16	LVN noted lower back wound with gray/brown drainage tunneled 1 inch to tailbone. LPN did not notify RN.
September 18	LVN noted dead tissue areas on right inner knee and ankle; physician informed of tailbone wound odor, ordered wound dressing care continued twice a day. LPN did not notify RN. Alternating pressure mattress, obtained by family member, received and placed on bed during this week.
September 23	LVN noted silver surgical rod showing in right inner knee wound; physician had not seen rod at patient’s appointment earlier that day and was not notified of the exposure of the rod.
September 25	Patient’s family made complaint about HHA’s care to state Home and Community Support Agency.

Date	Action

September 28	State surveyor began on-site complaint survey. At patient's home, it was determined that an immediate and serious threat to the patient existed.
	
	• Patient had large, deep lower-back wound pressure sore with foul smelling odor; had 102 degree fever; smelled of urine and incontinent bowel; had dry skin, dry mouth, and sunken eyes; moaned when touched or turned; and had difficulty swallowing liquid Tylenol.
	• Skilled nurse called and informed physician of temperature and stated that patient was "usual self, alert and oriented," and did not report other symptoms.
	
	Surveyor contacted 911, and patient was sent to emergency room by surveyor and admitted to hospital with
	
	• pressure sores:[a]
	    • stage III—lower back approximately 4 inches (that went to bone),
	    • stage III—right knee 2-1/3 inches with orthopedic screw visible,
	    • right ankle—1-inch diameter,
	    • probable stage IV—both right and left hips with areas of blackened dead tissue, and
	    • right shoulder—1 inch.
	
	• Osteomyelitis (bone infection), malnutrition, metabolic abnormalities, anemia, dehydration, low protein level in blood, dry mouth, and sunken eyes.
	
	Physician's admitting notes stated "Chance of her surviving this is exceedingly poor."

October 6	Patient died in hospital.
State survey agency and HCFA regional office actions from September 29, 2000, through July 1, 2001	
September 29	State surveyor found six conditions of participation deficiencies—organization, services, and administration; group of professional personnel; acceptance of patients, plan of care, and medical supervision; skilled nursing services; home health aide services; and evaluation of the agency's program, as well as 34 standard deficiencies. Surveyor sent Enforcement Action Recommendation to State Department of Human Services Enforcement Manager to immediately suspend HHA's license and seek administrative penalties. Surveyor recommended to HCFA regional office that HHA be immediately terminated from Medicare.
October 17	HCFA regional office sent a letter to HHA to inform it that its Medicare agreement would terminate on November 7, 23 days after survey receipt, and stating no current revisit would be authorized.
October 26	Letter from HHA to HCFA regional office requesting a revisit.
November 7	This is the date the recommended 23-day termination would have occurred. On this date, a federal court issued a temporary restraining order to prevent the HHA's termination by HCFA; the order was to expire on November 16.
November 9	HCFA regional office letter to HHA granting an extension of HHA's termination date from November 7 to November 25. Letter also stated: "… Medicare agreement will remain in effect until the state survey agency makes a positive verification that you have corrected the deficiencies which resulted in your agency being found out of compliance with five Medicare Conditions of Participation, those unmet Conditions were listed in our letter of October 17." State survey found six COPs out of compliance. State Department of Human Services sent a letter to the HHA to inform it that it proposed to revoke the HHA's state license and assess administrative penalties of $3,750. The HHA also was informed it had an opportunity to show compliance with all requirements of law, in order to retain its license, by requesting an informal reconsideration of the proposed license revocation action. The letter explained that informal reconsideration did not extend to the assessment of administrative penalties.

Date	Action
November 15-17	HHA's first follow-up resurvey conducted with two state surveyors. Three conditions of participation—organization, services, and administration; acceptance of patients, plan of care, and medical supervision; and skilled nursing services—and 13 standards—were out of compliance. Serious and immediate threats to the health and safety of some patients were cited.
November 16	Prior to the November 16 expiration of the temporary restraining order, HCFA and the state agency agreed to conduct a state resurvey of the HHA.
November 25	The second 23-day termination date would have expired.
December 4	State Department of Human Services letter to HHA informing HHA that since it did not exercise its opportunity to request an informal reconsideration or to submit any evidence to contest or disprove the proposed adverse action, its license would be revoked and $3,750 in penalties would be assessed. The HHA was informed it still had two options to either accept the adverse action and surrender its license and pay the $3,750 in penalties or to request a hearing, in writing, within 20 calendar days.
December 14	HCFA regional office letter to the HHA regarding the November 17 survey findings of three COPs—organization, services, and administration; acceptance of patients, plan of care, and medical supervision; and skilled nursing services—still out of compliance. The HHA was informed that it had 10 days from receipt of the letter to submit its corrective action plan, and if the plan was submitted, HCFA would authorize another revisit. If revisit indicated that the HHA was still out of compliance, then HCFA would give the HHA a termination date.
January 5, 2001	The HHA switched its parent office to its branch and vice versa. The branch office from which the complainant patient had been provided services became the parent HHA office.
April 2-5	The HHA underwent a second follow-up resurvey with same two state surveyors from the November survey and one federal surveyor from HCFA regional office. Two COPs—organization, services, and administration and skilled nursing services—and 10 standards—were still out of compliance.
April 17	State Department of Human Services' letter to HHA informing it that it was still out of compliance at April 13 follow-up site visit.[b]
April 24	Letter from HHA's law firm to CMS regional office informing that HHA would withdraw from Medicare effective July 1, 2001, and cease to provide home health services effective June 25, 2001.
April 27	HCFA regional office acknowledged the April 24 letter from HHA's law firm and indicated that, when provider agreement is terminated involuntarily or while under threat of involuntary termination, a new agreement will not be accepted until it is determined that the reasons for termination of the previous agreement have been removed and there is reasonable assurance those reasons will not recur.
May	State recommended revocation of the HHA's state license and that administrative/monetary penalties be levied.
June	During June, the HHA's appeal of state Enforcement Action/Compliance Review was conducted; the HHA negotiated $3,500 administrative penalty and a reduction in the state licensure revocation period from 5 years to 1 year.
July 1	The HHA's state license was revoked. The HHA voluntarily terminated from Medicare participation under threat of involuntary termination.[c]

[a]Stages of pressure sore formation are I—skin of involved area is reddened; II—upper layer of skin is involved and may be blistered or abraded; III—skin has an open sore, involving all layers of skin down to underlying connective tissue; and IV—tissue surrounding sore has died and may extend to muscle and bone and involve infection.

[b]Date of April 2 through 5 survey does not match April 13 survey date used in letter.

[c]HHA's OSCAR termination code is "Voluntary—risk of involuntary termination."

Source: Documentation provided by and discussions with Texas state agency and CMS Dallas Regional Office.

Appendix IX: Comments from the Centers for Medicare and Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JUN 26 2002

TO: Kathryn G. Allen
Director, Health Care—Medicaid
and Private Health Insurance Issues
General Accounting Office

FROM: Thomas A. Scully
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: General Accounting Office (GAO) Draft Report, *Medicare Home Health Agencies: Weaknesses in Federal and State Oversight Mask Potential Quality Issues*, (GAO-02-382)

Thank you for the opportunity to review and comment on the above-referenced draft report.

We concur with the recommendations in the report. In fact, we are already taking action on many of the issues that have been raised. We are taking a closer look at home health agency branch offices, developing clinical investigational protocols to assist surveyors, ensuring the budget is adequate for states to comply with survey requirements, and enhancing our oversight of survey and certification programs. The information gathered by GAO, in conjunction with our own internal analysis, will help us make sound policy decisions about how best to move forward in our continuing efforts to assure quality care to patients of home health agencies (HHAs).

We appreciate the effort that went into this report. Our specific comments to the recommendations are attached.

The Centers for Medicare & Medicaid Services' Comments
to the General Accounting Office Draft Report,
"Medicare Home Health Agencies: Weaknesses in Federal and State Oversight Mask Potential Quality Issues, (GAO-02-382)

GAO Recommendations

To strengthen the ability of the HHA survey process to identify and address problems that affect the quality of care, GAO recommends that the Administrator of CMS

- **Develop more specific branch oversight criteria and procedures for states and assign unique identification numbers for each HHA branch office to enable CMS to track survey results and facilitate its own branch oversight.**

CMS Response

We concur and are taking steps to improve our oversight of branch offices. We are currently drafting guidance to our regional offices and state survey agencies that will begin to assign provider identification numbers to every existing branch of a parent HHA and subunit. The identification system will be implemented nationally and will uniquely identify every branch of every HHA certified to participate in the Medicare home health program. It will also link the parent or subunit to the branch.

In addition, we are currently exploring how to incorporate branches into the HHA survey schedule. With the advent of the branch-specific outcome information, we anticipate being able to provide guidance to surveyors on how to investigate "unusual" findings or patterns present in the Outcome and Assessment Information Set (OASIS)-derived reports. As we develop new survey protocols, we will be able to help state survey agencies target resources towards "poor performers," invest fewer resources on providers with good quality of care, and conduct ongoing off-site monitoring. We also believe that if we have sufficient resources, we will be able to direct the surveyors to visit those branches whose outcome reports are well below the national reference point and investigate the care practices that are producing the poor outcomes.

Lastly, we recently clarified our policy (see survey and certification memorandum 02-30) on approving branch offices. The policies outlined in this memorandum focus on the ability of the HHA to demonstrate how it can monitor all services provided by the branch to ensure compliance with the conditions of participation found at 42 C.F.R section 484.10. We believe that the decision to approve a branch should be based on the HHA's ability to meet the regulatory requirements and adequately supervise the branch to assure that the quality and scope of items and services provided to all patients are of the highest practicable functional capacity for each patient so as to meet his/her medical, nursing,

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and rehabilitative needs. We are also re-evaluating the regulatory definition of a branch and may suggest changes that address the industry's concerns while also protecting the Centers for Medicare & Medicaid Services' (CMS) ability to provide adequate oversight and important beneficiary protections.

GAO Recommendation

- **Develop more specific guidance and training for distinguishing between COP-level and lesser deficiencies and for improving the consistency across state in documenting deficiencies.**

CMS Comment

We concur. We currently instruct surveyors that, when analyzing information and making determinations about the importance of specific incidents, they should focus on the effect or potential effect on the patient; the degree of severity; the frequency of occurrence; and the impact on the delivery of services. An isolated incident that has little or no effect on the delivery of patient services does not warrant a deficiency citation. On the other hand, a condition of participation (COP) may be considered out of compliance for one or more deficiencies, if, in a surveyor's judgment, the deficiency constitutes a significant or a serious problem that adversely affects, or has the potential to adversely affect patients. However, we recognize additional guidance and training are required to assist surveyors in determining the effectiveness of the HHA's care delivery and how it directly impacts patient care.

Specifically, we are currently exploring the feasibility of developing several clinical investigational protocols to assist surveyors during the survey process. In October 2001, we entered into a 33-month contract with the University of Colorado Health Services Research Center to develop improved survey protocols, which effectively and efficiently measure the quality of care delivered in HHAs, as well as promote consistency in the survey process. With the establishment of the OASIS national repository, we now have the opportunity to more effectively use the patient-specific outcome information to direct and supplement onsite surveys and to initiate data analysis necessary to help us explore ways to build a process that is more focused on patient outcomes and less focused on Agency process.

We anticipate that the protocols developed as a result of this contract could be used in HHAs whose outcome reports indicate quality of care problems. For example, we may develop protocols that can be used in the following situations:

- To determine if care delivery was related to a specific adverse event;
- To determine the effectiveness of the HHA's treatment, prevention, and interventions for specific adverse events;
- To determine if improper medication administration or medication side effects were avoidable or unavoidable;

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- To determine the effectiveness of the HHA's medication administration guidelines and monitoring of medications;
- To determine if a patient's hypo/hyperglycemia was avoidable or unavoidable;
- To determine the effectiveness of the HHA's hypo/hyperglycemia monitoring and prevention guidelines;
- To determine if functional decline was avoidable or unavoidable; and
- To determine the effectiveness of the HHA's discharge policy for patients with ongoing needs.

We believe that this additional guidance will assist surveyors with evaluating the quality of care an agency is providing and in identifying deficiencies. We plan to include training on this additional guidance during our basic surveyor training course in September and are making plans to make that portion of the training available through internet web cast so that we can efficiently get that information to all HHA surveyors. In addition, each home health basic course will include a detailed review of our policy on determining immediate jeopardy, which is contained in Appendix Q of the State Operations Manual, and is interpreted as a crisis situation in which the health and safety of individual(s) are at risk. We will continue to stress that every surveyor use these guidelines to assist them in recognizing situations that may cause harm or immediate jeopardy.

We plan to award a contract by the end of fiscal year (FY) 2002 which will inventory all the home health data CMS collects. Currently, the purpose of this contract is to identify and create an inventory of all home health data collected by CMS and its contractors and make these data accessible to CMS management and staff in a single program. The CMS will then be able to validate, analyze, and assess the data to determine their utility in overseeing survey and certification activities at the state, regional, and national levels. As part of the deliverables, we expect to receive recommendations on types of reports that CMS staff and management need to effectively and efficiently manage and monitor survey and certification activities of the states as well as on the ability to easily gain access to these reports from individual desktops.

To help enhance our training program and monitor attendance to required training courses, CMS is in the process of implementing an automated system for tracking surveyor training. This system will enable us to better monitor individual surveyor experience as well as each state's overall survey workforce. With this information, CMS will be able to begin a critical assessment of the professional qualifications of all surveyors. We will also be able to determine whether CMS should establish minimum requirements for training and work experience.

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GAO Recommendation

- **Improve the adequacy of the sampling process, such as increasing the size of the sample of medical records and patient visits, to better determine the prevalence of quality-of-care problems.**

CMS Comment

We concur that the sampling process needs to be improved. However, we are investigating ways that may not necessarily increase the sample of medical records that a surveyor looks at; rather, we are looking for a more effective and efficient sampling process. Last October, CMS began to study and evaluate how best to use patient outcome data in a revised survey process as part of a contract with the University of Colorado described above.

We believe that the sampling process for HHAs should be related to quality of care provided by the agency rather than to the number of patient admissions per year. Our goal is to make the home health survey process more effective, efficient, consistent, data-driven, and outcome-oriented. With these enhancements, we hope to impose greater objectivity and consistency in our quality oversight procedures.

We also intend to develop criteria that can be used to distinguish HHAs whose outcome performance may indicate quality of care problems from those HHAs whose outcome performance is adequate or superior. Surveyors will be directed to increase the sample sizes, as necessary, for record review and home visit for those HHAs with identified problems in order to better determine the prevalence of the quality of care problems or adverse events. We would also like to note that the current sample sizes for record review and home visit that are contained in the State Operations Manual state the minimum number of patients whom surveyors are directed to review. Surveyors always have the option to increase the sample size if problems are identified that need further investigation.

GAO Recommendation

- **Ensure that resources are adequate for states to fully comply with the requirement to survey all HHAs at least once every 36 months and certain HHAs more frequently.**

CMS Comment

We concur. The CMS notes that its national budget for HHA surveys adequately supports the estimated workload. The CMS currently projects the national HHA survey budget based on a 3-year trend analysis of actual state reported survey workload and survey hours, including a trend analysis to project the national HHA facility count. These actual survey workload and survey hour data include the effects of the variable survey

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schedule implemented in 1996 – thus, the impact of the variable survey schedule is assumed within the national HHA budget projection.

We think that state survey agencies receive enough funding in the President's budget to perform these surveys. We believe that states made choices to do other surveys instead. We have restructured the next budget call letter to assure that states understand that it is absolutely required that they perform all statutorily required surveys. We will examine the feasibility of increasing the HHA survey coverage level in FY 2003 to ensure adequate resources for those states that must survey over 1/2 of their HHAs annually in accordance with the flexible survey criteria and compliance trends.

As we begin to finalize a survey process that routinely includes survey of HHA branches, we expect we will need to increase the level of funding to the state survey agencies in 2004 and beyond in order to accommodate an increased level of effort associated with the inclusion of more HHA branches.

GAO Recommendation

To ensure that the complaint process adequately addresses quality-of-care problems, GAO recommends that the Administrator

- **Ensure that states eliminate barriers to filing complaints by improving the accessibility and effectiveness of hotlines and by not requiring complaints to be filed in writing;**
- **Monitor states' responsiveness to complaints, including developing assurances that serious allegations are promptly investigated and resolved; and**
- **Provide technical assistance to states as appropriate to develop consistently effective complaint tracking systems.**

CMS Comment

We concur. The identification of activities to improve our complaint management, policies, and procedures is paramount. Conducting complaint surveys is, and will continue to be a visible and important aspect of the survey and certification process. In addition to our own awareness, this report highlights the need for improved state agency complaint investigation processes and stronger CMS oversight.

We are currently in the process of redesigning a data system, i.e., the Quality Improvement and Evaluation System (QIES) that captures survey and certification information. One of the components of QIES will be an automated complaint tracking subsystem to assist state agencies in the processing and tracking of complaints. The ASPEN Complaint Tracking System or ACTS will enable states to create electronic intake records and update them as necessary. The complaint subsystem will track

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complainants' allegations, investigations of complaints, referrals, and resolution. The ACTS has been implemented in seven states and includes complaint information for HHAs. We expect this system to be implemented nationally in October 2002. Analysis of the data related to complaints will assist CMS in its monitoring and oversight efforts.

In addition to the new complaint tracking system described above, we currently have a contract with the Center for Health Systems Research and Analysis (CHSRA) at the University of Wisconsin at Madison to evaluate the nursing home complaint process. This project is referred to as the Nursing Home Complaint Improvement Project and will identify steps to take to strengthen and improve the nursing home complaint process. The project includes describing the complaint process and assessing its effectiveness, determining how states can be more responsive to residents and families, making recommendations regarding the process, oversight and management; and discussing the elements in a national database. A draft of CHRSA's report has been received at CMS and is currently undergoing review. While this report is focused on nursing home complaints, we expect to examine how the findings could be related to other provider types as well, including the home health complaint system.

GAO Recommendation

To ensure that states comply with home health statutory, regulatory, and other CMS requirements designed to protect patient health and safety, GAO recommends that the Administrator

- **Adopt comprehensive state performance standards for HHAs, such as holding states accountable for (1) performing HHA surveys based on CMS's variable 12- to 36-month survey schedule and (2) improving the timeliness and reliability of states' OSCAR data entry; and**
- **Use OSCAR and other means to monitor and assess state survey performance on an ongoing basis.**

CMS Response

We concur. The CMS has several initiatives in place that involve enhancing our ability to oversee our survey and certification programs. The CMS recently developed standards for adequate state survey agency performance (see Survey and Certification Memoranda 01-11 and 02-28) that hold states accountable for certain program requirements. While the impetus of developing these standards was to improve our nursing home survey and certification program, the standards do include evaluations of such things as timely planning, scheduling, and conducting of surveys as well as timely data entry of survey results. With some of GAO's concerns directed at inconsistent surveyor training and performance, we may want to explore the possibility of adding a standard that speaks to oversight of training. As we improve our methods for collecting oversight information, we expect to be able to use this process to focus on oversight of HHAs and other provider

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types. The challenge now is to ensure that adequate resources will be available to build policies and procedures for actively and regularly monitoring compliance with our standards at the national, regional, and state levels.

As mentioned previously, CMS is currently working with a contractor to develop a system to access all the home health data from a single program. This will assist CMS in managing and monitoring all survey and certification activities for HHAs, as well as increase the efficiency and effectiveness of survey and certification processes. In this way, CMS will be able to more effectively monitor the activities of the states in determining whether the Medicare approved HHAs in the states are meeting Federal standards. We will also be able to analyze critical information related to surveys, including timing and type of surveys, complaint activity, branch activity, deficiency citations, and outcome reports.

During the development of this new oversight program, CMS will work with the contractor to review the current survey and certification process for the adequacy and effectiveness of the home health data that are currently used to monitor and manage the survey and certification process at the state, regional, and national level. We will also review the current survey and certification process for determining what type of reports would be most useful to the central and regional office survey and certification staff and management and identify any duplication, inconsistencies, and/or gaps in the data and reports currently used for the survey and certification process. We intend to analyze the current data collected and recommend improvements that would make the survey and certification process more efficient.

In addition, we expect to work with this contractor to explore the feasibility of developing home health monitoring reports similar to those currently used in nursing homes. The CMS recently designed a system for high-level oversight of the nursing home survey and certification program called the Survey and Certification Management Reporting (SCMR) tool. The SCMR provides exceptions data and dashboard-like displays of critical information that are currently focused on the nursing home survey process. It is designed to provide both the regional and central offices with a management-level look at potential problem areas in the states and to provide a reading of general program status. The SCMR currently portrays such things as compliance with timeframes for processing enforcement actions and average number of low-level, mid-level, and high-level deficiencies cited in nursing homes across states in each region.

Appendix X: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff Acknowledgments

The following staff made important contributions to this work: Jack Brennan, Patricia A. Jones, Dean Mohs, Beth Morrison, Peter Schmidt, Paul M. Thomas, and Opal Winebrenner.

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