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MEDICARE HOME HEALTH AGENCIES

Certification Process Is Ineffective in Excluding Problem Agencies

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Mr. Chairman and Members of the Committee:

I am pleased to be here today as the Committee examines fraud and abuse associated with one of the fastest growing components of the Medicare program—the home health benefit. We believe the foundation for protecting this benefit rests on controlling which home health agencies (HHA) are allowed to bill Medicare and ensuring that they provide quality services for each Medicare dollar they receive.

Only HHAs that are surveyed and certified as meeting Medicare's conditions of participation and associated standards may be paid by Medicare for their services. As a result of changes in Medicare law, regulations, and policy in the 1980s, more people are receiving home health services for longer periods of time. This has led to rapid growth in the number of certified HHAs—from 5,700 in 1989 to almost 10,000 at the beginning of 1997. In some states, the number of HHAs has more than doubled. During this same period, Medicare payments for home health care jumped from \$2.7 billion to about \$18 billion and are estimated to reach \$21.9 billion in fiscal year 1998.

Because of this Committee's concerns about whether the rapid growth of HHAs in the Medicare program has been effectively managed, you and Senator Breaux asked us to determine how Medicare (1) controls the entry of HHAs into the Medicare program and (2) ensures that HHAs in the program comply with Medicare's conditions of participation and associated standards. Today, I will discuss the preliminary results of our ongoing review of Medicare's survey and certification process for HHAs. In conducting our review, we obtained information from the Health Care Financing Administration's (HCFA) central office and regional offices in California, Illinois, Massachusetts, and Texas; state survey agencies in California, Maine, Massachusetts, and Texas; the offices of Medicare claims processing contractors, known as regional home health intermediaries, located in California, Iowa, Maine, and South Carolina; the Department of Health and Human Services' (HHS) Office of the Inspector General; and several industry groups. Our final report to the Committee this fall will address in greater detail the issues I am about to discuss.

In summary, we are finding that Medicare's survey and certification process imposes few requirements on HHAs seeking to serve Medicare patients and bill the Medicare program. The certification of an HHA as a Medicare provider is based on an initial survey that takes place so soon after the agency begins operating that there is little assurance that the HHA

is providing or is capable of providing quality care. Moreover, once certified, HHAs are unlikely to be terminated from the program or otherwise penalized, even when they have been repeatedly cited for not meeting Medicare’s conditions of participation and for providing substandard care.

Background

HHS is charged with ensuring that HHAs meet conditions of participation in the Medicare program that are adequate to protect the health and safety of beneficiaries. As shown in table 1, Medicare has 12 conditions of participation covering such areas as patient rights; acceptance of patients, plans of care, and medical supervision; and skilled nursing services. Most conditions, in turn, comprise more detailed standards; for example, the skilled nursing condition has two standards—one addresses the duties of registered nurses and the other the duties of licensed practical nurses. The conditions and standards are further clarified in interpretive guidelines, which explain relevant statutes and regulations.

Table 1: Medicare’s Conditions of Participation and Associated Standards for HHAs

Conditions of participation	Standards
Patient rights ^a	— Notice of rights
	— Exercise of rights and respect for property and person
	— Right to be informed and to participate in planning care and treatment
	— Confidentiality of medical records
	— Patient liability for payment
	— Home health hotline
Compliance with federal, state, and local laws; disclosure and ownership information; and accepted professional standards and principles ^a	— Compliance with federal, state, and local laws and regulations
	— Disclosure of ownership and management information
	— Compliance with accepted professional standards and principles

(continued)

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Conditions of participation	Standards
Organization, services, and administration	— Services furnished — Governing body — Administrator — Supervising physician or registered nurse — Personnel policies — Personnel under hourly or per-visit contracts — Coordination of patient services^a — Services under arrangements — Institutional planning — Laboratory services
Group of professional personnel	— Advisory and evaluation function
Acceptance of patients, plan of care, and medical supervision ^a	— Plan of care — Periodic review of plan of care — Conformance with physician orders
Skilled nursing services	— Duties of the registered nurse — Duties of the licensed practical nurse
Therapy services	— Supervision of physical therapy assistant and occupational therapy assistant — Supervision of speech therapy services
Medical social services	
Home health aide services ^a	— Home health aide training — Competency evaluation and in-service training — Assignment and duties of the home health aide — Supervision — Personal care attendant: evaluation requirements
Qualifying to furnish outpatient physical therapy or speech pathology services	
Clinical records ^a	— Retention of records — Protection of records
Evaluation of the agency's program	— Policy and administrative review — Clinical record review

^aConditions and standards reviewed during a standard survey.

Source: 42 C.F.R. 484.

Medicare—as authorized by title XVIII of the Social Security Act—can reimburse only those HHAs that have been surveyed and certified as being

in compliance with its conditions of participation. This survey and certification process is administered by HCFA through state survey agencies—usually components of the state health departments. HCFA funds these survey agencies to assess HHAs against Medicare’s conditions of participation and associated standards. Surveys are conducted on-site at the HHA and involve activities such as clinical records review and home visits with patients. HCFA’s State Operations Manual provides guidance to state surveyors on conducting their surveys.

Once an HHA passes its initial survey and meets certain other requirements, HCFA certifies it as a Medicare provider and issues a provider number, which the agency uses to bill Medicare. To retain its certification, an HHA must remain in compliance with all of the conditions of participation. Each HHA is supposed to be recertified every 12 to 36 months following the same process used in the initial survey process, with the frequency depending upon factors such as whether ownership changed and the results of prior surveys. But complaints about HHA services may trigger an earlier survey. HHAs can lose their certification and be terminated from the program if they do not comply with one or more conditions; for example, an HHA providing substandard skilled nursing care that threatens patient health and safety can be terminated. However, HHAs not complying with a condition of participation can avoid termination by implementing corrective actions.

HHAs Easily Obtain Medicare Certification

Practically anyone who meets state or local requirements to start an HHA can be virtually assured of Medicare certification. It is rare that any new HHA is found not to meet Medicare’s three fundamental certification requirements: (1) being financially solvent; (2) complying with title VI of the Civil Rights Act of 1964, which prohibits discrimination; and (3) meeting Medicare’s conditions of participation. HHAs self-certify their solvency, agree to comply with the act, and undergo a very limited initial certification survey that few fail. Currently, HCFA certifies about 100 new HHAs each month.

Once an HHA meets state and local laws, regulations, and licensing requirements, Medicare imposes few additional restrictions to becoming certified. Title XVIII of the Social Security Act does not require HHA owners to have prior health care experience. For example, we found one owner whose most recent work experience was driving a taxi cab and another who owned and operated a pawn shop in addition to his HHA. Finally, there are no capitalization requirements, and a criminal background is not a

deterrent to agency certification unless that criminal activity specifically prohibits the individual from Medicare participation.

Each certified HHA must provide skilled nursing services and one other covered service—physical, speech, or occupational therapy; medical social services; or home health aide services. HHAs can offer all of these services if they choose to do so. Only one of an HHA's services must be delivered exclusively by its staff; any additional covered services the HHA offers can be provided either directly or under contract with another health care organization that does not have to be Medicare certified.

During the initial certification process, surveyors conduct what is called a standard survey; this survey is required by statute to assess the quality of care and scope of services the HHA provides as measured by indicators of medical, nursing, and rehabilitative care. The standard survey addresses an HHA's compliance with 5 of the 12 conditions of participation plus one of the standards associated with a sixth condition that HCFA believes best evaluate patient care (see table 1). If surveyors identify substandard care during the standard survey, they are to conduct a more in-depth review of the HHA's compliance with the other conditions of participation.

These initial surveys often take place so soon after an HHA begins operating that surveyors have little information with which to judge the quality of care an HHA provides or the HHA's potential for providing such care. We found that initial surveys frequently are made when HHAs have served as few as one patient for less than 1 month and have not yet provided all the services for which they are to be certified. The surveyor may never see any patients or otherwise assess the care the HHA is providing, even though visiting patients is recognized by HCFA and state surveyors as the best way to evaluate an HHA's care. Furthermore, the HHAs are typically caring for non-Medicare beneficiaries at the time of their initial survey; these patients may have medical conditions that differ from those of Medicare beneficiaries needing home health care.

The fact that the law allows this ease of entry into Medicare has probably contributed to the rapid growth in the number of Medicare-certified HHAs; it has also allowed some questionable agencies to participate in the program. For example:

- An individual with no experience in health care started her Texas HHA in the pantry of her husband's restaurant. Within 4 months of the HHA's certification, state surveyors started receiving complaints that the HHA had

been (1) enrolling patients who were either ineligible for the Medicare home health benefit or who had been referred for care without a physician's orders and (2) hiring home health aides on the condition that they first recruit a patient. Approximately 10 months following initial certification, state surveyors substantiated the complaints and also found that the HHA was not complying with four conditions and multiple standards, including four standards that the HHA had been cited for violating during its initial survey. The surveyors also identified 13 cases in which they suspected the HHA provided unnecessary services or served ineligible beneficiaries; the surveyors referred these cases to the Medicare claims processing contractor. One month later, the surveyors conducted a follow-up survey and found that the agency had implemented corrective actions, as it had following its initial survey. No further surveys had been conducted at the time of our review.

- Another individual with no home health care experience started a California HHA, which was Medicare certified in 1992. Within 1 year of certification, state surveyors and the Medicare claims processing contractor received numerous complaints alleging that the HHA had served patients ineligible for the Medicare benefit, falsified medical records, falsified the credentials of the director of nursing, and used staff inappropriately. A recertification survey about 15 months after initial certification found that the HHA was not complying with multiple conditions of participation and had endangered patient health and safety. By September 1993, after Medicare had paid the HHA over \$6 million, the HHA closed. The owner, a former drug felon, and an associate later pled guilty to defrauding Medicare of over \$2.5 million.

HCFA regional office and state survey officials have acknowledged that the initial certification survey provides little assurance that an HHA can and will provide quality care. They believe that newly certified HHAs should be resurveyed after they are fully operational and that, at that time, they should also be assessed for compliance with all of Medicare's conditions of participation for all of the services the HHA provides. HCFA central office officials told us that, while they have the statutory authority to assess new HHAs against all of the conditions of participation at any time and it would be desirable to resurvey an agency several months after initial certification, this would require additional funding for state survey agencies—funding that they said is not available. Another alternative, also within HCFA's statutory authority, is to require that HHAs seeking Medicare certification have treated a minimum number of patients. Several HCFA regional offices now suggest that an HHA should have cared for at least 10 patients at the time of its initial survey. However, HCFA central office

officials said that this would not be a reasonable requirement for all HHAs seeking certification. In some rural states, 10 patients may represent an entire year's patient workload. Setting a 10-patient minimum on a national basis could therefore result in denying beneficiaries access to home health care services if they live in sparsely populated areas of the county, according to the HCFA officials.

Medicare's Recertification Process Contains Serious Weaknesses

Medicare's recertification process does not ensure that only those HHAs that provide quality care in accordance with Medicare's conditions of participation remain certified. The primary problems are that (1) HHAs do not have to periodically demonstrate compliance with all of Medicare's conditions of participation; (2) surveyors do not fully review an HHA's branch office operations; (3) rapidly growing HHAs do not receive more frequent surveys, even though rapid growth has been linked to difficulties in complying with Medicare's conditions; and (4) HHAs repeatedly cited for serious deficiencies identified during a standard survey are rarely terminated or otherwise penalized.

HHAs Are Not Assessed Against All Conditions of Participation

HCFA initially certifies and then recertifies most HHAs without requiring them to ever demonstrate compliance with all the conditions of participation. Instead, HCFA asks the surveyors to initially limit their evaluation of HHAs to the standard survey and then expand the survey to the other conditions only if they find problems. As a result, HCFA and Medicare patients usually do not know whether an HHA is complying with conditions not included in the standard survey.

A recent Operation Restore Trust (ORT) project in California targeted 44 HHAs that provided unusually high numbers of services to their patients and received high levels of Medicare payments compared with their peers.¹ HCFA and state surveyors evaluated these HHAs against 11 of the 12 conditions of participation, rather than initially limiting their evaluation to the 5 conditions and 1 standard reviewed during a standard survey.² HCFA and state surveyors identified a significant number of HHAs that were noncompliant with conditions typically excluded from review—conditions

¹ORT initially was a 2-year, multiagency effort in five states that targeted fraud and abuse by three types of Medicare providers: HHAs, skilled nursing facilities, and durable medical equipment suppliers. In May 1997, the Secretary of HHS announced that ORT would continue for another 2 years and include projects in 12 additional states.

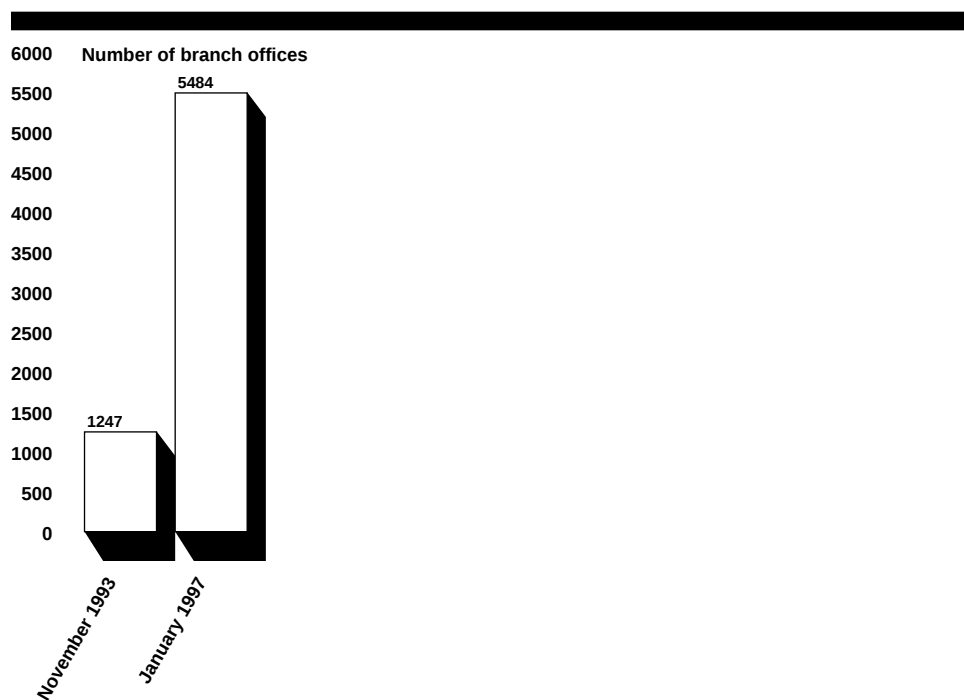
²This project did not cover HHA compliance with the condition regarding qualifications to furnish outpatient physical therapy or speech pathology services because none of the HHAs provided such services on an outpatient basis at their parent or branch offices.

that address the HHA's operations and the care it provides to Medicare beneficiaries. Nearly three-quarters of the HHAs failed to comply with at least one of the conditions not covered in the standard survey, and 21 of the 44 HHAs either voluntarily withdrew their certification or had their certification terminated by HCFA. Although this project targeted HHAs suspected of problems, it does demonstrate that criteria other than those used in the limited standard survey may be better predictors of compliance with all the conditions of participation.

Branch Offices of HHAs Are Frequently Not Evaluated

HCFA defines a branch office of an HHA as a unit within the geographic area served by the parent office that shares administration, supervision, and services with the parent office. Since the mid-1980s, many HHAs have created branch offices. As shown in figure 1, about 2,200 HHAs operated nearly 5,500 branch offices in January 1997—over four times the number in November 1993. In Texas, for example, we identified 106 HHAs with 3 or more branches, and 1 HHA had 25 branch offices.

Figure 1: Growth in the Number of
HHA Branch Offices



Source: HCFA's On-line Survey Certification and Retrieval System.

Since they are considered to be an integral part of an HHA, branches are not required to independently meet the conditions of participation. Further, HCFA does not require surveyors to visit patients served by each branch office. Since new branch offices do not undergo an initial certification survey, HCFA cannot be assured that they meet Medicare's definition of a branch office. And, most importantly, not directly surveying branch operations means that quality-of-care issues within an HHA's overall operations may be missed. When branches have been surveyed because the HHA wanted to convert them to parent offices, significant problems have been found. Several examples follow:

- In California, surveyors found that one branch of an HHA cared for 581 patients over the 12 months ending September 1996—more than the average number of patients cared for by an HHA in the state during that time. Moreover, the branch was not complying with one condition of participation, and the surveyors recommended denial of the HHA's initial certification. Among its problems was that the branch had no system in place to ensure that its contractor staff had the appropriate qualifications and licenses.
- Similarly, a branch office of a Massachusetts HHA had cared for 69 patients since the HHA's last survey. The branch was denied initial certification as a parent office because it failed to meet nine standards associated with several conditions of participation. For example, the surveyors found that the branch office, in 10 of 12 cases examined, did not follow the plan of care and provide services as frequently as ordered by a physician. At the time of our review, the HHA had not yet submitted its correction plan and had not been certified as a parent office.

While HCFA's guidance allows surveyors to conduct the entire recertification survey of an HHA at a branch office, state surveyors told us that this is seldom, if ever, done. Branch offices typically do not maintain all the personnel files or clinical information that surveyors need in their evaluation. As a practical matter, surveyors told us that they may not have time to conduct home visits with branch office patients and still finish the survey within their allotted time and resources.

**No Thresholds Exist to
Trigger More Frequent
Surveys of Rapidly
Growing Agencies**

Increasing workload may necessitate changes in an HHA's operations; this, in turn, can affect its compliance with Medicare's participation requirements. While HCFA's criteria for setting survey frequency include many factors, they do not include consideration of whether an HHA is

growing rapidly or maintaining a stable level of operations—information state surveyors generally would not have before conducting their survey.

New HHAs have the potential for rapid growth and, as a result, are more likely to have difficulties complying with Medicare’s conditions of participation. As shown in table 2, we found that nearly one-fourth of the HHAs initially certified in 1993 in California and Texas received Medicare payments exceeding \$1 million in 1994—their first full year of Medicare certification—and the average number of patients they treated in a year at least tripled between 1993 and 1995. For example, in 1993, one California HHA treated 11 patients and received \$33,000 from Medicare; in 1995, the HHA treated 1,810 patients and received \$12.7 million in Medicare payments. Also, the percentage of these rapidly growing HHAs cited for noncompliance with the conditions of participation exceeded the national norm. Nationwide, about 3 percent of all HHAs each year are cited for failing to meet Medicare’s conditions of participation. In contrast, 40 percent of the high-growth HHAs in California and 11 percent of the high-growth Texas HHAs did not meet the conditions in their most recent surveys.

Table 2: Characteristics of High-Growth HHAs in California and Texas That Were Initially Certified in 1993

	California	Texas
Number of HHAs initially certified in 1993	116	174
Number of these HHAs that received more than \$1 million in Medicare payments in 1994	30	44
Average Medicare payments to these HHAs in 1995	\$2.9 million	\$3 million
Change in average number of patients treated between 1993 and 1995 by these HHAs	Quadrupled	Tripled
Percentage of these HHAs that did not meet conditions of participation in latest survey	40	11

HCFA issued its survey frequency criteria in May 1996, after legislation authorized it to increase the maximum interval between surveys from 15 months to 3 years. As previously noted, HCFA’s criteria consider factors such as an HHA’s prior survey results, changes in ownership, and complaints. By not considering an HHA’s rate of growth when setting survey frequency, however, HCFA is missing an opportunity to more quickly identify and correct compliance deficiencies. Such information is available from Medicare contractors and HCFA.

Few HHAs Are Involuntarily Terminated

Once certified as a Medicare provider, an HHA is virtually assured of remaining in the program even if repeatedly found to be violating Medicare's conditions of participation and associated standards. There are no penalties short of termination because HCFA has not developed intermediate sanctions as it was authorized by the Congress to do a decade ago. HCFA officials told us that they wanted experience with the skilled nursing facility intermediate sanctions, which became effective in July 1995, before implementing intermediate sanctions against HHAs.

Until the advent of ORT, the likelihood of an HHA's being terminated from the Medicare program was remote. In fiscal years 1994, 1995, and 1996, about 3 percent of all certified HHAs were terminated, and most of these were voluntary terminations arising from either mergers or closures. Only about 0.1 percent of all certified HHAs in fiscal years 1994 and 1995 and 0.3 percent in fiscal year 1996 were involuntarily terminated as a result of noncompliance with the conditions of participation. California accounted for almost half of the 32 involuntary terminations nationwide in 1996, with 8 of its 15 involuntary terminations that year stemming from the ORT project.

To terminate an HHA, the surveyors must find that it did not comply with one or more conditions and remained out of compliance 90 days after a survey first identified the noncompliance.³ If an HHA threatened with termination takes corrective action and state surveyors verify through site visits that this action has brought the HHA back into compliance, HCFA will cancel the termination process.

Under Medicare's termination procedures, HHAs remain in the program, to the potential detriment of beneficiaries, even if they repeatedly fail to comply with Medicare's conditions of participation.

- In California, for example, an HHA's second recertification survey revealed that the HHA was deficient in meeting five standards, three of which had been identified in the previous year's survey and supposedly corrected. Several months later, at this same HHA, an ORT survey team found eight conditions and numerous standards not met. When this HHA was resurveyed 5 months later, the surveyors found that it was back in compliance with all conditions but that it had yet to meet seven standards. Most of these deficiencies in meeting standards had been cited in the preceding surveys, and some had existed for a long time. For example, for

³If the deficiency jeopardizes patient health and safety and is considered immediate and serious, HCFA places the HHA on an accelerated termination timetable.

the three most recent surveys, this HHA had been cited for not following physicians' orders in the written plan of care. The HHA remains certified despite its repeated problems.

- Moreover, on a Texas HHA's first recertification survey, 1 year after initial certification, the state surveyor found four standards not met and referred several cases of possible fraud to the Medicare contractor. Within 10 months of that survey, state surveyors resurveyed the HHA and found it was not in compliance with seven conditions of participation, and the previously cited deficiencies in meeting standards had not been corrected. HCFA issued a termination letter, but within 2 months of the last survey the HHA had corrected the deficiencies, and the termination process was halted. On a complaint investigation 6 months after the deficiencies had been corrected, the surveyors found the HHA was again out of compliance with three of the same seven conditions. On this most recent survey, the surveyors attributed the death of one patient directly to this HHA. At the time her attorney advised her to surrender her state license and Medicare certification, the owner/operator of this HHA had already hired a nurse consultant to bring the HHA back into compliance.

HHAs are not threatened with termination if they are complying with the conditions of participation but are violating one or more standards and subsequently submit a corrective action plan. But surveyors often do not revisit the HHA to verify that it has implemented the plan and actually corrected the deficiencies. For example, Illinois surveyors did not revisit 13 of 21 HHAs that had submitted plans to correct their violations of Medicare's standards.

Because of circumstances such as those discussed above, the threat of termination has little, if any, deterrent value. The Congress, recognizing that HCFA should have more enforcement options than that of terminating an HHA, enacted provisions in the Omnibus Budget Reconciliation Act of 1987 to address this issue. These provisions authorized the Secretary of HHS to impose intermediate sanctions for a period not to exceed 6 months on HHAs violating Medicare's conditions of participation. If the HHA continued to violate conditions after that 6-month period, it was to be terminated from the program. The act required the Secretary of HHS to develop and implement, not later than April 1, 1989, a range of intermediate sanctions that were to include civil monetary penalties for each day of noncompliance, suspension of Medicare payments to the HHA, and HCFA's appointment of a temporary manager to manage the HHA. HCFA proposed alternative sanctions for HHAs in August 1991 but never finalized its implementing regulations. Therefore, the only alternative currently

available to HCFA to penalize deficient HHAs is to terminate them from the program.

Conclusions

HHAs provide valuable services that enable a growing number of beneficiaries to continue living at home. Accompanying this increase in beneficiaries have been sharply increasing Medicare payments and rapidly rising numbers of certified HHAs. HCFA's HHA survey and certification process, however, fails to provide beneficiaries with reasonable assurance that their HHA meets Medicare's conditions of participation and provides quality care. Yet, certification represents Medicare's "seal of approval" on the services provided by an HHA.

Our ongoing work suggests that it is simply too easy to become Medicare certified. Before they are certified, HHAs do not have to demonstrate a sustained capability to provide quality care to a minimum number of patients for all types of services. And because the requirements are minimal, HCFA certifies nearly all HHAs seeking certification. While many HHAs are drawn to the program with the intent of providing quality care, some are attracted by the relative ease with which they can become certified and participate in this lucrative, growing industry. HHAs can remain in the program with little fear of losing their certification. Most will never have to demonstrate compliance with all of the participation conditions, and, even if they are found out of compliance, temporary corrective actions are sufficient to allow them to continue to operate.

These problems suggest that HCFA needs to pay closer attention to how it surveys and certifies HHAs. We expect that our upcoming report will contain specific recommendations on how HCFA can strengthen the survey and certification process so that it provides greater assurance that only those HHAs that provide quality care in accordance with requirements participate in Medicare.

Mr. Chairman, this concludes my prepared statement. I would be pleased to respond to any questions you or Members of the Committee may have.

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