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MEDICARE HOME HEALTH AGENCIES

Certification Process Ineffective in Excluding Problem Agencies

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The Honorable Charles E. Grassley
Chairman
The Honorable John B. Breaux
Ranking Minority Member
Special Committee on Aging
United States Senate

As a result of changes in Medicare law, regulations, and policy, more Medicare beneficiaries are receiving more home health services and for longer periods of time. Home health care enables beneficiaries with short-term, acute-care needs, such as recovery from a hip replacement, as well as those with long-term, chronic conditions, such as congestive heart failure, to receive care in their homes. The use of home health care has grown because of the liberalization of the benefit as well as increases in the elderly population, longer life expectancy, and the ability to deliver services in the home that previously were provided only in hospitals or skilled nursing facilities (SNF). However, abusive billings for excessive care and visits for noncovered services have inflated this growth to some extent.

The number of home health agencies (HHA) certified to care for Medicare beneficiaries has increased rapidly—from 5,700 in 1989 to nearly 10,000 at the beginning of 1997—and more than doubled in some states. During the same period, Medicare spending for home health care jumped from $2.7 billion to about $18 billion and is estimated to reach $21.9 billion in fiscal year 1998. Home health care has been, and continues to be, one of the fastest growing components of the Medicare program.

Only HHAs that are surveyed and certified as meeting Medicare's conditions of participation and associated standards can be reimbursed by Medicare for their services. This survey and certification process is administered by the Health Care Financing Administration (HCFA), in the Department of Health and Human Services (HHS), through state survey agencies, which are usually components of state health departments. These survey agencies assess whether HHAs have the appropriate staff, policies, procedures, medical records, and operational practices to deliver quality care. Surveyors conduct part of their work on site at HHAs and perform a variety of tasks, such as reviewing clinical records, interviewing HHA staff, and visiting patients in their homes.

Because of your concerns about the rapid growth in the number of certified HHAs and the effectiveness of the survey and certification process, you asked us to determine how HCFA (1) controls the entry of HHAs into the Medicare program and (2) ensures that certified HHAs continue to comply with Medicare's conditions of participation and associated standards. We also looked at HCFA's process for decertifying HHAs that are not complying with Medicare's requirements. This report expands on our July testimony before your Committee, in which we presented the preliminary results of our work.[1]

To address these issues, we interviewed officials and gathered pertinent data about survey and certification activities at HCFA, state survey agencies, Medicare claims processing contractors, the HHS Office of the Inspector General, and trade groups representing the home health industry. We concentrated our work in California, Illinois, and Texas, which were among the original five states HCFA targeted under Operation Restore Trust (ORT) for reviews addressing home health agencies.[2] We conducted our work between March 1996 and July 1997 in accordance with generally accepted government auditing standards, with one exception. We did not examine the internal and automatic data processing controls related to the On-line Survey, Certification and Reporting database (OSCAR), which HCFA and its state surveyors use to manage the survey and certification process for HHAs. Further details on our scope and methodology are provided in appendix I.

Results in Brief

Becoming a Medicare-certified HHA is relatively easy—probably too easy, given the large number of problem agencies identified in various studies over the past few years. If HHA owners have not been previously barred from Medicare, they can obtain certification without having any health care experience. Although such entrepreneurs can hire qualified health care professionals, Medicare's initial certification survey is so limited that it does not provide a sound basis for judging an HHA's ability to provide quality care.

[1]Medicare Home Health Agencies: Certification Process Is Ineffective in Excluding Problem Agencies (GAO/T-HEHS-97-180, July 28, 1997).

[2]ORT initially was a 2-year multiagency effort that targeted fraud and abuse in three areas of Medicare—HHAs, SNFs, and durable medical equipment suppliers. This effort was conducted in the five states (California, Florida, Illinois, New York, and Texas) that represented about 40 percent of all Medicare and Medicaid beneficiaries. In May 1997, the HHS Secretary announced that the ORT effort would continue for another 2 years and include projects in 12 additional states.

Although certified HHAs must be periodically recertified, serious deficiencies in the process allow problems to go undetected. HCFA recertifies HHAs by screening them against a subset of the conditions of participation, but when surveyors assessed 44 targeted HHAs against all applicable conditions of participation, almost half had problems serious enough to warrant decertification. Also, many HHAs operate branch offices, but these offices are not subject to the same oversight afforded the parent offices. HHAs are resurveyed every 12 to 36 months, depending on a variety of factors, but rapid growth and high utilization rates, which may indicate potential problem HHAs, are not included among those factors.

Once certified, HHAs have little reason to fear that they will suffer serious consequences from failing to comply with Medicare's conditions of participation and associated standards. Few problem HHAs are terminated from the program: Instead, they are provided repeated opportunities to correct their deficiencies, even if the same deficiencies recur from one survey to the next. Moreover, HCFA has not implemented a range of penalties to sanction problem HHAs, even though the Congress provided it the authority to do so over 10 years ago.

Background

Medicare, the nation's largest health care payer, provides insurance coverage to more than 38 million elderly and disabled Americans. The program provides protection under two parts. Part A, the hospital insurance program, covers inpatient hospital care, posthospital care in skilled nursing homes, hospice care, and care in patients' homes. Part B, the supplementary medical insurance program, primarily covers physician services but also covers home health care for beneficiaries not covered under part A. In 1996, Medicare paid approximately $17.7 billion for home health services under part A and $300 million under part B. HCFA uses six contractors (usually insurance companies) to process and pay home health claims.

At the inception of the Medicare program, the home health benefit under part A provided limited posthospital care—up to 100 visits for 1 year, following a hospitalization of at least 3 days, and for the same illness that required the hospitalization. Similar requirements applied to SNFs. Part B had no prior hospitalization requirement and covered up to 100 visits per year that were not covered by part A. However, legislative and regulatory changes in the 1980s (1) dissolved the direct link to prior hospitalization under part A; (2) abolished limitations on the number of covered visits; and (3) in effect, expanded the home health care benefit to include

long-term home care for the chronically ill. The Balanced Budget Act of 1997 (P.L. 105-33) defined the conditions under which part A or part B will pay for home health care.[3]

To provide home health services to Medicare beneficiaries, an HHA must be certified by HCFA and assigned a provider number for billing purposes. In recent years, about 800 to 900 HHAs per year have been initially certified to serve Medicare beneficiaries, and the demand for initial certification continues. HHAs may be freestanding or hospital based, for-profit or not-for-profit, public or private. Some are associated with regional or national health care provider organizations. A growing number operate branch offices as a way of expanding their operations. As defined by HCFA, branch offices provide services within the geographic area served by the parent office and share administration, supervision, and services with the parent office.

Home health services covered by Medicare include part-time or intermittent skilled nursing and home health aide services, physical and occupational therapy, speech language pathology services, medical social services, and the provision of certain medical supplies and equipment. With the exception of providing medical supplies and equipment, no copayments or deductibles are associated with these services. 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, physical therapy, or speech language pathology services.

HCFA contracts with state health departments to survey HHAs and determine if they comply with Medicare's conditions of participation.[4] There are 12 conditions of participation covering such topics as patient rights, acceptance of patients and plans of care, skilled nursing services, and clinical records. Most conditions are subdivided into more detailed

[3]Beginning in 1998, for individuals covered by both parts A and B of Medicare, part A will cover up to 100 home health care visits a beneficiary receives following a minimum 3-day hospital stay, with part B paying for any other visits, including those without an associated hospitalization. For individuals without part B coverage, all home health care visits will be covered under part A, and no prior hospitalization requirement will apply.

[4]Alternatively, HHAs may elect to be surveyed and accredited by either the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) or the Community Health Accreditation Program (CHAP). A small number of HHAs that are surveyed according to HCFA's prescribed survey frequency by either of these accrediting bodies and that pass their surveys are "deemed" to meet Medicare's conditions of participation. JCAHO conducts more deeming surveys than CHAP. We previously reviewed HCFA's evaluation of these two accrediting bodies' ability to ensure that HHAs adhere to Medicare's conditions. See Home Health Care: HCFA Properly Evaluated JCAHO's Ability to Survey Home Health Agencies (GAO/HRD-93-33, Oct. 26, 1992) and Home Health Care: HCFA Evaluation of Community Health Accreditation Program Inadequate (GAO/HRD-92-93, Apr. 20, 1992).

standards and requirements. For example, the "skilled nursing services" condition of participation is divided into two broad standards that cover the duties of a registered nurse and the duties of a licensed practical nurse. These standards, in turn, are further defined by 15 requirements: 8 for a registered nurse, 5 for a licensed practical nurse, and 2 overall general requirements. (See app. II for a complete list of conditions of participation.) Surveyors assess whether an HHA is meeting the requirements and, ultimately, whether the HHA is in compliance with the "skilled nursing services" condition of participation. Noncompliance with an overall condition is considered a "condition-level" deficiency, and all other deficiencies are considered "standard-level" deficiencies.

HCFA proposed significant revisions to the conditions of participation in March 1997. The proposed new conditions emphasize improving patient outcomes and establishing performance improvement programs within HHAs. HCFA is now assessing comments received on its proposal.

During an initial HHA survey, the surveyor conducts a "standard survey" to assess the HHA's capacity to deliver quality care. Once an HHA passes its initial survey and meets certain other requirements, HCFA certifies it as a Medicare provider and issues it a provider number for billing purposes. The HHA is then supposed to be recertified every 12 to 36 months following the same survey process, with the exact frequency dependent upon factors such as whether HHA ownership changed and the results of prior surveys. But complaints about HHA services may trigger an earlier survey.

Certified HHAs can lose their certification if they are out of compliance with one or more conditions; for example, an HHA providing substandard skilled nursing care that threatens patient health and safety can be terminated. If the deficiency jeopardizes patient health and safety and is considered immediate and serious, the HHA is placed on an accelerated termination timetable; otherwise, HCFA follows a 90-day termination procedure. HHAs can avoid termination by implementing corrective actions that bring them back into compliance with Medicare's conditions of participation. An HHA can continue to participate in Medicare even if multiple standards are unmet, provided it has prepared an acceptable plan of correction.

HHAs Easily Obtain Medicare Certification

Medicare's initial survey and certification process was not designed to screen out potentially fraudulent or abusive billers, but rather to assess whether an HHA is capable of delivering quality home health services.

Therefore, it is not surprising that unscrupulous HHAs obtain certification. But although the certification process was intended to screen out HHAs that are unlikely to deliver quality care, it does not adequately do so. HHAs do not need health care experience to be certified by Medicare. In addition, the certification process covers fewer than half of Medicare's conditions of participation, is carried out too soon after an HHA has begun providing services, and does not involve a complete review of HHA operations. The overall result is that practically anyone who meets state or local requirements for starting an HHA is virtually guaranteed Medicare certification—a circumstance that probably contributes to Medicare fraud and abuse. Moreover, although Medicare requires HHAs seeking certification to complete a form detailing ownership and management information, HCFA has only recently begun verifying the accuracy of that information. It is unclear if or how the proposed new conditions of participation would affect the initial certification process and the problems we identified with this process.

Few Requirements Exist for HHAs Seeking Medicare Certification

Practically anyone who meets state and local requirements for starting an HHA can be almost certain of obtaining Medicare certification. It is rare for an HHA to not 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 law, and undergo an initial certification survey that few fail. On September 15, 1997, the HHS Secretary announced a moratorium on the entry of any new HHAs into Medicare while regulations are written to address fraud in the home health industry. Among the actions announced by the Secretary, HCFA will require HHAs to demonstrate experience and expertise in home care by serving a minimum number of patients before seeking Medicare certification. Before September 1977, Medicare was certifying about 100 new HHAs each month.

HHAs face few other obstacles to becoming certified. For example, Medicare law does not require HHA owners to have health care experience. We identified one owner whose most recent work experience was driving a taxicab, another who owned and operated a pawn shop in addition to his HHA, and a third who was a realtor specializing in ranch sales. None had experience in the health care field. Further, until passage of the Balanced Budget Act of 1997, a criminal background was not a deterrent to HHA certification unless that criminal activity was related to Medicare, other federal health programs, or illicit drugs. The law now allows HHS to refuse

Medicare participation to HHA owners if they have a felony conviction under federal or state law that is considered detrimental to the best interests of the program or its beneficiaries.

Regarding service delivery, Medicare law requires only that HHAs provide skilled nursing services plus one other covered service and that HHAs deliver one of their covered services exclusively by their own staff. Except for the one covered service that HHAs must provide directly, HHAs may decide how to deliver their services—either directly or by another individual or entity under contract with them. Such contractors do not have to be Medicare certified; the certified HHA is responsible for supervising their work. The one service delivered directly does not have to be skilled nursing care, physical therapy, or speech language pathology services—one of which individuals must need in order to qualify for the home health benefit. In 1996, for example, Medicare certified a Massachusetts HHA that delivered medical social services directly with one social worker but relied upon 12 registered nurses from another entity to deliver all of its skilled nursing services.

While contracting for services can give HHAs certain advantages, such as the flexibility to manage staffing as patient populations fluctuate, it can also lead to problems. For example, HHAs that rely heavily on contractors may not exercise full control over the care they provide, and excessive contracting may be an indication the HHA is exceeding its capacity to effectively care for its patients. Further, heavy use of contractors may indicate that the HHA is a "shell"—that is, little more than a fax machine and a nurse used to bill Medicare for services. HCFA regional office officials, for example, told us that HHAs that rely extensively on contractors for skilled nursing services often cannot provide a list of patients with their diagnoses or their clinical records because the HHAs have little contact with the contract nurses. HCFA recognizes these problems and has proposed under its new conditions of participation that HHAs deliver at least half of their skilled services directly.

Initial Surveys Provide Little Assurance That HHAs Are Capable of Furnishing Quality Care

Medicare's initial certification process does not provide a sound basis for judging whether an HHA does or will provide quality care in accordance with Medicare's conditions of participation. Initial surveys often cover fewer than half of Medicare's conditions of participation, occur too soon after an HHA has begun providing services, and do not involve a complete review of an HHA's operations. As a result, state surveyors and HCFA do not have sufficient, adequate information to verify that the HHA is capable of

furnishing quality care for all its services or is in compliance with all of the conditions of participation.

During the initial certification process, surveyors conduct a standard survey that 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 the HHA's compliance with 5 of the 12 conditions of participation—and with one standard associated with a sixth condition—that HCFA believes best evaluate patient care. During the initial survey, according to HCFA officials, reviewing HHA compliance with all of the conditions is often impractical because some of them measure HHA activities over a period of time. For example, the "group of professional personnel" condition calls for an advisory panel to meet frequently and participate in evaluating the HHA's program; at the time of an HHA's initial survey, the panel may not yet have met. However, HCFA does not require HHAs to demonstrate compliance with all conditions of participation at any point following their initial certification, unless the surveyors find at least one condition-level deficiency.[5]

Medicare sets no minimum standards for how long HHAs must be operational before being surveyed, and these surveys typically occur soon after HHAs begin providing services. As a result, surveyors have limited information with which to judge the quality of care provided by HHAs. For example, HCFA certified a Massachusetts HHA that had 1 month's operational experience at the time of its initial survey, and a Texas HHA had been delivering care for 7 weeks when it was initially surveyed. Because of the short time period between their opening and their initial certification survey, many HHAs have treated few patients. California, Massachusetts, and Texas surveyors told us that it is not uncommon for HHAs to be caring for just one patient at the time of their initial survey. Several HCFA regional offices recently issued guidance to their state survey agencies suggesting that HHAs should have cared for at least 10 patients before the initial survey. Such a criterion is not required at the national level. HCFA central office officials said that imposing such a requirement in rural states would create an access problem for some beneficiaries if their HHA cared for only a few patients during the year.

We also found that, at the time of their initial survey, HHAs may not have delivered all the services they will become certified to provide. For

[5]If they find one or more condition-level deficiencies, surveyors are required to conduct an extended survey and review compliance with all conditions of participation.

example, an HHA certified to provide physical therapy services may not have cared for a patient that needed this service at the time of its initial certification. Further, surveyors do not always conduct home visits to patients receiving care from HHAs, although such visits are recognized by HCFA and state surveyors as the best indicator of an HHA's performance. Surveyors told us that they prefer to conduct home visits when HHA staff are delivering services, but patients may not always be scheduled to receive care when the surveyors are on site at the HHA. Also, the patient may refuse a visit by the surveyor.

Limitations of Certification Process Can Lead to Quality Problems and Fraudulent Practices

The relative ease with which HHAs become certified has likely resulted in certifying some HHAs that fail to provide high quality care and that abuse or defraud Medicare. 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 order and (2) hiring home health aides on the condition that they first recruit a patient. Approximately 10 months after initial certification, state surveyors substantiated the complaints and also found that the HHA was not complying with four conditions of participation and multiple standards, including four standards that the HHA had been cited as not meeting 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 HCFA's claims processing contractor. One month later, the surveyors conducted a follow-up survey and found that the HHA had implemented corrective actions, as it had following its initial survey. No further surveys had been conducted at this HHA 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 HCFA's 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 had closed. The owner, who was a former

drug felon, and an associate later pleaded guilty to defrauding Medicare of over $2.5 million.

HCFA regional office and state survey agency officials recognize that the initial certification process provides little assurance that an HHA can and will provide quality care to its patients in accordance with Medicare's conditions of participation. They believe that newly certified HHAs should be resurveyed after several months of actual operation, when they have treated a number of beneficiaries and demonstrated the quality of their care. They also said that the HHAs should be assessed against all of Medicare's conditions of participation at this time, thus providing assurance that an HHA is in total compliance with Medicare's participation requirements. 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 that it would be desirable to resurvey an HHA several months after initial certification, these actions would require additional funding for state survey agencies, which is currently unavailable.

New Enrollment Process Requires Verification of HHA Information

HCFA recently established an enrollment process for different types of health care organizations, including HHAs, that are seeking initial entry into the Medicare program or whose ownership has changed. Starting in mid-1997, those owners of an HHA with a 5-percent or greater financial interest in the HHA began to be required to supply HCFA with information, such as their names and whether they had ever been excluded from participating in Medicare, before an initial certification survey could be carried out. The Medicare claims-processing contractors are responsible for verifying this information within 21 days of receipt; in particular, they verify that (1) the owners, managing employees, and subcontractors have not been sanctioned or otherwise excluded from participating in the program; (2) the HHA, if applicable, is appropriately licensed by the state;[6] and (3) on the basis of a check with the current or prior Medicare contractor that dealt with these individuals, there are no indications, or proof, of fraud or abuse committed by the owners or managing employees.

The Balanced Budget Act of 1997 strengthened the HHA enrollment process further by requiring HHA owners to supply HCFA with their Social Security numbers; before this legislation, HCFA asked HHA owners for this information but could not require it. Having owners' Social Security numbers, Medicare contractors should be better able to use various

[6]As of 1996, nine states had no requirements for licensing HHAs.

databases to determine if an owner has previously been sanctioned by, or barred from, Medicare or other federal health programs.

If the enrollment process does not identify any problems, the Medicare contractor notifies the state survey agency so that it can conduct an initial certification survey of the HHA.

Medicare's Recertification Process Contains Serious Weaknesses

Medicare's recertification process does not ensure that only those HHAs that provide quality care throughout their operations and comply with all of Medicare's conditions of participation retain certification. The process does not require HHAs to periodically demonstrate compliance with all conditions of participation, nor does it require a complete assessment of an HHA's branch operations. Thus, shortcomings with the recertification process may cause quality of care issues to go undetected, to the potential harm of beneficiaries.

Rapidly growing HHAs are surveyed as frequently as other HHAs, even though rapid growth is an indicator of compliance deficiencies with Medicare's participation requirements. Also, most state survey agencies do not routinely receive information from HCFA contractors, such as average number of services per patient provided by an HHA and its average Medicare payments per patient, that would be useful to them when surveying HHAs; recent ORT studies have demonstrated that such information sharing would be advantageous to Medicare.

HHAs Are Not Assessed Against All Conditions of Participation

HCFA recertifies most HHAs without requiring them to demonstrate compliance with all the conditions of participation. As in the initial survey process, state surveyors conduct a standard survey and assess HHAs against 5 of the 12 conditions plus one standard associated with a sixth condition; if they find an HHA out of compliance with one or more of these conditions, they must expand the survey to check an HHA's compliance with all of the remaining conditions. Each year, on average, only about 3 percent of all certified HHAs are cited for having one or more conditions out of compliance. Therefore, many HHAs function for years without ever being assessed for compliance with all of Medicare's conditions of participation. As a result, neither HCFA nor beneficiaries know whether HHAs are complying with the conditions not included in a standard survey.

HCFA believes that the standard survey effectively evaluates an HHA's patient care and its compliance with Medicare's conditions of

participation. Evaluating HHAs against all of the conditions on each recertification survey would take additional resources that are not available, according to HCFA officials. However, legislation passed in 1996 provides HCFA with increased flexibility, given existing resources, to periodically evaluate HHAs against all conditions of participation. This legislation increased the allowed intervals between recertification surveys to up to 36 months, from the previous requirement of approximately every 12 months. Because fewer existing HHAs have to be recertified each year, the resources needed to assess some against all of the conditions of participation might become available.

When selected HHAs were assessed against nearly all of Medicare's conditions of participation in a recent ORT study in California, surveyors identified significant quality-of-care problems that led to terminating many of the HHAs. During this ORT study, HCFA targeted 44 HHAs that provided unusually high numbers of services to their patients and received high levels of Medicare payments, compared with their peers. HCFA and state surveyors evaluated these HHAs against 11 of the 12 conditions of participation[7] rather than the 5 conditions and one standard reviewed during a standard survey. Approximately 80 percent of the targeted HHAs, when first surveyed, were out of compliance with at least one of the conditions not covered in a standard survey, and 21 of these targeted HHAs either voluntarily withdrew from Medicare or were terminated by HCFA from the program. The following examples describe some of the problems identified in the California ORT that relate to conditions of participation not covered in a standard survey.

- Surveyors found an HHA out of compliance with all of the conditions they surveyed and identified the following quality of care issues: (1) The HHA could not provide the surveyors with a list of active patients, did not know which patients would receive care on a particular day, and did not exercise control over the services provided by contractor staff; (2) HHA staff provided patients with medication that had not been ordered by a physician; and (3) the HHA failed to ensure that therapists were qualified and prepared progress notes. HCFA subsequently terminated the HHA's Medicare certification.
- Another HHA was found out of compliance with seven conditions, including four not covered in a standard survey. Quality-of-care problems identified by the state surveyors included the following: (1) The HHA failed to monitor or control laboratory services and ensure that they were provided as

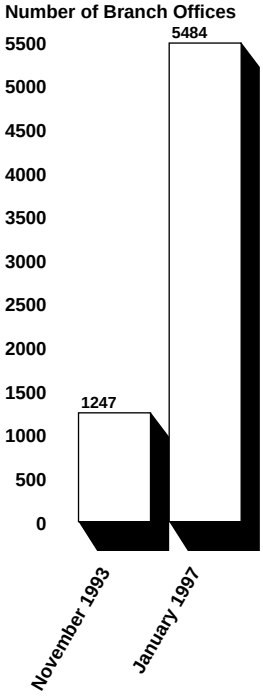
[7]The study did not check HHA compliance with the condition regarding HHA qualifications to furnish outpatient physical or speech pathology services because none of the targeted HHAs provided these services.

ordered, (2) nurses did not provide care as ordered and failed to initiate necessary revisions to patients' plans of care, and (3) the HHA failed to verify that therapists hired under contract were qualified to deliver therapy services. HCFA terminated the certification of this HHA.

Medicare's Recertification Process Does Not Fully Cover HHA Branch Office Operations

Since the mid-1980s, more and more HHAs have created branch offices at increasingly greater distances from the parent office, with many HHAs operating multiple branches. In Texas, for example, we identified 106 HHAs as of January 1997 with 3 or more branch offices, including 1 HHA that had 25 branch offices. Figure 1 shows that there were nearly 5,500 branch offices in January 1997—over four times the number that existed in November 1993.

Figure 1: Growth in the Number of HHA Branch Offices, November 1993-January 1997



Source: HCFA's OSCAR.

HCFA considers branch offices integral parts of an HHA and, therefore, does not require them to be surveyed and certified. Without such an investigation, however, HCFA has no way of knowing whether a new site actually meets Medicare's definition of a branch office or should more appropriately be classified as an independent HHA, which must be surveyed and certified. As a result, HHAs can expand their operations by creating new branch offices and avoid the scrutiny of the survey and certification process. Further, HHAs may open new branches before demonstrating their own capability for providing quality care. For example, a Massachusetts HHA planned to open three branch offices in different parts of the state immediately following its initial certification, which was based on care provided to two patients.

Significantly, Medicare does not require surveyors to conduct home visits with patients served by any of the branch offices at the time of an HHA's recertification. This means that quality-of-care issues within an HHA's overall operations may be missed, especially if the branch offices care for a significant percentage of the HHA's patients. For example, as of October 1996, one Texas HHA cared for 49 patients at its parent office and 160 patients at a total of 10 branch offices; two of the branches each cared for more patients than the parent office. While HCFA's regulations recognize that surveyors should visit patients served by a branch office when recertifying an HHA, they do not actually require it or establish criteria for defining which branches and their patients should be included in the survey. As a practical matter, surveyors told us that they sometimes do not have time to conduct home visits with branch office patients and still finish the survey within their allotted time and resources.

According to HCFA officials, visiting patients treated by some or all HHA branch offices is a resource issue and conducting home visits with patients treated by each branch office would be impractical when recertifying HHAs. However, now that the time frame for recertification has been relaxed, HCFA should have greater flexibility to have surveyors conduct more home visits with branch office patients. Moreover, developing targeting criteria for surveyors to follow in selecting which branch offices or patients to visit would allow a more efficient use of HCFA's survey and certification budget.

By not surveying branch operations, significant problems can go undetected. This became evident when branch offices were surveyed because the HHAs wanted to convert them into independent HHAs. 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 entire HHA in the state during that time. The branch was not complying with one condition of participation, and the surveyors recommended the branch office be denied certification as an independent HHA. Among its problems was the fact that the branch office 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 an independent HHA 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 the branch office had not been certified as an independent HHA.

We also found that it is common for HHAs to have branch offices located hundreds of miles from the parent office, which may result in branch office staff receiving less direct supervision from their parent office than is required by Medicare. For example, one Texas HHA has branch offices located over 300 miles from the parent office. A California HHA located near Sacramento operates four branch offices in other parts of the state as far as 200 miles away. HCFA does not define how far a branch office can be located from the parent office because, according to HCFA officials, a fair definition that applies on a national basis would be difficult to develop because of variations in geography and population throughout the country. However, some states have set limits. For example, one state requires that a branch office be located no more than 100 miles from its parent office, while another restricts a branch to being no more than 1 hour's drive from the parent office. In 1996, an administrative law judge addressed the issue in a California case about whether an entity should be designated as a branch or an independent HHA. The judge ruled that parent offices must be capable of sharing required functions on a daily basis with their branches and that a branch office located approximately 50 miles from the parent office, which could, in heavy traffic, be up to 2-1/2 hours' driving time away, did not meet this criterion.

HCFA's Survey Frequency Criteria Need to Be Expanded

Under HCFA's recertification criteria, HHAs are to be resurveyed every 12 to 36 months, depending upon such factors as how long they have been certified, results of prior surveys, and changes in ownership. Excluded

from consideration are factors such as whether an HHA is quickly increasing its patient population, receiving large increases in Medicare payments, or experiencing high utilization rates—factors that can affect an HHA's compliance with Medicare's conditions of participation.

Our work in California and Texas, in fact, suggests that HHAs that have grown rapidly often have difficulty complying with Medicare's participation requirements. 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. By their second year of operation, these HHAs averaged about $3 million in Medicare payments, and the average number of patients they treated more than tripled between 1993 and 1995. Accompanying that growth, however, was noncompliance with the conditions of participation. Forty percent of the high-growth HHAs in California did not meet one or more conditions of participation in their latest survey—almost double the percentage of the other HHAs certified that same year. In Texas, about 11 percent of the high-growth HHAs failed to comply with one or more conditions in their latest survey, compared with about 6 percent of the other HHAs certified in 1993.

Without input from Medicare contractors, state surveyors must generally wait until they survey the HHAs to obtain information about the number of patients HHAs have and how much they are receiving in Medicare payments. In 1989, we recommended that HCFA establish a procedure for its contractors to use in providing state surveyors with information that could be useful in their assessments of HHA compliance with the conditions of participation.[8] Until the advent in 1995 of ORT activities, this information, which would help surveyors better target their efforts toward problem HHAs, had not been routinely shared by the contractors.

The HHS Office of the Inspector General (OIG) recently reported that HHAs that have abused or defrauded Medicare or misappropriated Medicare funds tend to exceed national and state averages for the number of visits and reimbursements per patient.[9] We found that HHAs that exceed such state averages are also likely to experience problems complying with Medicare's conditions of participation. In California, HCFA targeted 44 HHAs for inclusion in its ORT project, largely on the basis of information supplied by the two contractors processing home health claims for HHAs in the

[8]Medicare: Assuring the Quality of Home Health Services (GAO/HRD-90-7, Oct. 10, 1989).

[9]HHS, OIG, Home Health: Problem Providers and Their Impact on Medicare (OEI-09-96-00110) (Washington, D.C.: HHS, July 1997).

state. Specifically, the contractors developed a rank-order list of HHAs that had the highest average number of visits per patient and Medicare payments per patient. In 1995, California HHAs averaged 45 visits per patient and received approximately $4,000 per patient from Medicare. In contrast, one of the 44 targeted HHAs provided an average of 174 visits per patient that year and received an average Medicare payment per patient of $15,700. Another targeted HHA provided an average of 148 visits per patient and received an average of $12,700 per patient from Medicare. With this targeted approach, surveyors found most of the 44 targeted HHAs out of compliance with multiple conditions of participation, and almost half are no longer in the program. Had the HHAs in the following examples not been targeted for the ORT survey, they would likely have continued providing substandard care for as long as 3 years before they were resurveyed under HCFA's survey frequency criteria.

- A California HHA initially certified in 1988 more than doubled its Medicare payments between 1993 and 1994 to $7 million while increasing the number of patients it treated from 715 to 1,034. This HHA's average Medicare reimbursement per patient in 1995 was $7,613. When surveyed under the ORT project, this HHA terminated its participation after being found out of compliance with six conditions of participation.
- Another California HHA, initially certified in 1990, approximately doubled its Medicare payments to $6 million and increased its patient population almost 20 percent from 1993 to 1994. Its average Medicare reimbursement per patient in 1995 was $5,867. ORT surveyors initially found this HHA out of compliance with three conditions, but after a third follow-up survey, it was found to be in compliance with all conditions and therefore its certification was not terminated.

Once Certified, Few HHAs Lose Their Certification

Once an HHA has been certified as a Medicare provider, it is virtually assured of remaining in the program, with no penalty, even if found to be repeatedly deficient in complying with Medicare's conditions of participation. An HHA's participation in the Medicare program is not terminated on the basis of volume of deficiencies or repeat deficiencies, but rather on the basis of surveyors' finding lack of compliance with at least one condition of participation that the HHA does not subsequently correct. Even when an HHA is cited for serious deficiencies and threatened with termination, termination rarely occurs. As explained by HCFA central office officials, once the HHA takes corrective action to remove any immediate threat and is thereby moved from the accelerated termination

track to the 90-day termination track, the HHA is virtually assured of remaining in the Medicare program.

Until the advent of ORT, a project that in 1995 began targeting "high-risk" HHAs in several states on the basis of suspected aberrant billing practices, the likelihood that an HHA's Medicare participation would be terminated by HCFA was remote. In fiscal years 1994, 1995, and 1996, about 3 percent of all certified HHAs nationwide discontinued Medicare participation—most of them voluntarily, as a result of either mergers or closures. Terminations initiated by HCFA as a result of uncorrected deficiencies identified during the survey process were even more rare—ranging from about 0.1 percent of HHAs nationwide in 1994 to 0.3 percent in 1996. In 1996, however, as a result of its participation in ORT, California accounted for almost one-half of the 32 HCFA-initiated terminations nationwide, with 8 of its 15 terminations that year stemming from the ORT project.

Corrective Actions Are Often Temporary

For HCFA to terminate an HHA's Medicare certification, the surveyors must find that it did not comply with one or more of the conditions of participation and remained out of compliance 90 days after a survey first identified the noncompliance.[10] 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. An HHA, however, can subvert the termination process by taking corrective action for a short time, reverting to noncompliance by the next survey, taking corrective action again, and so on and still remain certified almost indefinitely—or at least until a patient is seriously harmed.

While surveyors return to an HHA to verify that noncompliance with conditions has been corrected, this is not always the case when the noncompliance is limited to standards. For standard-level deficiencies, just submitting an acceptable plan of correction may be enough. For example, Illinois surveyors did not revisit 13 of 21 HHAs included in its ORT project because they had submitted plans to correct their violations of Medicare's standards. Moreover, surveyors do not always review prior survey reports to better focus on problematic areas before beginning a new survey. In one state, for example, we found one group of surveyors that always prepared for a survey by reviewing previous survey reports in order to identify the types of deficiencies previously found and the extent

[10]If the deficiency jeopardizes patient health and safety and is considered immediate and serious, HCFA places the HHA on an accelerated termination timetable of 23 days.

of complaints received involving the HHA or its branch operations. In that same state, however, another group of surveyors intentionally did not review prior reports in order to avoid biasing the current survey.

Even when surveyors visit HHAs and verify that corrective actions have been taken, HHAs may not sustain their corrective efforts over time. For example, after a Massachusetts HHA was initially certified in 1989, surveyors found it out of compliance with one or more conditions in 1991, 1993, 1994, and 1996.

To some extent, HCFA has relied on HHAs to police themselves between surveys, with questionable results. For example, one condition of participation requires a group of professional personnel to establish and annually review HHA policies and operations. This group is to meet frequently to advise the HHA on professional issues, program evaluation, and liaison with other health care providers. Another condition requires an overall evaluation of the HHA's program at least once a year by the group of professional personnel, HHA staff, and consumers. This evaluation must assess the extent to which the HHA's program is appropriate, adequate, effective, and efficient. Also, health professionals must review a sample of active and closed clinical records at least quarterly to determine whether established policies are followed. Neither of these conditions, however, is reviewed as part of the standard survey process. In fact, when HHAs were actually surveyed against these conditions in the California ORT project, most were found not in compliance with these two conditions.

Given multiple opportunities to correct their deficiencies, it is not unusual for HHAs to have conditions and standards out of compliance from one survey to another and remain in the program, as the following examples illustrate:

- A California HHA's second recertification survey revealed that the HHA had deficiencies in meeting five standards and that three of the deficiencies 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 the HHA was resurveyed 5 months later, it was found to be back in compliance with all conditions, but 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 the three most recent surveys, this HHA had been cited for not following physicians' orders

in the written plan of care. The HHA was still certified at the time of our work.

- 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 its 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 so that it could remain certified.
- State surveyors found deficiencies in 12 standards when conducting a California HHA's first recertification survey in 1993. At its next survey in 1995, the surveyors found nine standards out of compliance, three of which had been identified in the preceding survey. In 1996, the ORT survey team found 10 conditions and multiple standards out of compliance, including most of the standards cited in previous surveys. The surveyor's report documented a case in which the HHA accepted a patient who had a surgical wound on the knee that had not healed properly. Over a 5-week period, the HHA never reported the deteriorating condition of the patient's wound to the attending physician. The patient was ultimately admitted to an acute-care hospital, where his leg was amputated. As a result of this latest survey, HCFA notified the HHA that it would be terminated. Before the effective date of termination, the HHA voluntarily surrendered its state license and Medicare provider number.

Because of circumstances such as these, the threat of termination has little, if any, deterrent value, and problem HHAs seem to operate with impunity. 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. The act authorized the Secretary of HHS to impose intermediate sanctions for a period not to exceed 6 months on those HHAs found deficient, in lieu of terminating their certification. If the HHA was still found deficient 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 was to include civil monetary penalties for each day of noncompliance, suspension of Medicare payments, and assumption of management of the HHA. The act also required that these regulations provide for progressively more severe sanctions for repeated or uncorrected deficiencies.

HCFA proposed alternative sanctions for HHAs in August 1991 but never finalized its implementing regulations. HCFA officials told us that they wanted experience with the SNF intermediate sanctions, which became effective in July 1995, before implementing intermediate sanctions against HHAs.

Conclusions

HHAs provide important needed services to an increasing number of beneficiaries where they most desire to receive their care—in their homes. However, HCFA grants certification to HHAs without adequate assurance that they provide quality care or meet Medicare's conditions of participation. There are few barriers to certification once an HHA has been licensed by the state; and not all states license their HHAs. As a result, few HHAs are denied entry to the program. While most HHAs seek entry to Medicare with the intent of providing quality care, some are drawn to Medicare because of the relative ease with which they can become certified and partake in this lucrative, fast-growing industry.

There has been little use of targeting to focus surveys on potential problem HHAs or those more likely to have difficulty meeting Medicare's conditions of participation. Targeting would lend itself to identifying branch offices for survey, particularly when those branches are serving more patients than the parent office. By considering such factors as growth, high costs per patient, and high numbers of visits per patient, specific HHAs could be targeted for more frequent or more comprehensive surveys. HCFA contractors develop information during their claims processing efforts that could be used to flag potential quality-of-care problems at HHAs, but this information is not routinely shared with state survey agencies.

Once certified, there is little likelihood that an HHA will be terminated from the program for not meeting Medicare's conditions of participation. Furthermore, because surveys do not always consider an HHA's survey history, HHAs can have the same problems over and over again and still remain in the program, provided they take temporary corrective action. HCFA has not implemented intermediate sanctions and thus has no way to

penalize deficient HHAs other than threatening termination, a threat that can be defused through corrective action plans.

Recommendations

We recommend that the Administrator of HCFA take the following actions:

- Establish minimal requirements for how long an HHA must be operational and how many patients it must have treated before it is eligible to be surveyed and certified. HCFA could grant exceptions to such a national policy for those situations in which HHAs treat few patients and access to home care is an issue.
- Require that HHAs be certified to provide only those services for which they have been surveyed; the addition of a new service should prompt a recertification survey.
- Establish targeting criteria to select HHAs for survey against all conditions of participation. These criteria should ensure that all HHAs are periodically assessed against all conditions of participation.
- Require that branch offices be periodically surveyed to ensure that they meet Medicare's definition of a branch office and provide quality care in accordance with the conditions of participation. HCFA should develop criteria, such as the number of patients served by a branch office relative to the number served by the parent office, that would help surveyors select which branch offices should be surveyed as part of an HHA's recertification.
- Monitor state surveyors to ensure that they conduct home visits with patients treated by HHA branch offices. Additionally, HCFA should develop criteria defining how surveyors are to select branch office patients to visit.
- Revise the survey frequency criteria to include consideration of other factors that may indicate problem HHAs, such as rapid growth and high utilization patterns. As part of this effort, HCFA should establish procedures for contractors to routinely provide state survey agencies with information that would help them assess compliance with the conditions of participation.
- Issue implementing regulations regarding the intermediate sanctions authorized by the Congress that allow for penalizing and terminating HHAs that are repeatedly out of compliance with Medicare's conditions of participation.

Agency Comments and Our Evaluation

We provided the Administrator of HCFA a draft of this report for comment. With one exception, HCFA concurred with our recommendations but also noted that implementing some of the recommendations could require

additional funding for certification surveys. We recognize that requiring more surveys is a resource issue, but options do exist to provide additional funding for such activities. Both the HHS OIG and HCFA have supported charging fees for certification surveys. We also recently suggested that the Congress may wish to consider enacting legislation directing HCFA to carry out a pilot demonstration to address the issue of abusive billing practices by HHAs.[11] Under such a demonstration, once improper billing that identified an HHA as an abusive biller had been detected, follow-up audit work would be conducted, the cost of which could be assessed against the HHA. Under a similar approach, HCFA could charge HHAs for all surveys, except for those HHAs on the 36-month survey frequency cycle. Being placed on such a survey cycle would mean that the HHA had been in compliance with the Medicare conditions of participation for at least the past 3 years.

HCFA did not agree with our recommendation that the addition of a new service by an HHA should prompt a recertification survey. HCFA believes that if an HHA is in compliance with the conditions of participation, it is responsible for ensuring that all services provided to the patients are monitored and appropriately supervised. HCFA stated that our recommendation would place an unnecessary burden on the survey process and budget and could result in patients' having to wait for needed services.

We disagree, for several reasons. First, when state surveyors conduct standard surveys of HHAs, they select a case-mix stratified sample of records to review and patients to visit. Using this sample, the surveyors assess compliance with conditions of participation for the services the agency actually provides—not services the HHA may provide in the future. Second, Medicare law already provides that a change in HHA ownership, management, or administration is sufficient reason to conduct a new survey to determine whether such changes have resulted in any decline in the quality of care furnished by the HHA, thereby potentially affecting the HHA's compliance with Medicare's conditions of participation. Similarly, adding a new type of service should raise questions about whether the HHA has the structure, resources, and qualified staff needed to deliver that service. Finally, although the large number of HHAs already certified makes it unlikely that a patient would have to wait for needed services, HCFA could allow agencies in areas in which the needed services are not

[11]See Medicare: Need to Hold Home Health Agencies More Accountable for Inappropriate Billings (GAO/HEHS-97-108, June 13, 1997).

otherwise available to provide new services until a recertification survey could be arranged.

HCFA concurred with our recommendation that regulations on interim sanctions be issued and stated that a final regulation was being developed. HCFA has had the authority to establish interim sanctions for nearly 10 years, and it still has not indicated when it expects to finalize this regulation.

HCFA also made several technical comments, which we have addressed. HCFA's comments are included in their entirety as appendix III.

As arranged with your office, unless you release its contents earlier, we plan no further distribution of this letter for 30 days. At that time, we will make copies available to other congressional committees and Members of Congress with an interest in these matters, and the Secretary of Health and Human Services.

This report was prepared by Robert Dee and Donald Hunter, under the direction of William Reis, Assistant Director. Please call me at (202) 512-7114 or Mr. Reis at (617) 565-7488 if you or your staffs have any questions about this information.

William J. Scanlon
Director, Health Financing and
Systems Issues

Contents

Abbreviations

CHAP	Community Health Accreditation Program
HCFA	Health Care Financing Administration
HHA	home health agency
HHS	Department of Health and Human Services
JCAHO	Joint Commission on the Accreditation of Healthcare Organizations
LPN	licensed practical nurse
OIG	Office of the Inspector General
ORT	Operation Restore Trust
OSCAR	On-line Survey, Certification and Reporting database
OT	occupational therapy
PT	physical therapy
RN	registered nurse
SNF	skilled nursing facility

Scope and Methodology

In developing information for this report, we interviewed officials at the Health Care Financing Administration's (HCFA) central office in Baltimore as well as at its regional offices in Boston, Chicago, Dallas, and San Francisco; the Department of Health and Human Services' (HHS) Office of the Inspector General (OIG); five contractors that process and pay home health claims for HCFA: Blue Cross of California, the Associated Hospital Service of Maine, the Health Care Service Corporation, Palmetto Government Benefits Administrators, and IASD Health Services Corporation; state survey agencies in California, Illinois, Maine, Massachusetts, and Texas; and the National Association for Home Care, the California Association of Health Services at Home, and the Home and Hospice Association of California, which are home health agency (HHA) trade associations. We concentrated our work in California, Illinois, and Texas—three states that have been actively involved in conducting Operation Restore Trust (ORT) studies directly related to the HHA survey and certification process. Additionally, these states are among the 10 states with the highest numbers of certified HHAs. We also performed limited work in Maine and Massachusetts—two states that use the traditional survey and certification process and were not part of the original ORT effort.

To determine how HCFA controls the entry of HHAs into Medicare, we met with HCFA central office and regional officials to determine HCFA's roles and responsibilities, reviewed legislation and pertinent regulations, reviewed and analyzed Medicare's conditions of participation, interviewed state survey agency officials, determined the roles and responsibilities of HCFA's contractors, interviewed HHS OIG officials, interviewed trade association representatives, reviewed related reports and the literature, and kept abreast of pending changes to the conditions of participation and provider enrollment processes.

To determine how HCFA ensures that certified HHAs continue to comply with Medicare's conditions of participation and provide quality care, we reviewed HCFA's On-line Survey, Certification and Reporting (OSCAR) database to determine the extent to which HHAs (1) do not meet Medicare's conditions of participation during surveys, (2) have repeated violations of Medicare's conditions and associated standards over time, and (3) create branch offices.[12] Through meetings with HCFA and state survey agency officials and a review of survey reports, we determined the type of problems that the survey and certification process identifies. Further, we

[12]OSCAR contains such information about certified HHAs as names, addresses, provider numbers, survey results, and terminations.

reviewed survey reports and other documents prepared for the ORT studies in California, Illinois, and Texas and determined HCFA's process for targeting HHAs during these studies. We met with HCFA contractor officials to discuss their involvement in the ORT studies and the processes they have in place to identify HHAs suspected of fraud and abuse.

To examine HCFA's process for decertifying HHAs, we analyzed HCFA information related to the number of HHA terminations and the reasons for them. We also met with a representative of the HHS Office of the General Counsel to determine Medicare's termination process and reviewed Medicare's termination regulations. We also discussed issues related to this objective with trade association representatives and obtained related reports.

Conditions of Participation, Standards, and Underlying Requirements for HHAs

Conditions of participation	Standards	Underlying requirements
Patient rights	Notice of rights	HHA provides patient written notice of rights.
		HHA maintains documentation of compliance with patient rights.
	Exercise of rights and respect for property and person	Patient has right to exercise rights as a patient of HHA.
		Patient has right to have property treated with respect.
		Patient has right to voice grievances regarding treatment or care without reprisal.
		HHA must investigate complaints regarding treatment or care.
	Right to be informed and to participate in planning care and treatment	Patient has right to be informed in advance about care and changes in care.
		Patient has right to participate in planning care.
		HHA maintains policies and procedures regarding advance directives.
	Confidentiality of medical records	Patient has right to confidentiality of clinical records.
		HHA must advise patient of record disclosure policies and procedures.
	Patient liability for payment	Patient has right to be advised of cost of care before care is initiated.
		HHA must inform patient orally and in writing of who will pay for services.
		Patient has right to be informed of changes in the cost of care or in who pays for the care no later than 30 days after the change.
	Home health hot line	Patient has right to be advised of availability of toll-free HHA hot line.
Compliance with federal, state, and local laws; disclosure and ownership information; and accepted professional standards and principles	Compliance with federal, state, and local laws and regulations	HHA and staff must comply with federal, state, and local laws and regulations.
	Disclosure of ownership and management information	HHA must comply with disclosure of ownership and management information requirements.
		HHA must disclose ownership and management information for each survey and whenever changes are made.

(continued)

Conditions of participation	Standards	Underlying requirements
	Compliance with accepted professional standards and principles	HHA and staff must comply with accepted professional standards and principles.
Organization, services, and administration	[a]	Delegation of responsibility is clearly set forth in writing.
		Administrative and supervisory functions are not delegated to another HHA.
		All services not provided directly are monitored and controlled by the parent HHA.
		Administrative records for each subunit are maintained by the parent HHA.
	Services furnished	HHA must provide skilled nursing services and at least one other therapeutic service, one of which the HHA must provide with its own staff.
	Governing body	Governing body assumes full legal authority and responsibility for the HHA.
		Governing body appoints qualified administrator.
		Governing body arranges for professional advice.
		Governing body adopts and periodically reviews written by-laws.
		Governing body oversees management and fiscal affairs of HHA.
	Administrator	Administrator organizes and directs HHA functions.
		Administrator employs qualified personnel and ensures adequate staff education and evaluation.
		Administrator ensures accuracy of public information materials and activities.
		Administrator implements an effective budgeting and accounting system.
		Qualified person is authorized in writing to act in absence of administrator.
	Supervising physician or registered nurse (RN)	Services furnished are under the supervision of a physician or RN.
		Supervisor or alternate is available during operating hours.
		Supervisor participates in activities relevant to furnished services.

(continued)

Conditions of participation	Standards	Underlying requirements
	Personnel policies	HHA has written personnel policies, and personnel records include staff's current licenses and qualifications.
	Personnel under hourly or per-visit contracts	Hourly and per-visit personnel have written contracts.
	Coordination of patient services	Personnel providing services coordinate effectively.
		Coordination of patient services is documented in the clinical records or minutes of case conferences.
		Written summary report for each patient is sent to attending physician every 62 days.
	Services under arrangements	Services for which the HHA contracts are subject to a written contract.
	Instructional planning	Annual operating budget and capital expenditure plan are prepared.
		Plan and budget are prepared under direction of governing body.
		Plan and budget are reviewed and updated at least annually.
	Laboratory services	If HHA provides laboratory testing or refers specimens elsewhere, it must comply with the requirements of the Clinical Laboratory Improvement Amendments of 1988.
Group of professional personnel	[a]	Group includes physician, RN, and professionals from other appropriate disciplines.
		Group establishes and annually reviews HHA policies.
	Advisory and evaluation function	Group meets frequently to advise agency on professional issues.
		Meetings are documented by dated minutes.
Acceptance of patients, plan of care, and medical supervision	[a]	Patients are accepted on basis of reasonable expectation that needs can be met at home.
		Written plan of care is established and periodically reviewed by physician.

(continued)

Conditions of participation	Standards	Underlying requirements
	Plan of care	Plan of care covers all diagnoses, required services, visits, and so on. Physician is consulted to approve modifications to plan. Orders for therapy services specify procedures and modalities to be used and their amount, frequency, and duration. Therapist and other personnel participate in developing plan.
	Periodic review of plan of care	Plan is reviewed by attending physician and HHA personnel as necessary, but at least every 62 days. HHA staff promptly alert physician to changes that suggest need to alter plan.
	Conformance with physician's orders	Drugs and treatment are administered only as ordered by physician. RN or therapist records and signs oral orders and obtains physician countersignature. Staff check all medicines to identify ineffective drug therapy, adverse reactions, drug allergies, and so on and report problems to physician.
Skilled nursing services	[a]	Skilled nursing services are furnished by or under supervision of an RN. Skilled nursing services are furnished in accordance with plan of care.

(continued)

Conditions of participation	Standards	Underlying requirements
	Duties of the RN	RN makes initial evaluation visit.
		RN regularly reevaluates patient nursing needs.
		RN initiates plan of care and necessary revisions.
		RN furnishes services requiring substantial or specialized nursing care.
		RN initiates appropriate preventive or rehabilitative procedures.
		RN prepares notes, coordinates with physician and other staff, and informs physician and other staff of changes.
		RN counsels patient and family in meeting nursing and related needs.
		RN participates in in-service program and supervises and teaches staff.
	Duties of the licensed practical nurse (LPN)	LPN furnishes services in accordance with HHA policy.
		LPN prepares clinical and progress notes.
		LPN assists physician and RN in performing specialized procedures.
		LPN prepares equipment and materials observing aseptic techniques.
		LPN assists patient in learning self-care techniques.
Therapy services	[a]	Therapy services are given by a qualified therapist, or qualified therapist assistant under supervision of qualified therapist, in accordance with the plan of care.
		Therapist helps physician evaluate functional level and helps develop plan of care.
		Therapist prepares clinical and progress notes.
		Therapist advises and consults with family and other HHA personnel.
		Therapist participates in in-service programs.

(continued)

Conditions of participation	Standards	Underlying requirements
	Supervision of physical therapy (PT) assistant and occupational therapy (OT) assistant	Services provided by a PT or OT assistant must be supervised by a qualified PT or OT. PT and OT assistants help prepare clinical notes and progress reports. PT and OT assistants participate in educating patient and family and in in-service programs.
	Supervision of speech therapy services	Speech therapy is furnished only by, or under the supervision of, a speech pathologist or audiologist.
Medical social services	[a]	Services are provided by a qualified social worker or social worker assistant. Social worker participates in developing the plan of care. Social worker prepares clinical and progress notes. Social worker works with family. Social worker uses appropriate community resources. Social worker participates in discharge planning and in-service programs. Social worker consults with other HHA personnel.
Home health aide services	[a]	Home health aides are selected according to personnel qualifications specified in regulations.

(continued)

Conditions of participation	Standards	Underlying requirements
	Home health aide training	Aides must have at least 75 hours of training in specific subject areas; 16 hours must be supervised practical training. Aides must have at least 16 hours of classroom training before beginning practical training. Aides must have good communication skills; ability to observe, report, and document care; and ability to recognize emergency situations and needs of patients. Any organization may conduct training except an HHA that, within the past 2 years, has not complied with Medicare requirements, has been penalized by Medicare, or has had Medicare payments suspended. The practical portion of training must be supervised by, or carried out under the supervision of, an RN with at least 2 years' experience, 1 of which is in home health. Other individuals may provide instruction under the supervision of a qualified RN. Aide training must be documented.
	Competency evaluation and in-service training	Aides may furnish services only after successfully completing a competency evaluation program. HHA is responsible for ensuring its aides meet the competency evaluation requirements. Competency evaluations must meet specific requirements specified in the regulations. HHA must complete a competency evaluation of each aide at least every 12 months. Aides must receive at least 12 hours of in-service training each year. Competency evaluations may be provided by any organization except an HHA that, within the past 2 years, has not complied with Medicare requirements, has been penalized by Medicare, or has had Medicare payments suspended. Competency evaluation must be performed by an RN, and in-services must be supervised by an RN.

(continued)

Conditions of participation	Standards	Underlying requirements
		Performance in specified subject areas must be evaluated by observation; for others, evaluation may be by observation or oral or written examination. Aides may not continue to perform tasks evaluated as unsatisfactorily carried out. An aide has not passed the competency evaluation if performance in more than one required area is considered unsatisfactory. Competency evaluation must be documented. HHA may use only aides who meet competency requirements.
	Assignment and duties of the home health aide	Aides are assigned to a specific patient by an RN. Written instructions for patient care are prepared by an RN or a therapist. Duties of an aide include performing simple procedures as an extension of therapy, providing personal care, assisting in exercise, carrying out household services, and assisting with self-administered medications. Aides report changes in patient care and needs. Aides complete appropriate records.
	Supervision	Aides must be supervised. When only aide services are being provided, an RN must make a supervisory visit to patient's home at least once every 60 days. Supervisory visit must occur when aide is furnishing care. When skilled nursing or therapy services are also being provided, an RN must make a supervisory visit to patient's home at least every 2 weeks whether the aide is present or not. When therapy services are being provided—without aide or skilled nursing services—a skilled therapist may make the supervisory visits.
	Personal care attendant—evaluation requirements	Individuals hired only to provide personal care services under Medicaid must be found competent by the state.

(continued)

Conditions of participation	Standards	Underlying requirements
Qualifying to furnish outpatient physical therapy or speech pathology services	[a]	HHA providing outpatient therapy services on its own premises must meet all pertinent conditions for an HHA as well as additional specified health and safety requirements.
Clinical records	[a]	Clinical records containing past and current findings must be maintained for each patient in accordance with accepted professional standards.
	Retention of records	Clinical records must be retained for at least 5 years after the applicable cost report is filed with the contractor. A copy of the clinical record or abstract is sent with patient when transferred to another health facility.
	Protection of records	Clinical records are safeguarded against loss or unauthorized use. Written procedures govern the use and removal of records and conditions for release of information. Patient's written consent is required for release of information not authorized by law.
Evaluation of the HHA's program	[a]	Written policies require an annual evaluation of the HHA's total program. Evaluation consists of an overall policy and administrative review and a clinical record review. Evaluation assesses the appropriateness, adequacy, effectiveness, and efficiency of the HHA's program. Results of the evaluation are reported to and acted upon by those responsible for operating the HHA. Results of the evaluation are maintained separately as administrative records.
	Policy and administrative review	Evaluation includes a review of policies and administrative practices of the HHA. Mechanisms are established in writing to collect data for the evaluation.

(continued)

Conditions of participation	Standards	Underlying requirements
	Clinical record review	Appropriate health professionals must review a sample of active and closed clinical records quarterly to ensure policies are being followed. Active clinical records must be reviewed every 62 days to assess adequacy of plan of care and appropriateness of continuing care.

[a]No standard was specified for these requirements.

Source: HCFA.

Comments From the Health Care Financing Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

NOV 26 1997

TO: William J. Scanlon
Director, Health Financing and Systems Issues
General Accounting Office

FROM: Nancy-Ann Min DeParle NMD
Administrator
Health Care Financing Administration

SUBJECT: GAO Draft Report, "Medicare Home Health Agencies (HHAs): Certification Process Ineffective in Excluding Problem Agencies"

We appreciate the opportunity to review your draft report to Congress concerning the use of home health care services and the certification and recertification of HHAs. Our comments are attached. Should you have any questions or require additional information, kindly contact Rita Reinsel of the Office of Financial Management at (410) 786-7444.

Attachment

Comments of the Health Care Financing Administration (HCFA)
on the General Accounting Office (GAO) Draft Report
"Medicare Home Health Agencies (HHAs): Certification Process Ineffective
in Excluding Problem Agencies"

Overview

To date, HCFA has relied primarily on HHA health and safety inspections by the state agencies (SAs), complaint surveys, routine audits by the servicing fiscal intermediaries, and special projects connected with Operation Restore Trust (ORT) and "wedge" projects to exclude poor quality providers and providers with questionable billing practices from the Medicare program. However, a prior GAO report on "Inappropriate HHA Billings" and recent Congressional hearings on the subject examined HCFA's current home health oversight activities and pointed out many of the weaknesses in the coverage and payment areas, e.g., failure to substantiate medical necessity for claims, billings for non-covered services or supplies, inadequate documentation, etc. Clearly, current oversight in the area of HHA coverage and payment is inadequate and not coordinated. HCFA needs a more global approach to address HHAs that operate in a questionable manner.

GAO Recommendation

We recommend that the Administrator of HCFA:

-- establish minimal requirements for how long an HHA must be operational and how many patients it must have treated before it is eligible to be surveyed and certified. HCFA could grant exceptions to such a national policy for those situations where HHAs treat few patients and access to home care is an issue.

HCFA Comment

We concur. In July 1997, HCFA permitted its regional offices (ROs) to designate a minimum number of patients required for an initial HHA survey. Based on HCFA's field experience with ORT and other fraud and abuse initiatives, HCFA is planning to impose a national policy for the 10-patient minimum as a prerequisite to receiving an initial HHA survey. We will evaluate the necessity to develop exceptions criteria for the 10-patient minimum on a case-by-case basis.

GAO Recommendation

-- require that HHAs be certified to provide only those services for which they have been surveyed; the addition of a new service should prompt a recertification survey.

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HCFA Comment

We disagree with this recommendation. If the HHA is in compliance with the conditions of participation (CoPs), it has the responsibility to ensure that all services provided to the patients are monitored and appropriately supervised (see 42 CFR 484.14). We believe this requirement would impose an unnecessary burden on the state survey agency and the survey and certification budget. In addition, it could result in patients having to wait for needed services if there were a delay in the survey.

GAO Recommendation

-- establish targeting criteria to select HHAs for survey against all CoPs. These criteria should ensure that all HHAs are periodically assessed against all CoPs.

HCFA Comment

HHAs that are found to have substandard care (i.e., a condition level deficiency) are already subjected to an extended survey and are surveyed against all CoPs. We will explore the feasibility of this approach for those HHAs that have a history of good performance. However, this policy change would require additional funding for the survey and certification program.

GAO Recommendation

-- require that branch offices are periodically surveyed to ensure that they meet Medicare's definition of a branch and provide quality care in accordance with the CoPs. HCFA should develop criteria, such as the number of patients serviced relative to the parent office, which would help surveyors select which branch offices should be surveyed as part of an HHA's recertification.

HCFA Comment

We concur with this recommendation. HCFA makes the final determination on whether an off-site location of the parent HHA is a branch or sub-unit. In some instances, these determinations require a separate on-site survey. We concur with the recommendation that periodic on-site surveys of branches are needed and, in fact, it is our policy that branch locations are included in, or replace, the unannounced standard survey of a parent HHA. We also agree that it would be helpful to surveyors if HCFA developed criteria, such as number of patients served relative to the parent office, to assist them in determining which branch offices should be surveyed as part of an HHA's recertification.

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GAO Recommendation

-- monitor and ensure that state surveyors conduct home visits with patients treated by HHA branch offices. Additionally, HCFA should develop criteria defining how surveyors should select branch office patients to visit.

HCFA Comment

We concur with this recommendation. Our current policy directs surveyors to include home visits and record reviews of patients served by HHA branches as part of a survey. However, this is frequently not done since many branches are too far from the parent HHA. We are addressing this problem separately. (See August 1997 Program Memorandum: Policy Clarification: HHA Parent, Branch, and Sub-unit Criteria, attached.) However, any organized and systematic process that would expand the frequency and time on-site for branch surveys would require additional funding for the survey and certification program above current levels.

GAO Recommendation

-- revise the survey frequency criteria to include consideration of other factors which may be indicative of problem HHAs, such as rapid growth and high utilization patterns. As part of this effort HCFA should establish procedures for intermediaries to routinely provide state survey agencies with information that would help the survey agencies assess compliance with the CoPs.

HCFA Comment

We concur. In July 1997, we provided the ROs with a fraud and abuse "Tool Kit" (see 7/31/97 memorandum attached). We recommended that RO staff make maximum utilization of information provided in the HCFA-855 provider enrollment form and the HCFA Customer Information System (HCIS) fraud and abuse data base which could identify those HHAs experiencing rapid growth and high utilization. However, as stated earlier in our response, any increase in the frequency of on-site health and safety inspections must be linked with appropriate increases in funding for these activities.

GAO Recommendation

-- issue implementing regulations regarding the intermediate sanctions authorized by Congress that allow for penalizing and terminating HHAs which are repeatedly out of compliance with Medicare's CoPs.

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HCFA Comment

We concur with this recommendation. There is a final regulation (HSQ-169-F) under development in HCFA that would impose intermediate sanctions on HHAs.

Technical Comments

Now on p. 4.

1. On page 7 of the report, the characterization of the home health qualifying criteria is not accurate and should be revised. In order to qualify for home health services, a beneficiary must be confined to his or her home, have a plan of care signed by a physician, and need intermittent skilled nursing care, or physical or speech therapy. (See sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Social Security Act.) Therefore, "part-time or" should be deleted from the last sentence of the first paragraph.

Now on p. 7.

2. On page 11 of the report, the discussion in the second paragraph regarding those services which must be furnished by HHAs is not accurate and should be revised. The regulation at 42 CFR 484.14(a) provides that an HHA must provide at least one of the qualifying services directly through agency employees. Accordingly, the fourth sentence should be revised to comport with this regulatory provision.

Related GAO Products

Medicare Home Health Agencies: Certification Process Is Ineffective in Excluding Problem Agencies (GAO/T-HEHS-97-180, July 28, 1997).

Medicare: Home Health Utilization Expands While Program Controls Deteriorate (GAO/HEHS-96-16, Mar. 27, 1996).

Medicare: Allegations Against ABC Home Health Care (GAO/OSI-95-17, July 19, 1995).

Home Health Care: HCFA Properly Evaluated JCAHO's Ability to Survey Home Health Agencies (GAO/HRD-93-33, Oct. 26, 1992).

Home Health Care: HCFA Evaluation of Community Health Accreditation Program Inadequate (GAO/HRD-92-93, Apr. 20, 1992).

Medicare: Increased Denials of Home Health Claims During 1986 and 1987 (GAO/HRD-90-14BR, Jan. 24, 1990).

Medicare: Assuring the Quality of Home Health Services (GAO/HRD-90-7, Oct. 10, 1989).

Medicare: Need to Strengthen Home Health Care Payment Controls and Address Unmet Needs (GAO/HRD-87-9, Dec. 2, 1986).

Savings Possible by Modifying Medicare's Waiver of Liability Rules (GAO/HRD-83-38, Mar. 4, 1983).

The Elderly Should Benefit From Expanded Home Health Care But Increasing These Services Will Not Insure Cost Reductions (GAO/IPE-83-1, Dec. 7, 1982).

Medicare Home Health Services: A Difficult Program to Control (GAO/HRD-81-155, Sept. 25, 1981).

Response to the Senate Permanent Subcommittee on Investigations' Queries on Abuses in the Home Health Care Industry (GAO/HRD-81-84, Apr. 24, 1981).

Home Health Care Services—Tighter Fiscal Controls Needed (GAO/HRD-79-17, May 15, 1979).

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