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Health, Education, and
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The Honorable Pete Stark
Ranking Minority Member
Subcommittee on Health
Committee on Ways and Means
House of Representatives

The Honorable John Lewis
House of Representatives

Medicare: HCFA's Approval and Oversight of Private Accreditation Organizations

To protect the health and safety of Medicare beneficiaries, the Health Care Financing Administration (HCFA) has established requirements that health care providers must meet to participate in the program. To demonstrate compliance with Medicare requirements, some providers can choose to be accredited by a recognized private organization—such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)—in lieu of periodic inspections and ongoing monitoring by the federal government. Concerned about HCFA's reliance on private accreditation organizations, you asked us to describe (1) HCFA's criteria for approving accreditation organizations; (2) HCFA's ongoing oversight of accreditation organizations that have been granted deemed status¹; and (3) recent evaluations of accreditation organizations' performance. You asked us to pay particular attention to HCFA's review of organizations' standards, enforcement processes, and conflict-of-interest requirements.

To identify HCFA's criteria for granting deemed status and its process for providing ongoing oversight, we reviewed relevant laws, regulations, and HCFA documents. We also interviewed HCFA officials in the Center for Medicaid and State Operations and the Center for Health Plans and Providers, as well as representatives of accreditation organizations. In addition, we reviewed recent Department of Health and Human Services (HHS) studies that evaluated the use of private accreditation: a 1999 set of reports by the Office of Inspector General (OIG) and a 1998 HCFA report to the Congress. Our review included the use of private accreditation for both fee-

¹Deemed status allows the use of privately conferred accreditation as proof of compliance with federal regulations.

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for-service providers (including hospitals, home health agencies, clinical laboratories, ambulatory surgery centers, and hospices) and managed care plans. We performed our work in August and September 1999 in accordance with generally accepted government auditing standards.

In summary, HCFA is required to consider several factors when evaluating a private accreditation organization for deemed status. First, HCFA must assess an organization's standards to ensure that the providers they accredit will meet or exceed Medicare requirements. The agency is also required to evaluate an accreditation organization's ability to monitor and enforce provider compliance with its requirements. HCFA has not developed specific criteria to prohibit conflict of interest between organizations and the providers they evaluate, even though accreditation organizations are typically governed by a board of directors that includes industry representatives. Instead, HCFA requires each organization to document its policies and procedures regarding employee professional or financial affiliation with the facilities being accredited. To monitor the performance of accreditation organizations and ensure continued equivalence to Medicare standards, HCFA requires organizations to provide accreditation survey findings and to submit any proposed changes to its accreditation requirements. A recent evaluation of accreditation organization performance by the HHS OIG found that JCAHO's collegial approach to hospital accreditation relies heavily on education and performance improvement, with less emphasis on regulatory approaches, which include unannounced surveys, responding to complaints, and collecting standard performance measures. Also, HCFA examined the potential for deeming of nursing homes and, in a report, recommended against relying on JCAHO for such deeming. Specifically, the report questioned whether JCAHO surveyors would identify serious care deficiencies in nursing homes and expressed concerns that JCAHO's current requirements for nursing home accreditation were not sufficient to ensure that Medicare conditions and requirements would be met.

BACKGROUND

Medicare participating providers, such as hospitals, skilled nursing facilities, hospices, and home health agencies, must demonstrate compliance with HCFA's conditions of participation. This requirement is commonly met through inspection by a state agency that has contracted with HCFA to perform survey and review functions for Medicare. In some cases, it can be met through private accreditation by an organization approved for deeming purposes.² Other than hospitals, only a small proportion of providers demonstrate compliance with Medicare requirements through accreditation. (See table 1.)

²A provider entity eligible for deeming is defined in statute as "a provider of services, supplier, facility, clinic, agency, or laboratory." Durable medical equipment suppliers and end-stage renal disease facilities are specifically excluded from deeming.

Table 1: Number of Providers That Chose the Accreditation Option to Fulfill Medicare Requirements, as of September 1999

| Provider type | Active Medicare providers | Providers accredited by a deeming organization | Percent |
|-----------------------------|---------------------------|--|---------|
| Hospitals | 6,141 | 4,714 | 76.8 |
| Home health agencies | 8,260 | 243 | 2.9 |
| Clinical laboratories | 168,729 | 17,636 | 10.5 |
| Ambulatory surgical centers | 2,844 | 182 | 6.4 |
| Hospices | 2,284 | 0 | 0 |

Source: HCFA's Online Survey, Certification, and Reporting System (OSCAR) database and accreditation organization reports to HCFA, as of September 10, 1999.

The use of private accreditation for ensuring provider compliance with Medicare requirements began with the enactment of the Medicare program in 1965. The Congress granted deemed status for hospitals accredited by JCAHO.³ The Social Security Act was later amended to allow the Secretary of HHS to grant deeming authority to organizations other than JCAHO and for other categories of providers besides hospitals. As shown in table 2, HCFA has approved nine accreditation organizations for deeming purposes, covering five provider categories. These include hospitals, home health agencies, clinical laboratories, ambulatory surgical centers, and hospices.⁴

³Known at that time as the Joint Commission on Accreditation of Hospitals.

⁴Other providers or suppliers that could meet Medicare requirements through private accreditation in lieu of survey and certification by a state agency include skilled nursing facilities, rural health clinics, comprehensive outpatient rehabilitation facilities, screening mammography services, critical access hospitals, and agency providers of outpatient therapy services. However, no accrediting organization for any of these provider categories has been approved by HCFA for deeming purposes.

Table 2: HCFA-Approved Medicare Deeming Organizations

| Provider type | Accrediting organization | Year approved |
|-----------------------------|---|----------------------|
| Hospitals | JCAHO | 1965 |
| | American Osteopathic Association | 1966 |
| Home health agencies | Community Health Accreditation Program | 1992 |
| | JCAHO | 1993 |
| Clinical laboratories | JCAHO | 1995 |
| | College of American Pathologists | 1995 |
| | American Association of Blood Banks | 1995 |
| | American Osteopathic Association | 1995 |
| | Commission on Office Laboratory Accreditation | 1993 |
| | American Society of Histocompatibility and Immunogenetics | 1994 |
| Ambulatory surgical centers | JCAHO | 1996 |
| | Accreditation Association for Ambulatory Health Care | 1996 |
| | American Association for the Accreditation of Ambulatory Surgery Facilities | 1998 |
| Hospices | Community Health Accreditation Program | 1999 |
| | JCAHO | 1999 |

The Balanced Budget Act of 1997 (BBA) gave HCFA authority to approve private accreditation organizations for deeming Medicare+Choice plans in compliance with specified Medicare requirements. The act authorized HCFA to accept private accreditation in place of direct oversight for some, but not all, of the Medicare requirements—those for (1) quality assessment and performance improvement and (2) confidentiality and accuracy of enrollee records. HCFA expects to review and select private accrediting organizations once it finalizes regulations for the Medicare+Choice program.

HCFA EVALUATION OF APPLICATIONS FOR DEEMING AUTHORITY

The procedures that an accreditation organization must follow when applying to be approved for deeming purposes and the process that HCFA will follow in granting approval are outlined in federal Medicare regulations. The organization must be national⁵ in scope and must provide information about its accreditation standards, the process used to apply and enforce those standards and its capacity for survey and monitoring activities. HCFA requires the organization to demonstrate that (1) its standards meet or exceed Medicare requirements, (2) it applies and enforces its standards, and (3) its surveyors are free from conflicts of interest.⁶ (Enclosure I provides further detail on regulatory requirements for approval of accreditation organizations.)

Accreditation Standards Must Meet or Exceed Medicare Requirements

The Social Security Act requires HCFA to specifically find that accreditation “demonstrates that all of the applicable [Medicare] conditions or requirements are met or exceeded” by the provider entity before the accrediting organization is approved for deeming purposes.⁷ Although the accreditation standards do not have to adopt the exact language of the Medicare requirements, HCFA requires the organization to provide a detailed comparison of its accreditation standards to the applicable Medicare requirements, generally in a side-by-side—or crosswalk—format. Regulations require HCFA to review the comparison for equivalence to ensure that each Medicare requirement for the provider category is covered.⁸ Applicants approved for deeming for Medicare+Choice plans will also be required to demonstrate that their standards are no less stringent than Medicare requirements.

Accreditation Organizations Must Apply and Enforce Their Standards

To determine whether organizations apply and enforce their standards, HCFA is required to evaluate the adequacy of each organization’s (1) survey process, (2) resources for conducting surveys and supplying information for enforcement, and (3)

⁵HCFA defines national on the basis of eight dimensions, including the number of facilities accredited, the number of states where these facilities operate, the geographic/regional distribution of those states, and the distribution of administrative/support offices.

⁶Except for JCAHO’s certification program for hospitals, accreditation organizations are also required to reapply for continuing HCFA approval at least every 6 years.

⁷Prior to 1996, HCFA’s general standard for approval of deeming authority was if the accreditation program provided “reasonable assurance” that the Medicare requirements and conditions were met. In 1996, the Congress imposed a stronger standard for approval of deeming organizations; an organization must now demonstrate that Medicare conditions or requirements are “met or exceeded” by accredited providers.

⁸This comparative review is performed primarily by HCFA’s Office of Clinical Standards and Quality. In the case of organizations that accredit clinical laboratories, the review function is shared between HCFA and the Centers for Disease Control and Prevention.

monitoring procedures for providers that are found to be out of compliance. Although the regulations do not specify minimum criteria for approval on the items evaluated, HCFA may use the procedures followed by state survey agencies as a benchmark for approval of private accreditation organizations. HCFA officials reported conducting on-site visits to verify the information submitted.

HCFA requires detailed information on many aspects of the survey and monitoring process, including

- the frequency of surveys;
- survey notification requirements;
- copies of survey forms, guidelines, and instructions;
- a description of the accreditation-status decisionmaking process; and
- a description of the evaluation systems used to monitor surveyor performance.

To verify that the organization has sufficient resources to conduct surveys and follow-up activities, HCFA requires information such as

- the size and composition of the survey teams,
- the education and experience requirements surveyors must meet,
- the content and frequency of training provided,
- the ability to provide HCFA with data needed for evaluating the organization's monitoring processes, and
- the number of staff and sufficiency of funding for performing required inspections.

To assess organizations' ability to enforce provider compliance with their standards, HCFA is required to review each organization's procedures and capacity for (1) reporting deficiencies to providers and responding to provider plans of correction in a timely manner, (2) monitoring providers found to be out of compliance with program requirements, and (3) withholding or removing the accreditation status of provider entities that fail to meet the standards. Organizations must also provide HCFA with information on their procedures for responding to complaints against accredited facilities and the coordination of their activities with appropriate licensing bodies and ombudsman programs.

Conflict-of-Interest Requirements Apply Only to Individual Surveyors

HCFA has not developed specific criteria to prohibit conflict of interest between accrediting organizations—typically governed by boards of directors that include industry representatives—and the entities they accredit. However, the agency does require applicant organizations to submit their policies and procedures regarding employee participation in the survey or the accreditation decision process of any facility with which the individual is professionally or financially affiliated. HCFA officials stated that when conducting site visits to accrediting organizations, they

assess how this policy is being implemented, and they examine background information on senior management and governing boards to look for possible professional or financial conflicts.

The proposed criteria for granting deeming authority for Medicare+Choice may contain more specific requirements addressing potential conflicts of interest. According to HCFA officials, the interim final rule for implementing Medicare+Choice specifies that an approved accrediting organization must not be controlled by the entities it accredits. HCFA indicates that it has, for other purposes, defined "control" to exist "if an individual or an organization has the power, directly or indirectly, to significantly influence or direct the actions or policies of an organization or institution." One accreditation organization we spoke to expressed concerns that HCFA's definition of control could be interpreted to prohibit health plan involvement with an accrediting organization's board of directors. In response to this and other concerns, HCFA is modifying its final rule for the Medicare+Choice program.

HCFA OVERSIGHT OF DEEMING ORGANIZATIONS' ACTIVITIES

HCFA has several tools available to monitor the performance of accreditation organizations and the continued equivalence of their standards. These include documentation and notification requirements, comparability reviews, complaint surveys, validation surveys, and on-site reviews. For most provider categories, the agency requires written documentation for each survey conducted by a deeming organization.⁹ These organizations are also required to notify HCFA before modifying their standards so HCFA can review the changes for continued comparability to Medicare requirements. HCFA also conducts its own validation surveys of some provider groups and, according to HCFA officials, conducts site visits to accreditation organization offices every few years to monitor their performance and verify representations made upon application.

HCFA's primary means of oversight is the review of survey documentation and other paperwork submitted by the accreditation organizations. Specifically, the agency requires accreditation organizations to submit a copy of every accreditation survey conducted, original deficiency letters, and resolution letters showing when and how any deficiencies were resolved or corrected.

HCFA may use comparability reviews when either an accrediting organization or HCFA makes changes to standards or other requirements. Accreditation organizations are required to notify HCFA 30 days in advance of making any modifications to their standards or survey processes. Similarly, within 30 days of receiving notice of a change in HCFA requirements for a provider category, the

⁹Because JCAHO is automatically approved in statute as a deeming organization for hospitals and is not required to periodically reapply for deeming authority, HCFA's ability to exercise oversight in this area is limited.

accrediting organization must submit a written acknowledgement to HCFA along with a revised crosswalk showing how it plans to revise its accrediting requirements.

HCFA also makes use of validation surveys as a means to verify whether accredited providers are in compliance with Medicare requirements.¹⁰ However, validation surveys are only conducted for hospitals and clinical laboratories; HCFA has not yet conducted validation surveys to assess organizations approved for other providers, citing the small numbers deemed in these other categories. If the results of validation surveys indicate significant differences between the findings of the accrediting organization and HCFA, or if they indicate numerous or systemwide problems in the accreditation process, HCFA has authority to place the accrediting organization on probation and initiate a formal review of its deeming status. However, HCFA officials noted that the findings of validation surveys have been well below the threshold that would trigger such a review.¹¹

Finally, HCFA may use on-site inspections of accreditation organizations as part of its ongoing oversight. HCFA may visit accreditation organization offices to monitor performance, assess compliance with stated policies and procedures, and verify representations made in written application materials. HCFA officials reported that staff typically visit each nonhospital accrediting organization every year or two. These are generally announced visits with a list of key questions provided in advance. During these visits, HCFA staff may review documentation from surveys, complaint logs, and personnel records. They also may audit meetings, observe surveys, and conduct interviews with organizational staff.

RECENT STUDIES ON DEEMING FOR MEDICARE

Recent studies by the HHS OIG and by HCFA raised concerns about the use of private accreditation organizations as a means of ensuring provider compliance with Medicare requirements. These studies focus on the role of JCAHO as the primary Medicare deeming organization for hospitals and as a potential deeming organization for nursing homes. In general, the reports raise concerns about whether JCAHO requirements and processes are sufficient to identify serious deficiencies in patient care and about the adequacy of HCFA oversight of JCAHO activities.

The OIG study—designed to assess JCAHO's role in reviewing hospital quality and to determine how HCFA holds JCAHO and state agencies accountable for their quality

¹⁰Validation surveys are reviews of accredited providers conducted by state survey agencies within a specified time frame following an accreditation survey, generally within 60 days. Although validation surveys may be conducted on a representative sample basis, they are also initiated in response to substantial allegations of noncompliance.

¹¹Although HCFA does not have authority to withdraw JCAHO's deeming authority for hospitals, HCFA is required to report annually to the Congress on its continuing validation of JCAHO's accreditation process for hospitals and on the performance of accrediting organizations for clinical laboratories.

reviews¹²—found that JCAHO accreditation heavily emphasizes education and performance improvement. JCAHO’s accreditation has a relatively minor emphasis on regulatory approaches such as unannounced surveys, responses to complaints or serious incidents, or the collection of standard performance measures. In addition, the OIG reported that HCFA does little to hold JCAHO accountable for its performance in hospital oversight. Based on these findings, the OIG recommended that HCFA more closely monitor oversight of hospitals to ensure an appropriate balance between collegial and regulatory approaches. The OIG also recommended that JCAHO and state agencies should be held more accountable for their performance in reviewing hospitals. The OIG’s findings are summarized in figure 1.

Figure 1: Summary of HHS’ OIG Findings on JCAHO Accreditation of Hospitals

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|---|
| <p>Findings on JCAHO</p> <ul style="list-style-type: none"> • JCAHO surveys are undertaken in a collegial manner and are tightly structured. This approach fosters consistency but leaves little room for probing. • JCAHO surveys serve as a means of reducing risk and fostering attention to continuous quality improvement but are unlikely to identify patterns or instances of substandard care. JCAHO conducts few unannounced surveys and devotes little time and emphasis to complaints. • JCAHO treats major adverse events as opportunities for improvement. Accordingly, it emphasizes education, prevention, and confidentiality, and limits public disclosure on such events. • JCAHO survey results fail to make meaningful distinctions among hospitals. Between May 1995 and June 1998, 99 percent of the hospitals surveyed clustered in two of the five possible accreditation levels. <p>Findings on HCFA</p> <ul style="list-style-type: none"> • HCFA obtains limited information on the performance of JCAHO. To assess JCAHO’s performance, HCFA relies on validation surveys conducted by state agencies. However, the value of these surveys is limited.^a • HCFA provides an annual report to Congress on the activities of JCAHO (based on the validation study findings), but it has typically been submitted years late. HCFA makes little information available to the public on the performance of either hospitals or JCAHO. |
|---|

^aUntil recently, the validation surveys have been based on a different set of standards and have been conducted subsequent to JCAHO surveys, when hospital conditions could have changed. During 1996 and 1997, HCFA piloted 20 observation surveys, where state and HCFA officials accompanied and observed JCAHO surveyors during hospital surveys.

Source: HHS OIG, The External Review of Hospital Quality.

¹²The OIG issued the results of its study as a set of four reports: The External Review of Hospital Quality: The Role of Accreditation, The External Review of Hospital Quality: The Role of Medicare Certification, The External Review of Hospital Quality: Holding the Reviewers Accountable, and a summary report The External Review of Hospital Quality: A Call for Greater Accountability, OEI-01-97-00053 (Washington, D.C.: HHS, July 1999).

As required by the 1996 HHS Appropriations Act, HCFA reported to Congress on private accreditation and deemed status for nursing homes.¹³ One of the study's objectives was to assess whether nursing homes should be offered a choice between the traditional state survey process and private accreditation to demonstrate their compliance with Medicare's nursing home requirements for participation. The report recommended against approving JCAHO for deeming of nursing homes, citing concerns that JCAHO requirements were not sufficient to ensure nursing home compliance with Medicare conditions of participation. (See enclosure 2 for more information on HCFA's basis for recommending against approval of JCAHO for deeming of nursing homes.) The report also questioned the ability of JCAHO surveyors to identify serious care deficiencies in nursing homes.¹⁴ Figure 2 summarizes HCFA's findings.

Figure 2: Summary of HCFA Findings on Private Accreditation of Nursing Homes

- JCAHO surveys do not collect sufficient information to ensure compliance with Medicare requirements. In particular, HCFA raised concerns about insufficient focus on observations of resident care and outcomes, as well as concerns about JCAHO's process for overseeing correction of identified deficiencies.
- JCAHO surveyors often miss serious deficiencies that HCFA surveyors identify.
- The potential cost savings of allowing nursing home accreditation does not justify the risk to the health and safety of nursing home residents. However, if another accrediting organization (or a revised JCAHO survey) more successfully met the criteria for comparability with HCFA's survey, accreditation of nursing homes should be considered.

Source: HCFA, Report to Congress: Study of Private Accreditation (Deeming) of Nursing Homes, Regulatory Incentives and Non-Regulatory Initiatives, and Effectiveness of the Survey and Certification System.

¹³HCFA, Report to Congress: Study of Private Accreditation (Deeming) of Nursing Homes, Regulatory Incentives and Non-Regulatory Initiatives, and Effectiveness of the Survey and Certification System (Washington, D.C.: HHS, July 1998). This HCFA report examined the three issues identified in the title. We have summarized only a portion of their findings, those addressing the issue of whether or not HCFA should permit private accreditation of nursing homes. The other issues examined were beyond the scope of this correspondence.

¹⁴Similar concerns have been raised about the ability of state survey agencies to identify and ensure correction of deficient care in nursing homes. Two recent GAO reports have noted problems with enforcement of nursing home compliance following state agency survey. As reported in Nursing Homes: Additional Steps Needed to Strengthen Enforcement of Federal Quality Standards (GAO/HEHS-99-46, Mar. 18, 1999), we found that one-fourth of nursing homes surveyed each year had serious deficiencies and that, despite correction of the deficiency, subsequent surveys showed that problems often returned. Sanctions initiated by HCFA against noncompliant nursing homes were not implemented in a majority of cases. HCFA has some tools to address repeated noncompliance but has not used them effectively. In another report, Nursing Homes: Complaint Investigation Processes Often Inadequate to Protect Residents (GAO/HEHS-99-80, Mar. 22, 1999), we found that states fail to investigate serious complaints of nursing home quality promptly. Also, HCFA provides states with minimal direction and oversight regarding nursing home investigations, and HCFA reporting systems for nursing home compliance history and complaint investigations do not collect timely, consistent, and complete information.

AGENCY COMMENTS

HCFA officials reviewed a draft of this correspondence and found it to be an accurate reflection of the procedures and processes the agency follows. They provided technical comments, which we have incorporated where appropriate.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this correspondence until 7 days from its date. At that time, we will send copies to the Honorable Donna E. Shalala, Secretary of HHS; the Honorable Nancy-Ann Min DeParle, Administrator of HCFA; and other interested parties. We will also make copies available to others upon request. If you have any questions about this correspondence, please call me at (202) 512-7119. Key contributors to this report are Eric Anderson, Jennifer Grover, and Victoria Smith, under the direction of Rosamond Katz, Assistant Director.

Sincerely,



Janet Heinrich
Associate Director, Health Financing
and Public Health Issues

Enclosures—2

APPROVAL CRITERIA AND REVIEW REQUIREMENTS
FOR DEEMING ORGANIZATIONS

The application and reapplication procedures reproduced in this enclosure (42 C.F.R. part 488) apply to private accreditation organizations requesting deeming authority for hospitals, critical access hospitals, skilled nursing facilities, nursing facilities, home health agencies, hospices, comprehensive outpatient rehabilitation facilities, or providers of outpatient physical therapy or speech pathology services. Similar requirements exist in regulations for clinical laboratories (42 C.F.R. part 493) and Medicare+Choice plans (42 C.F.R. part 422). (As of September 15, 1999, the final rule governing Medicare+Choice plans had not been published.)

There are specific factors listed that the Secretary of HHS must consider in determining whether to approve an organization for deeming authority. They include the prospective deeming organization's (1) requirements for accreditation, (2) survey process, (3) ability to provide adequate resources for conducting required surveys, (4) ability to supply information for use in enforcement activities, (5) monitoring procedures for provider entities found out of compliance with the conditions or requirements, and (6) ability to provide the HHS Secretary with necessary data for validation.

TITLE 42--PUBLIC HEALTH

CHAPTER IV--HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 488--SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES--Table of Contents

Subpart A--General Provisions

Sec. 488.4 Application and reapplication procedures for accreditation organizations.

(a) A national accreditation organization applying for approval of deeming authority for Medicare requirements under Sec. 488.5 or 488.6 of this subpart must furnish to HCFA the information and materials specified in paragraphs (a)(1) through (10) of this section. A national accreditation organization reapplying for approval must furnish to HCFA whatever information and materials from paragraphs (a)(1) through (10) of this section that HCFA requests. The materials and information are--

- (1) The types of providers and suppliers for which the organization is requesting approval;
- (2) A detailed comparison of the organization's accreditation requirements and standards with the applicable Medicare requirements (for example, a crosswalk);
- (3) A detailed description of the organization's survey process, including--
 - (i) Frequency of the surveys performed;
 - (ii) Copies of the organization's survey forms, guidelines and instructions to surveyors;
 - (iii) Accreditation survey review process and the accreditation status decision-making process;
 - (iv) Procedures used to notify accredited facilities of deficiencies and the procedures used to monitor the correction of deficiencies in accredited facilities; and
 - (v) Whether surveys are announced or unannounced;
- (4) Detailed information about the individuals who perform surveys for the accreditation organization, including--
 - (i) The size and composition of accreditation survey teams for each type of provider and supplier accredited;
 - (ii) The education and experience requirements surveyors must meet;
 - (iii) The content and frequency of the in-service training provided to survey personnel;
 - (iv) The evaluation systems used to monitor the performance of individual surveyors and survey teams; and
 - (v) Policies and procedures with respect to an individual's participation in the survey or accreditation decision process of any facility with which the individual is professionally or financially affiliated;
- (5) A description of the organization's data management and analysis system with respect to its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system;
- (6) The organization's procedures for responding to and for the investigation of complaints against accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs;
- (7) The organization's policies and procedures with respect to the withholding or removal of accreditation status for facilities that fail to meet the accreditation organization's standards or requirements, and other actions taken by the organization in response to noncompliance with its standards and requirements;

- (8) A description of all types (for example, full, partial, type of facility, etc.) and categories (provisional, conditional, temporary, etc.) of accreditation offered by the organization, the duration of each type and category of accreditation and a statement specifying the types and categories of accreditation for which approval of deeming authority is sought;
 - (9) A list of all currently accredited facilities, the type and category of accreditation currently held by each facility, and the expiration date of each facility's current accreditation; and
 - (10) A list of all full and partial accreditation surveys scheduled to be performed by the organization.
- (b) The accreditation organization must also submit the following supporting documentation--
- (1) A written presentation that demonstrates the organization's ability to furnish HCFA with electronic data in ASCII comparable code;
 - (2) A resource analysis that demonstrates that the organization's staffing, funding and other resources are adequate to perform the required surveys and related activities; and
 - (3) A statement acknowledging that as a condition for approval of deeming authority, the organization will agree to--
 - (i) Notify HCFA in writing of any facility that has had its accreditation revoked, withdrawn, or revised, or that has had any other remedial or adverse action taken against it by the accreditation organization within 30 days of any such action taken;
 - (ii) Notify all accredited facilities within 10 days of HCFA's withdrawal of the organization's approval of deeming authority;
 - (iii) Notify HCFA in writing at least 30 days in advance of the effective date of any proposed changes in accreditation requirements;
 - (iv) Within 30 days of a change in HCFA requirements, submit to HCFA an acknowledgement of HCFA's notification of the change as well as a revised crosswalk reflecting the new requirements and inform HCFA about how the organization plans to alter its requirements to conform to HCFA's new requirements;
 - (v) Permit its surveyors to serve as witnesses if HCFA takes an adverse action based on accreditation findings;
 - (vi) [Reserved]
 - (vii) Notify HCFA in writing within ten days of a deficiency identified in any accreditation entity where the deficiency poses an immediate jeopardy to the entity's patients or residents or a hazard to the general public; and
 - (viii) Conform accreditation requirements to changes in Medicare requirements.
- (c) If HCFA determines that additional information is necessary to make a determination for approval or denial of the accreditation organization's application for deeming authority, the organization will be notified and afforded an opportunity to provide the additional information.
- (d) HCFA may visit the organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents and interviews with the organization's staff.
- (e) The accreditation organization will receive a formal notice from HCFA stating whether the request for deeming authority has been approved or denied, the rationale for any denial, and reconsideration and reapplication procedures.

(f) An accreditation organization may withdraw its application for approval of deeming authority at any time before the formal notice provided for in paragraph (e) of this section is received.

(g) Except as provided in paragraph (i) of this section, an accreditation organization that has been notified that its request for deeming authority has been denied may request a reconsideration of that determination in accordance with subpart D of this part.

(h) Except as provided in paragraph (i) of this section, any accreditation organization whose request for approval of deeming authority has been denied may resubmit its application if the organization--

- (1) Has revised its accreditation program to address the rationale for denial of its previous request;
- (2) Can demonstrate that it can provide reasonable assurance that its accredited facilities meet applicable Medicare requirements; and
- (3) Resubmits the application in its entirety.

(i) If an accreditation organization has requested, in accordance with part 488, subpart D of this chapter, a reconsideration of HCFA's determination that its request for deeming approval is denied, it may not submit a new application for deeming authority for the type of provider or supplier that is at issue in the reconsideration until the reconsideration is administratively final.

[58 FR 61838, Nov. 23, 1993]

HCFA STUDY OF PRIVATE ACCREDITATION
OF NURSING HOMES

This enclosure summarizes HCFA's basis for recommending against approval of JCAHO for deeming of nursing homes as well as its conclusion, findings, and study methodology.

HCFA BASIS FOR RECOMMENDING
AGAINST APPROVAL OF JCAHO FOR
DEEMING OF NURSING HOMES

The 1996 HHS Appropriations Act required HCFA to conduct a study and report to the Congress on private accreditation and deemed status for nursing homes. (The act also required HCFA to report on regulatory and nonregulatory incentives to improve nursing home care and on the effectiveness of the current system of survey and certification of nursing homes.) HCFA contracted for assistance in conducting the study and focused the analysis exclusively on JCAHO as an alternative to the traditional state survey and certification process.

HCFA CONCLUSION

HCFA found that the potential cost savings likely to be associated with allowing JCAHO to conduct private accreditation of nursing homes would not justify the risk to the health and safety of the vulnerable nursing home population. HCFA said that its findings from this study do not necessarily apply to other potential accrediting organizations. HCFA noted that some evidence from the new Long-Term Care Evaluation and Accreditation Program (LEAP), a competitor of JCAHO that began accrediting nursing homes in November 1997, suggests that its survey might be very different from JCAHO's. HCFA concluded that if future empirical studies produce convincing evidence that LEAP, other accrediting organizations, or a revised JCAHO survey meet all the criteria for comparability with the HCFA survey, it may revisit the issue of private accreditation for nursing homes.

HCFA FINDINGS

- JCAHO would have to change the content of several standards to provide reasonable assurance that Medicare requirements would be met.
- JCAHO standards are heavily weighted toward structure and process measures, while HCFA standards have a more resident-centered and outcome-oriented focus.
- JCAHO's minimum qualifications for surveyors—a master's degree and 5 years' long-term care management experience—are higher than HCFA's.
- In contrast to HCFA surveys, observed JCAHO surveys did not collect sufficient information to ensure compliance with Medicare requirements. Generally, observations of resident care were not a priority.

- HCFA's survey system is more stringent in defining steps to be taken to correct deficiencies.
- JCAHO surveyors seem to miss serious deficiencies that HCFA surveyors identify.
- Public access to JCAHO survey findings is severely limited.

HCFA METHODOLOGY

HCFA assessed two components of accreditation—(1) setting standards against which nursing home performance will be measured and (2) enforcing standards by measuring performance and exacting compliance—and developed criteria for assessing each component.

To assess JCAHO's standard setting, HCFA considered three criteria:

- Comparability of the accrediting organization's standards and federal standards.
- Validity of the standards. Do standards for resident outcomes reflect the most rigorous recent research on outcome measurement and linkages of outcomes to organizational structure and the processes of care?
- Accountability in the process of setting and revising standards. Does the public have access?

To assess JCAHO's ability to enforce standards, HCFA considered five criteria:

- Comparability of JCAHO's and HCFA's survey processes, deficiency rules, enforcement, and follow-up procedure.
- Capacity defined by background and numbers of trained surveyors.
- Validity of JCAHO's survey process in identifying deficiencies. Does JCAHO's survey process find valid deficiencies compared to the federal survey process and compared to independent assessments of quality of care and quality of life in surveyed nursing homes?
- Accountability to the public and government. Do the public and government officials have complete access to JCAHO survey findings? Do providers and consumers have access to appeals processes?
- Effectiveness in achieving the objectives of federal regulation.

HCFA conducted the following analyses to develop findings on these eight criteria:

- Content analysis of JCAHO standards and HCFA regulations for long-term care
- Comparison of HCFA and JCAHO surveyor training
- Observational study of the JCAHO long-term care facility survey process
- Comparative analysis of HCFA and JCAHO survey results
- Comparison between JCAHO's accreditation survey and a concurrent nursing home quality survey
- Comparison of enforcement and JCAHO follow-up
- Comparative analysis of HCFA and JCAHO survey costs

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