The External Review of Hospital Quality
Holding the Reviewers Accountable
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EXECUTIVE SUMMARY

PURPOSE

To assess how the Health Care Financing Administration holds the Joint Commission and State agencies accountable for the external review of hospital quality.

BACKGROUND

External Quality Review of Hospitals in the Medicare Program

Hospitals routinely offer valuable services, but also are places where poor care can lead to unnecessary harm. The external quality review of hospitals plays an important role not only in protecting patients from such harm, but also in complementing the hospitals’ own internal quality efforts. The Federal Government relies on two types of external review to ensure hospitals meet the minimum requirements for participating in Medicare: accreditation, usually by the Joint Commission on Accreditation of Healthcare Organizations, and Medicare certification, by State agencies. About 80 percent of the 6,200 hospitals that participate in Medicare are accredited by the Joint Commission.

This Inquiry

This report, part of a series of four companion reports that resulted from our inquiry, focuses on the Health Care Financing Administration’s (HCFA’s) oversight of both the Joint Commission and State agencies. Our inquiry draws on aggregate data, file reviews, surveys, and observations from a rich variety of sources, including HCFA, the Joint Commission, State agencies, and other stakeholders.

We organized this report around a three-part framework that HCFA can use to hold accrediting bodies and State agencies accountable: (1) obtaining information on performance, (2) providing feedback on performance, and (3) disclosing information publicly.

FINDINGS

The HCFA obtains limited information on the performance of the Joint Commission or the States. In both cases, HCFA asks for little in the way of routine performance reports. To assess the Joint Commission’s performance, HCFA relies mainly on validation
surveys conducted, at HCFA’s expense, by the State agencies. But for a number of reasons the value of these surveys has been limited. The methodology for selecting the hospitals to survey fails to consider hospital size or type and draws on hospitals surveyed only in certain months. More fundamentally, the surveys have been based on different standards (the Medicare conditions of participation as opposed to the Joint Commission standards) and have been conducted subsequent to the Joint Commission’s survey (when hospital conditions could have changed). During 1996 and 97, HCFA piloted 20 observation surveys—during which State and HCFA officials accompanied Joint Commission surveyors. This approach appears to have much promise, but HCFA has not yet issued any evaluation of the pilots.

The HCFA rarely observes State agencies survey hospitals, and conducts no validation surveys of them.

The HCFA provides limited feedback to the Joint Commission and the State agencies on their overall performance. Its feedback to the Joint Commission is more deferential than directive. It’s major vehicle for feedback to the Joint Commission is its annual Report to Congress, which is based on the flawed validation surveys and has typically been submitted years late. The HCFA is more directive to the State agencies, which carry out their survey work in accord with HCFA protocols, but gives them little feedback on how well they perform their hospital oversight work.

Public disclosure plays only a minimal role in holding Joint Commission and State agencies accountable. The HCFA makes little information available to the public on the performance of either hospitals or of the external reviewers. By contrast, HCFA posts nursing home survey findings on the Internet and requires nursing homes to post them within the facility as well. The Joint Commission has been more proactive than HCFA in making hospital survey results widely available on the Internet and through other means.

CONCLUSION

The clear and disturbing conclusion of this report is that both the Joint Commission and State agencies are only minimally accountable to HCFA for their performance in reviewing hospitals. While we recognize that these entities are also accountable to others and that they must have considerable flexibility to function effectively, we maintain that it is vitally important for HCFA to ensure that they adequately fulfill their responsibilities to protect Medicare beneficiaries. How, then, can HCFA hold these entities accountable while minimizing burdensome oversight? How can it recognize their inherent strengths and limitations, and tailor performance measurement accordingly? We address these and other related questions in our summary report, A Call for Greater Accountability. That report also contains our recommendations, which we direct to HCFA.
COMMENTS

Within the Department of Health and Human Services, we received comments from HCFA. We also solicited and received comments from the following external parties: Joint Commission on Accreditation of Healthcare Organizations, Association of Health Facility Survey Agencies, American Osteopathic Association, American Association of Retired Persons, Service Employees International Union, National Health Law Program, and Public Citizen’s Health Research Group. We include the detailed text of all of these comments and our responses to them in our summary report, The External Review of Hospital Quality: A Call for Greater Accountability (OEI-01-97-00050).
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PURPOSE

To assess how the Health Care Financing Administration holds the Joint Commission and State agencies accountable for the external review of hospital quality.

BACKGROUND

Hospital Safety

Hospitals are an integral part of our healthcare system, offering services that improve, extend, and even save lives. But they are also places where inappropriate care can lead to unnecessary harm. This reality was clearly underscored in 1991, when a Harvard medical practice revealed the results of its review of about 30,000 randomly selected records of patients hospitalized in New York during 1984. The study found that 1 percent of the hospitalizations involved adverse events caused by negligence. In the public eye, these scholarly inquiries have been overshadowed by media reports that describe, often in graphic detail, the harm done to patients because of poor hospital care.

Medicare’s Interest in External Hospital Quality Review

The Medicare program covers about 38 million elderly and disabled individuals, many of whom are high users of hospital care. In 1997, Medicare spent about $136 billion on hospital care.
billion on Part A, the hospital insurance benefit. This figure is just over half the total amount the Federal government spent on all Medicare benefits. In the same year, Medicare spent over $80 billion for inpatient acute hospital care alone.

Since Medicare’s inception, external quality review has been a part of the Medicare program. When Congress enacted the Medicare Act in 1965, it required hospitals to meet certain minimum health and safety requirements to participate in the program. Those minimum requirements, called the Medicare conditions of participation, were published in 1966, revised in 1986, and are now being revised again (see appendix A).

The Joint Commission and State Agencies as External Reviewers

The Federal Government relies on two processes of external review to determine hospital compliance with these conditions of participation: accreditation, usually by the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission), and Medicare certification, by State survey and certification agencies. Both processes involve a team of trained surveyors visiting a hospital, interviewing staff, reviewing documents, and inspecting the facility. However, the nature of these processes is very different.

Accreditation is a voluntary “conformity-assessment process” whereby industry experts define what standards organizations must conform to in order to be accredited and then surveyors systematically assess the organization’s performance against those standards. It is a form of self-regulation for which hospitals pay a fee. The Joint Commission enjoys a special status because, by Federal statute, hospitals accredited by the Joint Commission are deemed to meet the Medicare conditions of participation. As the largest accreditor of hospitals, accrediting about 80 percent of the nation’s 6,200 hospitals, the Joint Commission is responsible for the majority of the nation’s external quality review of hospitals. In 1972, Congress enacted amendments that gave the Health Care Financing Administration (HCFA) responsibility for overseeing the Joint Commission.

The Medicare certification process, on the other hand, is a public regulatory process that aims to ensure hospitals wishing to serve Medicare beneficiaries, but not wishing to be accredited, meet the conditions of participation. The HCFA relies on the 51 State survey and certification agencies (hereafter called State agencies) to determine compliance with the Medicare conditions of participation. Hospitals pay no fee for this process. States agencies currently certify 1,442 nonaccredited hospitals nationwide. These State agencies are paid and trained by HCFA and use HCFA’s survey instrument to survey nonaccredited hospitals.
This Inquiry and Report

This report describes how HCFA holds the Joint Commission and the State agencies accountable for the external review of hospital quality. Toward that end, on the following page we offer a framework for considering how external reviewers can be held accountable. We offer our findings in accord with this framework.

This report is one of four companion reports that resulted from our inquiry. Another report, *The Role of Accreditation* (OEI-01-97-00051), examines the contributions of accreditation in external hospital review. A third, *The Role of Medicare Certification* (OEI-01-97-00052), describes the extent and nature of HCFA and State agencies’ external review of nonaccredited hospitals. The fourth report, *A Call for Greater Accountability* (OEI-01-97-00050), provides a summary of external review of hospital quality and presents the recommendations emerging from our inquiry.

Our inquiry draws on a variety of sources. These include: data from HCFA’s Online Survey Certification and Reporting System; aggregate data from the Joint Commission concerning hospital survey activity; a mail survey to State agencies in the 50 States and District of Columbia (hereafter referred to as a State); observations of 7 hospital surveys conducted by the Joint Commission and one conducted by a State agency; observation of two complaint investigations by State agencies; reviews of accreditation manuals, policies, and hospital survey files from the Joint Commission; the systematic gathering of information from representatives of HCFA central and regional offices, State agencies, the Joint Commission, American Hospital Association, consumer groups, professional associations, and representatives of other organizations we considered to be stakeholders in hospital oversight; and reviews of laws and regulations and articles from newspapers, journals, newsletters, and magazines. We also interviewed officials from the American Osteopathic Association and reviewed their accreditation materials. The American Osteopathic Association accredits about 100 to 150 hospitals, some of which are also accredited by the Joint Commission. For purposes of this inquiry, however, we focused on the Joint Commission. See appendix B for more details on our methodology.

We conducted this inspection in accordance with the *Quality Standards for Inspections* issued by the President’s Council on Integrity and Efficiency.
The following is a generic framework for considering the mechanisms that HCFA can use to hold accrediting bodies and State agencies accountable. We base the framework on existing mechanisms. The framework serves as a starting place for discussions, to which mechanisms can be added or deleted. We present it in the context of hospitals, but it can also be considered in the context of other provider types. We apply it to the Joint Commission and State agencies on the following pages.

Obtaining Information on Performance

1. Validation Surveys. These are onsite reviews of hospitals that are conducted some time after the accreditors’ or State agencies’ own visits. Validation surveys aim to ensure that reviewed hospitals meet certain minimums.

2. Observation Surveys. These are onsite reviews conducted at the same time as the accreditors’ or State agencies’ surveys. Their intent is to directly observe the surveyors and to use those observations as the basis for constructive feedback.

3. Performance Reports. Such reports involve the regular sharing of data and analysis to enable HCFA to remain well-informed of the hospital review activities.

4. Policy and Procedural Updates. These are regular notices to HCFA on the key policies and procedures governing the bodies’ reviews of hospitals.

Providing Feedback on Performance

1. Performance Assessments. These represent HCFA’s feedback to the accreditors and state agencies on how well they are performing. They can be regularly scheduled or on an as-needed basis.

2. Policy and Procedural Guidance. Through such guidance, HCFA can convey to the bodies those approaches and priorities that it regards to be of national significance.

Disclosing Information Publicly

1. Performance of Hospitals. Publicly disclosing information on hospitals conveys not only something about the hospitals’ performance but also assurance that a process exists for overseeing hospitals that wish to serve Medicare beneficiaries. Such disclosure fosters a trust that the public’s safety is paramount.

2. Performance of Accrediting Bodies/State Agencies. By publicly disclosing information on these entities, HCFA conveys that it is monitoring the work they do on its behalf. It fosters trust that HCFA is promoting public safety.
The HCFA obtains little information on Joint Commission performance.

Validation Surveys: These surveys are fundamentally limited as tool of accountability because they are based on different standards that are applied at different points in time. They are also costly to implement and based on a sample that not only is flawed, but also has been shrinking over time.

The validation survey process is the centerpiece of HCFA’s approach to holding the Joint Commission accountable. Yet its value is limited. It seeks to measure the Joint Commission’s performance through hospitals’ compliance with the Medicare conditions of participation, not the Joint Commission’s own standards. This difference in reference points not only complicates the interpretation of validation surveys, but also inherently compromises their value. Any reasonable tool of oversight needs a common frame of reference. The validation survey now must bridge the Joint Commission’s several hundred standards, which are categorized into 45 groups, with the few dozen Medicare conditions. Moreover, Joint Commission standards--considered by many even within HCFA to be state-of-the-art--are constantly evolving, whereas the Medicare conditions rarely change: first published in 1966, revised substantially in 1986, and under revision again now.

Further undermining the validation process as a tool for accountability is its retrospective nature: validation surveys occur within 60 days of the Joint Commission’s routine hospital survey. During that elapsed time, hospitals have likely corrected some problems and experienced new ones, undergone staff changes, expanded or eliminated services--in other words, any number of changes could affect the validation survey results.

Validation surveys are labor-intensive. A team of at least two surveyors conducts a full hospital survey, lasting 2 to 5 days, depending on the size of the hospital. Alone, the survey portion of the validation probably costs upwards of $2 million per year. Beyond that, though, are costs associated with the preparation and analysis. For example, HCFA staff choose the sample for validation, collect and compare the accreditation and validation survey results, and analyze them. Considering the basic limitations identified above, devoting these resources to validation surveys is questionable.

Other concerns about HCFA’s approach to validation stem from how it selects hospitals for validation surveys. For example, until recently, HCFA selected hospitals for
validation surveys only from those having undergone Joint Commission accreditation surveys between January and July of each year. The HCFA reports that in January 1998 it began drawing a random sample of accredited hospitals each month to correct this problem. While an improvement, HCFA’s approach to sampling still fails to consider hospital characteristics such as past performance, bedsize or rural or urban location.

Other problems with the validation sample appear to be improving. For example, although the size of the sample for validation fell over the past few years, it appears to be on the rise. Between 1991 and 1997, the size of the validation sample fell 50 percent, from 227 surveys in 1991 to 113 surveys in 1997 (about 2 percent of all accredited hospitals). In 1998, HCFA reports that it conducted 164 validation surveys, an increase of 31 percent over the previous year. Still, some hospitals selected for validation never get validated, although that also appears to be improving. In 1996, for example, HCFA validated no hospitals in 16 States, including Missouri, Iowa, Nebraska, and Kansas--an area comprising an entire Federal region of the country. Likewise, in 1997, HCFA validated none of the 30 selected hospitals in New Mexico, Texas, Oklahoma, Arkansas, and Louisiana--another Federal region. In 1998, however, HCFA reports that each Federal region had at least one validation survey conducted in it and 76 percent of the hospitals selected for validation did, in fact, have a validation survey.

**Observation Surveys:** The HCFA has piloted an observation survey that has promise but remains largely undeveloped.

The HCFA developed an observation survey process as part of a larger initiative to reinvent its oversight of accreditation (HCFA generally refers to these surveys as reinvention surveys, see appendix B for more information on the reinvention initiative). The process developed called for State and HCFA surveyors to silently follow and observe while Joint Commission surveyors conduct accreditation surveys--a major shift from traditional validation surveys. In developing the observation surveys, HCFA aimed to address the fundamental problems with the traditional validation (such as different reference points and time frames). A workgroup involving officials from HCFA, State agencies, and the Joint Commission devoted considerable effort to defining an observation process as a tool for accountability. The observation survey represented an opportunity for State and HCFA surveyors to assess first-hand the process of an accreditation survey. It promised to provide what the traditional validation could not: the same snapshot of a hospital and insights into accreditation surveyor skills and processes (defined as survey preparation, survey process, interpersonal, presentation, and teamwork).²³

In 1996 and 1997 HCFA and State agency surveyors tested their newly developed observation survey process by observing 20 accreditation surveys across 4 States. But HCFA has yet to report on the results. Indeed, its plans for revising or expanding the observation surveys are undeveloped. Using skilled Medicare surveyors to be what essentially amounts to silent observers of an accreditation survey process is a questionable
use of scarce resources. Furthermore, we observed neither much interaction with, nor any feedback to, accreditation surveyors on the one survey observation in which we participated. In fact, because HCFA has yet to produce an evaluation on the pilot, it has yet to result in feedback to the Joint Commission.

**Performance Reports:** The HCFA obtains few reports addressing Joint Commission performance.

The HCFA asks for little regular reporting from the Joint Commission beyond the survey scheduling and results it needs to carry out its validation surveys. For example, it asks for no regular reports from the Joint Commission on topics such as the nature or pattern of complaints received about accredited hospitals, appeals of accreditation decisions, or the extent and nature of actions taken as a follow-up to surveys. It also asks for no aggregate data on the timeliness of surveys or training of surveyors. Nor does it ask for any regular reports on how many special surveys (for example in response to unexpected deaths or preventable injuries) the Joint Commission conducts. These types of data are already being collected by the Joint Commission and could provide HCFA with insights into how well accredited hospitals are performing, what new problem areas are emerging, and how well the accreditation results are being received.²⁴

Regular reporting from the Joint Commission to HCFA has been largely limited to information HCFA needs to carry out its validation surveys. For example, the Joint Commission provides HCFA’s central office with lists of upcoming surveys, accredited hospitals and their accreditation status, and individual hospital performance reports. The HCFA has also received data on Joint Commission standards commonly found out of compliance and a report on hospital withdrawals from accreditation, mergers, and acquisitions.

**Policy Updates:** The HCFA receives regular updates on Joint Commission policies and procedures.

The Joint Commission communicates with HCFA regularly and through several avenues. For example, officials from HCFA meet several times a year with representatives of the Joint Commission. Their meetings cover an array of topics, including the reinvented survey process, electronic exchange of data, and changes in the accreditation survey process, among others. In the course of developing and implementing the observation survey pilot, HCFA and Joint Commission officials met regularly and HCFA staff even attended Joint Commission surveyor training. Staff from the Joint Commission communicate regularly to clarify policy and procedural issues, either in person, in writing, on the telephone, or, more recently, via electronic mail. And at least two HCFA officials serve as members of Joint Commission committees, which provides additional opportunities for HCFA to remain well-
informed of existing and emerging policies. The communication involves largely the HCFA central rather than regional office staff.

The HCFA provides minimal feedback to the Joint Commission.

Performance Assessments: The main vehicle for feedback on the Joint Commission’s performance is the Report to Congress. That report is of limited value.

The Congressional mandate that requires HCFA to publish a summary of the validation reports as part of its Medicare Annual Report to Congress shapes both the method and content of HCFA’s feedback to the Joint Commission. The HCFA uses this report to provide feedback about the validation surveys to the Joint Commission. It uses no other formal mechanism for feedback. Thus, outside of validation survey results, the Joint Commission receives little in the way of detailed, operational feedback or recommendations for improvement.

We have already raised questions about the basic value of the validation surveys. Beyond that, by the time HCFA releases its Annual Reports, the validation data are dated, further limiting their value. For example, in 1993 HCFA released the reports to Congress for the Fiscal Years 1989 and 1990. It published the results of the 1991 and 1992 validation surveys in the 1992 Report, released in September 1994. The 1994 validation survey results never left the Department, and HCFA released the most recent reports, containing the 1995 and 1996 validation results, in late 1997. Given these delays, the Joint Commission’s standards and procedures could have changed between the time the validation surveys were conducted and the time the Joint Commission receives its copy of the Medicare Annual Report.

The delays of HCFA’s validation feedback impede meaningful discussion with the Joint Commission about the findings. While HCFA does not provide the Joint Commission with an opportunity to formally respond to the validation findings, some such discussion has occurred. For example, in response to the results of the 1991 and 1992 validation findings, which raised concerns about the Joint Commission’s attention to life safety codes, HCFA observed the Joint Commission’s surveyor training and consulted with it about interpreting life safety code standards.
Policy and Procedural Guidance: The HCFA’s guidance to the Joint Commission on policy and procedural matters is negligible.

The HCFA’s posture toward the Joint Commission is more deferential than directive. The Joint Commission, which has dominated the hospital accreditation market for the past 30 years, has amassed expertise that HCFA relies upon. Indeed, many officials in HCFA refer to the Joint Commission as maintaining the “gold standard” or higher bar toward which HCFA can aspire. The HCFA even modeled the recently proposed hospital Conditions of Participation after Joint Commission’s Agenda for Change.28

On occasion, representatives of both HCFA and the Joint Commission will be on-site at the same hospital at the same time. This is especially apt to occur following an incident of patient harm in an accredited hospital, to which both parties are responding. According to HCFA regional officials with whom we spoke, the HCFA takes on no coordinating nor information-sharing roles during those responses. In fact, during one high profile case of a preventable death in a hospital, the HCFA regional office staff reported that they played a significant role in coordinating the responses of HCFA and State officials, but not the Joint Commission. A HCFA official from another region captured this hands-off approach when he said “[We] wouldn’t want to interfere with their process.”

While the HCFA lacks a seat on the Joint Commission’s Board of Commissioners, it does have opportunities to provide policy and procedural guidance through its participation in two Joint Commission committees.29 In the Professional and Technical Advisory Committee for hospital standards, HCFA staff can weigh in as new standards are discussed and developed. Likewise, HCFA can weigh in on discussions of performance measurement by participating in the Council on Performance Measurement. However, the expectations of Committee membership, as defined by the Joint Commission, call for participants to not only provide advice, but also “to serve as [an] external advocate[s]” for the accreditation program.30 Such expectations could run counter to HCFA’s role in holding the Joint Commission accountable.

Other factors also play some role in limiting HCFA’s ability to provide meaningful policy or procedural guidance to the Joint Commission. For example, within HCFA itself, no center of responsibility exists for hospital-related issues. Rather, responsibility for issues related to hospitals is divided among several divisions and groups in the Center for Medicaid and State Operations, the Center for Health Plans and Providers, and the Office of Clinical Standards and Quality. The HCFA’s organizational changes in the last few years have left many HCFA staff and managers with steep learning curves with respect to hospital quality review. Indeed, many HCFA officials with whom we spoke characterized their interactions with the Joint Commission as more educational than evaluative.
The Joint Commission and especially HCFA make limited use of public disclosure as a tool of accountability.

Performance of Hospitals: The Joint Commission makes basic information on accredited hospitals’ survey results public, but keeps most information about adverse events confidential.

In December 1994, the Joint Commission began releasing accreditation information about hospitals, on request, in the form of performance reports. These reports include the hospital’s overall survey score from its most recent triennial survey, the hospital’s scores in the 45 areas surveyed, comparative data on the percentage of hospitals receiving each possible score in the 45 areas, and a list of the areas in having specific recommendations for improvement, including the status of the improvement. The reports exclude any details on the problems identified during the surveys. But the reports do come with a guide for interpreting and understanding the scores and an explanation of the 45 performance areas.

As of late 1998, the Joint Commission had 13,408 performance reports for hospitals, nursing homes, and other provider types available to the public, and that list keeps growing. Between late 1996 and early 1997, requests for performance reports grew from 13 per quarter to over 2,000. These reports are free and readily available by mail, phone, or through the Internet.

However, the Joint Commission keeps most information on adverse events in hospitals confidential. In April 1998, it implemented a policy fostering hospitals to self-report such events and conduct their own analysis of the cause of the events. By keeping the information confidential, the Joint Commission aims to provide hospitals with a safe venue for reporting adverse events, thereby allowing it to develop a database for researching and preventing such events.

Performance of Accrediting Bodies: The HCFA has little to disclose on the performance of the Joint Commission, but does make its Report to Congress available on request.

The HCFA does not mandate that information on the performance of the Joint Commission be disclosed. In fact, it has little to disclose. It does have the Report to Congress, its main vehicle for providing feedback to the Joint Commission. That report is available to anyone who requests it, but, as we have seen, it is of limited value. Independent of HCFA, the Joint Commission makes some information about its own performance public through its newsletter, website, and occasional articles in magazines.
The HCFA obtains little information on State agencies’ performance.

Validation Surveys: The HCFA does not conduct such surveys of State agencies’ hospital activities.

None of the 10 HCFA regional offices reported conducting validation surveys of nonaccredited hospitals over the past few years. Based on our accountability framework presented on page 7, by validation survey we mean an onsite survey, conducted sometime after a State agency survey, that aims to verify that the hospital meets certain minimums. The HCFA’s workload, like that of State agencies, is dominated by nursing homes and home health agencies rather than hospitals. And while HCFA may validate those surveys, it has not validated hospital certification surveys in recent years.

Observation Surveys: The HCFA rarely conducts such surveys of State agencies’ hospital activities.

As we have seen, the bulk of State agencies’ work is directed toward nursing homes and home health agencies rather than hospitals, and HCFA’s oversight of the agencies reflects this. State agencies conduct relatively few surveys of nonaccredited hospitals each year, thereby limiting the opportunities for HCFA to observe their survey process. Indeed, 4 of the 10 HCFA regional offices reported conducting no onsite monitoring at all over the past year or so. The other 6 regional offices reported observing 15-20 State agency surveys of hospitals over the past 3 years. This represents about 2 percent of all nonaccredited hospitals, or less than 1 percent per year. The six regions that did observe State agency survey hospitals reporting using different approaches in their observation. For example, some regional offices may provide feedback to the State surveyors while observing, others may wait until after the survey is complete.

Performance Reports: Nationally, HCFA obtains little information on State agencies’ performance concerning hospitals.

In 1996, HCFA established the State Agency Quality Improvement Plan (SAQIP) to promote ongoing improvement in all aspects of survey and certification, including hospitals. Toward that end, HCFA developed a set of core performance standards for agencies (see appendix C for standards). For the most part, the standards developed by HCFA apply generally to all provider types rather than being specific to hospitals. For example, “All surveys are conducted by qualified individuals,” applies across provider
types, including nursing homes and home health agencies. In fact, when we asked States about their improvement plans, only six identified goals specific to hospitals, such as improving the review of complaints related to hospital dumping.\textsuperscript{38}

Under SAQIP, HCFA requires States to design a plan for quality improvement specific to the performance standard. The HCFA regional offices assist the State agencies and receive copies of the quality improvement plans, thus they have a general picture of the State agencies’ progress. Centrally, HCFA relies on its mid- and year-end SAQIP reports for a picture of the States’ performance.\textsuperscript{39}

This approach, however, provides HCFA with a superficial and somewhat blurred picture of States’ performance in overseeing hospitals. For example, the 1997 year-end SAQIP report indicated State agencies had taken on general improvement projects ranging from training programs for documenting deficiencies to better tracking systems for survey data.\textsuperscript{40} But the report also highlights such vague examples of improvement as “initial success was opening communication,” “review done, goal met,” and “State intends to use SAQIP in its licensure program.”\textsuperscript{41} The HCFA grouped these and other examples into such categories as “enthusiasm,” “positive feedback received,” and “improved communication.” Overall, such examples provide little in the way of meaningful insights into a States’ performance.

While SAQIP provides a standard means for State agencies to approach quality improvement, it fails to provide either a means of comparing the performance across States or insights specific to hospitals. To some extent, HCFA can rely on other means for these. For example, it logs all hospital anti-dumping complaints received and investigated by the States. It also maintains a database of State agencies’ survey activities and findings. The States input data reflecting their survey work into the database, which HCFA then can access and aggregate. The HCFA can glean the extent of survey activity and trends in hospitals choosing or dropping accreditation, complaints, and survey findings, among others. Staff in the HCFA regional offices reported relying on such data occasionally, but the data have limits. For example, HCFA maintains logs of patient dumping that list complaints chronologically, but lack summary data and analysis of trends. Also, HCFA cannot determine trends in hospital termination notices. In other words, HCFA does not know how many times it issued hospital termination notices based on findings during Medicare certification surveys of nonaccredited hospitals.\textsuperscript{42} It does know, however, how many hospitals are actually terminated.

Policy and Procedural Updates: The HCFA determines the policies and procedures used by the States.

The HCFA provides State agencies with the survey protocols and interpretive guidelines they need to survey hospitals. Its relationship with State agencies is akin to a contractual relationship, with HCFA’s expectations spelled out in an agreement renewed
annually.\textsuperscript{13} It ranks their activities by priority in the annual budgeting process.\textsuperscript{44} Some regional offices hold regular conference calls with their States to pass along updates, others hold regional conferences. The HCFA regional offices provide technical assistance to State agencies as needed, and generally have close working relationships with them. The HCFA also regularly provides training for State agency staff. The training agenda reflects statutory, regulatory, and procedural changes as well as the workload of the States, which means long-term care dominates the training agenda. For example, among about 20 courses, HCFA offered 1 that was specific to hospitals in Fiscal Year 1997. In Fiscal Year 1998, 3 of 25 courses HCFA offered were specific to hospitals.

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**The HCFA provides limited feedback to State agencies.**

**Performance Assessments:** The HCFA largely relies on the State agencies to conduct their own performance assessments. It provides little feedback specific to their hospital work.

The HCFA’s SAQIP is the primary means for assessing State agencies’ performance. By design, SAQIP calls for State agencies to work with HCFA regional offices to develop and implement States’ own quality improvement plans. Since implementing SAQIP, HCFA has centrally produced two status reports: one in mid-year 1997 and one at the year’s end. The HCFA sent copies of both reports to all State agencies. These reports, though, provide no State-specific feedback. They neither identify States nor offer assessments of performance specific to hospitals or other provider types. They include no summaries of activities such as hospital surveys conducted or complaints received. They also lack any feedback on specific areas for States to focus their improvements, or actions such as follow-up. In fact, the status reports give almost as much attention to the SAQIP process and its challenges as they do to the challenges of survey and certification activities.

As we have seen, the State agencies tend to work closely with the HCFA regional office staff in the SAQIP process, offering opportunities for feedback. In fact 32 of 51 State agencies reported receiving feedback from HCFA regarding their hospital oversight activities, and 20 reported making improvements based on that feedback.\textsuperscript{45} For example, several States reported implementing training programs, changing the emphasis of their approach to validation surveys, and establishing protocols for handling complaints based on HCFA feedback.

Nevertheless, the feedback that State agencies receive from HCFA appears to be of limited value. For example, when asked about the usefulness of HCFA’s oversight, 29 of 51 State agencies rated it not or somewhat useful, 15 as moderately useful, and 7 as very or extremely useful. While it varies by region, just one HCFA regional office indicated that it provides narrative assessments of its State agencies’ performance. Others
indicated that feedback to the State agencies tends to be narrow and focused on a specific hospital rather than broad and relevant to the range of responsibilities States hold with hospitals. For example, HCFA’s feedback on a States’ performance is more akin to technical assistance in documenting a hospital’s condition than assistance in prioritizing or managing their resources devoted to hospital activities.

**Policy and Procedural Guidance:** The HCFA gives State agencies considerable guidance, often on a case-by-case basis involving specific hospitals.

The bulk of State agencies’ hospital work is related to investigating complaints, adverse events, and conducting validation surveys. The HCFA works closely with the agencies in carrying out each these activities. When it comes to hospital complaints, for example, the agencies’ workload extends to accredited as well nonaccredited hospitals, and HCFA regional offices tend to be closely involved in determining not only which get investigated, but also to what extent. This is particularly true when the complaint relates to an accredited hospital. In those cases, the HCFA reviews the complaint in light of the Medicare Conditions of Participation and determines whether the State needs to investigate. If an investigation ensues, the HCFA staff oversee the process step-by-step: they review the survey findings, summary of deficiencies, and any follow-up. In some cases, especially high-profile complaints, the HCFA may send one of its own surveyors to accompany the State agency. Indeed, in one State with a highly publicized series of hospital deaths, HCFA was so concerned about the State agency’s ability to handle the case that it stepped in with its own surveyors to respond.

The HCFA regional offices also provide considerable guidance on routine certification surveys. As with complaint surveys, the HCFA staff will review the survey documentation. Indeed, if the State agency finds a hospital out of compliance with a Medicare condition of participation, then HCFA is directly involved in the follow-up, by issuing termination notices, for example. The HCFA also provided feedback for those 15-20 monitoring surveys HCFA conducted over the past few years, usually by means of a formal debriefing with the State surveyors.

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**The HCFA makes limited use of public disclosure as a means of holding hospitals or State agencies accountable.**

**Performance of Hospitals:** The HCFA discloses results of its hospital certification and complaint surveys upon request.

The HCFA will disclose most of the survey documents, except those related to peer review that are considered confidential. Thus, upon request, HCFA will disclose the hospital’s statement of deficiencies, which spells out, condition by condition, the problems
identified during the survey and the hospital’s plan for correction. It only lists those areas
where the surveyors identified problems, and excludes any comparative or trend
information. The HCFA will also disclose data from its database that records the findings
and trends of hospital surveys.\textsuperscript{47} Neither the statement of deficiencies nor the data itself is
available through HCFA’s website. Rather, interested parties must contact HCFA
directly. By contrast, Federal law mandates that nursing homes post their statements of
deficiencies in a manner readily accessible to residents and their families.\textsuperscript{48} In addition,
HCFA’s website allows visitors to view the results of nursing home surveys, including the
scope and severity of any deficiencies.\textsuperscript{49}

The survey and certification agencies in some States have gone further than HCFA
in disclosing hospital-specific information, based on their own States’ authority rather than
HCFA’s. For example, New Jersey maintains a website that displays resolved hospital
violations and New York collects and reports hospital- and physician-specific performance
data on cardiac surgery.

\textbf{Performance of State Agencies: The HCFA discloses little on the performance of
State agencies.}

Unlike the mandate for the Report to Congress on the Joint Commission’s
performance, no such mandate exists for HCFA to report on how well State agencies are
performing. Nevertheless, HCFA has some, albeit limited, information on States’
performance. As we have seen, it is has mid-year and year-end SAQIP reports plus
databases reflecting the State agencies’ survey work. As noted above, HCFA will release
the data, but it would take considerable knowledge and work to array the data to facilitate
State-by-State comparisons or in some way measure State agency performance.
According to HCFA officials with whom we spoke, although HCFA does not distribute
the SAQIP reports beyond the States themselves, it will release them upon request. Of
course, the SAQIP reports lack any State-specific assessment of performance.
The clear and disturbing conclusion of this report is that both the Joint Commission and State Agencies are only minimally accountable to HCFA for their performance in reviewing hospitals. While we recognize that these entities are also accountable to others and that they must have considerable flexibility to function effectively, we maintain that it is vitally important for HCFA to ensure that they adequately fulfill their responsibilities to protect Medicare beneficiaries. How, then, can HCFA hold these entities accountable while minimizing burdensome oversight? How can it recognize their inherent strengths and limitations, and tailor performance measurement accordingly? We address these and other related questions in our summary report, *A Call for Greater Accountability*. That report also contains our recommendations, which we direct to HCFA.
Methodology

We collected information presented in this report from the following sources:

The HCFA

We obtained dates of certification surveys from HCFA’s Online Survey Certification and Reporting System (OSCAR). The HCFA authorizes States to update and maintain this database with survey information. We extracted survey data pertaining to the frequency of certification surveys. We subsequently verified the accuracy of our extraction by comparing it to on-line OSCAR system information to ensure the dates we used corresponded to routine certification surveys, rather than complaint investigations or other types of surveys. We are satisfied that our information is as accurate as HCFA’s OSCAR system.

Additionally, we selected 4 States (California, Kansas, Minnesota, and Texas) that contain over 50 nonaccredited hospitals and represented different regions of the United States. We then examined the OSCAR data for those States in greater detail. We verified the operational status of the nonaccredited hospitals in those States that had not been surveyed in over 5 years using the American Hospital Association’s 1997 Hospital Guide.

We also interviewed staff and managers at each HCFA regional office and the central office. We reviewed a variety of HCFA documents, including budget call letters, reinvention materials, and reports to Congress, among others.

The State Survey and Certification Agencies

In August 1997, we mailed a pretested survey to the hospital certification agencies in the 50 States and the District of Columbia. The response rate for this survey was 100 percent. The State survey addressed four areas of hospital quality oversight: private accreditation of hospitals, Medicare certification of hospitals, HCFA oversight of State certification agencies, and State licensure of hospitals. We interviewed State officials on the telephone or in person as well.
Accrediting Organizations

We interviewed officials from both the Joint Commission on Accreditation of Healthcare Organizations and the American Osteopathic Association. We also reviewed documents from both organizations, including mission statements, accreditation manuals, policies, and hospital survey files. We requested and received aggregate data from the Joint Commission reflecting its recent hospital survey activity. All Joint Commission data are presented as reported by the Joint Commission, unless otherwise noted. For purposes of this inquiry, we focused our analysis on the Joint Commission.

Survey Observations

Based on schedules of upcoming triennial surveys, we identified nine hospitals in which to observe triennial Joint Commission surveys. Of those, we were able to observe seven. In two cases, the hospitals declined the Joint Commission’s request that we be allowed to observe. The 7 hospitals varied in size from 80 to 775 beds, represented both teaching and community hospitals, and were located in different areas of the country (both rural and urban). We also observed one random unannounced Joint Commission survey. Although we observed different teams of surveyors, the survey agenda, lines of inquiry, and tone were consistent across the surveys, which were conducted in accordance with Joint Commission policy, based on review of survey manuals and interviews with representatives of the Joint Commission. Finally, we observed a certification survey and parts of two complaint investigations performed by State surveyors under HCFA’s auspices.

Stakeholder Interviews

We interviewed representatives of organizations we considered to be stakeholders in hospital oversight. These stakeholder organizations included a union, professional organizations, hospital associations, and consumer groups.

Other Documents

In addition to the documents referenced above, we reviewed statutory and regulatory language and a variety of articles from newspapers, journals, magazines, and newsletters.
HCFA’s Reinvented Oversight of Hospital Accreditation

Dissatisfaction with Validation

Interest in reinventing HCFA’s approach to overseeing accreditation stemmed from growing dissatisfaction with the validation survey process. In 1990, 16 years after HCFA began to validate the Joint Commission surveys, the General Accounting Office (GAO) published a report criticizing HCFA’s validation program. The GAO found the comparison of HCFA and Joint Commission survey findings yielded little information about the effectiveness of Joint Commission process. Because HCFA measures hospital quality using the Medicare Conditions of Participation and the Joint Commission uses its own standards, the GAO saw little use in comparing the results of these surveys without a crosswalk linking the two sets of measures. In response to this report, HCFA developed a crosswalk. The process was labor-intensive and time-consuming, resulting in a document over 800 pages long. However, HCFA found using this cumbersome crosswalk produced the same results as its old method of comparing survey results and discontinued use of the crosswalk.

Other concerns about the validation process emerged and gained credence through the early 1990s. For example, HCFA came to believe that using hospitals as a proxy to evaluate the Joint Commission accreditation process was not only indirect but also could be inaccurate if hospital performance changed since an accreditation survey.

The Reinvention Workgroup

In 1993, HCFA organized a workgroup comprising members from HCFA, States, the American Hospital Association, American Osteopathic Association, and Joint Commission to reinvent the validation. This workgroup identified an alternative or reinvented approach to the validation through which HCFA would evaluate the Joint Commission’s accreditation process by conducting concurrent, on-site observations of the Joint Commission surveys instead of comparing HCFA and Joint Commission survey results. This reinvented validation survey would involve HCFA and State surveyors participating in Joint Commission surveys as silent observers. The workgroup also proposed that HCFA and the Joint Commission should mutually develop both surveyor-based and hospital-based performance indicators to be used by HCFA and State observers. This on-site assessment was planned to be one part of a larger comprehensive evaluation (see box).
Planned Components of the Reinvention

Review of Accreditation Organization’s

- Philosophy and Mission
- Survey Protocols
- Surveyor Support
- On-Site Survey
- Decision process
- Deficiency Resolution
- Timeliness
- Performance Improvement
- Intra-Cycle Activity
- Response to Complaints


The Two Completed Reinvention Phases

The reinvention workgroup has planned and completed two phases of the reinvention, both pertaining to the on-site assessment piece of the validation. As Phase I, the workgroup drafted a methodology and developed evaluation criteria for the reinvention surveys. The workgroup identified five surveyor based performance indicators: survey preparation, survey process, interpersonal, presentation, and teamwork. It also agreed upon 11 core hospital functions: assessment, patient preparation, treatment, nutrition, medication use, discharge coordination, environmental safety, patient safety, infection control, quality improvement, and information management. The HCFA regional office and State teams of surveyors attended Joint Commission surveyor training and as well as training on how to use the newly developed surveyor and hospital criteria. The HCFA piloted a total of 20 reinvention surveys in 4 States: Pennsylvania, Georgia, Illinois, and Colorado.
State Agency Quality Improvement Plan

Standards

The HCFA developed the following standards through a workgroup that included State agency representatives:

Quality Improvement Standards

Standard 1: The State agency documents deficiencies consistent with the Principles of Documentation.

Standard 2: The Plans of Correction accepted by the State agency reflect appropriate action and time frames to correct cited deficiencies.

Standard 3: All surveys are conducted by qualified individuals.

Standard 4: The State agency assures consistency in survey performance.

Standard 5: The State agency has an effective program to measure accuracy and improve consistency in the application of long-term care enforcement remedies.

Standard 6: The State agency effectively investigates and processes complaints (including those related to Section 1867) about participating providers and suppliers.

Standard 7: The State agency monitors expenditures and supports charges to Federal programs in accordance with existing regulations, guidelines, policies, approved funding levels and allocation methodologies.

Quality Control Standards

Standard 8: The State agency ensures that each home health agency (HHA), skilled nursing facility (SNF) nursing facility (NF), and SNF/NF is subject to a standard survey not later than 15 months after the previous survey, and that the statewide average interval between standard surveys does not exceed 12 months.
Standard 9: The State agency ensures that it meets all survey coverage percentages negotiated with the regional office for Title XVIII and/or Title XIX providers and suppliers, excluding HHAs, SNFs, NFs, and SNF/NFs.

Standard 10: All surveys, including complaint investigations, are conducted unannounced, or are announced consistent with HCFA instructions.

Standard 11: The State agency budget request, activity plan, and expenditure reports are prepared and submitted in accordance with Federal instructions and accurately reflect the allocation of costs between State and Federal programs.

Standard 12: The State agency effectively maintains the OSCAR system database.

Standard 13: Annual surveys of intermediate care facilities for the mentally retarded and recertification actions completed before the expiration of the time-limited agreement.
Endnotes


2. The 17.7 percent refers to adverse events considered by the authors to be serious. The authors defined adverse events as “situations in which an inappropriate decision was made when, at the time, an appropriate alternative could have been chosen” and serious as ranging from “temporary disability to death.” See Lori B. Andrews et al, “An Alternative Strategy for Studying Adverse Events in Medical Care,” *The Lancet* 349 (February 1, 1997) 309-313.


3. One example is a November 1998 *New York Times* article under the headline: “Death in Surgery Reveals Troubled Practice and Lax Hospital.” The article described a “botched” operation on a young woman by a surgeon who was on probation by the State medical board and who used unauthorized medical equipment brought in to the operating room by a medical supply salesman. Such incidents can happen even in the best of hospitals, but they underscore the point that hospitals can be dangerous places and that oversight systems can be lax. See also “Overdoses Still Weigh heavily at Dana Farber,” *The Boston Globe* (26 December 1995); “Florida Doctor Sanctioned in New Amputation,” *The Boston Globe* (19 July 1995); “Two Surgeons Surrender Licenses After Mistakenly Removing Kidney,” *The Boston Globe* (6 June 1996); “How Can We Save the Next Victim?” *New York Times Magazine* (15 June 1997); “Another Hospital Death Probed,” *The Boston Globe* (26 July 1997); “Patient Dies After Drinking Poison Left on Nightstand,” *San Diego Union-Tribune* (6 March 1998); ”Man Arrested for Posing as Doctor for 4 years,” posted at the CNN interactive webpage (16 May 1998); “Deadly Restraint: Patients Suffer in a System Without Oversight,” *The Hartford Courant* (13 October 1998).

5. Ibid.

6. Ibid.

7. Ibid.


10. Congress also provided that hospitals accredited by the American Osteopathic Association could be considered in compliance, but only to the extent than the Secretary deemed appropriate.

11. Two companion reports entitled The Role of Accreditation and The Role of Medicare Certification explore the role of accreditation and Medicare certification in greater detail.


13. Nonaccredited hospitals can go through the Medicare certification process for free.


17. Validation surveys are onsite reviews of hospitals conducted after a Joint Commission survey. State agency surveyors conduct the validation surveys based on the Medicare conditions of participation.

18. We acknowledge the dual purpose of validation surveys. As originally envisioned, they were to serve as an assurance that accredited hospitals met the Medicare conditions of participation: “Our validation program is concerned chiefly with the equivalency of accreditation standards to Federal requirements, and assuring that Medicare participating facilities deemed by virtue of accreditation would meet those requirements if surveyed against them.” (58 CFR 61831, see also Senate Report 92-1230). Over time, the purpose and use of validation surveys evolved to a more
encompassing role as a tool of oversight for the Joint Commission. Indeed, these roles overlap and their distinctions may be blurred. For purposes of this report, we focus on validation surveys and their potential as a tool of oversight.

19. In 1990, the General Accounting Office criticized HCFA’s approach to validation surveys, citing specifically the lack of a crosswalk linking the Medicare conditions with the Joint Commission’s own standards. In response, HCFA created such a crosswalk, but the undertaking was not only labor-intensive, but also cumbersome: it resulted in an 800-page document. And when HCFA relied upon that crosswalk for validation surveys in 1989 and 1990, the results were the same as without a crosswalk (See Health Care Financing Administration, “The Reinvention of the Hospital Validation Survey,” undated, and U.S. General Accounting Office, Health Care: Criteria Used to Evaluate Hospital Accreditation Process Needs Reevaluation, GAO/HRD-90-89, 11 June 1990).

20. See our companion report entitled The Role of Accreditation for a discussion of the Joint Commission’s standards.

21. The HCFA’s instructions to State agencies also allow for validation surveys to occur within 60 days of HCFA’s notice to the State agency.

22. While we acknowledge our estimate is a rough one, we base it the conservative assumption that 2-3 surveyors would travel to a hospital for 2-3 days. While highly variable, we estimated the costs of surveyor salary and travel would be $2,000 to $4,000 each. And considering about 150 surveys per year, we believe the estimate of about $2 million is reasonable.


25. The Joint Commission currently has HCFA officials serving on its Hospital Professional and Technical Advisory Committee and its Council on Performance Measurement.


29. The Joint Commission’s board has 28 members, including 6 public members and an at-large nursing representative. Most members are appointed by organizations such as the American College of Physicians, the American College of Surgeons, the American Dental Association, the American Hospital Association, and the American Medical Association.


31. In November 1996, the Joint Commission waived the $30 report fee.

32. The 45 performance areas, divided into 15 categories, are:

**Patient Rights and Organization Ethics:** Patient Rights, Organization Ethics

**Assessment of Patients:** Initial Assessment Procedures, Pathology and Clinical Laboratory Services, Reassessment Procedures, Processes for patient Care Decision, Relevant Policies, Needs Assessment for Specific Patient Populations

**Care of Patients:** Planning and Providing Care, Anesthesia Care, Medication Use, Nutrition Care, Operative Procedures, Rehabilitation Care, Special Treatment Procedures

**Education:** Patient and Family Education

**Continuum of Care:** Continuity of Care

**Improving Organizational Performance:** Improvement Planning, Design of New Services, Measurement of Processes and Outcomes, Assessment of Data, Improvement of Performance

**Leadership:** Strategic Planning, Departmental Leadership, Integrating and Coordinating Services, Leader’s Role in Improving Performance


**Management of Human Resources:** Human resources Planning; Orienting, Training, and Education of Staff; Assessing Staff Competence; Managing Staff Requests

**Management of Information:** Information Management Planning, Availability of Patient-Specific Information, Data Collection and Analysis, Literature to Support Decision-Making, Use of Comparative Information

**Infection Control:** Infection Control

**Governance:** Governance

**Medical Staff:** Organization, Bylaws, Rules, and Regulations; Credentialing

**Nursing:** Nursing

**Management:** Management
33. The HCFA staff we contacted, particularly in the regional offices, were largely unaware of these reports and their availability.

34. For further discussion of this policy, see our companion report, *The Role of Accreditation*.


36. As we noted in our companion report, *The Role of Medicare Certification*, nursing homes, intermediate care facilities for the mentally retarded, and home health agencies all precede nonaccredited hospitals in survey priority.


38. The Emergency Medical Treatment and Labor Act (42 U.S.C. 1395dd) prohibits hospitals from refusing emergency patients or women in labor medical screening and/or treatment. If a hospital willfully or negligently fails to meet the requirements of the act, it can be fined or its participation in Medicare can be suspended or terminated.

39. The HCFA also has its On-Line Survey and Certification data system (referred to as OSCAR) for insights into the extent of hospital surveys conducted by the States.


41. Ibid.

42. The HCFA tracks survey results through its OSCAR database, but it does not track termination notices, which can be 23-day or 90-day notices based on the severity of the survey findings.

43. Referred to as the 1864 Agreement, this document spells out HCFA’s delegation of authority to the States and the functions States must carry out.

44. See the companion report, *The Role of Medicare Certification*, for more detail on the budget priorities.

45. Based on the Office of Inspector General mail survey in September 1997. The survey defined hospital activities to include Medicare certification surveys for nonaccredited hospitals, responses to complaints, and validation surveys of accredited hospitals.
46. See the companion report, *The Role of Medicare Certification*, for more detail on State agencies’ workloads.

47. Referred to as the On-line Survey and Certification Reporting System. The HCFA may charge a small fee for processing this data.


49. The HCFA calls this “Nursing Home Compare” and it is available at http://www.medicare.gov.