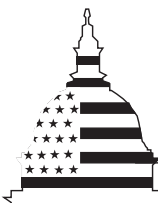


July 2004

MEDICARE

CMS Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals



G A O

Accountability * Integrity * Reliability



Highlights of [GAO-04-850](#), a report to congressional requesters

Why GAO Did This Study

Hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) are considered in compliance with Medicare participation requirements. GAO examined the extent to which JCAHO's pre-2004 hospital accreditation process identified hospitals not complying with Medicare requirements, the potential of JCAHO's new process for improving the detection of deficiencies in Medicare requirements, and the effectiveness of CMS's oversight of JCAHO's hospital accreditation program. GAO analyzed CMS data on hospitals state surveyors found to have deficiencies in Medicare requirements that JCAHO surveyors did not detect, analyzed CMS's measure of JCAHO's ability to detect noncompliance with Medicare requirements, and interviewed JCAHO officials.

What GAO Recommends

GAO believes that Congress should consider giving CMS the authority over JCAHO's hospital accreditation program that it has over other accreditation programs and recommends that CMS modify its methods for assessing JCAHO's performance. CMS agreed with GAO's recommendations. JCAHO stated that GAO's methodology was incomplete and did not comprehensively assess its overall performance. GAO emphasized that its engagement was limited to one aspect of deficiency detection and was not intended to reflect JCAHO's overall performance.

www.gao.gov/cgi-bin/getrpt?GAO-04-850.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Janet Heinrich at (202) 512-7119.

MEDICARE

CMS Needs Additional Authority to Adequately Oversee Patient Safety in Hospitals

What GAO Found

JCAHO's pre-2004 hospital accreditation process did not identify most of the hospitals found by state survey agencies in CMS's annual validation survey sample to have deficiencies in Medicare requirements. In comparing the results of the two surveys, CMS considered whether it was reasonable to conclude that the deficiencies found by state survey agencies existed at the time JCAHO surveyed the hospital. In a sample of 500 JCAHO-accredited hospitals, state agency validation surveys conducted in fiscal years 2000 through 2002 identified 31 percent (157 hospitals) with deficiencies in Medicare requirements. Of these 157 hospitals, JCAHO did not identify 78 percent (123 hospitals) as having deficiencies in Medicare requirements. For the same validation survey sample, JCAHO also did not identify the majority—about 69 percent—of deficiencies in Medicare requirements found by state agencies. Importantly, the number of deficiencies found by validation surveys represents 2 percent of the 11,000 Medicare requirements surveyed by state agencies in the sample during this time period. At the same time, a single deficiency in a Medicare requirement can limit the hospital's capability to provide adequate care and ensure patient safety and health. Inadequacies in nursing practices or deficiencies in a hospital's physical environment, which includes fire safety, are examples of deficiencies in Medicare requirements that could endanger multiple patients.

The potential of JCAHO's new hospital accreditation process to improve the detection of deficiencies in Medicare requirements is unknown because the process was just implemented in January 2004. JCAHO plans to move from using announced to unannounced surveys in 2006, which would afford JCAHO the opportunity to observe hospitals' operations when the hospitals have not prepared in advance to be surveyed. In addition, the pilot test of the new accreditation process was of limited value in predicting whether it will be an improvement over the pre-2004 process in detecting deficiencies. Limitations in the pilot test included that hospitals were not randomly selected to participate; that observers from JCAHO accompanied each surveyor, thus possibly affecting surveyors' actions; and that JCAHO evaluated the results instead of an independent entity.

CMS has limited oversight authority over JCAHO's hospital accreditation program because the program's unique legal status effectively prevents CMS from taking actions that it has the authority to take with other health care accreditation programs to ensure satisfactory performance. For example, requiring JCAHO's hospital accreditation program to submit to a direct review process or placing the program on probation while monitoring its performance. Further, CMS relies on a measure to evaluate how well JCAHO's hospital accreditation program detects deficiencies in Medicare requirements that provides limited information and can mask problems with program performance, uses statistical methods that are insufficient to assess JCAHO's performance, and has reduced the number of validation surveys it conducts.

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Abbreviations

AOA	American Osteopathic Association
CMS	Centers for Medicare & Medicaid Services
COP	condition of participation
HHS	Department of Health and Human Services
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
OIG	Office of Inspector General
PPF	priority focus process
PPR	periodic performance review

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United States Government Accountability Office
Washington, DC 20548

July 20, 2004

The Honorable Charles E. Grassley
Chairman
Committee on Finance
United States Senate

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

In fiscal year 2002, nearly 7.4 million Medicare beneficiaries received inpatient health care at hospitals that participated in Medicare. Federal law establishes criteria for hospitals for purposes of Medicare. The Centers for Medicare and Medicaid Services (CMS), the agency responsible for administering Medicare, has established quality and patient safety requirements called conditions of participation (COP) that hospitals must meet in order to be eligible for Medicare payment. Hospitals that are accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) are generally deemed under federal law to be compliant with Medicare requirements for patient safety and health and become eligible for payments from Medicare.^{1,2} No other health care accreditation program has this same statutory authority.

JCAHO is a private, not-for-profit organization that accredits most of the hospitals that participate in Medicare. JCAHO sets standards that accredited hospitals must meet and reports that these standards are more comprehensive than the Medicare COPs.³ In January 2004, JCAHO implemented a new hospital accreditation process with goals that included further enhancing health care quality and safety.

¹See 42 U.S.C. § 1395bb(a) (2000).

²JCAHO is referred to in statute under its former name, the Joint Commission on Accreditation of Hospitals.

³JCAHO develops its standards with a committee of experts and stakeholders, such as the government, hospitals, and consumers.

CMS oversight of JCAHO's hospital accreditation program is limited because it cannot restrict or remove JCAHO's accreditation authority if the agency detects problems. To oversee the program, CMS conducts on-site validation surveys of a sample of JCAHO-accredited hospitals and reports annually to Congress on the results of these surveys. The validation surveys, which are performed by agencies that CMS has agreements with in each state, help CMS determine whether Medicare quality and safety requirements are being met. CMS compares the results of these state surveys against survey results obtained through JCAHO's hospital accreditation program. CMS uses a measure called the rate of disparity that summarizes the extent to which an accreditation program has failed to cite deficiencies identified by state agency validation surveys. We are using the term serious deficiency in this report to indicate a deficiency in one or more Medicare COPs. Examples of serious deficiencies include a hospital's inability to provide adequate nursing services or failure to implement and enforce infection control policies. According to CMS, serious deficiencies substantially limit a hospital's capability to render adequate care and adversely affect the safety and health of patients.

Questions have been raised by the Department of Health and Human Services' (HHS) Office of Inspector General (OIG) and others regarding whether accreditation by JCAHO ensures that hospitals provide adequate care. Specifically, experts have questioned how well JCAHO's hospital accreditation process identifies deficiencies in hospitals that could jeopardize patient safety and health. A comprehensive study by the HHS OIG found that JCAHO's surveys were not likely to identify patterns of deficient care.⁴

You asked that we examine the effectiveness of JCAHO's hospital accreditation process in ensuring that hospitals comply with Medicare COPs to ensure the safety and health of Medicare beneficiaries. Specifically, we (1) examined the extent to which JCAHO's pre-2004 hospital accreditation process identified deficiencies in Medicare COPs that were identified by state survey agencies, (2) determined whether JCAHO's new hospital accreditation process has potential for improving the detection of deficiencies in Medicare COPs and whether the process was adequately tested, and (3) examined the effectiveness of CMS's oversight of JCAHO's hospital accreditation program.

⁴HHS OIG, *The External Review of Hospital Quality: A Call for Greater Accountability*, OEI-01-97-00050 (Washington, D.C.: July 1999).

To determine the extent to which JCAHO's pre-2004 hospital accreditation process identified deficiencies in Medicare COPs that were identified by state survey agencies, we used data from a CMS comparison of state validation survey findings with findings of JCAHO's hospital accreditation surveys, which indicated whether JCAHO found deficiencies in its standards. Of the four possible outcomes to this comparison of survey findings—(1) JCAHO and state agencies both identify no deficiencies, (2) JCAHO identifies deficiencies not found by state agencies, (3) JCAHO and state agencies both identify the same deficiencies, and (4) state agencies identify deficiencies that JCAHO does not—we focused on the fourth because it highlights the need for CMS oversight of the hospital accreditation program. For the second outcome, there could be two reasons for the disparity between JCAHO's and state survey agencies' findings: hospitals corrected deficiencies identified by JCAHO prior to the state agency survey or the state survey agency did not identify a deficiency that existed. In addition, not all JCAHO findings are equivalent to noncompliance with a Medicare COP. To determine whether JCAHO's findings on deficiencies in its standards were comparable to the state agencies' findings, CMS staff compared the two surveys and considered whether it was reasonable to conclude that the deficiencies found by state survey agencies existed at the time JCAHO surveyed the hospital. For deficiencies that CMS determined that JCAHO failed to identify, CMS met with JCAHO to address disputed findings and consider additional evidence on comparability offered by JCAHO. CMS provided results for a sample of 500 JCAHO-accredited hospitals from fiscal years 2000 through 2002. We determined that the data CMS provided on serious deficiencies were adequate for addressing the issues in this report. On the basis of this sample of 500 JCAHO-accredited hospitals, we determined, using CMS's data, both the percentage of serious deficiencies and the percentage of hospitals with serious deficiencies identified by the state survey agencies where JCAHO surveyors did not find comparable deficiencies. The analysis we performed on the results of the validation surveys was limited to the hospitals included in the validation survey sample and cannot be generalized to all JCAHO-accredited hospitals.

To determine whether JCAHO's new hospital accreditation process has potential for improving the detection of serious deficiencies, we identified changes in the accreditation process and analyzed significant new features. To determine whether JCAHO's new hospital accreditation process was adequately tested, we reviewed the testing procedures and results that JCAHO used to determine the effectiveness of its new survey process in identifying quality and safety deficiencies. Because the new accreditation process was implemented recently, we did not have

information to compare JCAHO survey performance in detecting serious deficiencies with state agency survey performance.

To determine the adequacy of CMS's oversight of JCAHO's hospital accreditation program, we reviewed relevant statutory and regulatory provisions regarding oversight of health care accreditation programs and how CMS had implemented this authority in order to provide oversight. To supplement our review, we conducted interviews with officials from CMS, state survey agencies, and JCAHO; representatives from other organizations active in health care accreditation and the hospital industry; and experts in quality of care. We conducted our work from June 2003 through July 2004 in accordance with generally accepted government auditing standards. (For a complete description of our scope and methodology, see app. I.)

Results in Brief

JCAHO's pre-2004 hospital accreditation process did not identify most of the hospitals found by state survey agencies in CMS's annual validation survey sample to have serious deficiencies in Medicare COPs. In a sample of 500 JCAHO-accredited hospitals, state agency validation surveys conducted in fiscal years 2000 through 2002 identified 31 percent (157 hospitals) with serious deficiencies; of these, JCAHO did not identify 78 percent (123 hospitals) as having serious deficiencies. For the same validation survey sample, JCAHO also did not identify the majority—about 69 percent—of serious deficiencies found by state agencies. Importantly, the number of deficiencies found by validation surveys represents 2 percent of the 11,000 Medicare COPs surveyed by state agencies in the sample during this time period. At the same time, a single serious deficiency can limit a hospital's capability to provide adequate care and ensure patient safety and health. Inadequacies in nursing practices or deficiencies in a hospital's physical environment, which includes fire safety, are examples of serious deficiencies that could endanger multiple patients.

The potential of JCAHO's new hospital accreditation process to improve the detection of serious deficiencies over the pre-2004 process is unknown because the process was just implemented in January 2004. JCAHO plans to move from announced to unannounced surveys in 2006, which would afford JCAHO the opportunity to observe hospitals' operations when the hospitals have not prepared in advance to be surveyed. In addition, the pilot test of the new accreditation process was of limited value in predicting whether it will be an improvement over the pre-2004 process in detecting deficiencies. Limitations in the pilot test included that hospitals

participating in the pilot were not randomly selected and that JCAHO evaluated the results instead of an independent entity.

CMS has limited oversight authority over JCAHO's hospital accreditation program because the program's unique legal status effectively prevents CMS from taking actions, such as requiring JCAHO's hospital accreditation program to submit to a direct review process or placing the program on probation while monitoring its performance, that it has the authority to take with other health care accreditation programs to ensure satisfactory performance. Furthermore, CMS's existing oversight of JCAHO's hospital accreditation program needs improvement. Although CMS officials said that validation surveys are conducted to assure Congress that JCAHO's accreditation process provides a reasonable assurance that hospitals comply with Medicare requirements, there are limitations to the agency's validation survey program. CMS has no formal written protocol for selecting the hospitals to include in the state agency validation survey sample; relies on a measure—the rate of disparity—that provides limited information and could mask problems with an accreditation program's performance in detecting serious deficiencies; uses statistical methods that are insufficient to accurately portray JCAHO's performance; and has reduced the percentage of validation surveys from 5 percent to approximately 1 percent of JCAHO-accredited hospitals, which provides less reliable information on the performance of JCAHO's hospital accreditation program.

We suggest that Congress consider giving CMS the same oversight authority over JCAHO's hospital accreditation program that CMS has for all other health care accreditation programs. To improve CMS's assessment of JCAHO's hospital accreditation process, we recommend that CMS modify the measure it uses to indicate how well an accreditation program detects serious deficiencies in Medicare COPs; maximize the extent to which validation survey findings can be generalized to all JCAHO-accredited hospitals and include its survey protocol in its annual reports to Congress; and annually conduct validation surveys on a sample of JCAHO-accredited hospitals that is equal to at least 5 percent of all JCAHO-accredited hospitals.

CMS and JCAHO commented on a draft of this report. In its comments, CMS concurred with our findings and recommendations. JCAHO stated that it did not object to our matter for congressional consideration that CMS be given the same oversight authority over JCAHO's hospital accreditation program that it has over other health care accreditation programs. JCAHO took issue with our methodology, which it said was

incomplete and did not comprehensively assess the performance of JCAHO's hospital accreditation program. Our review was not intended to be a comprehensive evaluation of JCAHO's hospital accreditation program. Rather, we focused on the ability of JCAHO's hospital accreditation program to ensure that hospitals that accept Medicare patients comply with Medicare COPs. In the same vein, JCAHO stated that the report does not sufficiently recognize JCAHO's identification of deficiencies in its surveys that may be corrected before state surveyors arrive. We added language to the report to emphasize that our focus was on the serious deficiencies state survey agencies found that JCAHO did not because these serious deficiencies demonstrate the importance of CMS oversight of the hospital accreditation process. JCAHO also stated that we misrepresented the potential of its new accreditation process to detect deficiencies in Medicare COPs and provided new data for the first quarter of 2004 that indicate that 2004 JCAHO surveys may have detected a greater percentage of deficiencies related to patient care compared with the pre-2004 accreditation process. However, we maintain that until CMS validation surveys for 2004 are completed, there is no basis on which to determine whether the new process improves the detection of noncompliance with Medicare COPs. CMS and JCAHO also provided technical comments on the report, which we incorporated as appropriate.

Background

To participate in Medicare, hospitals must maintain standards of patient safety and health that comply with Medicare COPs. For example, the COP related to nursing services includes such requirements for hospitals as providing a 24-hour nursing service that is supervised or furnished by a registered nurse. There are currently 23 Medicare COPs.⁵ (See app. II for a description of the 23 Medicare COPs.) CMS proposed revisions to all of the COPs in 1997, but it did not finalize them. Since then, CMS has revised several of the COPs, including those concerning the life safety code; quality assessment and performance improvement; organ, tissue, and eye donations; and nurse anesthetist supervision.

Health care accreditation programs other than JCAHO's hospital accreditation program may generally adopt their own requirements if CMS determines that an accreditation program's requirements are at least

⁵One of the 23 COPs cannot be deemed by an accreditation organization. CMS relies on organizations other than the accreditation organizations to certify that hospitals comply with the COP that requires hospitals to establish a utilization review plan for services provided to Medicare beneficiaries.

equivalent to Medicare COPs.⁶ If CMS also determines, among other things, that the accreditation program’s survey process is likely to identify any serious deficiencies in COPs, it must generally grant “deeming authority” to the accreditation program and treat entities accredited by these organizations as meeting Medicare COPs. CMS has the authority to review these programs, and it can impose a probationary period while monitoring performance and remove deeming authority if warranted.

JCAHO

Most hospitals demonstrate compliance with standards equivalent to Medicare COPs through accreditation by JCAHO.⁷ In 2002, JCAHO accredited 4,211, or 82 percent, of Medicare-participating hospitals.⁸ Hospitals accredited by JCAHO received payments for Medicare-covered inpatient services of approximately \$98 billion, or 90 percent, of the \$109 billion that was spent on hospital care in 2002. JCAHO, as part of its accreditation-related activities, also develops survey procedures, trains its surveyors, and formulates performance measures. JCAHO is governed by a 29-member board of commissioners and has a staff of over 1,000.⁹

JCAHO’s deeming authority for hospitals is established in statute and therefore can only be changed by Congress. As a result of this unique statutory authority, hospitals accredited by JCAHO—because they meet

⁶Specifically, the agency’s regulations require the accreditation organization’s standards to be at least as stringent as the Medicare COPs, when taken as a whole. *See* 42 C.F.R. § 488.6(a) (2003).

⁷Forty-nine states allow JCAHO hospital accreditation as a full or partial substitute for meeting health care quality standards and other requirements for state licensure.

⁸The remaining 18 percent of hospitals choose to be accredited by the American Osteopathic Association (AOA) or to be certified by state survey and certification agencies.

⁹The board includes seven members chosen by the American Hospital Association, seven chosen by the American Medical Association, three chosen by the American College of Physicians—American Society of Internal Medicine, three chosen by the American College of Surgeons, and one chosen by the American Dental Association. In addition, the board consists of a nurse-at-large and six public members. The president of JCAHO is an ex officio member of the board.

JCAHO standards—are deemed to meet Medicare COPs as well.¹⁰ In contrast, the American Osteopathic Association (AOA)—a private, not-for-profit professional organization that offers accreditation services for hospitals and other health care organizations—holds deeming authority that is subject to CMS’s direct review and approval.¹¹ While hospital accreditation is its largest program, JCAHO also has accreditation authority under Medicare for certain other health care providers, including clinical laboratories, hospices, ambulatory surgical centers, and home health care agencies. All of these other JCAHO accreditation programs are subject to CMS’s direct review and approval.

To be accredited by JCAHO, a hospital must meet eligibility requirements, satisfactorily complete a triennial on-site survey process, and continue to maintain JCAHO’s standards between surveys. The accreditation surveys that JCAHO conducts every 3 years are particularly important. For most hospitals, the triennial survey is the only time that JCAHO conducts an on-site review of the hospital’s compliance with all quality standards and issues decisions on how well the hospital has complied with JCAHO’s standards. In 2004, JCAHO implemented a new hospital accreditation survey process, which, according to JCAHO, is intended to reduce the cost of accreditation to health care organizations and JCAHO, enhance public confidence that health care organizations are in continuous compliance with standards, increase the real and perceived value of accredited organizations, meet the requirements of deeming authorities and purchasers, and improve satisfaction for hospitals participating in the accreditation program.

¹⁰When Congress first established JCAHO’s deeming authority in 1965, it prohibited federal authorities from issuing standards on patient health and safety for hospitals higher than comparable requirements for hospital accreditation by JCAHO in deference to the expertise of professional accreditation organizations sponsored by medical and hospital associations. *See* Pub. L. No. 89-97, § 102(a), 79 Stat. 286, 315 (1965). Subsequent legislation removed the prohibition and required JCAHO to demonstrate that its standards were at least equivalent to any such higher standards issued by the Secretary in order to have deeming authority in that area. *See* Pub. L. No. 92-603, § 244(c), 86 Stat. 1329, 1423 (1972).

¹¹AOA solely accredits approximately 2 percent of hospitals and JCAHO and AOA jointly accredit less than 1 percent of hospitals. While JCAHO and AOA are currently the only hospital accrediting organizations, federal law permits CMS to approve any other national accreditation body that demonstrates that Medicare requirements will be met by hospitals it accredits.

CMS Oversight of JCAHO

CMS exercises oversight of JCAHO's hospital accreditation program primarily through its validation surveys and annual reports to Congress. Under federal law, CMS must continually study the operation and administration of Medicare, including validating the JCAHO hospital accreditation process, and submit annual reports to Congress.¹² CMS has agreements with state agencies to conduct validation surveys. There are different kinds of validation surveys, including traditional validation surveys—surveys conducted on a sample of hospitals within 60 days of their triennial JCAHO survey.¹³ Traditional validation surveys provide the basis for assessing the effectiveness of JCAHO's hospital accreditation process in detecting deficiencies in Medicare COPs, which JCAHO-accredited hospitals are treated as meeting. Validation surveys also include 18-month surveys, which monitor how well JCAHO-accredited hospitals are complying with Medicare COPs midway between their 3-year JCAHO surveys, and allegation surveys, which are triggered by complaints or other reports of situations that pose potential threats to patient health and safety in JCAHO-accredited hospitals. CMS has the authority to remove the deemed status of a JCAHO-accredited hospital where a state agency's validation survey results in a finding that the hospital is out of compliance with one or more Medicare COP.

CMS uses a rate of disparity measure to summarize the extent to which an accreditation program, such as JCAHO's hospital accreditation program, has not found serious deficiencies identified by CMS through state agency validation surveys. For a hospital accreditation program, using the results from validation surveys, the rate of disparity for hospitals surveyed by the state survey agencies is calculated as the difference between the number of hospitals found with serious deficiencies by state agencies and the number of hospitals found with comparable deficiencies by the accreditation program, divided by the number of hospitals sampled. CMS regulations provide that if the validation survey results for an accreditation organization with deeming authority indicate a rate of disparity that reaches the threshold level of 20 percent disparity or greater, CMS will notify the organization that its deeming authority may be in jeopardy and that the agency is initiating a deeming authority review.¹⁴ With respect to JCAHO, CMS includes the rate of disparity in its annual

¹²See 42 U.S.C. § 1395ll(b).

¹³For this report, we will refer to traditional validation surveys as validation surveys.

¹⁴42 C.F.R. 488.8(e).

reports to Congress in which it reports the results of its validation program for JCAHO's hospital accreditation program.

JCAHO's Pre-2004 Hospital Accreditation Process Often Did Not Detect Serious Deficiencies Found by State Survey Agencies

JCAHO's pre-2004 hospital accreditation process often did not identify either hospitals with serious deficiencies or the individual serious deficiencies found by state survey agencies through CMS's validation program. In a sample of 500 JCAHO-accredited hospitals, state agency validation surveys conducted in fiscal years 2000 through 2002 identified 31 percent (157 hospitals) with serious deficiencies; of these, JCAHO did not identify 78 percent (123 hospitals) as having serious deficiencies. For the same validation survey sample, the majority of the serious deficiencies state survey agencies identified but JCAHO did not were in the physical environment COP category, which covers fire safety and prevention.

JCAHO Did Not Identify Three-Quarters of the Hospitals That State Survey Agencies Found to Have Serious Deficiencies

From fiscal years 2000 through 2002, JCAHO did not identify 123 of the 157 hospitals (78 percent) with serious deficiencies that CMS's validation program identified out of a sample of 500 JCAHO-accredited hospitals. Table 1 shows the hospitals with serious deficiencies that state survey agencies identified and JCAHO did not during fiscal years 2000 through 2002. In 343 of the 500 hospital validation surveys, state agency surveyors did not find serious deficiencies. Both state agency surveyors and JCAHO surveyors identified 34 hospitals as having a serious deficiency.

Table 1: Hospitals in CMS’s Validation Survey Sample with Serious Deficiencies that State Survey Agencies Identified but JCAHO Surveyors Did Not, Fiscal Years 2000-2002

Fiscal year	Number of hospitals in CMS’s validation sample	Hospitals state survey agencies found to have serious deficiencies		Hospitals with serious deficiencies identified by state survey agencies but not identified by JCAHO ^a	
		Number	Percent	Number	Percent
2000	184	61	33	49	80
2001	204	61	30	49	80
2002	112	35	31	25	71
Total	500	157	31	123	78

Source: GAO analysis of CMS data.

Note: Hospitals with serious deficiencies are defined as those not meeting one or more of the Medicare COPs. From fiscal year 2000 through 2002, JCAHO surveyed 4,666 hospitals for accreditation.

^aDetermined by CMS through its matching of deficient COPs found by state agency surveyors to JCAHO surveyors’ findings of JCAHO standards out of compliance.

According to JCAHO, disparity between state agency and JCAHO findings in the 123 hospitals in part may be attributed to the timing of the two surveys, JCAHO’s phasing in of new requirements, different interpretations of the COPs by state surveyors, and inherent surveyor bias. However, in its comparison to determine disparity between the two surveys, CMS does consider whether it is reasonable to conclude that the deficiencies found by state survey agencies existed at the time JCAHO surveyed the hospital.

JCAHO Did Not Detect Two-Thirds of the Serious Deficiencies Identified by State Survey Agencies

From fiscal year 2000 through 2002, JCAHO did not detect 167 of the 241 serious deficiencies (69 percent) identified through CMS’s validation program from a sample of 500 JCAHO-accredited hospitals. The number of serious deficiencies found by CMS’s validation program represents 2 percent of the 11,000 Medicare COPs surveyed by state agencies in the sample and were found in 157 hospitals. However, one serious deficiency in any one of these hospitals could limit its ability to provide adequate care to its patients. For example, a serious deficiency in the nursing services COP at a hospital in Texas found by a state agency but missed by JCAHO in 2000 included such problems as failure to prepare and administer drugs in accordance with federal and state laws, inadequate supervision and

evaluation of the clinical activities of nonemployee nursing personnel, and nursing care and procedures provided to patients that were not within the scope of accepted standards of practice. Among hospitals with serious deficiencies identified by CMS's validation program but not by JCAHO, there were on average 1.1 serious deficiencies per hospital, with a range from 1 to 6. Table 2 shows the percentage of serious deficiencies identified by CMS's validation program but not by JCAHO for fiscal years 2000 through 2002.

Table 2: Percentage of Serious Deficiencies Identified by State Survey Agencies but Not by JCAHO Surveyors in CMS's Validation Survey Sample, Fiscal Years 2000-2002

Fiscal year	Number of serious deficiencies identified by state survey agencies	Number of serious deficiencies identified by JCAHO	Serious deficiencies identified by state survey agencies but not by JCAHO ^a	
			Number	Percent
2000	82	12	70	85
2001	103	40	63	61
2002	56	22	34	61
Total	241	74	167	69

Source: GAO analysis of CMS data.

Note: Hospitals with serious deficiencies are defined as those not meeting one or more of the Medicare COPs.

^aDetermined by CMS through its matching of deficient COPs found by state agency surveyors to JCAHO surveyors' findings of JCAHO standards out of compliance.

Of the 167 serious deficiencies identified by CMS's validation program from fiscal year 2000 through 2002 but not detected by JCAHO, 87 were related to a hospital's physical environment, which includes life safety code standards on fire prevention and safety.¹⁵ For these 3 years, JCAHO did not detect 81 percent of the serious physical environment deficiencies identified by state agency surveyors. Table 3 shows the number of serious deficiencies, by category, identified by state survey agencies in CMS's

¹⁵Between fiscal years 2000 and 2002, JCAHO used more recent life safety code standards than state survey agencies performing validation surveys. CMS stated that these differences could account for some of the disparate findings between JCAHO's surveys and state agency validation surveys. However, CMS considered these different standards in determining whether JCAHO had not detected serious deficiencies in the life safety code.

validation program but missed by JCAHO surveyors. The larger number of deficiencies in physical environment may be related to the difference in how state agencies generally survey separately a hospital's compliance with the life safety code portion of the physical environment COP. JCAHO surveys assess compliance with the life safety code using a combination of the hospital's self-assessment, a hospital building tour, and observations made by all surveyors during the survey process. Examples of deficiencies in physical environment that JCAHO did not identify but CMS's validation program found in a hospital in Alabama in 2000 included the following: several exterior exits lacked emergency exit lighting; several exterior exits were illuminated only by single light bulbs; fire alarm system and fire extinguishers had not been inspected annually as required; and an automatic sprinkler system had not been inspected annually and maintained by certified personnel as required. Serious deficiencies in the COP on physical environment compromise patient safety and health.

Table 3: Number of Serious Deficiencies, by COP, Identified by State Survey Agencies but Not by JCAHO Surveyors in CMS’s Validation Survey Sample, Fiscal Years 2000-2002

COP	Number of serious deficiencies identified by state survey agencies	Number of serious deficiencies identified by state survey agencies but not by JCAHO^a
Physical environment	107	87
Quality of care		
Anesthesia services	3	2
Discharge planning	2	2
Emergency services	2	2
Food and dietetic services	5	4
Governing body	16	7
Infection control	15	9
Laboratory services	1	1
Medical record services	7	4
Medical staff	10	1
Nursing services	17	10
Organ, tissue, and eye procurement	5	5
Outpatient services	1	1
Patients’ rights	10	9
Pharmaceutical services	14	9
Quality assurance	18	8
Radiologic services	1	0
Rehabilitation services	1	1
Respiratory care services	1	1
Surgical services	5	4
Total quality-of-care COPs	134	80

Source: GAO analysis of CMS data.

Note: Neither state survey agencies nor JCAHO identified serious deficiencies in two of the categories—compliance with laws and nuclear medicine services—which are not included in this table.

^aDetermined by CMS through its matching of deficient COPs found by state agency surveyors to JCAHO surveyors’ findings of JCAHO standards out of compliance.

The total number of deficiencies not identified by JCAHO in the quality-of-care COP categories—those COPs that involve the oversight and delivery of patient care—is similar to the number not identified by JCAHO in the

physical environment COP. While the number of serious deficiencies not found by JCAHO in individual quality-of-care COP categories is smaller than the number not found in physical environment, when these quality-of-care COPs are combined, the proportion of serious deficiencies JCAHO missed is almost 60 percent of the total number of serious deficiencies identified by state survey agencies. The following are examples of hospitals found to be out of compliance with multiple quality-of-care COPs:

- In 2000, CMS removed the deemed status as a Medicare provider of a JCAHO-accredited hospital in California for failure to comply with two COPs, one of which was infection control. The hospital failed to provide a sanitary environment to avoid sources and transmission of infections and communicable diseases and failed to develop a system for ensuring the sterilization of medical instruments.
- Also in 2000, CMS notified a hospital in Texas that if it did not implement a plan of correction the hospital's participation in the Medicare program would be terminated. Serious deficiencies at this hospital included lack of compliance with the pharmaceutical services and nursing services COPs because medications were administered without physician orders and a double dose of narcotics was given in the emergency room, with no explanation for the excessive dosage, to a patient who later died.

State surveyors in CMS's validation program also may miss serious deficiencies. In related work on skilled nursing facilities and home health agencies, we found that the number of serious deficiencies found by state agencies was highly variable among states and may be understated.¹⁶ State agencies' detection of serious deficiencies in hospitals also varied widely among states for the 3 years we reviewed. For example, state survey agencies in California, Illinois, and Ohio found serious deficiencies in over 45 percent of the surveys they conducted between fiscal years 2000 through 2002. In contrast, Florida and New York found serious deficiencies in less than 10 percent of the surveys they conducted, and Louisiana did not find serious deficiencies in any of the surveys it conducted.¹⁷

¹⁶U.S. General Accounting Office, *Medicare Home Health Agencies: Weaknesses in Federal and State Oversight Mask Potential Quality Issues*, [GAO-02-382](#) (Washington, D.C.: July 19, 2002) and U.S. General Accounting Office, *Nursing Home Quality: Prevalence of Serious Problems, While Declining, Reinforces Importance of Enhanced Oversight*, [GAO-03-561](#) (Washington, D.C.: July 15, 2003).

¹⁷All six states conducted at least 15 validation surveys from fiscal year 2000 through 2002.

Potential of JCAHO's New Hospital Accreditation Process Is Unknown, and Testing Was Limited

The potential of JCAHO's new hospital accreditation process to improve the identification of serious deficiencies is unknown because it is too soon after its January 2004 implementation for a meaningful evaluation; in addition, JCAHO's testing of the new process was limited. CMS has not had the opportunity to complete its validation program for 2004 to determine whether JCAHO surveyors using the new process are missing serious deficiencies later identified by state agency validation surveys. While unannounced surveys, which are planned for implementation in 2006, have the potential to improve the detection of serious deficiencies, other features of the new process that JCAHO did not test before implementation may have limitations that could affect the potential of the new process to identify problems with patient care. JCAHO's pilot test of the new process had limitations, including using a sample of hospitals that volunteered for the pilot instead of using a random sample and self-evaluating the results instead of using an independent entity.

Potential of New Process Is Unknown

Because JCAHO's new accreditation process was implemented in January 2004, it is too soon to know whether the new process is better at detecting serious deficiencies in Medicare COPs than the pre-2004 accreditation process. A JCAHO official told us the new process will aid in the detection of deficiencies, but we found that some of the features may have shortcomings that could limit their effectiveness. New features of the accreditation process include the hospital's self-assessment of compliance with accreditation standards midway through the accreditation cycle, surveyor review of the care provided to specific patients to determine the adequacy of the hospital's health care delivery system, and performance of all accreditation surveys on an unannounced basis beginning in 2006. (See app. III for a description of selected new features of JCAHO's new hospital accreditation process.)

Periodic Performance Review

Periodic performance reviews assess hospital compliance with applicable standards and are performed at the 18-month midpoint between 3-year on-site accreditation surveys. According to JCAHO, the periodic performance review will have several benefits. These include providing hospitals with a process to assess their ongoing compliance and requiring them to correct or plan to correct all deficiencies identified. Periodic performance reviews must be conducted either by the hospital as a self-assessment or, if the hospital chooses, by JCAHO through an on-site review.

However, periodic performance reviews may not necessarily improve the detection of deficiencies. JCAHO did not pilot test these reviews for the potential to detect deficiencies and did not test whether hospitals that

Priority Focus Process and Patient Tracer Methodology

conducted reviews do a better job of continuing to comply with standards. In addition, for hospitals performing self-assessments, JCAHO will not check these self-assessments to determine whether hospitals fully and accurately identified quality problems and developed adequate corrective action plans to address the problems identified.

According to JCAHO, the priority focus process and patient tracer methodology together have the potential to enhance the ability of surveys to detect deficiencies by directing the attention of surveyors to key patient care areas. The priority focus process uses a data-based formula to identify a limited number of areas in each hospital that are particularly important to patient health and safety. Priority focus areas might include infection control, medication management, or patient safety. Surveyors use the priority focus process combined with the patient tracer methodology to focus their surveys to specific areas for review. The patient tracer methodology guides their choice of current patients to “trace” through the experience of care within an organization. For example, if the hospital’s priority focus process data suggest that a patient with an orthopedic-related diagnosis such as a hip fracture should be traced, the JCAHO surveyor would review the patient’s medical record, noting where the patient had entered into the hospital and any services and transfers that occurred. Then the surveyor would retrace the steps in the patient’s care process by observing and talking to staff in some of the areas in which the patient received care. If the patient entered through the emergency department, was transferred to a medical/surgical unit, and then went to the operating room, the surveyor would go to these areas to interview staff about the care given to this specific patient. With information from patient tracers, the surveyor will assess whether any compliance issues exist with JCAHO standards. If the surveyor identifies a compliance issue while tracing one patient, the surveyor may review the records of similar patients to determine whether the problem is isolated or represents a pattern of care.

However, JCAHO did not test the extent to which the priority focus process and the patient tracer methodology could help surveyors detect deficiencies. A JCAHO official told us these new features of the accreditation process were intended to help surveyors trace patients in a consistent way and not necessarily to improve the detection of deficiencies.

Unannounced Surveys

JCAHO plans to conduct all hospital accreditation surveys on an unannounced basis beginning in 2006.¹⁸ JCAHO stated that unannounced surveys will ensure that hospital performance is based on the observation of hospitals' routine operations rather than on how they operate after they have the opportunity to prepare to be surveyed. A JCAHO official also indicated that unannounced surveys will be more likely to detect deficiencies. The OIG and other organizations share JCAHO's position on the value of unannounced surveys of hospitals and other health care organizations. The value of unannounced surveys also has been recognized for nursing homes, which state agencies survey on an unannounced basis.

JCAHO's Pilot Test of New Process Was Limited

JCAHO's pilot test of its new hospital accreditation process was limited and therefore unable to help determine the potential of the new process to detect deficiencies in Medicare COPs. According to JCAHO, the pilot test suggests that the new process was more likely than the former process to find quality problems. However, the pilot test sample included hospitals that volunteered or were selected by JCAHO and were not randomly selected, pilot test surveyors were accompanied by observers from JCAHO's central office, and pilot test results were not independently evaluated. In addition, CMS has not completed its fiscal year 2004 validation program, which will include hospitals surveyed by JCAHO using the new process and thus does not yet have sufficient data on which to base a meaningful evaluation.

According to JCAHO's analysis of the pilot test, the new hospital accreditation process is more likely to identify quality problems since proportionately more hospitals under the new process received unfavorable accreditation decisions. JCAHO based its conclusion on a comparison of survey outcomes, called accreditation decisions, between 18 hospitals in the pilot test conducted in 2002 and 2003 and the 1,524 hospitals that had been surveyed under the pre-2004 accreditation process during 2003. Table 4 presents the data JCAHO used to make the comparison. As shown, proportionately fewer hospitals under the new process were accredited without having to make corrections. Although JCAHO provided the accreditation decision outcomes for these 18 pilot

¹⁸In 2004 and 2005, JCAHO will continue to conduct its accreditation surveys on an announced basis.

tests, it stated it preferred to use the number of “requirements for improvement” as the basis for analysis.

Table 4: Accreditation Decisions for Hospitals Surveyed Under JCAHO’s New Survey Process Pilot Test as Compared to Results from JCAHO’s Pre-2004 Survey Process

Accreditation decision	Pilot test of new survey process		Pre-2004 survey process	
	Number of hospitals surveyed	Percentage of hospitals surveyed	Number of hospitals surveyed	Percentage of hospitals surveyed
Accreditation	0	0	320	21
Survey findings with requirements for improvement ^a	13	72	1,191	78
Conditional accreditation	3	17	13	1
Preliminary denial of accreditation	2	11	0	0
Total	18	100	1,524^b	100

Source: JCAHO.

Note: JCAHO reported that it conducted pilot tests of the new accreditation process in an additional 12 hospitals in 2001. However, JCAHO was unable to provide the accreditation decisions for these 12 pilot site hospitals.

^aHospitals in the pilot test with deficiencies were accredited contingent upon evidence of correcting deficiencies. The hospitals in the comparison group with deficiencies received accreditation with requirements for improvement.

^bThese 1,524 hospitals represent all those surveyed for accreditation by JCAHO during 2003.

However, JCAHO’s pilot test analysis was limited in three respects, which may have accounted for the smaller number of favorable accreditation decisions hospitals received under the new process.

- The hospitals participating in the pilot test were not randomly selected by JCAHO. As a result, these hospitals may not be representative of all JCAHO-accredited hospitals and therefore results cannot be generalized.

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- During the pilot test, an observer from JCAHO’s central office accompanied each surveyor, and the knowledge that they were being observed may have influenced the surveyors’ actions.¹⁹ Under the pre-2004 process, observers only rarely accompanied JCAHO surveyors.
 - JCAHO conducted its own evaluation of pilot test results. Evaluation of the pilot test by an entity independent of either JCAHO or the hospitals tested could help to ensure that survey outcomes were impartially interpreted. For example, CMS used an independent group to evaluate its redesign of the nursing home survey process.

CMS Oversight Authority of JCAHO’s Hospital Accreditation Program Is Limited and Needs Improvement

CMS has limited oversight authority over JCAHO’s hospital accreditation program, and its existing oversight activities need improvement. The unique status of JCAHO’s hospital accreditation program, which is specified in statute, does not permit CMS to take corrective action, such as restricting or removing its deeming authority. Additionally, CMS uses a measure that provides limited information to evaluate the performance of JCAHO’s hospital accreditation program, has significantly reduced the number of surveys conducted as part of CMS’s validation program, and does not use measures that are based on sound statistical methods to assess the performance of JCAHO’s hospital accreditation program.

CMS Oversight Authority of JCAHO Is Limited

Because of JCAHO’s unique legal status, CMS’s oversight of JCAHO’s hospital accreditation program is limited in two major ways: Unlike other accreditation programs with deeming authority, JCAHO does not have to reapply to CMS to reauthorize its deeming authority, and CMS cannot take action to address performance problems with JCAHO’s hospital accreditation program.

JCAHO’s hospital accreditation program is the only Medicare accreditation program for which CMS does not have to conduct an evaluation of the accreditation standards and the processes used to conduct surveys. Without this evaluation, CMS is deprived of key oversight tools it is authorized to use with other accreditation programs: detailed information

¹⁹For example, we found in our nursing home survey work in 1999 that state surveyors may perform their tasks more attentively when they are being observed by federal surveyors than they would if performing their surveys unobserved, thus masking a state surveyor’s typical performance. U.S. General Accounting Office, *Nursing Home Care: Enhanced HCFA Oversight of State Programs Would Better Ensure Quality*, [GAO/HEHS-00-6](#) (Washington, D.C.: Nov. 4, 1999).

about any proposed changes to the accreditation process and public input. CMS cannot require JCAHO to provide information about proposed changes to its accreditation requirements and hospital survey processes. Also, because it is not required to reapply to CMS for deeming authority, JCAHO does not have to provide CMS information that other accreditation programs must provide, such as a detailed description of its survey processes, a comparison of its standards to Medicare requirements, and the qualifications of its surveyors, which CMS reviews to ensure that the programs comply with Medicare requirements. For example, when JCAHO's hospice accreditation program applied for deeming status in 1999, CMS required changes to JCAHO's hospice accreditation process, including requiring JCAHO to make unannounced surveys of Medicare-certified hospices. According to a CMS official, JCAHO's hospital accreditation program has provided much of the information required of other accreditation organizations; however, CMS has no authority to require JCAHO to make changes to the hospital accreditation program as it does with other health care accreditation programs. Statutory provisions regarding public notice and comment do not apply to JCAHO's hospital accreditation program as they do to other accreditation programs. The reapplication process for other accreditation programs requires affording the public an opportunity to provide input to CMS on an accreditation program's request for deeming authority. Because JCAHO does not have to reapply for deeming authority, the public does not have the opportunity to review and comment on JCAHO's hospital accreditation program.²⁰

A second limitation is CMS's inability to address any performance issues with JCAHO's hospital accreditation program. Although the rate of disparity for JCAHO's hospital accreditation program exceeded 20 percent in fiscal years 2000, 2001, and 2002—a rate that would have triggered a deeming authority review for any other Medicare accreditation program—CMS was unable to take enforcement action to address JCAHO's performance. When other Medicare accreditation programs have a rate of disparity of 20 percent or more, CMS can take steps such as imposing a year-long probationary period and removing deeming authority at the end of the probationary period if the rate of disparity remains at 20 percent or more. For JCAHO, however, CMS's actions toward correcting the program's deficiencies are limited to including recommendations for

²⁰Whenever CMS considers, approves or removes an accreditation organization's deeming authority, the agency is required to publish detailed notices in the *Federal Register*, and consider public comment. See 42 U.S.C. § 1395bb(b)(3); 42 C.F.R. § 488.8(b) and (f)(7).

improvement in its annual reports to Congress and negotiating with JCAHO to voluntarily adopt CMS's recommendations.

In its annual report to Congress, CMS made recommendations in fiscal year 2002 aimed at improving JCAHO's ability to detect serious deficiencies in the life safety code, part of the COP on physical environment. CMS noted that JCAHO permits hospitals to self-assess compliance with life safety code requirements.²¹ While CMS stated that it did not object to the concept of hospital self-assessment of life safety code requirements, it made five recommendations to JCAHO for improving implementation:

1. Require hospitals to use qualified personnel, such as fire marshals and architects, to conduct self-assessments of compliance with the life safety code requirements.
2. Set minimum standards for identifying and improving life safety code deficiencies identified by hospital self-assessments.
3. Require hospitals to submit their self-assessments on life safety code issues prior to JCAHO conducting accreditation surveys to provide surveyors and personnel in JCAHO's central office time to review the material prior to the accreditation surveys.
4. Increase the use of JCAHO experts in the life safety code requirements in its central office.
5. Address the issue of hospitals that do not make improvement within self-determined time frames.

JCAHO did not adopt all of these recommendations. It disagreed with the first recommendation. Its response indicated that its requirement to use qualified personnel to complete the self-assessment, while more general, was sufficient. It further indicated that policies were in place for CMS's second and fifth recommendations. CMS later agreed that JCAHO's policies do satisfactorily address the fifth recommendation. JCAHO planned to examine ways to adopt CMS's third and fourth recommendations. CMS however, had no authority to compel JCAHO to

²¹Beginning in 1995, JCAHO-accredited hospitals have assessed their own compliance with the life safety code and developed correction plans, which JCAHO must approve. If hospitals are in compliance with their correction plans, JCAHO's surveyors do not record outstanding life safety code deficiencies.

comply with the remaining recommendations. According to CMS, it continues to discuss implementation of its recommendations with JCAHO. JCAHO stated that while its initial response to CMS's recommendations in 2003 reflected then current JCAHO policies, subsequent policy evolutions are addressing CMS's recommendations. Specifically, JCAHO is working with the American Society of Hospital Engineers to develop a process for review by experts of hospital self-assessments on life safety code issues prior to JCAHO's conducting on-site accreditation surveys and to identify those hospitals for which engineering expertise should be added to on-site surveys.

CMS's Validation Program Needs Improvement

CMS states that the goal of its validation program is to provide reasonable assurance to Congress that the JCAHO accreditation process ensures hospital compliance with Medicare COPs. However, the measure CMS uses to evaluate the performance of JCAHO's hospital accreditation program provides limited information and could mask problems with an accreditation program's performance in detecting serious deficiencies, and it is based on a target sample size of 1 percent of JCAHO-accredited hospitals. In addition, CMS does not report the extent to which its sample reflects the performance of the larger population of JCAHO-accredited hospitals.

Rate of Disparity

The rate of disparity between JCAHO's hospital accreditation survey findings and state survey agency findings, as currently calculated by CMS, does not fully explain the performance of JCAHO's hospital accreditation program in detecting serious deficiencies. CMS uses this measure in its reports to Congress to assess JCAHO's hospital accreditation program and as the basis for making recommendations for improvement. CMS calculates the rate of disparity as the difference between the number of hospitals found with serious deficiencies by state survey agencies and the number of hospitals found with serious deficiencies by the accreditation survey, divided by the number of hospitals in the sample. For example, if state survey agencies conducted 200 surveys as part of CMS's validation program and found 60 hospitals out of compliance with at least one COP, but JCAHO's survey found that only 22 of the hospitals were out of compliance, the rate of disparity would be 19 percent $((60 - 22)/200)$.

CMS has established in regulation a rate of disparity of 20 percent or greater as the threshold for taking action against an accreditation program. According to a CMS official, the use of 20 percent as the threshold is not based on empirical evidence but rather on what CMS believed Congress would find acceptable. Consequently, the threshold

may not be appropriately placed to indicate unacceptable performance by a hospital accreditation program. For example, if JCAHO failed to identify serious deficiencies in all 14 hospitals that the state agencies identified with serious deficiencies from a sample of 79 hospitals, the rate of disparity would be a satisfactory 18 percent $((14-0)/79)$.²²

CMS's rate of disparity measure used in isolation does not consistently reflect an accreditation program's ability to detect serious deficiencies. As the number of hospitals with serious deficiencies detected by state survey agencies decreases, regardless of JCAHO's performance in detecting them, it is more likely that the rate of disparity will be less than CMS's 20 percent threshold. As a result, the performance of JCAHO's hospital accreditation program is difficult to judge based on this measure alone. For example, if state survey agencies performed 200 validation surveys and found 100 hospitals or 50 percent with serious deficiencies and JCAHO found 30 hospitals or 30 percent of the hospitals found by state agencies, the rate of disparity would be 35 percent $((100-30)/200)$. However, if the state agencies found 50 hospitals, or 25 percent, of the 200 hospitals with serious deficiencies and JCAHO found 15 hospitals, or 30 percent of the hospitals that the state agencies identified, the rate of disparity would be almost 18 percent $((50-15)/200)$. The percentage of serious deficiencies found by state survey agencies and also by JCAHO remained the same in both examples, but the rate of disparity was improved significantly by the larger number of hospitals without serious deficiencies in the second example. This indicates that the rate of disparity does not consistently measure the accreditation program's ability to detect serious deficiencies found by state survey agencies. (See table 5.) In addition to the rate of disparity, other components, such as the proportion of hospitals with serious deficiencies and the total number of serious deficiencies found by state agencies but missed by the accreditation program, are important indicators of an accreditation program's overall performance.

²²The example is based on the analysis of the rate of disparity in American Institutes of Research, *Measurement and Evaluation of Revised Accredited Hospital Validation and Oversight* (Washington, D.C.: Nov. 6, 2002).

Statistical Analysis of
Validation Survey Sample

Table 5: Hypothetical Examples of the Effect on the Rate of Disparity of a Decrease in the Number of Hospitals with Serious Deficiencies in a Sample of 200 Hospitals

	Example 1		Example 2	
	State agencies	JCAHO	State agencies	JCAHO
Number of hospitals with serious deficiencies	100	30	50	15
Percentage of hospitals state agencies found with serious deficiencies that were also found by JCAHO		30%		30%
Percentage of hospitals without serious deficiencies identified by state agencies		50%		75%
Rate of disparity	35% ((100-30)/200)		18% ((50-15)/200)	
Performance level	Above threshold		Below threshold	

Source: GAO.

Note: CMS's rate of disparity threshold is 20 percent.

CMS does not analyze the statistical results of its validation survey samples in ways that would allow it to better assess JCAHO's ability to detect serious deficiencies. CMS has not documented the methods it uses to select hospitals for validation surveys and did not supply us with clear technical justification for the methods used. Further, CMS's validation sample includes hospitals that, because of its sampling method, have varying chances of selection, but it does not take this into account when calculating statistics based on the sample. According to CMS's sampling method, the selection of hospitals is influenced by factors such as the month in the fiscal year that JCAHO performed the accreditation survey and how many hospitals were targeted for completion that year in the state in which the hospital was located. Thus, some hospitals have a greater chance of selection than others. CMS also does not take these different chances of selection into account when calculating statistics for its annual reports to Congress, which prevents CMS from accurately assessing JCAHO's performance. Moreover, CMS does not measure and report in its annual reports the extent to which its estimates based on the

validation survey sample are likely to reflect how well JCAHO detects deficiencies in the larger population of hospitals it accredits.²³

In addition, the number of usable traditional validation surveys completed is smaller than the number of hospitals CMS samples for validation surveys. This difference may affect the accuracy of the data that CMS presents to Congress if the hospitals where the traditional surveys were completed produce different results than those where surveys are not completed or are not usable. During its sampling process, CMS selects a sample size close to the targeted number of hospitals each year. Some hospitals from this sample may be excluded because CMS chose to perform another type of survey for them that cannot be used to validate a JCAHO accreditation survey. In addition, state agencies are not always able to complete the requested traditional validation surveys within 60 days from the JCAHO accreditation survey, as required, or a hospital may be excluded because it lost its deemed status or closed. The size of the difference between the number of hospitals sampled and the number of usable traditional validation surveys completed therefore varies, as it did during the 3-year review period (see table 6).

Table 6: Number of Hospitals Targeted for Validation Surveys Compared with Usable Traditional Validation Surveys Completed

Fiscal Year	Hospitals targeted for validation surveys^a	Hospitals sampled for validation surveys^b	Usable traditional validation surveys completed^c
2000	236	236	184
2001	227	217	204
2002	227	235	112

Source: CMS.

^aThe targeted number is set at the beginning of the fiscal year and is used for planning and resource allocation by CMS and the state survey agencies.

^bThe sampled hospitals are the hospitals selected for validation surveys during the year.

^cUsable surveys exclude those not completed, those completed after the required 60-day time frame, and other types of surveys that can not be used to validate a JCAHO accreditation survey.

²³For example, CMS does not measure and report the precision of the estimates from the sample of validation surveys through the use of confidence intervals or margins of error, which define the range of estimates that sample results would yield given different random samples for a specified level of certainty.

Annual Number of Validation Surveys

CMS reduced the number of validation surveys conducted by state agencies from a target of approximately 5 percent of the total number of hospitals that JCAHO accredits to a target of approximately 1 percent, with at least one survey in each state. Reducing the target of validation surveys from 5 percent to 1 percent results in the number of validation surveys being reduced from 227 in fiscal year 2002 to a target of 75 validation surveys in fiscal year 2003 and 72 in fiscal year 2004.

Reducing the targeted number of validation surveys to 1 percent provides less reliable information on how well JCAHO's hospital accreditation program ensures compliance with Medicare COPs. For example, for a 5-percent target, the estimate of the proportion of JCAHO-accredited hospitals with a particular deficiency that is derived from the validation survey could be as much as 6.0 percentage points higher or lower, for a range of 12.0 percentage points. If the 5-percent target produced an estimate that 50 percent of JCAHO-accredited hospitals had a particular deficiency, the percentage of JCAHO-accredited hospitals not complying could range from 44.0 to 56.0 percent. However, for a 1-percent target the estimate could be 11.4 percentage points higher or lower, for a range of about 22.8 percentage points. For example, if the 1-percent target produced an estimate that 50 percent of JCAHO-accredited hospitals had a particular deficiency, the percentage of JCAHO-accredited hospitals not complying with a Medicare COP could range from 38.6 to 61.4 percent.²⁴

This reduction in the number of validation surveys is of additional concern because it coincides with the implementation of JCAHO's new accreditation process, which has an unproven capacity to detect deficiencies. CMS's target sample size for traditional validation surveys for fiscal year 2004 will be further reduced because the sample also includes 18-month validation surveys. In 2004, CMS is planning to conduct 17 of these 18-month surveys as part of its overall validation survey target of 72. Thus, CMS could be using as few as 55 validation surveys to determine JCAHO's performance.

²⁴These estimates were developed assuming that the validation surveys are conducted on a simple random sample of JCAHO-accredited hospitals and a 95 percent confidence level.

Conclusions

For 3 consecutive years, JCAHO's hospital accreditation program, which accredits most of the hospitals participating in Medicare, exceeded CMS's threshold for unacceptable performance. CMS validation surveys during that time period confirmed that JCAHO missed the majority of serious deficiencies found by state survey agencies. Yet, CMS was unable to take action against JCAHO's hospital accreditation program as it can with other accreditation programs because it lacked the authority to do so. Although CMS has recommended in its annual reports to Congress that JCAHO make changes in its hospital accreditation program to improve its ability to detect serious deficiencies, some of these recommendations have not been implemented. Thus, it is vital for patient safety that JCAHO hospital accreditation surveys detect existing serious deficiencies and deny accreditation to hospitals that do not comply with Medicare COPs.

CMS is unable to present to Congress an adequate assessment of JCAHO's performance because of limitations in its process for selecting hospitals for validation surveys and analysis of the survey results. CMS does not consistently portray the extent to which serious deficiencies are missed and does not identify the limitations in reporting the estimates it makes from its survey sample. CMS cannot assure Congress that JCAHO-accredited hospitals meet Medicare COPs because the measure for the rate of disparity, which determines poor performance, allows JCAHO to miss the majority of serious deficiencies and still be in an acceptable range of performance. Further, CMS's reduction in the number of validation surveys it uses to determine the performance of JCAHO's hospital accreditation program will provide less reliable information at a time when JCAHO is implementing a new hospital accreditation process that is unproven in its ability to detect serious deficiencies. In light of these limitations in CMS's validation of JCAHO's hospital accreditation program, we believe that CMS must improve its oversight so it can provide Congress with more accurate information regarding JCAHO's performance.

Matter for Congressional Consideration

Given the serious limitations in JCAHO's hospital accreditation program and that efforts to improve this program through informal action by CMS have not led to necessary improvements, Congress should consider giving CMS the same kind of authority over JCAHO's hospital accreditation program that it has over all other Medicare accreditation programs.

Recommendations for Executive Action

To strengthen the ability of CMS to identify and report to Congress on JCAHO's ability to ensure that the hospitals it accredits protect the safety and health of patients through compliance with the Medicare COPs, we recommend that the Administrator of CMS take the following three actions:

- modify the method used to measure the rate of disparity between validation survey findings and accreditation program findings to provide a reasonable assurance that Medicare COPs are being met and consider whether additional measures are needed to accurately reflect an accreditation program's ability to detect deficiencies in Medicare COPs;
- provide in the annual report to Congress an estimate, based on the validation survey sample, of the performance of all JCAHO-accredited hospitals, including the limitations and protocols for these estimates based on generally accepted sampling and statistical methodologies; and develop a written protocol for these calculations; and
- annually conduct traditional validation surveys on a sample of JCAHO-accredited hospitals that is equal to at least 5 percent of all JCAHO-accredited hospitals.

Agency and Other External Comments and Our Evaluation

CMS and JCAHO commented on a draft of this report. In its comments, CMS concurred with our recommendations. JCAHO stated it had no objection to our suggestion that Congress give CMS the same authority over its hospital accreditation program as it does over other Medicare accreditation programs. However, JCAHO took issue with the methodology we used for evaluating the performance of its hospital accreditation program. CMS's and JCAHO's specific comments and our response follow. CMS's comments are reprinted in appendix IV and JCAHO's comments are reprinted in appendix V. CMS and JCAHO also provided technical comments, which we incorporated as appropriate.

CMS stated that it has begun to examine the need for additional or alternative measures for the rate of disparity calculation. CMS also stated it will seek additional resources to further develop and implement new sampling and statistical methodologies that may allow results to be projected to all JCAHO-accredited hospitals, and to increase the validation sample size. CMS specifically noted that it considers life-safety code compliance, on the part of all provider types, to be critically important. In the past 8 years, in its annual reports to Congress and its dialogues with JCAHO regarding its hospital accreditation program, it has identified physical environment as an important area where JCAHO needs to focus attention, and CMS noted that 68 percent of facilities that had a deficiency

finding not identified by JCAHO had them in the physical environment area.

JCAHO stated that our methodology for evaluating the performance of its hospital accreditation program was incomplete and did not provide a comprehensive assessment of its program's performance. We did not intend to do a comprehensive evaluation of JCAHO's overall hospital accreditation program. Rather, we focused our evaluation on how well JCAHO's hospital accreditation program ensures hospitals' compliance with Medicare participation requirements. There are four possible outcomes to a comparison between JCAHO's accreditation survey and a state validation survey: (1) both JCAHO and state agencies identify no deficiencies, (2) JCAHO identifies deficiencies not found by state agencies, (3) both JCAHO and state agencies identify the same deficiencies, and (4) state agencies identify deficiencies that JCAHO does not. We limited our evaluation to the fourth outcome because it illustrates the need for CMS oversight of the hospital accreditation process. We have clarified the scope of our evaluation to emphasize our focus on this outcome.

JCAHO raised a concern that our characterization of JCAHO's missed deficiencies that state survey agencies found misleads readers to believe that JCAHO misses hospitals with deficiencies 78 percent of the time. We have revised language in the report to further emphasize that the missed deficiency rate applies to hospitals in the validation survey sample in which the state survey agencies found deficiencies and cannot be generalized to all JCAHO-accredited hospitals. JCAHO further stated that our report does not take into account that JCAHO's hospital accreditation program detects deficiencies in hospitals that CMS does not find. However, it is to be expected that state survey agencies will not find all deficiencies found by JCAHO because hospitals may have corrected the deficiencies prior to the state agency surveys.

JCAHO stated that we misrepresented the potential of the new accreditation process in detecting deficiencies in Medicare COPs and provided new data regarding its first quarter 2004 performance that indicate that JCAHO surveys may have detected a greater percentage of deficiencies related to patient care compared with the pre-2004 accreditation process. However, we maintain that until CMS validation surveys for 2004 are completed, there is no basis on which to determine whether the new process improves the detection of deficiencies in Medicare COPs. In addition, JCAHO stated and we agree that evaluating and improving the quality of care in hospitals is not about counting deficiencies, it is about finding those deficiencies that, if not fixed, will

generate poor results for patients and making sure that these deficiencies are remedied in a timely fashion.

JCAHO stated that we mischaracterized its response to the five recommendations that CMS made in 2002 to improve JCAHO's ability to detect deficiencies in the life safety code and that it is involved in frequent and ongoing dialogue with CMS regarding the recommendations and other life safety code issues. We have clarified language in the report regarding JCAHO's response to CMS's recommendations.

As agreed with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days after its date. We will then send copies of this report to the Secretary of Health and Human Services and other interested parties. We will also make copies available to others upon request. In addition, the report will be available at no charge at the GAO Web site at <http://www.gao.gov>.

If you or your staffs have any questions about this report, please call me at (202) 512- 7119. Another contact and key contributors are listed in appendix VI.



Janet Heinrich
Director, Health Care—Public Health Issues

Appendix I: Scope and Methodology

We examined the extent to which JCAHO's pre-2004 survey process identified hospitals with deficiencies and individual deficiencies in Medicare COPs that were identified by state survey agencies. We chose these measures because they reflect performance in detecting and correcting serious deficiencies, which according to CMS, substantially limit a hospital's capability to render adequate care and adversely affect the health and safety of patients. We reviewed data, provided by CMS, on 500 traditional validation surveys conducted by state survey agencies during fiscal years 2000 through 2002. In these validation surveys, state survey agencies documented whether they found serious deficiencies in Medicare COPs. CMS compared state survey agency findings with JCAHO's accreditation surveys that identified deficiencies in JCAHO's standards. CMS then determined whether the state survey agencies' findings on serious deficiencies in the 22 Medicare COPs that can be deemed were comparable to JCAHO's findings on deficiencies in JCAHO's standards in the following way. Two CMS experts such as nurses reviewed the comparability of serious deficiencies in the quality-of-care conditions identified in validation surveys to deficiencies in JCAHO's accreditation standards identified in JCAHO's hospital accreditation surveys. Two experts, such as building engineers, reviewed the comparability of serious deficiencies identified in the validation surveys on the condition on physical environment. Where there was disagreement, the two experts met to resolve their differences. CMS does not have written protocols for determining comparability. Experts are expected to use their best professional judgment. CMS experts also had to consider whether it is reasonable to conclude that the deficiencies existed at the time that JCAHO surveyed the hospital. For those deficiencies that CMS determines that JCAHO has failed to identify, it met with JCAHO to address disputed findings and to consider additional evidence on comparability offered by JCAHO. There are four possible outcomes to this comparison of survey findings—(1) JCAHO and state agencies both identify no deficiencies, (2) JCAHO identifies deficiencies not found by state agencies, (3) JCAHO and state agencies both identify the same deficiencies, and (4) state agencies identify deficiencies that JCAHO does not—we focused on the fourth because it highlights the need for CMS oversight of the hospital accreditation program. For the second outcome, there could be two reasons for the disparity between JCAHO's and state survey agencies' findings: hospitals corrected deficiencies identified by JCAHO prior to the state agency survey or the state survey agency did not identify a deficiency that existed. In addition, not all JCAHO findings are equivalent to noncompliance with a Medicare COP.

From these 500 surveys, we determined the number of hospitals with serious deficiencies and the total number of serious deficiencies identified by state agencies but that CMS determined were not identified by JCAHO. These data include 123 hospitals in which state survey agencies identified one or more serious deficiencies and JCAHO did not make comparable findings according to CMS. These data also include 167 serious deficiencies identified by state agencies but that CMS determined comparable findings were not identified by JCAHO.

For fiscal years 2001 and 2002, we obtained from CMS a comparison between the validation surveys conducted by the state survey agencies and the accreditation surveys conducted by JCAHO, which identified serious deficiencies identified by the state agencies but not by JCAHO as determined by CMS. For fiscal year 2000, CMS did not supply its determinations of the comparability of findings in validation and accreditation surveys for 31 of 82 serious deficiencies. We followed a protocol similar to the one used by CMS to determine the comparability of the remaining 31 serious deficiencies, which included 29 quality-of-care serious deficiencies and 2 physical environment serious deficiencies. Two analysts with nursing backgrounds compared the findings and made determinations on their comparability based on their professional judgment. In cases of disagreement, a third analyst with a background in nursing made the determination.

We did not include 1998 and 1999 data in our analysis because CMS used a method that undercounted the number of deficiencies identified by state survey agencies but not identified by JCAHO. CMS did not count as deficient those cases in which state survey agencies determined that a hospital was not meeting the COP on physical environment but JCAHO determined that the hospital was in compliance because the hospital was following correction plans approved by JCAHO.

To determine the potential of JCAHO's new accreditation process in improving the detection of deficiencies in Medicare COPs, we reviewed material supplied by JCAHO on development and testing of its new process and interviewed JCAHO officials about the steps taken to test the new process and to analyze results. We also examined the features of the new accreditation process by reviewing descriptive material obtained from JCAHO and interviewing experts in health care quality. Because the new accreditation process was implemented in January 2004, we were limited in our ability to determine the effectiveness of the new accreditation process because we were not able to perform a comparative

analysis of validation survey and JCAHO survey results under the new process.

To examine the effectiveness of CMS's oversight of JCAHO's accreditation process, we analyzed the laws and regulations that define CMS's authority and JCAHO's authority. We reviewed the annual reports submitted to Congress on JCAHO's performance in identifying serious deficiencies and reviewed correspondence between CMS and JCAHO and interviewed officials in both organizations. We analyzed the rate of disparity that CMS uses to determine the performance of JCAHO's hospital accreditation process in identifying deficiencies in Medicare COPs.

To evaluate CMS's statistical methodology for the validation surveys, we interviewed CMS officials about the sampling and statistical methods. In the absence of written methodological documentation, we relied on information provided by CMS officials to evaluate the methodology. They gave us the following information about their sampling method. At the beginning of each year, CMS determines a target for the number of hospitals that will be sampled for validation surveys in each state. Each month, CMS receives a list of hospitals scheduled for a JCAHO accreditation survey in that month. Prior to sampling, CMS removes from the list those hospitals that have received a validation survey in the last 3-year accreditation cycle and hospitals that do not participate in Medicare. In the first month of the year, CMS selects a random sample of hospitals to be surveyed from JCAHO's list. In subsequent months, CMS removes hospitals in states in which the state target has been met and then selects a random sample of hospitals. Prior to sending the list to state survey agencies, CMS determines which hospitals will receive traditional validation surveys and which will receive other types of surveys that cannot be used to assess the performance of JCAHO's hospital accreditation program. State survey agencies must then complete traditional validation surveys within 60 days of the completion of JCAHO's accreditation survey for the results to be used by CMS to measure the performance of JCAHO's hospital accreditation program. According to CMS officials, the sampling procedures CMS uses are necessary because they are not informed more than 1 month in advance which hospitals JCAHO will survey for accreditation.

In reviewing the sampling procedures they described, we determined that CMS initially selects a probability sample of hospitals for its state agency validation surveys.¹ However, hospitals have varying chances of selection in the sample depending on the month in the fiscal year that JCAHO performs the accreditation survey and the number of hospitals targeted for completion that year in the state in which the hospital was located. Additionally, the way that CMS determines which type of survey the sampled hospital receives is not random. Therefore, the analysis we performed is limited to those hospitals included in the validation survey sample and cannot be projected to all JCAHO-accredited hospitals.

¹In a probability sample, each eligible hospital accredited in a given year would have to have a known, nonzero chance for selection in the sample.

Appendix II: Medicare Conditions of Participation

To participate in Medicare, hospitals must maintain standards of patient safety and health that comply with Medicare requirements. There are currently 23 Medicare COPs. Table 7 provides a description of each Medicare COP.

Table 7: Medicare Conditions of Participation

Medicare COP	Description
Anesthesia services ^a	Anesthesia services must be well organized and directed by a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered.
Compliance with federal, state, and local laws	A hospital must comply with applicable federal laws on patient health and safety and state and local laws on hospital and personnel licensing.
Discharge planning	A hospital must have a discharge planning process applicable to all patients. Policies and procedures must be in writing.
Emergency services ^a	If emergency services are provided they must be organized under the direction of a qualified member of the medical staff and have adequate medical and nursing personnel qualified in emergency care to meet the needs anticipated by the facility.
Food and dietetic services	Dietary services must be organized, directed, and staffed by qualified personnel. Contracted services must meet certain requirements.
Governing body	A hospital must have a legally responsible governing body or persons charged with the responsibilities of a governing body.
Infection control	A hospital's sanitary environment must avoid sources and transmission of infections and communicable diseases. It must have an active program to prevent, control, and investigate infections and communicable diseases.
Laboratory services	The hospital must maintain, or have available, adequate laboratory services.
Medical record services	A hospital must have a medical record service that has administrative responsibility for medical records.
Medical staff	A hospital must have an organized medical staff that abides by bylaws approved by the governing body and is responsible for the quality of patient medical care.
Nuclear medicine services ^a	Nuclear medicine services must meet the needs of the patients in accordance with acceptable standards of practice.
Nursing services	An organized nursing service must provide 24-hour nursing services that are supervised or furnished by registered nurses.
Organ, tissue, and eye procurement	The hospital must have and implement written protocols on procurement and have adequate organ transplant policies.
Outpatient services ^a	Outpatient services must meet patient needs consistent with acceptable standards of practice.
Patients' rights	A hospital must protect and promote patients' rights.
Pharmaceutical services	The hospital must have pharmaceutical services that meet patient needs.
Physical environment	Hospital construction, arrangements, and maintenance must ensure patient safety and provide diagnostic and treatment facilities and special hospital services appropriate to community needs.
Quality assessment and performance improvement	A hospital must have an effective, hospitalwide quality assurance program.

Appendix II: Medicare Conditions of Participation

Medicare COP	Description
Radiologic services	The hospital must maintain, or have available, diagnostic radiologic services. Therapeutic services provided must meet professionally approved standards for safety and personnel qualifications.
Rehabilitation services ^a	Rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services must be organized and staffed to ensure the health and safety of patients.
Respiratory services ^a	Respiratory services must meet patient needs in accordance with acceptable standards of practice.
Surgical services ^a	Surgical services must be well organized and provided in accordance with acceptable standards of practice. Outpatient services must be consistent with inpatient care quality in accordance with the complexity of services offered.
Utilization review	Utilization review plans must provide for review of the services that a hospital and its medical staff provide to Medicare and Medicaid patients.

Source: GAO summary of Medicare COPs.

^aOptional services not required by Medicare.

Appendix III: Features of JCAHO's New Accreditation Process

In January 2004, JCAHO introduced a new hospital accreditation process that includes several new features. Table 8 includes a description of selected new features of JCAHO's hospital accreditation process.

Table 8: JCAHO's Description of Features of Its New Hospital Accreditation Process

Feature of the new accreditation process	Description
Periodic performance review	<p>The periodic performance review (PPR) is a new form of evaluation that is conducted by the organization and focuses on patient safety and quality of care issues. The organization self-evaluates its compliance with all standards that are applicable to the services that the organization provides, and develops a plan of action for all areas of performance identified as needing improvement. JCAHO will work with the organization to refine its plan of action to assure that its corrective efforts are on target. The organization will also identify measures of success for validating resolution of the identified problem areas when the organization undergoes its complete on-site survey 18 months later.</p> <p>Three options to the full PPR are available to organizations. The options and their requirements are:</p> <p>Option 1</p> <p>The organization performs the mid-cycle self-assessment, develops the plan of action and measures of success but does not submit PPR data to JCAHO. The organization attests that it has completed the foregoing activities but has, for substantive reasons, been advised not to submit its self-assessment or plan of action to JCAHO.</p> <p>The organization may discuss standards-related issues with JCAHO staff without identifying its specific levels of standards compliance.</p> <p>At the time of the complete on-site survey, the organization provides its measures of success to JCAHO for assessment.</p> <p>Option 2</p> <p>The organization need not conduct a mid-cycle self-assessment or develop a plan of action.</p> <p>The organization undergoes an on-site survey at the mid-point of its accreditation cycle. The survey will be approximately one-third the length of a typical full on-site survey and the organization will be charged a fee to cover survey costs.</p> <p>The organization develops and submits to JCAHO a plan of action to address any areas of non-compliance found during the on-site survey. JCAHO will work with the organization to refine its plan of action. At the time of the complete on-site survey, the organization provides its measures of success to JCAHO for assessment.</p> <p>Option 3</p> <p>The mid-cycle survey would be performed, as in Option 2, but, if the organization chooses, no written documentation or report of the survey would be left with the organization. Findings would be conveyed orally. This would eliminate the availability of a survey report for possible discovery from the organization, and would permit the organization, as is the case with Option 1, to control the language and documentation of the mid-cycle assessment activity. At the subsequent full survey, surveyors would not discuss with the organization, unless asked to do so, the fact that any particular standard had been found out of compliance at the mid-cycle assessment. Rather, they would focus on compliance with those standards at the time of the full survey.</p> <p>If the plan of action is approved, the organization's accreditation decision will remain the same. However, if the plan of action is not approved, the organization's accreditation decision will be changed to reflect the appropriate status. At the triennial on-site survey, implementation of the plan of action will be validated</p>

**Appendix III: Features of JCAHO's New
Accreditation Process**

Feature of the new accreditation process	Description
Priority focus process	<p>The priority focus process (PFP) is a data-driven tool that focuses survey activity on issues most relevant to patient safety and quality of care at the specific health care organization being surveyed. The PFP uses automation to gather pre-survey data from multiple sources including JCAHO, the hospital and other public sources. The PFP then applies rules to 1) identify relevant standards and appropriate survey activities, and 2) guide the selection of patient tracers. As part of the priority focus process, surveyors will track patients through their experience of care within an organization, assessing the quality and safety of care provided. The PFP does not imply that priority areas are out of compliance or deficient in any way. Rather, it lends consistency to the surveyor's on-site sampling process. The PFP also helps to focus the surveyor's assessment on quality and safety issues specific to an individual health care organization.</p> <p>The output of the PFP process will include: the top four to five priority focus areas—the processes, systems, or structures within a health care organization known to significantly impact the safety and quality of care specific to the health care organization being surveyed.</p>
Tracer methodology	<p>An evaluation method in which surveyors select a patient and use that individual's record as a roadmap or "tracer" to assess and evaluate an organization's compliance with selected standards and the organization's systems of providing care and services. Using tracers, JCAHO surveyors will look at the care provided by each department within an organization, and how departments work together. Surveyors retrace the specific care processes that the individual experienced by observing and talking to staff in areas that the individual received care. As the individual's case is examined, the surveyor may identify performance issues in one or more steps of the process—or the interfaces between steps—that affect the care of the patient. Surveyors will look for commonalities that might point to potential system-level issues in the organization. The tracer activity also provides several opportunities for surveyors to provide education to organization staff and leaders, as well as to share best practices from other similar health care organizations.</p> <p>Tracer patients will primarily be selected from an active patient list. Typically, individuals selected for the tracer activity are those who have received multiple or complex services</p>

Source: JCAHO.

Appendix IV: Comments from the Centers for Medicare & Medicaid Services




DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: JUL 14 2004

TO: Janet Heinrich
Director, Health Care – Public Health Issues
General Accounting Office

FROM: Mark B. McClellan, M.D., Ph.D. 
Administrator

SUBJECT: General Accounting Office Draft Report: *MEDICARE: CMS Needs Additional Authority and Better Measures to Adequately Oversee the Hospital Accreditation Program* (GAO-04-850)

Thank you for the opportunity to comment on the above-referenced draft report from the General Accounting Office (GAO). The Centers for Medicare & Medicaid Services (CMS), state survey agencies, and the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) conduct frequent reviews of hospital performance. In the three years under consideration in the GAO study (2000-2002), there were 17,780 surveys in the approximately 4,500 accredited hospitals in the United States, including the following:

- 4,616 JCAHO full triennial surveys;
- 1,290 JCAHO complaint or “for cause” special investigations;
- 500 CMS-sponsored validation surveys to assess the adequacy of JCAHO surveys;
- 7,542 complaint investigations by CMS or state agencies; and
- 3,832 revisits or other investigations by CMS or states to follow-up on prior complaint investigations, assess whether hospitals took action to fix significant problems identified on earlier surveys, or similar purposes.

These 17,780 reviews reflect a considerable national investment in external quality assurance for hospitals. They are complemented by the external assistance provided by Quality Improvement Organizations (QIOs) and, of course, the internal quality efforts of hospitals themselves.

Each year CMS conducts or arranges with states for a full survey of a sample of accredited hospitals that have undergone a JCAHO accreditation survey. We call these “CMS validation surveys” because their purpose is to assess the extent to which any disparity exists between the JCAHO findings and those of CMS. The GAO study focuses on the disparity information made possible by the 500 CMS validation surveys.

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In 343 out of the 500 hospitals in which full CMS validation surveys were conducted during the three-year time period of the GAO study, no serious deficiencies were identified in the hospital. In the 157 hospitals in which a serious deficiency was found through the CMS validation surveys, the number of deficiencies averaged about 1.6 per hospital. “Physical environment” issues (principally fire-safety) represented the single most frequent issue, one we discuss in more detail later in this letter. The GAO report observes that serious deficiencies identified in hospitals represent only 2 percent of all the Medicare requirements surveyed during the three-year period under study.

While we regard all deficiencies as serious matters, the overall low rate of identified deficiencies relative to the total number of hospitals is an encouraging sign that suggests that the overall accreditation process has merit.

However, additional improvements can and should be made, no matter how much progress has already been accomplished or how low the rate of deficiency might be. Our own on-going, two-year study indicates that there may be further actions we can take under existing law to strengthen both CMS oversight and JCAHO’s efforts. Examples include the following:

CMS Validation Surveys: Within the President’s 2005 budget request we are working to increase the number of CMS validation surveys beyond the current level.

More Sensitive Performance Indicators: We developed the conceptual framework for more sensitive indicators to improve our ability to discern the nature and extent of any JCAHO performance issues. We will soon initiate testing of specific options for such indicators.

Complaint Data: We will explore the extent to which the approximately 2700 complaint investigations conducted each year by CMS or states may be used as a valuable database to assess JCAHO accreditation practice.

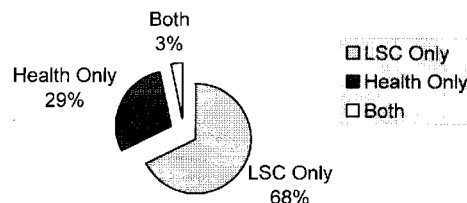
We are gratified by observations in the report that the CMS has properly executed its statutory responsibility to continually study the operation and administration of the JCAHO hospital accreditation process and to submit an annual report to Congress.

With regard to JCAHO’s performance, it is worth noting that “physical environment” represents the area of greatest discrepancy between the JCAHO findings and the CMS-sponsored validation surveys. Compliance with life-safety codes is the most common issue in the area of “physical environment,” typically involving fire-safety precautions.

Of all facilities in which JCAHO missed a deficiency finding, about 68 percent were accounted for by “physical environment” issues. This compared with a facility discrepancy rate of about 29 percent for health care only, and 3 percent where there was a finding of deficiency for both health care and physical environment.

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Facilities with Findings Missed by JCAHO
FY 2000-2002



In the past eight years, in its annual reports to Congress and in its dialogue with JCAHO, CMS has identified the issue of physical environment as an important area that needs further attention. For example, the 1996 report to Congress observed that “validation surveys show that the CoP of Physical Environment continues to be the most frequently cited condition based on noncompliance with LSC.” More recently, CMS’ 2002 report to Congress continued to emphasize that “we have identified inconsistencies in its [LSC] implementation that we believe contributes to the differences in the validation findings.”

CMS has always considered life-safety code compliance, on the part of all provider types, to be of critical importance. For this reason the 2002 CMS report to Congress summarized five specific remedial steps that we recommended to JCAHO, and the 2003 report reported on the extent of progress being made. While JCAHO implementation of these recommendations has not been as expeditious as we desired, we are pleased to see some significant progress. The most recent example of such progress is the JCAHO agreement with the American Society for Healthcare Engineering (ASHE) to construct an electronic assessment tool, train JCAHO staff, and to support JCAHO’s efforts to recruit health care facility engineers.

We will continue to emphasize with JCAHO the need to improve both health care and life-safety code compliance. Improvement in the area of life-safety code compliance would, by itself, bring JCAHO accreditation considerably closer to the findings rendered in the CMS-sponsored validation surveys.

With respect to the role of CMS and the CMS validation program, the report contends that the “rate of disparity” measure, as codified in federal regulations, is not sufficiently sensitive. The “rate of disparity” measure is used to gauge an accreditation organization’s performance. In addition, the GAO report contends that the methodology for sample selection is not conducted in a statistically sophisticated manner, nor are the results presented in a way that extends the findings to all JCAHO hospitals through the application of an algorithm. Finally, the report conveys concern about the previous CMS decision to reduce the validation sample size from 5 percent to a state-stratified 1 percent sample.

We concur with GAO’s view that the sampling methodology, sample size, and the formula for calculating the rate of disparity should be reevaluated. As GAO staff are aware, CMS has been

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actively studying these issues in the past two years. We have reached conclusions similar to those in the GAO study, as articulated in the attached document.

Thank you again for the opportunity to review and comment on the draft report. We look forward to seeing the final report and to working together to improve hospital care for the nation's Medicare beneficiaries. Attached are CMS' specific comments to GAO's recommendations.

Attachment

**Centers for Medicare & Medicaid Services' Comments to the GAO
Draft Report: *MEDICARE: CMS Needs Additional Authority and Better Measures to Adequately Oversee the Hospital Accreditation Program (GAO-04-850)*.**

GAO Recommendation

Modify the method used to measure the rate of disparity between validation survey findings and accreditation program findings to provide a reasonable assurance that Medicare COPs are being met and consider whether additional measures are needed to accurately reflect an accreditation program's ability to detect deficiencies in Medicare COPs.

CMS Response

The rate disparity calculation is specified in Federal regulations at 42 CFR section 488.8. However, it is quite appropriate to reexamine the rule and to consider additional or alternative measures to assess the performance of the accreditation organizations. The CMS has already begun to examine this issue as part of the agency's hospital quality improvement activities. We are working to refine existing measures and develop new ones.

It will be necessary to undertake rulemaking to revise the formula for calculating the rate of disparity measure, as well as to validate the threshold for acceptable performance or reasonable assurance. We believe that the notice and comment procedures inherent in the rulemaking process will provide an appropriate forum for this discussion of this significant public policy and will allow all of the stakeholders to participate. It will also provide for exposure to new perspectives and may yield innovative approaches to these problems that may have eluded us in the past.

In addition, we will explore regulatory strategies to address the long-standing JCAHO performance issues with respect to the Life Safety Code. We will propose that this initiative be added to the Department's Regulatory Plan for FY 2005. These approaches will require additional CMS resources in terms of FTEs and additional funding.

GAO Recommendation

Provide in the annual report to Congress an estimate, based on the validation survey sample, of the performance of all JCAHO-accredited hospitals, including the limitations and protocols for these estimates based on generally accepted sampling and statistical methodologies; and develop a written protocol for these methodologies.

CMS Response

It is appropriate to explore the possibility of developing and implementing new sampling and statistical methodologies within generally accepted statistical practices. We will examine whether alternate measures can more appropriately be generalized to the universe of all JCAHO hospitals. We will attempt to secure the additional resources necessary to undertake a thorough

Page 2 – Attachment

examination of these issues, to propose alternative sampling methodologies and develop more robust statistical analyses.

GAO Recommendation

Annually conduct traditional validation surveys on a sample of JCAHO-accredited hospitals that is equal to at least 5% of all JCAHO-accredited hospitals.

CMS Response

We will seek to increase the validation sample size as we formulate future budget requests. However, rather than simply increasing the sample rate to 5 percent, there may be more cost-effective approaches to enhancing our survey activities.

We note that a return to the 5 percent validation sample would require additional survey and certification funding that ranges from about \$2.6 million annually to almost \$4.8 million per year, depending on the sampling methodology. Thus, additional cost-effective methods to assess JCAHO performance that would offset the need for major additional investments in full, traditional CMS validation surveys are likely to be valuable.

One such approach may be to make use of the database represented by the approximately 2700 complaint investigations conducted in accredited hospitals by CMS and states. We will undertake an initiative to analyze the extent to which this database may be useful in assessing JCAHO accreditation practice, and then develop analytic tools to put relevant findings into an improvement plan with JCAHO. In addition, to the extent that we can increase surveyor time in accredited hospitals, we will explore risk-based approaches that valuable surveyor time on those areas of JCAHO accreditation in which problems are most likely.

Finally, we will also seek regulatory changes that would provide CMS with additional and more substantial information on the JCAHO processes and findings so as to improve both overall CMS oversight and the effectiveness of CMS validation surveys.

Appendix V: Comments from the Joint Commission on Accreditation of Healthcare Organizations



Joint Commission
on Accreditation of Healthcare Organizations

July 12, 2004

Mr. David Walker
Comptroller General
Government Accountability Office
441 G Street, N.W.
Washington, DC

Dear Mr. Walker:

We would like to thank the Government Accountability Office for the opportunity to review the draft report entitled *Medicare: CMS needs Additional Authority and Better Measures to Adequately Oversee the Hospital Accreditation Program*. Because evaluating the performance of any organization is a complex undertaking, solicitation of the views of the entity under scrutiny helps to improve the accuracy of the analysis and provides context for the assessment.

The GAO's key recommendation is that "Congress should consider giving CMS the same kind of authority over the Joint Commission's hospital accreditation program that it has over all the other Medicare accreditation programs." The Joint Commission interposes no objection to this suggested statutory change, but takes great exception to the fact that the GAO arrives at this conclusion based upon a flawed study methodology and erroneous, alarming statistics that seriously mislead the public and do a great disservice to the Joint Commission.

When the deeming provision respecting hospital oversight was incorporated into the Medicare statute in 1965, the Congress did so on its own cognizance. The Joint Commission never sought this deemed status relationship nor was it even aware of the framing of the statutory provision respecting hospital accreditation that, to this date, limits the Executive Branch's oversight of the Joint Commission.

Nevertheless, the Joint Commission has always worked with CMS as if CMS had the same oversight authority for hospitals that it exercises for the other newer federal deemed status relationships with the Joint Commission (e.g., for home health care, for ambulatory surgery centers). This long-standing, positive working relationship has provided the nation enormous benefits through assuring continuous access to state-of-the-art evaluation of health care quality and patient safety in hospitals that are unparalleled in the world, and are looked to internationally as the gold standard for assessing hospital services. Further, the fact that only 2% of Medicare Conditions of Participation were found out of compliance by the CMS in hospitals during the three years of this subject GAO study is testimonial to the positive impacts of the effective working relationship between the Joint Commission and the CMS (and its predecessor) over the past four decades. These efforts to continuously improve health care quality and patient safety not only give beneficiaries confidence in their providers, but also ensure that the government is getting value for its spending. The Joint Commission leadership role in this area is evident in the

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Member Organizations
American College of Physicians
American College of Surgeons

American Dental Association
American Hospital Association
American Medical Association

fact that many private insurers and employers insist that hospitals serving their plan members be accredited by the Joint Commission.

The Joint Commission launched a new accreditation process in January of this year after three years of careful design and field testing. Each of the evaluation techniques incorporated into the new evaluation approach had previously been validated by other established evaluators both in health care and in other venues. We undertook this set of sweeping changes because of our commitment to continuous quality improvement and because we believe that a patient-centered approach to evaluation provides the most meaningful assessment of hospital performance. It also provides a strengthened vehicle for assuring continuous hospital attention to our standards requirements. While technically not authorized to approve the new accreditation process, CMS staff was briefed on its design on several occasions. Were CMS to have had such authority, this would have clearly made the Joint Commission even more comfortable in implementing the new accreditation process.

Thus, the Joint Commission takes no exception to the GAO's recommendation that the Congress consider giving CMS the same authority over the Joint Commission's hospital accreditation program that it has over the other deemed Joint Commission accreditation programs. However, such a change would make sense irrespective of the performance of the Joint Commission, and certainly should not be colored by the inflammatory, grossly inaccurate portrayal of the Joint Commission that is set forth in this seriously flawed GAO study. On July 7, 2004, the Joint Commission submitted to the GAO a 26-page technical corrections document which details the serious errors in and omissions from the draft GAO study. These are summarized below:

Methods and Use of Statistics

Evaluating performance is a complex task. Like so many issues involving assessment, if one asks the wrong question, one gets the wrong answer. The GAO methodology seeks to assess the ability of the Joint Commission to evaluate hospital compliance with the Medicare CoPs by conducting "missed deficiency rate" analyses. However, the calculations performed by the GAO are at best incomplete, for the GAO has not included in the calculus the number of deficiencies found by the Joint Commission but not found by the State Survey Agency (SSAs.) The GAO has continued to ignore this key point, and has been undeterred in its focus on how many times the Joint Commission agrees with the SSAs. Essentially, what the GAO is providing to the reader is an incomplete ratio of "non-agreement" between the Joint Commission and the State Survey Agencies.

This ratio, especially when used in isolation from other information, is neither a true indicator of Joint Commission effectiveness, nor an adequate exploration of whether the Joint Commission's hospital accreditation program ensures that Medicare beneficiaries receive high quality care in keeping with the Medicare program's expectations. Specifically, the GAO does not acknowledge that non-agreement between the SSA and the Joint Commission is influenced by a number of factors, including differences in interpretation of standards compliance; the disproportionate rigidity of the CoPs requirements and their related scoring mechanisms compared to the Joint Commission's accreditation process; variations in the timing of the Joint Commission and SSA surveys; and other artifacts inherent in the validation program. Even with these imponderables, it is extraordinary that accredited hospitals are found to be in compliance with 98 percent of the CoPs in SSA validation surveys. It is even more extraordinary that this significant finding is omitted from the highlights page and is buried in the text under a finding that misleads the Congress and policymakers into believing that the Joint Commission does not identify serious deficiencies.

We further note that while the GAO claims that the Joint Commission misses 69 percent of out-compliance CoPs, the GAO has neither the complete files of survey information nor the expertise necessary to make such a calculation. This allegation is therefore no more than conjectural and cannot be defended.

A paradox inherent in the GAO's statistical applications is that the GAO has chosen an even more inappropriate measure of evaluating whether COPs are in compliance than the one that they criticize the CMS for using over the past few years. Using the GAO metric, the greater the degree of Joint Commission success in ensuring that hospitals are, or become, in compliance with the CoPs following its on-site accreditation surveys, the greater the likelihood that any SSA findings later in time will be considered "new" deficiencies. Even if these new deficiencies are exquisitely small in number, they will then represent a 100 percent "missed deficiency rate," thereby further misleading and potentially alarming the Congress and the public.

Furthermore, to provide an adequate, more accurate assessment of the Joint Commission's performance in assuring that safe, high quality care is available to Medicare beneficiaries, the GAO should be advising the CMS to take into account: (1) the actual number of serious deficiencies that existed in hospitals to be surveyed by SSAs before the Joint Commission and SSA surveys and how many of these were identified by the Joint Commission and corrected before the validation surveys; (2) the percentage of allegation (complaint) surveys that resulted in a finding that the hospital had at least one serious deficiency (an astounding low number of hospitals during the GAO study period, as previously reported to the Congress); and (3) the multiple value-added requirements that the Joint Commission requires of accredited organizations, such as the public reporting of clinical performance data, special requirements related to national patient safety goals, and over 100 standards that do not have corresponding Medicare requirements and reflect expectations relating to the state-of-the-art provision of care in hospitals. While Medicare's CoPs have not been fully updated since 1986, the Joint Commission has annually updated its standards – with public sector input – to push hospitals to continually improve the quality and safety of the care they provide.

The New Survey Process

The GAO misunderstands and misrepresents the Joint Commission's evolution to a new accreditation process and in so doing appears to lack a basic understanding of the tenets of quality improvement. The Joint Commission's goal is to leverage hospitals to become better at what they do and to give the public confidence that their care is meeting contemporary standards. The GAO has been unrelenting in its focus on whether the pilot test findings of the new accreditation process would have led to a different distribution of hospitals with full accreditation status versus lower levels of accreditation, such as conditional or provisional. Further, the GAO has ignored the compelling data provided by the Joint Commission which show that the new survey accreditation process results in better discernment of the types of deficiencies that are directly related to patient care than the old process. We cannot over-emphasize this important fact. Evaluating and improving the quality of care in hospitals is not about counting deficiencies; it is about finding those deficiencies which, if not fixed, will generate poor results for patients, and making sure that these deficiencies are remedied in a timely fashion.

Life Safety Code (LSC)

The GAO has mischaracterized the Joint Commission's response to the five 2002 CMS recommendations for improving the LSC disparity rate. The Joint Commission has taken significant steps to address each of the CMS recommendations, and that information was provided to the GAO. Evidence of our commitment to the CMS recommendations is reflected by the fact that there was an approximately 50 percent decline in the number of hospitals found to be out of compliance with the LSC in the validation surveys during the study period. While the "disparity rate" declined only slightly over the study period, the number and percentage of hospitals that were found to be out of compliance with the LSC by the SSAs during this time period declined from 43 hospitals (23 percent) in the 2000 Medicare validation report to the Congress to 25 hospitals (12 percent) in the 2002 Congressional report. This point underscores the inadequacy of the "missed deficiency rate" metric suggested by the GAO. By its nature, this metric does not account for improvements in hospital standards compliance.

An additional important point not mentioned in the GAO report is that the Joint Commission lobbied strongly and eventually successfully to have the CMS adopt the 2000 version of the LSC rather than the 1985 version in use throughout the GAO study period. This difference in requirements contributed significantly to the identified disparities between Joint Commission and SSA surveys.

Finally, the GAO report fails to put hospital physical safety issues into perspective for the Congress, thus leaving the reader with the impression that accredited hospitals are not safe. Hospitals are in fact one of the safest health care occupancies in the nation, owing in large part to the attention that the Joint Commission has placed on the safety of the physical environment.

Conclusion

In closing, the Joint Commission is deeply concerned that the GAO has provided the public with a report that neither uses credible metrics nor includes highly relevant information about the Joint Commission's performance. In our view, it is irresponsible to alarm the public using statistics that have little meaning, and that do not reflect the true oversight of America's hospitals through Medicare's public-private sector partnership with the Joint Commission.

Sincerely,



Dennis S. O'Leary, M.D.
President

Appendix VI: GAO Contact and Staff Acknowledgments

GAO Contact

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Related GAO Products

Medicare Home Health Agencies: Weaknesses in Federal and State Oversight Mask Potential Quality Issues. [GAO-02-382](#). Washington, D.C.: July 19, 2002.

Medicare: HCFA's Approval and Oversight of Private Accreditation Organizations. [GAO/HEHS-99-197R](#). Washington, D.C.: September 30, 1999.

Home Health Care: HCFA Properly Evaluated JCAHO's Ability to Survey Home Health Agencies. [GAO/HRD-93-33](#). Washington, D.C.: October 26, 1992.

Health Care: Criteria Used to Evaluate Hospital Accreditation Process Need Reevaluation. [GAO/HRD-90-89](#). Washington, D.C.: June 11, 1990.

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