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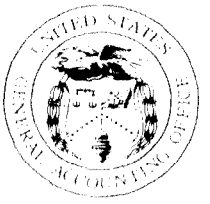
Report to the Secretary of Health and Human Services

September 1991

HEALTH CARE

Actions to Terminate Problem Hospitals From Medicare Are Inadequate



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GAO

United States
General Accounting Office
Washington, D.C. 20548

Human Resources Division

B-245099

September 5, 1991

The Honorable Louis W. Sullivan, M.D.
The Secretary of Health and Human Services

Dear Mr. Secretary:

At the request of the Chairman, Subcommittee on Health, House Committee on Ways and Means, we examined the Health Care Financing Administration's (HCFA) process of validating accreditation surveys conducted by the Joint Commission on Accreditation of Healthcare Organizations. We provided the Committee with information on the validation process and other related matters during hearings in June 1990,[1] and in two reports.[2] During this effort, we found that HCFA is not complying with regulations governing the termination of acute care hospitals from the Medicare program when deficiencies are not corrected within required time frames. This report discusses specific areas that need improvement and alternative enforcement options that can be used against problem hospitals to supplement termination.

Background

To participate in the Medicare program, a hospital must comply with health, safety, and organizational standards (referred to as conditions of participation) prescribed in the Code of Federal Regulations. HCFA applies 20 conditions of participation to its Medicare program. These conditions relate to areas of hospital operations, such as quality assurance, nursing services, and infection control. A hospital's failure to comply with one or more of these conditions can result in its termination from the Medicare program. The threat of termination and the publication of the names of hospitals that have received a termination notice are the only enforcement options HCFA has to deal with such situations.

To help it assure that acute care hospitals are complying with Medicare requirements, HCFA contracts with state agencies to conduct (1) validation surveys in a sample number of hospitals accredited by the Joint

[1]Health Care: HCFA Needs Better Assurance That Hospitals Meet Medicare Conditions of Participation (GAO/T-HRD-90-44, June 21, 1990).

[2]Health Care: Criteria Used to Evaluate Hospital Accreditation Process Need Reevaluation (GAO/HRD-90-89, June 11, 1990); and Health Care: Hospitals with Quality of Care Problems Need Closer Monitoring (GAO/HRD-91-40, May 9, 1991).

Commission,[3] (2) annual surveys of all nonaccredited hospitals, and (3) surveys to follow up on complaints received about the quality of care provided in any given hospital. Hospitals identified as having deficiencies that represent an immediate and serious threat to patient health and safety must take corrective action within 23 calendar days from completion of the state agency survey or be terminated from the Medicare program. If the deficiencies do not pose an immediate and serious threat to a patient's health and safety and credible evidence is received that compliance has been achieved, HCFA regulations require that its regional offices authorize the cognizant state agency to make a follow-up visit within 45 days of completion of the initial survey.[4] If compliance has not been achieved by the 55th day after completion of the survey, the regional office must notify the hospital that termination action will proceed. If noncompliance continues, on the 70th day an official notice will be sent to the hospital informing it that it is being terminated from the Medicare program. On the 75th day an announcement will be published in the local media that termination action is in process. Termination will take effect by the 90th day. There are, however, some exceptions.

Small rural hospitals can receive a temporary waiver of certain Medicare personnel requirements for a period of up to 1 year if the waiver does not jeopardize or adversely affect the health and safety of patients. Such a hospital must be located in a rural area, have 50 or fewer beds, and must have made a good faith effort to comply with personnel requirements consistent with any waiver (e.g., the requirement for 24-hour nursing service or the need for certain technical personnel, such as a respiratory therapist). In addition, hospitals that are having problems with their physical structure and, thus, require long periods of time to achieve full compliance with Medicare requirements can receive a temporary waiver from HCFA if such waivers will not jeopardize the health and safety of patients. Finally, HCFA will not initiate termination action against an accredited hospital if (1) it believes that continued full

[3]Hospitals that receive accreditation from the Joint Commission are considered to be in compliance with Medicare conditions of participation unless a validation survey or a survey conducted as the result of a complaint received by HCFA determines otherwise. Any hospital that loses its accreditation from the Joint Commission is no longer considered to be meeting Medicare requirements and is subject to immediate state agency review.

[4]Credible evidence is considered to be a corrective action plan accompanied by the hospital's assurance that the problems will be resolved within a specific time frame. A corrective action plan should be submitted to HCFA within 10 days after receiving HCFA's notice of deficiencies.

review by the state survey agency is not needed, (2) the Joint Commission accepts the state survey findings and agrees to monitor the correction of the deficiencies in accordance with specified time frames, and (3) the Commission provides HCFA with periodic reports of the hospital's progress toward correction.

Results in Brief

State survey agencies frequently identify acute care hospitals that are out of compliance with one or more Medicare conditions of participation. Most hospitals correct the problems identified to the satisfaction of state surveyors within the required 90 days. But many do not, and HCFA rarely terminates them from the Medicare program.

Termination for failure to correct deficiencies within 90 days may not, however, be appropriate in all circumstances. Several states—in enforcing their own licensing requirements—have recognized this and supplement their termination authority with enforcement options that can be tailored to the severity of the deficiency identified.

HCFA Does Not Follow Its Termination Procedures

HCFA is not terminating problem hospitals from the Medicare program as required by regulation. As a result, the credibility of its primary enforcement tool—the threat of termination from the Medicare program—is substantially diminished. Specifically, HCFA is not sending termination notices to all hospitals that have not corrected identified problems within 75 days after the initial survey and it is not terminating hospitals from the Medicare program when corrective action is not achieved within the required 90 days.

Hospitals Not Complying With Medicare Conditions of Participation

During the period October 1, 1986, to October 31, 1989, surveyors in the five regions we visited identified 195 accredited and nonaccredited acute care hospitals that were not complying with Medicare conditions of participation. Of these hospitals, 147 corrected the identified deficiencies to the satisfaction of state agency surveyors and 2 were terminated from the Medicare program within the required 90 days. Of the remaining 46 hospitals, none received state agency approval of corrective actions within the required 90-day time frame and only 1 hospital was ultimately terminated from the Medicare program. The following table summarizes the time frames involved in the five states' survey agency follow-up efforts.

Table 1: Number of Hospitals That Required More Than 90 Days for State Agency Approval of Corrective Actions Taken (Fiscal Years 1987-89)

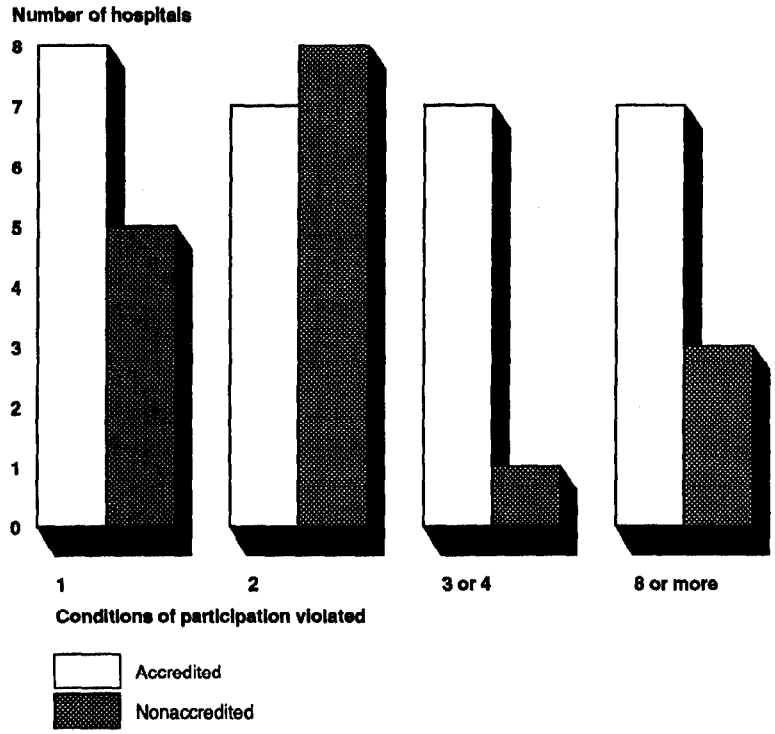
Year and type of hospital	Number of days to approve corrective actions			Hospitals terminated	No. of hospitals
	91-180	181-365	Over 365		
1987					
Accredited	3	4	1	0	8
Nonaccredited	5	1	0	0	6
1988					
Accredited	7	1	1	0	9
Nonaccredited	2	2	0	0	4
1989					
Accredited	9	3	0	0	12
Nonaccredited	6	0	0	1	7
Total	**32**	**11**	**2**	**1**	**46**

Only 10 of the 46 hospitals submitted their corrective action plans to HCFA within the required 10 days after receiving the notice of deficiencies, and 6 took more than 90 days to submit them. HCFA issued termination notices to only 13 of the 46 hospitals although each should have been issued one because none were granted waivers from the Medicare requirements by HCFA. Four notices were sent within the required 75 days after the initial survey was complete; the remaining 9 notices were issued from 78 to 224 days after the initial survey. After receiving a termination notice, 12 of the 13 hospitals took from 7 to 139 days to achieve corrective action and 1 hospital that could not achieve compliance was terminated from the program. Of the hospitals that received termination notices, 7 were accredited and 6 were nonaccredited.

Hospitals that did not receive state agency approval of their corrective actions within the 90-day time frame were frequently out of compliance with more than one Medicare condition of participation. Twenty-one of the 29 accredited hospitals were out of compliance with two to seven Medicare conditions, and 12 of the 17 nonaccredited hospitals were not complying with two to nine conditions.[5] The following figure provides a breakout of the number of conditions of participation that hospitals violated during a given survey.

[5]Sixteen of the accredited hospitals were identified as the result of validation surveys conducted by a state agency within 60 days of a Joint Commission accreditation survey. The remaining 13 accredited hospitals were identified through surveys conducted as a result of complaints received by HCFA.

Figure 1: Hospitals Not Complying With Medicare Conditions of Participation



The conditions of participation that were most often violated by both accredited and nonaccredited hospitals involved quality assurance (24); hospital organization and policies governing the delivery of care (18); infection control (14); nursing service (10); and physical aspects of the facility, such as the condition of the building (13). A complete listing of the Medicare conditions of participation and the number of times they were violated is in appendix II.

Regional Office Personnel Reluctant to Terminate Hospitals From Medicare Program

HCFA regional office personnel have been reluctant to terminate hospitals from the Medicare program for a variety of reasons. Several believe that such action is warranted only if a hospital has a history of serious problems and does not seem inclined to correct them. Others are concerned that the state agency surveyors' findings may not be accurate. Some HCFA regional personnel also stated that, in their opinion, HCFA regulations preclude termination action against a hospital accredited by the Joint Commission unless (1) an identified problem results in a high probability that serious patient harm or injury could occur or has

occurred and the problem has not been corrected, (2) the hospital's operating license is in jeopardy of being revoked by the cognizant state, or (3) identified deficiencies are repeated continually. But regulations allow termination of accredited hospitals under other circumstances. In response to the opinions of these regional office personnel, on March 14, 1989, HCFA's Director, Health Standards and Quality Bureau, informed all regional administrators that termination procedures can be used against hospitals accredited by the Joint Commission. According to HCFA headquarters officials, this memorandum was issued explicitly to reinforce the fact that termination action can be taken against accredited hospitals that are not in compliance with Medicare conditions of participation.

The Director of HCFA's Health Standards and Quality Bureau believes that the threat of termination from the Medicare program is an effective deterrent to continued noncompliance with Medicare conditions of participation by acute care hospitals. But he acknowledges that HCFA regional offices may not have consistently followed the regulations governing termination of hospitals. On August 2, 1991, the director stated that since the issuance of the March 1989 policy clarification, HCFA's role has become clearer and regional consistency has improved considerably. He also stated that the policy clarification has resulted in an increased number of termination notices being issued by the regions. Thus, he believes that the problem has been resolved. This assessment needs close examination, however. The policy clarification deals only with accredited hospitals, and 17 of the 46 hospitals cited in our analysis are nonaccredited. Further, HCFA is using an increase in the number of termination notices being sent to hospitals as evidence that the problem is being resolved. While this is an indication of improvement, it does not reveal the number of termination notices that should have been issued but were not.

Alternatives to Termination Provide Enforcement Flexibility

Hospitals found to be out of compliance with applicable federal or state quality assurance requirements must achieve compliance within a specific period of time or risk losing their state operating license or their privilege to participate in the Medicare program. The methods used by federal and state regulatory agencies to bring these hospitals into compliance vary. HCFA relies solely on the threat of termination to achieve compliance—several states have more enforcement alternatives available.

In a 1990 report, Medicare: A Strategy for Quality Assurance, the Institute of Medicine (IOM) recommended that HCFA adopt intermediate sanctions to help deal with hospitals that are not adhering to Medicare requirements. In the Institute's opinion, termination alone is too drastic an enforcement measure, and intermediate sanctions (e.g., fines, suspensions from Medicare admissions, and other restrictions) allow an enforcement response to be commensurate with the problem being addressed. The study concluded that such sanctions would help strengthen HCFA's survey and certification process.

The Institute found that HCFA officials were reluctant to terminate hospitals from Medicare. Many factors contribute to this reluctance. Federal and state officials are primarily motivated by the desire to make Medicare benefits widely available; they prefer to work with substandard hospitals to bring them into compliance; and they are subject to political pressure to keep facilities open, if at all possible. Further, due-process protections and the difficulty of documenting quality problems less obvious than gross negligence discourage enforcement attempts. Thus, termination action is taken only in extreme cases.

Several state health care agencies use a variety of enforcement mechanisms, including termination, to obtain compliance with their states' hospital standards. These options allow the cognizant state enforcement agencies to impose sanctions that are commensurate with the severity of specific problems. In our discussions with experts in the area of enforcement sanctions in the health care community and officials in five state health departments we asked them to identify the sanctions most commonly utilized with acute care hospitals.

They identified the following:

- assessing monetary penalties or fines for noncompliance or failure to correct deficiencies within certain time frames,
- publishing in the local media adverse reports of or sanctions imposed on hospitals for quality of care violations, and
- suspending all or some hospital admissions or services until corrective action is taken on identified problems.

Administrative Fines Vary Widely by State

Administrative fines used in four of the five states we visited range from $100 to $5,000 per violation, with one state agency authorized to impose penalties of up to $5,000 per day with no statutory limit on the number of days for which the fines can be assessed. The fines are based

on factors, such as the presence of imminent danger, length of time the violation has existed, whether the violation is a repeat offense, and the amount state law allows. Procedures allowing for informal or preliminary hearings before imposition of a final assessment are in place to allow providers to contest the state's assessment.

The following table shows the maximum fines allowed for quality of care violations in the five states we visited.

Table 2: State Authority to Assess Fines

State	Maximum amount allowed
New Jersey	$1,000 per day per violation
New York	$1,000 per violation
Pennsylvania	$100 per day per violation
South Carolina	$5,000 per violation or $5,000 per day
Tennessee	No authority to impose fines

Note: Table is based on information provided by state health officials and, in some instances, state legislation.

Administrative fines can be imposed for a wide variety of reasons. For example, a New York hospital that had violated state hospital operating standards related to medical staff requirements, patients' rights, radiology, nursing, emergency services, and compliance with state and local law over a period of several years was fined $65,000. Ultimately, a negotiated settlement was reached whereby the hospital was assessed a fine of $23,000, of which $6,000 would be waived if the hospital took appropriate corrective action. In Pennsylvania, fines are imposed on any hospital that does not correct a serious hospital licensure violation, such as mistreating or abusing patients, failure to submit a reasonable timetable for correcting deficiencies, or operating in an incompetent or negligent manner.

Threats of Adverse Publicity Encourage Hospitals to Correct Deficiencies

The Director of the American Hospital Association's (AHA) Policy Branch believes that the fear of adverse publicity is a powerful and effective motivator for hospitals to achieve and maintain compliance with pertinent state and federal regulations. State officials agree, and told us that publicizing a hospital's violations, either as the sole sanction or in conjunction with other sanctions, is one of the most effective actions that can be taken to prevent further violation of state standards. In four of the five states we visited, sanctions imposed as a result of violation of state standards are made public by issuing press releases or

by answering press inquiries. AHA officials caution, however, that organizations publicizing violations or sanctions imposed must be sure that their findings are correct and provision is made for due process before publication.

HCFA has the authority to publicize the names of hospitals that have received notification that they are being terminated from the Medicare program. But this action does not occur as often as it should because HCFA does not issue termination notices to problem hospitals that do not correct identified deficiencies within the required time frames. In addition to not complying with its own regulations, HCFA is missing an excellent opportunity to achieve rapid corrective action on identified problems. Hospital officials are sensitive to the reputation of their facilities and try to avoid sanctions that become public knowledge. For example, in South Carolina, where fines imposed are not publicized, but appeals may be, no hospital has ever appealed a fine. In Pennsylvania, health department officials threaten to notify third-party payers of a violation. This action could impact hospital revenues to a greater extent than the imposition of civil penalties. New York State Department of Health officials told us that hospital administrators will negotiate settlements rather than insist upon hearings because they do not want the publicity generated by a hearing.

Suspending Hospital Admissions Is an Option That Must Be Used Judiciously

Suspending new admissions to an acute care hospital or to any one of its medical services has the potential to deny patients access to care. This could pose a severe hardship for patients served by hospitals that are either geographically remote or are the only provider in the immediate area. Thus, it is not recommended as a routine sanction by most officials and groups we interviewed. For example, national consumer organization representatives and some state officials indicated that the acute care nature of hospitals makes suspension of new admissions difficult, particularly if patients need immediate care. But AHA staff told us that such action should be taken in cases where hospitals are repeat offenders.

Two of the states we visited (New York and Pennsylvania) grant their health departments the authority to ban new hospital admissions or reduce a hospital's number of authorized beds when violations are serious enough to threaten patient safety. New Jersey law does not specifically authorize banning admissions, but officials told us that it can be done under the state's authority to safeguard the public's health. The other two states do not ban hospital admissions.

Joint Commission Bases Its Enforcement Action on the Significance of the Problem

The Joint Commission is not a regulatory agency and the procedures it follows to assure that hospitals comply with its standards are not the same as HCFA's. The severity of any enforcement action taken by the Joint Commission against hospitals that do not fully comply with its standards depends on the nature and seriousness—from a patient health and safety perspective—of the deficiency identified. For example, if a hospital is found to have problems that pose an immediate threat to the life and safety of patients, it can lose its accreditation within 10 to 14 days of completion of the initial survey. In all other instances, a noncompliant hospital is given 6 months or more to correct identified deficiencies.

A hospital that has widespread and pervasive problems that are not life threatening can receive a conditional accreditation and can be given up to 9 months from completion of the initial accreditation survey before a resurvey will be conducted to determine whether corrective action has been achieved.[6] If problems still exist after resurvey, a recommendation will be made to revoke the hospital's accreditation and HCFA will be notified of the Commission's decision. Hospitals that receive Commission accreditation with Type I recommendations[7] will be monitored by the Commission through surveys focused on specific deficiencies or written progress reviews at stated times over the 3-year accreditation cycle.

The Director of HCFA's Health Standards and Quality Bureau believes that the Joint Commission's time frames to achieve corrective action have been inconsistent with HCFA's enforcement program (e.g., corrective action required within 90 days after completion of the initial survey) and should be shortened. The Commission agrees that its time frames for dealing with conditionally accredited hospitals are too long and is willing to give early notification to HCFA of problem hospitals. Specifically, the Commission has stated that it is willing to provide notice to HCFA of preliminary conditional accreditation and denial of accreditation recommendations at the same time that such notice is provided to affected hospitals. The Joint Commission is also willing to provide HCFA with the names of all hospitals that receive a "no compliance"

[6]The Commission currently takes about 60 days from completion of the initial accreditation survey to determine whether a hospital should be conditionally accredited. The affected hospital is then given 30 days to submit a plan for corrective action. If the plan is acceptable, the hospital will be notified that a follow-up survey will be conducted by the Commission within 6 months following Commission approval of the plan.

[7]A Type I recommendation represents an area of deficiency in which a hospital is ordinarily expected to achieve substantial or significant compliance with the relevant Commission standard within a specified time.

score on any Joint Commission standard. On August 2, 1991, the Director of HCFA's Health Standards and Quality Bureau told us that HCFA is analyzing the Commission's proposal to determine if it is sufficient to deal with HCFA's concerns.

Conclusions

The objective of HCFA's enforcement action is to bring a hospital into compliance with Medicare conditions of participation and keep it in compliance. But the penalty for noncompliance must be credible enough to make a hospital take immediate action to resolve a stated problem. HCFA's limited application of termination procedures casts some doubt on its willingness to terminate any but the worst hospitals from the Medicare program.

Termination may be too harsh a penalty to impose on some hospitals. In our opinion, HCFA should have a variety of enforcement options available that can be applied on the basis of a problem's impact on the health and safety of the patients, the willingness of a hospital to correct the problem, and the hospital's history of compliance with Medicare requirements. The options could include penalties, such as media coverage of identified problems, monetary penalties, bed closures, or a combination of these penalties. Termination should, however, be kept as an enforcement option to be used against those few hospitals that either cannot or will not comply with Medicare requirements.

While we believe HCFA should have some flexibility in the enforcement options it has available to deal with problem hospitals, we also believe that HCFA must make maximum use of the authority it already has. Under existing regulations, HCFA can publicly identify hospitals that have been issued termination notices. But HCFA is not issuing termination notices as frequently as it should, so the publicity aspect of this enforcement mechanism is muted. Further, in the absence of alternative enforcement options, HCFA must do a better job in complying with its current termination requirements.

Recommendations

We recommend that you direct HCFA to comply with termination procedures pertaining to hospitals that are not in compliance with Medicare conditions of participation. If you determine that the initiation of termination action against noncomplying hospitals is too harsh a sanction for HCFA to pursue, we recommend that you develop a proposal to the Congress authorizing HCFA's use of alternative enforcement actions.

We are sending copies of this report to the Chairman, Subcommittee on Health, House Ways and Means Committee, and to interested congressional committees and members. We will also make copies available to others upon request.

This report contains recommendations to you. As the Secretary of Health and Human Services, you are required by 31 U.S.C. 720 to submit a written statement on actions taken on these recommendations to the Senate Committee on Governmental Affairs and the House Committee on Government Operations not later than 60 days after the date of this report and to the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of this report.

If we can provide any further assistance or if you have any questions about this report, please call me at (202) 275-6207. Major contributors to this report are listed in appendix III.

Sincerely yours,

David P. Baine

David P. Baine
Director, Federal Health
Care Delivery Issues

Contents

Abbreviations

AHA	American Hospital Association
HCFA	Health Care Financing Administration
IOM	Institute of Medicine

Scope and Methodology

In performing this review, we examined state survey agency reports prepared from 1987 to 1989 under the auspices of five HCFA regional offices.[1] We identified hospitals that were found to be out of compliance with Medicare conditions of participation by (1) interviewing cognizant personnel in HCFA's central and regional offices to clarify or expand on data contained in the survey reports, (2) examining federal regulations and procedures that govern how hospitals that are out of compliance with Medicare conditions of participation should be dealt with, and (3) comparing HCFA's enforcement requirements to the enforcement actions taken by regional personnel to determine the extent to which regulations were being complied with. For comparative purposes, we interviewed officials in several state health departments to determine what enforcement mechanisms they use to deal with hospitals that fail to comply with their licensure requirements.

At the HCFA regional offices visited, we examined case files on accredited and nonaccredited hospitals that were out of compliance with Medicare requirements to determine what action HCFA took to assure that hospitals corrected deficiencies, the timeliness and adequacy of these follow-up actions, and the frequency of repeat deficiencies. We also interviewed HCFA regional office personnel for their perceptions about the efficacy of termination actions, whether alternative enforcement actions are feasible, and the problems they envision in implementing alternative enforcement options if they were to become available.

We interviewed officials in five state health agencies (New Jersey, New York, Pennsylvania, South Carolina, and Tennessee) that conduct hospital surveys for HCFA as well as surveys for state licensing to obtain their views on the need for and use of alternative enforcement actions. We also examined case files at each agency to (1) identify the use of alternative enforcement actions and, when used, whether they achieved compliance; (2) determine what impediments existed to using these alternatives; (3) obtain resource estimates needed to impose alternative enforcement actions; and (4) determine the potential for the use of these actions at the federal level.

[1] We visited HCFA's regional offices in Georgia, California, Illinois, New York, and Colorado.

Medicare Conditions Out of Compliance at Hospitals That Did Not Take State-Approved Corrective Actions Within 90 Days

	Conditions out of compliance	
Medicare condition	**At accredited hospitals**	**At nonaccredited hospitals**
Quality assurance	16	8
Governing body	10	8
Physical environment	7	6
Infection control	9	5
Laboratory	6	5
Nursing service	6	4
Medical staff	5	2
Medical records	7	1
Pharmacy	7	2
Food and dietary	5	1
Respiratory care	4	1
Outpatient care	2	0
Federal and other laws	1	3
Surgical service	1	1
Radiology	0	1
Rehabilitation	1	0
Emergency service	0	0
Patient dumping	0	0
Utilization review	0	0
Anesthesia services	0	0
Total	**87**	**48**

Major Contributors to This Report

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