

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**The External Review of Hospital Quality**

**The Role of Medicare Certification**



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# EXECUTIVE SUMMARY

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## PURPOSE

To assess the role of the Health Care Financing Administration and Medicare certification in the external review of hospital quality.

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## BACKGROUND

### External Quality Review of Hospitals in the Medicare Program

Hospitals routinely offer valuable services, but also are places where poor care can lead to unnecessary harm. The external quality review of hospitals plays an important role not only in protecting patients from such harm, but also in complementing the hospitals' own internal quality efforts. The Federal Government relies on two types of external review to ensure hospitals meet the minimum requirements for participating in Medicare: accreditation, usually by the Joint Commission on Accreditation of Healthcare Organizations, and Medicare certification, by State agencies. About 20 percent of the 6,200 hospitals that participate in Medicare are nonaccredited and certified by the States.

### This Inquiry

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

We organized this report around a framework for considering the external review of hospital quality. This framework consists of five components: announced, on-site surveys of hospitals; unannounced, on-site surveys of hospitals; responses to complaints concerning hospitals; responses to major adverse events in hospitals; and collection and dissemination of standardized performance measures.

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## FINDINGS

### The HCFA's routine hospital certification surveys are a low priority.

**The backlog of surveys is growing.** The proportion of nonaccredited hospitals not surveyed within the 3-year industry standard grew from 28 percent in 1995 to 50 percent

in 1997. For those hospitals waiting over 3 years for a survey, the average time between surveys is over 5 years. In fact, the total number of certification surveys conducted decreased from 286 surveys in 1995 to 184 surveys in 1997, a drop of 36 percent.

**The HCFA's survey and certification budget goes first to nursing homes and home health agencies, which have mandated survey cycles that hospitals lack.**

Hospital certification surveys appear 10<sup>th</sup> on a list of 12 HCFA workload priorities for States, behind surveying both nursing homes and home health agencies. Congress mandates that HCFA survey nursing homes and home health agencies on a regular cycle. Hospitals lack such a mandate.

**The HCFA's hospital review focuses on complaints and serious incidents.**

State survey agencies are the front-line responders to complaints and serious incidents at both accredited and nonaccredited hospitals. The HCFA assigns responding to such events a higher budget priority than routine surveys.

**The HCFA's certification survey results fail to make meaningful distinctions among nonaccredited hospitals.**

Certification surveys simply result in a status of certified or not certified; no grades or rankings stem from the survey. Hospitals rarely fail to achieve certification. The HCFA decertified 7 hospital in 3 years.

**The HCFA has not sought to collect or disseminate standardized performance data for nonaccredited hospitals.**

While HCFA has made strides in collecting data from other provider types, such as home health, managed care, and nursing homes, it is not currently collecting or analyzing such data as part of its system of hospital review. However, the proposed revision of the hospital conditions of participation (issued on December 19, 1997) invite comments on whether HCFA should collect performance data and what that data should encompass.

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## **CONCLUSION**

In the domain of external quality reviews, the State agencies play major roles as troubleshooters: responding to complaints and serious incidents at accredited and nonaccredited hospitals. But given the limited pool of Federal funds available to support State survey and certification activities in general and the relatively low priority of routine hospital surveys in particular, the 1,442 nonaccredited hospitals across the country receive insufficient attention through external reviews. Surveys of such hospitals tend to be

triggered on the basis of a serious incident involving patient harm rather than as part of a routine review intended to prevent such incidents. This is the central and troubling conclusion of this report. In our summary report, *A Call for Greater Accountability*, we direct our recommendations to HCFA stemming from this report and our entire inquiry.

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## COMMENTS

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

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# INTRODUCTION

## PURPOSE

To assess the role of the Health Care Financing Administration's Medicare certification in the external review of hospital quality.

## BACKGROUND

### Hospital Safety

Hospitals are an integral part of our healthcare system, offering services that improve, extend, and even save lives. But they are also places where inappropriate care can lead to unnecessary harm. This reality was clearly underscored in 1991, when a Harvard medical practice study revealed the results of its review of about 30,000 randomly selected records of patients hospitalized in New York State during 1984. The study found that 1 percent of the hospitalizations involved adverse events caused by negligence.<sup>1</sup> On the basis of its sample, the study team estimated that during that year, negligent care provided in New York State hospitals was responsible for 27,179 injuries, including 6,895 deaths and 877 instances of "permanent and total disability." Many other more recent studies have reinforced the concerns raised by the Harvard study. Of particular note was one that focused on the care received by 1,047 hospitalized patients in a large teaching hospital affiliated with a medical school. It found that 17.7 percent of these patients received inappropriate care resulting in a serious adverse event--ranging from temporary disability to death.<sup>2</sup> In the public eye, these scholarly inquiries have been overshadowed by media reports that describe, often in graphic detail, the harm done to patients because of poor hospital care.<sup>3</sup>

Hospitals rely upon a variety of internal mechanisms, from physician credentialing, to peer review and benchmarking, in order to try to avoid such incidents and to improve the quality of care provided in their facilities. External quality review serves as a vital additional safeguard. It provides a more detached, independent mechanism for assessing the adequacy of hospital practices. Such oversight is of fundamental importance to patients and to the public and private entities that purchase health care services on their behalf. Protecting patient safety and improving the quality of patient care must be a top priority of external review.

### Medicare's Interest in External Hospital Quality Review

The Medicare program covers about 38 million elderly and disabled individuals, many of whom are high users of hospital care.<sup>4</sup> In 1997, Medicare spent about \$136

billion on Part A, the hospital insurance benefit.<sup>5</sup> This figure is just over half the total amount the Federal government spent on all Medicare benefits.<sup>6</sup> In the same year, Medicare spent over \$80 billion for inpatient acute hospital care alone.

Since Medicare's inception, external quality review has been a part of the Medicare program. When Congress enacted the Medicare Act in 1965, it required hospitals to meet certain minimum health and safety requirements to participate in the program.<sup>7</sup> Those minimum requirements, called the Medicare conditions of participation, were published in 1966, revised in 1986, and are now being revised again (see appendix A).<sup>8</sup> Within the Medicare Act itself, however, Congress provided that hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations were deemed to be in compliance with the conditions of participation. Congress also provided that hospitals accredited by the American Osteopathic Association could be considered in compliance, but only to the extent that the Secretary deemed appropriate.<sup>9</sup> Thus, accreditation by the Joint Commission or the American Osteopathic Association provides entree into the Medicare program. About 80 percent of the 6,200 hospitals that participate in Medicare are accredited by the Joint Commission. Those hospitals wishing to participate in Medicare without accreditation must go through a Medicare certification process. The Health Care Financing Administration (HCFA) relies on State survey and certification agencies (hereafter called State agencies) to conduct certification surveys at these hospitals to determine compliance with the Medicare conditions of participation. States currently certify 1,442 nonaccredited hospitals nationwide.<sup>10</sup>

Regardless of the route a hospital takes to Medicare participation, Medicare bears a cost for the external review, either directly by funding State agencies or indirectly through hospital charges that include the overhead cost of periodic accreditation surveys.

## **The Nature of Medicare Certification**

The Medicare certification process is a public, regulatory function. It aims to ensure that hospitals wishing to serve Medicare beneficiaries, but not wishing to be accredited, meet the conditions of participation. The 51 State agencies conduct the onsite certification surveys on HCFA's behalf. The Medicare certification process is available at no cost to hospitals.

## **This Inquiry and Report**

This report examines the role of Medicare certification in the external review of hospital quality. It focuses on the hospital survey work undertaken by State certification agencies on behalf of HCFA. In this report, we offer a framework for considering the external review of hospital quality and apply that framework to Medicare certification.



This report is part of a series of four companion reports that resulted from our inquiry. A second, *The Role of Accreditation* (OEI-01-97-00051), assesses the Joint Commission’s approach to hospital accreditation. A third, *Holding the Reviewers Accountable* (OEI-01-97-00053), describes how HCFA oversees both the Joint Commission and the State survey agencies. The fourth report, *A Call for Greater Accountability* (OEI-01-97-00050), provides a summary of external hospital quality review and presents the recommendations emerging from our inquiry.

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

We conducted this inspection in accordance with the *Quality Standards for Inspections* issued by the President’s Council on Integrity and Efficiency.

# HOSPITAL REVIEW FRAMEWORK

The following five components present a framework for considering the external quality review of hospitals. They are intended to complement the internal quality assurance and improvement efforts that hospitals undertake themselves. They are approaches that health care purchasers, such as Medicare and Medicaid, can rely upon to ensure that their beneficiaries receive quality services from hospitals. They can also be of use to beneficiaries and other consumers concerned about the quality of their hospital care.

We present the components to facilitate analysis of the extent and type of external review that is desirable, whether carried out by accreditation bodies, certification agencies, Medicare Peer Review Organizations, HCFA, or others. Each component has strengths and limitations. Moreover, each can be used in support of a review philosophy based on continuous quality improvement, more traditional compliance enforcement, or some combination thereof.

We omitted a sixth component: the retrospective review of medical records to determine appropriateness of care. Formerly a role of the Medicare Peer Review Organizations, such medical record review is no longer carried out on such a large scale. However, some medical record review does occur as part of the components described below.

## ***1. Announced, On-Site Surveys of Hospitals***

These involve some combination of observations of facility and equipment; reviews of medical credentials, and other records and documents; and interviews. They result in a pass/fail or some kind of score intended to distinguish level of performance. They can also involve follow-up to correct or improve.

## ***2. Unannounced, On-Site Surveys of Hospitals***

The approach is basically the same as above except that the hospital has not had time to prepare. The intent is to gain a clear assessment of the facility as it typically functions and to trigger any necessary follow-up.

## ***3. Response to Complaints Concerning Hospitals***

These involve complaints of a particular instance of care or more encompassing matters concerning a hospital's performance. The response to complaints can range from a minimal distant review to a thorough on-site review. The process can trigger corrective actions and system improvements.

## ***4. Response to Major Adverse Events in Hospitals***

These involve cases where substantial patient harm resulted from what may be poor performance on the part of the hospital and/or its practitioners. Here, too, the response can range from minimal to thorough and can trigger corrective actions and system improvements.

## ***5. Collection and Dissemination of Standardized Performance Measures***

The aim here is to establish the standardized use of measures in ways that enable purchasers, consumers, accrediting bodies, and others to compare hospital performance. The comparisons can focus on a hospital's own performance over time and/or on how its performance compares to other hospitals. The data can be drawn from surveys of patients or providers, billing claims, and the hospitals' own records.

# PROFILE OF CERTIFICATION

The table below summarizes our assessment of Medicare’s approach to certifying nonaccredited hospitals, based on the framework we presented on the previous page. The report generally follows this profile in its evaluation of Medicare certification.

State agencies carry out certification surveys under the same guidelines from HCFA. However, their implementation is likely to vary from State to State. We observed one routine, announced certification survey, and include our observations in appendix C.

Element	Description	Degree of Emphasis
Routine, Announced, On-Site Surveys	State agencies conduct surveys, on behalf of HCFA, to assess compliance with Medicare conditions of participation. Can involve follow-up.	Minor. Low spending priority. No mandate requiring certification surveys at regular time intervals.
Random, Unannounced, On-Site Surveys	Not Conducted.	None
Responses to Complaints	State agencies conduct focused, unannounced surveys in both accredited and nonaccredited hospitals on any condition of participation involved in a complaint. Survey can be expanded to include all conditions if the State agency finds conditions out of compliance. For accredited hospitals with conditions found out of compliance, HCFA can remove deemed status. Can involve follow-up.	Major. Core of HCFA’s oversight. High spending priority.
Responses to Serious Incidents	Same as complaints.	Same as complaints; HCFA makes no distinction.
Standardized Performance Data	Not Collected.	12/19/97 Federal Register Notice solicited comments on whether HCFA should collect performance data.

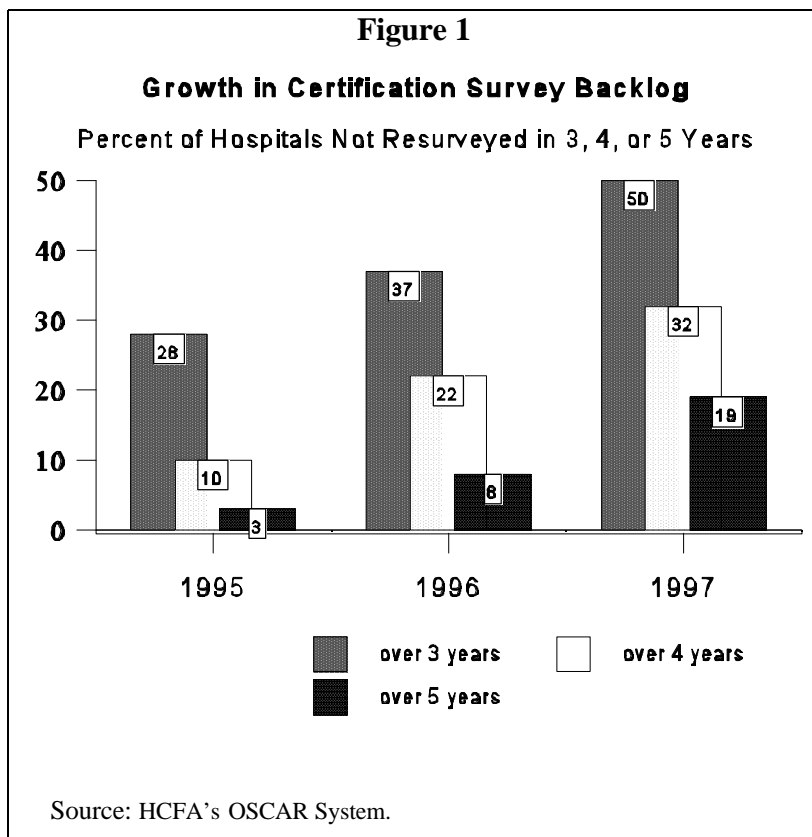
# FINDINGS

## The HCFA's routine hospital certification surveys are a low priority.

### The backlog of surveys is growing.

In 1995, 28 percent of nonaccredited hospitals nationwide had not been surveyed within the 3-year industry standard.<sup>11</sup> By 1996, that backlog grew to 37 percent. By

1997, 50 percent of the 1,361 nonaccredited hospitals in the 50 States and the District of Columbia had not had a survey in at least 3 years (see Figure 1).<sup>12</sup>



The average elapsed time between surveys is currently just over 3 years. Just a few years ago, States were doing much better, with elapsed times averaging 1 and 2 years.<sup>13</sup> The increasing time between surveys coincides with the dramatic rise in home health agencies--which State agencies must also survey.

The average elapsed time is growing for all but a handful of States. For those hospitals waiting over 3 years for a survey, the average time

between certification surveys is over 5 years. Nationwide, 1 in 5 States had at least 1 hospital go as long as 8 years without a survey. Indeed, the total number of certification surveys conducted has dropped 36 percent in 2 years: from 286 surveys in 1995 to 184 surveys in 1997.<sup>14</sup>

The situation is worse in States with the most nonaccredited hospitals. Four States account for 27 percent of the nonaccredited hospitals in the country: Texas, Kansas,

California, and Louisiana. Each of those States has over 50 nonaccredited hospitals. The average elapsed time between surveys in Texas is 4.4 years; in Kansas, 4.6 years; in California, 4.5 years; and Louisiana, 3.8 years. Between October 1, 1996 and September 30, 1997, Texas conducted just 4 routine certification surveys; Kansas conducted 8; California, 13; and Louisiana, 3.<sup>15</sup>

Of course, nonaccredited hospitals are also subject to State licensure laws, another form of external hospital oversight. Indeed, every State except Ohio requires hospitals to be licensed. But what that licensure translates to in terms of on-site surveys at nonaccredited hospitals varies considerably across the States. Surveying nonaccredited hospitals on-site is a costly undertaking for States.<sup>16</sup> Indeed, 25 States reported trying to piggyback their State licensure surveys onto Medicare certification surveys whenever possible--making licensure surveys unlikely without a certification survey. The number of recent licensure surveys among the four States with the most nonaccredited hospitals ranged from surveying all (California) to surveying none (Texas); with Kansas and Louisiana surveying 30 and 40 percent respectively.<sup>17</sup>

## **The HCFA's survey and certification budget goes first to nursing homes and home health agencies.**

Hospital certification surveys appear 10th on a list of 12 HCFA workload priorities for States, behind surveying nursing homes, Intermediate Care Facilities for the Mentally Retarded, home health agencies, and all types of complaint investigations and allegations of patient dumping.<sup>18</sup> By statute, HCFA must survey nursing homes and home health agencies at regular time intervals, an activity that uses up most of the survey budget.<sup>19</sup> Hospitals, however, lack such a mandate, making hospital surveys significantly more vulnerable to budget cutting. In fact, the portion of HCFA's 1997 survey budget dedicated to hospital certification surveys appears to have dropped by about half from that of 1996.<sup>20</sup>

For Fiscal Year 1999, HCFA funded States to survey 10 percent of the 1,415 nonaccredited hospitals, or a total of 140 hospitals.<sup>21</sup> With this level of funding, States could survey hospitals every 10 years. By contrast, HCFA funds surveys for 62 percent of home health agencies per year.<sup>22</sup> That means for 1999, HCFA will fund surveys for over 6,000 of the 10,119 home health agencies.<sup>23</sup> At that level of funding, States could survey home health agencies about every 18 months. One director of a State Health Department captured some of the frustration surrounding hospital survey funding in a 1997 letter to the Secretary of Health and Human Services where she writes:

At a time when the health care system is changing more rapidly than ever before and pressure for cost reduction creates the potential for reduced quality, our budget in the Health Department has been cut in half. An example of the impact of this cut is the incredible reduction in funds for hospital survey activity...This

potentially means that Medicare beneficiaries may be deprived of access to a hospital where they can receive quality health care services. Most of the Medicare allocation...supports...[regulating] nursing homes.

In addition to contending with low Federal priority, half the States report having fewer hospital survey staff now than they did 5 years ago. States do, however, have some flexibility in deciding which hospitals to survey with their limited resources. Most States identified two factors as playing major roles in those decisions: complaints received about hospital care (identified by 41 of 50 States) and time elapsed since the last certification survey (identified by 35 of 50 States). (For a summary of our observations from one Medicare certification survey conducted by one State agency, see appendix C.)

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## **The HCFA's hospital review focuses on complaints and serious incidents.**

The HCFA spends most of its hospital survey budget investigating complaints and serious incidents at either accredited or nonaccredited hospitals. These activities fall third on HCFA's list of survey budget priorities.<sup>24</sup> Thus, HCFA and the States devote far more resources to responding to complaints than conducting announced surveys of nonaccredited hospitals, which fall 10th on that list. In fact, according to data reported by HCFA, State agencies conducted several thousand complaint surveys over the past few years: 2,166 in 1996, 2,079 in 1997, and 1,577 in 1998. This level of attention reflects the expectations of stakeholders who largely view government--State and Federal--as public protectors: in their words, "It falls on the government to be the bad guy, or policeman" and "it's a traditional government function [to respond to such events]."<sup>25</sup>

The focus on responding to complaints and serious incidents has grown in recent years: 38 of the 51 States (75 percent) we surveyed reported that the number of hospital complaints they receive has increased over the last few years. Of course, some of this increase could be due to the anti-dumping laws passed in 1986, which spawned complaints.<sup>26</sup> Plus, errors in hospitals appear to be garnering the media's, and therefore HCFA's and the States', attention.<sup>27</sup> The HCFA regional offices also receive complaints and refer them on to the States. The States, in turn, look to HCFA for guidance on which complaints to investigate, especially when the hospitals in question are accredited.

Unlike certification surveys, which are announced in advance, most responses to complaints and incidents are unannounced. The responses tend to be intensive, focusing on a specific service area or incident--at least at the start--because Federal law requires the scope of that response to be limited to the particular condition in question.<sup>28</sup> But, if the surveyors find a hospital to be out of compliance with a condition during that narrow investigation, they can expand the scope of their response to encompass all the conditions of participation.<sup>29</sup> Responses to complaints and incidents also tend to last longer than the

few days it takes to conduct a certification survey. For example, we observed parts of one response that lasted 2 weeks.

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## **The HCFA's certification survey results fail to make meaningful distinctions among nonaccredited hospitals.**

Certification surveys simply result in a status of certified or not certified. They neither rank nor grade hospitals. Surveyors can find three levels of deficiencies: condition-level, standard-level, and requirement-level. One hospital could have deficiencies in one, two, or all three levels. Condition-level deficiencies are the most serious. Hospitals with standard- and/or requirement-level deficiencies can maintain their Medicare certification. In fact, HCFA does not require such hospitals to make corrections. Only condition-level deficiencies can terminate a hospital's certification status. And that rarely happens. The HCFA reports that it terminated 7 hospitals over the past 3 years: 2 in 1996, 3 in 1997, and 2 in 1998.

The path to termination is not direct, however, as the survey process gives hospitals opportunities to correct their condition-level deficiencies. Medicare surveyors use termination notices to prompt hospitals to make corrections. The HCFA uses a termination notice as a temporary certification status; hospitals either correct their deficiencies and receive full certification or are terminated. When Medicare surveyors find a hospital to be out of compliance with the conditions to such an extent that patients are in jeopardy, they use the 23-day termination notice. For hospitals with condition-level deficiencies but no finding of patients in jeopardy, surveyors use a 90-day termination notice. The HCFA does not track the number of hospitals that receive termination notices.

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## **The HCFA has not sought to collect or disseminate standardized performance data for nonaccredited hospitals.**

The HCFA is not currently collecting or analyzing standard hospital performance data or quality measures as part of its system of reviewing hospitals. The proposed revisions to the hospital conditions of participation (issued on December 19, 1997) invite comments on both whether HCFA should collect standardized performance data and what that data might encompass. But while the proposed conditions note an intent to collect such data, they fall short of requiring it because "we do not believe it is reasonable to establish any related requirements at this time, in view of the lack of any current consensus or science that could establish a reliable and valid set of measures."<sup>30</sup> Stakeholders with whom we spoke endorsed the concept of HCFA establishing and collecting standardized performance data, identifying it as an "appropriate role" and a "route toward nationally comparable data."

The HCFA has been more involved in standardized performance data in other provider settings than it has in hospital settings. For example, it led in developing the home health data set, which will support performance measurement, for home health agencies.<sup>31</sup> Furthermore, it recently developed the a set of quality standards for managed care organizations.<sup>32</sup> It has also called for the managed care organizations that enroll Medicare beneficiaries to report certain standardized data in the form of indicators.<sup>33</sup> Indeed, it was involved in developing the indicators for the Medicare population.<sup>34</sup> Additionally, HCFA was involved in the development of the Quality Assurance Reform Initiative, a guide for State Medicaid agencies as they develop methods and standards for monitoring the quality of care provided to Medicaid managed care enrollees.

To date, however, no single system of performance data for hospitals has emerged as the industry standard. Hundreds of such systems exist, though, and hospitals all over the country have implemented them according to their own needs. The proposed conditions do call for hospitals to have their own system of performance measurement in place. Their approaches must encompass a “continuous effort to improve...performance, incorporating to the greatest extent possible an approach that focuses on the hospital’s performance in improving patient outcomes and satisfaction...[and] would require that each hospital develop, maintain, and evaluate an effective data-driven quality assessment and performance improvement program.”<sup>35</sup> Indeed, many hospitals have already invested in a variety of such systems.



# CONCLUSION

In the domain of external quality reviews, the State agencies play major roles as troubleshooters: responding to complaints and serious incidents at accredited and nonaccredited hospitals. But given the limited pool of Federal funds available to support State survey and certification activities in general and the relatively low priority of routine hospital surveys in particular, the roughly 1,415 nonaccredited hospitals across the country receive insufficient attention through external reviews. Surveys of such hospitals tend to be triggered on the basis of a serious incident involving patient harm rather than as part of a routine review intended to prevent such incidents. This is the central and troubling conclusion of this report. In our summary report, *A Call for Greater Accountability*, we direct our recommendations to HCFA stemming from this report and our entire inquiry.

**Medicare Conditions of Participation**

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The Medicare conditions of participation (COP) were first published in 1966 and revised in 1986 (42 C.F.R. 482.1-482.66). On December 19, 1997, HCFA published a proposed COP for hospitals ( 62 Fed. Reg. 66,726). On July 2, 1999, it published an interim final rule concerning patients’ rights. Below are the components of the existing COP for non-specialty hospitals from 1986, followed by the components of the new proposed COP.

<b>Existing COP</b>	<b>Proposed COP</b>
<b>Subpart A- General Provisions</b>	<b>Subpart A- General Provisions</b>
Provision of emergency services by nonparticipating hospitals	Patient Rights (issued as an interim final rule July 2, 1999)
<b>Subpart B- Administration</b>	<b>Subpart B- Patient Care Activities</b>
Compliance with Federal, State, and local laws Governing Body	Patient Admissions, assessment, and plan of care Patient care Quality assessment and performance improvement Diagnostic and therapeutic services or rehabilitation services Pharmaceutical services Nutritional services Surgical and anesthesia services Emergency services Discharge Planning
<b>Subpart C- Basic Hospital Functions</b>	<b>Subpart C- Organizational Environment</b>
Quality assurance Medical staff Nursing services Medical record services Pharmaceutical services Radiologic services Laboratory services Food and dietetic services Utilization review Physical environment Infection control	Administration of organizational environment Infection control Human resources Physical environment Life safety from fire Blood and blood products transfusions Potentially infectious blood and blood products Utilization review
<b>Subpart D- Optional Hospital Services</b>	
Surgical services Anesthesia services Nuclear medicine services Outpatient services Emergency services Rehabilitation services Respiratory care services	

## Methodology

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

### The HCFA

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

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

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

### The State Survey and Certification Agencies

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

### Accrediting Organizations

We interviewed officials from both the Joint Commission on Accreditation of Healthcare Organizations and the American Osteopathic Association. We also reviewed documents from both organizations, including mission statements, accreditation manuals,

policies, and hospital survey files. We requested and received aggregate data from the Joint Commission reflecting its recent hospital survey activity. All Joint Commission data are presented as reported by the Joint Commission, unless otherwise noted. For purposes of this inquiry, we focused our analysis on the Joint Commission.

## **Survey Observations**

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

## **Stakeholder Interviews**

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

## **Other Documents**

In addition to the documents referenced above, we reviewed statutory and regulatory language and a variety of articles from newspapers, journals, magazines, and newsletters.

## Certification Survey

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During the course of our inquiry, one Office of Inspector General (OIG) analyst observed one Medicare certification survey. What follows is a summary of the observations from that survey.

### Background

The survey was of a 34-bed nonaccredited county hospital located in a rural area. The hospital had recently undergone major renovations but still used parts of the older buildings, which were at least 50 years old. Staff could pass from the renovated parts of the building to the older parts, and construction was still underway. Plastic strips hung in doorways to minimize the dust from the ongoing renovations. The pharmacy and operating rooms were housed in the older building, which was plagued by roof leaks and a finicky cooling system, leaving the area humid and musty. Warehouse style buildings in the back of the hospital housed the medical records and some administrative offices.

The hospital came under new management 2 years prior to the observed survey. During the time of the survey, the hospital had an average daily census of 13, an increase over prior years. Most of the surgeries performed at this hospital were hernia repairs, cholecystectomies, or gynecological procedures. Since the renovations, the hospital experienced an increase in deliveries.

Three experienced nurse surveyors and one surveyor in training (also a nurse) surveyed this hospital. One served as team leader. All of the surveyors had clinical nursing experience. At least one surveyor had been at the hospital previously. Before arriving at the hospital, they reviewed the State's historical files of compliance and complaints for this hospital. Thus they were familiar with the hospital's history of compliance problems. They were also aware of the hospital's recent problems involving physicians on the hospital staff. For example, one physician on staff was imprisoned for narcotics abuses and another lost his medical license due to a pattern of unnecessary surgeries, high complication rates, and poor care.

The State survey agency notified the hospital of the survey 3 weeks in advance.

## Summary Observations

The survey began around 11:30 in the morning on the first day and went until noon on the third day, lasting about 19 hours total. The surveyors continued surveying until 5:30 or 6:00 PM on the first 2 days. The survey began with an opening conference that included the surveyors and the hospital's leadership. After general introductions and reviewing a loose agenda, the hospital presented an overview of its recent improvements. Then the surveyors began their document reviews, which covered hospital logs, minutes, bylaws, and medical records, among others. By early afternoon, the surveyors split up to begin their sessions, with the trainee always assigned to follow a senior surveyor.

The surveyors relied on interviews, document reviews, and observations. Once or twice a day, the surveyors would compare notes and share concerns so others could pursue them in different areas of the hospital. The surveyors selected the files they would review themselves, based on staff rosters; surgical, admission, and emergency logs; and other documents. They also pushed alarm bells and observed responses. They tested the hospital staff's knowledge by asking them to demonstrate certain tasks, such as turning on pieces of equipment, testing a defibrillator, changing oxygen tanks, and sterilizing a scope.

Through the information gleaned from the above, the surveyors identified a range of concerns. Among them were the following:

- ▶ Staff were untrained in certain hospital equipment. For example, when surveyors asked for a demonstration of the hospital's new negative pressure room, no one knew how to turn it on.
- ▶ The hospital's emergency call systems were inadequate. For example, the surveyors pulled call bells in the emergency room and procedures room. No one answered the calls.
- ▶ Medical record documentation was problematic. In particular, patient consent forms failed to spell out risks in lay terms and included broad consent for "any other necessary procedure." Physician signatures were also missing from records. Legibility was a problem, too.
- ▶ The nursing department appeared to have inadequate staff. Also, the nursing department failed to use individualized care plans, follow-through on incident reports, or identify patients' educational needs.

- ▶ The hospital lacked a policy for transferring high-risk obstetrical patients, had a high c-section rate, and lacked documentation for fetal distress. For example, the hospital delivered an infant at 27-weeks gestation even though it lacked neonatal capacity. Furthermore, three of six obstetrical records the surveyors reviewed documented some sort of adverse outcome.
- ▶ The hospital lacked a performance appraisal system for its medical staff and its reappointment process excluded peer review data. Furthermore, physicians covering the emergency room lacked privileges for common emergency procedures, such as placing chest tubes and performing tracheotomies.
- ▶ The appropriateness of care in three or four records was questionable. The surveyors copied those records and forwarded them to a peer review organization for review.

During the exit conference (the last session of the survey), the surveyors discussed their findings, but couched their comments as preliminary. After all, they had collected a variety of documents to review and analyze off-site. Findings from those documents could alter their on-site findings. The hospital would not know the final survey outcome until that process occurred (see page 23 for a final summary of the survey's findings).

Sessions observed by the OIG included, in part or in whole, pharmacy, medical staff, nursing, discharge planning, operating and recovery rooms, procedure room, emergency room, dietary, and the building and grounds tour. Highlights of some of the observed sessions follow.

### **Medical Staff Session**

This session lasted 3 hours on the first day and continued for 1 hour on the second day. Before beginning the session, the surveyor read the bylaws. During the session, she interviewed the administrative staffperson in charge of credentialing and reviewed credential files. She selected the files herself, and by the end of the second day, had reviewed the credentials of each of the six staff physicians, among others. In questioning the staff and reviewing the files, the surveyor was especially interested in how the medical staff took responsibility for quality, how the hospital delineated privileges, and evidence of a reappraisal and peer review system. No one from the medical staff participated in this session.

The surveyor interview covered the following topics: appointment and reappointment process, language skills of foreign medical graduates, reliance on the American Medical Association's physician profile database, conscious sedation, emergency room coverage and procedures, the on-call system, pending litigation, licensure limitations, prerequisites for active staff, availability of surgical services, use of podiatrists and psychologists, autopsies, organ donation, physician experience and competence with certain procedures, unexpected surgical outcomes such as perforations, role of chart review, and medical staff involvement in appraisal process.

As this session unfolded over the 2 days, the surveyor asked for more and more files, and then operating room logs and other documents to confirm the range of procedures the hospital provided fell within the privileges granted. By the end of the session, the surveyor identified some areas of concern. For example, she expressed concerns about privileges because physicians responsible for covering the emergency room lacked privileges for common emergency room procedures such as chest tubes. The surveyor offered examples of similar problems at other hospitals that lead to unnecessary deaths. She also questioned whether medical staff were involved in the evaluation of patient care and physician appraisal. Other concerns related to the staff's failure to follow its own bylaws, the lack of written guidelines for certain high-risk patients, and illegibility of medical records.

## **Pharmacy Session**

One surveyor conducted the pharmacy review, which lasted about 1 hour. The hospital's pharmacy, located in the old part of the hospital, had one full-time pharmacist and one part-time technician. The pharmacist's background was in retail pharmacy and he was new to practicing in a hospital.

The surveyor reviewed the pharmacist's license and other documents. She was particularly interested in documentation of proper narcotics tracking, logs tracking after-hours access to the pharmacy, and protocols for any performance improvement projects. In addition to reviewing the papers, she asked for copies to take with her. While in the pharmacy she also inspected the hood and scanned the storage shelves, where she noted narcotics that were labeled without strength identified.

The surveyor's questions covered the following areas: formulary development, mechanism for drug recalls, restocking and security of crash carts, computerization, drug utilization review, hospital strategic planning, performance improvement projects, drug errors, and reliance on and competency of the pharmacy technician. Because of the



obvious humidity problem in the small pharmacy, the surveyor asked questions about the impact of the dampness on the efficacy and storage of the drugs.

The surveyor focused, however, on narcotics and adverse drug reactions and how the hospital tracked them. Apparently the nursing department viewed it as a pharmacy responsibility and the pharmacist viewed it as nursing. The surveyor was concerned about the lack of accountability and spent a lot of time educating the pharmacist about what he needed to track and why, referencing requirements of the Drug Enforcement Administration.

## Nursing

This session lasted about 2 hours and involved the director of nursing and one surveyor. The director of nursing was new. In fact, she was the 15<sup>th</sup> director of nursing the hospital hired in 7 years. The surveyor reviewed documentation of the hospital's nurse staffing plan, among other documents. Low staffing and acuity emerged as major concerns. Among the topics the surveyor questioned the director of nursing about were: reliance on contract nurses, orientation and training of new nurses, determining baseline competency, role of charge nurses, nurse roles in tracking and reporting adverse drug reactions, anatomical gifts, contingency plans, incident reporting (falls, needle sticks, and employee injuries), use of telephone and verbal orders, and infection control.

## Statement of Deficiencies Stemming from the Certification Survey

Within a few weeks of the on-site portion of the survey, the State agency sent the final statement of deficiencies to the hospital. The statement included deficiencies at each of the three levels (condition, standard, and element) as noted below:

### **Condition of Participation: Governing Body** (42 CFR 482.12)

Two elements under this condition were unmet, concerning the accountability of the medical staff and its appointment process.

### **Condition of Participation: Quality Assurance** (42 CFR 482.21)

One standard under this condition was unmet, concerning implementation of the quality assurance plan. Two elements under this condition were also unmet, both concerning clinical plans: one because the hospital lacked evidence that it

evaluated drug errors and one because it lacked evidence that it evaluated a recent increase in c-sections.

**Condition of Participation: Medical Staff** (42 CFR 482.22)

This condition was unmet based on the medical staff's failure to operate under its bylaws and develop or implement a system of accountability. Two standards and four elements were also out of compliance under this condition. One unmet standard concerned the accountability and organization of the medical staff; the other, the medical staff's failure to abide by its bylaws. The unmet elements included the failure of the medical staff to conduct periodic appraisals of its members and to delineate clinical privileges, among others.

**Condition of Participation: Nursing Services** (42 CFR 482.23)

Two elements under this condition were unmet. One concerned the lack of individualized nursing care plans for each patient. The other concerned the problems with the reporting of medication errors.

**Condition of Participation: Medical Record Services** (42 CFR 482.24)

Two elements under this condition were unmet. One concerned illegibility and one concerned delinquent medical records.

**Condition of Participation: Pharmaceutical Services** (42 CFR 482.25)

One element, concerning the security of drugs, was unmet.

**Condition of Participation: Physical Environment** (42 CFR 482.41)

One standard was unmet. This element encompassed several concerns related to patient safety and well-being: the lack of working alarm systems, lack of staff knowledge of and response to alarm systems, lack of staff knowledge on certain patient care equipment, lack of safe emergency exits, and lack of mechanism to monitor temperature and humidity in the pharmacy, among others.

**Condition of Participation: Surgical Services (42 CFR 482.51)**

Two elements were unmet. One concerned the hospital's failure to delineate surgical privileges in accordance with competency. The other concerned the lack of a properly executed informed consent form.

**Condition of Participation: Emergency Services (42 CFR 482.55)**

One element was unmet. It concerned the medical staff's failure to abide by policies and procedures governing care provided in the emergency department and the nursing staff's failure to adhere to established triage policy.

Based on the above findings, the State survey team conducted two more surveys at this hospital, both within 2 months of the original survey observed by the OIG. As of the last follow-up survey, the hospital had corrected its deficiencies to the satisfaction of the survey team.

## Endnotes

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1. Troyen A. Brennan et al, "Incidence of Adverse Events and Negligence in Hospitalized Patients," *The New England Journal of Medicine* 324 (February 7, 1991) 6: 370-376.

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

See also Lucian L. Leape, "Error in Medicine," *Journal of the American Medical Association* 272 (December 21, 1994) 23: 1851-1857; David C. Classes et al, "Adverse Drug Events in Hospitalized Patients," *Journal of the American Medical Association* 277 (January 22/29, 1997) 4: 301-306; Mark R. Chassin et al, "The Urgent Need to Improve Health Care Quality: Institute of Medicine National Roundtable on Health Care Quality," *Journal of the American Medical Association* 280 (September 16, 1998) 11: 1000-1005; David W. Bates et al, "Effect of Computerized Physician Order Entry and a Team Intervention on Prevention of Serious Medication Errors," *Journal of the American Medical Association* 280 (October 21, 1998) 1311-1316; Robert A. Raschke et al, "A Computer Alert System to prevent Injury from Adverse Drug Events: Development and Evaluation in a Community Teaching Hospital," *Journal of the American Medical Association* 280 (October 21, 1998) 1317-1320; and David C. Classen, "Clinical Decision Support Systems to Improve Clinical Practice and Quality of Care," *Journal of the American Medical Association* 280 (October 21, 1998) 1360-1361.

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

4. <http://WWW.hcfa.gov/Medicare/Medicare.htm>
5. Health Care Financing Administration, 1996 Data Compendium, HCFA March 1995.
6. Ibid.
7. P.L. 89-97.
8. The HCFA published its proposed hospital conditions of participation on December 17, 1997 (62 Fed. Reg. 66,726). On July 2, 1999, it published an interim final rule on patients' rights (64 Fed. Reg. 36070).
9. 42 U.S.C 1395bb.
10. Health Care Financing Administration, OSCAR 10 Report, as of May 30, 1998.
11. The industry standard is every 3 years, as set by hospital accrediting organizations, like the Joint Commission on Accreditation of Healthcare Organizations.
12. From HCFA's OSCAR System. Special Report Dated Oct. 1, 1997. Data is exclusive of Puerto Rico, Virgin Islands, and American Samoa.
13. "Until about 1990,...the federal government contributed enough money to do inspections every year. After that, federal money began diminishing, and last year [1997] it was enough to finance inspections at only 10 percent of hospitals." (Nancy Ruzicka, Iowa's Bureau Chief for Medicare Certification and Hospital Licensing, in Tom Carney, "Hospital Reviews Judged Too rare," *Des Moines Register*, 7 February 1998.)
14. States conducted 286 certification surveys from October 1, 1994 to September 30, 1995 and 184 certification surveys from October 1, 1996 to September 30, 1997. From HCFA's OSCAR System. Special Report Dated Oct. 1, 1997. Data is exclusive of Puerto Rico, Virgin Islands, and American Somoa.
15. Based on OIG analysis of data reported by HCFA.
16. Those hospitals tend to be small, rural, and remote, making them often difficult to travel to [Institute of Medicine, *Medicare: A Strategy for Quality Assurance*, Volume I (Washington, D.C.: National Academy Press, 1990) 120].
17. Based on Office of Inspector General telephone survey to State Survey and Certification Agencies, July and August of 1998.

18. HCFA to States, FY 1999 State Survey and Certification Budget Call Program Requirements and Budget Guidelines.

19. Under current law (42 U.S.C. Sec. 1396r), all skilled nursing facilities and nursing facilities are subject to a standard survey not later than 15 months after the previous standard survey, with a Statewide average interval between standard surveys of not more than 12 months. Home health agencies are subject to a standard survey not later than 36 months after the previous standard survey (42 USC Sec. 1395bbb). The frequency for surveys of HHAs within this 36 month interval shall be commensurate with the need to assure delivery of quality home health services.

20. Health Care Financing Administration. The HCFA does not track actual spending by category.

21. HCFA to States, FY 1999 State Survey and Certification Budget Call Program Requirements and Budget Guidelines.

22. HCFA funds States to perform a standard survey of every home health agency no later than 36 months after the previous standard survey. In addition, HCFA also funds States to conduct initial certification surveys for new home health agencies, and more frequent surveys for problem home health agencies. All told, HCFA will survey about 60-65 percent of all home health agencies in a given year.

23. From HCFA's OSCAR-10 Report dated 3/27/97.

24. HCFA to States, FY 1999 State Survey and Certification Budget Call Program Requirements and Budget Guidelines.

25. State agencies expect certification to play a greater role responding to complaints than accreditation: 92 percent of the States agencies responding to our survey expected that they be involved to a great or very great extent while 47 percent of States expected that accrediting organizations be involved to that extent. States held similar views concerning response to adverse events involving patient harm: 90 percent expected State certification agencies play a great or very great role and 58 percent expected accrediting bodies play a great or very great role.

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

27. “Overdoses Still Weigh Heavily at Dana Farber,” *The Boston Globe* (26 December 1995); “Florida Doctor Sanctioned in New Amputation,” *The Boston Globe* (19 July 1995); “Two Surgeons Surrender Licenses After Mistakenly Removing Kidney,” *The Boston Globe* (6 June 1996).; “How Can We Save the Next Victim?” *The New York Times Magazine* (15 June 1997); “Another Hospital Death Probed,” *The Boston Globe* (26 July 1997); “Patient Dies After Drinking Poison Left on Nightstand,” *San Diego Union-Tribune* (6 March 1998); “Man Arrested for Posing as Doctor for 4 years,” posted at the CNN interactive webpage (16 May 1998); “Deadly Restraint: Patients Suffer in a System Without Oversight,” *The Hartford Courant* (13 October 1998); and “Death in Surgery Reveals Troubled Practice and Lax Hospital,” *The New York Times* (15 November 1998).
28. 42 C.F.R., sec. 488.7.
29. 42 C.F.R., sec. 488.7.
30. 62 Fed. Reg. 66,729, December 19, 1997.
31. The HCFA refers to this data set as OASIS, which stands for Outcomes and Assessment Information Set (62 Fed. Reg. 11,004, March 10, 1997).
32. Referred to as the Quality Improvement System for Managed Care (QISMC). Under QISMC, HCFA and State agencies use a uniform set of quality standards to determine that an organization is eligible to enter into a Medicare or Medicaid contract. These QISMC standards, which were released in June 1998, are scheduled to be effective as of January 1999.
33. The indicators referred to are those contained in the Health Plan Employee Data and Information Set (HEDIS), which is the National Committee for Quality Assurance’s (NCQA) set of performance measures for the managed care. The NCQA collects data from over 300 managed care plans across the country. The HCFA’s 1997 contracts with risk-based managed care organizations called for them to submit HEDIS 3.0 data.
34. The HCFA participated in the latest HEDIS development task force. The latest version of HEDIS contains Medicare and Medicaid specific requirements.
35. 62 Fed. Reg. 11,004, March 10, 1997.