Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

The External Review of Hospital Quality

A Call for Greater Accountability

JUNE GIBBS BROWN
Inspector General

JULY 1999
OEI-01-97-00050

OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, is to protect the integrity of the Department of Health and Human Services programs as well as the health and welfare of beneficiaries served by them. This statutory mission is carried out through a nationwide program of audits, investigations, inspections, sanctions, and fraud alerts. The Inspector General informs the Secretary of program and management problems and recommends legislative, regulatory, and operational approaches to correct them.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) is one of several components of the Office of Inspector General. It conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The inspection reports provide findings and recommendations on the efficiency, vulnerability, and effectiveness of departmental programs.

OEI's Boston regional office prepared this report under the direction of Mark R. Yessian, Ph.D., Regional Inspector General. Principal OEI staff included:

BOSTON

Joyce M. Greenleaf, *Project Leader*
Lynne G. Dugan, *Senior Analyst*
Meredith A. Vey, *Program Analyst*

HEADQUARTERS

Jennifer Antico, *Program Specialist*
Alan Levine, *Program Specialist*

To obtain copies of this report, please call the Boston Regional Office at 617/565-1050.
Reports are also available on the World Wide Web at our home page address:

http://www.dhhs.gov/progorg/oei

EXECUTIVE SUMMARY

PURPOSE

To provide a summary and recommendations based on our assessment of the external review of hospitals that participate in Medicare.

BACKGROUND

External Quality Review of Hospitals in the Medicare Program

Hospitals are a vital part of our healthcare system, routinely providing valuable services. But they are also places where poor care can lead to unnecessary patient 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. On the basis of these findings, it estimated negligent care in New York hospitals in that year was responsible for about 27,000 injuries, including almost 7,000 deaths and close to 1,000 instances of "permanent and total disability." More recently, a 1997 study of about 1,000 hospitalized patients in a large teaching hospital found that almost 18 percent of these patients received inappropriate care resulting in a serious adverse event. In the public eye, such scholarly inquiries have been overshadowed by media reports that describe, often in graphic detail, the harm done to patients because of poor hospital care.

Hospitals rely upon many internal mechanisms to avoid such incidents and to improve the quality of care. External review serves as an additional safeguard. The Federal government relies primarily on two types of external review to ensure hospitals meet the minimum requirements for participating in Medicare: accreditation, usually by the Joint Commission on Accreditation of Healthcare Organizations, and Medicare certification, by State Agencies. About 80 percent of the 6,200 hospitals that participate in Medicare are accredited by the Joint Commission.

This Summary Report

This report synthesizes the findings we present in three parallel reports. It is based on our broad inquiry of the external quality oversight of hospitals, for which we drew on aggregate data, file reviews, surveys, and survey observations from a rich variety of sources, including the Health Care Financing Administration (HCFA), the Joint Commission, State agencies, and other stakeholders.

The report, as our study as a whole, focuses on the roles played by the Joint Commission and the State agencies in reviewing hospitals and by HCFA in overseeing these bodies. Other bodies, most especially the Medicare Peer Review Organizations and State Professional Licensure Boards, play important related roles. We have reviewed their performance in numerous prior studies and will continue our examination of them in future studies. They are not discussed in this report.

FINDINGS

The current system of hospital oversight has significant strengths that help protect patients.

Joint Commission surveys provide an important vehicle for reducing risk and fostering improvement. Hospital leadership takes these accreditation surveys seriously. Hospitals spend months preparing for them, seeking to ensure that their hospitals meet and, where possible, exceed the Joint Commission's standards.

State agency investigations offer a timely, publicly accountable means for responding to complaints and adverse events. The HCFA funds these investigations as a high priority. For both accredited and nonaccredited hospitals, they serve as a significant front-line response to major incidents involving patient harm.

But it also has major deficiencies.

Joint Commission surveys are unlikely to detect substandard patterns of care or individual practitioners with questionable skills. Quick-paced, tightly structured, educationally oriented surveys afford little opportunity for in-depth probing of hospital conditions or practices. Rather than selecting a random sample, the surveyors tend to rely on hospital staff to choose the medical records for review. Further, the surveyors typically begin the process with little background information on any special problems or challenges facing a hospital.

The State agencies rarely conduct routine, not-for-cause surveys of nonaccredited hospitals. The percent of nonaccredited hospitals that have not been surveyed within the 3-year industry standard has grown from 28 percent in 1995 to 50 percent in 1997. In some cases, nonaccredited hospitals, usually in rural areas, have gone as long as 8 years without a survey.

Overall, the hospital review system is moving toward a collegial mode of oversight and away from a regulatory mode.

A collegial mode of oversight is one that focuses on education and improved performance. It emphasizes a trusting approach to oversight, rooted in professional accountability and cooperative relationships. A regulatory mode focuses on investigation and enforcement of minimum requirements. It involves a more challenging approach to oversight, grounded in public accountability. It is helpful to consider external hospital oversight in terms of a continuum, characterized by the collegial approach on one side and the regulatory approach on the other.

The Joint Commission, the dominant force in external hospital review, is leading this movement. It is grounded in a collegial approach to review that stresses education and improvement. It focuses on systems in its quest to improve hospital processes and patient outcomes.

The State agencies are rooted in a more regulatory approach to oversight. But HCFA, through the proposed Medicare conditions of participation, is looking for them to follow the Joint Commission's lead. Traditionally, the State agencies have emphasized investigatory approaches that aim to protect patients from harm more than to improve the overall standard of care. The proposed conditions call for them to move in a direction parallel to that of the Joint Commission.

The emerging dominance of the collegial mode may undermine the existing system of patient protection afforded by accreditation and certification practices. It contrasts significantly with the current regulatory emphasis in nursing home oversight. Both the collegial and regulatory approaches to oversight have value. As the system increasingly tilts toward the collegial mode, however, it could result in insufficient attention to investigatory efforts intended to protect patients from questionable providers and substandard practices.

For nursing homes, recent concerns about the quality of care provided have led to a HCFA crack-down involving more immediate penalties, surprise surveys, and posting of survey results on the Internet, with scant attention to collegial approaches. Such a heavy regulatory emphasis may well not be required for hospitals, but it does reinforce the point that when patients are found to be at risk, regulatory approaches have an important part to play. As we have noted, many recent studies and media reports make it clear that hospitals, too, are places where inappropriate care can and frequently does put patients at risk.

The HCFA does little to hold either the Joint Commission or the State agencies accountable for their performance overseeing hospitals.

The HCFA obtains limited information on the performance of the Joint Commission or the States. In both cases, HCFA asks for little in the way of routine performance reports. To assess the Joint Commission's performance, HCFA relies mainly on validation

surveys conducted, at HCFA's expense, by the State agencies. But for a number of reasons the value of these surveys has been limited. The methodology for selecting the hospitals to survey fails to consider hospital size, type, or past performance. More fundamentally, the surveys have been based on different standards (the Medicare Conditions of Participation as opposed to the Joint Commission standards) and have been conducted subsequent to the Commission's surveys (when hospital conditions could have changed). During 1996 and 97, HCFA piloted 20 observation surveys--during which State and HCFA officials accompanied Joint Commission surveyors. This approach appears to have much promise, but HCFA has not yet issued any evaluation of the pilots.

The HCFA observes few hospital surveys conducted by State agencies and conducts no validation surveys of them.

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

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

RECOMMENDATIONS

We offer one guiding principle and two recommendations that set forth ways in which HCFA can, over time, provide leadership to address the shortcomings we have identified in our inquiry, holding the Joint Commission and State agencies more accountable for their performance.

GUIDING PRINCIPLE: The HCFA, as a guiding principle, should steer external reviews of hospital quality so that they ensure a balance between collegial and regulatory modes of oversight.

The HCFA must recognize that both approaches have value and that a credible system of oversight must reflect a reasonable balance between them. In our assessment, a balanced system would involve the continued presence of on-site hospital surveys, both announced and unannounced; an ongoing capacity to respond quickly and effectively to

complaints and adverse events; further development and application of standardized performance measures; and, even though it is not much in evidence at this time, a mechanism for conducting retrospective reviews of the appropriateness of hospital care. A balanced system would also be one in which performance measures are used to protect patients from harm as well as to improve the standard of care.

In its steering role, HCFA must recognize the inherent strengths and limitations of accrediting bodies and the State agencies. Each contributes to the external review of hospitals, but they do so differently. Thus, in steering, HCFA should look to the Joint Commission to tilt (but not too far) toward the collegial end and the State agencies to tilt (but not too far) toward the regulatory end.

RECOMMENDATION 1: The HCFA should hold the Joint Commission and State agencies more fully accountable for their performance in reviewing hospitals.

▸ Revamp Federal approaches for obtaining information on Joint Commission and State agency performance by de-emphasizing validation surveys, giving serious consideration to the potential of observation surveys, and calling for more timely and useful reporting of performance data.

▸ Strengthen Federal mechanisms for providing performance feedback and policy guidance to the Joint Commission and State agencies. Given the major role played by the Joint Commission, the public purposes associated with its special deemed status authority, and the importance of achieving a more balanced system of external review, HCFA should negotiate with the Joint Commission to achieve the following changes:

- Conduct more unannounced surveys.
- Make the "accreditation with commendation" category more meaningful, or do away with it altogether.
- Introduce more random selection of records as part of the survey process.
- Provide surveyors with more contextual information about the hospitals they are about to survey.
- Jointly determine some year-to-year survey priorities, with an initial priority on examining credentials and privileges.
- Conduct more rigorous assessments of hospitals' internal continuous quality improvement efforts.
- Enhance the capacity of surveyors to respond to complaints within the survey process.

▸ Assess periodically the justification for the Joint Commission's deemed status authority.

- Increase public disclosure on the performance of hospitals, the Joint Commission, and State agencies, by, at a minimum, posting more detailed information on the Internet.

RECOMMENDATION 2: The HCFA should determine the appropriate minimum cycle for conducting certification surveys of nonaccredited hospitals.

Nonaccredited hospitals are subject to limited external review other than those reviews triggered by complaints and adverse events. Unlike nursing homes and home health agencies, hospitals lack a mandated minimum cycle for surveys. While complaints and adverse events may well warrant priority over routine surveys, such surveys play an important role in external review, and by determining a minimum cycle HCFA can increase the level of attention to hospital oversight.

COMMENTS

Within the Department of Health and Human Services, we received comments on our draft reports from HCFA--the Departmental agency to which all of our recommendations are directed. We also solicited and received comments from the following external organizations: the Joint Commission on Accreditation of Healthcare Organizations, the Association of Health Facility Survey Agencies, the American Osteopathic Association, the American Hospital Association, the American Association for Retired Persons, the Service Employees International Union, the National Health Law Program, and Public Citizen's Health Research Group. In appendix E, we present each organization's comments in full. Below, we summarize the thrust of the comments and, in italics, offer our responses.

HCFA Comments

The HCFA reacted positively to our findings and recommendations. It offered a detailed hospital oversight plan that incorporates our many recommendations. The plan reflects HCFA's commitment to more frequent surveys of nonaccredited hospitals, to strengthened oversight of both the State agencies and the Joint Commission, and to a balance between collegial and regulatory approaches to oversight. In addition, HCFA presented a hospital performance measurement strategy based on developing standardized performance measures that are consumer- and purchaser-driven and that are in the public domain.

The HCFA's action plan is highly responsive to the recommendations we set forth. As it is carried out, it can be of considerable value in improving patient safety and the quality of patient care.

Joint Commission and Association of Health Facility Survey Agencies Comments

The Joint Commission and the State survey agencies, which the Association of Health Facility Survey Agencies represents, are the two key parties that HCFA relies upon to conduct external reviews of hospital quality. The Joint Commission agreed with the principle of balance between collegial and regulatory approaches, but regarded our concerns about an emerging dominance of the collegial approach to be unfounded. It also objected to the limitations we cited about its survey approach and to our conclusion that the Joint Commission devotes minimal attention to complaints. It did express support for stronger, more performance-oriented HCFA oversight of the Joint Commission. The Association, while agreeing with the thrust of our assessment, noted some reservations about phasing out the validation surveys in favor of an observation survey approach that is largely untested.

We stress here, as we did in the text, the importance of a balance in oversight that avoids tilting too far toward either the collegial or the regulatory ends. We believe that we established credible bases for such a balanced approach. Similarly, we believe that our assessments of Joint Commission practices are balanced and well-supported. We identified various strengths that the Joint Commission brings to the field of quality oversight. We regard the limitations that we cited as an important part of the overall picture. With respect to the Association's reservations about the observation surveys as a tool of oversight, we suggest that the problems we pointed out about the validation process are significant ones and that the potential of the observation surveys is compelling enough to warrant further exploration.

Comments of Other External Organizations

Overall, the other stakeholder organizations offered considerable support for our findings and recommendations. But they also expressed concerns. The American Hospital Association took issue with how we applied the collegial and regulatory concepts and stressed that hospital liability concerns preclude the kind of public disclosure we urge. The American Osteopathic Association noted reservations about more unannounced surveys and suggested that a closer review of medical care during on-site surveys would be more productive. The American Association of Retired Persons agreed with the thrust of our recommendations.

The Service Employees International Union, the National Health Law Program, and Public Citizen's Health Research Group called for even stronger Federal actions than we recommended. These included a stronger emphasis on regulatory approaches, greater reliance on unannounced surveys, more extensive public disclosure, and firmer HCFA action in overseeing the Joint Commission and in reassessing its deeming authority.

These stakeholders raise concerns and urge directions that we often heard expressed during our study. As HCFA carries out its hospital quality oversight plan, we suggest that it take these perspectives into account. We believe that our recommendations (and HCFA's announced action plan) sets forth a balanced course of action that draws to some degree on the insights of each of these stakeholders. This course is one that can substantially improve the external review of hospital quality in the years ahead.

TABLE OF CONTENTS

PAGE

EXECUTIVE SUMMARY

INTRODUCTION 10

FINDINGS

Strengths of Hospital Oversight 14

Deficiencies of Hospital Oversight 15

Oversight is Moving Toward a Collegial Mode 16

Little Accountability 19

RECOMMENDATIONS 22

COMMENTS ON THE DRAFT REPORTS 32

APPENDICES

A: Medicare Conditions of Participation 35
B: Summary of the Roles of Accreditation and Certification 36
C: Methodology 37
D: Certification Survey 40
E: Comments on the Draft Reports 47
F: Endnotes 90

INTRODUCTION

PURPOSE

To provide a summary and recommendations based on our assessment of the external review of hospitals that participate in Medicare.

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 during 1984. The study found that 1 percent of the hospitalizations involved adverse events caused by negligence.[1] 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.[2] 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.[3]

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.[4] In 1997, Medicare spent about $136 billion on Part A, the hospital insurance benefit.[5] This figure is just over half the total amount the Federal government spent on all Medicare benefits.[6] In the same year, Medicare spent over $80 billion for inpatient acute hospital care alone.[7]

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.[8] 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).[9] 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.[10] 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. States currently certify 1,442 nonaccredited hospitals nationwide.[11]

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

Both accreditation and Medicare certification involve a team of trained surveyors visiting a hospital, interviewing staff, reviewing documents, and inspecting the facility.[12] However, the nature of these processes is very different.

The Nature of Accreditation

Accreditation is a voluntary assessment process whereby industry experts define what standards organizations must meet in order to be accredited and then systematically review the organization's performance against those standards.[13] It is a form of self-regulation for which hospitals pay a fee.[14] The Joint Commission enjoys a special status because, by Federal statute, hospitals accredited by the Joint Commission are deemed to meet the Medicare conditions of participation.[15] As the largest accreditor of hospitals,

accrediting about 80 percent of the nation's 6,200 hospitals, the Joint Commission is responsible for the majority of the nation's external quality review of hospitals. In 1972, Congress enacted amendments that gave the Health Care Financing Administration (HCFA) responsibility for overseeing the Joint Commission.[16]

The Nature of Medicare Certification

The Medicare certification process, on the other hand, is a public regulatory process that aims to ensure hospitals desiring to serve Medicare beneficiaries, but not desiring to be accredited, meet the conditions of participation. The HCFA relies on the 51 State survey and certification agencies (hereafter called State agencies) to determine compliance with the Medicare conditions of participation. Hospitals pay no fee for this process. States agencies certify 1,442 nonaccredited hospitals nationwide.[17] These State agencies are paid and trained by HCFA and use HCFA's survey instrument to survey nonaccredited hospitals.

This Inquiry and Report

This inquiry focuses on the roles played by the Joint Commission and State survey agencies and by HCFA in overseeing these bodies. Other bodies, most especially the Medicare Peer Review Organizations and State professional licensure boards, also play important roles. We have reviewed their performance in prior studies and will continue to examine them in future studies.[18] They are not discussed in this report.

This report summarizes the three other reports that resulted from our inquiry and contains our recomendations. The other reports are: *The Role of Accreditation* (OEI-01-97-00051), which assesses the Joint Commission's approach to hospital accreditation; *The Role of Medicare Certification* (OEI-01-97-00052), which assesses the extent and nature of the external review for nonaccredited hospitals; and *Holding the Reviewers Accountable* (OEI-01-97-00053), which assesses how HCFA oversees both the Joint Commission and the State survey agencies. We offer a summary of two of the reports, *The Role of Accreditation* and *The Role of Medicare Certification*, in appendix B.

Our inquiry draws on a variety of sources. These include: data from HCFA's Online Survey Certification and Reporting System; aggregate data from the Joint Commission concerning hospital survey activity; a mail survey to State agencies in the 50 States and District of Columbia (hereafter referred to as a State); observations of 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 C for more details on our methodology.

A Systemic Review

In this report we focus on the overall system of external review carried out by the Joint Commission, State survey and certification agencies and HCFA. We address issues that have a significant bearing on how well that system works. In so doing, we draw on a wide body of evidence from the sources we noted above. Our findings and recommendations represent our conclusions based on our assessment of this evidence. We present them with the intent of providing helpful directions on how HCFA, the Joint Commission, and the State agencies can play a more effective role in protecting patients and improving quality.

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

FINDINGS

The current system of hospital oversight has some significant strengths that help protect patients.

Joint Commission surveys provide an important vehicle for reducing risk and fostering improvement in hospitals.

The Joint Commission's triennial surveys form the core of its accreditation process. As such, they serve as the means for a Joint Commission presence in accredited hospitals every 3 years. Hospitals know the surveyors are coming, take the process seriously, and prepare for it. This institutionalizes attention to the basic protections that are encompassed within the Joint Commission standards--standards that promote the delivery of quality health care and are widely considered to be state-of-the-art. In preparing for the Joint Commission, many hospitals hire consultants to conduct mock surveys, update their manuals, and familiarize their staffs with the standards. While at the hospitals, the Joint Commission surveyors often take on the role of educator, explaining the standards' intent and relationship to patient care.

The Joint Commission has also been a leader in promoting performance improvement in hospitals. Indeed, attention to performance improvement pervades the entire hospital survey process: it is generally the topic of the opening session and most sessions include some discussion about improvement projects. The hospitals, in preparing for the surveys, display storyboards and posters highlighting their improvement projects throughout the hospital.

State agency investigations offer a timely, publicly accountable mechanism for responding to complaints and adverse events in both accredited and nonaccredited hospitals.

State agencies are the front-line responders to complaints and to major adverse events in hospitals. Adverse events involving serious patient harm often attract attention from the media and concerned citizens who clamor for information and reassurance. The State agencies' investigations fulfill a vital role by ensuring the public's safety is being looked after. The results of the State agencies' investigations, which are based on the Medicare conditions of participation, are available to the public.

Responding to complaints and adverse events is a high priority for the State agencies: HCFA ranks responding to such events third--after routine nursing home and

home health surveys but before routine hospital surveys--in its priorities for State agencies' survey and certification budgets.

But it also has major deficiencies.

Joint Commission surveys are unlikely to detect substandard patterns of care or individual practitioners with questionable skills.

Joint Commission surveyors get a broad rather than in-depth view of hospitals they survey. The surveys generally last just a few days. The survey agendas are packed with back-to-back sessions that allow 45 minutes to an hour for most areas of the hospital. Furthermore, the surveyors lack much background information on the hospital that could help them hone their surveys.

The surveyors' broad view of the hospitals, coupled with the Joint Commission's approaches to medical record and credentials reviews, make such surveys unlikely to uncover patterns or individuals responsible for poor care. First of all, surveyors do not select the records for review based on indications of poor quality. Indeed, the hospitals themselves often choose the records for review. In reviewing medical records, surveyors focus more on processes than appropriateness of care: surveyors "do not judge directly whether the care given is good or bad, right or wrong."[19] Likewise, the review of physician credentials and privileges falls short of identifying individuals whose skills may be questionable: the sessions are too short for an in-depth review, hospitals often choose the records themselves, and the questioning rarely uncovers marginal practitioners. The Joint Commission's own publications note that the process "does not evaluate the quality of care provided by individual medical staff members."[20]

The State agencies rarely conduct routine, not-for-cause surveys of nonaccredited hospitals.

Routine surveys of nonaccredited hospitals are a low priority. Only a few years ago, State survey agencies surveyed nonaccredited hospitals every year or two. But as of October 1997, the average elapsed time between surveys was about 3.3 years and growing. Indeed, fully half of the nonaccredited hospitals had not had a survey within 3 years as of late 1997. The total number of certification surveys for nonaccredited hospitals fell from 286 in 1995 to 184 in 1997, a drop of 36 percent in 2 years. The decline in routine hospital surveys coincides with the dramatic rise in home health agencies, which States must also survey.

The HCFA sets the survey and certification budget priorities for the State agencies: routine nursing home and home health agency surveys and responses to

complaints of any kind all precede routine surveys of nonacredited hospitals.[21] Unlike nursing homes and home health agencies, hospitals lack a mandated minimum cycle for surveying. For fiscal year 1998, HCFA funded State agencies to survey 10 percent of their nonaccredited hospitals and 60 percent of their home health agencies.

Overall, the hospital review system is moving toward a collegial mode of oversight and away from a regulatory mode.

It is helpful to consider external hospital oversight in terms of a continuum, characterized by a collegial approach on one side and a regulatory approach on the other. External reviewers in the collegial mode focus on education and improved performance; those in the regulatory mode focus on investigation and enforcement of minimum requirements. In the continuum below, we list the major characteristics we associate with each side.

Collegial Mode (Educate and Elevate)	**Regulatory Mode** (Investigate and Enforce)
Cooperative	Challenging
Flexible	Rigid
Foster Process Improvements	Enforce Minimums
Guidance	Directive
Trusting	Skeptical
Professional Accountability	Public Accountability
Confidentiality	Public Disclosure
Systems Focus	Outlier Focus
Improve Patient Outcomes	Minimize Preventable Harm

The Joint Commission is leading this movement toward the collegial mode.

The Joint Commission is and has been the dominant force in the external review of hospitals. As such, its approach holds great sway. And its approach is grounded in the collegial mode. Indeed, its very mission statement demonstrates this: "to improve the quality of care provided to the public through the provision of accreditation and related services that support performance improvement in health care organizations."[22] Support for performance improvement is widespread. Its approach is grounded in the theory that

improving overall performance even marginally is far more important than dealing with the poor performers at the margin.[23]

The Joint Commission recently implemented a policy for dealing with serious adverse events in hospitals that embodies the collegial approach to oversight.[24] This policy stresses research, education, and prevention--all laudable goals that favor the collegial side of the continuum. It relies on hospitals to self-report certain events, thereby stressing professional accountability and trust. And it emphasizes confidentiality for the self-reporting hospitals. Indeed, the success of the policy's research and prevention goals rest in large measure on the safe venue that the assurance of confidentiality provides to reporting hospitals. Through this approach, the Joint Commission seeks to encourage hospitals to address a variety of adverse events that would never even come to the attention of the Joint Commission, the State agencies, the media, or the public in general.

Other aspects of the Joint Commission's hospital accreditation program also demonstrate it to be grounded in the collegial mode. For example, it has increasingly stressed systems and continuous quality improvement. Its surveyors tend to applaud hospitals' improvement efforts with little skepticism of their underlying value. Furthermore, its announced surveys tend to be carried out in a collegial manner, focus on education, and leave little opportunity for the kind of digging or inspecting that would characterize a more regulatory approach.

State agencies have traditionally stressed the regulatory mode. But HCFA, through the proposed Medicare conditions of participation, is looking for them to follow the Joint Commission's lead.

According to HCFA's instructions, State survey agencies prioritize responding to complaints and adverse events higher than any other hospital-related activity.[25] These surveys tend to be unannounced. They aim not only to investigate the event but also to respond to public fears about the safety of the hospital. Their focus tends to be on ensuring safety and preventing harm. All this grounds State agencies on the regulatory side of the continuum. Activities that would be more characteristic of the collegial mode, such as performance improvement projects, are not part of the existing Medicare certification system for hospitals. (For a summary of our observations of one Medicare certification survey conducted by a State agency, see appendix D.)

By contrast, the proposed conditions of participation for hospitals, published on December 19, 1997, reveal a major move toward the collegial mode.[26] They eliminate prescriptive, process-oriented conditions in favor of more patient-centered conditions, more nearly like those of the Joint Commission.[27] They shift away from a focus on enforcing minimums toward one stressing improvements. Accordingly, they call for States to work in "partnerships for improvement" with the hospitals and they call for hospitals to conduct a minimum number of data-driven performance improvement projects.[28]

At the core, the proposed changes appear to be constructive ones, because they give greater emphasis to actual hospital performance as opposed to mere paper compliance and because they will facilitate evaluations of the Joint Commission (because the proposed conditions are more nearly parallel to the Joint Commission's standards). Yet, it is noteworthy that the proposed conditions fail to recognize the important role State agencies fulfill as front-line, publicly accountable responders to complaints and adverse events--situations where a "partnership" approach could be a disadvantage. In this context, it is also notable that the conditions suggest there may be a lesser need for on-site compliance surveys as hospitals and State agencies work together toward improvement. The frequency of such surveys, as we have noted, has dropped significantly in recent years.

The emerging dominance of the collegial mode may undermine the existing system of patient protections afforded by accreditation and certification practices. It contrasts significantly with the current regulatory emphasis toward nursing home oversight.

The collegial mode holds much promise, with its focus on systems and improvements. We do not seek to discredit it. But we find that there is a danger of relying too heavily upon it as the basis for external oversight. In this context, we direct attention to the recent conclusions of the National Roundtable on Health Care Quality, convened by the Institute of Medicine.[29] The Roundtable's conclusions support a balanced approach to oversight, one that avoids depending too extensively on any one approach. In addressing the collegial approach represented by continuous quality improvement initiatives, it indicates that advocates can point to important successes, especially "when used as an integral part of a scientific approach to improving clinical practice."[30] But the Roundtable also pointed out that minimal data exist to document the effectiveness of this approach, and that "even exemplary practitioners have had difficulty in disseminating its benefits uniformly throughout their institutions."

In addressing the regulatory approach, the Roundtable underscored that it "is the only mechanism we have to protect the public from egregiously poor providers."[31] But then it added that this approach tends to be "inflexible" and is poorly suited "to motivate those already performing well to strive for even greater achievement."[32]

This emerging emphasis on a collegial approach to hospital oversight contrasts significantly with the highly regulatory approach being taken toward nursing home oversight. During 1998, a HCFA Report to Congress, a General Accounting Office report on nursing home oversight, a congressional hearing, a presidential press conference, and various HCFA announcements have all reiterated the inadequacy of current nursing home oversight practices and called for much tougher enforcement.[33] Among the many initiatives being taken or proposed are those calling for immediate penalties on nursing homes violating Federal standards, more "surprise" inspections on weekends and at night,

posting of information on the Internet information about nursing home survey results, and background criminal checks on nursing home personnel. The initiatives are presented as part of a "crack down" that involves tough, no-nonsense enforcement.[34] One finds little mention of collegial approaches involving continuous quality improvement.

Our point in noting this contrast is not to address the merits of these nursing home initiatives or to suggest that they be mirrored in hospital oversight. Rather, it is to reinforce the point that regulatory approaches have a place in oversight systems intended to protect patients. In our conversations with stakeholders, we have heard that such tough approaches toward hospitals are unwarranted because hospitals lack a similar history of patient abuses, because they have more peer review and physician involvement, and because they have more community involvement. These are reasonable points, but we found no data to support a contention that hospitals are safer places than nursing homes, and recent studies and media reports reinforce the point that hospitals are, indeed, places where inappropriate care can and often does lead to patient harm.

The HCFA does little to hold either the Joint Commission or the State agencies accountable for their performance in overseeing hospitals.

The HCFA obtains limited information on the performance of the Joint Commission or the State agencies.

The HCFA has relied on three major mechanisms for obtaining performance information: validation surveys, observation surveys, and reports. For the Joint Commission, HCFA uses mostly validation surveys, through which State surveyors conduct reviews of accredited hospitals after a Joint Commission survey. But for a number of reasons the value of these surveys is limited. They are based on different standards that are applied at different points in time. The HCFA's methodology for selecting the sample of hospitals to validate fails to consider hospital size, type, or past performance.[35] Furthermore, validation surveys are costly to conduct. The HCFA does not conduct such surveys to monitor the State survey agencies' performance.

The observation surveys, on the other hand, aim to address the fundamental flaws of the validation surveys, as HCFA and/or State surveyors accompany Joint Commission surveyors to hospitals and observe the survey directly. But HCFA uses these surveys only minimally. The HCFA piloted observation surveys with the Joint Commission in 20 hospitals in 1996 and 1997, but its plans for expansion are unknown. And among the HCFA regional offices, charged with overseeing the State agencies, only 6 of 10 reported conducting observation surveys to monitor the States' performance in hospitals.

Finally, HCFA asks for little in the way of routine reporting from the Joint Commission or the State agencies. Indeed, most of what it asks for from the Joint Commission is simply scheduling information used to carry out the validation surveys. The HCFA asks for little in the way of aggregate data on accreditation survey trends or results, complaints or adverse events, or surveyor training. Likewise, on a national basis, HCFA obtains little information on the State agencies' performance specific to hospitals. Rather, it gets a rather superficial and blurred picture of the States' performance across provider types, such as nursing homes, home health agencies, and hospitals. Furthermore, HCFA does not track trends of such basic information as how many termination notices it issues based on the findings of certification surveys of nonaccredited hospitals, although it does track actual terminations.[36]

The HCFA provides limited feedback to the Joint Commission and the States on their overall performance.

The HCFA's feedback to the Joint Commission is negligible. Its main vehicle for feedback is its Report to Congress, which provides a summary of the validation surveys. Historically, the Report to Congress has been of limited value not only because the survey results are dated (sometimes by as much as 3-4 years), but also because it is based on the validation surveys themselves, which are fundamentally flawed. Furthermore, HCFA designs the report to meet the needs of Congress--indeed, the report itself is mandated by Federal law--so its use as feedback to the Joint Commission is secondary.[37]

The HCFA takes little advantage of other opportunities for feedback to the Joint Commission. Indeed, its posture to the Joint Commission is more deferential than directive. For example, HCFA modeled its revisions of the hospital conditions of participation on the Joint Commission's approach to hospital oversight--both in content and tone.[38] The HCFA also tends to defer to the Joint Commission when both are at one hospital at the same time, investigating a particular incident. In such instances HCFA plays no coordinating or information-sharing role.

When it comes to the State agencies, HCFA is more directive on the one hand, yet gives them little feedback on how they perform their hospital oversight work, on the other. For example, HCFA routinely gives State agencies step-by-step guidance on investigating and documenting problems in a specific hospital. But it relies on the State agencies themselves to assess their own performance, and by working with the HCFA regions, to develop and implement their own quality improvement plans.[39] This process is called the State Agency Quality Improvement Program, or SAQIP. Once or twice a year, HCFA distributes a summary report of all the States' SAQIP activities to each State agency. That report provides few meaningful insights into the challenges or successes of any one State in overseeing hospitals or other providers, but it devotes considerable attention to the SAQIP process itself, and the challenges States face in its implementation.

Public disclosure plays only a minimal role in holding the Joint Commission and States accountable.

Publicly disclosing information about hospitals and their reviewers conveys an assurance that a process exists for the external review of hospitals and that the reviewers are also accountable. Public disclosure can also serve as a key motivator for improvement on the parts of both the hospitals and the reviewers. Despite progress in general in the availability of healthcare information and the rise of consumerism, little public information is available on hospitals and their reviewers. The Joint Commission has been a leader in making hospital survey results accessible through its performance reports.[40] But despite its strides in public disclosure, there are significant limits to what the Joint Commission discloses. For example, the Joint Commission treats as confidential the details on adverse events and their causes as reported by hospitals. Still, the hospital information is in some ways more accessible from the Joint Commission than it is from HCFA. While HCFA will disclose survey findings--including those associated with adverse events--it lacks a web page or central number from which to request such information. By contrast, HCFA has a web page devoted to nursing homes that allows visitors to view information on the scope and severity of survey findings. By Federal law, nursing homes must post their survey findings so they are accessible to residents and their families.[41] No such mandate exists for hospitals.

Likewise, little valuable information is readily available on the performance of the external reviewers. For example, while HCFA releases its Report to Congress, its value is questionable as it is based on the validation surveys. Similarly, HCFA has little of value to disclose on the performance of States agencies: its SAQIP reports lack any State identifiers or comparisons and its survey database would need considerable massaging to provide insights into a State's performance. Both the survey data and the SAQIP reports are available upon request.

RECOMMENDATIONS

Hospitals are places where patients routinely receive valuable, even life-saving services. Yet, as many studies have shown, they are also places where patients can be exposed to unnecessary harm.[42] External review, as a complement to hospitals' own internal review systems, can serve as a vital safety valve that minimizes the likelihood of such harm and enhances quality. The HCFA relies upon the Joint Commission and State survey agencies as its primary agents in carrying out external reviews to help protect Medicare beneficiaries when they rely upon hospital services. Both make important contributions that HCFA would be hard-pressed to match.

Given the degree of HCFA's dependence on these external agents, it is important that HCFA provides leadership to address the shortcomings we have identified, holding the Joint Commission and State agencies more accountable for their performance. Through one guiding principle and two recommendations, directed to HCFA, we set forth ways in which it can provide this leadership.

In our recommendations we call upon HCFA to devote more concerted attention to hospitals and their external quality review systems. We recognize that in an environment of limited resources and competing priorities, such attention is not easily or readily provided. In that context, we present the recommendations as a blueprint for action that can be carried out over a reasonable period of time.

Through the guiding principle and recommendations, we call upon HCFA to lead and stay attuned to important nuances involving the relationships among HCFA, the Joint Commission, the State agencies, and the hospitals themselves. In this context, we stress that while HCFA has authority and leverage it can assert, it must approach the Joint Commission and State agencies not as subordinates in a chain of command, but as partners sharing a commitment to high-quality hospital care. Similarly, we stress that external review generally should be conducted in ways that minimize the regulatory burden on hospitals and seek to complement hospitals' own internal quality review efforts.

GUIDING PRINCIPLE. The HCFA, as a guiding principle, should steer external reviews of hospital quality so that they ensure a balance between collegial and regulatory modes of oversight.

Both approaches have ardent supporters, with consumer advocates urging more regulatory types of oversight and professional groups stressing the advantages of collegial approaches. From HCFA's standpoint, it is important to recognize that both approaches have value and that a credible system of oversight must reflect a reasonable balance between the two. Thus, as HCFA moves toward an increasingly data-driven system, as reflected in the proposed conditions, it should ensure that such systems are used both as means to foster improvement as well as means to enforce minimums. In other words, data present opportunities for both sides of the continuum. Well-designed data systems could include elements that, for example, elevate standards of care overall as well as identify outliers requiring interventions.

In aiming to achieve balance between the collegial and regulatory modes of oversight, it is instructive to note the conclusion of a recent case study of regulatory approaches of the Occupational Safety and Health Association (OSHA):

> It has become cliche for critics of regulation to tout increased cooperation as a means of curing what they perceive ails the regulatory process. While cooperation holds promise as an effective enforcement technique, the policy literature suggests that caution is due. Although a mix of cooperation and punishment is likely to be an optimal enforcement policy, the literature provides no clear guidance concerning what policy is optimal. OSHA's situation confirms that agencies should maintain a viable enforcement program while cautiously experimenting with additional cooperative approaches.[43]

As we noted earlier, the conclusions of the National Roundtable on Health Care Quality also reinforce the theme of balance. They suggest that while both collegial and regulatory approaches have advantages, neither is backed with sufficient data to warrant a concentration on one at the expense of the other. Thus, as the overall system of quality oversight becomes increasingly oriented to the collegial side of the continuum, the risks begin to mount, with potentially significant consequences to patients. The Roundtable, it is important to remember, stated that regulation "is the only mechanism we have to protect the public from egregiously poor providers."[44] The Prospective Payment Assessment Commission reinforced this theme of balance, noting that "continuous quality improvement activities need to be accompanied by effective methods to identify and monitor providers of questionable performance."[45]

We recognize no precise definition of what represents a balance between collegial and regulatory approaches exists. Balance depends on judgment and continuing assessments of the thrust and impact of the different components of external quality review. A balanced system, in our view, will involve the continued presence of on-site hospital surveys, both announced and unannounced; an ongoing capacity to respond quickly and effectively to complaints and adverse events; further development and application of standardized performance measures; and, even though it is not much in evidence at this time, a mechanism for conducting retrospective reviews of the appropriateness of the care received by hospitalized patients. Each of these approaches can add value and a measure of patient safety. Until much more compelling evidence can be mustered, no one approach should dominate. Accordingly HCFA should view with some concern the emerging dominance of the collegial mode.

In its steering role, HCFA must develop a broad perspective so that it can clearly determine not only how the external review systems as a whole are functioning but also when and how to adjust them. Thus, it is particularly important that, as a general point, HCFA recognize the distinctive strengths and limitations of both the Joint Commission and the State agencies, which we elaborate on below.

Recognize the inherent strengths and limitations of accrediting bodies and the State agencies.

Each of these entities contributes to the external review of hospitals. But they contribute differently. If HCFA is to steer effectively, it must act in accord with the inherent strengths and limitations of these two types of bodies.

Accreditation, first of all, is a form of self-regulation.[46] The Joint Commission's board, for example, is dominated by members closely associated with the hospital industry. Notwithstanding the presence of non-industry members on its board or of various advisory bodies or of certain public purposes it may fulfill, it is primarily responsive to the interests of entities it accredits. In this context, it is important to view the Joint Commission as an entity closely connected with the hospital industry and having greater credibility with that industry than any governmental entity is likely to have. That connection makes the Joint Commission inherently inclined to tilt toward the collegial side of the oversight continuum we presented. Working cooperatively with its hospital constituency and drawing on its considerable expertise on hospital practices , it can provide leadership in defining accreditation standards and helping hospitals achieve them. It can (and must) play a certain regulatory role as well, but if it begins to tilt in this direction, it will likely encounter greater resistance from its core constituency that could undermine its efforts to educate and elevate.

State agencies, on the other hand, are public bodies (usually health departments) with traditional regulatory responsibilities. Within their States, they are accountable to

executive and legislative leaders who expect them to protect consumers. This is especially apparent whenever there is a high profile adverse event or major complaints involving a hospital. In such cases, elected officials as well as the local media are likely to look to the State agency as a front line of response in determining what went wrong and what to do about it. Thus, State survey agencies are inherently inclined to tilt toward the regulatory side of our continuum. That is not to suggest that they can not and do not play a role in fostering improvements through a collegial orientation, but any substantial movement in that direction is likely to conflict with their longstanding role in enforcing minimum standards and ensuring patient safety.

Thus, as HCFA exerts its steering role in years ahead, it would be sound policy for it to look to the Joint Commission to tilt (but not too far) toward the collegial end and the State survey agencies to tilt (but not too far) toward the regulatory end. Such a frame of reference can be helpful as HCFA weighs specific policy and operational choices. For example, as HCFA incorporates, through its proposed conditions, certain aspects of the Joint Commission's approach to oversight, it should maintain the primacy of the State agencies' role as front-line responders to complaints and adverse events, and all that that role entails, such as probing and challenging approaches to surveys. Furthermore, it would make sense for HCFA to support the Joint Commission's sentinel event policy, which treats adverse events confidentially and as opportunities for improvement, as long as the State agencies still responded to such events in a way that held hospitals publicly accountable. Similarly, it would make sense to continue to support explorations for data-driven measures of outcome that someday could provide an important basis for external quality review, as long as that vision does not undermine a strong, continued role for on-site inspections. It is likely, after all, to be some time before the development and application of data-driven systems of oversight are sufficiently sophisticated to justify a deemphasis of on-site surveys.

RECOMMENDATION 1. The HCFA should hold the Joint Commission and State agencies more fully accountable to HCFA for their performance in reviewing hospitals.

The Joint Commission is a private entity accountable to its governing board and to the hospitals that pay for its accreditation services. The State survey agencies are public bodies accountable to their States' governors and legislatures. But in carrying out their external reviews of hospitals, both the Joint Commission and State agencies are also accountable to HCFA for services they are performing on behalf of Medicare and Medicaid beneficiaries. They must balance this line of accountability with their own reporting channels to their respective board and legislatures. And while HCFA should be respectful of these channels, it should, as we have indicated, be ready to exert stronger leadership to ensure that Federal interests are upheld.

In accord with the accountability framework we have developed for this inquiry we specify below the kind of operational steps HCFA should take in (1) obtaining information, (2) providing feedback, and (3) disclosing information.

1. a. Revamp Federal approaches for obtaining information on the Joint Commission and State agency performance.

Validation Surveys. The HCFA should deempahsize and perhaps even phase out validation surveys as a tool for overseeing the Joint Commission's performance. Our findings revealed fundamental limitations associated with this approach to accountability. In our assessment the limits are substantial and may well be too basic to correct. The HCFA should seek to identify more cost-effective approaches that are less intrusive to hospitals. Given the current congressional mandate for validation surveys, HCFA would have to seek legislation to achieve the intent of this recommendation.

In the case of State surveys of nonaccreditated hospitals, HCFA has not been conducting validation surveys as a means of obtaining performance information on the States' expectations. We recommend that it not initiate such surveys, even if the resources become available.

Observation Surveys. The HCFA should give serious consideration to incorporating these surveys as a major tool of oversight of both the Joint Commission and State survey agencies. The great advantage of accompanying the Joint Commission or State surveyors during a hospital visit is that it provides direct and immediate information on the performance of both the surveyors and the hospitals. The HCFA conducted a pilot of this process through 20 observation surveys--during which HCFA and State officials observed the performance of Joint Commission surveyors. But it has yet to issue its evaluation of the experience. This lack of followup represents a significant missed opportunity, one that should be addressed.

In further consideration and/or testing of observation surveys, HCFA should consider adapting two features that were not part of the initial pilot. One would be to conduct some such surveys on an unannounced basis. This could add an important element of balance to the approach. A second feature would be to allow the observing surveyors to participate to some degree in the survey process. It appears untenable and unnecessary to us to have skilled, experienced surveyors from State agencies (or HCFA) serving as silent witnesses when they could contribute along the way.

Performance Reports. The HCFA should obtain more timely and useful performance-related information, both from the Joint Commission and State survey agencies. This is particularly important with respect to the Joint Commission, from which it obtains little ongoing information. We suggest that HCFA work with the Joint Commission to develop a set of specifications for limited, but regular reporting, preferably through electronic

format. We suggest that such reporting be presented in a manner that facilitates an understanding of trends and at a minimum include information on the following:

- **On-site surveys** (such as the number of triennial, random unannounced, and unscheduled surveys)
- **Survey results** (for example, the number of hospitals achieving each level of accreditation, accreditation scores, most common problems identified, and the number and types of follow-up actions, by survey type)
- **Complaints** (such as the number and types received overall, then broken down to reflect those received centrally and on-site, and finally the number and type of complaints resulting in recommendations for improvement)
- **Adverse events** (for example, the number and type of sentinel event reports, the number of hospitals placed on Accreditation Watch, the number resulting in a change of accreditation status because of the sentinel event, and the number resulting in recommendations for improvement)
- **Performance measures** (such as the number of hospitals participating in the Joint Commission's performance measurement programs: Oryx and Oryx+)

We suggest that each year, this information be compiled and presented in an annual report that facilitates year-to-year comparisons. That report should be submitted to HCFA and to Congress. It should also be available on the Internet.

With respect to State survey agencies, HCFA already requires considerable reporting through its Online Survey Certification and Reporting (OSCAR) system. It includes some but not all of the categories of information noted above. We suggest that HCFA reexamine the OSCAR reporting system to ensure that at a minimum it include categories of information parallel to those set forth above. We also suggest that HCFA reexamine the reporting that the States currently provide on their improvement projects, with the intent of generating more precise and comparable information.

Finally, if HCFA were to incorporate the observation surveys as a major tool of oversight, it would be important to specify the extent and type of information to be collected from those surveys. It would be essential that data from these surveys be fed into a central data base that HCFA could draw upon in giving performance feedback to the Joint Commission and State survey agencies.

1. b. Strengthen Federal mechanisms for providing performance feedback to the Joint Commission and State agencies.

Performance Assessments. The HCFA should provide timely, ongoing feedback to the Joint Commission and State survey agencies on the basis of information obtained through the observation surveys (which we recommend) and, in the case of the Joint Commission, through the validation surveys (as long as they remain). Such feedback is a vital element

that is now almost completely missing in the system of external review. In some fashion, the feedback should follow each observation visit or validation survey. It should also be provided on a cumulative basis, drawing on a number of such visits or surveys. Ideally, such cumulative feedback would be part of an annual report, paralleling the annual report we suggest that State agencies and the Joint Commission submit to HCFA.

The HCFA should also give attention to feedback in the form of special alerts based on accumulated information revealing a problematic pattern of performance by the Joint Commission or by individual States. In such cases, the Joint Commission or the States involved should be expected to indicate how they will respond and correct the situation identified by HCFA.

All such performance feedback noted above, as well as the performance reports noted earlier, could be part of the annual report to Congress that is mandated by statute. While that mandate applies only to the Joint Commission, it would be helpful to incorporate in that report a full array of information applying to nonaccredited as well as accredited hospitals. That way, Congress and the interested public could gain a better appreciation of the overall adequacy of external systems for reviewing hospital quality.

Policy and Procedural Guidance. Our focus is on guidance to the Joint Commission. Given that HCFA now provides minimal such guidance, given that the Joint Commission is the primary external reviewer for about 80 percent of the hospitals in the country, and given our call for a more balanced system of oversight, we recommend that HCFA negotiate with the Joint Commission to achieve some redirection in Joint Commission priorities and practices. We suggest that this can be done in a manner that respects the Joint Commission's considerable expertise on accreditation practices, yet calls for the Joint Commission to accommodate public purposes associated with its special deemed status. To the extent that HCFA continues to rely on the Joint Commission, it should negotiate the following to help achieve a more balanced system of oversight:

> ***1. Conduct more unannounced surveys, both regular surveys and surveys made in response to complaints.*** Further, unlike the Joint Commission's current "unannounced" surveys, we suggest that such surveys involve no prior notice at all for the hospitals. We recognize that such practice may add some operational difficulties to the survey process--for example, records and policies may not be assembled and ready for surveyors. However, it is certainly plausible that such an on-the-spot review would offer insights that an announced survey would not and that it would add a measure of public credibility to the entire accreditation process.

2. Make "accreditation with commendation" a more meaningful category or do away with it altogether. This top level of accreditation tends to suggest a greater level of distinction than is warranted by the underlying scoring system. Hospitals use it for marketing purposes to suggest a degree of excellence that can be misleading to the public. We suggest that the degree of rigor called for in attaining this designation be increased or that the designation be dropped.

3. Introduce more random selection of records as part of the survey process. Allowing hospitals to select records for review by the surveyors introduces too much possibility for manipulation and undermines the credibility of the process. Here is a practice where the move toward collegiality seems to go too far. It is essential that surveyors gain a balanced assessment of hospital practices, not one that is likely to enhance the positives.

4. Provide surveyors with more contextual information about the hospitals they are about to survey. Background information on organizational or ownership changes involving the hospital, on developments in the local healthcare marketplace, and on other such matters can help surveyors ask more probing and challenging questions during their visits. The goal of fostering consistency in surveyor practices should not be pursued at the expense of vital contextual information that can help surveyors focus on the distinctive features and situations at each hospital.

5. Jointly determine some of the year-to-year priorities. For instance, the Joint Commission determined at one point that restraint reduction--certainly a desirable objective--would be a priority. We suggest that HCFA could play a role in suggesting such priorities. Based on our inquiry, a good initial priority would focus on hospital privileging and credentials verification practices--an area where we found Joint Commission reviews to be too superficial. One aspect of this inquiry could be further attention to hospitals' compliance with Federal requirements to report to the National Practitioner Data Bank.

6. Conduct more rigorous assessments of hospitals' internal continuous quality improvement (CQI) efforts. Within the hospital community, the Joint Commission has helped raise awareness and interest in CQI efforts. But the survey process raises few questions about such efforts. The time has come to raise the bar and subject hospitals to greater scrutiny in terms of the purpose, methods, and consequences of their CQI efforts.

7. Enhance the capacity of surveyors to respond to complaints as part of the survey process. The rigid schedule of surveyors leaves little opportunity to review a complaint, either in its own right or as a possible indicator of a broader problem. To the extent that information about complaints can be provided to surveyors prior

to the visit, such opportunities could be enhanced. As a complementary approach, the Joint Commission could also give more attention during its triennial survey to hospitals' internal complaint systems and whether they serve as a means of identifying broader, systems problems.

1. c. Assess periodically the justification for the Joint Commission's deemed-status authority.

Once a hospital is accredited by the Joint Commission, it is deemed to meet the Medicare conditions of participation. This delegation of authority to the Joint Commission is granted by Congress, not by HCFA. As such, it is a unique authority held by no other accrediting body in the healthcare field.

We are not addressing whether the Joint Commission warrants this special authority. But we do suggest the granting of this unique status should not be for perpetuity, without accountability for performance. The HCFA already has the regulatory authority to review the deeming authority when validation survey results reach a certain disparity rate.[47] That rate has never been reached, however. Accordingly, we call for HCFA from time to time to assess whether the Joint Commission's performance continues to warrant its unique deeming authority and to report its conclusions to Congress as part of an annual report or otherwise. Any change in this status would, of course, depend upon congressional action.

If HCFA were to move in the direction we call for here, it would be particularly important for it to collect information and provide feedback--as we call for in the preceding recommendations. In fairness, it would also be important that it communicate in advance to the Joint Commission what its own criteria would be for determining adequate performance. This is a matter that it could profitably address with the Joint Commission itself, as well as with other parties.

1.d. Increase public disclosure.

The HCFA is in a unique position to give the public information on the performance of individual hospitals and also of entities that oversee those hospitals. Ultimately HCFA is responsible for the oversight of hospitals and it should be committed to making every aspect of oversight as meaningful and effective as possible. One way to accomplish that is to make results widely available to the public through the Internet and other appropriate mechanisms.

Through greater disclosure of information, HCFA can reinforce that hospitals and external reviewers of hospitals are accountable to the general public as well as to the government.[48] Disclosure on the Internet can be a particularly effective tool in this regard as the media, advocates, and other interested parties can draw on it to inform wider

audiences. Also, such disclosure can be helpful to healthcare purchasers interested in quality-of-care issues.

The HCFA should consider putting some hospital-specific information on the Internet in a way that facilitates comparisons among hospitals and gives a sense of what each oversight body does and what each has found at a given hospital. The HCFA has already made strides in making information on nursing home survey results available. Perhaps that can serve as a model.

Performance of Hospitals. The HCFA could make any or all of the following performance information available by hospital on its Web site: the most recent survey date, survey results, and information on complaints or adverse events.

Performance of the Joint Commission and State Agencies. In previous recommendations, we call for both the Joint Commission and State agencies to submit regular reports to HCFA. The HCFA could easily post these reports on its Web site, or require State agencies and the Joint Commission to post the reports on their Web sites.

RECOMMENDATION 2. The HCFA should determine the appropriate minimum cycle for conducting certification surveys of nonaccredited hospitals.

The backlog for routine surveys of nonaccredited hospitals is large and it is growing. And, unlike nursing homes and home health agencies, hospitals lack a congressionally mandated cycle for surveys. Thus, nonaccredited hospitals are subject to limited external review. Furthermore, the proposed conditions of participation suggest an even lesser role for routine certification surveys.[49] Current policy gives priority to responding to complaints and adverse events in hospitals over routine surveys, which we endorse. But by determining an appropriate minimum cycle for hospital surveys, HCFA will increase the attention hospital quality issues receive and improve oversight comparability from State to State.

COMMENTS ON THE DRAFT REPORTS

Within the Department of Health and Human Services, we received comments on our four draft reports from HCFA. Outside of the Department, we solicited and received comments from the Joint Commission, the Association of Health Facility Survey Agencies, the American Osteopathic Association, the American Hospital Association, the American Association for Retired Persons, the Service Employees International Union, the National Health Law Program, and Public Citizen's Health Research Group.

We include the complete text of these comments in appendix E. Below we summarize the comments and, in italics, offer our responses. First we focus on the comments offered by HCFA, the Department component to which we directed all of our recommendations. Second, we turn to the perspectives of the Joint Commission and of the Association of Health Facility Survey Agencies, which represents the State survey and certification agencies. The HCFA relies upon these agencies and the Joint Commission as the major agents of external review of hospital quality. Finally, we present the responses of other key stakeholder organizations.

HCFA Comments

The HCFA supported our findings and reacted to our recommendations as an opportunity to make significant improvements in hospital oversight and to see that these changes fit in with its broader goals of performance measurement. It offered a detailed hospital quality oversight plan, which incorporated our many recommendations, and it presented a performance measurement strategy based on developing standardized hospital performance measures that are consumer- and purchaser-driven and that are in the public domain.

The HCFA's oversight plan affirmed its commitment to more frequent State surveys of nonaccredited hospitals, to strengthened oversight of both the State agencies and the Joint Commission, and to balancing the collegial and regulatory approaches to oversight. Toward the latter end, it indicated that it will look to the Medicare Peer Review Organizations, with which it contracts, as its chief agents in pursuing collegial approaches to advance the quality of care in hospitals. It will rely upon the Joint Commission and in particular on its on-site surveys as a key part of the regulatory framework needed to enforce compliance with Medicare standards.

We find HCFA's detailed action plan to be highly responsive to the shortcomings we identified in hospital quality oversight and to our specific recommendations. This plan sets forth an agenda that can be of great significance in improving patient safety and improving the quality of patient care.

With respect to HCFA's comments on how it will foster a balance between collegial and regulatory approaches, we urge that HCFA give adequate recognition to the important regulatory role that State survey agencies have to play not only in conducting surveys but also in responding to complaints and adverse events. We agree that Joint Commission on-site surveys represent an important regulatory mechanism that should be more fully used, but note that as an accrediting body that is engaged in standard-setting and that has close ties with the hospital industry, the Joint Commission can also serve as an important force in quality improvement.

Joint Commission and Association of Health Facility Survey Agencies Comments

The Joint Commission agreed with the principle of balance between collegial and regulatory approaches, but felt that our concerns about the emerging dominance of the collegial approach were unfounded. It also took issue with our findings that Joint Commission surveys were unlikely to detect substandard patterns of care or individual practitioners with questionable skills and that the Joint Commission devotes little emphasis to complaints and treats major adverse events as opportunities for improvement. It noted that some of the specific suggestions we made for improving the survey process have already been put in effect and that all the remaining ones are under consideration. It also expressed support for our recommendation that HCFA obtain more useful and timely performance-related information from the Joint Commission.

We stressed the principle of balance because there is insufficient evidence to support an emphasis on either the collegial or regulatory approach. We cited the conclusions of the National Roundtable on Health Care Quality and other sources as support for our conclusion. We still conclude that Joint Commission surveys are unlikely to detect substandard patterns of care, such as inappropriate surgeries or high complication rates, or to identify individual practitioners with poor skills. (In this regard, we found the on-site process of reviewing hospital privileging and credential verification procedures particularly lacking.) In the text, we spell out in some detail the bases for these findings. Similarly, we believe that the evidence is clear that the response to complaints is a relatively minor part of the accreditation process and that adverse events are treated as opportunities for improvement.

The Association of Health Facility Survey Agencies agreed with our assessment of the current system of hospital oversight. It devoted particular attention to our discussion of validation and observation surveys. It indicated that the aim of validation surveys is not to evaluate the Joint Commission but rather to validate hospital compliance with Medicare standards. Further, on the basis of the experience of an Association member who participated in an observation survey, it expressed reservations concerning the effectiveness of this approach in improving patient care and outcomes. Finally, it supported the posting on websites of in-depth information on how hospitals fared as a result of survey visits and complaint investigations.

We appreciate the Association's supportive comments. Regarding the Association's concerns about validation surveys, we found that they have served as the single most important mechanism for assessing Joint Commission performance. We note that HCFA, in its comments to our report, indicated that it will clarify that the purpose of validation "is to evaluate the performance of the accrediting body in assuring that the Secretary's standards are met or exceeded." We urge that the Association consider the significant limitations we addressed about the effectiveness of the validation surveys and examine further the potential of observation surveys as a more cost-effective and timely tool of oversight. We recognize that further experimentation with this approach is required, but suggest that it may well be worthwhile.

Comments of Other External Organizations

Overall, the other stakeholder organizations expressed considerable support for our findings and recommendations. Yet, they also noted a number of concerns. The American Hospital Association took issue with how we applied the regulatory and collegial concepts and stressed that hospital liability concerns impede the kind of public disclosure we recommend. The American Osteopathic Association noted reservations about more unannounced surveys and suggested that a closer review of medical care during on-site surveys would offer better value. The American Association of Retired Persons agreed with the thrust of our recommendations.

The Service Employees International Union, the National Health Law Program, and Public Citizen's Health Research Group each called for even stronger Federal actions than we recommended. These included a stronger emphasis on regulatory approaches, greater reliance on unannounced surveys, more extensive public disclosure, and firmer HCFA action in overseeing the Joint Commission performance and in reassessing its deeming authority.

As HCFA carries out its hospital quality oversight plan, we suggest that it take into account the perspectives of these various stakeholders. They express concerns and offer suggestions that we often heard expressed during our inquiry. We believe that our recommendations set forth a balanced course of action that draws to some degree on the insights of each of these stakeholders and that, overall, can substantially improve hospital quality oversight.

APPENDIX A

Medicare Conditions of Participation

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 (64 Fed. Reg. 36,070). Below are the components of the existing COP for non-specialty hospitals from 1986, followed by the components of the proposed COP.

Existing COP

Subpart A- General Provisions

Provision of emergency services by nonparticipating hospitals

Subpart B- Administration

Compliance with Federal, State, and local laws
Governing Body

Subpart C- Basic Hospital Functions

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

Subpart D- Optional Hospital Services

Surgical services
Anesthesia services
Nuclear medicine services
Outpatient services
Emergency services
Rehabilitation services
Respiratory care services

Proposed COP

Subpart A- General Provisions

Patient Rights (issued as an interim final rule on July 2, 1999)

Subpart B- Patient Care Activities

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

Subpart C- Organizational Environment

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

Roles of Accreditation and Medicare Certification

Element	Joint Commission (Accreditation)	State Survey Agency (Medicare Certification)
Announced Surveys	Core of accreditation process Routine presence on a 3-year cycle Collegial Tight structure Limited opportunity to follow leads or respond to complaints Dynamic standards Spurs hospital improvement Reduces risk Unlikely to identify patterns of substandard care or individual practitioners with questionable skills Survey results fail to make meaningful distinctions across hospitals	Low priority Elapsed time between surveys growing Medicare Conditions of Participation outdated Survey results fail to make meaningful distinctions across hospitals
Random Unannounced Surveys	Used for about 5 percent of accredited hospitals per year Not truly unannounced; hospitals get 24-48 hours notice Focuses on five areas commonly found out of compliance	Not applicable
Response to Adverse Events	Approach is oriented toward research and prevention Relies on self-reporting Ensures hospital confidentiality No public accountability	Core activity with higher priority than routine hospital certification or validation surveys Includes authority to respond to events in accredited as well as nonaccredited hospitals Publicly accountable
Responses to Complaints	Considered adjunct to triennial surveys Surveys present limited opportunities to follow-up on complaints No public accountability	Core activity with higher priority than routine hospital certification or validation surveys Includes authority to respond to events in accredited as well as nonaccredited hospitals Publicly accountable
Standardized Performance Data	Lacks uniformity, thus comparability across hospitals Not linked to accreditation	Not applicable

Source: Office of Inspector General, *The Role of Accreditation* (OEI-01-97-00051) and *The Role of Medicare Certification* (OEI-01-97-00052).

APPENDIX C

Methodology

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 geographic regions of the United States. We then examined the OSCAR data for those States in greater detail. We verified the operational status of the nonaccredited hospitals in those States that had not been surveyed in over 5 years using the American Hospital Association's *1997 Hospital Guide*.

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

The State Survey and Certification Agencies

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

Accrediting Organizations

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

Survey Observations

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

Stakeholder Interviews

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

Other Documents

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

A Systemic Review

APPENDIX C

In this report we focus on the system of external review considered as a whole. We address issues that have a significant bearing on how well that system works. In so doing, we draw on a wide body of evidence from the sources we noted above. Our findings and recommendations represent our conclusions based on our assessment of this evidence. We present them with the intent of providing helpful directions on how HCFA, the Joint Commission, and the State agencies can play a more effective role in protecting patients and improving quality.

APPENDIX D

Certification Survey

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 scandals with its medical 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 staff person 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 15th 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.

APPENDIX E

Detailed Comments on the Draft Reports

In this appendix we present the full comments of all parties that responded to our four draft reports. In order, the comments that we present in this appendix are from the following parties:

Health Care Financing Administration, U.S. Department of Health and Human Services

Joint Commission on Accreditation of Healthcare Organizations

Association of Health Facility Survey Agencies

American Osteopathic Association

American Hospital Association

American Association of Retired Persons

Service Employees International Union

National Health Law Program

Public Citizen's Health Research Group

APPENDIX E

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

DATE: JUL 2 1999

FROM: Administrator NMD
Health Care Financing Administration

SUBJECT: Office of Inspector General (OIG) Draft Report, "The External Review of Hospital Quality--A Call for Greater Accountability"

TO: June Gibbs Brown
Inspector General

I want to thank you and your staff for conducting a thorough review of the external quality oversight of hospitals in the United States and the roles played by the Health Care Financing Administration (HCFA), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and the State survey agencies (SAs). I want to assure you that HCFA welcomes the report's findings and views the findings as an opportunity to make the changes necessary to improve the oversight and quality of care in hospitals participating in the Medicare and Medicaid programs and to ensure that our actions fit within our larger goals of performance measurement.

I appreciate the OIG's feedback regarding the proposed changes to the hospital conditions of participation (CoP) that were published in December, 1997. Specifically, I appreciate the feedback on the perception that HCFA plans to mirror the JCAHO's more collegial approach in the CoPs and appears to want to abandon the regulatory approach to hospital oversight. HCFA desires to incorporate a balance between the regulatory and collegial approaches to hospital quality oversight, as the OIG recommends. We will clarify any misperceptions of our regulatory intent in the preamble to the final rule for new hospital CoP and emphasize accountability. The OIG report notes that the JCAHO accreditation process is founded in a collegial approach to oversight. However, HCFA will emphasize in the preamble to the final rule that we view the Peer Review Organizations (operating in largely a "penalty-free" environment), not the JCAHO, as our agent to advance the quality of care in the hospital setting. HCFA views the JCAHO as a very valuable component in our regulatory oversight framework in that the JCAHO performs onsite surveys which may serve as the basis for regulatory actions.

Page 2 - June Gibbs Brown, Inspector General

Finally, I want to share with you HCFA's strategy for performance measures in hospitals. We plan to incorporate our strategy into the final hospital CoP rule. This strategy consists of three principles: 1) performance measures should be purchaser and consumer-driven, 2) performance measures and the tools needed to collect them should be in the public domain with a publicly-held copyright, and 3) the content and collection of data and performance measures derived from the data should be standardized. Eventually, we plan to use these performance measures to support our direct evaluation of nonaccredited hospitals as well as our evaluation of the JCAHO. Hospital performance measures will be a proxy for how well accrediting bodies assure quality of care in hospitals.

Attached you will find two documents. The first is HCFA's agency-wide action plan to address your recommendations. The second is HCFA's performance measurement strategy for hospitals.

Nancy-Ann Min DeParle

Nancy-Ann Min DeParle

Attachments-(2):
1) HCFA's oversight plan to address the OIG recommendations
2) HCFA's performance measurement strategy for hospitals

APPENDIX E

HOSPITAL QUALITY OVERSIGHT PLAN

The Office of the Inspector General's (OIG) Draft Report, "The External Review of Hospital Quality--A Call for Greater Accountability"details the pros and cons of both the collegial and regulatory approaches to hospital quality oversight. The OIG associates the term "collegial" with a quality improvement focus and the term "regulatory" with a focus on the enforcement of minimum standards. The OIG recommends, as a guiding principle, that the Health Care Financing Administration (HCFA) steer external reviews of hospital quality so that they ensure a balance between collegial and regulatory modes of oversight. The OIG also recommends that HCFA hold the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the State survey agencies (SAs) more fully accountable for their performance in reviewing hospitals. In addition, the OIG recommends that HCFA determine the appropriate minimum cycle for conducting certification surveys of nonaccredited hospitals. The following goals detail HCFA's response to the Inspector General's recommendations and react to the content of the OIG's four volume report.

GOAL 1: Strike a balance between both the quality improvement approach and the regulatory approach to hospital oversight

ACTIONS--

1.) HCFA will explain, in the preamble to the final hospital CoP regulation, that HCFA did not mean to suggest, in the NPRM, an abandonment of our regulatory role.

2.) HCFA will strengthen the preamble by emphasizing accountability. Even though the JCAHO accreditation process is founded in a collegial approach, HCFA will emphasize in the preamble that HCFA views the JCAHO as a very valuable component in our regulatory oversight framework in that the JCAHO performs onsite surveys which may serve as the basis for regulatory actions. HCFA will explain that it views the Peer Review Organizations (operating in largely a "penalty-free" environment), not the JCAHO, as our agent to advance the quality of care in the hospital environment, even though the JCAHO considers itself as having a similar role.

3.) HCFA will incorporate into the final hospital CoP rule HCFA's strategy for

1

performance measures. This strategy consists of three principles:

- performance measures should be purchaser and consumer-driven,
- performance measures and the tools needed to collect them should be in the public domain with a publicly-held copyright
- the content and collection of data and performance measures derived from the data should be standardized.

4.) HCFA will ensure that future data-driven systems of hospital quality oversight foster both quality improvement activities and the enforcement of minimum quality standards.

5.) HCFA is committed to information disclosure and publishing data on hospital performance (e.g., survey data, future performance measure results, etc.).

GOAL 2: Improve Oversight of the JCAHO's Activities

ACTIONS--

1.) HCFA will reevaluate the current process for oversight of the JCAHO, working with the JCAHO to improve accountability.

2.) HCFA will develop and articulate clear criteria for JCAHO performance as a recognized accreditor for hospitals seeking deemed status participation in Medicare.

3.) HCFA will examine the current validation activity; that is, the process that involves conducting Medicare surveys within 60 days of the JCAHO survey and making an assessment of JCAHO performance from the results of that survey.

- HCFA will consider either supplementing or replacing current validation surveys with observation surveys that would be conducted at the same time as the accreditation survey and should look at both the JCAHO onsite performance and the ability of the hospital to meet the CoPs.

- An observation survey protocol, using the experience from the Federal Oversight Support Survey (FOSS), Federal Monitoring

2

System (FMS), and other oversight pilot models would need to be developed.

4.) HCFA will clarify that the purpose of the validation program is to evaluate the performance of the accrediting body in assuring that the Secretary's standards are met or exceeded.

5.) HCFA will continue to give complaints of condition-level deficiencies in accredited hospitals high priority for investigation. HCFA will conduct complaint investigations in accredited hospitals in accordance with the current process of surveying the hospital against the Medicare CoP.

6.) HCFA will work with the JCAHO to set its annual survey priorities for areas of focus during accreditation surveys. For example, if HCFA were to work with the JCAHO today, HCFA's priorities would be to focus on medication errors, complications from medical errors (e.g., amputation of the wrong foot), and patient falls.

7.) HCFA will seek the JCAHO's compliance with the following objectives:

- The JCAHO should conduct more unannounced surveys.
- The JCAHO should make the "accreditation with commendation " category more meaningful, or do away with it altogether.
- The JCAHO should introduce more random selection of records as part of the accreditation survey process.
- The JCAHO should provide surveyors with more contextual information about the hospitals they are about to survey.
- The JCAHO should conduct more rigorous assessments of hospitals' internal continuous quality improvement efforts.
- The JCAHO should enhance the capacity of surveyors to respond to complaints within the survey process.
- The JCAHO should provide more timely and useful performance related data to HCFA (e.g., an annual report from the JCAHO) which summarizes the JCAHO findings, results, decisions, adverse events and monitoring activities regarding accredited hospitals.

8.) HCFA will provide more direct, timely feedback to the JCAHO on its performance. This information will come from observation survey results, validation surveys, and Medicare's annual Report to Congress, as well as other sources. As hospital performance measures develop and mature, they

3

will substantially enhance our oversight of the JCAHO. HCFA will explore sending special alerts to the JCAHO on problems identified/special concerns, expectations for JCAHO response, and consequences for nonperformance.

9.) HCFA will develop a coordinated effort with the JCAHO for information sharing and complaint/sentinel event investigations.

10.) HCFA will redesign the survey data system--the OSCAR system. HCFA could either link the OSCAR system to the JCAHO's accreditation survey data system or expand OSCAR to include data on the JCAHO survey results, complaints, sentinel events and performance measures. This would give HCFA the universe of information on Medicare participating hospitals and allow HCFA to better monitor hospital quality and how well the JCAHO monitors its accredited hospitals.

11.) HCFA will consider pursuing program changes (administrative, regulatory, or statutory) designed to promote JCAHO accountability to HCFA and increase HCFA's ability to negotiate the changes recommended by the OIG. HCFA will also consider pursuing program changes to remove the restriction and barriers from the Act that preclude or inhibit HCFA from releasing survey information to the public.

GOAL 3: Improve Oversight of SA Activities

ACTIONS--

1.) HCFA will reevaluate the current process for oversight of SAs, working to improve accountability.

2.) HCFA will examine the implementation and the utility of the SAQIP program. This would include the amount of resources (budget & human resources) devoted to SA oversight and the use of SAQIP data by HCFA to improve the quality of SA operations. HCFA will explore alternatives for improvement.

3.) HCFA will develop and articulate clear criteria for SA performance.

- Criteria for SA performance should be consistent with the Section 1864 Agreement and HCFA procedures.

4

- Articulate criteria via manual instructions.

4.) HCFA will provide more direct, timely feedback to the SAs on their performance.

5.) HCFA will develop clear feedback mechanisms to alert the SAs of special problems and expectations for SA response to address those problems and consequences for nonperformance.

GOAL 4: Improve Oversight of Nonaccredited Hospitals

ACTIONS--

1.) HCFA is committed to establishing a more frequent survey cycle for nonaccredited hospitals so that nonaccredited hospitals are surveyed as frequently as the accredited hospitals.

2.) HCFA is committed to obtaining the funds necessary to establish a more frequent survey cycle for nonaccredited hospitals.

PERFORMANCE MEASUREMENT STRATEGY in HOSPITALS

Purpose: The purpose of this document is to describe HCFA's strategy for using performance measurement for accountability purposes which enables public reporting of comparisons in clinical performance among Medicare participating hospitals. HCFA uses performance measures to achieve the Agency's goals of: 1) becoming a prudent purchaser of quality health care, 2) informing beneficiaries about hospital clinical performance, and 3) over-seeing the accreditation of hospital performance by select accreditors on behalf of the Agency.

Background: Historically, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has established performance measurement requirements for hospitals to meet accreditation standards. The measures have not been standardized for all hospitals, leaving individual hospitals to select from multiple and different performance measurement systems. Individual hospitals can use these selected measures for internal quality improvement efforts but not for comparisons among hospitals nationally. Standardized measures would achieve comparability among like providers. HCFA has a responsibility to be accountable to the public concerning the quality of health care services. In order to adequately and appropriately assess and report on the quality of care in hospitals, HCFA must assert a leadership agenda to guide and inform measurement and reporting requirements. This strategy serves as a guide for policy formulation, decision-making, and communication with interested parties.

HCFA has developed a set of guiding principles with regard to the issue of the Agency's national performance measurement strategy. These principles include:

- Performance measures should be **consumer and purchaser-driven**.
- Performance measures and the collection tools needed to collect them should be in the **public domain** with a publicly-held copyright.
- The content and collection of data and performance measures derived from that data, should be **standardized**.

HCFA will establish a performance measurement leadership agenda in order to **pursue standardization of hospital performance measurement.** HCFA will:

1. **Establish a set of Hospital Performance Measures:** In order to require hospitals to report on a standardized set of performance measures, a core set of performance measures needs to be established. HCFA will institute requirements for a core set through national clinical priorities as a fundamental aspect of the Peer Review Organization (PRO) program. In the PRO 6th Scope of Work, HCFA has standardized the requirements among hospitals for clinical performance measurement in 6 clinical priority areas, with 4 of the 6 reflecting hospital care. The PRO, working in partnership with the providers as they utilize common data elements, analyzes data to determine opportunities for improvement in the care delivered to the Medicare beneficiaries in that State and among like providers nationally. HCFA's PROs, the JCAHO, and the State Hospital Associations (Georgia, Arizona, and Rhode Island) have begun to test and implement

state-based pilot projects to evaluate alternative mechanisms for collaborating on performance measurement, quality improvement and accountability to meet survey requirements.

2. **Require Standardized Performance Measurement by Hospitals:** Through the proposed Hospital Conditions of Participation (CoP), HCFA is seeking to require hospitals to report on a standardized set of hospital performance measures.

3. **Provide performance measurement data collection tools in the public domain:** HCFA is providing a national strategy for standardizing the collection and then reporting of comparable data based on nationally defined data elements. This strategy is reflected in two of the Agency's national efforts: a)HCFA's work with the Health Insurance Portability and Accountability Act (HIPPA) and its mandate to standardize nationally the electronic transfer of individual health care information transactions, claims, referrals, etc. through the use of a common data dictionary, as well as through
b) HCFA's provision of common data collection tools to PRO program participants. Hospitals are experiencing increased burden to provide information. Providing information is costly. PROs, as HCFA's measurement and improvement agents, can provide data collection and reporting tools that can be used by hospitals at minimal cost (e.g. MEDQUEST).

The strategy described above is congruent with HCFA's performance measurement intitatives both in managed care and other fee-for-service settings as described below.

PROVIDER	INITIATIVE	DATA COLLECTION INSTRUMENT	CURRENT STATUS REQUIRED/R or UNDER DEVELOPMENT/U	OWNERSHIP PUBLIC/PUB OR PRIVATE/PRIV OR Peer Review Org/PRO	
				DATA	/ TOOL
MCO	HEDIS: The major activity in managed care has been the mandatory adoption of the set of Health Plan Employer Data and Information Set (HEDIS) quality, access and utilization performance measures for all Medicare MCOs. States have the option of using HEDIS for the Medicaid program.	HEDIS	R for MCOs	PUB*	PUB or PRIV VIA NCQA
	Medicare Health Outcomes Survey (formerly Health of Seniors): This survey-based measure set, based on the SF-36, is the first global outcome-based HEDIS performance measure for managed care.	Medicare Health Outcomes Survey	R for MCOs	PUB*	PUB or PRIV VIA NCQA
	Consumer Assessment for Health Plan Study (CAHPS): At the same time that HCFA required Medicare plans to participate in HEDIS, we also directed them to participate in a standardized survey of the satisfaction of their beneficiaries. A CAHPS survey for disenrollees of managed care is under development.	CAHPS	R for MCOs; U for FFS	PUB*	PUB

3

PROVIDER	INITIATIVE	DATA COLLECTION INSTRUMENT	CURRENT STATUS REQUIRED/R or UNDER DEVELOPMENT/U	OWNERSHIP PUBLIC/PUB OR PRIVATE/PRIV OR Peer Review Org/PRO	
				DATA	TOOL
ESRD	ESRD Quality Improvement Initiative: The BBA directed the development of a method to measure quality of services in renal dialysis facilities. HCFA awarded a contract to a PRO to develop a set of clinical performance measures by January of 1999. This contract will incorporate the ESRD core indicator project and be implemented nationally by January of 2000.	ESRD Clinical Performance Measures	U	Net-work*	PUB
PHYSICIANS	HER Contract on Performance Measurement in Fee-for-Service: HCFA is testing the feasibility of quality performance measures in FFS at the national, small geographic and large group practice level (1997-2000). The Medicare Health Outcomes Survey is also being pilot-tested in this project (see above under MCO).	Subset of HEDIS	U	PUB*	PUB
HOSPITALS	In the PRO 5th Scope of Work (SoW), PRO Projects such as the Cooperative Cardiovascular Project, have utilized a standardized set of performance measures to evaluate quality improvement initiatives on a population basis, and have led to meaningful improvement in care. Six national clinical priorities have been established for the 6th SOW, four of which primarily involve inpatient quality measures: acute myocardial infarction (AMI), heart failure (HF), stroke/atrial fibrillation, and pneumonia/influenza. Using administrative claims data to identify cases, a sample of hospital charts will be abstracted in each state and evaluated for performance on the established measures.	MEDQUEST	R for PRO Program Rates available prior to beginning 6th SoW	PRO*	PUB
	Hospital Core Performance Measure Set: HCFA is exploring the concept of requiring Medicare participating hospitals to report on a national standardized set of performance measures. HCFA will work with the Forum on Quality Measurement and Reporting, hospital associations, and accrediting organizations to standardize a core set of hospital performance measures. During this initial stage, for example, HCFA has available through the PRO Program, performance measures for pneumonia, heart failure, stroke and myocardial infarction to offer as a starting point to initiate this effort.	To be developed	U	PUB*	PUB

* Individual identification of patients and practitioners is protected by law and the level of data (individual vs. aggregated; State vs. facility-specific) determines public release.

4

PROVIDER	INITIATIVE	DATA COLLECTION INSTRUMENT	CURRENT STATUS REQUIRED/R or UNDER DEVELOPMENT/U	OWNERSHIP PUBLIC/PUB OR PRIVATE/PRIV OR Peer Review Org/PRO	
				DATA	/ TOOL
NH/SNF	Quality Indicators for Nursing Homes: All certified long term care facilities were required to transmit their MDS records to the State (and States to HCFA) as of June 22, 1998. Facilities may use RAVEN, a HCFA product, or a privately developed software product that meets RAVEN's specifications, to capture and transmit the MDS data. RAVEN, is a software data entry tool that provides specifications that will allow collection of standardized NH/SNF patient assessment information. RAVEN's specifications are available in the public domain and can be included in any software package. Information based on the MDS will begin to be used to focus the long term care survey process as of July 1, 1999, and facility and resident level QI reports will be available to the facility about that time. HCFA is also in the process of developing and testing additional quality indicators for LTC and post-acute settings.	MDS MDS transmission using RAVEN specifications	R (1990) R (6/22/98)	PUB* PUB*	PUB PUB
HHA	OASIS/OBQI: HCFA developed the Outcome Assessment Information Set (OASIS) system, which is a clinical data set designed specifically to develop outcome-based quality indicators (OBQI) for home health care. HCFA is currently sponsoring a major demonstration project to test OBQIs for use in quality improvement and, it is anticipated, for survey and certification. The final OASIS regulations were published on January 25,1999. There is a delay in HHAs collecting , encoding and reporting OASIS data to their respective State agencies due to lack of related clearances (Paperwork Reduction Act & System of Records Notice). Resumption dates will be published in the FR. In order to encode/capture data, HHAs may use a HCFA product, HAVEN, or, any privately developed software that meets HAVEN specifications, to capture and transmit the data. HAVEN is a software data entry tool, available in the public domain on the HCFA website, that will allow collection of standardized home health patient assessment information. HAVEN provides common specifications that can be used in any software tool. Outcome reports will be generated by the State agency based on patient-level data, providing feedback to the HHA which will stimulate quality improvement projects.	OASIS OASIS data transmission using HAVEN specifications	R (1/25/99)-ON HOLD R (1/25/99)-ON HOLD	PUB* PUB*	PUB PUB
OUT-PATIENT	In the PRO 6th SoW Administrative claims data will be used to evaluate state-specific performance on delivery of influenza immunizations, pneumococcal polysaccharide vaccinations, mammograms and care for people with diabetes, in the outpatient setting among the fee-for-service population.	Claims-based or MEDQUEST for diabetes	R for PRO Program Rates available prior to beginning 6th SoW	PUB*	PUB

* Individual identification of patients and practitioners is protected by law and the level of data (individual vs. aggregated; State vs. facility-specific) determines public release.

5

PROVIDER	INITIATIVE	DATA COLLECTION INSTRUMENT	CURRENT STATUS REQUIRED/R or UNDER DEVELOPMENT/U	OWNERSHIP PUBLIC/PUB OR PRIVATE/PRIV OR Peer Review Org/PRO	
				DATA	/ TOOL
GENERAL BENEFICIARY-BASED	Population-Based Surveys: This envisions conducting an annual, standard, list-based telesurvey at the State level on health status, risk factors, and preventive services receipt. Under the 6th SOW, as well as GPRA and NPR, there are many Quality Indicators that must be monitored to ensure achievement of HCFA's and the PRO's mission in the outpatient setting. Standardization of survey instruments and data collection methods will allow HCFA to implement any required system changes due to new or revised program initiatives centrally, uniformly, and in a timely manner.	Medicare Quality Monitoring System (MQMS) Telesurvey	U	PUB*	PUB

* Individual identification of patients and practitioners is protected by law and the level of data (individual vs. aggregated; State vs. facility-specific) determines public release.

Joint Commission
on Accreditation of Healthcare Organizations

May 28, 1999

June Gibbs Brown
Inspector General
Office of the Inspector General
5250 Wilbur J. Cohen Building
330 Independence Avenue, S.W.
Washington, DC 20201

Re: OEI-01-97-00050, OEI-01-97-00051, OEI-01-97-00052, OEI-01-97-00053

Dear Ms. Brown:

We appreciate the opportunity to provide comments on the four draft inspection reports on the *External Review of Hospital Quality* prepared by the Office of Inspector General (OIG). The Guiding Principle contained in the summary report (*A Call for Greater Accountability*) sets forth the need for a measured balance between collegial and regulatory approaches in the quality oversight system for hospitals. The Joint Commission agrees with this fundamental principle and specifically supports an appropriate mix of announced and unannounced on-site surveys; timely and effective responses to complaints and identified adverse events; the identification and application of standardized performance measures (including those related to appropriateness of care); and focused emphasis both on patient safety and quality improvement. We believe that our continuing efforts to provide a state-of-the-art accreditation process and our long-standing collaborative relationship with the Health Care Financing Administration (HCFA) demonstrate our continuing commitment to achieving these objectives. We offer the following specific comments regarding the findings and recommendations contained in the report pertaining to the OIG's assessment of the Joint Commission's current accreditation process and HCFA's role in monitoring the Joint Commission's performance under the existing hospital deeming authority.

Finding: The emerging dominance of the collegial mode may undermine the existing system of patient protection afforded by accreditation and certification practices. It contrasts significantly with the current regulatory emphasis in nursing home oversight.

We believe that the OIG's conclusion that the Joint Commission's collegial approach to the survey process "may undermine the existing system of patient protection" is unfounded and not substantiated by the evidence cited in the report. Nor are we aware of any evidence that a strict regulatory approach, which involves "immediate penalties, surprise surveys, and posting of survey results on the Internet," has had any lasting effects in improving patient safety or quality of care in hospitals, nursing homes, or other care settings. This is not to say that opportunities for improvement in the Joint Commission's accreditation process do not exist; they clearly do. Indeed, there is strong correlation between the specific findings cited in this OIG report respecting the Joint Commission's survey process and our own internal self-assessment conducted through 1997-1998, the findings of which were shared with the OIG staff. Nevertheless, we believe it important that distinctions be made among the three key conceptual frameworks at play in the quality oversight process. These are the "collegial/regulatory" continuum; the accreditation standards themselves; and the processes through which compliance with the standards is assessed.

One Renaissance Boulevard
Oakbrook Terrace, IL 60181
(630) 792-5000

Member Organizations
American College of Physicians
American College of Surgeons
American Dental Association
American Hospital Association
American Medical Association

First, we would challenge any assertion that a collegial posture is incompatible with rigorous standards compliance assessment processes. There are steps that the Joint Commission can and will take to make these assessment processes more rigorous; however, we are not persuaded that these efforts need be pursued in an adversarial context. Indeed, we would submit that the educational thrust embodied in a collegial orientation is the most critical element in achieving lasting improvement in organization performance.

Second, we would vigorously take issue with any suggestion that current Joint Commission standards themselves fall short in creating a framework for substantive patient protections and for rigorous assessment processes that support this objective. Joint Commission standards are regularly updated -- in contrast to the Medicare Conditions of Participation for Hospitals which were last updated 13 years ago -- are widely imitated both by public and private sector quality oversight bodies in this country and by other accrediting bodies around the world. We now have specific evidence that rigorous application of current Joint Commission standards -- in a context modeled after anticipated future changes in our assessment processes -- yields significant findings of substantial breadth and depth that are highly relevant to patient protection. We will be prepared to share this evidence with you in the near future.

Finally, we believe the principal focus of attention -- as reflected in the OIG report -- should be on the assessment process and its results. Joint Commission Board-level Task Forces have been analyzing improvement opportunities since early 1998, and plan to begin issuing specific recommendations later this year. Some of the specific suggestions made in the OIG report -- an increase in the number of for-cause unannounced surveys and random selection of records as part of the survey process -- are already in effect. All of the remaining specific survey process suggestions in the OIG report, as well as additional issues surfaced in our own self-assessment process will be the subject of Task Force recommendations to be considered by our Board of Commissioners later this year. Earlier this Spring, we sent a letter to the HCFA Administrator detailing our plans respecting these efforts, invited the agency's comments, and requested the opportunity to work together with HCFA staff to advance these initiatives. We appreciate the OIG's encouragement that HCFA and the Joint Commission work together on these priority enhancements.

We note that the strict regulatory approach to conducting quality reviews -- taken by HCFA and the State agencies -- has at best produced mixed results. Since its inception, the Medicare program has terminated very few hospitals for reasons of substandard quality of care. Further, as the OIG report notes, hospitals with standard or Conditions of Participation level deficiencies can maintain their Medicare certification because they are not required by HCFA to take corrective action. While hospitals with substandard performance are threatened with termination unless compliance is achieved, there are currently no data to show that these hospitals remain in compliance once that threat is removed. Similar issues of recidivism exist with HCFA's oversight of nursing homes, as has been recently validated by several General Accounting Office reports. It seems apparent that some significant change in the HCFA regulatory approach is warranted as well.

Finding: Joint Commission surveys are unlikely to detect substandard patterns of care or individual practitioners with questionable skills.

A review of the Joint Commission's survey findings and aggregate accreditation decisions -- a process completed by the OIG during this study -- does not support this conclusion. While opportunities do exist to increase the rigor of the on-site evaluation process, over 85 percent of hospitals accredited by the Joint Commission are cited for deficiencies in their systems or processes and are closely monitored over time until the substandard patterns of performance are remedied. The Joint Commission requires specific corrective

June Gibbs Brown
May 28, 1999
Page 3

actions and may conduct focused on-site surveys to verify the hospital implementation of appropriate corrective actions. We would finally note that the identification of individual practitioners responsible for poor care through restrospective case review is not part of either the federal certification process or the private sector accreditation processes, but rather is assigned to other entities under the Medicare statutes.

Finding: The Joint Commission devotes little emphasis to complaints...and treats major adverse events as opportunities for improvement.

We take substantial issue with this assertion. The Joint Commission has a comprehensive process that proactively encourages, facilitates, and responds to the reporting of quality concerns and complaints about accredited hospitals. This process specifically includes a toll free telephone number (1-800-994-6610), descriptive information and guidance on our Web site regarding the complaint intake and response process, provision for interviews by the surveyors with any interested or concerned parties as part of the on-site evaluation process, and dissemination of various written materials regarding the Joint Commission's management of and response to complaints. During 1998, we reviewed over 3,100 complaints and pursued the validation of the most serious of these complaints through on-site, special surveys of the affected hospitals. Other, less serious complaints are either investigated during the hospital's next scheduled survey or are entered into our Quality Monitoring database for monitoring. Our Board of Commissioners and staff take this responsibility very seriously and routinely review the trends in the complaints that have been reviewed and processed. We also provide complaintants with a summary of our findings and/or actions following our review of a complaint. We certainly agree that improvements can be made and are currently using the GAO's (William Scanlon's testimony of March 22, 1999 before the Senate Special Committee on Aging) recent report critical of the federal process of responding to complaints about nursing homes as guidance in improving our own processes.

We would further challenge the assertion made (at p. 27 in *Role in Accreditation*) that "responses to ...serious incidents...play relatively minor roles in the Joint Commission's accreditation process." As acknowledged elsewhere in the OIG report, the Joint Commission's Sentinel Event Policy, which explicitly requires accredited organizations to demonstrate satisfactory analysis and resolution of major adverse events has no counterpart requirement in the federal regulatory process of which we are aware. Early this year, the Joint Commission introduced new standards for all accredited organizations that require them to establish mechanisms for identifying, reporting, analyzing and preventing sentinel events.

Finding: HCFA obtains limited information on the performance of the Joint Commission or the States.

The OIG is also critical of HCFA's monitoring of Joint Commission performance under the existing hospital deeming authority, and recommends that a more effective and comprehensive process be considered. The Joint Commission believes that the public is best served through the administration of a vital and active public-private sector partnership between the Joint Commission and HCFA that is based on the coordination of complaint monitoring activities, the exchange and comparative evaluation of hospital performance information, and the collaborative review of hospitals performing at a substandard level. The effectiveness of the HCFA - Joint Commission partnership is dependent on the sincere commitment of both entities to an effective and positive working relationship. The Joint Commission would welcome HCFA's interest and collaboration to this end.

The report further states that HCFA can better perform its oversight responsibilities by requesting more information, for example, more timely and useful performance reports from the Joint Commission and the State agencies. We concur with this recommendation. On a number of occasions, HCFA and the Joint

June Gibbs Brown
May 28, 1999
Page 4

Commission have met to evaluate the quality and frequency with which relevant information is exchanged. It is clear that more can be done in this area, and we appreciate the OIG's suggestion that HCFA work with us to develop a set of specifications for what the Joint Commission should routinely report to HCFA in the future. We also concur with the OIG's recommendation that there should be more federal feedback to the Joint Commission respecting its performance and that this feedback should be timely. Absent such feedback, it becomes very difficult for the Joint Commission to assess how well it is meeting its public accountabilities.

Conclusion

We are pleased that the OIG finds significant value in the Joint Commission's accreditation process for hospitals and that the report recommends an enhanced level of collaboration between the Joint Commission and HCFA to achieve improvements in the system of hospital quality oversight. The Joint Commission is particularly eager to work with HCFA to develop a more effective methodology for immediate oversight of the Joint Commission's performance in the hospital quality oversight process. We are also hopeful that HCFA will be motivated by your recommendation to work with the Joint Commission to develop and implement an observation survey process to replace the ineffective validation survey process currently employed. We worked collaboratively with HCFA over a two-year period ending in 1997 to develop such a process, but the results of the pilot study were never shared with the Joint Commission and changes were never implemented by HCFA.

We appreciate the opportunity to comment on the draft report on *External Review of Hospital Quality*, and look forward to a positive working relationship with HCFA as it considers responses to the report's recommendations.

Sincerely,

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

f:\shared\govern\oig.lwp

APPENDIX E

Association of Health Facility Survey Agencies Response to OIG Report

June 1999

The mission and purpose of the Association of Health Facility Survey Agencies (AHFSA) is to strengthen the role of its member state agencies in advocating, establishing, overseeing and coordinating health care quality standards that will assure the highest practicable quality of health care for all state and federally-regulated health care providers. In addition to other functions, AHFSA offers advice and recommendations to the Health Care Financing Administration (HCFA). The comments AHFSA offers below concerning the Department of Health and Human Services Office of Inspector General (OIG) report entitled "The External Review of Hospital Quality" are intended to improve the effectiveness of oversight and regulation of our nation's hospitals.

In reviewing the report, our association is in agreement with the OIG's assessment of the current system of hospital regulation and oversight provided by HCFA, state regulatory agencies and the Joint Commission on the Accreditation of Healthcare Organizations (Joint Commission). There are both positive and negative components to the processes of accreditation and Medicare certification that can be developed and strengthened with HCFA's guidance and direction.

In the report, the OIG mentions that HCFA's validation survey process is ineffective in monitoring the Joint Commission's survey performance. The purpose of the validation survey process, as we understand it, is not to validate the Joint Commission's performance, but instead to validate that Joint Commission standards and the application of those standards and process does, in fact, assure compliance with Medicare Conditions of Participation. Therefore, it is our position that validation surveys do have a place in hospital regulatory oversight. However, in order to promote consistency in all hospital surveys (validation or standard surveys) from state to state, and thereby, ascertain whether these surveys are effective, we believe HCFA should develop and provide hospital training on a survey process for states to use as a guide when surveying hospitals. Ideally, the survey process would be similar in format to survey processes developed for other Medicare programs such as long term care. Additionally, whereas at present, HCFA often may not require a hospital to submit a plan of correction and receive follow-up visits as a result of validation survey results, we believe the process would be more efficacious if all hospitals with deficiencies from validation surveys be required to submit plans of corrections and receive follow-up visits.

The OIG notes the recently piloted Observation survey process whereby state agencies accompany Joint Commission surveyors during accreditation surveys as one solution in monitoring Joint Commission's survey performance. However, an AHFSA member from a state who participated in the Observation survey process did not feel it was effective in assuring minimum standards of care were met, but only determined whether the entity conducting the survey did, or did not, follow

their prescribed survey process. Therefore, we have reservations as to the effectiveness of the Observation survey with regards to improving patient care and outcomes.

Concerning the issue of inspections of non-accredited hospitals, AHFSA takes the position these facilities should be surveyed at least every three (3) years and that a portion of the surveys should be unannounced. This survey cycle would be consistent with the minimum survey cycle offered by the Joint Commission. Additionally, as HCFA has clearly demonstrated its priority and commitment in monitoring the quality of care provided to residents in long term care facilities, it should also do the same for patients receiving care in hospitals by providing the necessary funding to state agencies needed to accomplish the regulatory oversight of hospitals.

The OIG report mentions that surveys conducted by the Joint Commission are structured such that there is little time for investigation of complaints. To identify possible substandard care in hospitals during accreditation surveys, we believe it is essential the Joint Commission place more time and emphasis on conducting complaint investigations. This includes communicating with state agencies prior to accreditation surveys in order to gather information about the hospital's compliance/complaint history. The Joint Commission should consider random selection of medical records for review, including those patients in the hospital at the time of the survey and those who have been discharged. Additionally, we believe the Joint Commission should conduct more unannounced accreditation surveys in order to obtain a more realistic picture of the care being provided by hospitals.

Concerning the measure of quality care provided by hospitals, we believe potential patients and their families would best be served by on-line computer viewing such as a website of survey results from Joint Commission surveys and, where applicable, state agency surveys. We believe such a website should go beyond a survey score or level of accreditation, but should include more in-depth information such as areas noted to be out of compliance with standards or regulations identified by Joint Commission or state agency surveyors during hospital inspections, including those inspections based on complaint allegations.

In conclusion, we believe it is essential for state agencies, HCFA and the Joint Commission to work collaboratively in the regulatory oversight of our nation's hospitals. Only through such collaboration can we begin to make strides in assuring quality health care is provided by hospitals and the health care interests of the public are protected.

DIVISION OF HEALTHCARE FACILITIES ACCREDITATION

HFAP Healthcare Facilities Accreditation Program

American Osteopathic Association

ACCREDITING HEALTHCARE FACILITIES FOR OVER 50 YEARS

142 East Ontario Street • Chicago • IL 60611-2864 • 800-621-1773 • 312-202-8000 • FAX 312-202-8206

June 30, 1999

June Gibbs Brown
Inspector General
Office of Inspector General
Department of Health and Human Services
330 Independence Avenue S. W.
Room 5246
Washington, D.C. 20201

RE: **The External Review of Hospital Quality: OEI-01-97-00050 through OEI-01-97-00053**

Dear Inspector General Brown:

BACKGROUND

As President of the American Osteopathic Association (AOA), I appreciate the opportunity to respond to the OIG's four reports on, "The External Review of Hospital Quality - A Call for Greater Accountability" 00050, " - The Role of Accreditation" 00051, - The Role of Medicare Certification" 00052, and - Holding the Reviewers Accountable 00053.

The AOA is the official osteopathic accreditation organization for osteopathic physicians, osteopathic colleges of medicine and osteopathic hospitals. The AOA's Accreditation Requirements for Healthcare Facilities presently conforms to existing Federal and State requirements regarding Hospital Conditions of Participation.

OVERVIEW

AOA applauds the four reports, which as a whole, focus on the roles played by the Joint Commission and the State agencies in reviewing hospitals and by HCFA in overseeing these bodies. As your cover letter indicates, while there are clear strengths in this system, there are also major deficiencies that call for attention.

We appreciated the opportunity afforded the AOA to participate in the initial development of the study and to be able to review and comment on the reports. The AOA recognizes that the study focuses on the Joint Commission as the largest accreditation organization (AO) but we believe that the findings provide valuable insight for all voluntary AO's, whether they already have or are seeking deeming authority from HCFA. In this sense the Joint Commission serves as a surrogate for all AO's. This material is especially

HTTP://WWW.AOA-NET.ORG

valuable as HCFA is currently in the process of reviewing applications for renewal of deeming authority from a variety of AO's. Because the AOA is an accreditation organization we will focus our comments on that portion of the OIG findings applicable to accreditation organizations.

The OIG reports mention the special deeming authority of the Joint Commission. In the last several years HCFA has "opened the door" to additional accreditation organizations applying for deeming authority. Additional entrants into the accreditation marketplace will tend to create competition and may also contribute to the oversight of healthcare facilities through innovations that smaller organizations are often able to achieve. In order to realize these potential benefits it will be important for HCFA to try to provide a level playing field for all AO's. AOA believes that the standardization of application for renewal of deeming authority under 42 CFR Part 488 is a good beginning.

FINDINGS

Selection of Medical Records for Review

- Finding: Rather than selecting a random sample, the Joint Commission surveyors tend to rely on hospital staff to choose the medical records for review. Further, the surveyors typically begin the survey process with little background information on any special problems or challenges facing a hospital.

AOA agrees that the surveyors and not the hospital staff should select hospital medical records for review. Selection of medical records by the survey team is a routine component of HFAP surveys.

HFAP surveyors are provided with background on the services offered, the results of the last full survey and background and results of any Focused Survey since that full survey, any complaints received regarding the hospital and response for the facility or accreditation actions taken, and finally media articles if available. AOA suggests that consideration be given to allowing AO's access to the State's historical files of compliance and complaints for hospitals as an additional source of background information.

Collegial versus Regulatory Modes of Survey

- Finding: Overall, the hospital review system is moving toward a collegial mode of oversight and away from a regulatory mode. It emphasizes a trusting approach to oversight, rooted in professional accountability and cooperative relationships. This approach is common for accreditation organizations.

  A regulatory mode focuses on investigation and enforcement of minimum requirements. It involves a more challenging approach to oversight, grounded in public accountability. State agencies are rooted in a more regulatory approach to oversight. HCFA, through the proposed Medicare conditions of participation, is looking for them to move towards the collegial approach.

AOA agrees that both collegial and regulatory modes of survey provide value to hospital oversight. The AOA program called the Healthcare Facilities Accreditation Program (HFAP), like the Joint Commission is geared to be collegial and educational in nature. In an effort to improve the quality of the program, HFAP materials have been completely redeveloped to assure coverage of the Medicare Conditions of Participation (CoPs). In addition, HFAP survey protocols allow time for extensive follow-up on incidents or quality concerns developed during the survey.

Observation Surveys and Feedback

- Finding: To assess the Joint Commission's performance, HCFA relies mainly on validation surveys conducted, at HCFA's expense, by the State agencies. But for a number of reasons the value of these

surveys has been limited. During 1996 and 97, HCFA piloted observation surveys during which State and HCFA officials accompanied Joint Commission surveyors. This approach appears to have much promise, but HCFA has not yet issued any evaluation of the pilots.

The AOA agrees there should be a shift from validation surveys to observation surveys. The observation survey approach was developed in a cooperative effort, called the Reinvention of the Validation Survey Program, by staff from the HCFA central office, HCFA regional offices, State agencies, the Joint Commission, the AOA, and the American Hospital Association. We concur that the approach should have much promise. It will be important to assure that the "feedback loop" originally designed into the program is used. This feedback loop was intended to assure that the AO's get information about observations by HCFA observers that can be used over time as a quality monitoring and improvement system.

OIG RECOMMENDATIONS

Guiding Principle: The HCFA, as a guiding principle, should steer external review of hospital quality so that they ensure a balance between collegial surveys (a trait of Joint Commission and AOA surveys) and regulatory modes of oversight (a trait of State agency surveys).

- Finding: OIG recommends that HCFA recognize that both the collegial and regulatory approach have value and that a credible system of oversight must reflect a reasonable balance between them. OIG suggests a balanced system would involve the continued presence of 1) on-site hospital surveys, both announced and unannounced; 2) an ongoing capacity to respond quickly and effectively to complaints and adverse events; 3) further development and application of standardized performance measures; and 4) a mechanism for conducting retrospective reviews of the appropriateness of hospital care.

The AOA agrees with the recommendations presented by the study, especially with the recognition that adjustments can be made over time, holding the Joint Commission and State agencies more accountable for their performance. Again, we recognize that the Joint Commission serves as a surrogate for all AO's.

Recommendation 1: The HCFA should hold the Joint Commission and State agencies more fully accountable for their performance in reviewing hospitals.

- Revamp Federal approaches for obtaining information on Joint Commission and State agency performance by de-emphasizing validation surveys, giving serious consideration to the potential of observation surveys, and calling for more timely and useful reporting of performance data.

As indicated above, the AOA supports the use of validation surveys. AOA also supports more timely and useful reporting of performance data, as recommended in the OIG report. This concern is currently being addressed in the data reporting requirements by HCFA in the criteria for renewal of deeming authority. Two committees have been created comprised of staff from HCFA and several AO's (including representation from AOA) to address the issues of a data dictionary and data format.

- Strengthen Federal mechanisms for providing performance feedback and policy guidance to the Joint Commission and State agencies. HCFA should negotiate with the Joint Commission to achieve the following changes:

  1. Conduct more unannounced surveys.
  2. Make the "accreditation with commendation" category more meaningful, or do away with it altogether.
  3. Introduce more random selection of records as part of the survey process.

External Review of Hospital Quality OEI-01-97-00050 through OEI-01-97-00053

4. Provide surveyors with more contextual information about the hospitals they are about to survey.
5. Jointly determine some year-to-year survey priorities, with an initial priority on examining credentials and privileges.
6. Conduct more rigorous assessments of hospital's internal continuous quality improvement efforts.
7. Enhance the capacity of surveyors to respond to complaints within the survey process.

AOA agrees with most of these concepts. However, we suggest that rather than a conducting more unannounced surveys, a closer review of medical care during surveys could provide better value.

- Assess periodically the justification for the Joint Commission's deemed status authority.

AOA considers this issue part of the concept of a level playing field for all accreditation organizations.

- Increase public disclosure on the performance of hospitals, the Joint Commission, and State agencies, by, at minimum, posting more detailed information on the Internet.

AOA supports this concept in general. HFAP is developing the ability to display accreditation information by facility in an HFAP website within the AOA website. We are concerned however about the scope and type of information to be displayed, its ability to reflect the overall quality of care provided at the facility, and its understandability by the general public.

The AOA appreciates the opportunity to respond and comment on this important series of reports. We look forward to working with the OIG and HCFA in the future on this and other issues of concern to the osteopathic medical profession.

Sincerely,

Ronald A. Esper, DO

Ronald A. Esper, D.O.
AOA President

cc. Members – Bureau of Healthcare Facilities Accreditation, AOA
Members – Appeal Committee, Bureau of Healthcare Facilities Accreditation, AOA
Members – Task Force on Healthcare Facilities Accreditation, AOA
Chairman, Council on Federal Health Program, AOA
President-Elect, AOA
Executive Director, AOA
Director Government Relations, AOA
Director Membership, AOA

June Gibbs Brown
Office of the Inspector General
Department of Health and Human Services
Washington, D.C. 20201

June 4, 1999

Dear Ms. Gibbs Brown:

The American Hospital Association (AHA) representing nearly 5,000 hospitals, health systems and other providers appreciates the opportunity to respond to your reports on hospital oversight. These reports provide a good overview of current hospital oversight. While we disagree with some of the underlying assumptions and conclusions in the report, we do support several of the recommendations.

Overall Concern

The report is based on the concept of two separate and distinct methods for accountability, labeled in your report as "collegial" and "regulatory." You imply that emphasis on one detracts from the other and that because the collegial approach is not achieving certain results, oversight entities should re-emphasize a "regulatory" approach.

The AHA disagrees with this distinction. The term "collegial" should not exclude regulators. Regulators use both approaches. In order to recognize the validity of a regulator using a non-punitive approach a more appropriate label might be "punitive" and "non-punitive."

When a regulator determines how to best use these approaches, the calculation is not how far to go one way or the other, but how to establish a system where the two approaches best complement each other. The goal is to ensure a safe environment for patients that permits ongoing improvement in performance of patient care. HCFA balances these two approaches on a daily basis within their Peer Review Organizations (PROs) and between the PRO program, JCAHO surveys and their contracted state surveyors.

These reports note that in recent years oversight organizations have begun utilizing non-punitive approaches. This is because the measurement and accreditation field has made tremendous strides in developing tools, both standards and measurement instruments,

AHA 100 YEARS

Washington, DC Center for Government and Public Affairs
Chicago, Illinois Center for Health Care Leadership

Liberty Place, Suite 700
325 Seventh Street, N.W.
Washington, DC 20004-2802
(202) 638-1100

providers and health systems can use to assess and improve performance. The philosophy underlying this movement is that while weeding out the poor performers results in individual practitioner change, focusing on system changes provides an opportunity to achieve higher safety and quality care for a much broader population.

The development and application of these new tools have not, as the report seems to imply, replaced a more punitive approach to oversight. As noted previously both are currently utilized.

The report concludes that because the non-punitive approach does not achieve certain results, the oversight pendulum must swing back towards the punitive mode. It is unclear why this is the conclusion. We find no evidence or discussion of whether the problems identified in the report, for example, the lack of ability to detect substandard patterns of care or individual practitioners with questionable skills, have grown worse as oversight organizations have emphasized a non-punitive approach. Additionally, there is very little discussion of why increasing punitive efforts will be more effective.

Much of the criticism is aimed at the JCAHO and is based on goals that accreditation were never intended to meet. For example, the report criticizes the JCAHO process for not assessing the appropriateness of care and not identifying poor performing practitioners. While a critical goal, the primary function of accreditation is to reduce risk by ensuring that certain structures and processes are present and functioning according to their intended activity. Accreditation ensures that the organization has appropriate mechanisms in place to address appropriateness of care.

AHA agrees these issues must be addressed, but the solution is not to de-emphasize quality improvement and re-emphasize a punitive approach. To do so could hinder quality improvement efforts without any guarantee that a more punitive approach would improve the situation.

Disclosure of Information

The report criticizes hospitals and JCAHO for resistance to information disclosure, but does not provide a full discussion of this issue. The AHA believes that the public, patients and purchasers do need more information in order to facilitate their decision-making. They need information at many different decision points -- when choosing a plan, a provider, and making treatment decisions. However, the information has to be useful for its intended purpose and the disclosure of the information should be done in a manner that supports internal quality improvement.

June Gibbs Brown
Page 3
June 4, 1999

Hospitals are often reluctant to increased disclosure because of liability concerns, questions regarding the utility of the information and a fear that release might hinder internal openness to discussing errors and mistakes.

Hospitals, physicians and other caregivers must be able to participate in frank, open discussions about errors and mistakes in a non-punitive environment. This is an integral part the process of learning from errors and improving the quality of health care delivery in hospitals.

Unfortunately, under current laws, regulations and case law, public disclosure of this information can result in extraordinary liability for the participants and the institution. Requiring disclosure would have an immediate chilling effect on sharing of information critical to quality improvement efforts.

AHA continues to support federal legislation that would foster the sharing of information to improve the quality of care without fear of liability. However, until we are assured that disclosure of this information will not be subject to discovery, admissibility or disclosure, we are unable to support external disclosure.

In addition to the liability and quality concerns hospitals are also reluctant to disclose information because it is unclear whether that information will be useful to patients or accurately reflect the performance of the institution. It is very difficult to find measures that are useful and reliable across institutions. For example, a C-section rate would not be useful as a measure for a hospital that performed few births. Hospitals also question what C-section rates might say about a hospital. Could a consumer use this information to determine which hospital to use? They would have to know about the population the hospital served to determine whether a high or low rate was more appropriate.

Lack of Public Resources

The report does not address one critical factor in determining the effectiveness of HCFA's survey and certification process. The state surveyors and HCFA are criticized for not surveying non-accredited hospitals often enough, and for not actively enforcing current standards. However, in the last few years, survey and certification funds have remained constant, while Congress has continued to place new demands on surveyors, particularly in the oversight of nursing homes and home health providers.

June Gibbs Brown
Page 4
June 4, 1999

Recommendations

The AHA agrees with, and would emphasize the need for, action on several recommendations, specifically:

- HCFA could provide stronger leadership to ensure a more coordinated process. Our members often express dismay that the JCAHO and HCFA do not seem to communicate about timing of surveys, interpretation of standards, etc.

- HCFA should develop a more formal oversight process to establish and maintain priorities. This should not be done without input from many parties, but they need to take the lead. This should include working with JCAHO to establish priorities for, and updating their standards.

- HCFA needs to create a more dynamic process to ensure that their standards do not lose relevance. In particular, they need to create a process to update the conditions of participation on a more regular basis. For example, they are still requiring an outmoded Life Safety Code of 1985, even though the field has moved, including JCAHO, to the current state of the art in life safety as recognized in the 1997 code.

It is critical to continually re-examine the effectiveness of regulatory and private sector oversight. We commend you for taking on the task. However, we are concerned that the conclusions in your report were often based on misperceptions and an incomplete analysis of the causes of some of the weaknesses in the current system. We hope our comments have been useful in clarifying some of those misperceptions.

Sincerely,

Mary R. Grealy,
Chief Washington Counsel

AARP

July 8, 1999

The Honorable June Gibbs Brown
Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, N.W.
Washington, D.C. 20201

Dear Ms. Brown:

AARP is pleased to have this opportunity to comment on the Office of Inspector General draft reports on "The External Review of Hospital Quality."

Quality of health care is a significant consumer concern. Although much of the attention lately has been focused on quality and patient protection in managed health care plans, assuring quality in hospitals remains a key component in the quality of care any system is able to deliver. The hospital remains the most visible location of health care. It is where we receive our most acute, urgent, life-saving services. Currently, the federal government oversees the quality of every hospital that treats Medicare patients through one of two processes, *accreditation* or *certification*.

Under accreditation the hospital must meet standards established by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), a private, voluntary accreditation organization. If successful, the hospital is then deemed to be in compliance with Medicare's Conditions of Participation.

Certification occurs through review by a state agency that is charged with reviewing hospital quality. Hospitals that choose not to seek JCAHO accreditation must be state certified in order to treat Medicare patients. Approximately twenty percent (20%) of hospitals choose certification rather than accreditation.

The four draft OIG reports constitute a valuable contribution to an understanding of the current roles of accreditation and certification in the effort to assure quality of care in hospitals. Among the especially impressive elements of the reports are:

- The comprehensive research methodology that included surveys, interviews, site visits, document review and legal analysis.
- Inclusion of detailed statistical information concerning the recent experience with accreditation and certification.
- The well thought out charts and matrices that facilitate the reader's understanding of the issues and findings addressed by the reports.

601 E Street, NW Washington, DC 20049 (202) 434-2277 www.aarp.org
Joseph S. Perkins *President* Horace B. Deets *Executive Director*

- The discussion about HCFA's recent interaction with JCAHO and state agencies in light of HCFA's mandated oversight responsibilities.

- A careful assessment of the movement towards a quality improvement model of external oversight. While raising some significant concerns about the current state of quality monitoring, the reports, nevertheless, acknowledge the benefits of a continuous quality improvement (CQI) approach.

OIG's data and analysis validates some strengths of the current accreditation and certification processes. However, the reports also document a number of disturbing deficiencies. The summary of strengths and weaknesses on pages 12-19 of the concluding draft study underscores the need for a serious effort to improve the processes of accreditation and certification so that they serve as reliable, effective patient protections.

AARP agrees with the thrust of the recommendations OIG proposes to address the documented weaknesses. In particular, we support the call for greater accountability for quality oversight through:

- routine collection and strengthened reporting of JCAHO and state agency performance data.

- determination of an appropriate minimum cycle for states to conduct certification surveys of nonaccredited hospitals.

- JCAHO site visit designs that provide for unannounced surveys, more random selection of records for review, significantly more specific hospital contextual information for surveyors, and enhanced surveyor capacity to respond to complaints.

- substantially increased HCFA feedback to JCAHO and state agencies based on HCFA monitoring activities, feedback that OIG finds is now virtually nonexistent.

With respect to the critical element of HCFA monitoring, OIG makes a strong case for greater reliance on "observation surveys" as a means of HCFA overseeing the accreditation process. Whether this should entail, as OIG suggests, a phasing out of HCFA validation surveys is a matter for further careful evaluation. However, the report's finding that HCFA has failed to issue its own evaluation of a pilot project involving observation surveys is distressing; AARP echoes OIG's call for the assessment to be completed.

The Honorable June Gibbs Brown
July 8,1999
Page 3

As indicated, one of the report's major contributions lies in its examination of the emerging emphasis, in both the accreditation and certification processes, on quality improvement approaches vis-a-vis the older inspection model. OIG urges HCFA to steer a balanced course, adopting some of the Joint Commission's collegial approach and some of the State survey agencies' regulatory approach. For example, the report suggests,

> "as HCFA incorporates, through its proposed (hospital) conditions (of participation), certain aspects of the Joint Commission's approach to oversight, it should maintain the primacy of the State agencies' role as front-line responders to complaints and adverse events, and all that that role entails, such as probing and challenging approaches to surveys. Furthermore, it would make sense for HCFA to support the Joint Commission's sentinel event policy, which treats adverse events confidentially and as opportunities for improvement, as long as the State agencies still responded to such events in a way that held hospitals publicly accountable."

This OIG review and assessment of the current state of hospital oversight merits serious follow-up consideration. AARP believes HCFA should take action to develop a workable strategy for addressing the deficiencies OIG has documented.

AARP would be pleased to participate with other interested parties in such an endeavor. If you have any questions about our comments please contact Cheryl Matheis of our Federal Affairs staff at (202) 434-3770.

Sincerely,

John Rother

John Rother
Director
Legislation and Public Policy

May 31, 1999

Ms. June Gibbs Brown
Inspector General
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Ms. Gibbs Brown:

The Service Employees International Union appreciates this opportunity to comment on the Office of Inspector General's four reports on the external review of hospital quality. Healthcare quality is a critical issue for SEIU's 1.3 million members, half of whom work in healthcare settings.

The IG did an excellent job of documenting the failures of the existing, JCAHO-dominated accreditation system, highlighting the serious lack of accountability in the review of hospital performance, and demonstrating the need for improvement in quality oversight of nonaccredited hospitals.

We strongly endorse most of the IG's specific recommendations, but believe even stronger action is needed to protect consumers against hospital errors and abuses.

SEIU's research and our own members' experience strongly and directly supports the IG's findings that JCAHO procedures, surveys and reports fail to effectively and impartially monitor hospital quality. While we commend JCAHO's recent move toward dialogue with stakeholders outside hospital management, we believe the IG's report shows that neither JCAHO's voluntary changes, nor piecemeal reforms, are sufficient to create a survey process that protects consumers from hospital quality failures.

Our specific comments follow, starting with a set of comments keyed to the IG's recommendations as they appear on pages 23-29 of the summary report, "A Call for Greater Accountability," OEI-01-97-00050. We recognize that some of our recommendations, particularly those relating to public disclosure, may require legislative action. In addition, we have made separate recommendations, based principally on the IG's findings, for action by Congress and by state-level hospital regulators.

Recommendation 1a.

We agree that validation surveys as currently conducted do not adequately measure JCAHO's effectiveness as a deeming authority. We believe, however, that the appropriate test would be an unannounced HCFA survey – conducted in timely fashion at a large number of hospitals – specifically designed to determine what percentage of JCAHO-accredited hospitals fully satisfy Medicare Conditions of

ANDREW L. STERN
International President

BETTY BEDNARCZYK
International Secretary-Treasurer

ANNA BURGER
Executive Vice President

PATRICIA ANN FORD
Executive Vice President

ELISEO MEDINA
Executive Vice President

PAUL POLICICCHIO
Executive Vice President

SERVICE EMPLOYEES
INTERNATIONAL UNION
AFL-CIO, CLC

1313 L Street, N.W.
Washington, D.C. 20005
202.898.3200
TDD: 202.898.3481
www.seiu.org

Participation. This is essential both because JCAHO standards do not parallel Medicare Conditions of Participation and because the pre-announced JCAHO survey gives hospitals ample time to temporarily conceal violations.

We are inclined to oppose the use of the "observation survey" as the major tool for oversight of JCAHO, because observing a survey which follows the JCAHO format cannot tell HCFA whether or not JCAHO's approach accurately measures compliance with Medicare conditions of participation. If, however, HCFA is considering making the observation survey a major oversight tool, we recommend that results of the 1996 and 1997 test surveys be made available for stakeholder comment.

We agree that HCFA must provide timely feedback to JCAHO and the State agencies, and that the feedback recipients should be required to state how they "will respond and correct the situation identified by HCFA." We further recommend that there be specified timelines for correction.

Given the array of data collected by JCAHO but not reported to HCFA, we agree that HCFA should obtain more information, on a frequent and regular basis. We endorse disclosure of information from on-site surveys, survey results, complaints, adverse events and performance.

Recommendation 1b.

We concur with the changes recommended in JCAHO practices, but would strengthen certain specific recommendations for change as follows:

1. *All accreditation surveys for the purpose of deeming should be unannounced.*. (At present, hospitals actually receive 24-48 hours advance notice of certain types of "unannounced" survey.)
   We further recommend that certain triggering events should make an unannounced survey mandatory. These might include: (a) a "sentinel event" associated with the death of a patient; (b) a specified number of non-fatal "sentinel events" during a specified time period; (c) the presentation to JCAHO or HCFA of strong evidence that the facility falsified information presented to surveyors in its most recent triennial accreditation survey or (d) the receipt by JCAHO or HCFA of strong evidence of an apparent violation of Medicare Conditions of Participation (COP).
2. *All (at least most) records examined by surveyors on the triennial and other surveys should be randomly selected, by the surveyors themselves.*
3. *All health care workers and patients interviewed by surveyors on the triennal and other surveys should be randomly selected by the surveyors themselves.*
4. *To obtain "contextual information" from a source independent of hospital management, surveyors should be required to meet with any independent organizations of caregivers (such as nursing association chapters or nurses' or other healthcare workers' unions) if they exist in the hospital.* Surveyors should devote no less time to such meetings than they currently devote to meetings with hospital administration.
5. *To encourage well-documented complaints from knowledgeable persons, surveyors should be required to respond in writing to any complaint that*

identifies one or more specific violations of JCAHO standards or Medicare Conditions of Participation. If requested by the complainants, JCAHO should agree to meet with them confidentially off-site as part of any triennial or other survey.

With regard to all the "performance feedback" issues raised in 1b., we share the IG's concern (as stated in the report "Holding the Reviewers Accountable") that HCFA's participation in two JCAHO committees[1] creates a conflict of interest between HCFA's regulatory role and the JCAHO expectation that committee participation "serve as [an] external advocate for the accreditation program." *We therefore recommend that HCFA remove itself from these committees and instead adopt an external regulatory posture toward JCAHO.*

Recommendation 1c. *We concur with the recommendation that HCFA "assess periodically the justification for the Joint Commission's deemed status authority" but would add that the IG's findings, together with research done by Public Citizen and by the New York City Public Advocate already constitute strong evidence that this status is unjustified absent major reforms at JCAHO. In our view, these and other reports documenting JCAHO's failure to protect consumers against dangerously substandard quality of care effectively shift the burden of proof to JCAHO..*

Recommendation 1d. *We would strengthen the recommendation to "increase public disclosure" to propose that, with regard to any hospital deemed to have met Medicare Conditions of Participation based on a JCAHO survey:*

JCAHO and/or HCFA publicly disclose on their respective web sites the full Official Accreditation Decision Report.[2]

JCAHO publicly disclose on its web site the full results of any survey or investigation it undertakes based wholly or partly on a complaint from one or more members of the public, as well as the results of its unannounced and for-cause surveys.

JCAHO provide HCFA, State health agencies, and any independent organization of caregivers in accredited hospitals all the information it provides hospital administration regarding survey findings and recommended changes to hospital policies and procedures.

JCAHO provide data fully comparable to the OSCAR data collected by State agencies from nonaccredited hospitals.

HCFA make *the OSCAR data currently collected from nonaccredited hospitals available on the Internet, as is currently done for nursing homes.*

---

1 The Professional and Technical Advisory Committee for hospital standards and the Council on Performance Measurement

2 JCAHO -- which currently makes the *Official Accreditation Decision Report* available to hospital administration, state officials and federal officials but not to consumers or caregivers -- has advanced various arguments asserting that full public disclosure would have an adverse impact on the accreditation process. However, health authorities in at least one state, New York, already release *Official Accreditation Decision Reports* for that State's hospitals to any member of the public when requested under FOIA. New York's practice has had a positive impact on public access to information and no identifiable negative impacts.

Recommendation 2. *We concur with Recommendation 2 regarding the need for more regular scheduling of State certification surveys of nonaccredited hospitals.* As the report notes, there is no clear evidence "to support a contention that hospitals are safer places than nursing homes." We therefore further recommend that the minimum cycle should be the same as that mandated for nursing home surveys: 9-15 months.

Conclusion regarding IG's recommendations to HCFA: Except as noted above, we generally concur with the major recommendations to HCFA. However, we see a need for clarification of the "guiding principle" enunciated on page 4 of the summary IG's report. Specifically, we believe it essential that HCFA and the state health agencies perform a strong regulatory and consumer protection role. We would therefore oppose any changes in a "collegial" direction which weaken HCFA's regulatory and enforcement functions.

Our recommendation to Congress

The IG's recommendations principally address administrative actions that HCFA has the authority to take under existing law. As the reports explicitly state, the IG did not attempt to make any recommendations on the underlying crucial accreditation question: Congress's delegation of Medicare deeming authority to JCAHO.

In our view, the information contained in the IG's report is sufficient to provide a basis for Congressional action. Specifically, we recommend that, *if Congress chooses to continue JCAHO's deeming role despite the many problems identified by the IG's report and other independent investigations, it make such continuation contingent upon the following fundamental changes in JCAHO's policies and practices.*

Alter JCAHO's governing body so that a majority of members represent government agencies, consumer organizations independent of the industry and bona fide membership organizations representing non-management health care workers.

Make all JCAHO surveys used for deeming purposes entirely unannounced, on an unpredictable schedule similar to that currently used for nursing home surveys.

Make the full results of JCAHO surveys used for deeming freely available to the public.

Include, in surveys and survey reports used for deeming, coverage similar in scope to that of state-conducted nursing home surveys, with a comparable level of publicly released detail.

Require JCAHO surveyors to devote a substantial part of their survey time to meetings with knowledgeable hospital employees and consumers under conditions – including full confidentiality where appropriate – that will make them feel comfortable providing complete and accurate reports on accreditation-related issues. The best model is the OSHA inspection process, where both union and management representatives are simultaneously notified and have equal access to surveyors.

Provide employees and consumers who report violations of JCAHO standards or Medicare Conditions of Participation appropriate "whistleblower protection" and require that reprisals against such persons be severely sanctioned with penalties ranging up to denial of accreditation.

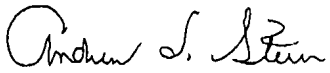
As the IG's report notes, the Medicare program effectively pays for JCAHO surveys – because it reimburses hospitals for much of the cost – and a government "takeover" of the accreditation process would thus not impose major new net costs on the government. Nonetheless, specific steps to create an appropriate funding mechanism must be taken if JCAHO deeming is ended and HCFA and/or state health agencies are to take over the accreditation role. We would support a imposition of a JCAHO-like fee on hospitals to cover part of all of the cost of government-conducted surveys.

Our recommendation to state health departments

In addition to providing valuable information for its intended audience of federal health policymakers, the IG's reports also raise questions which should be addressed by state health officials in those states which use JCAHO accreditation to deem hospitals to have met state licensure requirements. We recommend that such States critically examine and evaluate JCAHO's performance in monitoring the delivery of quality of care. In addition to the IG's report, they should examine the New York Public Advocate's study cited above and a report by the Pennsylvania Auditor General which showed that Pennsylvania has eighty-five licensure requirements not covered by JCAHO standards[3]. We recommend that any state which finds that JCAHO surveys don't fully address its specific licensure requirements consider ending the use of JCAHO for state-level deeming.

On behalf of the members of SEIU, I would like to thank you and your staff for your excellent work on this most important issue of health care quality, and for the privilege of submitting comments on them. We look forward to your feedback and the release of the reports.

Sincerely,



Andrew L Stern
International President

[3] Mark Green, Public Advocate for the City of New York, *False Fronts: The Failure of "Privatized" Hospital Inspections in New York,"* January, 1998. Pennsylavnia Department of the Auditor General, *Quality of Care in Hospitals May Be Threatened by Ridge Adminstration's Lax Oversight, July 16, 1998.*

APPENDIX E

National Health Law Program, Inc.

MAIN OFFICE
2639 South La Cienega Boulevard
Los Angeles, California 90034
(310) 204-6010
Fax #: (310) 204-0891

BRANCH OFFICES
1101 14th Street, N.W. Suite 400
Washington, D.C. 20005
(202) 289-7661
Fax#: (202) 289-7724

211 N. Columbia St. 2nd Floor
Chapel Hill, N.C. 27514
(919) 968-6308
Fax#: (919) 968-8855

May 30, 1999

June Gibbs Brown
Inspector General
Department of Health and Human Services
Washington, DC. 20201

Re: Comments Draft Inspection Reports on External Review of Hospital Quality

Dear Ms. Gibbs:

Thank you for the opportunity to review and comment upon the four draft inspection reports on the external review of hospital quality. As an organization that works to promote accountability in the health care system, we want to commend you for your efforts and those of your staff. The reports identify many of the same, serious shortcomings that previously have been identified by consumer organizations regarding hospital oversight.

Through legislation, the Joint Commission on Accreditation of Healthcare Organizations has been vested with authority to serve as the gatekeeper for hospitals that want to participate in the Medicare program. Through the accreditation process, JCAHO effectively has a non-exclusive license to control whether federal funds flow into our hospitals. Yet, as your report makes clear, they do so with little or no accountability. Through advertising campaigns and carefully worded marketing slogans, examples of which are noted in Appendix D of *The Role of Accreditation*, consumers have been led to believe that JCAHO accreditation provides a meaningful and *independent* appraisal of a hospital's safety record. Yet, as your report notes, the JCAHO's survey process is replete with shortcomings and is not designed to identify questionable care practices, let alone tell consumers about them when, and if, they are found.

Given the reports' findings, we are concerned that the reports' recommendations are not strong enough or specific enough to result in meaningful reforms. Our specific comments are noted below:

1. Although the reports note that JCAHO is primarily responsive to the interests of entities it accredits (*A Call for Greater Accountability*, p. 22), the report does not fully explore the relationship of JCAHO to its "customers" and to those who sit on its board. Few consumers

http://www.healthlaw.org

understand this relationship, and many are shocked to learned that hospitals and other health care facilities pay large fees to JCAHO for accreditation services. The inherent conflict of interests that flow from this relationship need to be addressed through specific actions:

a. The JCAHO and accredited health care entities should be required to disclose the fact that the hospital (or other health care facility or network) paid JCAHO for accreditation services. Disclosure should be required in all printed materials and any other mediums used to market hospital services to the public.

b. JCAHO should be prohibited from using the word "independent" to describe it's relationship to the facilities it accredits.

c. Alternatively, if HCFA is going to rely on JCAHO accreditation, then HCFA should contract with JCAHO for these services, not individual hospitals and health care entities.

2. In light of the reports' findings regarding the lack of rigor in JCAHO surveys, among others, HCFA (or the Federal Trade Commission) should review advertising claims made by hospitals and whether JCAHO advertising guidelines provide adequate safeguards against consumer fraud.

3. The report notes in several places that JCAHO conducts "unannounced" surveys on a limited basis. The report also notes that these surveys are not truly unannounced because JCAHO gives 24 to 48 hours prior notice. The report then continues to make reference to JCAHO "unannounced" surveys. These surveys are not unannounced and should not be called unannounced surveys. The continued used of JCAHO's "tag line" misleads consumers and corrupts the plain meaning of common words.

4. With respect to performance reports, the report recommends that HCFA obtain more timely and useful performance related information, both from JCAHO and State survey agencies. The report then makes suggestions about how the information should be reported. (*A Call for Greater Accountability, p.* 25). It appears that OIG only is recommending reporting aggregate data, not hospital specific data. OIG needs to recommend reporting of hospital-specific data, which is more useful and promotes greater accountability. Also, the minimum information specified in the recommendation regarding complaints is not adequate. Specifically, OIG recommends that HCFA require reporting of "the number received overall, then broken down to reflect the number received centrally and the number received on site, and finally the number resulting in recommendations for improvement." Id. Missing from the list is a requirement that HCFA collect information on the *type* of complaint, the results of the investigation and the outcome.

5. We fully support OIG's recommendations that HCFA provide increased public access to information on the performance of individual hospitals. These recommendations need to be strengthened, however. Consumers and the public should have access to JCAHO survey results (not just the grid scores), to the same degree that they have access to nursing facility survey reports.

6. We also fully support strengthening federal mechanisms for providing performance feedback to the Joint Commission and State agencies and agree will all seven specific recommendations. We are troubled by the fact that you twice have recommended that HCFA *negotiate* with JCAHO to achieve these needed reforms.

First, the use of the word "negotiate" implies that HCFA does not have sufficient authority as the oversight agency to achieve a more balanced system of oversight. The report ought to squarely address this important issue. On the one hand, the law clearly gives HCFA authority to conduct "validation surveys" and to withdraw deemed status if a facility fails to meet Medicare conditions of participation. While this has rarely happened, it is a powerful enforcement tool that could be used for leverage to foster greater accountability on the part of JCAHO. On the other hand, Congress has been extremely responsive to industry lobbying and repeatedly has evidenced a willingness to weaken HCFA's oversight of JCAHO and to reign in the Administrator's discretion when making decisions about deemed status. Thus, to the extent that HCFA's hands may be tied, the reports' recommendations should directly address Congress' role in fostering more meaningful oversight and protecting the public's health.

Second, the report fails to recognize a role for other stakeholders with an interest in hospital oversight such as other professional organizations, labor and consumers. To achieve greater accountability, and more meaningful oversight, there needs to be a strong recommendation that other interests groups participate in any negotiated policy change or rulemaking.

Again, thank you for the opportunity to review these important reports.

Sincerely,

Claudia Schlosberg

APPENDIX E

Comments by Sidney M. Wolfe, MD, Director
and Lauren Dame, JD, MPH, Consultant
Public Citizen's Health Research Group

Concerning the HHS Inspector General Reports on *The External Review of Hospital Quality*
(OEI-01-97-00050; -00051; -00052; & OEI-01-97-00053)

June 1, 1999

If you announce well in advance that you are going to do a survey, allow the hospital to hand-pick most of the medical records which are going to be reviewed, make no significant efforts to uncover systemic problems by eliciting criticism of hospital practices from employees (with anonymity guaranteed) or patients and their families, and view the hospital as your "customer" rather than an institution which must be regulated, it is not likely you will discover the serious, often life-threatening problems which exist in many hospitals. If you behave that way, you are probably called the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). In each of the following tragic examples, the hospitals were JCAHO-accredited, often with very high grades, at the time the patient was killed or injured as a result of negligence.

- In December 1994 Betsy Lehman, a 39-year-old *Boston Globe* health reporter being treated for breast cancer at the prestigious Dana-Farber Cancer Institute in Boston, died after mistakenly being given four times the recommended dose of a potent anti-cancer drug each day over a four-day period. Another patient at Dana-Farber given a similar series of overdoses suffered permanent, serious heart damage.

- At Quincy Hospital in Quincy, Mass., surgeons mistakenly removed a 76-year-old woman's healthy kidney instead of its cancerous twin. The wrong kidney had been "booked" for removal in the medical records, and the surgeons failed to check her x-rays before the operation. (May 1996)

- At Memorial Sloan-Kettering Cancer Center in New York City, a surgeon operated on the wrong side of a patient's brain after bringing the x-rays of a different patient into the operating room. (May 1995)

- At University Community Hospital in Tampa, Fla., a surgeon amputated the wrong leg from a 51-year-old diabetic patient. One month later, a 77-year-old man was killed when a respiratory technician mistakenly disconnected his respirator, and during the same period, a surgeon performed arthroscopic surgery on a female patient's wrong knee.

In Virginia, in 1996, according to the *Hartford Courant*:

Had Gloria Huntley been able to move, had she not been bound to her bed with leather straps for days on end, perhaps she would have tried to draw the attention of the inspectors who were conducting a three-day [JCAHO] tour of Central State Hospital. Had she been able to move, had she not been pinned down by the wrists and ankles, she might have held up a sign, as she had done before when a visitor came through Ward 7.... 'Pray for me. I'm dying.' But the inspection team from the nation's leading accreditation agency never noticed Gloria Huntley before leaving the Petersburg, Va. psychiatric hospital. The three inspectors from the Joint Commission on the Accreditation of Healthcare Organizations issued Central State a glowing report card--92 out of 100 points. They also bestowed the commission's highest ranking for patients rights and care when they concluded their review on June 28, 1996. The next day, Gloria Huntley died. She was 31.

At Charter Pembroke, in Massachusetts, part of the nation's largest chain of psychiatric hospitals, investigators from *60 Minutes* found the following:

> *...Charter Pembroke was being inspected by the Joint Commission on Accreditation of Healthcare Organizations, the only body in the country that accredits psychiatric hospitals. Dr. Dennis O'Leary is the Joint Commission's president.*
>
> *ED [BRADLEY]: In the last year, Charter Pembroke has had a riot, they've had a patient die in restraints, they've had a child psychiatrist convicted of molesting his patients. Charter didn't report any of this to its surveyors. How can the Joint Commission accredit a hospital that tries to keep that kind of information quiet?*
>
> *DR. O'LEARY: If this information is brought to our attention--actually I believe you have brought this to our attention--I want to assure you that we will follow through on an active evaluation.*
>
> *ED: But wait a minute. You've got--you've got a hospital where there's a riot that takes place? Where someone is killed? And where a child psychiatrist is--is convicted of molesting his patients? And you don't know anything about it?*
>
> *DR. O'LEARY: The information has to be brought to our attention. Ed, we're not there all the time, every day.*
>
> *ED: But this was in the, I mean, this isn't secret information. This was in the newspaper. It was on the Internet. People who live there know about it. How can the Joint Commission, which is responsible for accrediting this hospital, not know about it? Shouldn't you know about it?*
>
> *DR. O'LEARY: Well, I think that we should know about it.*
>
> . . . . .
>
> *In the last two and a half years, at least 32 patients have died while being restrained in facilities other than Charter.*

[Excerpts from *60 Minutes* Transcript]

It is likely that most, if not all of these hospitals were JCAHO-accredited.

These are just a few hospital "horror stories" that managed to reach the news media in the past few years. There is no reason to believe that they are isolated incidents; based on a 1990 hospital study by Harvard Medical School researchers, it is estimated that more than 1 million patients a year are injured in hospitals, and that almost one-third of these injuries are due to negligence. Of those patients who are negligently injured, an estimated 80,000 die each year. Based on another study, it is estimated that approximately 750,000 patients a year suffer an adverse drug reaction, very often preventable, while in the hospital.

In reviewing this set of Inspector General reports, it is important to keep in mind that the system for providing external review for hospitals to participate in Medicare is the *major* source of external review of hospitals in this country. Thus, it should constitute a key link in hospital safety. In light of the vital role this external review is supposed to serve, there are several very alarming findings in these reports.

The Most Alarming Findings of the Inspector General's Reports Are:

1. Joint Commission surveys are unlikely to detect patterns, systems, or incidents of substandard care.

According to the Inspector General's reports, Joint Commission's surveys, the *primary* source of external review for approximately 80 percent of the hospitals in this country, are unlikely to reveal problems "such as inappropriate surgeries, high complication rates, or poor or unexpected outcomes." The Joint Commission's approach is characterized as "educational" and "collegial," rather than regulatory, and hospitals are not only notified far in advance of survey dates, but often are allowed to select the records to be reviewed by the Joint Commission. As a result, the survey process may not reveal any problems when in fact systemic problems exist. One example noted in the Inspector General's reports included a hospital where a Joint Commission survey failed to uncover what a State agency subsequently identified as deep-rooted problems: "[I]n the Spring of 1996, the Joint Commission awarded one hospital its highest level of accreditation: accreditation with commendation. That Fall, the hospital experienced an unexpected death, triggering the State agency to investigate. In the Spring of 1997, more unexpected deaths occurred, and the agency returned. After a 3-week investigation, that agency found systemic problems in both quality assurance and medical staffing." Detecting patterns of substandard care before injury or death occurs should be a central goal for a system of hospital review; the Inspector General's finding that the current system does not adequately perform this role is highly disturbing.

2. Joint Commission surveys are unlikely to identify individual practitioners whose judgment or skills to practice medicine are questionable.

Although a Joint Commission survey includes a review of the hospital's method for ensuring the competence of its practitioners, the Inspector General's reports found that the Joint Commission's review is "a preliminary and superficial assessment," and is unlikely to identify individual practitioners who pose risks to their patients. The collegial nature of the process, the limited time, an approach to medical records that includes allowing the hospital to choose the files for review, and lack of background information combine to create a process that "falls short of identifying individuals whose skills may be questionable." The Inspector General's investigation also found little evidence that the Joint Commission examines how the hospital identifies or deals with physicians whose skills are marginal. Indeed, the Joint Commission standards do not even reference the federal law that requires hospitals to report to the National Practitioner Data Bank any practitioner the hospital has disciplined with a restriction on privileges lasting more than 30 days, even though an earlier Inspector General report found widespread failure of hospitals to comply with this federal law. As of December 1998, more than eight years after the National Practitioner Data Bank started, only 38.3% of American hospitals had reported taking a disciplinary action against even one physician. This means that 3,914 American hospitals, most of which have dozens if not hundreds of physicians with admitting privileges, either have not disciplined even one physician sufficiently to trigger reporting to the Data Bank, or, if they have disciplined some physicians, have failed to report the physicians as required by federal law.

3. For the 20 percent of the hospitals in the country that are not accredited by the Joint Commission, external review is infrequent and tends to be triggered by a serious incident involving patient harm rather than as part of a routine review intended to prevent such incidents.

There are more than 1,400 hospitals across the country that do not participate in the Joint Commission accreditation process, and instead are surveyed by State agencies in order to be certified for Medicare participation. Because of the low priority given to routine hospital surveys by the Health Care Financing Administration (HCFA), however, half of these hospitals have not been surveyed within the 3-year industry standard, and some hospitals have gone for as long as eight years without a survey. In

addition, in all but a few states, the length of time between surveys is growing.

4. In spite of the fact that the present system of hospital review is already heavily tilted towards a collegial, industry-friendly approach, the current trend is towards even more of a collegial mode of oversight and away from a regulatory mode.

As the Inspector General's reports point out, the Joint Commission is the dominant force in the external review of hospitals, surveying approximately 80 percent of hospitals, and its approach is grounded in the collegial mode. "Notwithstanding the presence of non-industry members on its board or of various advisory bodies or of certain public purposes it may fulfill, it is primarily responsive to the interests of entities it accredits." Given this large imbalance between collegial and regulatory modes of oversight, we are greatly alarmed by the Inspector General's conclusion that the movement in the field is towards an even greater use of the collegial mode. The Inspector General's reports note the danger of relying too heavily upon the collegial mode as the basis for external oversight, and state that "[t]he emerging dominance of the collegial mode may undermine the existing system of patient protections afforded by accreditation and certification practices." The Inspector General's reports cited the conclusion reached by the National Roundtable on Health Care Quality that "as the overall system of quality oversight becomes increasingly oriented to the collegial side of the continuum, the risks begin to mount, with potentially significant consequences to patients."

*5. The Joint Commission and State agencies are only **minimally** accountable to HCFA for their performance in reviewing hospitals.*

In surveying hospitals for accreditation or certification, the Joint Commission and State agencies are performing what is essentially a regulatory function--ensuring that hospitals can provide the quality care necessary in order to participate in Medicare. Yet according to the Inspector General's reports, HCFA provides only slight oversight of their performance: HCFA asks for little in the way of routine performance reports; provides little feedback; and makes little information available to the public on the performance of hospitals or external reviewers.

Recommendations Beyond Those Made by the Inspector General

After reading these reports, we are all the more convinced that the external review of hospitals should be conducted by a publicly accountable body. As the reports make clear, the failure of our current system to adequately detect patterns of substandard care or to identify marginal practitioners--*before* harm to patients occurs-- is a critical failure. While some of the tragedies that have occurred in our hospitals in recent years have initially seemed to be horrible, unpredictable accidents, subsequent investigations often reveal a series of mistakes, patterns of substandard practices, and inattention to mounting problems. Clearly a vital component of any system of external review, therefore, would be to detect such problems before harm occurs.

We recommend that the Department of Health and Human Services propose legislation to repeal the federal law that "deems" Joint Commission-accredited hospitals to satisfy Medicare requirements.

Let the Joint Commission, with its close ties to the hospital industry, focus on an educational approach to promoting hospital improvement, but locate the regulatory role of insuring that our hospitals are safe, quality institutions in a publicly accountable body. If, however, this legislative change does not happen, then we believe that the Inspector General's recommendations, while a step in the right direction, are not strong enough in light of the disturbing findings contained in these reports, and should be strengthened by setting specific, numerical targets for improvement, and establishing time limits for change including those listed below.

1. Increase the number of unannounced surveys. At least 50% of Joint Commission routine surveys should be unannounced, with no prior notice given to the hospitals. Only through unannounced surveys can the Joint Commission be sure that it is seeing the hospital as it functions from day to day, rather than what it looks like after an extensive "clean-up" and cosmetic improvement program.

2. Records reviewed during Joint Commission surveys should be randomly selected, and when any randomly selected record in a sample indicates a problem or raises questions, the sample size should be increased, and more records reviewed. The Inspector General reported on one Joint Commission survey where the credentials review in a hospital with more than 500 active staff consisted of a review of only three practitioners' files. Even when the surveyor found a problem with one of the three, he did not review any additional files of that practitioner. Clearly it does little good to detect what may be a problem if the matter is not explored further; the Joint Commission should establish a rule that questionable records will automatically trigger further review.

3. The Joint Commission should formally incorporate additional sources of information into its survey process, particularly information gathered from hospital employees, and complaints from patients, and should be required to submit summaries of such information to HCFA, along with a statement of the Joint Commission's findings. It is very likely that hospital employees and patients can provide the Joint Commission with information different from that obtained through the rest of the survey process, especially information about substandard practices that could lead to patient harm.

4. There should be greatly increased public disclosure of the results of hospital surveys. With the advent of the Internet, it is now possible to vastly improve public disclosure in a meaningful way. Disclosure should include not only scores and simplified charts that might facilitate comparison among hospitals, but should also provide detailed hospital-specific information about complaints and problems.

5. HCFA should establish a minimum 3-year cycle for conducting certification surveys in non-accredited hospitals, with immediate attention paid to those non-accredited hospitals that have gone the longest without a survey.

6. HCFA should establish a 5-year time limit for changes in the Joint Commission process, and at the end of five years, if the problems identified by the Inspector General's reports have not been eliminated, and the above recommendations as well of those of the Inspector General been implemented, then the Department of Health and Human Services should seek legislation to repeal "deemed" status for Joint Commission accreditation.

We recommend that HCFA use the findings of these Inspector General reports to make extensive changes in the system of external review. HCFA should especially note the Inspector General's warning about the dangers of a system overly tilted towards a collegial approach, and set a time frame for changes with the Joint Commission process to reduce the problems associated with its current "collegial" approach. We are not optimistic, however, of the ability of the Joint Commission to reform its process enough to become the independent body needed for the task of external review, because of the Joint Commission's inherent conflict of interest between its role as hospital inspector and its role as "educator" to its paying clients--the hospitals it inspects. At the end of five years, HCFA should examine the state of external hospital review, and if the problems identified by the Inspector General's reports have not been eliminated, then the Department of Health and Human Services should seek legislation to repeal "deemed" status for Joint Commission accreditation.

5

Endnotes

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 can happen even in the best of hospitals, but they underscore the point that hospitals can be dangerous places and that oversight systems can be lax. See also "Overdoses Still Weigh heavily at Dana Farber," *The Boston Globe* (26 December 1995); "Florida Doctor Sanctioned in New Amputation," *The Boston Globe* (19 July 1995); "Two Surgeons Surrender Licenses After Mistakenly Removing Kidney," *The Boston Globe* (6 June 1996); "How Can We Save the Next Victim?" *New York Times Magazine* (15 June 1997); "Another Hospital Death Probed," *The Boston Globe* (26 July 1997); "Patient Dies After Drinking Poison Left on Nightstand," *San Diego Union-Tribune* (6 March 1998); "Man Arrested for Posing as Doctor for 4 years," posted at the CNN interactive webpage (16 May 1998); "Deadly Restraint: Patients

Suffer in a System Without Oversight," *The Hartford Courant* (13 October 1998).

4. http://WWW.hcfa.gov/Medicare/Medicare.htm

5. Ibid.

6. Ibid.

7. Ibid.

8. P.L. 89-97.

9. The HCFA published its proposed hospital conditions of participation on December 19, 1997 (62 Fed. Reg. 66,726). On July 2, 1999, it published an interim final rule concerning patients' rights (64 Fed. Reg. 36,070).

10. Social Security Act, sec. 1865, 42 U.S.C 1395bb.

11. Health Care Financing Administration, OSCAR 10 Report, as of May 30, 1998.

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

13. Michael S. Hamm, *The Fundamentals of Accreditation* (Washington, D.C.: American Society of Association Executives, 1997) 3.

14. Nonaccredited hospitals can go through the Medicare certification process for free. Although the President's Department of Health and Human Services Fiscal Year 1999 Budget included a proposal authorizing the Secretary to impose a user fee for certification surveys, that proposal was excluded from the budget bill passed by Congress.

15. 42 U.S.C. 1395bb.

16. 42 U.S.C. 1395aa.

17. Health Care Financing Administration, Oscar 10 Report, as of May 30, 1998.

18. Office of Inspector General, *Medical Licensure and Discipline: An Overview* (June 1986)*; The Utilization and Quality Control Peer Review Organization Program: Quality Review Activities* (September 1988); *The Utilization and Quality Control Peer Review Organization Program: Sanction Activities* (November 1988)*; The Utilization and Quality Control Peer*

Review Organization Program: An Exploration of Program Effectiveness (February 1989); *Performance Indicators, Annual Reports, and State Medical Discipline: A State-by-State Review* (August 1990); *Quality Assurance Activities of Medical Licensure Authorities in the US and Canada* (February 1991)*; Educating Physicians Responsible for Poor Medical Care: A Review of the PROs' Efforts* (February 1992); *The Sanction Referral Authority of Peer Review Organizations* (April 1993); *The Peer Review Organizations and State Medical Boards: A Vital Link* (April 1993); *The Beneficiary Complaint Process of the Medicare Peer Review Organizations* (November 1995); *The Role of Medicare PROs in Identifying and Responding to Poor Performers* (December 1995); and *Monitoring and Evaluating the Health Care Quality Improvement Program* (August 1988).

19. Joint Commission on Accreditation of Healthcare Organizations, "Understanding the 197 hospital Performance Report," 4.

20. Ibid., 10.

21. HCFA to States, FY 1997 State Survey and Certification Budget Call Program Requirements and Budget Guidelines.

22. Joint Commission on Accreditation of Healthcare Organizations.

23. See D. E. Berwick, "Continuous Quality Improvement as an Ideal in Health Care," *New England Journal of Medicine* 320 (January 5, 1989) 1: 53-56 and The Institute of Medicine, *Medicare: A Strategy for Quality Assurance* (Washington, D.C.: National Academy Press, 1990).

24. Referred to as the Sentinel Event policy. For a fuller discussion of this policy, see our companion report, *The Role of Accreditation.*

25. For a fuller discussion of the ranking of State survey agency activities, see our companion report, *The Role of Medicare Certification*.

26. 62 Fed. Reg. 66726, Dec. 19, 1997.

27. Ibid.

28. Ibid., 66728.

29. 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.

30. Ibid., 1004.

31. Ibid.

32. Ibid.

33. HCFA, *Report to Congress on the Study of: Private Accreditation (Deeming) of Nursing Homes, Regulatory Incentives and Non-Regulatory Initiatives, and Effectiveness of the Survey and Certification System,* July 1998; General Accounting Office, *California Nursing Homes: Federal and State Oversight inadequate to Protect Residents in Homes with Serious Care Violations,* GAO/T-HEHS-98-219 (July 28, 1998); Hearings Before the Senate Special Committee on Aging, July 27-28, 1998; see also President Clinton's remarks announcing the new nursing home regulations, July 21, 1998 (in *Weekly Compilation of Presidential Documents*, July 27, 1998, p 1446).

34. In his remarks on July 21, 1998 President Clinton called for a "crackdown on unsafe nursing homes...[and] a step up [in] investigations" (in *Weekly Compilation of Presidential Documents,* July 27, 1998, p 1446).

35. Until January 1998, HCFA only selected hospitals for validation surveys from those undergoing Joint Commission surveys during certain months of the year. The HCFA reports that it corrected this problem.

36. Tracking termination notices would provide HCFA insights into how often hospitals are unable to correct problems identified through a survey within 45 days, because HCFA only issues termination notices when problems go uncorrected for 45 days.

37. 42 U.S.C.1395ll.

38. 62 Fed. Reg. 66726, Dec. 19, 1997.

39. The HCFA implemented this approach to overseeing the State survey agencies (referred to as the State Agency Quality Improvement Program, or SAQIP) in 1996. The HCFA defined a core set of performance standards that apply generally to survey and certification activities for any provider, for example nursing homes, hospitals, or home health agencies. The HCFA expects State agencies to develop improvement plans for specific standards.

40. Performance reports from the Joint Commission are available upon request and through the Joint Commission's website. For further discussion of the performance reports, see our companion report, *Holding the Reviewers Accountable*.

41. 42 U.S.C. 1395aa.

42. See Lori B. Andrews et al, "An Alternative Strategy for Studying Adverse Events in Medical Care," *The Lancet* 349 (February 1, 1997)309-313; 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; 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.

43. Sidney A. Shapiro and Randy S. Rabinowitz, "Punishment versus Cooperation in Regulatory Enforcement: A Case Study of OSHA," *Administrative Law Review* 49 (1997)4: 713-762.

44. National Roundtable on Health Care Quality, p 1004.

45. Prospective Payment Assessment Commission, *Report and Recommendations to the Congress* (March 1997) 13.

46. Hamm, *Fundamentals of Accreditation*, 3.

47. 42 CFR 488.8. These regulations define a 20 percent disparity rate between the accrediting organization and the State agency as a trigger for a deeming authority review.

48. Stephen F. Jencks, "The Government's Role in Hospital Accountability for Quality of Care," *The Journal of Quality Improvement* (July 1994)364-369.

49. 62 Fed. Reg. 66728, Dec. 19, 1997.