

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) commends the Chairman and Representative Cummings for holding this hearing on medical testing errors. As the nation's preeminent health care standard-setting and accrediting body, the Joint Commission would like to take this opportunity to affirm the value of private-sector accreditation and to stress the urgent need for federal action on patient safety legislation. The Joint Commission, therefore, submits the following testimony for the record.

Founded in 1951, the Joint Commission is a private sector, not-for-profit entity dedicated to improving the safety and quality of health care provided to the public. Our member organizations are the American College of Surgeons; the American Medical Association; the American Hospital Association; the American College of Physicians; and the American Dental Association. In addition to these organizations, the 29-member Board of Commissioners includes representation from the field of nursing as well as public members whose expertise spans such diverse areas as ethics, public policy, and insurance. Furthermore, the Board includes guest representation from the federal government.

The Joint Commission accredits approximately 17,000 health care organizations, including a preponderance of the hospitals in this country. Our accreditation programs also evaluate the performance of home care agencies; ambulatory care settings whose services range from primary care to outpatient surgery; behavioral health care programs; nursing homes; hospices; assisted living residencies; clinical laboratories; and managed care plans. Further, the Joint Commission is active internationally and has provided consultation and accreditation services in over 60 countries.

The Joint Commission considers laboratory an essential hospital service and has been evaluating and accrediting hospital laboratories services since 1979. The Joint Commission also has been accrediting freestanding laboratories since 1995. Today, JCAHO accredits more than 2,600 organizations with laboratory services, including independent laboratories and those connected with other types of health care

organizations. Thus, the Joint Commission is committed to ensuring that laboratories operating in a JCAHO-accredited facility provide safe, high quality services. Because the impetus for today's hearing is the tragic medical testing errors at a laboratory accredited by the College of American Pathologists (CAP) in a JCAHO-accredited hospital, we believe that our testimony will be helpful to the subcommittee.

Private Sector Accreditation

Joint Commission accreditation demonstrates the value of private-sector oversight because accreditation is based upon the highest achievable, professionally recognized standards. For more than fifty years, private-sector accreditation has been an effective approach for reducing risks to patients and improving the safety and quality of health care services in our nation. The Joint Commission has forged strong relationships with both the federal government -- especially with the Medicare program -- and state governments, such as licensing agencies, to provide effective oversight of health care facilities.

Accreditation evaluations form a sound basis for many programmatic decisions made by governmental bodies, and serve as an important partner in our country's oversight fabric.

With thousands of health care facilities throughout the country, it is essential that both private and public oversight bodies work collaboratively to optimize their impact on safety and quality. One avenue with for such collaboration is the sharing of information on complaints and survey findings. To that end, the Joint Commission has been continuing its work to improve facilitation of the sharing of complaint and deficiency data with the Centers for Medicare & Medicaid Services, as well as with other oversight bodies. To ensure safety and quality on a continuing basis, accrediting bodies and governmental enforcement programs must rely on both patients and concerned health care staff to raise issues that accreditors can evaluate. The Joint Commission values such input as a key component of our accreditation program. Formalized mechanisms exist within the Joint Commission's accreditation process to solicit information from staff and patients. Moreover, complaint information is used to focus the normal onsite inspection

process to determine whether additional, for-cause visits to accredited facilities are necessary.

The Joint Commission's Cooperative Accreditation Initiative

A JCAHO-accredited hospital is required to have its laboratories accredited by either the Joint Commission or another accrediting body that is recognized by our Cooperative Accreditation Initiative (CAI). The CAI provides the Joint Commission a mechanism to reduce duplication by relying on the process, findings, and decisions of another accrediting body that Joint Commission has deemed competent. To be recognized under the Joint Commission's CAI, an organization must meet a set of threshold eligibility criteria, including having —

- a national presence;
- accreditation experience with at least 100 organizations;
- recognition as an accrediting entity by other national or state agencies;
- an on-site survey cycle comparable to the Joint Commission's; and
- an approach to the disclosure of survey results that is comparable to that of the Joint Commission.

To be recognized by the Joint Commission, the applicant accrediting body must have a program that also demonstrates an overall comparability with JCAHO standards, survey process, and methods of ensuring surveyor competence. To ensure this overall comparability, JCAHO staff observes the organization's accreditation process during an on-site review. In addition, JCAHO conducts an assessment of the organization's accreditation policies with a specific focus on (1) the use of random unannounced surveys, (2) the integration of performance measurement into survey process, (3) the use of methods to identify life-threatening events and their underlying cause; and (4) the use of public input and complaints about in the survey process. JCAHO ensures that the organization's accreditation program continues to be comparable by observing and analyzing their survey standards and process on a semi-annual basis.

Recognition of the College of American Pathologists

The College of American Pathologists (CAP) has been recognized by the Joint Commission's CAI program for over 20 years. CAP routinely provides the Joint Commission with information on its survey activities within JCAHO-accredited hospitals. This information includes a list of all the laboratories CAP accredits and a notification (within 3 working days) of a determination that a laboratory is no longer CAP-accredited. Upon request, CAP will provide a full inspection report (including deficiencies) of any CAP-accredited laboratory within a JCAHO-accredited facility.

In addition, the Joint Commission and CAP share complaint information regarding CAP-accredited laboratories within JCAHO-accredited hospitals. If CAP determines that a complaint requires an investigation, they advise the Joint Commission and provide a report of all the follow-up action undertaken to resolve the issue. If the Joint Commission is not satisfied with the corrective action undertaken for CAP, we will conduct our own investigation and require any additional corrective action deemed necessary.

Maryland General Hospital Laboratory

The incident at Maryland General Hospital involved a mechanical failure, human error, concealed information, and an inadequate response of leadership to problems within the laboratory. In response to notification by government officials, the Joint Commission promptly sent a surveyor to the facility in March 2004 to conduct an unannounced for-cause survey. After reviewing written documentation and interviewing managers and staff, the surveyor reported that Maryland General Hospital was out of compliance with Joint Commission standards, including patient rights and ethics, performance improvement, and patient safety. The Joint Commission is working with the hospital, CAP and the state to ensure that these deficiencies are corrected.

The problems at Maryland General Hospital point to the value of having a culture of safety within an organization that encourages the voluntary reporting of concerns by staff to their leadership, and ultimately to their accrediting body. Without such a culture, information will be hidden or surface too late to avoid patient risk.

Patient Safety Legislation

Since 1996, the Joint Commission has been a leader in the effort to create an environment that encourages health care professionals and institutions to surface, evaluate and share information about medical errors and adverse events. The Joint Commission developed standards around the need for a culture of safety within healthcare organizations, so that staff will feel encouraged to report concerns about the quality and safety of care. The standards further require organizations to develop “root cause” analyses on any serious “sentinel” events. However, many staff and organizational leaders are fearful of surfacing patient safety issues for fear that the information will turn into a Health care must move from a culture of “blame and shame” to an environment of open, honest, and confidential communication. By making this change, providers can learn from one another and find ways to make the system-wide changes necessary to prevent the occurrence of devastating events. Creating an environment where issues of patient safety can be reported in a confidential, non-punitive manner is essential to achieving this universal goal.

The Joint Commission began an aggressive initiative a number of years ago to bring national attention to patient safety problems, their causes, solutions, and the need for federal legislation in the patient safety area. As part of a coalition of more than 100 health care stakeholders, the Joint Commission has worked with members of Congress to pass critically-needed patient safety legislation. Without such legislation, too many issues of patient safety will remain hidden from those who can take corrective action. If we are to achieve a significant reduction in patient safety problems in this country, we need to create mechanisms for surfacing, vetting, and sharing sensitive data within the health care community.

The Patient Safety and Quality Improvement Act of 2003 (H.R. 633), passed by the House of Representatives last year, aims to create federal protections for certain information about medical errors voluntarily reported to a Patient Safety Organization (PSO). Legislation along these lines is desperately needed. A similar bill before the Senate (S.720) also provides protections for health care professionals and institutions to report information on errors to PSOs. The Senate bill has been passed out of Committee and awaits full Senate action. The bill strikes the proper balance between maintaining confidentiality and legal protections for reporting safety-related information, and the need to ensure accountability throughout the health care delivery system. We are hopeful that Congress will go to conference on these two bills this summer.

However, we also want to urge Congress not to adopt a provision in H.R. 663 that we believe will be interpreted to deny access to patient safety information, thereby impeding the ability of accreditors to work with health care organizations to improve their process of care and delivery of services. Specifically, H.R. 663 precludes protected patient safety information received by the Joint Commission in its PSO role from being shared with a Joint Commission accreditation survey team, even when the survey team is onsite to assist the health care organization with its safety issues. This restriction will limit an accretor's ability to provide needed technical assistance in a non-punitive fashion, and will greatly diminish the information available to accrediting bodies that can be used in creating safety standards, setting safety goals, and developing tools to assist accredited providers.

In the event that S.720 passes a Senate vote and a conference committee is formed to work through bicameral differences in the respective bills, the Joint Commission strongly urges Congress to consider the impact the final legislative language will have on an accredited organization's ability to share information with its accrediting body.