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HEALTH CARE

Initiatives in Hospital Risk Management

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The Honorable Ron Wyden
House of Representatives

Dear Mr. Wyden:

In your July 28, 1987, letter, you recognized that effective risk management can improve the quality of care in hospitals and requested that we examine risk management programs in today's hospital environment.

This report discusses what risk management is; how it evolved; who the key participants are in the process outside of the hospital environment; and what initiatives are underway that could affect future risk management programs. Although it contains no conclusions or recommendations, the report shows that risk management (1) is gaining general acceptance as a very important mechanism to identify and control areas of potential liability for a hospital and (2) should be closely coordinated with a hospital's quality assurance activities. In fact, many of our nation's hospitals are now required to either implement risk management programs or meet certain risk management program standards as a condition of state licensure or accreditation by the Joint Commission on Accreditation of Healthcare Organizations.

Background

Hospital risk management is defined as an organized effort to identify, assess, and reduce, where appropriate, risks to patients, visitors, staff, and hospital assets. It involves activities that are designed to (1) reduce the hospital's risk of a malpractice suit by maintaining or improving the quality of care, (2) reduce the probability of a claim being filed after a potentially compensable event has occurred, and (3) preserve the hospital's assets once a claim has been filed. Risk management may include quality assurance or related activities, such as medical staff credentialing, occurrence screening or incident reporting or both, and peer review. Other risk management activities include

- promoting effective communication between patients and staff in the belief that patients with a positive attitude toward a hospital and its staff are less likely to sue for malpractice;
- performing preventive maintenance of patient care equipment to ensure that it is kept clean, calibrated, and in good repair;
- adopting patient safety measures, such as ensuring that a functioning nurse call system exists; and

- incorporating employee and visitor safety measures, such as lighted parking lots and walkways and the use of security personnel.

Risk management was first applied to health care facilities during the medical malpractice crisis of the early 1970s when jury awards and settlements increased sharply. During this period many insurance companies either substantially increased hospitals' premiums or stopped writing malpractice insurance for them. In response, hospitals increasingly began to implement risk management programs in an effort to help control their financial losses.

Often, the programs were viewed as separate and distinct from quality assurance activities. That view, however, has changed with recognition that financial loss most often results from adverse patient events, such as misdiagnoses and surgical errors. These are quality-of-care as well as risk management issues. As a result, the sharing of information and coordination between risk management and quality assurance activities is now seen as essential.

Until recently, most risk management programs had been instituted at the discretion of a hospital's management team. Now, organizations that deal both directly and indirectly with hospitals are taking a more active role in either requiring or actively encouraging the implementation of risk management programs. These organizations include the Joint Commission on Accreditation of Healthcare Organizations, several states, insurance and other related companies, and the Department of Health and Human Services (HHS).

Emphasis on Coordinating Risk Management and Quality Assurance

By establishing several new standards for accreditation dealing with risk management, the Joint Commission has both reinforced and highlighted the importance of coordinating risk management and quality assurance activities. Effective January 1, 1989, every hospital that seeks Joint Commission accreditation must show substantial compliance with several specific standards that apply only to the quality-of-care and patient safety aspects of risk management. Given that about 5,000 (or 70 percent) of the nation's hospitals participate in the Joint Commission's accreditation process, meeting this requirement could be a problem for those hospitals that have not yet become actively involved in risk management.

In essence the new standards call for a hospital's management or governing body or both to

- provide resources and support systems for the quality assurance and risk management functions that relate to patient care and safety;
- establish and maintain operational linkages between risk management functions related to patient care and safety and quality assurance functions;
- ensure that existing information relating to the quality of patient care is readily accessible to both quality assurance and risk management functions; and
- support the identification, evaluation, and correction of problems in patient care through risk management activities.

The Joint Commission is not the only organization emphasizing the close relationship between risk management and quality assurance. Several states, the American College of Surgeons, and the American Society of Healthcare Risk Management (ASHRM) have all incorporated this concept in legislation, patient safety manuals, or model language for a health care risk management program.[1] (See app. I.)

Ten States Require Hospital Risk Management Programs

Between 1976 and 1988, at least 10 states enacted legislation or promulgated regulations requiring hospitals to implement risk management programs.[2] For the most part, state risk management program requirements were established in response to malpractice insurance problems and were made a condition for state licensure of hospitals. The laws and regulations address many aspects of risk management programs, such as hospital governing body involvement, risk identification systems, educational programs, sharing of risk management information, medical staff credentialing, and patient grievance procedures. The laws and regulations vary widely in their level of detail, types of risk management program activities included, and emphasis on state monitoring and enforcement of the requirements. Appendix II contains a comparison of the various state laws. Appendix III contains a more in-depth look at the Maryland and New York risk management requirements.

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[1]ASHRM, a part of the American Hospital Association, serves as the professional organization representing risk management nationwide. As such, ASHRM is responsible for educating risk managers on critical risk management issues and for being proactive concerning those that affect them in the workplace. As of December 31, 1988, ASHRM had 1,975 members, according to one of its officials.

[2]Alaska, Colorado, Florida, Kansas, Maryland, Massachusetts, New York, North Carolina, Rhode Island, and Washington.

Insurers Strongly Endorse Risk Management Programs

Four insurance companies that collectively provide liability insurance to about one-third of the nation's hospitals strongly encourage insured hospitals to implement risk management programs as a means of reducing financial liability.[3] In addition, each company provides a variety of services designed to enhance the effectiveness of hospital risk management efforts. These services include the development of occurrence reporting systems, periodic on-site risk assessment surveys, educational programs, publications, and malpractice claims studies. The companies, however, do not require insured hospitals to implement predesigned risk management programs having specified components, nor do they generally base policy premium levels on the type of risk management programs being operated. (See app. IV.)

Current Initiatives in Risk Management

Several studies now being conducted have the potential to affect how risk management programs will be conducted in the future. One such study, funded by the Robert Wood Johnson Foundation,[4] is attempting to assess the effectiveness of various "early warning systems" for malpractice claims management and prevention. Over 40,000 incident reports from a dozen institutions are being analyzed to yield basic data on ways to improve the functioning of risk management, loss prevention (including quality assurance), and claims management.

HHS's National Center for Health Services Research funded a study of the effectiveness of risk management. This study, which involved 40 Maryland hospitals, analyzed all open and closed malpractice claims filed in Maryland from 1977 to 1985. The results have provided some of the first empirical evidence showing that some hospitals with certain risk management processes had a better claims experience than others without those processes. (See app. I.)

Objectives, Scope, and Methodology

Our objective was to obtain information that would provide an overview of how hospital risk management activities have evolved since the substantial increase in medical malpractice actions in the early 1970s. We conducted an extensive literature search to identify materials that define and address various aspects of hospital risk management programs. Automated data bases were used as a starting point for the

[3]St. Paul Fire and Marine Insurance Company; MMI Companies, Inc.; Pennsylvania Hospital Insurance Company; and Farmers Insurance Group of Companies.

[4]Robert Wood Johnson Foundation is a private organization in Princeton, New Jersey, whose purpose is the improvement of health services in the United States.

development of a bibliography and were supplemented with publications recommended by risk management experts and professional organizations. In identifying risk management initiatives, we contacted officials of, and reviewed selected documentation issued by, the Joint Commission, ASHRM, HHS, several states that had enacted laws or promulgated regulations requiring hospitals to implement risk management programs, four insurance companies underwriting hospital malpractice liability coverage, two major hospital corporations, and several other insurance-related organizations involved in risk management activities.

In general, each of these organizations was asked to describe past, current, and planned activities related to the design and implementation of risk management programs at the hospital level. Insurance companies were also asked for more specific information on whether they (1) require insured hospitals to implement approved risk management programs, (2) consider the existence of risk management programs in setting premium levels, (3) are involved in risk management education and training at the hospital level, and (4) require insured hospitals to submit data generated by the risk management program.

At the state level, we analyzed the laws and regulations from 10 states that require hospitals to implement risk management programs to gain an understanding of what the hospitals required. Our analysis generally consisted of a comparison of selected program requirements (see app. II). We also interviewed state or hospital association representatives or both in each state to learn how risk management requirements were being implemented and monitored.

Our review was carried out from March 1988 through January 1989 in accordance with generally accepted government auditing standards.

We did not request written comments on a draft of this report from the organizations contacted during our review. We did, however, give each organization an opportunity to review pertinent sections of the report that involved them and incorporated their views where appropriate.

We are sending copies of this report to interested Senate and House Committees, and will make copies available to others on request. The major contributors to this report are listed in appendix V.

Sincerely yours,

David P. Baine
Director of Federal Health
  Care Delivery Issues

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Appendix V
Major Contributors to
This Report

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Abbreviations

ASHRM	American Society of Healthcare Risk Management
HHS	Department of Health and Human Services
MMI	MMI Companies, Inc.
PHICO	Pennsylvania Hospital Insurance Company

Increasing Emphasis on Hospital Risk Management and Its Relationship With Quality Assurance

Hospital risk management involves the identification, evaluation, and management of situations within a hospital that may result in injury to patients, visitors, or staff. These functions are designed in large measure to reduce liability resulting from situations such as surgical errors or uncorrected fire hazards. Also included are actions to limit damage awards once such situations have occurred. Because both quality assurance and risk management are concerned with preventing adverse patient incidents, professional organizations and others have become increasingly interested in greater coordination and interaction of the two functions along with medical staff credentialing. For example, the Joint Commission on Accreditation of Healthcare Organizations has adopted risk management standards that, in part, are aimed at assuring such integration.

The Evolution of Hospital Risk Management

Originally developed by the insurance industry, risk management activities were designed to help business entities control insurance claim losses. Their application to the health care industry is a more recent phenomenon. During the early 1970s, medical malpractice jury awards and out-of-court settlements with hospitals and physicians increased sharply. Many insurance companies reacted by charging much higher premiums and in some instances stopped writing malpractice insurance policies for hospitals. To counter this situation, hospitals began to implement risk management programs in the belief that such programs could help control their financial losses. As the concept gained acceptance as a means to protect hospitals from costly malpractice claims, states and other interested outside organizations became increasingly involved in defining the components of risk management programs.

As hospitals began to implement these programs, it became clear that certain functions they performed would overlap existing quality assurance activities. This caused some hospitals to examine ways to organize and coordinate their quality assurance and risk management functions. This in turn led the American Hospital Association to form an Interdisciplinary Task Force on Quality Assurance and Risk Management in 1980. The purpose of the task force was to define the relationship of hospital risk management to quality assurance.

Table I.1 compares the risk management and quality assurance functions, as defined by the task force.

Table I.1: Comparison of Risk Management and Quality Assurance

Risk management	Quality assurance
Protects the financial assets of the hospital.	Reflects a hospital's philosophy of providing quality care.
Protects human and intangible resources.	Improves the performance of all professionals and protects patients.
Prevents injury to patients, visitors, employees, and property.	Focuses on the quality of patient care delivered in the hospital.
Reduces loss by focusing on individual loss or on single incidents.	Sets the quality of care delivered against standards and measurable criteria.
Prevents incidents by improving the quality of care through continuing and ongoing monitoring of hospital activities.	Prevents future losses or patient injuries by continuous monitoring of problem resolution areas.
Reviews each incident and the patterns of incidents through the application of the risk management process: risk identification, risk analysis, risk evaluation, and risk treatment.	Searches for patterns of nonconformance with goals and standards using the following quality assurance processes: problem identification, problem assessment, corrective action, follow-up, and report of findings.

Source: Hospitals, Vol. 55, June 1, 1981.

The task force concluded that risk management and quality assurance are two activities whose functions sometimes overlap and, when they do, their purposes and methods are almost indistinguishable. The task force also identified major differences between risk management and quality assurance, as shown in table I.2.

Table I.2: Differences Between Risk Management and Quality Assurance

Risk management	Quality assurance
Concerned with acceptable levels of care from a legal standpoint.	Concerned with optimal level of care.
Directed toward all persons, events, and environs in the health care setting.	Directed toward patient care.
Focused on legal, insurance, and risk financing activities.	Focused on improving care.

The task force believed that integrating the two activities, where feasible, could

- maximize the use of limited resources;
- eliminate duplication, because sources of data for both activities are the same;
- provide a means for developing new solutions to problems;
- facilitate the development of training programs; and
- improve the budget process by identifying and consolidating budget requirements for both activities.

American Society of Healthcare Risk Management Defines Minimal Components

In late 1985 and early 1986, ASHRM, on its own initiative, created a legislative task force to develop model language for risk management legislation and regulation. The language was expected to be used to assist states that were considering legislation aimed at requiring hospitals to implement risk management programs. The task force ultimately identified what it considered to be the minimal components of a risk management program and made it available to many organizations and states with the caveat that it was for their guidance and information only. These components are summarized as follows:

- There must be a designated, trained, and experienced risk manager who must obtain at least 8 hours of continuing risk management education annually.
- Risk managers must have access to all necessary credentialing, management, and medical data.
- Facilities must commit the necessary resources to risk management through a written policy statement that is adopted by the governing body, medical staff, and administration.
- Facilities must have a system in place for the identification, review, and analysis of unanticipated adverse outcomes.
- Facilities must have the means to centralize risk management data and to share and integrate data collection and analysis with other clinical and administrative departments.
- Risk managers must periodically, at least annually, provide the hospital's governing body a report that reviews and evaluates risk management program activity.
- Risk managers must ensure that medical staff and new employee educational programs on minimizing patients' risks and addressing high-risk clinical areas are provided.
- Risk managers must forward to the committees that evaluate the competency of medical staff, risk management information on individual practitioners, such as malpractice claim history, knowledge of adverse outcomes, and incident reporting data.

The task force also developed provisions relating to confidentiality of risk management data and immunity from liability for those who provide risk management information.

Joint Commission Develops Additional Risk Management Standards

In April 1986, the Joint Commission's Board of Commissioners approved an effort by its staff to develop risk management standards. The standards ultimately proposed were approved by the board in December 1987, became effective on January 1, 1989, and apply only to the quality-of-care and patient safety aspects of risk management.

Now, every hospital must show substantial compliance with the following risk management requirements before it can attain Joint Commission accreditation.

- The hospital's governing body must provide resources and support systems for the quality assurance and risk management functions related to patient care and safety.
- The hospital's chief executive officer, through the management and administrative staff, must assure appropriate medical staff involvement in and support for (1) identification of areas of potential risk in patient care and safety, (2) the development of criteria for identifying cases with potential risk in patient care and safety and the evaluation of these cases, (3) the correction of problems in patient care and safety identified by risk management activities, and (4) the design of programs to reduce risk in patient care and safety.
- The hospital's management must establish and maintain operational linkages between the risk management functions related to patient care and safety and quality assurance functions.
- The hospital's management must ensure that existing information relative to the quality of patient care is readily accessible to both the quality assurance and risk management functions.

In a related effort, the Joint Commission now also requires that certain information that may indicate a physician is having performance problems be submitted to the hospital's medical staff committee before appointment and reappointment decisions are made. Such information includes judgments or settlements involving professional liability actions, involuntary or voluntary loss of a state medical license, and involuntary or voluntary limitation, reduction, or loss of clinical privileges at another hospital.

Risk Management Activities by HHS and Others

In August 1986, the Secretary of Health and Human Services established a task force to study medical liability and malpractice issues. The task force gathered information from representatives of the hospital, medical, legal, insurance, consumer, and research communities. It then issued

a report in August 1987, stating, among other things, that risk management activities should be encouraged as a means to control financial losses associated with malpractice claims and should be coordinated and integrated with quality assurance activities. The report also stated that HHS should operate risk management programs in all facilities under its control and encourage states and other entities to do the same. In addition, the report recognized the need for further research on risk management issues.

HHS's National Center for Health Services Research and Health Care Technology Assessment funded a study of the relationship between medical malpractice claims for the years 1980-87 and the nature and extent of risk management activities in 40 Maryland community hospitals in 1980.[1] The results, reported to HHS in August 1988, showed that hospitals with certain risk management processes had a better claims experience than hospitals without such processes.[2]

Hospital characteristics associated with better claims experience included

- a policy to notify clinical chiefs of adverse medical incidents,
- a policy specifying who had responsibility for informing the patient or family of errors,
- governing board receipt of risk management reports on a regular basis,
- governing board oversight of risk management or quality assurance and risk management activities, and
- education efforts concerning the responsibilities of physicians and nurses in quality assurance and risk management.

The Robert Wood Johnson Foundation has financed a study that is attempting to assess the value of early identification systems to malpractice claims management. Over 40,000 incident reports from 12 institutions are being analyzed to provide basic data on ways to improve the functions of risk management, loss prevention (including quality assurance), and claims management.

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[1] "Do Hospital Risk Management Programs Make a Difference?" In Malpractice Claims: The Maryland Experience, 1977-1985, Final Report to the National Center for Health Services Research and Health Care Technology Assessment, Public Health Service, HHS, under Grant No. Rol HS05108, August 1988.

[2] Hospitals were ranked according to the volume of surgical procedures performed, obstetrical procedures performed, and emergency room admissions, and then divided into higher risk and lower risk hospitals based on these indicators.

Major Risk Management Tools

Prompt identification of patient, visitor, and staff injuries and accidents has been a primary concern of risk management programs since they were first used in hospitals. Through such action hospital management address a potential problem and correct its cause before it can occur again. Further, hospital management can initiate immediate action to avoid or lessen the cost of a lawsuit. Three systems used to accomplish this are incident reporting, occurrence reporting, and occurrence screening.

Incident Reporting

Incident reporting systems were developed in the late 1940s and early 1950s to identify any events, such as malfunctioning equipment or medication errors, that were not consistent with the routine operation of the hospital or the routine care of particular patients or visitors. Such systems rely on hospital personnel to recognize and report an incident to a risk manager, a quality assurance coordinator, or another member of hospital management. Such systems have tended to generate reports focused on falls, burns, and equipment problems that could result in claims against a hospital. But these systems, by themselves, do not produce a complete picture of the number of incidents that occur in a hospital.

Based on reports from various hospital and insurance company programs, in 1985 the American College of Surgeons estimated that incident reporting systems identify only 5 to 30 percent of the adverse patient occurrences at a hospital. The American College of Surgeons listed several reasons why hospital staff often do not report incidents: lack of understanding of what a reportable incident is, fear of punitive action, concern that incident reporting exposes them to personal liability, reluctance to report incidents involving physicians, lack of time for paperwork, and lack of knowledge about what results an effective incident reporting system can achieve.

Occurrence Reporting

Rather than rely on the judgment of individuals to determine what is to be reported (e.g., incident reporting), some states and insurers require or encourage hospitals to develop lists of specific adverse patient occurrences that must be reported by hospital staff, physicians, or both. This is often called occurrence reporting. For example, a list of adverse patient occurrences to be reported by obstetrics staff could include maternal or infant death, infant injury (e.g., skull fracture, paralysis), or a mother's unplanned return to the delivery or surgical unit. If any of these situations occur, they must be reported. In 1985, the American

College of Surgeons estimated that 40 to 60 percent of all adverse patient occurrences can be identified through a reporting system that specifies the events to be reported. The list of adverse events that are to be reported may vary according to the discretion of hospitals, insurance companies, and states. However, as might be expected many incidents still are not likely to be reported because the system relies on individuals for reporting.

In addition to specifically citing what occurrences must be reported, other factors are being considered to promote better reporting. In recent years, some states have acted to grant persons who provide or evaluate risk management information with immunity from legal action. In addition, state legislation has been passed in some states to protect against the possibility that documents generated by the risk management program will become public information (see app. II).

Occurrence Screening

Occurrence screening systems are designed to identify deviations from normal procedures or expected treatment outcomes. These systems (1) may be used in both risk management and quality assurance programs, (2) use criteria to ultimately identify adverse patient occurrences, and (3) do not rely on hospital staff to report adverse events. Rather, trained data screeners, usually quality assurance nurses or medical record analysts using preestablished criteria, systematically review patient records to identify specific events that have taken place during a patient's treatment in the hospital that represent deviations from normal procedures or expected treatment outcomes. Peer reviewers then determine if a deviation from acceptable standards of care occurred. This review of medical records can be done during or after the patient care or at both times.

Examples of occurrence screening criteria that would be compared to a patient's medical record might include transfer from a general care unit to a special care unit, infection not present on admission, and unplanned return to an operating room. The American College of Surgeons estimated that occurrence screening systems typically identify 80 to 85 percent of adverse patient occurrences, a higher percentage than incident reporting systems. The college also stated that using a quality assurance and risk management system that combines occurrence screening and other data sources (such as incident reporting, infection surveillance, and medical staff peer review functions like surgical case review and antibiotics use review) can identify a greater proportion of adverse patient occurrences (90-95 percent) than any individual system.

Patients Can Help Identify Problems

Activities designed to handle patient complaints and measure patients' attitudes toward their hospital experience also are important risk management tools. Such activities may include patient satisfaction surveys, patient complaint follow-up procedures, and staff education on how to respond to patient concerns. These activities are premised on the assumption that information from patients can be a means of identifying problems needing attention within the hospital. Further, experts believe that patients are more likely to file a claim when there has been poor rapport between them and the hospital staff.

Credentialing and Privileging Important to Effective Risk Management

Medical staff credentialing is designed to help assure that a hospital is staffed by only qualified individuals and that their performance is maintained at an acceptable level. Credentialing activities consist of a complete review of the licenses, education, and training of all applicants seeking employment. In addition, physicians must regularly have their privileges updated. This involves an evaluation by a hospital of the physicians' clinical experience, competence, ability, judgment, and demonstrated performance in specified functions (e.g., heart surgery) before they can be reappointed.

In terms of risk management, credentialing and privileging is important because it is the primary mechanism available to a hospital to help it ensure that only competent personnel are employed and that they perform only those procedures for which they are deemed competent. This, in turn, reduces the likelihood of any negligent acts occurring that could result in a claim against the hospital. Further, a hospital with a nonexistent or ineffective credentialing or privileging process could find itself in an indefensible position if a malpractice claim were filed since the absence of such a process may indicate that the hospital was negligent in assuring that it employed only competent health care providers.

Federal Legislation That Affects Risk Management

The Health Care Quality Improvement Act of 1986, signed into law on November 14, 1986, as title IV of Public Law 99-660, requires reports to be made to the Secretary of HHS and to state licensing boards on medical malpractice payments and certain professional review actions taken by health care entities against a physician or licensed health care practitioner. In addition, hospitals are required to report actions taken to limit physician privileges. The act also requires state boards of medical examiners to report physician disciplinary actions to the Secretary of HHS and, in most cases, seeks to promote professional peer review activities

by protecting persons providing information to a professional peer review panel from related liability.

Hospitals are required to query the HHS data base every 2 years on any physician or practitioner who is on the hospital's staff. This data base will, for the first time on a nationwide basis, give hospitals critical information on the qualifications and work history of physicians and other health care practitioners before medical staff appointments regardless of where they previously practiced.

At the time of our review, according to HHS, the data base had not been developed, because of delays in receiving the necessary appropriations. In December 1988, HHS awarded a $15.9 million contract to UNISYS Corporation to operate the data base, which is supposed to be operational by the summer of 1989.

Risk Management Activities by Others

In addition to the aforementioned activities and those undertaken by certain states and insurance companies, as discussed in appendixes II, III, and IV, other organizations have been actively involved in developing and implementating risk management systems in hospitals. For example, officials of two major hospital corporations (Humana and Hospital Corporation of America) with whom we spoke said that while they do not require specific risk management programs of their member hospitals, they strongly encourage their implementation and integration with quality assurance. Both organizations provide risk management advice and services to their member hospitals.

Three other organizations that we visited provide similar services. The Chicago Hospital Risk Pooling Program, a trust program that provides liability coverage to member hospitals; the Professional Risk Management of California, Inc., administrator of several self-insurance programs; and the Risk Management Foundation of the Harvard Medical Institutions, an agent of a captive insurance company,[3] all provide their hospitals with such services as risk management education, consultation, and publications as well as incident investigations and claims studies. All three encourage coordination of risk management and quality assurance.

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[3]An insurance company formed and wholly owned by a noninsurance company or group of companies to insure their own risks or risks common to the group.

In recent years, various groups of physicians have also worked to develop guidelines or standards for patient care. Since they are intended to reduce the likelihood of patient injury in risky areas of the hospital (e.g., emergency room, obstetrics departments), such standards have the potential to increase the effectiveness of risk management. For example, an organization of emergency room physicians in Massachusetts has developed risk management guidelines for the emergency room in the hope that patient injuries and physician insurance premiums will decrease.

Similarly, the Risk Management Foundation of the Harvard Medical Institutions has convened groups of anesthesiologists and obstetricians from its hospitals to develop standards for patient care applicable to their specialties.

Physician liability insurers also have been active in areas that affect hospital risk management. Some such insurers conduct analyses on the causes and outcomes of claims filed against insured physicians and educate physicians on how to reduce the likelihood of becoming a defendant in a malpractice action.

Major Characteristics of Risk Management Programs Required by States

As of January 1989, 10 states (Alaska, Colorado, Florida, Kansas, Maryland, Massachusetts, New York, North Carolina, Rhode Island, and Washington) had passed legislation or promulgated regulations requiring hospitals to implement risk management programs. In most of these states, risk management requirements (1) are specifically designed to interrelate with other quality assurance initiatives in the hospital environment and (2) are made a condition for the states' hospital licensure. The requirements generally focus on preventing and controlling risks to patients, rather than on other aspects of risk management, such as fire prevention, preventive maintenance (equipment calibration, adjustment, repair, etc.), and safety and security for visitors and staff.

Major characteristics of the states' requirements include

- assignment of responsibility for the risk management program within the hospital,
- involvement in risk management programs by hospital governing boards,
- identification of risks,
- investigation or analysis of risks or both,
- risk management education,
- sharing of information with other personnel involved in quality assurance,
- handling patient grievances, and
- immunity and confidentiality.

The emphasis placed on different aspects of risk management, levels of detail in discussing program requirements, the scope of program requirements, and emphasis on state monitoring and enforcement of program requirements vary considerably among the states.

Analysis of the legislation and regulations in the 10 states that require risk management indicates that there are certain characteristics included in most of these programs. The degree to which they are required and the level of specificity of the legislation and regulation vary widely. But, in all instances, a framework is established for implementing a basic risk management program. Compliance surveys by state personnel were being conducted in seven states at the time of our review in mid-1988. The main characteristics contained in the risk management legislation and regulations are cited in table II.1.

Table II.1: General Characteristics of State Risk Management Requirements

Characteristics	AK, 1976	RI, 1979	FL, 1985	NY, 1985	KS, 1986	MD, 1986	WA, 1986	MA, 1986	NC, 1987	CO, 1988
Assigned responsibility for risk management program	•	•	X	X	X	X	X	X	X	X
Governing body involvement in risk management	•	•	X	X	X	X	X	X	X	X
Risk identification system	•	X	X	X	X	X	X	X	X	X
Investigation/analysis of risks	X	•	X	X	X	X	•	X	X	X
Education programs on risk management	X	X	X	X	•	X	X	X	X	•
Sharing of risk management information	•	•	•	X	•	X	X	X	X	X
Patient grievance procedure	X	X	X	X	•	X	X	X	•	•
Provisions for immunity and confidentiality	•	X	X	X	X	X	X	X	•	•
Follow-up of risk management activities	X	•	X	X	•	X	•	X	X	X

Responsibility for Risk Management Programs

Table II.2 shows how the states require hospitals to assign responsibility for risk management programs in their respective legislation. Depending on the state, hospitals are required to assign risk management responsibility to an individual or a committee or, in some instances, are allowed to choose between the two. Two states make no assignment of responsibility.

Table II.2: Responsibility for Risk Management

	AK	RI	FL	NY	KA	MD	WA	MA	CO	NC
Single risk management coordinator	•	•	X	•	X	X	•	•	•	X
Committee responsible for quality assurance/risk management	•	•	•	X	•	•	X	•	•	•
Option of committee or individual	•	•	•	•	•	•	•	X	X	•
No assignment of responsibility	X	X	•	•	•	•	•	•	•	•

Involvement of Governing Body in Risk Management Programs

The extent to which the states require hospital governing boards to support risk management programs varies. Where support is required, the emphasis ranges from assuring that governing bodies provide an adequate level of resources and support systems for risk management programs, to a minimal requirement that the governing bodies formally approve a risk management plan. In 6 of the 10 states, the governing

body or the hospital administrator must receive reports on the risk management program. Requirements range from a general statement that such reports must be made, to specific requirements for quarterly reports. Two states make no specific demands for governing body involvement.

Table II.3: Governing Body Involvement in Risk Management

	AK	RI	FL	NY	KS	MD	WA	MA	NC	CO
Adopts a policy on risk management	•	•	•	X	X	X	•	X	•	•
Receives periodic reports on risk management	•	•	X	X	•	X	•	X	X	X[a]
Quality assurance/risk management committee must include a member of governing body	•	•	•	X	•	•	X	X	•	•
No involvement required	X	X	•	•	•	•	•	•	•	•

[a]Hospital administrator may receive reports instead.

Identification of Risks to Hospital Patients

Nine of the 10 states, in effect, require hospitals to develop systems to identify risks to patients. Some legislation contains general wording that requires identification and collection of various risk data without establishing how that is to be accomplished. Other legislation/regulations require incident reporting that (1) operates on the assumption that all employees have a duty to report incidents or (2) specifies the types of incidents to be reported by hospital staff. Colorado, for example, requires that hospitals submit for state approval a general description of the types of cases, problems, or risks to be reviewed and the criteria to be used for identifying potential risks.

Massachusetts, which has very detailed requirements for risk identification, requires three risk identification processes. Hospitals must implement an incident reporting system based on the duty of all health care providers to report injuries and incidents. In addition, hospitals must develop focused occurrence reporting criteria that define specific adverse patient occurrences that must be reported within 24 hours after they are observed. Finally, hospitals must establish occurrence screening criteria, which are designed to reveal, through a chart review process, adverse or potentially adverse patient occurrences that might not otherwise be evident.

Table II.4: Risk Identification System Requirements

	AK	RI	FL	NY	KS	MD	WA	MA	NC	CO
Risk identification required, but no specific system mandated	•	X	•	•	•	•	X	•	X	•
Incident reporting system	•	•	X	X	X	•	•	X	•	X
Occurrence reporting system	•	•	•	•	•	X[a]	•	X	•	•
Occurrence screening criteria required	•	•	•	•	•	•	•	X	•	•
Patient grievance data required	X	X	X	X	•	•	X	•	•	X
Other quality assurance data required	•	X	•	X	•	X	X	•	•	X
No risk identification required	X	•	•	•	•	•	•	•	•	•

[a]Although Maryland law refers to an "Incident Reporting" requirement, its hospitals must list and describe incidents to be routinely reported. Thus, Maryland law, in effect, imposes an occurrence reporting system.

Investigation and Analysis of Identified Risks

Several states require that hospitals investigate or analyze or do both for identified incidents or risks to patients. North Carolina specified this requirement only in general terms, while others require that the frequency and causes of injuries be analyzed or that the analysis include the time, place, and persons involved.

Table II.5: Analysis of Identified Risks

	AK	RI	FL	NY	KS	MD	WA	MA	NC	CO
Requirement to investigate/ analyze identified risks	X	•	X	X	X	X	•	X	X	X
Trending of identified risks is required	•	•	X	•	•	X	•	X	•	X
Investigation or analysis of patient complaints by hospital is required	X	•	X	X	•	X	•	X	•	•
Hospital investigation reports required	•	•	X	X	•	•	•	•	•	•
No investigation/analysis required	•	X	•	•	•	•	X	•	•	•

Risk Management Education Programs

Eight of the 10 states mandate risk management education for hospital staff. Generally, the required education programs are to be provided either for all staff or for staff engaged in patient care activities. One state excludes physicians from the requirement and another's regulations require the education programs for all "appropriate" staff.

Massachusetts, New York, Rhode Island, Alaska, Florida, and Washington specified certain subjects to be included. These are injury prevention (3 states), improved communication (3 states), incident reporting or staff responsibility to report professional misconduct (4 states), other known causes of malpractice claims (3 states), patient safety (4 states), legal aspects of care (3 states), patients' rights (2 states), principles and techniques of infection control (1 state), and other topics specific to employees' job responsibilities (1 state).

Table II.6: Risk Management Education

	AL	RI	FL	NY	KS	MD	WA	MA	NC	CO
Risk management education programs required but no timeframes established	X	X	•	•	•	X	X	•	•	•
Annual risk management education for designated staff	•	•	X	X	•	•	•	X	X	•
Risk management education—specific topics covered	X	X	X	X	•	•	X	X	•	•
No education requirement	•	•	•	•	X	•	•	•	•	X

Sharing of Information

Six of the 10 states require information to be shared among hospital entities. Specifically, Colorado requires hospitals to coordinate all pertinent case, problem, or risk review information with other applicable institutional quality assurance or risk management activities. Maryland requires "a flow of information" among quality assurance, credentialing, peer review, and any risk management committee, while North Carolina requires "operational linkages" between risk management and other functions relating to patient care, safety, and staff performance. New York requires that hospitals review extensive information, including quality assurance data, complaints, incidents, and utilization review information to identify problems in patient care, and Massachusetts believes that credentialing, quality assurance, risk management, and peer review functions should be strong and thoroughly integrated.

Some states also consider credentialing and privileging to be linked with risk management. In Maryland, credentialing and risk management program regulations appear under separate sections of its legislation but are implemented and reviewed simultaneously by the state. Physician profiles, which must be reviewed biannually by hospital management before reappointment of professional staff, must include risk management information, such as claims filed against the physician, a review of

clinical skills, and compliance with continuing education requirements. Washington State requires the periodic review of the credentials, physical and mental capacity, and competence in delivering health care services for all persons employed or associated with the hospital, and as part of an evaluation of staff privileges. New York has a similar provision, and also requires that documentation of all quality assurance and risk management processes be contained in the credentials or personnel files of physicians who are the subjects of such review.

New York, Washington, Maryland, and Kansas specifically require that a quality assurance or peer review committee be responsible for acting to correct identified problems. In New York and Washington, the focus is on ensuring that risk management information is used to review and revise hospital policies and procedures. Maryland requires a process for referral of incidents and trend summaries to a medical staff committee for further action, while in Kansas the focus is on requiring an executive or peer review committee to recommend disciplinary action against hospital staff when necessary.

Required Patient Grievance Procedures

Patient grievance data are an important element in the risk management requirements of seven states. Of the 10 states we studied, only 3—Kansas, Colorado, and North Carolina—did not require grievance procedures. Maryland, which has one of the more detailed requirements for a patient complaint program, specifies that

- the risk management program must include a formal written program for addressing patient complaints;
- the hospital must give patients certain information about the program, including the name and phone number or address of a hospital representative that the patient may contact to make a complaint;
- the hospital's representative must treat the complaining patient with dignity and courtesy and due regard for privacy and must provide the patient with certain information about the complaint-handling process; and
- the hospital's representative must document the complaint and any action taken as a result of it.

Other states' requirements range from having all patients receive written notice of their rights within 24 hours of admission and be informed as to how they may file complaints (Massachusetts), to a general requirement that the hospital have a procedure to investigate, analyze, and respond to patient grievances related to patient care (Alaska).

Immunity and Confidentiality of Risk Management Information

Immunity and confidentiality provisions are designed to (1) shield those who report on or evaluate risk management information and (2) protect risk management records from subpoena, discovery, or other public disclosure.[1] Seven states provide for immunity from liability for those who provide information on incidents, while six provide for confidentiality. As shown in table II.7, Massachusetts, Florida, and Rhode Island provide for limited confidentiality of risk management records. But these states do not provide protection for documents that can be obtained from "original sources" or sources other than a peer review committee.

Table II.7: Immunity and Confidentiality Provisions Included in Legislation and Regulations

	AK	RI	FL	NY	KS	MD	WA	MA	CO	NC
Specifically prohibits retaliation/discrimination against employees who report incidents	•	•	X	•	X	•	•	•	X	•
Immunity from liability for those who provide risk management information in good faith	•	X	X	X	X	X	X	X	•	•
Immunity from liability for members of peer review, quality assurance, or risk management committee	•	X	X	X	X	X	X	X	•	•
Risk management documents generally confidential	•	•	Xa	X	X	•	X	•	•	•
Proceedings of medical staff/ peer review meetings confidential	•	•	•	•	X	X	•	•	•	•
Confidentiality specifically not provided for data obtained from other sources	•	X	•	•	•	•	•	X	•	•

aSome documents are discoverable (that is, may be revealed to opposing counsel but are not admissable in court).

Hospital Follow-Up or Review of Risk Management Activities

Provisions for the follow-up or review of a hospital's specific risk management actions were included in 5 of the 10 states' legislation and regulations. New York and Colorado both require hospitals to institute a method for evaluating the effectiveness of action taken by them to address risks or problems. Maryland requires that hospitals establish an internal committee structure to conduct reviews and evaluations of risk management activities. Massachusetts requires that hospitals create a system to assure compliance with incident reporting. The system must

[1] Information that is generally shielded from use in litigation is considered privileged. Most of the state laws providing this protection of risk management data, nonetheless, refer to it as confidential.

include random selection and review of patient charts to determine
whether incidents were identified and reported.

Table II.8: Risk Management Follow-Up Procedures Established

	AK	RI	FL	NY	KS	MD	WA	MA	CO	NC
Risk evaluation/follow-up[a]	X	•	X	X	X	•	•	X	X	•
Summary report of risk management actions to governing body	•	•	X[c]	X[c]	•	X	•	X[c]	X[b]	X[d]

[a]States that referred to "results of actions taken" were included as requiring follow-up.

[b]Administrator may receive reports instead.

[c]Reports quarterly.

[d]Reports annually.

An In-Depth Look at the Risk Management Requirements of Maryland and New York State

The legislative and regulatory requirements of Maryland and New York are relatively comprehensive and are presented in this appendix for illustrative purposes. Maryland is unique because it is the only state where the requirements represent a consensus of the hospital industry, legal interests, and the state government. New York has detailed requirements for a combined risk management and quality assurance program supported by an extensive, unique state survey process to monitor compliance.

Summary of Maryland's Risk Management Requirements

In 1986, Maryland enacted legislation requiring risk management programs in its 79 hospitals. Although there was little opposition to the risk management law when it was enacted, there were initial objections to regulations designed to implement it. The law had specified that minimum standards for a risk management program be established by the State Department of Health and Mental Hygiene in consultation with interested groups, including hospitals, physicians, and the Maryland Defense Bar and Plaintiffs' Bar. The groups eventually reached a consensus on the regulations' minimum standards, but the process of consultation took 18 months. The minimum standards include a designated risk management coordinator, commitment from hospitals' boards of directors, incident identification and evaluation, and a committee structure to review and evaluate hospital risk management activities. The law was part of a broader response to the malpractice crisis.

Required Program Elements

As of January 1, 1988, each hospital in the state was required to have a risk management program. The program—defined as a system designed to identify, evaluate, and reduce risks to patients in the provision of health care services—included the following elements.

Risk Management Coordinator

Each hospital must identify an individual as a risk management coordinator. The coordinator has three specified responsibilities:

- to coordinate risk management activities;
- to monitor all incidents related to patient care; and
- to provide for the flow of information among quality assurance, credentialing, peer review, and any risk management committee.

Board of Directors

The board of directors of each hospital must adopt a statement indicating its commitment to a hospitalwide risk management program. The

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board must also establish a mechanism for reporting risk management activities to it.

Incident Identification and Reporting

An identification and reporting process must exist to identify any circumstance or occurrence that may be injurious to a patient or that may result in an adverse outcome to a patient. Each hospital must further define for itself what constitutes a reportable incident and submit the resulting list of reporting criteria to the state. There is no formal evaluation of the list at the state level.

Other incident reporting requirements state that each hospital must

- set a time frame within which incidents must be reported,
- designate a representative to receive reports, and
- require that anyone aware of an incident who is employed by the hospital or appointed to the medical staff must report it.

The regulations also require quality assurance personnel to share information about incidents with the risk management coordinator.

Incident Review and Evaluation

There must be an incident review and evaluation process that provides for

- investigation of incidents,
- identification of trends among incidents,
- referral of incidents and trend summaries to evaluation committees when further action is necessary, and
- referral of incidents that require further action to medical staff credentialing and peer review committees for appropriate action.

Actions to Prevent Recurrence of Incidents

Risk management coordinators must refer identified problems to a medical staff committee. Any actions taken by quality assurance and peer review committees must be documented in committee minutes.

Internal Review of Risk Management

Each hospital must have a committee structure to review and evaluate hospital risk management activities. The regulations do not require that hospitals alter their existing committee structure or establish a risk management committee.

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| Patient Complaint Program | There must be a formal written program for addressing patient complaints, and patients must be provided with at least the name and phone number of a hospital representative to contact with a complaint. The hospital's representative must treat complaining patients with dignity, courtesy, and due regard for their privacy, and give them information regarding |

- whom in the hospital the patient may contact for information regarding the complaint,
- the procedure for investigating the complaint, and
- when the patient can expect a response or resolution to the complaint.

Each complaint and any action taken must be documented.

| Risk Management Education | Every hospital must establish risk management education programs for all staff. |

| Reporting to the State | Every hospital must submit a written description of its risk management program to the state. Any subsequent changes to the program also must be submitted. |

To accompany its risk management legislation and regulations, the state of Maryland established a process for surveying hospitals to determine their compliance with the requirements. The following discussion of that process is based both on documentation and on conversations with state officials.

State Monitoring of Hospital Risk Management Programs

Maryland's Department of Health and Mental Hygiene began surveying hospitals for compliance with the risk management regulations in spring 1988. By February 1989, a survey team consisting of a physician, two nurses, and sometimes the program director had surveyed 33 hospitals. The surveyors' main focus was on (1) whether risk management and other performance information was included in the files used to review a physician's performance at the time of reappointment and (2) whether a reasonable evaluation was made of that information.

Most of the 33 hospitals surveyed were out of compliance with the risk management requirements in some respect. Eight were cited for a deficiency related to collection of risk management, quality assurance, or

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utilization review data. For example, at these hospitals "physician-specific risk data are not collected in a planned, systematic, and formalized manner to provide information for evaluation at the time of reappointment." Twelve hospitals have been cited for insufficient integration of risk management and other data with credentialing. Seven were cited for inadequate risk management education programs, and five had inadequate documentation of the risk management process. For example, one hospital's risk management plan did not describe risk management educational programs for all hospital staff or adequately describe the patient complaint program. Ten had not complied with state requirements for a patient complaint program.

When a hospital is not in compliance with the regulations, it must submit a plan of correction. Ultimately, a hospital can lose its license or be fined $500 per day for noncompliance. According to a state official, all hospitals with findings against them had submitted corrective action plans as required, and no further state enforcement action is planned.

Summary of New York's Risk Management Requirements

In 1980 and 1981, New York State Department of Health investigators found inadequate patient care conditions in several New York hospitals that resulted in the state placing sanctions on these hospitals. Hospitals' liability insurance rates rose simultaneously. The State Department of Health and the state legislature responded by developing and implementing a statewide incident reporting system,[1] requirements for a quality assurance and risk management program, and a comprehensive facility survey process. It also continued to investigate complaints about health care providers. State officials believed that by increasing the data available to them regarding each facility, they could better identify problems and assure that the problems were being addressed.

New York's 1985 Medical Malpractice Law—which contained the state's risk management requirements—was enacted at about the same time as tort reforms aimed at reducing the cost of malpractice claims. New York requirements treat hospital quality assurance, risk management, credentialing, and peer review processes as a single, integrated process for enhancing the quality of care and preventing malpractice.

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[1] New York requires that specified incidents be reported to the state within 24 hours of when they occurred or of when the hospital has reasonable cause to believe they occurred.

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Required Program Elements

As of August 1986, every hospital licensed in the state had to maintain a quality assurance and risk management program for identifying and preventing medical malpractice. The requirements related only to those aspects of risk management that relate to patient care.

Quality Assurance and Risk Management Committee

A committee, rather than an individual, is responsible for overseeing each hospital's program and assuring that the required quality assurance, risk management, and other information is used to review and revise the hospital's policies and procedures. The multidisciplinary committee must include at least one member of the governing body and members of the hospital's medical staff, nursing staff, administration, and clinical and support departments.

The committee is charged with developing a comprehensive quality assurance and risk management plan detailing

- the program's objectives;
- a statement affirming the support of the hospital administrator, the governing body, and the medical staff for the program;
- a description of the reporting lines and the relationships between the committee and the remainder of the hospital;
- a statement attesting that every hospital or department or service must be involved in the program and delineating the quality assurance and risk management responsibilities assigned to each department;
- a definition of the committee's authority to recommend and implement corrective actions; and
- a statement assuring the confidentiality of all data collected for the program.

Governing Body Involvement

Each hospital's governing body is accountable for the hospital's quality of care. The three specific requirements for involvement are:

- one member of the governing body must be a member of the quality assurance and risk management committee;
- the governing body must state its support for quality assurance and risk management; and
- governing body bylaws must provide mechanisms for approval of medical staff bylaws, including those related to the appointment and reappointment of physicians.

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Problem Identification	Hospital quality assurance and risk management staff are required to examine specific information in order to identify problems with patient care. The quality assurance and risk management committee also is responsible for reviewing the work of all hospital staff. In addition, it must review deaths, unimproved cases, and morbidity (sickness) in circumstances other than those related to the natural course of disease or illness. The committee also is responsible for reviewing infections, complications, errors in diagnosis, transfusions, and results of treatments. Other documents that must be reviewed include medical records, medical care evaluation studies, complaints, incidents, staff suggestions regarding patient care or safety, utilization review findings, and physician profile analyses.
Review, Evaluation, and Correction of Identified Problems	The quality assurance and risk management program must assess the cause and scope of the problems or concerns identified. The hospital then must implement, through established mechanisms defined in its comprehensive plan, the action necessary to correct identified problems.
Education	Hospital policies must require all staff to receive orientation training and annual in-service training in the following areas:

- patients' rights,
- organization and goals of the quality assurance and risk management program,
- patient relations and complaint program,
- incident reporting program,
- reporting responsibilities for alleged professional misconduct,
- safety program, and
- department-specific safety practices.

Patient Grievance Procedure	Every complaint from a patient or the patient's designated representative must be investigated promptly and thoroughly. When a patient requests a written response, the hospital must provide one that details the results of the complaint investigation. A patient who expresses dissatisfaction with the findings must be directed to the State Department of Health.

Copies of the Patients' Bill of Rights must be provided to all patients or their representatives on admission to the hospital and posted in conspicuous areas throughout the hospital. |

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| Internal Documentation | Hospitals are required to document fully the implementation of all of the medical staff quality assurance and risk management review processes. Such documentation should be contained in the minutes of the medical staff committee conducting the review, as well as in the credentials or personnel files of the physicians and dentists who are subjects of such reviews. Specifically, a profile of each physician and dentist must be compiled from at least the following data sources: |

- morbidity and mortality review,
- blood utilization review,
- infection control review,
- utilization review,
- safety committee review,
- Peer Review Organization data,
- surgical case review,
- any medical care evaluations performed,
- tissue review,
- medical record review,
- incident report review,
- complaints,
- liability claims data,
- prescription review,
- medical case review, and
- continuing education programs and other training.

In addition to permanently maintaining complete files of all quality assurance and risk management documentation, the hospital must retain all malpractice liability coverage documentation, individual malpractice case files involving the hospital, and records of all expenses incurred in safety programs to reduce or eliminate patient injuries.

| Appointment, Reappointment, and Discipline of Medical Staff | Every 2 years, each hospital must review each employee's credentials, physical and mental capacity, and competence as part of an evaluation of staff privileges. Specific information must be collected before renewing an association with a provider. |

There must be a defined disciplinary process for violations of hospital procedures.

Also, hospitals must collect and consider information related to the physician's professional practice (both within the facility and at other facilities) within the last 10 years.

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Reporting to the State

Hospitals must report any sanctions on privileges for reasons related to incompetence, alleged mental and physical impairment, malpractice, or receipt of information concerning criminal conviction of a crime within 30 days of occurrence. They also must report the voluntary or involuntary resignation or withdrawal of staff privileges to avoid disciplinary measures.

The state's incident reporting program, adopted first by regulation in 1985 and later by legislation in 1986, requires that the following types of incidents be reported to the state:

1. Patient deaths or impairments of bodily functions in circumstances other than those related to the natural course of illness, disease, or proper treatment in accordance with generally accepted medical standards.

2. Fires in the facility that disrupt the provision of patient care services or cause harm to patients or staff.

3. Equipment malfunction during treatment or diagnosis of a patient that adversely affected or could have adversely affected a patient or health facility personnel.

4. Poisoning occurring within the facility.

5. Strikes by facility staff.

6. Disasters or other emergency situations external to the hospital environment that affect health facility operations.

7. Termination of any services vital to the continued safe operation of the health facility or to the health and safety of its patients and personnel.

The incidents must be reported within 24 hours of the occurrence or of the hospital's knowledge of an occurrence. For the first four categories of incidents, the hospital must estimate the date it will complete an internal investigation. A copy of the investigation report is due within 24 hours of that date.

In addition to providing hospitals with more detailed requirements for their quality assurance and risk management programs than many other

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states, New York also has instituted an extensive program for monitoring hospitals' compliance with the requirements. The following discussion is based on state documentation and conversations with state officials.

Implementation Monitoring

New York State has the most extensive monitoring and enforcement system of the 10 states that have implemented risk management legislation or regulations. Officials we spoke with at the State Department of Health were unaware of any other state with a similar system for surveying hospitals. They stressed that the system is new and will evolve based on survey experience.

Incident Reporting

State Department of Health officials can, at their discretion, investigate any of the incidents reported under the incident reporting program. According to state officials, since the inception of the program, the quality of hospitals' internal incident investigations has improved, requiring a smaller proportion of investigations by state officials. When the program was first implemented, officials investigated about 15 percent of incidents. In 1987, the figure was 11 percent, and at the time of our visit about 9 percent of incidents were being investigated.

The number of incidents reported to the state has increased from 1986 to 1988, but officials believe this is due to better knowledge by the hospitals of their incidents or better compliance with the reporting requirements or both rather than a true increase in patient injuries. Underreporting and overreporting of incidents by hospitals continue to limit the usefulness of the data, despite attempts to clarify what must be reported.

Annually, the state publishes a general summary of the incident data; however, on request, hospitals may obtain more specific data on their status relative to a smaller group of hospitals in their area. As of June 1988, about 12 hospitals had requested this type of information.

Comprehensive Survey

Between July 1988 and January 1989, five teams of surveyors conducted comprehensive surveys of 25 hospitals. The state plans to survey every licensed hospital in New York every 3 years using a team including at least two nurses, one physician, and one survey coordinator. The survey process includes reviewing the hospital's history, including Joint

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Commission reports; reviewing care based on examination of approximately 100 patient charts; observing patient care directly; and writing a statement of deficiencies, if necessary. Detailed protocols guide surveyors in their work.

According to state officials, about one-fifth of the hospitals surveyed thus far have had quality assurance and risk management programs that the state viewed as very effective; the rest were found to have deficiencies. Fines will be levied against any facility found to have major problems.

Insurance Companies Endorse Risk Management Programs

Since the malpractice crisis of the 1970s, insurance companies have played a key role in encouraging their insured hospitals to implement risk management programs. During this review, we contacted four companies that insure over one-third of the nation's 6,841 hospitals and found that each endorses the use of hospital risk management programs.[1] In their view, such programs help identify potential problems that, if uncorrected, may contribute to patient injuries and possible malpractice claims.

Each company conducts periodic surveys of its insured hospitals' risk management activities and may require program improvements as a condition of continued professional liability coverage. One company varied the premiums it charged hospitals based on the adequacy of their risk management activities. None of the organizations required its insured hospitals to use a prescribed risk management program. One insurance company official expressed the view that prescribing specific risk management programs would be inappropriate in view of the varying characteristics of hospitals in terms of their size, organizational structure, services offered, type of ownership, and preexisting review mechanisms, such as quality assurance departments that can be duplicative of certain risk management activities. Each company offered a variety of risk management services to their insured hospitals.

Although these companies do not require specific types of risk management programs, each conducts periodic surveys of their insured hospitals' risk management activities. After such a survey, the company may require implementation of corrective recommendations or improvements as a condition of continuing professional liability insurance coverage. At PHICO, for example, surveys of professional and general liability risk management activities are usually done every 3 years after initial survey by field representatives. Professional liability surveys include assessments of the effectiveness of the hospital's governing bodies and management, credentials of the medical staff, and the quality of medical records. At the general liability level, the surveys address the overall quality of care provided by the hospital and assess the risk management activities of the various departments, including anesthesia services, emergency services, nuclear medicine, laboratory, pharmaceutical services, radiology, and others.

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[1]St. Paul Fire and Marine Insurance Company; MMI Companies, Inc., Pennsylvania Hospital Insurance Company; and Farmers Insurance Group of Companies.

At MMI there is a direct relationship between the results of the risk management survey and the annual insurance premium paid by a given hospital. An MMI official told us that hospitals with questionable risk management assessments could be charged significant premium surcharges. Officials of the remaining companies stated that there may be an indirect relationship between the effectiveness of hospital risk management activities and annual premium levels. Hospitals with effective risk management programs could experience a decrease in the severity and frequency of malpractice claims. This, in turn, could eventually result in lower annual premiums, because claims history is often a factor in the premium determination calculation.

Risk Management Services Provided to Insured Hospitals

Each of the insurance companies we contacted offers insured hospitals a variety of risk management services. These services include consultation services, educational programs, publications, closed-claims studies, and software packages.

Consultation Services

Consultations between insurance company representatives and hospital risk management personnel are designed to help the hospital minimize its risk of malpractice claims. For example, at MMI these services may include auditing of claims, chart review, policy review, and evaluation of specific clinical areas. At Farmers, risk management consultation services are provided by professional liability representatives who have a specific group of hospitals assigned to them. These individuals spend their time in loss prevention and loss control activities. In this role, they keep up to date with changes in laws and standards of practice having implications for hospital liability, including lessons learned from cases involving actual losses and case law decisions.

Educational Programs

Educational services are provided to help hospitals minimize the frequency and severity of malpractice claims. These services can be provided in several formats, including national, regional, local, and hospital seminars and individualized training programs. MMI, for example, has divided its client education programs into two categories—national seminars and focused training workshops. The national seminars are designed to allow representatives of all insured hospitals to meet and discuss clinical, administrative, and legal risk management issues of

national appeal. Focused training workshops are intended to give individual risk managers a more in-depth examination of issues that directly affect the insured hospital.

MMI also offers a Healthcare Risk Management Certificate program for its risk managers. The program was developed in 1987 in consultation with the School of Related Health Sciences, Chicago Medical School, and was designed to give participants schooling in an emerging profession—risk management. The program is divided into 10 courses that can be completed while the risk manager continues to work. Each course consists primarily of self-study, specified readings, study questions, and projects. At the end of each course, participants must also complete a course summary, which consists of face-to-face instruction and evaluation by qualified faculty. The courses cover a variety of hospital risk management topics, including

- an overview of health care risk management,
- the identification and evaluation of risk exposure in the health care setting, and
- the health care risk management function.

Publications

Each of the companies we contacted periodically publishes materials designed to help hospitals manage their malpractice liability risk. These publications range from single-issue pamphlets addressing such topics as ways to prevent malpractice claims to regularly issued newsletters and bulletins addressing many topics on the subject. PHICO, for example, uses a multifaceted approach to communicate with its insured hospitals on how to reduce the number and severity of malpractice claims. First, all hospitals insured by PHICO receive a four-volume publication on risk management issues that is intended to assist management in doing more effective risk management. In addition, each hospital is sent bimonthly additions of updated materials that are to be inserted into the publication. Second, each hospital is provided with a bimonthly bulletin that gives risk managers current information related to the issue of malpractice liability insurance and how to avoid such claims. Third, each hospital receives a regular publication entitled Case Alerts, which gives the hospitals information about actual malpractice cases and what could have been done to more effectively manage the risk before the suit was filed. Fourth, hospital policyholders are offered a number of videotapes, films, and slide presentations on a wide variety of malpractice issues. Some of those available are entitled "Malpractice in the Emergency Department," "Medication Errors," and "Surgery: Minimizing Risks."

Claims Studies

Each of the insurance companies maintains a data base of open and closed malpractice claims filed against insured hospitals that are routinely analyzed to identify lessons learned so that future claims can be avoided. At Farmers, for example, professional liability representatives periodically analyze claims to identify factors that may have caused their submission. The factors are evaluated by the insurance company representatives and hospital officials in an effort to correct situations that led to the claim. The process is facilitated by computer reports that identify the frequency and severity of malpractice claims.

Software Packages

St. Paul offers its insured hospitals a software package that enables them to track and analyze physician performance in terms of, among others, adverse patient occurrences, infection rates, and pharmaceutical complications—all factors that can lead to later malpractice suits. This software is intended to enable hospitals to operate a more informed medical staff credentialing process by helping them to track trends that reflect physician performance. Hospital medical staff credentials committees making use of this information are in a better position to make more informed decisions regarding whether particular physicians should be allowed to practice.

Occurrence Reporting Systems Are Important Risk Management Tools

Occurrence reporting systems—a key element of an effective risk management program—are used in many hospitals. MMI, PHICO, and St. Paul have each developed their own systems and either require or encourage their insured hospitals to use them.

MMI requires each insured hospital to implement its Clinical Risk Modification programs. The programs, first introduced in 1985, focus on identifying and eliminating preventable patient injuries in three high-risk areas—obstetrics, anesthesia, and emergency department services. The programs are intended to assist hospitals in evaluating policies and procedures, identifying questionable clinical practices that make the hospital more vulnerable to malpractice suits, and enhancing its ability to review the quality of medical care provided.

The Clinical Risk Modification programs consist of three essential components: risk modification guidelines, statistical indicators and periodic reporting, and case review. The first component requires hospitals to adopt guidelines to identify and correct unsatisfactory situations before they result in malpractice claims. The second component requires hospitals to monitor on an ongoing basis certain indicators or occurrences

that tend to identify areas of concern regarding medical liability. One such indicator, developed for anesthesia services, is the number of cardiac arrests that occur within 24 hours of receiving anesthesia. Hospitals are required to submit monthly statistical reports on the incidence of such indicators to MMI for review and analysis.

The third component consists of a review of specific cases that have been identified as potential problems by ongoing screening activities. Hospitals are expected to establish and maintain a system of case review, and MMI may require hospitals to submit certain cases for follow-up review.

PHICO encourages insured hospitals to implement an occurrence reporting system called the PHICO Event Reporting and Trending System. This system calls for physicians, nurses, or other employees who discover or witness certain events to report them to the risk manager and other responsible hospital officials. Some of the events to be reported are specified and are generally described as patterns of care that are not consistent with the routine care of a particular patient or the routine operation of the facility.

Hospitals participating in the program are required to submit weekly reports to PHICO's Risk Management Department for inclusion in a trending and analysis report. These reports are forwarded to the hospital's risk manager and quality assessment coordinator for the identification of developing trends. They are also provided to risk management and quality assessment committees of the insured hospital for analysis and for the development of recommended corrective actions. Implementation of the recommendations, approved by the hospital's administration, is the responsibility of the risk manager or department head. As of December 31, 1988, 430 of the 504 PHICO-insured hospitals participated in the occurrence reporting program.

St. Paul also endorses the use of occurrence reporting and, since 1986, has provided policyholders with a computer software package enabling them to operate such a system. In essence, the system enables hospitals to track certain adverse experiences that may lead to malpractice allegations and suits. Some of the listed adverse experiences include drug overdoses, infections, neurological impairments, and skin injuries. Other events recorded by the software include unexpected returns to surgery, birth injuries, and unplanned admissions to the hospital following outpatient treatment for the same or a similar condition.

The aforementioned insurance companies are actively involved in, and supportive of, risk management activities. For the most part, however, they are not offering any premium concessions for hospitals that have such programs. This may be caused, in part, by the fact that there is not enough empirical evidence currently available to show a direct relationship between effective risk management and claims reduction.

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