

Report to the Chairman, Committee on Ways and Means, House of Representatives

September 1995

MEDICAL LIABILITY

Impact on Hospital and Physician Costs Extends Beyond Insurance





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

Accounting and Information Management Division

B-260671

September 29, 1995

The Honorable Bill Archer Chairman, Committee on Ways and Means House of Representatives

Dear Mr. Chairman:

As the Congress considers a number of legislative proposals intended to reduce tort liability in the health care industry, little consensus exists on the extent to which medical liability-related spending contributes to overall hospital and physician expenditures, a central issue in the health care reform debate. While such costs have long concerned hospitals and physicians, some economists and health care policy analysts assert that medical liability is not a major factor affecting health care costs. To provide a more comprehensive picture of medical liability's impact on hospital and physician costs, you asked us to identify and describe the types of medical liability costs that affect hospitals and physicians and to determine whether existing studies include these costs in their estimates of hospital and physician liability expenses.

Results in Brief

Widely cited estimates of hospital and physician medical liability costs are often misinterpreted. These estimates, roughly 1 percent of national health care expenditures, represent only a portion of all hospital and physician medical liability costs, generally those associated with malpractice insurance premiums. However, hospitals and physicians incur and pass on to consumers additional expenses that directly or indirectly relate to medical liability. Therefore, estimates of malpractice premiums—taken by themselves—understate the total effect of medical liability costs on national health care expenditures.

A more complete description of these costs would include the following four categories:

- medical malpractice insurance costs: insurance premiums, contributions to self-insurance trust funds, and uninsured losses;
- defensive medical costs: medical treatment that would not be provided if there were no threat of being sued;
- <u>liability-related administrative costs</u>: nonmedical activities performed to minimize the risk of liability and the expenses associated with legal

- actions that do occur, such as the management and settlement of claims; and
- medical device and pharmaceutical liability costs: manufacturers' insurance and liability-related production and warning costs passed on in the price of their products.

With the exception of commercial malpractice insurance premiums, only a portion of the first category mentioned above, medical liability costs have not been fully measured. State insurance laws generally require licensed insurance companies to report the costs of physician and hospital malpractice insurance policies and, thus, these costs are easily quantifiable. Because these reporting requirements do not capture other aspects of insurance costs, such as hospital self-insurance and uninsured losses, those costs are more difficult to quantify. In addition, due to the absence of information on liability costs in the medical device and pharmaceutical industries, costs that they pass on to hospitals and physicians are also difficult to quantify. Furthermore, the cost of defensive medicine is difficult to measure because it has not been clearly defined and "defensive" practices cannot be distinguished easily from medical care provided for clinical reasons. Similarly, for liability-related administrative cost estimates, it is difficult to distinguish hospital and physician activities designed to improve service quality or adhere to accreditation standards from activities intended to minimize medical liability.

Background

The major goals of medical tort laws are to (1) deter poor quality health care, (2) compensate the victims of negligent acts, and (3) penalize negligent providers. The system operates under the assumption that negligent behavior can be controlled and corrected by the hospitals and physicians themselves. It relies primarily on deterrence due to the threat of liability and disciplinary action. While this report focuses on the cost of medical liability borne by hospitals and physicians, the deterrence threat of tort law may lower costs incurred by consumers by reducing the number and severity of negligent medical acts. (See appendix I for a discussion of the legal basis for medical liability actions.)

At least two factors have prompted calls for medical liability reform. First, some research suggests that the medical tort system is not achieving its goals. For example, one study reported that only a fraction of malpractice injuries result in claims, compensation is often unrelated to the existence of medical negligence, the legal system is slow at resolving claims, and legal fees and administrative costs consume almost half of the

compensation.¹ The second factor is the perception among some hospital officials and physicians that the current tort system places an unreasonable burden on their industry. Officials from the American Hospital Association and the American Medical Association contend that liability-related costs are too high and unduly influence the way hospitals deliver services and physicians practice medicine. The Congress has before it a number of legislative proposals that are intended to directly and indirectly reduce tort liability in the health care industry.

Scope and Methodology

To identify the various types of medical liability costs, we interviewed and collected data from a variety of sources, including the American Hospital Association, the American Medical Association, the American Bar Association, the St. Paul Fire and Marine Insurance Company,² and individual hospitals and hospital systems. In addition, we reviewed recent professional and academic journals, such as the <u>Journal of the American Medical Association</u> and Health Affairs.

From our research, we identified three studies that estimate certain hospital and physician medical liability costs. These studies were prepared by the General Accounting Office (GAO),³ the Congressional Budget Office (CBO),⁴ and the Office of Technology Assessment (OTA).⁵ We reviewed these studies to determine whether their estimates included all types of medical liability costs. In addition, we examined other studies that (1) estimated components of medical liability costs not included in these three studies or (2) used different methodologies to arrive at their estimates.

We cannot project costs or generalize our findings because we did not use statistical methods to select the sources of the liability cost data we collected and did not collect data associated with all four categories of

¹Patients, Doctors, and Lawyers: Medical Injury, Malpractice Litigation, and Patient Compensation in New York, a report of the Harvard Medical Practice Study to the State of New York (Cambridge, Mass.: President and Fellows of Harvard College, 1990).

²The St. Paul Fire and Marine Insurance Company is the largest malpractice insurer in the United States. Its share of the medical malpractice insurance market was 11.6 percent in 1993.

³Medical Malpractice: Insurance Costs Increased but Varied Among Physicians and Hospitals (GAO/HRD-86-112, September 15, 1986).

⁴A CBO Study: Economic Implications of Rising Health Care Costs, CBO (October 1992), and Statement of Robert Reischauer, CBO, before the Committee on Ways and Means, U.S. House of Representatives, Appendix F, March 4, 1992.

⁵Impact of Legal Reforms on Medical Malpractice Costs, OTA (September 1993).

liability costs we identified. Also, because our work often involved data that some sources regarded as proprietary or sensitive, we agreed not to identify some sources in examples cited in our report. We did not verify the accuracy of the data.

We performed our review from January 1995 through April 1995 in accordance with generally accepted government auditing standards. We discussed a draft of our report with CBO and OTA officials and have incorporated their comments where appropriate.

Studies Focused on Purchased Malpractice Insurance

Malpractice insurance is the first category of medical liability costs we identified and the cost specifically measured by each of the three studies. Most physicians and hospitals purchase medical malpractice insurance to protect themselves from medical malpractice claims. In most cases, the insurer will pay any claims up to a specific limit of coverage during a fixed period in return for a fee. The insurer investigates the claim and defends the physician or hospital. While hospital and physician insurance contracts can vary greatly, we have included the following types of costs in the medical malpractice insurance cost category:

- premiums for purchased insurance,
- hospital contributions for self-insurance, and
- payments made from hospitals' general revenues and reserves and physicians' personal assets to cover uninsured malpractice losses.

(See appendix II for a detailed discussion of the types of hospital and physician insurance policies and related costs.)

The Studies Measured Components of Malpractice Insurance Costs

The CBO and OTA studies estimated costs primarily associated with purchased insurance. The CBO study reported the cost of purchased insurance in 1990, which totaled \$5 billion and represented 0.74 percent of national health care expenditures. The OTA study measured purchased insurance and self-insurance costs in 1991 and reported that purchased insurance totaled \$4.86 billion in 1991, or 0.66 percent of national health care expenditures. The study estimated self-insurance costs at 20 percent to 30 percent of premiums, which would mean that purchased insurance and self-insurance amounted to between \$5.8 billion and \$6.3 billion in 1991, less than 1 percent of national health care expenditures.

Other studies that measured purchased insurance and self-insurance for the same periods studied by CBO and OTA estimated costs to be higher. Tillinghast, an actuarial and consulting firm, used its internal database of state-by-state malpractice insurance costs rather than insurance industry data because those data do not include self-insurance. Tillinghast estimated malpractice insurance costs in 1990 at over \$8.2 billion. Another consulting firm, Lewin-VHI, Inc., used an estimate that malpractice insurance other than that purchased represents 86 percent of purchased insurance. This firm estimated malpractice insurance costs at \$9.2 billion in 1991. Table 1 summarizes the estimates of malpractice insurance costs in 1990 and 1991.

Table 1: Estimates of Costs for Malpractice Purchased Insurance and Self-Insurance for 1990 and 1991

Dollars in billions		
Source of estimate	Amount	
Estimates for 1990 CBO Tillinghast	\$5.0 ^a \$8.2	
OTA Lewin-VHI, Inc.	\$4.86 \$9.2	

^aThe CBO estimate included only the cost of purchased insurance, not self-insurance.

Our mid-1980s study measured all elements in our malpractice insurance cost category. To obtain information on hospital malpractice insurance costs, we analyzed data from a randomly selected sample of 1,248 hospitals. We obtained physician malpractice expense data from (1) American Medical Association reports quantifying expenses incurred by every known self-employed physician in the United States and (2) information collected from leading physician malpractice insurance companies. We reported that malpractice insurance costs for self-employed physicians averaged 9 percent of their total professional expenses in 1984, while malpractice insurance costs for hospitals accounted for 1 percent of their average inpatient per-day expense in 1985. Insurance company officials stated that the insurance market has changed since 1985 as more hospitals have established self-insurance programs and increased their self-insurance limits, thereby reducing their reliance on purchased insurance. However, the impact of this trend on costs has not been measured.

⁶Tillinghast, Tort Cost Trends: An International Perspective, 1992.

⁷Lewin-VHI, Inc., "Response to Medical Malpractice Article," memorandum to Jay Michael, President, Californians Allied for Patient Protection, April 15, 1994.

Malpractice Insurance Costs Affect Some Physicians and Hospitals More Than Others Physician malpractice insurance costs vary by state and can vary within a state. Figure 1 presents The St. Paul Fire and Marine Insurance Company's 1994 rates for mid-range liability risk physician⁸ mature claims-made policies⁹ with limits primarily at \$1 million/\$3 million.¹⁰ In certain states, lower limits are mandatory or more common due to patient compensation funds.¹¹ Variations by state and within states generally reflect the insurance company's claims and loss experience.

⁸A family practitioner performing standard obstetric procedures is an example of a mid-range liability risk physician.

⁹Generally, malpractice insurance is written on either an occurrence or a claims-made basis. An occurrence policy covers malpractice events that occurred during the policy period, regardless of the date of discovery or when the claim may be filed. A claims-made policy covers malpractice events that occurred after the effective date of coverage and for which claims are made during the policy period. Because the risk exposure to the insurer is lower, premiums for claims-made policies are generally lower during the first year of coverage but increase to approximate those of occurrence policies after about 5 years—when they "mature."

¹⁰Policy limits represent the maximum that the insurer will pay on each claim against the insured (per occurrence limit) and the maximum amount for all claims against the insured (aggregate limit) for the policy period. For example, limits of \$1 million/\$3 million means the insurer will pay up to \$1 million on a single claim and up to \$3 million for all claims during the policy period.

¹¹State-run patient compensation funds intend to limit the liability of participants to a specific amount and pay the full excess over that amount of any judgement or settlement against a member.

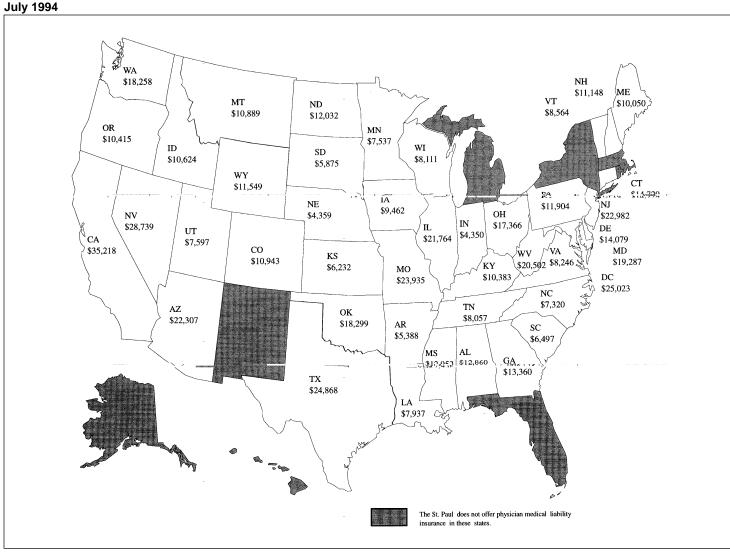


Figure 1: St. Paul Fire and Marine Insurance Company Average Annual Physician Malpractice Insurance Rates as of July 1994

Note: The rates are for policies with limits of \$1 million/\$3 million except for Wisconsin (\$400,000/\$1 million); Kansas, Nebraska, and Pennsylvania (\$200,000/\$600,000); and Indiana and Louisiana (\$100,000/\$300,000).

Source: The St. Paul Medical Services, Physician and Surgeon Update, June 1994.

Table 2 presents the rates the company provided for selected metropolitan areas that have rating territories separate from the remainder of their respective states. Across all rating territories, the annual premium for \$1 million/\$3 million coverage under claims-made policies ranged from a low of \$5,388 in Arkansas to a high of \$48,718 in Chicago.

Table 2: Average Malpractice Insurance Rates for Physicians as of July 1994 in Major Metropolitan Areas Established as Separate Rating Territories Compared With State Rates

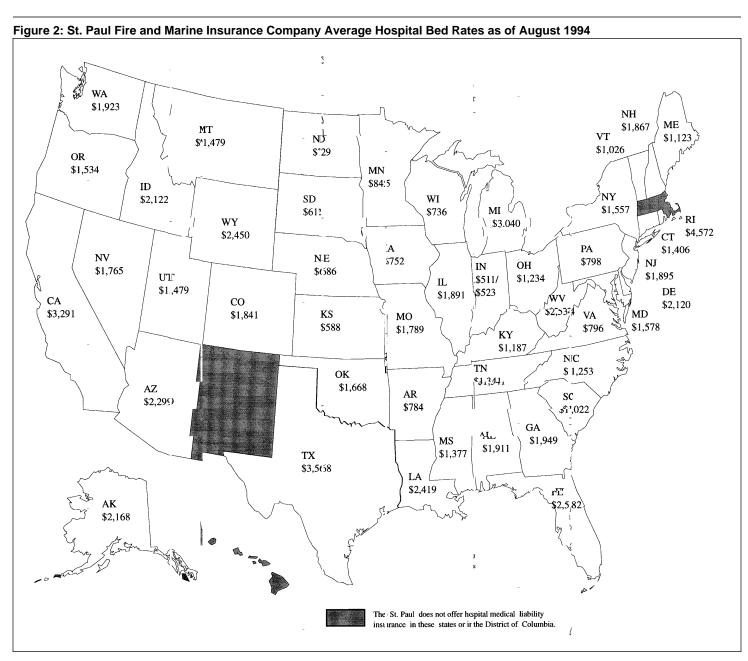
Metropolitan area	Metropolitan rate	State rate
Bridgeport, CT,	\$19,315	\$14,729
Chicago	\$48,718	\$21,764
Houston	\$37,246	\$24,888
Los Angeles	\$43,001	\$35,218
St. Louis	\$28,702	\$23,935
San Francisco	\$39,114	\$35,218

Note: These rates are based on class 3 doctor/mature claims-made rates with \$1 million/\$3 million limits

Source: The St. Paul Medical Services, Physician and Surgeon Update, June 1994.

Within each rating territory, physicians' malpractice insurance costs also vary by specialty. For example, one insurer's average 1993 mature claims-made rates for policies providing \$1 million/\$3 million coverage limits to physicians in Texas ranged from \$7,410 (except \$9,877 in Houston) for family practitioners performing no surgery, a low-risk practice, to \$54,834 (except \$73,089 in Houston) for physicians specializing in obstetrics and gynecology, a high-risk specialty. While malpractice insurance rates are generally insensitive to a physician's malpractice history, a physician's malpractice claims history can lead to denial or termination of coverage.

Hospital malpractice insurance costs vary according to claim trends in the state where the hospital is located, the number of occupied beds and outpatient visits, the limits of liability selected, the types of procedures performed, and the number of years the hospital has been insured under claims-made coverage. Malpractice insurance rates for hospitals are also frequently based on the malpractice loss experience (in terms of the number of claims filed and the amount per paid claim) of the individual hospital. Figure 2 presents The St. Paul Fire and Marine Insurance Company's per-bed average acute care rates for mature claims-made coverage at \$1 million/\$3 million limits of liability except in states where lower limits are mandatory or in states with patient compensation funds.



Note: The rates are for policies with limits of \$1 million/\$3 million except for Wisconsin (\$400,000/\$1 million); Kansas (\$200,000/\$600,000); Indiana (\$100,000/\$2 million and \$100,000/\$3 million); and Pennsylvania (\$200,000/\$1 million).

Source: The St. Paul Medical Services Hospital Update, August 1994.

Table 3 presents The St. Paul Fire and Marine Insurance Company's per-bed average acute care rates for hospitals in selected metropolitan areas that have rating territories separate from the remainder of their respective states. The annual per-bed rates ranged from a low of \$612 in South Dakota to a high of \$7,734 in Detroit.

Table 3: Average Acute Care Bed Rates for Hospitals as of July 1994 in Major Metropolitan Areas Established as Separate Rating Territories Compared With State Rates

Metropolitan areas	Metropolitan rate	State rate
Chicago	\$3,309	\$1,891
Cleveland	\$2,467	\$1,234
Detroit	\$7,734	\$3,040
Kansas City and St. Louis, MO	\$4,472	\$1,789
Los Angeles	\$4,114	\$3,291
Miami	\$3,367	\$2,582
New York City	\$3,424	\$1,557
Richmond	\$1,113	\$796
San Francisco	\$2,797	\$3,291

Source: The St. Paul Fire and Marine Medical Services Hospital Update, August 1994.

Defensive Medical Costs Were Not Measured

Defensive medicine includes the following hospital and physician actions aimed at reducing the risk of medical malpractice claims:

- additional or more complex diagnostic tests and procedures and
- additional patient visits and time spent with patients.

The costs of defensive medicine cannot be easily estimated because of difficulties in defining it and distinguishing it from clinically justified medical care. For example, if the definition includes only conscious defensive medicine, it could exclude defensive medical practices acquired during medical training. Thus, the definition would need to address the question of the physician's motive for performing tests: Should cost estimates for defensive medicine encompass only procedures performed for "purely" defensive purposes or should they also include procedures performed for "primarily" defensive purposes? Cost estimates would vary greatly depending upon the definition used. Also, it is difficult to segregate the costs of those defensive acts that produce little or no medical benefit from those that are medically justified, such as additional tests that rule out certain diagnoses.

Defensive medical practices can be classified as positive and negative. Positive defensive medicine involves tests and treatment that would not be provided if the threat of being sued were not present. For example, physicians may order more tests or procedures, take more time to explain risks or treatment options, and spend more time maintaining patient records than they would if there were no threat of malpractice suits. Negative defensive medicine involves not performing services because of the risk of malpractice actions. For example, physicians may restrict the scope of their practices to low-risk patients or procedures. While positive defensive medicine drives up the cost of health care, negative defensive medicine reduces its availability. The following discussion is limited to positive defensive medicine.

Certain physician specialists may practice more defensive medicine than others. Defensive medicine is generally considered to be more extensive in surgery, radiology, cardiology, emergency medicine, and obstetrics and gynecology. As we previously reported, in 1990 Maine imposed practice guidelines¹² by law that state officials expect will decrease these specialists' motivation to practice defensive medicine.¹³ These practice guidelines are intended to reduce the number of diagnostic tests and procedures that are performed for defensive purposes, including preoperative tests, such as some electrocardiograms and chest x-rays, cervical spine x-rays for some emergency room patients, some breast biopsies, and some colonoscopies. High rates of caesarean section are also cited as evidence of defensive medicine.

According to the results of our earlier review,¹⁴ the hospitals we visited analyzed their physicians' practice patterns in an effort to reduce costs. In some cases, the hospitals found that some physicians provided a significant amount of unnecessary or excessively sophisticated services but could not determine whether the provision of these services represents defensive medicine. For example, one hospital we visited

¹²Practice guidelines are also known as practice standards, protocols, algorithms, parameters, and preferred practice patterns. Maine's practice patterns attempt to resolve malpractice claims by specifying recommendations for medical treatment which, if followed by a physician, can be used to demonstrate that any injury to the patient did not result from negligent care.

¹³Medical Malpractice: Maine's Use of Practice Guidelines to Reduce Costs (GAO/HRD-94-8, October 25, 1993).

¹⁴Hospital Costs: Cost Control Efforts at 17 Texas Hospitals (GAO/AIMD-95-21, December 9, 1994).

reviewed its physicians' use of low osmolality contrast agents¹⁵ in its cardiac catheterization lab. Among health care professionals, the widespread use of low osmolality contrast agents is often viewed as a function of defensive medicine. Physicians use the low osmolality agents because high osmolality contrast agents have been associated with mild to moderate adverse reactions, such as nausea and vomiting, as well as more serious adverse reactions. The average cost of the low osmolality agent used in that hospital was \$146.10, compared to \$6.96 for the high osmolality agent, and represented 95 percent of the contrast media used in its cardiac catheterization laboratory. Because numerous research articles have suggested that the incidence of adverse effects were easily manageable and did not result in increased medical costs, the hospital limited the use of low osmolality agents to the approximately 30 percent of patients considered to be at high risk. Because the hospital performs 5,000 procedures in its cardiac catheterization laboratory annually, it projects yearly savings of over \$400,000. While hospital officials provided no conclusive evidence linking the unnecessary costs to defensive medicine, they stated that the physicians' desire to avoid adverse effects had prompted their use of the low osmolality contrast agent.

Neither our 1986 report nor the OTA study estimated the cost of defensive medicine. We reported that the cost of defensive medicine is impossible to quantify with any degree of confidence because of the difficulty in isolating defensive practices from medical care provided for clinical reasons. The OTA study, like our study, cited the difficulty in measuring the cost of defensive medicine and did not provide an estimate. The CBO study concluded that defensive medicine is probably not a major factor in the cost of medical care and did not provide an estimate.

In a separate study, ¹⁶ OTA reported that it found evidence that defensive medicine exists, estimating that as much as 8 percent of diagnostic procedures result primarily from physicians' conscious concern about professional liability. The strongest evidence found by OTA was produced in a study of caesarean deliveries in New York State. ¹⁷ That study reported that obstetricians who practice in hospitals with high malpractice claim

¹⁵A contrast agent is a substance used to improve the visibility of structures during radiologic imaging procedures such as angiography, computerized tomography, and cardiac catheterizations. Low osmolality contrast agents have an osmolality (that is, concentration of dissolved particles in solution) that is closer to the osmolality of body fluids than the other contrast agents.

¹⁶Defensive Medicine and Medical Malpractice, OTA, July 1994.

¹⁷Localio, Lawthers, Begston, Hebert, Weaver, Brennan, and Landis, "Relationship Between Malpractice Claims and Caesarian Delivery," vol. 269, <u>Journal of the American Medical Association</u>, pp. 366-373, January 20, 1993.

frequency and premiums do more caesarean deliveries than obstetricians practicing in areas with low malpractice claim frequency and premiums. However, ota also reported that it does not know whether the report's findings for obstetricians and caesarean deliveries can be generalized to other states, specialties, clinical situations, or procedures. Ota concluded that it is virtually impossible to accurately measure the overall level and national cost of defensive medicine because of the methodological problems associated with isolating defensive medical practices.

Through our research, we identified two studies that attempted to quantify the total cost of defensive medicine. An American Medical Association study estimated that in 1984, defensive medical costs were between \$9 billion and \$10.6 billion for primarily defensive medicine purposes. He \$10.6 billion estimate is based on the results of a physician survey, which may not accurately reflect the cost of defensive medicine. The \$9 billion estimate assumes a statistical correlation between an increase in physician fees and higher malpractice costs. This method might overstate the costs of defensive medicine because increases in fees might result from many factors besides physicians' defensive medical practices. A second study, prepared by Lewin-VHI, Inc., estimated hospital and physician defensive medicine costs at between \$4.2 billion and \$12.7 billion in 1991. This estimate is based primarily on the earlier AMA estimates and is subject to the same methodological limitations.

Liability-related Administrative Costs Were Not Measured

This third category of medical liability costs we identified includes

- certain risk management activities,
- time and travel associated with litigation, and
- creating and maintaining records subject to discovery²¹ or required for defense.

¹⁸The Hudson Institute, a not-for-profit research institute located in Indiana, estimated defensive medicine costs for one large urban hospital in Indiana. It reported that medical liability increased costs at the hospital by 5.3 percent, or \$450 per admission. It broke down the medical liability cost into two components: (1) defensive medicine, which accounted for 3.9 percent of the cost increase, or \$327 per admission, and (2) insurance, payments to patients, attorney's fees, and the cost of litigation, which increased costs by 1.4 percent, or \$123 per admission. David McIntosh and David Murray, "The High Cost of Medical Liability," Hudson Briefing Paper, No. 163, April 1994.

¹⁹Reynolds, R.A., et al, "The Cost of Medical Professional Liability," <u>Journal of the American Medical</u> Association, Vol. 257, No. 20, May 22/29, 1987.

²⁰Estimating the Costs of Defensive Medicine, Lewin-VHI, Inc., report prepared for MMI Companies, Inc., January 27, 1993.

²¹The term "discovery" refers to procedures for ascertaining facts prior to the time of trial.

Our study and the CBO and OTA studies did not attempt to provide a measure of liability-related administrative costs. Nor did we identify, during the course of our research and discussions, other studies that estimated hospital and physician liability-related administrative costs.

Hospital risk management activities are designed to (1) reduce the hospital's and its physicians' risk of malpractice suits by maintaining or improving the quality of care, (2) reduce the probability of a claim being filed by negotiating compensation with an injured patient prior to the patient filing a claim, and (3) preserve the hospital's assets once a claim has been filed. Risk management was first applied to health care facilities during the 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. Many hospitals intensified their risk management activities in the 1980s when an increasing number became at risk for malpractice losses as they began to self insure for smaller damage awards and settlements.

While hospitals perform some risk management activities specifically to reduce liability-related costs, they do not segregate the costs of these activities from the cost of practices designed to promote quality assurance or to satisfy accreditation standards. For example, occurrence screening systems—which are designed to identify deviations from normal procedures or expected treatment outcomes—involve costs associated with both promoting quality and reducing liability risk. By contrast, claims management is an example of a purely liability-related risk management cost. Claims management activities include claims investigation, claims filing, damage evaluation and reserve determination, planning remedial medical care, settlement strategy formulation, settlement structuring, and negotiating and "posturing" for defense or settlement.

Hospital officials and physicians also identified time spent at trials and other litigation-related events as liability-related administrative activities. As with liability-related risk management activities, hospitals and physicians did not routinely account for these activities separately. Examples of these activities include time and travel expenses associated with answering interrogatories and depositions. For instance, if a nurse is a defendant, the hospital will pay the nurse's expenses and salary while he or she prepares for and attends trial. The hospital would also incur additional costs contracting with a temporary nurse agency or using its supplemental nurse pool to perform the duties of the defendant nurse.

Similarly, a defendant physician would have to contract with another physician to care for patients during litigation.

Hospital officials also reported incurring additional liability-related administrative expenses associated with creating and maintaining records that may be required for defense. Such records would include detailed staffing schedules and precisely worded training, policy, and procedures manuals. Hospitals archive these records for decades since they may be needed for litigation long after an alleged negligent act. In some cases, hospitals spend considerable time locating physicians and other staff when malpractice actions involve events that occurred in the distant past, such as a law suit filed years after the birth of a child.

Medical Device and Pharmaceutical Liability Costs Were Not Measured

Hospitals and physicians incur the following types of medical device and pharmaceutical liability costs in the prices that they pay for their products:

- manufacturers' liability insurance and
- costs associated with product design and marketing that would not be incurred in the absence of the threat of suit.

Neither our study nor the CBO or OTA studies estimated manufacturers' medical device and pharmaceutical liability costs incurred in the purchase price hospitals and physicians pay for their products. During our research and discussions with industry officials, we did not identify other studies that estimated the liability costs passed on to hospitals and physicians in the prices of medical devices and pharmaceuticals.

Medical device and pharmaceutical industry officials and others we spoke with expressed concern about liability costs associated with medical products. They believe that litigation involving medical products is extensive and increasing. Because state product liability laws differ and most manufacturers sell products in many states, manufacturers are at risk of simultaneous suits in numerous jurisdictions with different legal standards. They also stated that drugs intended for chronic conditions or devices remaining in the body indefinitely may be used by patients for periods longer than the products were tested in clinical trials. As a result, problems may not be discovered until decades after use, when many patients may be using the product. Because only claims-made insurance is generally available for medical products, manufacturers with such coverage are not insured for suits in future years. When suits appear, the insurer can refuse to renew the policy, leaving the manufacturer without

insurance. Medical device and pharmaceutical industry officials told us that this legal environment drives up the cost of medical products.

Manufacturers pass on their liability costs to hospitals and physicians in their products' prices. Their liability costs include insurance and liability-related production and marketing costs. Manufacturer insurance costs, like those of hospitals, can include periodic self-insurance payments, payments made for purchased insurance, and payments made from general revenues to cover uninsured losses. Liability-related production and marketing costs include expenses associated with actions taken primarily to protect the manufacturer from liability, such as multiple layers of packaging and repeated safety warnings. ²²

Certain medical devices and pharmaceuticals involve a greater degree of liability risk than others. For example, stethoscopes pose little threat of liability risk. However, implanted devices such as heart valves, intrauterine devices, and breast implants have been involved in the most prominent medical device suits. Likewise, some pharmaceuticals like generic drugs and nonprescription drugs generally involve little risk of liability action. Most pharmaceutical litigation has involved brand name prescription drugs, such as Bendectin.²³

While some medical device and pharmaceutical cases and settlements have been widely publicized, such as those involving silicon breast implants and the Dalcon shield, little information is now available on the prevalence of litigation throughout the industry or the magnitude of the costs passed on to hospitals and physicians. Industry and insurance company officials stated that out of court settlements are common, and manufacturers are reluctant to disclose settlement terms for fear of encouraging new suits or inflating future claims. Manufacturers are also reluctant to disclose their pricing strategies because of competition.

Conclusion

Hospitals and physicians incur a variety of medical liability costs. Studies attempting to measure such costs have focused on the cost of purchased

²²Medical device and pharmaceutical industry officials believe that the threat of liability influences manufacturers' business operations in addition to imposing costs. The officials believe that some manufacturers will (1) not engage in research in areas with potential high litigation risk, (2) not market high-risk products, (3) withdraw high-risk products from the market, and (4) attempt to minimize the use of their products by potentially high-risk patients, such as children and women of child-bearing age.

²³Garber, Steven, Product Liability and the Economics of Pharmaceuticals and Medical Devices, prepared for the RAND Institute for Civil Justice, 1993.

malpractice insurance, which is readily quantifiable due to state reporting requirements. Other hospital and physician liability costs, however, are impractical, if not methodologically difficult to measure with any precision. Such costs include defensive medicine, liability-related administrative expenses, and medical device and pharmaceutical manufacturers' liability expenses that they pass on to hospitals and physicians in the prices of their products. However, a broader understanding of such costs and their implications is useful to the ongoing medical liability reform debate.

As agreed with your office, unless you publicly announce the contents of this report earlier, we will not distribute it until 30 days from its date. At that time, we will send copies to the Ranking Minority Member of the House Committee on Ways and Means and to other interested Members of the Congress. Copies of this report will also be available to interested parties upon request.

Please contact me at (202) 512-9542 if you or your staff have any questions concerning this report. Major contributors are listed in appendix III.

Sincerely yours,

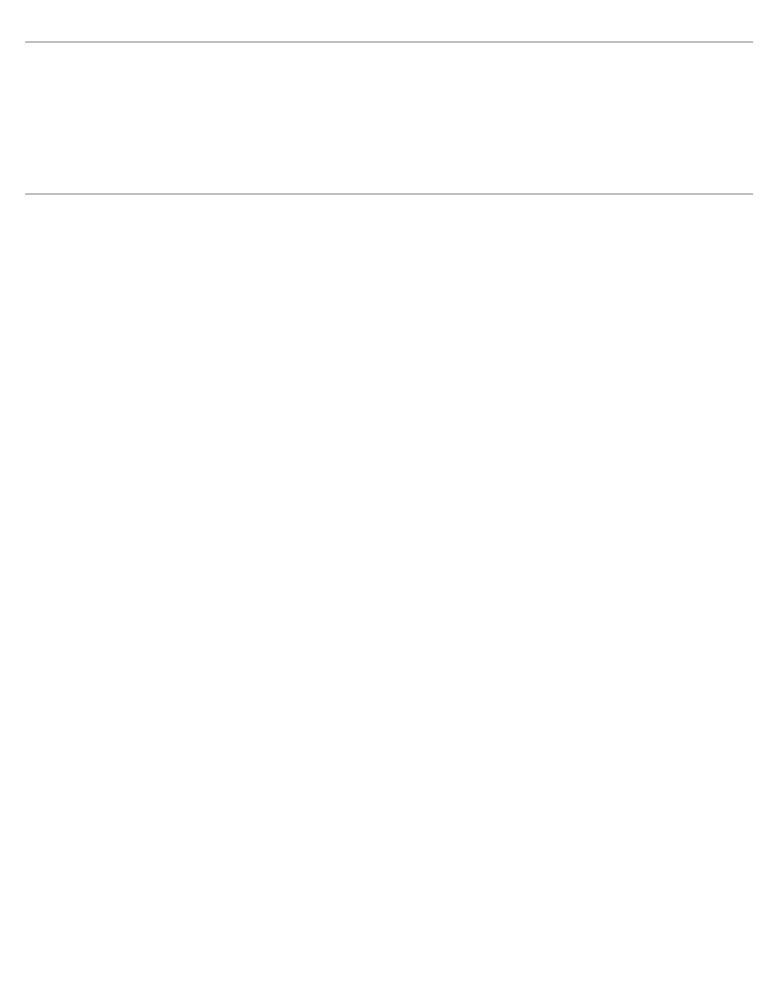
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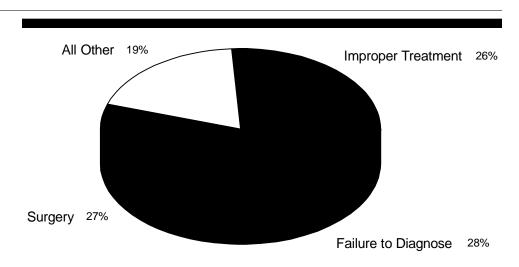


Legal Basis for Medical Liability Actions

Generally, medical malpractice suits are based on tort law. Plaintiffs select tort theory instead of alternatives, such as breach of contract, because they may recover larger damages and because the statute of limitations generally runs from the date the harm was discovered rather than the date the alleged malpractice occurred. When a third party such as a surviving spouse or parent brings suit, it generally must select tort theory because the plaintiff is neither a party to the original contract nor a third party beneficiary.²

Figure I.1 summarizes the types of malpractice action filed against physicians insured by The St. Paul Fire and Marine Insurance Company during the 5-year period from 1989 through 1993.

Figure I.1: Types of Malpractice Claims Filed Against Physicians Insured by the St. Paul Fire and Marine Insurance Company, 1989-1993



Source: The St. Paul Medical Services, Physicians and Surgeons Update, June 1994.

According to The St. Paul Fire and Marine Insurance Company, failure to diagnose was the most common malpractice claim—28 percent of all

¹Although a written contract between a patient and a physician generally does not exist, a contract is implied in fact. If a contract was not created, a physician would not have a cause of action for fees against a patient for not paying for services rendered.

²A third party beneficiary is a third person whom the parties to a contract intend to benefit by the making of the contract and to confer upon such person the right to sue for breach of contract, such as a life insurance contract wherein the insurance company promises the insured to make payments to the beneficiary.

claims—filed against physicians it insured during the 5-year period spanning 1989 through 1993. Failure to diagnose cancer was the most common claim in this category. Other frequent failure to diagnose claims involved fractures and dislocations, infections, myocardial infarctions, and pregnancy problems. Claims stemming from surgical procedures constituted the next largest category, 27 percent of all claims. The most frequent malpractice claim related to surgery was "postoperative complication." Inadvertent surgical acts and inappropriate or unnecessary surgeries also were frequent allegations in this category. Claims alleging improper treatment represented the third largest category, making up 26 percent of all claims during the period. Most of these claims were birth-related. Other claims made up the final category, including adverse reaction to anesthesia, injection site injuries, and lack of informed consent.

In addition to asserting physician negligence, plaintiffs may file malpractice claims against hospitals where treatment was provided through the vicarious liability³ doctrine or by establishing hospital corporate negligence in areas such as the selection and review of medical staff.⁴ In some jurisdictions, hospitals can be jointly and severally liable, which enables plaintiffs to recover most or all damages from a hospital even when the hospital was only partially responsible for the negligent act.

Plaintiffs can also file claims against medical device and pharmaceutical manufacturers under various legal theories, such as negligence, strict liability, and breach of warranty. Manufacturers are liable for negligence if they did not exercise due care and this lack of care caused injury. Manufacturers are liable under strict liability if their products are defective, making the products unreasonably dangerous and causing the injury. The three types of defects for which manufacturers can be found to be strictly liable are (1) a flaw in the product introduced in the manufacturing process (manufacturing defect), (2) a defect in the design of the product (design defect), and (3) a failure to adequately warn consumers of risks or give instructions regarding product use (warning defect). Under breach of warranty, manufacturers are liable if the product fails to work as expressly or implicitly warranted or promised.

³Under vicarious liability, an employer or principal can be held liable for the actions of an employee or agent.

⁴For example, in <u>Darling v. Charleston Community Memorial Hospital</u>, 211 N. E. 2d 253 (1965), the plaintiff had been admitted to the defendant hospital for treatment of a broken leg. Complications arose shortly after the physician fitted the leg with a cast. Ultimately, the plaintiff's leg became gangrenous and had to be amputated. The plaintiff then brought a successful action against the hospital for negligent medical treatment by claiming that the hospital failed to ensure quality care.

Hospital and Physician Malpractice Insurance Policies and Costs

Hospital and physician insurance coverage and costs can vary greatly. This appendix briefly discusses types of insurance and factors that can affect their costs.

Purchased Insurance Contracts and Costs

Several factors influence the cost of purchased malpractice insurance. The number of claims and the average cost per claim are the primary factors. However, within the prevailing legal environment, hospitals and physicians can reduce the cost of their premiums by purchasing insurance policies with characteristics that allow them to retain risk or to defer costs to future years.

One malpractice policy characteristic that influences the cost of insurance is the amount of coverage provided. Typically, medical malpractice insurance policies have a dollar limit on the amount that the insurance company will pay on each claim against the hospital or physician (per occurrence limit) and a dollar limit for all claims against the insured (aggregate limit) for the policy period. For example, limits coverage of \$1 million/\$3 million means that the insurer will pay up to \$1 million on a single claim and up to \$3 million for all claims during the policy period. The higher the limits, the more costly the policy. However, since small claims occur more frequently then large ones, the cost per dollar of coverage decreases as the coverage limits increase.

A deductible provision can also influence the cost of purchased insurance. Under a policy with a deductible provision, an insurer is liable only for losses in excess of a stated amount up to the policy limits. For example, if a hospital incurred a \$300,000 malpractice loss while insured under a \$1 million per occurrence policy with a \$100,000 deductible, the hospital would pay \$100,000 of the loss and the insurer would pay \$200,000. Generally, the higher the deductible, the lower the premium.

The type of policy purchased can also influence the cost of medical malpractice insurance. Generally, malpractice insurance is written on either an occurrence or a claims-made basis. An occurrence policy covers malpractice events that occurred during the policy period, regardless of the date of discovery or when the claim may be filed. A claims-made policy covers malpractice events that occurred after the effective date of the coverage and for which claims are made during the policy period. Because the risk exposure to the insurer is lower, premiums for claims-made policies are generally lower during the first year (approximately 25 percent of occurrence policies) but increase to approximate the

Appendix II Hospital and Physician Malpractice Insurance Policies and Costs

occurrence basis after about 5 years when they mature. To cover claims filed after a claims-made policy has expired—when, for example, a hospital changes insurers or after a physician retires, the hospital or physician must purchase insurance known as "tail coverage," which insurance company officials stated can cost between 100 percent and 200 percent of the last claims-made policy cost.

Self-insurance Costs

To minimize the cost of purchased malpractice insurance, most medium-size and large hospitals self-insure for smaller settlements and damage awards. In many cases, these hospitals establish self-insurance trusts¹ that they administer themselves or contract with third parties to administer. Self-insuring hospitals make periodic contributions to these trusts to pay for losses as defined under formal trust agreements. Generally, the contribution amounts are generally actuarily determined based upon the estimated present value of future indemnity payments and expenses.² Indemnity payments include amounts that the trusts will pay claimants as a result of settlements and damage awards. Expenses include defense attorneys, medical experts, private investigators, court reporters for depositions, and court costs.

Most self-insuring hospitals purchase "excess" insurance to cover that portion of large losses that exceeds their self-insurance limits. Whereas self-insurance coverage typically pays settlements or damage awards up to a few million dollars, excess coverage pays up to tens of millions of dollars above the self-insurance coverage limits. Some hospitals obtain an additional layer of coverage above their excess layer, often referred to as "blue sky" coverage, which pays that portion of settlements or damage awards exceeding the excess coverage limit up to \$100 million. Generally, the higher the limits, the more costly the insurance. However, the cost per dollar coverage decreases as the limits increase.

Like purchased insurance, hospital self-insurance costs are determined by the expected number and severity of claims. However, other factors can influence self-insurance costs. Costs can vary over time because estimated future losses may differ from actual losses. If the hospital incurs fewer losses than expected, the resulting surplus will enable the hospital to reduce trust contributions. If the hospital incurs more losses than

¹Some hospitals have established captive insurance companies, which operate like self-insurance trusts, to pay for smaller damages and awards.

²The estimated present value is used because the contributions are invested into interest- bearing securities.

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expected, the resulting deficit will force the hospital to increase trust contributions. Costs can also vary over time if estimated trust investment income differs from actual investment income. If trust investments return a higher or lower yield than expected, hospitals may be able to lower, or may be required to raise, trust contributions accordingly.

Uninsured Losses

In addition to self-insurance and purchased insurance, hospitals and physicians can also incur malpractice liability costs associated with uninsured losses. The most common uninsured loss involves deductibles paid by hospitals and physicians that have purchased primary coverage. Hospitals and physicians are also at risk for losses that exceed the limits of coverage. Hospitals and physicians can also incur losses associated with causes of action not covered by policies.

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