

Risk Management & Medical Liability

*A Manual for Indian Health Service
& Tribal Health Care Professionals*

Second Edition



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Introduction to Second Edition

An initiative began in 1986 at the Indian Health Service (IHS) Headquarters level to more thoroughly review and assess each medical malpractice tort claim that involved care within the IHS or Tribal network of hospitals and clinics. A database was developed to track these claims through the system and provide summary reports and feedback to the service units. The first edition of this Manual in 1996 reported the IHS experience with medical malpractice tort claims over a ten year period, and gave recommendations on risk management practices.

Now, ten years later, many things have changed. The number of claims filed against IHS and Tribal facilities has increased and the processes by which claims are reviewed have also evolved. More recently, the IHS has become a reporting entity to the National Practitioner Data Bank (NPDB), which has brought a whole new dimension to the Agency's Risk Management Program. This revision of the Manual delineates the process changes that have taken place, updates data on tort claims, describes the IHS role in NPDB reporting, and provides additional risk management guidance for local programs and health care professionals.

I. Healthcare Risk Management

Risk management refers to strategies that reduce the possibility of a specific loss. The systematic gathering and utilization of data are essential to this concept and practice. Risk management programs consist of both proactive and reactive components. Proactive components include activities to prevent adverse occurrences (i.e., “losses”), and reactive components include actions in response to adverse occurrences. In both cases, the risk management process comprises:

- Diagnosis—Identification of risk or potential risk
- Assessment—Calculation of the probability of adverse effect from the risk situation
- Prognosis—Estimation of the impact of the adverse effect
- Management—Control of the risk

All organizations need to address their particular risks. In this Manual, we will discuss risk management as it relates to medical care and medical malpractice tort claims within the federal system. On the proactive side, risk management techniques will help improve the quality of patient care and reduce the probability of an adverse outcome turning into a medical malpractice claim. With reactive risk management, it is important to analyze the tort claims that have occurred for system issues that require intervention. The overall goal in healthcare risk management in both situations is to minimize the risk of:

- harm to our patients
- liability exposure of our health care providers
- financial loss to the Agency

Malpractice tort claims are a fact of medical practice. Studies have shown, however, that most cases of iatrogenic complications or negligence never enter the tort system, and many tort allegations of negligence have no merit. Additionally, there is little evidence that the malpractice litigation process identifies bad doctors or deters malpractice. Therefore, efforts need to be directed toward quality improvement programs and risk management rather than disciplinary measures. **As a health care delivery system, Indian Health Service and Tribal health programs must continually strive to ensure that the highest possible quality care is provided to the patients we serve at all times.**

Indian Health Service (IHS) risk management (RM) program activities are addressed at both the service unit and Agency level. For the service unit, a RM or quality assurance committee often serves as the focal point for the overall program, and receives and acts upon information provided through personal contacts and reports. The following elements are generally found within a local RM Program, although other activities may be included as deemed necessary:

- Incident identification and reporting

- Methods of identifying and addressing potential tort claims, including the sequestering of medical records, and the investigation of medical accidents and near accidents
- Review of patient complaints concerning quality of care issues
- Review and documentation of sentinel events using a root cause analysis or other recognized method
- Methods by which a patient may be dismissed from care or refuse care
- Review of requests for medical records from outside attorneys representing patients
- Mechanisms for dealing with inquiries from governmental agencies, media, and advocate groups
- Ensuring the initial and ongoing competency of staff
- Compliance with applicable government regulations, healthcare accreditation standards, and all contractual agreements
- Occurrence reporting and data management
- Developing RM recommendations for local intervention
- Evaluation and feedback

From a national perspective, the IHS RM Program has primarily evolved from the analysis and review of malpractice tort claims that have been filed against the Federal Government involving medical care provided at IHS or tribally operated facilities.¹ In this regard, the Agency's RM Program is by nature predominantly reactive in scope. The program's responsibilities include but are not limited to:

- Coordinating the processing of tort claims through the Agency, including the solicitation of peer reviews and site reviews
- Communicating with the healthcare practitioners who provided the care in question
- Examining issues related to the determination of "standards of care"
- Working directly with federal attorneys who are evaluating and/or litigating the tort claims or subsequent suits
- Representing the IHS when claims are presented for review by the Malpractice Claims Review Panel chartered by the Department of Health and Human Services (Department)
- Maintaining case files and a database of all malpractice claims filed against the IHS since 1986, and providing compilations and analyses of the data for the Agency, the Department, and Congress, when requested

¹ More recently, an Agency-wide focus on patient safety and occurrence reporting has developed; therefore a discussion of specific patient safety issues will not be covered in this Manual.

- Providing case summaries, peer review, outcome information, and feedback of risk management recommendations to the local IHS and Tribal facilities and Area Chief Medical Officers
- Disseminating information about the review process within group settings or meetings
- Responding to outside credentialing organizations who are requesting tort claim-involvement histories on former IHS and Tribal employees
- Assisting providers to submit appeals to the Malpractice Claims Review Panel
- Submitting payment reports to the National Practitioner Data Bank
- The IHS case coordinators act as provider advocates and make every effort to support the position of the IHS or Tribal practitioner throughout the process.

The attitudes, knowledge, and skills important to the understanding of risk management and medical liability are outlined in this Manual. Details regarding the Federal Tort Claims Act and the processing of federal medical malpractice tort claims are provided, with particular focus on the Agency's role and the practitioner's responsibilities with respect to those processes. Finally, suggestions are provided in various sections indicating ways to possibly reduce the incidence of malpractice claims.¹ A good starting point is to examine situations that adversely influence the frequency of malpractice claims, as described in the next section.

¹ Although the text of this Manual frequently uses the term "physicians," the principles and concepts described pertain to all health care providers responsible for patient care.

II. Underlying Influences That Often Lead to Claims of Malpractice

Patients will file malpractice claims for a variety of reasons and pressures. Often, many issues are involved in an individual's decision to file a claim. The following list summarizes some of the major influences identified both in the literature and from experts in the field.

- **Medical Injury, Poor Result, or Adverse Outcome**

Adverse outcomes inevitably occur from time to time as a result of medical care, as many of the things we do are risk prone. There must be some form of injury identified if a malpractice legal action is contemplated. The injury need not be permanent or physical, but it is often more difficult for a claimant to seek damages solely for “pain and suffering” without a more tangible physical injury.

- **Provider Errors/Negligence**

Provider errors should never be covered up or denied, even at the risk of initiating a malpractice claim. The goal of health care quality assurance and risk management programs is to prevent provider errors and guard against negligence, not to suppress it when it occurs.

- **Unrealistic Public Expectations of Medical Outcomes**

The lay public often has expectations of medical outcomes that do not coincide with actual success rates. Providers who give false hopes or promise a cure add to this problem. Adequate informed consent and honest communication are always essential.

- **Litigious Patients/Society**

There is no question we live within a society and culture where looking for someone to blame is the norm. It is a fact of life that some individuals will grasp at opportunities to seek compensation for borderline or nuisance reasons. A few lawyers actively pursue potential malpractice cases.

- **Weak Doctor-Patient Trust**

If there is no trust in the doctor-patient relationship, the patient will be more likely to question both the competence and recommendations of the health care provider when an adverse outcome does occur. Trust must be earned, and it begins with the establishment of a good patient-physician relationship. Patients rarely bring tort action against providers they trust and like or perceive are trying their best to serve them.

- **Patient Depersonalization**

Patients deserve, and usually demand our respect. When patients are treated without dignity, their satisfaction level will obviously plummet. As a result, patients will not be as understanding when adverse outcomes occur, and may be more likely to file compensation claims out of anger or embarrassment.

- **Certain Patterns of Professional Behavior**

In addition to demanding respect, patients want to feel comfortable in the presence of their health care provider. Brash speech, off-colored humor, rough handling, and other

unprofessional behavior detract from a feeling of security and confidence. No patient could claim negligence because of such behavior in and of itself. However, when an adverse outcome does occur, patients may be more likely to seek action against a provider who has consistently been perceived as being unprofessional or uncaring.

- **Unresolved Misunderstandings**

Poor communication results in many misunderstandings and misguided expectations. Physicians who do not take the time to explain the diagnosis, treatment, precautions, and prognosis run significant risk of having an ill-informed, distrustful, and disgruntled patient.

Many of these adverse influences can be favorably modified by conscientious efforts on the part of the health care team. A professional and compassionate patient-provider relationship is the cornerstone of any risk management program. This very special relationship is further explored in the next section.

III. The Patient-provider Relationship

A. Building the Relationship

The technical quality of the care we provide is, of course, very important. However, the quality of the patient-provider relationship, as perceived by the patient, may have equal or even greater effects on the outcome of the encounter. Compliance has been shown to correlate with the quality of the patient-provider relationship, and the establishment of trust is essential if the patient is going to have faith in the physician's diagnostic and healing abilities. Finally, a solid patient-provider relationship can potentially help reduce the incidence of tort claims. Studies have shown that most cases of iatrogenic complications and adverse outcomes never enter the tort system.¹ Why is this? Perhaps one reason is that patients will be much less likely to sue when they have feelings of well-being, goodwill, satisfaction, and respect. Accessory motives for litigation are unhappiness and anger and, probably much less commonly, vengeance and greed.

While theoretical behavioral models abound, providers tend to develop their own style of practice influenced by many factors including their training, personal backgrounds, and life experiences. No one approach to patient relationships is appropriate for every provider. The following checklist and explanations provide a fairly simple and basic foundation for initiating a durable patient-provider relationship.

¹ Hiatt HH; Barnes BA; et al. Special Report, A Study of Medical Injury and Medical Malpractice [Harvard Medical Practice Study] NEJM: Vol.321, No. 7:pp480-484, 1989.

Patient Care Checklist¹

Setting the Stage for a Durable Patient-Provider Relationship

✓ Greet and Acknowledge the Patient by Name

- Patients should be respectfully greeted with expressions such as hello, good morning, or a similar expression in the native language using the patient's name.
- Local norms should determine if the first name is used, or Mr., Mrs., or some other culturally appropriate expression.

✓ Introduce Yourself

- Providers should introduce themselves by name at the first visit or if it has been a while since the patient has been seen.
- Provider name badges are a good idea because they help patients remember names, but should not take the place of self-introductions.

✓ Provide Support and Reassurance

- Try to assess the patient's level of physical and/or psychological distress (e.g., fear) through nonverbal cues or the way they respond to questions.
- Attempt to put patients at ease through attentiveness, nonverbal expressiveness, and reassurance, but following culturally acceptable norms of touch, eye contact, etc.

✓ Facilitate Dialogue

- Develop a “negotiated relationship” between provider and patient. Clearly not everything is subject to negotiation (e.g., many technical aspects of care, or emergency care), but issues that relate to patient choices of care (the goal being informed choice), or willingness to comply with recommendations, are important to negotiate with the patient.
- Critical to this process are carefully thought out non-judgmental questions, and attentive listening. Specific kinds of questions to consider include:
 - What are they presenting themselves (or their child) for (i.e., their request or problem)? Ask and listen, rather than assume.
 - What do they think is wrong, or what do they think is needed? Do they have alternative or traditional beliefs about their condition or need? Is the patient seeking assistance from available traditional healing methods, and how is this likely to influence the effects of medical care?
 - What do they expect from treatment (i.e., their expectations)? What level of responsibility are they assuming for their or their child's condition and/or follow-up to care?

¹ Adapted from *Promoting Health and Preventing Disease, Oral Health Program Guide*, Section II, Indian Health Service Dental Program, and work done by Eric Bothwell, DDS, Dental Services Branch, IHS Headquarters

✓ Respond and Teach

- Attempt to clarify to the patient (or family) what the options for care are.
- Do not talk down to patients, but also do not use jargon or concepts that are not familiar to them. The intent is to respectfully respond to their perspective and:
 - acknowledge and clarify the similarities and differences in their perspective; what is clinically evident, and what we are able to do for them, considering alternatives of traditional medicine if available and desired.
 - actively teach the patient, with the intent of informing and empowering them to assume appropriate responsibility for their health (or their child's).
 - negotiate with the patient and/or family to involve them in decisions that are appropriate and important in their care.
 - tailor treatment and follow-up, as much as possible, to the individual or family's existing routines, providing all important instructions in writing.

✓ Express a Warm Good-by

- Reach clear closure with patients with a gesture of good-by, following an opportunity for them to ask any final questions. Simply moving on to the next patient, without an opportunity of closure, can leave patients with an important, unanswered question and/or emotionally upset or troubled.

B. Ending the Patient-Provider Relationship

The proper termination of the patient–provider relationship is also very important. Ending the relationship in an adversarial manner can at times cause serious risk management concerns, and may even be illegal. Termination of the patient-provider relationship can occur in any one of the following acceptable manners:

1. **Provider services no longer needed.** This, of course, is the most common means of termination. Patients without chronic disease who have no need for regular follow-up account for most of these situations. Another reason might be the need for a higher level of expertise than the current practitioner can offer. In both cases, the termination is amicable and understood by the patient. There are no risk management issues to consider.
2. **Mutual consent of parties.** There are times when, for whatever reason, both the provider and patient agree that another provider should be identified to continue the patient’s medical care. No individual provider can satisfy every patient, and personality conflicts are occasionally unavoidable. If a patient requests another provider and the physician agrees, it is appropriate to make such a mutually agreeable transfer of care. The transfer of responsibility should be noted in the medical record.
3. **Withdrawal of provider from the case after reasonable notice to the patient and completion of current treatment.** Sometimes, the provider alone determines that he/she can no longer care for a particular patient; the patient on the other hand, may or may not understand the need for change. With just cause, it is acceptable for the provider to withdraw him/herself from the case, provided the following conditions are met:
 - a) The patient is notified of the desire to terminate the relationship;
 - b) The current treatment plan is completed or the patient’s condition is stable;
 - c) An alternative provider is identified and made available to the patient;
 - d) The termination process is documented in the medical record, including the reasons for ending the relationship.

Abandonment

Abandonment of patients is never acceptable, and would constitute substandard care even if the previous care had been flawless. This includes leaving patients without options for care both in the inpatient as well as the outpatient setting. Providers must be cautious to prevent the perception that abandonment has occurred. It is essential to always indicate follow-up plans on all patients with undiagnosed ailments or those in need of ongoing treatment. **Termination of care, when it occurs, must always be formally documented.**

IV. The U.S. Legal System: an Overview

This section provides basic knowledge regarding the U.S. legal system, emphasizing common legal terms and several issues relative to malpractice law. The information is meant to serve as an introduction to the remainder of this Manual and to allow the practitioner to have a better understanding of underlying legal principles.¹ Important legal terms have been underlined for easy reference.

Common Law

Precedent: The common law system in the United States is based on case precedent. The principle of adhering to precedent is referred to as *stare decisis*, Latin for “let the decision stand.” Except in special circumstances, legal principles established in one case are followed in similar cases in the same jurisdiction. Cases do not have to follow precedent if they can be distinguished as significantly different from the precedent-setting case. Case precedents in one jurisdiction are not binding upon courts in other jurisdictions (e.g., in other states) or upon higher courts in the same jurisdiction. However, even if a precedent is not binding, it may be persuasive in that it may influence the development of the law.

Civil versus criminal suits: The same act may constitute grounds for both a civil suit and a criminal prosecution. However, these two legal actions are independent, and the outcome of one has little or no impact on the outcome of the other.

- Civil suits are those involving individuals, groups, or other parties acting in a non-public capacity. Plaintiffs (individuals who initiate the action) in civil suits generally seek to obtain compensation for injuries suffered through the wrongful acts of defendants (individuals who are being sued). A suit may have multiple plaintiffs and defendants. A decision pertaining to one plaintiff or defendant does not necessarily pertain to other plaintiffs or defendants in the same suit. A defendant who loses a civil suit is said to be liable for damages. The term “guilty” is not technically applicable to a civil suit.
- Criminal suits are those brought by the federal, state, or local government to enforce laws that exist for the protection of society at large. Criminal actions are brought to punish the wrongdoer with a fine, imprisonment, or both. A defendant who loses a criminal suit is said to be guilty. The principal purpose of punishing convicted criminals is deterrence.

Burden of proof: The standard of proof required in criminal prosecutions is higher than the standard required in civil litigation. Plaintiffs in a civil suit must prove their case by a preponderance of evidence – that is, the court must be persuaded that the material elements of the case more likely than not are in favor of the plaintiff. The prosecution in a criminal case must prove its case beyond a reasonable doubt. This is consistent with the presumption by our legal system that the accused is innocent until proven guilty. The party bringing the suit (the plaintiff or the prosecutor) generally bears the burden

¹ Adapted from Rosoff, AJ: Legal Aspects of Medical Practice and Community Medicine, in *Preventive Medicine and Public Health*. 2nd edition, Harwal Publishing, Philadelphia, 1992

of proving all material elements in the case. Rarely, special circumstances may shift the burden of proof of certain elements to the defendant.

Jury versus non-jury trials: A right to trial by jury exists for most civil and criminal claims under federal and state constitutions, but a jury trial is not automatic. Unless one of the parties makes a request, the case is docketed (i.e., scheduled) for a non-jury trial. In fact, most cases are tried before a judge alone.¹

Functions of judge and jury: The function of the jury is to decide disputed issues of fact, where such issues exist. A summary judgment (i.e., a quick disposition of a case without a trial or resort to jury) will be entered when the judge determines that there are no material factual issues to be decided. The function of the judge is to control the procedural aspects of the trial, to supply the applicable law, and to decide disputed issues of law. If a jury is used, it may announce the verdict, but it is bound to apply the law as instructed by the trial judge.

Statute of limitations: A statute of limitations is a procedural rule that establishes a maximum period of time during which a legal suit may be initiated. After the statutory period is over, a suit cannot be initiated regardless of how strong the case may be. A statute of limitations requires parties to bring their suits to court while evidence is still fresh so that factual issues can be determined accurately. It also provides a cutoff date after which parties can be confident that no suit may be brought.

The period allowed for initiating a suit may vary from jurisdiction to jurisdiction for suits concerning similar legal matters. It also may vary within a given jurisdiction for suits concerning different legal matters. For example, the statute of limitations is commonly 4-6 years for contract actions and 1-3 years for personal injury actions. The statute of limitations can be stopped from running in special circumstances – for example, if the defendant is absent from the state or is mentally incompetent and, therefore, unable to be sued.

The beginning of the statutory period for medical malpractice is defined variously as: The date the alleged malpractice took place; the date the physician-patient relationship was terminated; the date the patient discovered the alleged malpractice; and the date the patient discovered, or by exercise of due care, should have discovered, the alleged malpractice (this is the most commonly used definition).²

Measure of damages: Determining the appropriate measure of damages is as important, and sometimes just as difficult, as determining whether the defendant is liable. A number of different measures may be used, either separately or in combination.

- Compensatory damages compensate the plaintiff financially for the harm caused by the defendant. Tangible economic losses, such as expenses for remedial care, loss of wages, and future loss of earnings due to physical impairment, are the principal elements of compensatory damages.
- Pain and suffering, mental anguish, and loss of consortium (i.e., loss of marital

1 Medical malpractice suits filed against the IHS or Tribal programs are argued before a federal judge in the appropriate US District Court. No jury is involved.

2 The statute of limitations for initiating a federal malpractice claim is two years (See Section X).

companionship, especially of a sexual nature) attempt to provide dollar compensation for losses that are real and discernible but that cannot be measured readily in financial terms.

- **Punitive damages**—that is, damages in excess of normal compensation—may be awarded against a defendant who acted in a grossly negligent manner or with deliberate wrongful intent. Their purpose is to punish wrongdoers and to deter them and others from acting similarly in the future. The defendant must pay punitive damages to the plaintiff along with any other damages awarded. The amount is generally computed with regard for the degree of culpability of the defendant's actions and the defendant's ability to pay.
- **Nominal damages** are awarded when the plaintiff has been able to establish the defendant's wrongdoing and, thus, the defendant's liability but has not been able to prove that the plaintiff suffered any monetary loss. A small sum, such as one dollar, is awarded as a symbolic acknowledgment that the plaintiff won the suit.
- **Legal expenses.** Under the American legal system, each party bears its own legal expenses, regardless of who won the litigation. However, court costs are assessed against one or the other or both parties at the discretion of the court.

Tort Law

Definition: Torts are civil wrongs – that is, injuries to an individual's person, property, or reputation. Torts can be negligent or deliberate. Remedies in tort suits generally are meant to compensate the aggrieved party to restore as nearly as possible the position the victim would have enjoyed had the tort not been committed. When an individual's conduct is particularly culpable, punitive damages may be awarded.¹ Tort law as applied against professionals is called malpractice.

Negligent torts: Most of the litigation relating to failures of medical care involves alleged negligence by health care providers. An individual who has been the victim of a tort conduct can sue for damages. However, unless the following four conditions are satisfied, there can be no recovery for the negligent tort.

- **Duty:** A duty is an obligation recognized by the law, the breaching of which is subject to legal sanctions. To recover damages, the plaintiff must establish that he/she was owed a duty and the nature and extent of that duty. The duty, or standard of care, generally must be established by expert testimony as to common practice within the relevant profession.
- **Breach of Duty:** The plaintiff must prove that the defendant performed significantly below the legally required standard of care.
- **Damage:** The plaintiff must prove that he was harmed and establish the nature and extent of that harm. In medical malpractice litigation, damages may be based on physical injury, psychological harm, and loss of reputation. Simple economic losses suffered by the plaintiff are generally not recoverable unless they are coupled with some other harm suffered.
- **Direct causation:** There can be no liability unless the defendant's negligence was the

¹ Punitive damage awards are not allowed for federal medical malpractice tort claims.

proximate cause of the plaintiff's injuries. A proximate cause is a factor without which the harm would not have occurred; it must be the predominant factor causing the harm. In medical malpractice cases, proximate cause is often difficult to establish since bad outcomes can occur even in the absence of negligence. Under the "loss of a chance" theory, some courts have begun to award damages if the plaintiff can establish that the defendant's acts significantly reduced the patient's chances of survival or recovery. This liberal definition of causation makes it easier to recover damages in cases of medical malpractice.

Standard of care: Identifying the standard of care is the cornerstone of proving whether or not medical negligence took place. Various rules and precedents apply. It should be noted that practically all standards of care are now based on a national model. This national standard is most stringently applied to specialists, but it would behoove all practitioners to provide care on a par with national benchmarks appropriate for their discipline.

- **Reasonable care:** The care usually required is that degree of care that a reasonably prudent individual would exercise in similar circumstances. The standard of care generally is fixed by reference to the customary practice of a given profession. Because the judge and jury cannot possibly know the customary practice of all professions, this must be established in court by expert testimony. Participation as an expert witness, which must be voluntary, is secured through negotiation of a witness fee. In contrast, testimony as to one's factual observations can be compelled through use of a subpoena (a court order to appear and testify). It is widely claimed, especially by plaintiffs' attorneys, that a conspiracy of silence among physicians makes it difficult to obtain expert testimony on behalf of plaintiffs in medical malpractice cases.
- **Locality rule:** The locality rule has largely been replaced by a new approach – national standards for health care practice, especially in cases where specialty care is rendered by board-certified practitioners. The "strict locality" rule requires that expert testimony on the standard of care be drawn from the geographic community in which the alleged malpractice occurred. In the late 1800s, courts recognized that customary medical and surgical practices in isolated areas were not on par with those in progressive urban areas, and a differential standard of care was allowed. The "same or similar community" standard measures the defendant's performance by reference to closely comparable medical communities. This liberalization of the locality rule makes it easier for plaintiffs to obtain expert testimony in support of their cases.
- **Generalist versus specialist standards:** When a physician claims the ability to provide the type of care that normally is rendered by a specialist, the standard of care applied is that of the appropriately trained specialist. Under emergency circumstances in which specialty care is not available, a general practitioner may provide care that normally is rendered by a specialist. In such cases, a generalist standard should be applied to measure the adequacy of the care rendered. Failure to refer a patient to a specialist when specialty care is indicated subjects the attending physician to liability (called negligent non-referral).

- **Proof of dereliction:** Whether or not the defendant performed up to the required standard of care is a factual matter, generally requiring proof. Although expert witnesses cannot be compelled to testify as to matters of opinion, they can be required (subpoenaed) to testify as to factual matters that they directly observed in the care of the patient (plaintiff). However, sometimes the care may have been so deficient that a judge or lay jury may infer negligence even in the absence of expert testimony under the doctrine of *res ipsa loquitur*, Latin for “the thing speaks for itself.” Thus, the plaintiff is spared the burden of producing further evidence of negligence. An example would be a surgical instrument discovered to have been left inside a patient during a previous operation.

Deliberate torts: Although most medical suits involve negligent torts, there is significant opportunity for suits charging deliberate (intentional) torts. To establish the required intent to support such a charge, it is not necessary to show that the defendant specifically meant to harm the plaintiff but only that the defendant deliberately performed the wrongful act. The following are the most significant types of deliberate torts in the medical arena.

- **Battery**, which is defined as touching an individual without permission, often leads to health care suits. The wrongful act to be avoided under battery is the invasion of a person’s right of bodily inviolability. A valid ground for complaint exists even if the defendant intended no harm and the patient suffered no physical damage. Monetary awards generally are small unless there is physical damage or the defendant meant to cause harm. Cases of alleged sexual assault by physicians are considered battery actions.
- **Fraud and deceit** are important grounds for deliberate tort suits. Cases in which a physician deliberately misrepresents facts to obtain a patient’s consent for a procedure are treated as matters of fraud and deceit. These cases can be distinguished from the more common cases of informed consent.
- **Breach of confidentiality** involves a disclosure of information about a patient’s case without his permission. This theory can support a suit based on an implied duty to keep patient information confidential, invasion of privacy, defamation, and unprofessional conduct.

Institutional liability: Increasingly, courts are holding health care institutions liable for malpractice committed by individuals in some relationship with the institution.

- **Vicarious liability** occurs when one party is held responsible for something that another does or fails to do. This is known as the doctrine of *respondeat superior*. This comes from old English law and translates as “let the master answer.” If a plaintiff wishes to recover from the employer under this doctrine, he need not prove that the employer was negligent. Instead he must only prove the employee was negligent and was acting within the scope of his employment. Scope of employment is a vague concept but has been defined as including any actions undertaken by the employee in furtherance of the employer’s business or any activities incidental to performing his daily work. This doctrine generally applies only to employers; a supervisor is not responsible for an employee’s actions unless the supervisor ordered the employee to take such actions.¹

¹ See Manual Section X on Federal Tort Claim Act

- Corporate negligence is an evolving legal theory by which an institution may be held directly (not “vicariously”) liable for a tort committed by an independent contractor, such as a staff physician, practicing in or through the institution. The institution has a duty to all patients treated in its facilities to take reasonable steps to assure the competence of all who are allowed to practice there. Liability can result from failing to check credentials adequately before granting staff privileges to an unqualified practitioner or from allowing privileges to be retained when the institution knows, or should know, that the practitioner poses a risk to patients.
- Governmental immunity still prevails in several jurisdictions, preventing or limiting suits against institutions run by governmental units. In states where the doctrine exists, the facts and circumstances of the individual case may determine whether the doctrine applies. Immunity for the institution may not extend to all health professionals practicing there.
- Peer review and professional discipline have been strengthened in response to increased institutional liability pressures. Reporting incidents of malpractice and adverse actions taken on a provider’s credentials to the National Practitioner Data Bank is now required. Healthcare institutions must consult this registry when granting staff privileges and periodically thereafter. Civil immunity is granted to health care entities that engage in peer review if prescribed due process safeguards for the practitioner are observed. States also are improving medical licensure and discipline mechanisms, providing various services and supports for “impaired physicians” (i.e., generally those suffering from substance abuse and other personality disorders), and demanding mandatory reporting by professionals of those known to pose a threat to patient safety.

V. Selected Patient Rights Issues

Three issues relating to patient rights will be reviewed briefly: refusal of treatment, terminally ill patients, and substituted judgment. For a general discussion of patient rights within healthcare facilities, the reader is referred to the Patient Rights Standards of the Joint Commission on Accreditation of Healthcare Organizations.

Refusal of treatment: A patient who is competent to give consent also is entitled legally to withhold it for whatever reasons he or she deems sufficient. This is true even if refusing treatment may result in serious harm or death. When a patient refuses treatment, the provider should document all of the information given to the patient concerning the consequences of the refusal. Failure to provide such information or the inability to prove that it was provided could result in liability on informed consent grounds. When the competence of the patient to make the treatment decision is questionable, the provider may rely on the principles of emergency consent and consent by the next of kin. However, a court order authorizing treatment should be considered.

Terminally ill and vegetative-state patients: Numerous state court decisions over the last 25 years have held that terminally ill patients and those in a “persistent vegetative state” have a right to refuse life-supporting care that would serve only to prolong the process of dying or a meaningless existence. However, patients do not have an unrestricted “right to die.” Courts and legislatures dealing with this matter have defined rather narrowly the cases in which patients can refuse life support.

Ending years of speculation on how it would rule on the issue, the U.S. Supreme Court held in 1990 that a patient does have the constitutional right to decline life-sustaining treatment.¹ However, the Court also upheld the right of the state to require strong evidence of the patient’s desires on the matter. Some courts traditionally have distinguished between the use of “ordinary” and “extraordinary” life-support measures. Ordinary measures generally have been held to include the provision of nutrition and hydration via nasogastric or other types of feeding tubes; extraordinary measures encompass cardiopulmonary resuscitation and the use of a ventilator to maintain respiration. Calling the use of a respirator extraordinary treatment, the New Jersey Supreme Court allowed an irreversibly brain-damaged and comatose young woman to be removed from the respirator that was presumably sustaining her life.² In 1985, the New Jersey Supreme Court held that it might be appropriate to discontinue nasogastric feeding and hydration for a senile, semiconscious 84-year-old nursing home patient who was in failing condition but whose death was not thought to be imminent.³ Extraordinary care was defined as care in which the expectable benefits to the patient cannot be justified when weighed against the burdens. Strict procedural safeguards were imposed to assure that the rights of nursing home patients are protected.

1 Cruzan v. Director, Missouri Department of Health, US Supreme Court, 1990

2 In re Quinlan, New Jersey, 1976

3 In re Conroy, New Jersey, 1985

“No code,” or “do not resuscitate” (DNR), orders entered by the attending physician generally are legally acceptable in appropriate cases involving terminally ill patients. If the patient is unconscious or incompetent, family members should be consulted about the DNR decision. Extreme care should be taken when it is known or suspected that a relative opposes the entry of a DNR order. Although some providers have been reluctant to enter a DNR order overtly in the patient’s chart, a written acknowledgment of the DNR decision is advisable. The physician should document carefully the consent of the patient or the next of kin to the entry of a DNR order. Pain-killing drugs may be used even when this may accelerate the death of a terminally ill and failing patient.

Numerous states sanction the use of a living will or natural death directive by which a patient can direct what care should be rendered in a terminal illness if the patient is not competent at that time to provide such direction. Even in states that have not yet officially recognized the legal validity of such devices, their use should help to protect those who act in response to sound medical judgment and the patient’s documented wishes.

Substituted judgment: Termination-of-treatment decisions for incompetent patients commonly are made by attempting to ascertain what the patients would choose for themselves if able. The Quinlan case established this principle as flowing from the patient’s right of self determination. The substituted judgment approach works best when the patient, before becoming incompetent, either expressed her wishes on the issue of termination-of-treatment or otherwise revealed enough about his/her beliefs so that his/her expressed wishes on the issue reasonably can be inferred.

The New Jersey Supreme Court’s Conroy decision (see previous page) established a three-tiered analytic framework for applying substituted judgment: a “subjective” test is used when patients expressly have stated their wishes at some previous time; a “limited objective” test is used when the patients’ wishes can be inferred from known religious, ethical, or lifestyle beliefs;¹ and a “pure objective” test is used when no information is available from which to infer what the particular patient would have wanted. Inferences must be drawn based upon what the “average” person would desire in such a situation. The 2005 case of Terri Schiavo brought many of these issues to the forefront of the Nation’s conscience, when her husband, family, the courts, politicians, and public opinion were all embattled over the husband’s decision to terminate Terri’s life-sustaining treatments. Although the issue was painful for the Nation to confront, recognition and emphasis has again been placed on the need for all adults to have in place documents that define their end-of-life wishes and healthcare proxies.

Two Agency policies relevant to this discussion of patient rights can be found in the Indian Health Manual, Part 3, Professional Services: Chapter 25, *Guidelines for Withholding Cardiopulmonary Resuscitation*, and Chapter 26, *Patient Self-Determination and Advanced Directives* (see www.ihs.gov/PublicInfo/Publications/IHSManual/index.cfm).

¹ Brophy v. New England Sinai Hospital, Inc., Massachusetts, 1986.

VI. Informed Consent

The basic premise of informed consent dates back to the early part of this century, and centers on the principle of battery. Courts have clearly ruled that “every human being of adult years and sound mind has a right to determine what shall be done with his own body.” Most states now have specific informed consent statutes, yet even in the absence of such laws physicians have a common law duty to ensure that diagnostic, medical, and surgical procedures are authorized by the knowledgeable consent of the patient or his/her legal representative. A physician who fails to obtain his/her patient’s consent to treatment commits a battery.

It is very important to realize that courts have increasingly held that informed consent is a **process**, not just a piece of paper. A written and signed consent form will not necessarily withstand a legal challenge if it can be shown that the patient was not adequately informed about the treatment, risks, and alternative procedures available.

Informed Consent Standards

Courts generally use one of two informed consent standards. The older “professional disclosure” standard is followed in about half the states. This standard requires the physician to disclose to the patient everything that is customary in the profession to disclose under the same or similar circumstances. In court, plaintiffs in these states must produce an expert witness to testify that the defendant’s actions fell below the standard of customary disclosure.

The newer “reasonable patient standard” has been adopted in the remaining states. Under this standard, physicians are required to tell their patients everything that would reasonably bear on a decision to submit to treatment. Because expert testimony is not needed, it is generally easier to sue on informed consent grounds in states using this standard. In the case of federal court malpractice suits, the standard of the state in which the facility is located is used.

Most courts also require proximate cause. This means that plaintiffs must also prove that a reasonable person would not have gone through with the procedure if they had been fully informed of the risks and alternatives. In the case of elective surgery, it is easier for a patient to prove that he/she would not want the procedure if additional information had been provided; for more urgent or life saving procedures, the plaintiff’s argument must be much more convincing. As a general rule, the more elective the procedure (and hence the greater the number of therapeutic alternatives), the more detailed the disclosure should be.

Required Elements: No matter what standard is applicable, there are five basic elements that must be disclosed to patients in language that a lay individual reasonably can be expected to understand:

- 1) The diagnosis, including the disclosure of any reservations the provider has concerning the diagnosis;
- 2) The nature and purpose of the proposed procedure or treatment;

- 3) The risks and consequences of the proposed procedure or treatment. This includes only those risks and consequences of which the physician has, or reasonably should have, knowledge. It is not necessary to disclose every potential minor risk or side effect.
- 4) Reasonable treatment alternatives. This includes other treatment modalities that are considered to be appropriate for the situation, even though they may not be the personal preference of the disclosing physician.
- 5) Prognosis without treatment. The patient must be informed of the potential consequences, if he/she elects not to have the recommended procedure.

Therapeutic Privilege: Under limited circumstances, courts have recognized that a physician may be justified in withholding information if it can be shown to be in the patient's best interest. This privilege applies only when a patient is unusually sensitive, anxious, or emotional.

Patient hypersensitivity should never be presumed. There must be ample justification for withholding information and the physician should carefully document his/her reasoning in the medical record. If the physician's use of the therapeutic privilege is challenged, it must be determined whether the physician acted appropriately. The use of this therapeutic privilege should be relied upon only in rare circumstances.

Implied Consent: Consent is either expressed (verbally or written) or implied. Consent may be implied under a variety of circumstances. For example, when a patient comes to see a physician for a particular ailment, it is implied that they consent to be examined. If a patient has a fractured arm, it is implied that he consents to casting. In general, physicians can assume that most patients would readily consent to care or treatments that are customary, noninvasive, and non-experimental.

Implied consent also relates to the performance of additional procedures when medically justified. When a physician is performing a hysterectomy, for example, an incidental appendectomy cannot be performed without the patient's expressed consent to do so. However, if the appendix is diseased, it is reasonable to assume that the patient would allow the procedure, unless the patient had expressly prohibited the appendix from being removed.

The use of general or blanket consent forms is not sound practice. These types of consent forms do not represent true informed consent as they are often solicited by an admission clerk, adequate information is not given, and they are not specific to any particular treatment or procedure. Blanket consent forms only serve as evidence of the patient's voluntary submission to treatment in general, which is usually self evident (implied), but these types of forms do not demonstrate that the patient understood specific indications and risks of any proposed invasive procedures. Again, it is recommended that blanket consent forms not be used.

Who May Give Consent: If the patient is a competent adult, the authority to give consent to treatment rests exclusively with the patient, unless the patient formally delegates that authority to someone else. Through the use of a document called a "power of attorney," executed in writing, a competent adult can delegate the responsibility for health care decisions to another competent adult.

A power of attorney in most states becomes ineffective when the person granting it becomes incompetent. For this reason, many states now recognize a “durable power of attorney,” which generally remains effective even after the person granting the power becomes incompetent. In the health care setting, a durable power of attorney is the preferred document. Health care providers should always be careful to ensure that the proposed treatment lies within the scope of the expressed authorization.

Individuals who have not attained the legal age of majority (in most states, age 18) cannot legally give consent except in the following situations:

- 1) The patient is an emancipated minor (e.g., the minor is married, lives away from their parent’s home, or is financially independent);
- 2) The state has fixed a lower limit of age for certain health care decisions (such as in the case of abortion, pregnancy, and treatment of venereal disease);
- 3) The state recognizes a “mature minor” exception, which allows minors to give consent to health care when there is a pressing need and the parent or guardian is unavailable. It is recommended that the reader be familiar with the laws in the state in which you practice.

The law holds that the closest available relative or legal guardian can authorize necessary and reasonable care when the patient is incapable of giving consent because of age, incompetency, or incapacity. A health care provider acting on the reasonable belief that a person is the patient’s next of kin is legally protected if the authorizing person turns out not to be a close relative.

Emergency Situations: When the need for care is urgent, the patient is unable to give consent, and it is not feasible to contact the patient’s next of kin, then the law does allow the physician to proceed with life saving diagnostic and therapeutic procedures without informed consent. The emergency consent exception is based on the following concepts:

- 1) The health care provider is entitled to presume that the patient would have chosen the care others would have chosen under similar circumstances, unless the provider has information to the contrary;
- 2) The exception only applies to situations where immediate action is necessary to preserve life (or in some states “to prevent serious physical harm”);
- 3) The circumstances justifying the emergency consent exception are well documented, including all attempts to notify the next of kin before treatment is begun.

Informed Refusal: The issue of documenting informed refusal is a relatively recent development. It is clear, as noted above, that patients have both the right to determine what is done to their body, and what is not. However, a patient should be very well informed if he/she is going to refuse a well established, common procedure such as a cancer screening test. On more than one occasion when patients have sued over a delayed diagnosis of cancer, courts have held that the physician was liable because he/she failed to adequately inform a patient about the consequences of the patient’s prior refusal to accept standard cancer screening procedures.

For this reason, it is becoming more common for physicians to send registered letters to patients who decline certain types of care, informing them of the consequences in detail. Alternatively there may be circumstances where it would be wise to have the patient sign a written “informed refusal” document. Is this necessary every time a patient declines a test? No, but it would seem prudent to assess each situation carefully.

Document, Document, Document: All physicians should accept the doctrine of informed consent. It has strong ethical and moral backing, it emanates from the right of self-determination and the right to privacy, and health care providers should not expect the courts to lose interest in patient rights.

In most states, verbal consent to treatment is legally sound, but it is very difficult for the provider to prove what the patient was told in the event that an adverse outcome leads to a malpractice claim. There is no question that written documentation enhances a physician’s credibility. It therefore makes for good defensive medicine to carefully document the informed consent process, which includes, but is not limited to, a form that details the information disclosed to the patient, signed by both the patient and provider, and witnessed by a third party. It is helpful to have a third person (preferably a health care provider) present at the counseling session to witness the exchange of information, help solicit and answer questions, verify that the patient understands the information, and attest that the session took place. By signing the consent form, the third party is serving as a witness, and he/ she is **not** liable for the quality and sufficiency of the information given.

The patient-counseling session must be documented. There should be ample written evidence that informed consent was given to the patient, and the process by which it was given. In addition to a signed consent form, a progress note should include the fact that a counseling session took place, the mode of information delivery, and any additional clinically important details not specified on the consent form.

The American College of Surgeons recommends that the following principles be adhered to when documenting informed consent:

- 1) There should be a clear explanation of each medical term in lay language;
- 2) There should be a listing of commonly occurring risks of the procedure;
- 3) Never describe a procedure as “simple,” “uncomplicated,” or “minor.” The consent form should include a statement that no result has been guaranteed;
- 4) Avoid the use of national statistics, as the operating surgeon’s own experience may vary from the national norm;
- 5) Indicate on the consent form if the patient has been given an informational brochure or shown a video;
- 6) The patient should acknowledge on the consent form that the information disclosed has been understood, that an opportunity to ask questions has been provided, and that all questions have been answered to the patient’s satisfaction;

- 7) The signature of both the patient and operating surgeon should be on the consent form, timed and dated;
- 8) The form should include a statement indicating that “unexpected risks or complications not discussed may occur,” and that “unforeseen conditions may be revealed requiring the performance of additional procedures, and I authorize such procedures to be performed.”

VII. The Medical Record

Documentation of Care Provided

An accurate and complete medical record serves several purposes. It

- provides a database for planning, evaluation, and treatment
- allows for continuity of care
- documents the patient's day-to-day condition
- documents communications between the primary care provider and other health care professionals involved, and
- provides written evidence that can be used to protect the legal interests of the hospital and/or health care provider(s).

The medical record is the *best device* we have to protect against malpractice claims, as well as the basic tool for monitoring and evaluating any patient's progress. Yet the patient chart is frequently taken for granted. In an era when computerized record management systems are finding their way into many facilities, patients' charts still too often lack sufficient patient care information. Poor record keeping remains a major deficiency that can be more of a burden than a help for the health professional at legal proceedings.

It is clear that it is the responsibility of the health care provider to maintain an orderly, precise, and legible document that describes the monitoring and care of his/her patient. The most caring and dedicated physician may be defenseless in a court of law when he/she is accompanied by a chart which is illegible or lacking in good documentation. In litigation, your care is only as good as your charting. The patient's memory of events will usually prevail over that of the physician. But if the physician has the event in question documented in the chart, then his/her case is strengthened considerably.

A good rule to remember is that every patient encounter deserves a thoughtful evaluation and notation, no matter how trivial the event may be. Minor everyday occurrences may be cause for litigation if the outcome is unacceptable to the patient. More importantly, in the absence of the attending physician, colleagues, consultants, and nurses need accurate information in order not to compromise care. If we make careful documentation a regular feature of our charting, it will become automatic.

The following are some elements of a defensible medical record. Whether it documents an admission or an outpatient/emergency room encounter, the characteristics are the same: completeness, objectivity, consistency, and accuracy.

- 1) Admission or encounter history:** Objectively assess the patient's subjective complaints, including duration. Always comment on previous visits or treatments for similar conditions. Indicate the source of information if it is not from the patient. Note allergies, immunizations, pertinent negatives, and relevant past medical history. Include sensitive topics such as sexual history, drug use, or psychological problems if they relate to the patient's illness or visit.

- 2) **Admission or encounter physical:** This compliments the history. You should fully address the organ system(s) related to the chief complaint and include a complete overall evaluation. Note changes that have occurred in physical findings since the last encounter. Be objective. Note pertinent negatives.
- 3) **Orders:** Clear, well written, and legible orders are essential, as serious and even fatal errors in medication or dose can occur as a direct result of careless or hurried writing. If you choose to abbreviate, use only abbreviations approved by the facility medical staff.¹ Specify details, especially when writing for medications. Don't write "call for fever," but rather say "call for temperature over 101°."
- 4) **Note all test results:** If you order laboratory or other investigations, always note the results in the record. Failure to acknowledge important laboratory data has been noted to occur as often as 20-50 percent of the time in some risk management studies.
- 5) **Progress notes:** Write regular, meaningful entries, with the date and time recorded. Avoid notes that simply say "status quo" or "no problems." The SOAP format is recommended because it encourages a complete entry. Include both subjective and objective elements, note changes in condition, and update your assessment and plan of action. Always acknowledge observations and contributions of other health care providers such as nurses and consultants (attorneys commonly search the nurses' notes and the physicians' notes for inconsistencies). If patients remain in the emergency room or outpatient department for an extended period of time, be sure to write an addendum to your initial evaluation that updates their progress.
- 6) **Operative reports/discharge summaries:** These should always be done in a timely fashion. Reports dictated long after a complication has occurred or the patient has been discharged can be construed as self-serving and less accurate than those dictated at the time of the procedure or discharge.
- 7) **Disposition:** It is important to note the condition of the patient when discharged from your care (inpatient and outpatient). Make comments relevant to why the patient presented and the level of improvement attained. Provide documentation of patient care instructions, verbal or written education, and return appointments.
- 8) **Legible handwriting and signatures:** These are always important. One study in the New England Journal of Medicine noted physicians' signatures to be illegible as often as 80% of the time.² Physicians may be called to testify simply because their notes are not readable. It is best to rubber-stamp or print your name next to your signature at all times.
- 9) **Use correct format for alterations:** Make changes in a way that demonstrates you are correcting an error and not trying to hide information. Draw a single line through an error; note the time and the date of change and initial it. "After the fact" additions or

1 The JCAHO National Patient Safety Standards contains a list of "Do Not Use" abbreviations for physician orders. Refer to your facility's JCAHO Manual.

2 White KB, Beany JF. Illegible handwritten medical records. NEJM, 314, 6:390-1, 1986.

changes should be added at the end of the record, never squeezed in between the lines of previously written progress notes (where they may be construed as an attempt to reconstruct the record). Always label late entries as such.

10) Document noncompliance: If a patient refuses to have a procedure performed or fails to follow recommendations, indicate in the chart why the treatment or procedure is necessary and that the patient chose not to follow your advice.

11) Outpatient clinic note: For outpatient notes, the same general documentation principles apply. For risk management purposes, however, it is important to acknowledge in the provider's note what the triage nurse or other practitioner(s) have written about the purpose of visit. Also, note all vital signs, even to say "unremarkable" or "normal."

Protecting Medical Records Once a Tort Claim is Filed

It is extremely important to have complete and accurate medical information when reviewing medical records in connection with malpractice tort claims. Although uncommon, copies of Indian Health Service (IHS) medical records submitted for review occasionally appear to have crucial information that is either missing or that may have been altered. Missing or adulterated documents may harm either the claimant's case or the government's case, depending on the circumstances.

The Office of General Counsel recommends that all IHS facilities adopt the following process once a tort claim alleging malpractice is filed.

- 1) As soon as you receive notification or have reason to believe that a tort claim has been filed, sequester the patient's entire medical records, (especially fetal monitor strips) and all of the x-rays. Make a copy of the medical record and all the x-rays.
- 2) Return the COPY of the medical record to the medical records room, and return the COPIES of the x-rays to the radiology files. The copies will be used for continued clinical care of the patient. New original records can be added to the files in circulation.
- 3) Paginate the original record by numbering the sequestered pages of the record from oldest to newest using indelible ink. Similarly, number the original x-rays from oldest to newest.
- 4) Keep the paginated original records and x-rays under lock and key for at least two years after the incident. Never send original records or x-rays to anyone.
- 5) If the patient has expired, sequester the record, paginate it, and hold it for at least two years. However, it is not necessary to make copies unless a claim is filed.
- 6) Copies of the original records may be sent to the claimant's attorney, provided proper consent is obtained. If the patient or the patient's living relative (with proper clearance) requests to review the sequestered original records, he/she may do so only in the presence of a service unit employee.

Electronic Medical Records (EHR)

There is evidence that the use of electronic medical records can reduce the costs associated with tort claims and malpractice judgments. It is intuitive that if EHR improves patient safety through provider order entry and clinical decision support, fewer tort claims will result. Just as important is the fact that most malpractice claims, settlements, and judgments occur because the clinical documentation is inadequate to explain or justify the clinical decisions and care provided to the patient. Private sector malpractice insurers often offer discounts to practices using electronic records because these practices have lower claim costs.

The use of EHR for both clinics and hospitals is slowly becoming more commonplace. The Veterans Health Administration is an example of a federal agency that has made the transition to a paperless medical records system. The IHS is also testing the use of a similar electronic health records system at a number of health centers (see section on EHR at the IHS web page at www.ihs.gov/cio/ehr). However, the same requirements for documentation of care and protection of information apply equally to EHR as they do to traditional paper files. Once a tort claim is filed, the information contained within the subject patient's EHR must be electronically locked and or stored to prevent alteration or loss of evidence.

Remember, the patient's record is both a medical and legal document; make it work for the benefit of the patient and the medical staff.

VIII. Issues of Provider Competence

There are five activities that relate directly to the issues of provider competence. A full discussion of each activity is beyond the scope of this Manual, but their importance warrants a brief overview.

- 1) **Credentialing and Privileging:** Although it is not a panacea, sound credentialing and privileging is the foundation for defining the level of competence of all health care providers. Credentialing and privileging flaws can emerge as a major contention during a malpractice legal proceeding. The Indian Health Service (IHS) has published credentialing and privileging standards,¹ and all health care accrediting organizations scrutinize this process carefully. Every IHS facility should be familiar with the Agency's requirements. These references are noted in Section XX of this Manual.
- 2) **Continuing medical education:** The current competency of a provider to perform a particular treatment or procedure is often called into question during malpractice litigation. It is the responsibility of every provider to maintain sufficient knowledge and expertise in the respective area of his/her discipline. The provider who uses outmoded therapies will have little defense if an adverse outcome occurs and the affected patient seeks compensation. Required training and experience, as well as continuing medical education should be carefully documented. The Joint Commission on Accreditation of Health Care Organizations (JCAHO) requires participation in continuing medical education for all individuals with delineated medical staff privileges. In addition, most medical boards now require ongoing maintenance of proficiency and recertification rather than an initial lifetime certification.
- 3) **Practice standards/guidelines:** Both the plaintiffs and defendants at malpractice trials most frequently rely on the testimony of expert medical witnesses to define the standard of care for the case in question. The other major source of information is the medical literature, including both authoritative texts and journal articles. Now more than ever, practice guidelines are also being used by both sides in malpractice cases.

Practice guidelines are defined by the Institute of Medicine as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.” The Agency for Healthcare Research and Quality (AHRQ) has published a series of Clinical Practice Guidelines, and numerous other specialty societies and provider organizations have advocated the use of guidelines to improve the quality of care. The AHRQ's National Guideline Clearinghouse website currently contains more than 1840 sets of guideline summaries available to practitioners, and the IHS also maintains a list National Comprehensive Guidelines on the Agency website (see Section XX Selected Resources for website links).

When a guideline becomes the standard of care is not clear. Because they indicate at least a potential standard of care and are based on expert opinion, clinical practice

¹ The 1995 IHS Circular No. 95-16, *Credentials and Privileges Review Process for the Medical Staff* is being revised and converted into a Manual Chapter due for release in 2006.

guidelines can bear on malpractice litigation. Malpractice litigants must prove that they have been injured by medical management that failed to reach a reasonably expected standard. It would follow that providers who comply with a guideline that sets forth a standard of care would have a strong defense in a malpractice case (exculpatory evidence). Failure to comply with a guideline might, in turn, be evidence of negligence and might constitute inculpatory evidence. It therefore behooves the practitioner to be familiar with practice guidelines appropriate to his/her specialty or discipline.

- 4) Peer review:** Health care providers have the ominous responsibility of assessing the performance of their peers on an ongoing basis. Similar to CME, medical staff members are required to participate in the measurement, assessment, and improvement of the clinical activities of those individuals with delineated medical staff privileges. It is easy to praise our co-workers for their positive contributions to quality patient care, but it is often stressful to define and acknowledge below standard care. Nonetheless, quality assessment and risk management requirements make this an essential task. All health care providers should be willing to accept peer recommendations for personal performance improvement.
- 5) Impaired physician:** Physicians (and other health care providers) may become unable to perform their duties for any number of reasons including physical illness, mental impairment, or substance abuse. However, because most physicians who participate in rehabilitation programs do so because of substance abuse, the term “impaired physician” has become synonymous with impairment due to some form of drug or alcohol abuse. The prevalence of chemical dependency among physicians is about the same as it is for the general population, between 8-12%. Without help or intervention, impaired physicians run the risk of harming their patients and certainly themselves.

As a concerned colleague, it is not the individual practitioner’s responsibility to determine whether or not a fellow practitioner is impaired or providing below standard medical care. Good quality assessment programs should hopefully identify providers who are performing below par for whatever reason. Medical staff bylaws should afford mechanisms to bring these issues to the attention of the appropriate hospital or clinic authorities to ensure that patients are protected and the affected physician receives the help he/she needs. Multiple legal and ethical issues increase the complexity of helping potentially impaired physicians. Confidentiality rules must be observed, and sensitive information should be carefully documented and shared only with those individuals who have a right to know. Legal counsel should be obtained in most cases to ensure federal regulations are being followed.

IX. IHS-Tribal Malpractice Tort Claim Experience, 1987-2004

The Office of Clinical and Preventive Services (formerly the Office of Health Programs), Indian Health Service (IHS) Headquarters, has twice compiled statistics from reviews of its case file data base of alleged malpractice incidents. The first involved cases stemming from claims that were filed between fiscal years 1987 to 1995, inclusive. The second involved cases filed between fiscal years 1996 through 2002. The results of both of those reviews have been combined for the purposes of this Manual. Cases include those alleging medical malpractice at IHS and Tribal sites.¹

Number of Cases per Year: Although it is common for individuals to file multiple tort claims with respect to one incident of alleged malpractice, the cases per year noted here reflect only the number of incidents, not the number of claims filed. This is an important distinction, because it is the incident itself that deserves the scrutiny of a risk management program; the number of claims filed by various parties affected by an incident is a poor indicator of the merits of the case in question.

Figure 1 Medical Malpractice Claims Processed
IHS/Tribal Tort Claims Experience

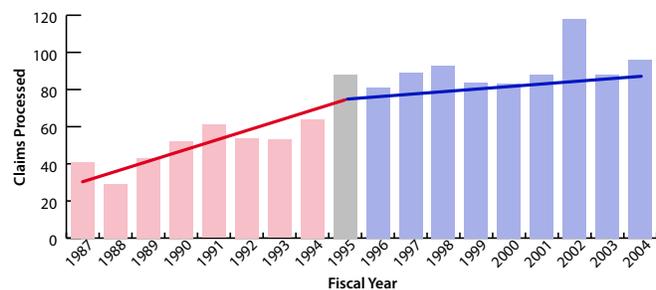


Figure 1, above right, shows the number of cases processed by fiscal year (FY), 1987-2004.² The case load generally increased over the nine year period 1986-1995, then appeared to level off during subsequent years. The exception was FY2002, when the IHS Risk Management Program processed 118 cases. One reason for the increase that year was a series of cases from the same law firm filed against a number of service units in the Southwest alleging negligent prescribing of the drug troglitazone, a medication that received considerable notoriety in the press nationwide.³ Since FY2002, the number of cases has again stabilized in the 88-96 range.

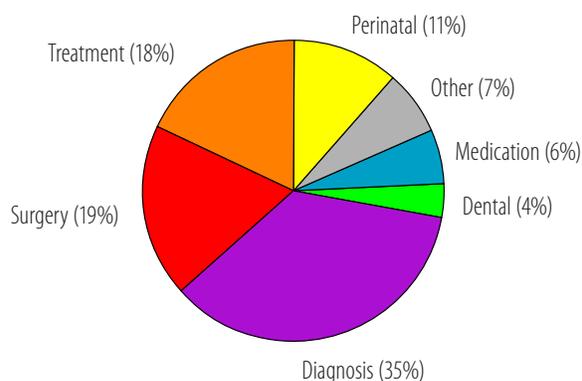
Location: Care at larger facilities with inpatient units has been the subject of approximately 85% of the cases filed during the study years, while care at facilities designated as health centers (without hospital beds) has accounted for 15% of cases. Overall, care provided in the outpatient setting (clinic or emergency room) has been the subject of 58% of cases, while inpatient care has been predominantly involved in 37% of cases. Five percent of cases involve incidents in other areas, such as ambulance services. In general, the location of the alleged malpractice incidents parallels the volume of care provided by various IHS and Tribal sites. Larger facilities with higher workloads account for the largest number of cases, and since the bulk of the system's workload is outpatient, most cases result from care provided in an ambulatory care setting.

- 1 Comparing IHS/Tribal medical malpractice claims experience to national data has proven difficult due to vastly different characteristics of these federal healthcare delivery programs and privately insured institutions or individuals. Therefore, no such comparisons have been included.
- 2 Cases for FY 2003 and 2004 have been included only for the analysis of the number of claims processed annually.
- 3 It should be noted that all these troglitazone related-related cases were found to have no merit.

Allegations of Negligence: The types of allegations found in this series of cases were categorized as follows (see Figure 2 below):

- 1) Failure to diagnose or delay in diagnosis—35%:** It is not surprising that this category is the most common. As noted above, the majority of the care provided by IHS and Tribal facilities is outpatient, not high risk inpatient procedures. Clinics and emergency rooms are usually busy and hectic places to work. Patients often present with vague symptoms that are not always readily diagnosable on the first visit. Some of the more common missed or delayed diagnoses include appendicitis, tubal pregnancy, occult cancer, sepsis, and myocardial infarction. It is important to remember that patients with uncertain diagnoses should be given specific follow-up visits within a reasonable period of time. This is particularly true of patients with abnormal physical findings or laboratory studies. Telling these patients to “return PRN” may increase the risk of future tort claims.

Figure 2 Allegations of Negligence
IHS/Tribal Tort Claim Experience, Fiscal Years 1987–2002



- 2) Negligent medical management—18%:** It is often difficult to separate an allegation of negligent management from one of failure to diagnose, so there is considerable overlap between these two categories. Included here are cases where the allegation was predominately one of medical mismanagement (not including surgical or perinatal cases). Here the diagnosis of a myocardial infarction or infection or cancer might have been made, but the choice of therapy was alleged to be wrong. Sometimes these cases involve competency issues, sometimes judgment calls. For the latter, courts will often turn to expert witness testimony or published standards of care.

Note: Added together, alleged misdiagnosis and medical mismanagement cases comprise 54% of all malpractice cases filed against the IHS and Tribal sites.

- 3) Negligent performance involving surgery/anesthesia—19%:** Allegations involving surgical procedures usually relate to improper performance. A number of claims involve retained sponges, bile duct injuries during laparoscopic cholecystectomy, or post operative adverse events. Complications will arise from surgery, even in the best of hands, so it is extremely important that detailed informed consent be obtained prior to the operation. When a known or predicable surgical complication occurs, it does not automatically imply negligence, especially if the surgeon’s complication rate is low and the patient has been adequately informed of the risks.
- 4) Negligent perinatal care—11%:** Claims involving perinatal care arise from adverse outcomes affecting the mother and/or the fetus or newborn infant. Sometimes the issue involves the prenatal care that was provided, but most often these claims allege mismanagement of labor and delivery. Delay in delivery and failure to identify fetal

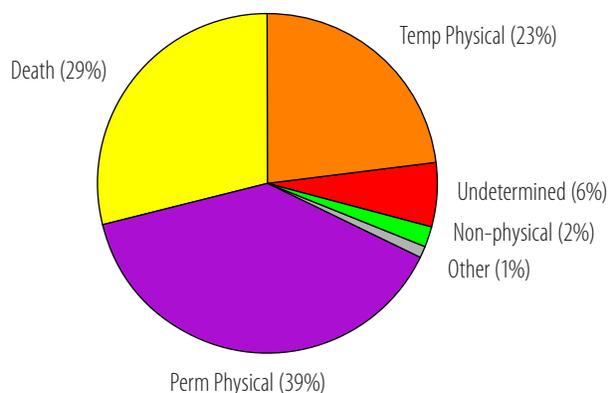
distress are common allegations. Detailed fetal monitor strips and labor progress notes are immensely helpful in reviewing these cases.

- 5) **Negligent treatment with drugs—6%:** This category involves claims where the allegation is limited to either a prescribing or dispensing error. Prescribing the wrong dose or dispensing the wrong medication is rarely defensible when the patient suffers an adverse outcome. Clear, concise written prescriptions and double checking names and doses help reduce the incidence of such errors. Medication errors have been brought under increased scrutiny over the last several years with respect to patient safety in the hospital setting. Most facilities are now carefully tracking their medication errors as part of a facility wide patient safety program.
- 6) **Negligent Dental Care—4%:** Alleged adverse outcomes from dental care account for only 2-3 cases per year. These may include the wrong tooth being extracted, persistent pain after a procedure, damage to the oral cavity, or cosmetic issues. When dental cases are settled, payments are usually quite small.
- 7) **Other/unknown—7%:** This category includes claims with a variety of allegations that do not fit into any one of the above categories. On occasion, the allegation is so vague, it is nearly impossible to appreciate the basis for the claimant's argument.

Types of Injury: In general, patients are more likely to file a claim when they suffer a significant injury. One reason for this is that the compensation awarded will potentially be much larger for permanent injuries or wrongful deaths, and attorneys may be more willing to pursue settlement of a claim if the opportunity for a sizeable contingency fee exists. Nonetheless, a claimant does not need to prove permanent physical injury or death; rather he or she may also sue for temporary (even trivial) injuries, mental anguish, or pain and suffering.

Thus, permanent physical injuries are the most common alleged injuries in IHS and Tribal claims, accounting for 39% of all cases. These injuries can include loss of function, scars, brain damage, chronic pain, and so on. Wrongful deaths are the next most common injuries, and they account for 30% of all IHS cases. This includes both fetal and newborn deaths as well as older children and adults (adult deaths being by far the most common type of wrongful death allegations). Temporary physical injuries account for 23% of all cases, and non-physical injuries are noted in 2.3% of cases. About 6% of the time, the alleged injury is not readily categorized or the claim or record does not give sufficient information to determine what (if any) injury actually occurred. Figure 3 ((right) illustrates the relative frequency of alleged injuries for this series of cases.

Figure 3 Types on Injuries Alleged
IHS/Tribal Tort Claims Experience, Fiscal Years 1987–2002



X. The Federal Tort Claims Act

This section is provided as guidance in response to frequently asked questions about the Federal Tort Claims Act. The reader is reminded that legal counsel should be sought whenever questions arise concerning federal employment laws within the confines of a particular set of circumstances. Consult the regional U.S. Attorney representing your IHS Area Office.

Prior to 1946, the Federal Government could not, under common law principles, be held liable because of the doctrine of sovereign immunity. This doctrine emanated from the era when governments were monarchies, and it was considered that “the King could do no wrong.” Under this doctrine, the United States Government could not be sued. In 1946 Congress passed a bill known as the Federal Tort Claims Act (FTCA).¹ By this Act, the Federal Government gave partial consent to be sued for its torts. It provides that the United States may be liable for negligent torts² occasioned by its employees (and certain contractors) while *acting within the scope* of their employment. In December 1988 and again in 1990, Congress extended the FTCA to negligent acts of Tribal contractors carrying out contracts, grants, or cooperative agreements pursuant to Public Law (P.L.) 93-638, the Indian Self-Determination and Education Assistance Act.³ Cases filed under the FTCA include all types of incidents involving personal injury, death, or property damage. Accordingly, it is under this Act that claims alleging negligent medical care are made against the Federal Government. Attorneys at the Office of General Counsel, Department of Health and Human Services (HHS), and the Department of Justice (DOJ) defend the actions for the United States.

Coverage: It is generally understood that the negligent acts or omissions committed by federal employees acting within the scope of their official duties are covered under the FTCA. Also federal employees assigned to a self-determination contractor under the Intergovernmental Personnel Act or commissioned officers detailed under a memorandum of agreement pursuant to section 214 of the Public Health Service Act are protected by the FTCA, as if they worked directly for a federal agency. The critical factor is whether, at the time of the alleged negligent act, the IHS or the Tribal program had the right to control or supervise the activity.

A personal services contractor under contract with the Indian Health Service (IHS) may also be covered if the contract creates a *de facto* employer/employee relationship and the services provided are within the scope of employment pursuant to the personal services contract. Independent contractors (those individuals working at IHS or Tribal facilities under non-personal services contracts (e.g. *locums tenens* providers from contracted agencies) are generally not covered under the FTCA and must carry their own malpractice insurance.

1 28 USC 1346(b); 2671-2680

2 See the Section on Tort Law, Page 12-15

3 25 U.S.C. & 450f(d) and 25 U.S.C. 458aaa-15

The legal extent of FTCA protection differs somewhat for the Tribal employee. Tribal employees are deemed to be federal employees for the purpose of FTCA coverage while acting within the scope of their employment in “carrying out” contracts/compacts under P.L. 93-638. This law also extends FTCA coverage to an individual under a personal services contract with the Tribe if the individual is acting within the scope of his/her employment pursuant to the Tribe’s P.L. 93-638 contract and the services are provided in a facility owned, operated, or constructed under the jurisdiction of the IHS.

Even when faced with a questionable situation about the applicability of FTCA protection, the DOJ has consistently given federal employees the benefit of the doubt. However, it is important to understand that any final decision about whether or not an individual is protected from personal liability by the FTCA is a factual determination made on a case-by-case basis by the HHS Office of General Counsel, the DOJ, and ultimately by the courts.

Scope of official duties (employment): One must be working under the scope of their officially prescribed duties in order to be covered under the FTCA. Official duties are those performed in the course of one’s job, or some authorized activity reasonably associated with it. Whether the employee was acting within the scope of his/her employment is determined under the law of the State where the care was provided. The factors to be considered are: (1) whether the employee was doing the kind of work he/she was employed to do (as set forth in the position description or billet); (2) whether the work occurred at the expected time or place; and (3) whether the work was undertaken to serve the IHS or Tribe. Moonlighting and other outside work activities, even if authorized, may not be covered by the FTCA. Furthermore, the FTCA does not provide coverage for intentional (deliberate) torts of federal employees, such as battery or fraud.¹

Remedy: The injured party or representative cannot initially commence a lawsuit but must first file an *administrative federal tort claim* with the Office of General Counsel, HHS. In addition, the injured party’s exclusive remedy is to file a federal tort claim; no legal action can be taken against any IHS or Tribal healthcare employee – that is to say, such employees are immune from civil liability.² A further provision is that Congress made the law in the local jurisdiction the decisive factor in determining liability; therefore, a plaintiff may recover for a particular action in one state but not in another.

Statutes of limitations: Claims must be filed within two years of the incident or knowledge of the alleged injury; otherwise the statute of limitations expires, and the claimant has no recourse. Once the claim is filed, the claimant may not file suit for six months. If the case is not resolved during the government’s six-month administrative review period, the claimant may file suit at any time, unless the government denies the administrative claim, in which case suit must be filed within six months of the date of denial.

Payments: Tort claims, suit settlements, or court judgments against the Federal Government are paid by the US Treasury, except those for \$2,500 or less which are “paid by

1 See Section on Tort Law, Page 12-15

2 Section 224 of the Public Health Service Act, 42 USC 233

the head of the federal agency concerned out of appropriations available to that agency.”¹ This applies to tort claims involving both IHS and Tribal programs.

Non-covered providers: Non-personal services contractors and other providers who do not fall under the FTCA umbrella can be sued individually in State court for alleged negligent acts committed while working within IHS or Tribal facilities. It is the responsibility of the governing body of each IHS or Tribal facility to ensure that all such providers verify their malpractice insurance coverage during the credentialing and privileging process.

¹ Under 28 USC 2672

XI. The Malpractice Tort Claim Review Process

When a medical malpractice tort claim alleging negligent care at Indian Health Service (IHS) or Tribal facilities is filed, the action is against the Federal Government. The review process involves individuals and programs from various offices within the Department of Health and Human Services (HHS). And if the tort claim becomes a suit, then the Department of Justice (DOJ) takes charge of the case. In order to better understand the process, it is first important to appreciate the responsible parties and their respective roles; subsequently, the details of the review process will be outlined.

The Department of Health and Human Services

The IHS Risk Management (RM) Program: The review and evaluation of medical malpractice tort claims is an inherent federal function that cannot be contracted, and therefore the IHS RM program processes malpractice claims arising from care provided at IHS direct care sites as well as tribally operated facilities. The Agency's RM program is organized within the Office of Clinical and Preventive Services, IHS Headquarters, Rockville, Maryland. The complete responsibilities of this program were outlined in the first section of this Manual. Currently (2006), two physicians – one fulltime, the other halftime—are managing the program, with occasional assistance from a dentist and a Headquarters nurse administrator.

The IHS is one of the operating divisions within HHS; therefore, any administrative tort claim (malpractice, injury, or other) involving an incident at an IHS or Tribal facility becomes the responsibility of the legal arm of the HHS, the Office of the General Counsel (OGC). There are two components of the OGC that have primary responsibility for the administrative tort claim review: the OGC Claims Office and the Claims and Employment Law Branch.

The OGC Claims Office: The Claims Office was formerly separate from the OGC, both in organization and distance. Originally known as the PHS Claims Office, the program was renamed the PSC Claims Branch in 1995 when HHS underwent a phase of reorganization. More recently in 2004, this office was again reorganized and is now under the OGC "roof," both in organization and location. Their functions and responsibilities, however, have remained basically the same. The Claims Office is primarily responsible for reviewing the validity of the claim, requesting medical records from the site of the incident, and responding to inquiries and questions about the claim. They also inquire about employment information for involved providers to determine if these providers are covered by the Federal Tort Claims Act (FTCA). The Claims Office also notifies IHS when claims are paid, and maintains a database of all claims filed against the Federal Government that involve any of the operating divisions of HHS.

The Claims and Employment Law Branch of the OGC (CELB): The CELB provides legal advice and review of all federal administrative tort claims (including medical malpractice) involving incidents at any of the facilities or programs that are part of the HHS. With respect to cases involving alleged medical malpractice, this includes the IHS, Tribal programs, the National Institutes of Health, and various healthcare delivery programs within the Health

Resources and Services Administration. An attorney is assigned to each malpractice tort claim received. The assigned attorney makes his or her decision to allow or disallow the claim based on the legal validity of the claim and whether or not there was a breach in the standard of care.¹ The attorney will usually discuss issues with the IHS risk manager before making a final decision regarding the claim. Depending on the amount of money involved, the OGC must communicate with the Department of Justice before agreeing to allow higher cost claims. If, after considering the facts, the law, and the medical standards involved, OGC decides that the claim is meritorious, settlement negotiations will be initiated with the claimant (or claimant's representative). If it is determined that there is no liability on the part of the Government, the claim is disallowed.

Malpractice Claims Review Panel (MCRP): The original name for the MCRP was the Quality Review Panel (QRP), which was formed in 1990. The QRP was given the responsibility to review all medical malpractice claims filed against the Federal Government that involved care provided at facilities controlled or funded by various operating divisions of the HHS and determine if 1) the standard of care was met or not met, or if a system breakdown caused the outcome of the care provided to be outside the control of the involved practitioner(s), and 2) which practitioners were primarily responsible for providing the care in question. Should payment be made on a claim, it is these identified practitioners who would be subject to be named to the National Practitioner Data Bank (NPDB). According to the original HHS policy, a NPDB report was required for every case, whether or not the standard of care was met.² The only exception was when the Panel had declared a "system breakdown."

Cases were presented to the QRP prior to being sent to OGC for legal deliberation. Therefore, the Panel's decision was also made available to OGC in addition to the other reviews obtained by the IHS RM Program. Over time, the Panel's workload increased to more than 250 cases annually, following the enactment of a law that brought a wide range of federally supported health centers under the auspices of the FTCA. In 2004, the Panel was re-chartered and became the MCRP. Under this new charter, the Panel does not review every malpractice tort claim; rather, only those cases that have been allowed by the OGC or paid in the course of litigation (e.g., settled or adjudicated) are reviewed.

The MCRP consists of approximately 15 members of a variety of medical disciplines, including physicians, dentists, nurses, advanced practice nurses, and pharmacists. It is responsible for reviewing HHS malpractice tort claims from all of its operating divisions, not just IHS and Tribal programs. Meetings are held monthly; an IHS RM Program representative presents the IHS-related cases. All the reviews and supporting documents are sent to all panel members prior to the meeting. Decisions regarding the standard of care are made by majority vote after the case has been discussed. Providers of record are determined in a similar fashion, with particular reference to the responsibilities of the practitioners involved.

1 These attorneys rely greatly on medical reviews submitted by operating division involved in each claim. See the Step-by-Step Guide to the Review Process on Page 37–38.

2 At the time this Manual was being prepared (February 2006) this particular aspect of the HHS policy was being reviewed. See Section XII for additional details on NPDB reporting.

Department of Justice

Once a suit (civil action) against the Federal Government is filed in the appropriate U.S. Court, it is the Department of Justice (DOJ) that is responsible for defending the case. An assistant U.S. District Attorney (AUSA) within the jurisdiction is assigned the case and assisted by a Departmental attorney. The AUSA will usually seek outside expert witnesses to defend the case, obtain depositions from involved providers, and procure all private records through discovery (this discovery process is not available at the administrative claim stage). While some cases with little merit are dismissed, the majority of cases are settled before going to trial. When cases do go to trial, they are argued before a judge in the respective U.S. District Court (non-jury trial). The applicable standard of care is that which is in effect in the state in which the incident occurred.

A Step-by-Step Guide to the Review Process

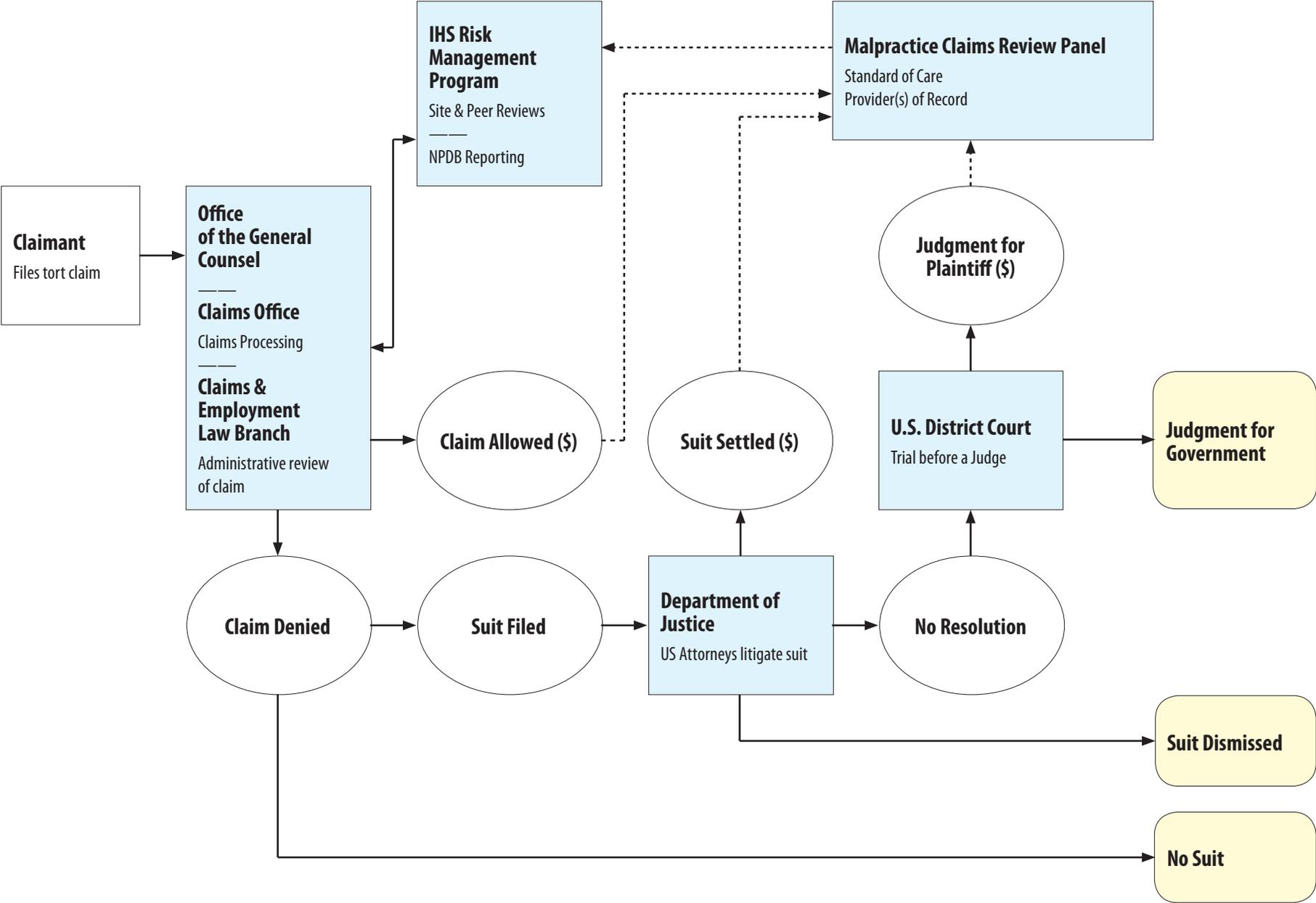
The following guide is provided to assist the reader's understanding of how a tort claim is worked through the system. The flow diagram on Page 39 will help to visualize the process.

- 1) A person who believes they have suffered an injury due to the negligence of an IHS/ Tribal health care provider or facility must first file a tort claim with the OGC Claims Office. No attorney at this point is required, but most prospective claimants do seek legal advice. To submit the claim, a claimant may use the "Standard Form 95," or simply state in a letter where and when the incident happened, what injury was sustained and how much compensation (in dollars) is being sought.
- 2) The Claims Office requests three copies of the relevant medical records from the site of the incident. Also requested are practitioner narratives and employment information for the practitioners involved (to ascertain whether or not the involved practitioners are covered by the FTCA). Upon receipt of these documents, a copy of the records and narratives are forwarded to the IHS RM Program.
- 3) When the IHS RM Program receives the tort claim and accompanying medical records from the Claims Office, the case is assigned to a Headquarters' risk manager to coordinate the medical review of the claim. The "case coordinator" reviews the case in detail and considers the need to request any additional information through the Claims Office (e.g. outside medical records, x-rays, etc).
- 4) The clinical director or risk manager at the involved site is contacted by the case coordinator to initiate a site review of the incident. Along with the site review, the coordinator asks that all providers involved in the care be notified about the claim, and be given the opportunity to respond with a practitioner narrative (if they have not already provided one) or to participate in the local review of the claim. The coordinator also requests specific practitioner identifying and credentialing information. For providers who may have left the facility, the coordinator requests the service unit send notification to that provider. While the claim is "open," former employees do have the opportunity to participate in the analysis of the claim with respect to the care they rendered.

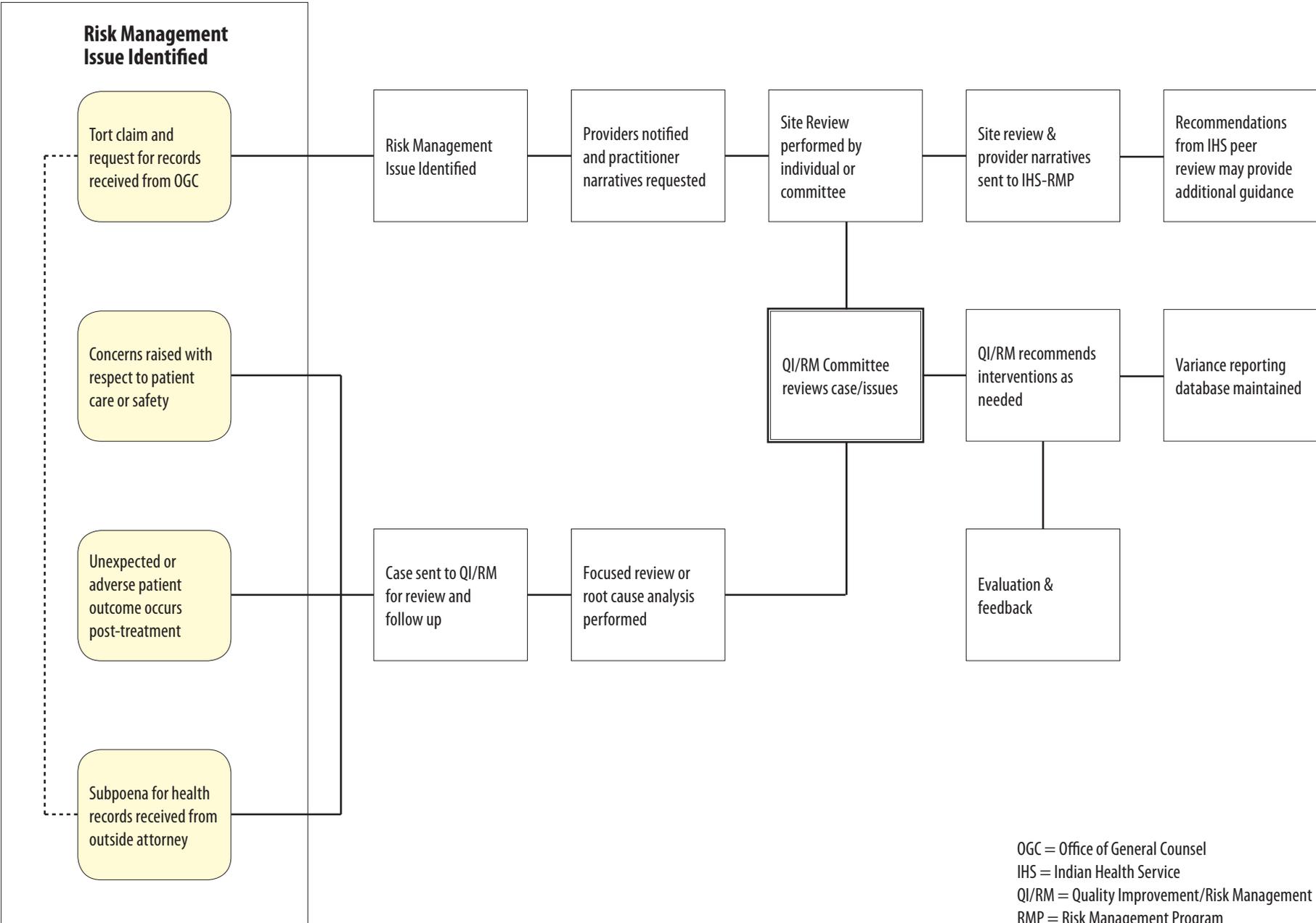
- 5) At the same time, the case coordinator will request a peer medical review of the case from an IHS provider distant from the site in question. The coordinator identifies someone with similar training to the individual(s) involved in the case. If a particular case involves care provided by practitioners of various disciplines, then additional reviews are sought.
- 6) Once the reviews and narratives are compiled, the case is sent to the OGC for legal review. If the OGC finds the case has merit, an attempt is made to negotiate a financial settlement. If the OGC finds there is no merit, the claim is disallowed.
- 7) A claimant may file suit against the government in Federal District Court under the following circumstances: the OGC fails to act upon a claim within six months of receipt of the claim; the settlement offer is unacceptable to the claimant; or the claim is disallowed by the OGC, and the claimant wishes to pursue further legal action.
- 8) When a suit does occur, the case becomes the responsibility of the Department of Justice. If the DOJ determines that the case is not defensible in court, then a settlement offer will be made in the best interest of the Federal Government. If the DOJ can build a strong defensible case, then a trial date will be set. Rarely, a suit is dismissed altogether by a judge on technical grounds.
- 9) Cases that go to trial are heard by the respective Federal District Court without a jury. The federal judge makes final judgment on the case and determines the amount of the award. The judge may also declare in his order which practitioners were, in the judge's opinion, negligent.
- 10) Information on payments of tort claims and suits is eventually sent back to the IHS RM Program. At this point the IHS coordinators will attempt to contact involved parties to inform them of the payment and help determine if additional information is available. Then, the case coordinator will present these cases to the MCRP. The MCRP determines the medical merit of the case (standard of care met, not met, or system breakdown) and the practitioners (if any) who were responsible for providing the care in question.
- 11) Once a determination has been made by the MCRP, the IHS case coordinator will communicate with the IHS/Tribal site in question, send an updated Case Summary to the clinical director, and discuss with the provider(s) of record issues related to National Practitioner Data Bank reporting, if necessary.
- 12) The IHS RM Program is then responsible for submitting Medical Malpractice Payment Reports (MMPR) on all appropriate cases to the NPDB. A separate MMPR is submitted for each practitioner named by the Panel for a particular case (see following section).

The service unit's response is key to the tort claim evaluation and risk management follow-up. The site evaluation of an incident may be triggered by the event itself (e.g., sentinel event analysis), when a claimant's attorney requests a patient's records before a claim is filed, or in response to the IHS RM Program's request. In any case, the local review and IHS evaluation should flow through the facility's RM program in such a way that any lessons learned are fed back to hospital staff. The flow diagram on Page 40 shows the dynamics of how a service unit's process of risk management review might function.

Malpractice Claims Review Process



Risk Management Process—Service Unit Level



XII. The National Practitioner Data Bank

The National Practitioner Data Bank (NPDB), which opened in 1990, serves as a clearinghouse to collect and release information concerning payments made on behalf of physicians, dentists, and other licensed health care practitioners as a result of malpractice actions and claims. In addition, it maintains information concerning certain adverse actions regarding the licenses and clinical privileges of physicians and dentists. Reports to the NPDB concerning malpractice claims or suits are only made if a payment is made, not merely if a tort claim or suit is filed, and the submitted report must be made “for the benefit of” (on behalf of) an individual provider, not an institution or health care program.

The NPDB Law

The mandate for the NPDB was contained in Public Law (P.L.) 99-660, the Health Care Quality Improvement Act of 1986. There were several concerns and issues that the Congress was attempting to address in the framing of this law: there was an increasing number of malpractice suits against health care providers, particularly physicians; there were reports of physicians with credentials problems moving from state to state to avoid detection; peer review of quality of care was being threatened by the fear of suit against individuals performing the peer review; and there was a general concern for the quality of health care being provided in this country.

Note: The Health Insurance Portability and Accountability Act of 1996 further authorized the establishment of a second and somewhat related national data bank, the Healthcare Integrity and Protection Data Bank (HIPDB). The HIPDB is a national collection program for the reporting and disclosure of certain final adverse actions taken against health care practitioners, providers, and suppliers with respect to fraud and abuse in the health insurance and health care delivery industries. The HIPDB is now combined with the NPDB, creating the rather ominous abbreviation NPDB-HIPDB. Since this Manual does not deal with fraud and abuse, the HIPDB will not be further mentioned.

Part A of P.L. 99-660 provides for professional immunity for peer review activities when they are taken in good faith to promote quality health care. Even though Indian Health Service (IHS) medical staff members are not individually liable for peer review activities as part of their employment by the IHS or a Tribe, it is essential for each medical staff to have an adequate notice and hearing process in the medical staff bylaws. This will provide a structure within which the medical staff will function should a practitioner challenge the denial or reduction of medical staff privileges, both of which are reportable to the NPDB if based on competence or conduct. Because these actions are reportable, they will likely be challenged, thereby requiring a workable and legally defensible notice and hearing process to protect both the Agency and the individual practitioners.

Part B of the law requires reports to the NPDB for *any payment*, including settlements, made as a result of a malpractice claim or suit and for adverse actions against the clinical privileges, state licensure, or professional society membership of physicians and dentists.

Querying the NPDB is also required when a hospital is considering an applicant for medical staff appointment and/or clinical privileges, and every two years for those on the medical staff and/or with privileges. An attorney who has filed a medical malpractice action or claim against a hospital may query the NPDB for information regarding a specific physician, dentist, or other health care practitioner who is also named in the action. However, this information will only be disclosed by the NPDB if the attorney submits evidence that the hospital failed to request information from the NPDB, as required by law. The information may be used solely with respect to malpractice action against the hospital named in the suit. Also of note, any information reported to the NPDB goes into a 30 day suspense file before it is placed in the computer. During this time, both the reporting institution and the practitioner in the report will receive verification documents in order to review the information that is to be entered in the NPDB. No information becomes available for querying before the practitioner has been notified.

The NPDB and the Federal Sector: The law establishing the NPDB did not require that federal programs be included in reporting and querying requirements. However, the Department of Defense, the Department of Veterans Affairs, and the Department of Health and Human Services (HHS) all stated that they would participate fully in both NPDB reporting and querying. Therefore, the rules and regulations of the NPDB published in the Federal Register (and found on the NPDB website) that govern how individual practitioners are to be reported do not necessarily apply to the federal sector. In regards to practitioners working for operating divisions of the HHS (and Tribal organizations), the policy and procedure for reporting to the NPDB can be found in a 1990 memorandum signed by the then Assistant Secretary of Health. This policy was being reviewed for possible revisions during early 2006. Separate policies deal with reporting adverse actions and querying.

National Practitioner Data Bank Reporting—Agency Experience: From 1991 until mid-1997, the HHS Claims Office was responsible for submitting reports to the NPDB for the Department. Approximately ninety-five reports were submitted during this time period. A small portion of these reports involved cases where it was determined that the standard of care had been met; in accordance with Department policy, a statement was added to each of these reports that the “standard of care was met.” During this time period, the IHS had no input into the information submitted to the NPDB. In 1997, the submission of NPDB reports by the Claims Office was interrupted for a variety of reasons, but the responsibility to prepare and submit reports was not transferred to another Department entity. Therefore, for more than seven subsequent years, very few providers’ names from paid IHS and Tribal cases were submitted to the NPDB.

In 2003, the Office of the Inspector General (OIG), HHS, determined that the various operating divisions of HHS that had the responsibility of providing health care were no longer following Department policy for NPDB reporting. A long series of discussions and meetings transpired over the next year and a half. Finally, the OIG made a final recommendation that the IHS (and other involved operating divisions of HHS) formulate a corrective action plan to reestablish a mechanism to achieve ongoing NPDB reporting, including the elimination of the backlog of cases. In early 2005, the IHS RM Program began this required process.

The IHS first dealt with the backlog of reporting, including some cases that date back to care provided in the early 1990s. The IHS has been submitting reports only on cases where it was determined by the HHS Malpractice Claims Review Panel (Panel) that the standard of care was not met. As of April 2006, no reports have been submitted by the IHS for any case where it was determined by the Panel that the standard of care was met, or that the adverse outcome was a result of a “system failure.”

To prepare a NPDB report, mandatory provider information, payment information, and clinical information has to be identified. Often, it is necessary to consult with the service unit risk manager, credentials coordinator, or clinical director to collect missing provider information. Before a report is submitted, the IHS makes every possible attempt to first notify the provider about this pending administrative action, even when the providers have long left governmental or Tribal employment.¹ Either by letter or phone, the provider is notified about the situation. If the provider had never been offered the opportunity to discuss their involvement in the case, or if they wish reconsideration, then they are afforded the opportunity to submit an appeal to the Panel. When necessary, attempts are made to retrieve the medical records. Provider appeals are taken back to the Panel only when new or clarified information is evident. The Panel then makes a determination whether to sustain or overrule their original decision regarding the standard of care, system issues, or provider(s) of record, whichever is being contested. The decision of the Panel regarding the appeal is final.

Once a NPDB report has been submitted, there are additional processes available to the reported individual in regards to dispute resolution. Also, the provider has the opportunity to electronically submit a “subject statement” that will be added to the NPDB report. Many providers will submit additional information further explaining their decision-making or actions relevant to the case in hand. Once reported, an individual practitioner is responsible for disclosing this information to the credentialing office of the facility or facilities where they practice, and to their State licensing board(s).

Issues Regarding NPDB Reporting:

- Particularly for older cases, it was a common finding that practitioners were either altogether unaware that a claim had been filed, or they were never offered the opportunity to participate in the claim review process. The IHS RM Program has taken steps to ensure that all providers are now given every opportunity to explain to the Panel their degree of involvement in a case.
- Also in the past, practitioners involved in tort claims were often not kept abreast of the progress of a tort claim as it worked its way through the OGC, Panel, and DOJ. This process often takes years to come to a conclusion. The IHS RM Program has made a renewed effort to maintain contact with practitioners and the IHS and Tribal facilities during the various stages of claim and suit negotiations.

¹ Neither the HHS reporting policy nor the NPDB regulations require practitioner notification before a payment report is submitted.

- The IHS cannot name to the NPDB individuals who are not covered under the Federal Tort Claims Act. Therefore, non-personal services contractors working in IHS or Tribal facilities cannot be considered for NPDB reporting, even when the care they provided was clearly below the standard of care and was responsible for the adverse outcome. These individuals must be covered by their own medical malpractice insurance policies and are subject to be sued individually. If the independent contractor's malpractice insurance company makes a payment on behalf of its policy holder, it is that company's responsibility to submit a NPDB report.
- Not uncommonly, providers and service unit officials do not understand the role that the Panel's decision has in the overall claim review process. There is confusion over the roles of the OGC, the DOJ, and the Panel in determining which providers are named to the NPDB. It is important to realize that the OGC and the DOJ are defending the Federal Government and are not involved in NPDB reporting decisions. In accordance with HHS policy, the MCRP is the sole entity with the responsibility for identifying which practitioners will be named to the NPDB for a particular claim or suit.

XIII. State Licensing Boards and the Federation of State Medical Boards

State Licensing Board

All Indian Health Service (IHS) physicians who have patient care responsibilities are required to maintain a valid and unrestricted state license. Medical malpractice payers (including the IHS) must report medical malpractice payments simultaneously to the National Practitioner Data Bank and the appropriate state licensing board authority. Each health care entity must also report to the respective state board of medical examiners the following actions:

- 1) Any professional review action that adversely affects the clinical privileges of a physician or dentist for a period longer than 30 days
- 2) Acceptance of the surrender of clinical privileges or any restriction of such privileges by a physician or dentist
 - a. While the physician or dentist is under investigation by the health care entity relating to possible incompetence or improper professional conduct, or
 - b. In return for not conducting such an investigation or proceeding
- 3) In the case of a health care entity that is a professional society, when it takes a professional review action.

Whether or not any action is taken against a physician's license who has been involved in a malpractice action depends on the severity of negligence and number of incidents. In general most tort claims or suits involving federal employees do not result in any license restrictions or suspensions. However, the state licensing board may wish to perform its own review of the incident and will seek discovery of the medical records involved. Federal Privacy Act statutes prevent the disclosure of medical records directly to state regulatory boards. State boards who wish to receive copies of IHS-controlled medical records must file a Freedom of Information Act Request (FOIA) with the Agency's FOIA Officer.¹ Once the FOIA request has been approved, the FOIA Officer is responsible for de-identifying the records prior to releasing them to the state board. Health care providers should never release such records on their own, even if they are issued a state court subpoena. All requests for medical records received at the local facility from outside agencies should be referred to the facility's administration for proper processing.

The Federation of State Medical Board

The Federation of State Medical Boards (FSMB) serves as the primary center for collection, maintenance, and reporting of disciplinary actions taken against physicians by its member boards and other governmental authorities. Disciplinary actions are reported to the FSMB by state licensing and disciplinary boards, Canadian licensing authorities, the U.S. armed forces, the U.S. Department of Health and Human Services, and the Education Commission for Foreign Medical Graduates.

¹ See section XVIII, Selected Resources, for address and telephone number of FOIA Officer.

FSMB's membership is comprised of the medical boards of all states, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands, and includes 11 of the 16 separate osteopathic boards in the United States. The ten Canadian provincial medical licensing authorities hold affiliate membership. The Federation is a parent and member organization of the National Board of Medical Examiners, the Accreditation Council for Continuing Medical Education, and the American Board of Medical Specialists.

Actions included in the FSMB Data Bank are revocations, probations, suspensions, and other regulatory actions such as license denials and reinstatements. Medicare sanctions and Department of Defense adverse privileging actions are also included in the FSMB Bank. Information on medical malpractice payments is not stored in this database.

XIV. The Less Said the Better

Health care practitioners of all disciplines have been taught to relay to their patients abundant information about underlying disease processes, medications, prognosis, and general health promotion. The axiom is the better informed the patient, the better health choices he or she can make. When it comes to medical malpractice tort claims however, the opposite is true; the less we say in public about an alleged malpractice incident or its accompanying legal proceedings, the better. Disclosing certain protected information may raise legal problems or lead to the discovery of damaging information by the claimant's attorney. The following bullets provide useful tips for practitioners with respect to potential or actual medical malpractice tort claims.

If an Adverse Event Occurs:

- It is prudent to tell patients about any errors in medical management or unanticipated clinical outcomes when they occur, but not to admit fault or liability in any way, either verbally or in the chart.¹
- Prior to communicating these situations with the patient, the chief executive officer, clinical director, and risk management should be alerted. A planning meeting with these individuals should be held before discussions with the patient occur; the IHS legal counsel may need to be included under certain circumstances. However, there should not be an undue delay in communicating the event to the patient.
- Do not try to point fingers at other providers for medical mishaps. Keep all medical records factual and to the point.
- If you witness potentially negligent acts or incompetence by fellow practitioners, do not place this information in the chart or discuss it in earshot of patients. Bring it to the attention of the medical director. The exception, of course, would be to intervene if the life or limb of a patient is in immediate jeopardy.
- Never encourage a patient to file a tort claim or take legal action. If a patient has concerns about the care they have received, refer them to the facility's patient advocate, risk manager, or the medical director.

Once a Tort Claim is Filed:

- If the allegation of negligence involves you as a practitioner, you may be more comfortable having a colleague take over the care of your patient; often this may be the most practical choice. Document the change of providers in the chart, but do not put anything about the tort claim in the medical record. If you are unclear of what your role should be in caring for the patient, discuss the situation with your medical director or call the IHS Headquarters Risk Manager.

¹ For more guidance on this issue, an IHS circular tentatively titled *Communicating Outcomes of Care to the Patient* is being planned for publication during late fiscal year 2006 or early 2007.

- Do not discuss a tort claim with the involved patient or their relatives; if the patient asks you questions about their case, politely decline to say anything.
- If you happen to get a call from a claimant's attorney, do not discuss the case or say anything. Be careful because occasionally an unscrupulous lawyer may try to trick you into divulging information. Refer the caller to the Government's legal counsel or simply say you are not permitted to say anything about the situation and hang up.
- You can confidently discuss the case with an attorney from the Office of General Counsel or an Assistant U.S. Attorney (AUSA) from the Department of Justice, as these individuals are representing "our side" and may need additional information from you to help the Government defend the case.
- Do not send or give copies of the claimant's medical chart or computer records to anyone. Leave the transfer of patient documents up to the medical records librarian or risk manager, who are trained to know what and with whom information can be shared.
- Outside medical records that are not in the possession of the IHS or Tribal facility after a tort claim is filed are not necessarily discoverable by the Federal Government (at the administrative tort claim stage). The patient may appropriately decline, at the advice of their attorney, to give permission for the facility to request these records.
- Never discuss a pending tort claim or suit with the media. Refer all such calls to the facility's chief executive officer. Decline all requests for interviews.
- Once a case goes into litigation (suit stage), there will be a discovery phase when you may be asked to give a deposition (see following section). This is the one and only time you will be authorized to discuss the case with the plaintiff's attorney. A specific meeting will be scheduled for this purpose, and an AUSA will be present to assist you.
- Finally, if you ever happen to be named to the National Practitioner Data Bank as a result of a federal malpractice tort claim or suit, your state licensing board may desire to perform their own independent investigation of the case. On occasion the board may call you directly requesting information on the case and even ask for copies of the medical record. Please do not send any copies of medical records directly to your state board as Federal Privacy Act statutes do not permit releasing these documents unless they have been properly de-identified; in most cases the requesting entity must first file a Freedom of Information Act request (see Section XIII). Refer all such calls to your facility risk manager or the IHS Risk Management Program.

XV. Giving a Deposition

During the pretrial discovery phase of malpractice suit litigation, it is not uncommon to be deposed to give testimony. The IHS or Tribal practitioner then becomes a “witness” for the defense (e.g., the Government). The plaintiff’s attorney interviews the witnesses, trying to extract information vital to his case. As a witness for the Government, the practitioner is not represented by his/her own legal counsel, but rather by the AUSA defending the case on behalf of the Government. The AUSA is there to provide guidance and assure that the plaintiff’s attorney does not reach beyond the bounds of ethical fact-finding.

Being deposed can be an agonizing experience for a healthcare practitioner, especially when his/her competence is being brought into question. Few practitioners have much experience giving depositions, so the best advice is to listen carefully to what the AUSA says in preparing you to testify, and follow their cues throughout the process. Most professional societies (such as the American College of Physicians, the American Academy of Pediatrics, and the American Academy of Family Physicians) provide guidance materials for giving testimony. There are also books and articles written on the subject of deposition process. The “Ten Rules for the Practitioner’s Deposition” on the following page have been adapted from one frequently quoted book on this subject.¹

Only a few Indian Health Service or Tribal medical malpractice suits ever go to trial, but it does happen. Similar to giving a deposition, the federally or tribally employed healthcare practitioner serves as a witness for the defense. It goes without saying that both the attorney and the practitioner must be equally well prepared: the medical records, textbooks, and other sources of authority must be thoroughly reviewed before the trial. The practitioner must realize that in the adversarial climate of a trial, his or her judgment and decisions will likely be challenged by the plaintiff’s attorney and any expert witnesses who may present opposing viewpoints.

¹ From T. Leaman & J. Saxton, *Preventing Malpractice: The Co-Active Solution*, pp.68-70 (Plenum, New York 1993).

Ten Rules for the Practitioner's Deposition

- 1) Know the case intimately—clinic records, hospital charts, statements by other health care professionals, the medical literature, and alternative treatments.
- 2) Listen to the attorney's question carefully and respond only when you understand it completely. Ask the attorney to rephrase the question if you do not understand the question. Never help to rephrase it or suggest a more appropriate question.
- 3) Respond thoroughly, but directly and to the point; do not tell stories, ramble, digress, or volunteer information.
- 4) Use the medical record; it can be the best defense tool, especially if it is in order.
- 5) The theatrics of the plaintiff's attorney should be disregarded. Sometimes the attorney will act surprised and shocked by a response, use body language, or repeat certain phrases in an attempt to irritate the defendant. Such theatrics are intended to make the practitioner uncomfortable and unsure of the response.
- 6) Be consistent with your responses. Plaintiff's attorney may ask the question over and over, each time phrasing it a bit differently, looking for an inconsistent response. Remember that the plaintiff's attorney has been working on these questions for weeks before the deposition; he/she will try hard to get the needed response or at least neutralize the damage from an unfavorable, unanticipated response.
- 7) Wait for the next question after finishing a response. Often the plaintiff's attorney will pause, using body language to urge the physician to say more. Do not try to fill the void, but simply wait patiently for the next question.
- 8) Be extremely cautious in responding to leading questions, such as "Is it a fair statement...", "Let me summarize your testimony as follows..." and "Doctor, just so I understand what you are saying..." Statement like these mean the plaintiff's attorney is about to reinterpret the practitioner's testimony. Agree only with those statements with which you are comfortable. If you disagree, then simply say so, and repeat the previous response.
- 9) Be careful of conversation during breaks, or before and after the formal taking of the deposition. A deposition is not the time for social niceties. Breaks should be used to relax and regain composure. One must be on guard from arrival at the deposition until departure.
- 10) Be courteous, professional, firm, and credible at all times. A deposition is neither the time nor the place for chitchat and humor. **Under no circumstances should you be offensive, insulting, or argumentative.**

XVI. What to Do If you Are Sued Individually

Reprinted from: "Medical Malpractice Claims, A Guide for PHS Health Professionals," U.S. Department of Health and Human Service, Public Health Service, Office of the Assistant Secretary for Health, 29/3948 (undated). Contact information updated for 2006.

As IHS or P.L. 93-638 health professionals, you are protected from civil liability for injury to a patient that may occur while performing duties within the scope of your employment. It is still possible, however, that you may be served with a summons and complaint naming you as a defendant and alleging negligent conduct on your part. The civil action is usually brought for such reasons as:

- 1) The claimant/attorney may believe that your conduct was not covered by the Federal Tort Claims Act;
- 2) The claimant/attorney may be unaware of the immunity protection afforded IHS or P.L. 93-638 health professionals.

Such legal actions are usually brought in State court. There are specific statutes (28 USC 2679, 42 USC 233(a)-(f)) which apply to the situation in which a IHS or P.L. 93-638 health professional is sued for damages resulting from the performance of medical or related functions while acting within the scope of employment. The lawsuit would be removed from the State court, before trial, to the appropriate federal district court. The U.S. Government would then be substituted as the proper defendant and the action against the health professional would be dismissed. The suit against the United States would then be dismissed if no administrative tort claim had been filed with the agency.

Time is of the essence for having the civil action naming you as a defendant removed to a federal district court in order to substitute the U.S. Government as the defendant. Your failure to respond to the State action could result in a default judgment against you. Therefore, it is essential, in the event you are personally served with a summons and complaint based on your official duties, that you inform your supervisor (or the pertinent organization, if the alleged injury occurred at a past assignment) and deliver to the appropriate person or organization a copy of the legal papers served upon you, as soon as possible. Members of the National Health Service Corps practicing in non-PHS health facilities should notify their Regional Health Administrator.

Depending upon the established policies in the health facility concerned, either the supervisor or the person who has been designated to act as liaison with the Office of the General Counsel should immediately telephone the following office to report that an IHS or P.L. 93-638 health professional has been named in a civil action:

Chief, Claims and Employment Law Branch, Office of the General Counsel, DHHS, Cohen Building, Room 4758, 330 Independence Avenue, S.W., Washington, D.C. 20201; Telephone (202) 619-2155

The following materials will be required to be provided to the Office of General Counsel:

- 1) A copy of the summons and complaint served upon the individual;
- 2) An affidavit from the supervisor that the individual involved was acting within the scope of his/her official duties at the time the incident occurred;
- 3) A letter from the individual requesting that the Justice Department represent him/her in the action;
- 4) The address and telephone number (home and work) of the individual sued.
- 5) If the employee is a member of the National Health Service Corps, serving in a non-IHS health facility, the following additional information may be requested:
 - a. A narrative summary of what happened;
 - b. Names, addresses, and phone numbers of witnesses and a summary of their statements, if possible.
 - c. A copy of the pertinent medical records should be requested through appropriate officials of the facility.

XVII. Risk Management *DOs* and *DON'Ts*

DO

- + Do maintain proper licensure, credentials, and privileges at all times.
- + Do maintain professional decorum at all times.
- + Do treat patients with dignity and respect.
- + Do write legibly.
- + Do use only standard terminology and avoid abbreviations when charting. Chart professionally. Use proper grammar, punctuation, and spelling.
- + Do chart as soon after the event as possible. Entries must be “reasonably contemporaneous” with the care that was given.
- + Do chart comprehensively. Chart as much as is reasonably possible. Ideally you would chart in detail everything that was done. This would include charting results that are essentially normal or unremarkable; “if it’s not charted, it didn’t happen.”
- + Do be objective and descriptive in your progress notes; avoid being subjective or conclusory. For example, do not say, “The patient is a long-time drunk.” A better entry would read, “The patient reports a history of alcohol consumption of approximately [amount] for the past x years.”
- + Do note in the chart any non-compliance with the prescribed treatment regimen. This could include, for example, failure to keep appointments, failure to adhere to treatment regimens, failure to take prescribed medications, etc. Make sure these entries are polite and objective. Do not use the record to insult, chastise, or denigrate the patient.
- + Do initial and date all laboratory slips as they are reviewed. This shows that the laboratory results were reviewed and considered.
- + Do initial and date all ECG rhythm strips, fetal monitor strips etc. while they are running. Whenever medications are given or other actions are taken that could affect the heart rate or other physiological measures under observation, this should be noted by making an entry on the strip.
- + Do obtain proper written, informed consent prior to any non-emergency invasive procedure.
- + Do establish and maintain an accurate system of warning labels on charts of all patients with known drug sensitivities.
- + Do respect Tribal customs.

Risk Management DOs and DON'Ts



DO NOT

- Do not reprimand, criticize, or complain about other members of the health care team within sight or hearing of patients.
- Do not criticize other staff members in the medical record.
- Do not write in the record that malpractice occurred or that anyone is legally liable.
- Do not engage in debate within the medical record.
- Do not become emotional in chart entries. The chart is not the place for catharsis. Nor is it the proper place for editorials or opinion pieces.
- Do not obliterate or alter errors in the chart. Correct them by drawing a single line through the error, writing “error” above the lined out wording, recording the correct information and signing and dating the correction.
- Do not discard or destroy any part of the medical record or any other hard copy diagnostic printouts such as monitor strips, blood gas readings, etc.
- Do not promise a “cure” or improvement and do not guarantee specific results. Avoid saying or doing anything that would unreasonably raise patient expectations.
- Do not talk directly to a claimant’s or plaintiff’s attorney. Refer all such calls to the Government’s legal counsel, or simply say you cannot provide any information to them.

XVIII. Selected Resources

IHS Headquarters—Clinical Issues

- Office of Clinical and Preventive Services, Indian Health Service Headquarters, 801 Thompson Avenue, Suite 300, Rockville, MD 20852, Tel: (301) 443-3644

IHS Risk Management/Tort Claims

- IHS Risk Management Program Office, Albuquerque Indian Health Center, 801 Vassar Drive, Albuquerque, NM 87106; Tel: (505) 248-4047
- IHS Clinical Support Center, Two Renaissance Square, Suite 780, 40 North Central Avenue, Phoenix, AZ 85004; Tel: (602) 364-7742

Legal Counsel/Tort Claims

- Claims Office, Office of General Counsel, 330 Independence Avenue SW, Cohen Building, Room 4256, Washington, DC 20201, (202) 205-5995
- Chief, Claims and Employment Law Branch, Office of General Counsel, DHHS, Cohen Building, Room 4758, 330 Independence Avenue, SW, Washington, DC 20201, Tel: (202) 619-2155
- *Medical Malpractice Claims, A Guide for PHS Health Professionals*, U.S. Department of Health and Human Service, Public Health Service, Office of the Assistant Secretary for Health, 29/3948 (undated)

Clinical Guidelines

- National Guideline Clearinghouse, Agency for Healthcare Research and Quality, at www.guideline.gov
- IHS NC4 Clinical Resources National Comprehensive Guidelines, at www.ihs.gov/NonMedicalPrograms/NC4/nc4-clinguid.cfm

Freedom of Information Act

- Freedom of Information Act Coordinator, Indian Health Service, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20852, (301) 443-6177

Medical Staff Issues/Credentialing and Privileging

- 2006 Accreditation Manual for Hospitals, Joint Commission on Accreditation of Healthcare Organizations. Section: Medical Staff Standards
- Indian Health Manual, Chapter 3, Part 1, “Medical Credentials and Privileges Review Process.” See www.ihs.gov/PublicInfo/Publications/IHSManual/index.cfm (Anticipated release is Summer of 2006)
- IHS Medical Staff Credentialing and Privileging Guide, online at www.ihs.gov/NonMedicalPrograms/nc4/nc4-cred.cfm

National Practitioner Data Bank

- Telephone Hotline, Tel: (800) 767-6732;
- Website: www.npdb-hipdb.com