

Risk Management and Medical Liability

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

Third Edition



Paul R. Fowler, DO, JD, FCLM, FAOCOPM, FAAFP
Risk Management Program
Office of Clinical and Preventive Services
Indian Health Service Headquarters
August 2018

Table of Contents

Introduction to Third Edition	i
I. Healthcare Risk Management	1
II. Underlying Influences That Often Lead to Claims of Malpractice	4
III. The Patient-Provider Relationship	6
IV. Informed Consent	10
V. The Medical Record	15
VI. Issues of Provider Competence	19
VII. The Federal Tort Claims Act	21
VIII. The Malpractice Tort Claim Review Process	24
IX. The National Practitioner Data Bank	31
X. State Licensing Boards and the Federation of State Medical Boards	33
XI. The Less Said the Better	35
XII. Giving a Deposition	37
XIII. What to Do If you Are Sued Individually	38
XIV. Risk Management DOs and DON'Ts	40
XV. Selected Resources	42

Introduction to the Third Edition

An initiative began in 2009 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.

Now, almost ten years later, many things have changed. The number of claims filed against IHS and Tribal facilities has decreased and the processes by which claims are reviewed have also evolved. The IHS is an active reporting entity to the National Practitioner Data Bank (NPDB). This revision of this manual provides 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 quality assurance committee or Improving Patient Care (IPC) Coordinator 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.² 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 (MCRP) chartered by the Department of Health and Human Services (Department)

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 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 RM 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.

- **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. Most cases of iatrogenic complications and adverse outcomes never enter the tort system. 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.

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., Ms., 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?
 - 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, 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 Goodbye

- Reach clear closure with patients with a gesture of goodbye, 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. 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 in the patient’s medical record.**

IV. 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**, and is not evidence by a signature on 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.

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 lifesaving 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 visits a physician for a particular ailment, it is implied that he consents 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 but that evidence of properly obtained informed consent be documented in the medical record.

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 the parental 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 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 lifesaving 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 a patient has both the right to determine what

is or is not done to her body. 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 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, and it emanates from the right of self-determination.

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;

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;

- 6) The signature of both the patient and operating provider should be on the consent form, timed and dated;
- 7) 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."

V. 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 too many facilities, patients' charts still 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. 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 Joint Commission's [National Patient Safety Standards](#) contains a list of "Do Not Use" abbreviations for physician orders. Refer to your facility's Joint Commission's manual.

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.

I0) 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.

II) 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. Work with OGC to get a litigation hold in place which will help to ensure that documents pertaining to the claim are protected.
- 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 until you have been advised by the IHS Risk Manager that the litigation hold has been lifted. 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. Requests for copies of IHS records must comply with federal regulations at 45 C.F.R. Parts 2 or 5

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 IHS clinics and hospitals is commonplace. 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.

VI. 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. Every IHS facility should be familiar with the Agency's requirements. These references are noted in Section XV 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. In addition, most medical boards now require ongoing maintenance of proficiency and recertification.
- 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 guideline summaries available to practitioners.

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

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. Also, mandatory confidentiality laws and rules apply to all peer review proceedings.
- 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. 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.

VII. 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. Consult the appropriate HHS 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 torts 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.² 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 U.S.C. §§1346(b), 2401(b), 2671-2680

2 25 U.S.C. § 5321 (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.

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.

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 acting within the scope of his employment or contract— that is to say, such employees are immune from civil liability.¹ 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 or the claimant can request reconsideration within six months of the date of denial.

1 Section 224 of the Public Health Service Act, 42 U.S.C. § 233.

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.

VIII. 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 review process involves individuals and programs from various offices within the Department of Health and Human Services (HHS). And if the tort claim proceeds into litigation, then the Department of Justice (DOJ) is primarily responsible for handling 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 (2018), two physicians – one fulltime, the other halftime—are managing the program.

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. Its 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. It also inquires about employment information for involved providers (commonly referred to as “scoping” information) to determine if these providers are covered by the Federal Tort Claims Act (FTCA). The Claims Office also notifies IHS when claims are paid.

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.

Medical 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).

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 from 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 pp. 29-30.

Department of Justice

Once a suit (civil action) against the federal government is filed in the appropriate U.S. Court, the Department of Justice (DOJ) is responsible for defending the case. An assistant U.S. District Attorney (AUSA) within the jurisdiction is assigned the case and assisted by an HHS OGC 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 no merit or a procedural defect are dismissed, the majority of cases are settled before going to trial. When cases do go to trial, a judge in the respective U.S. District Court determines whether the United States is liable (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 29 will help to visualize the process.

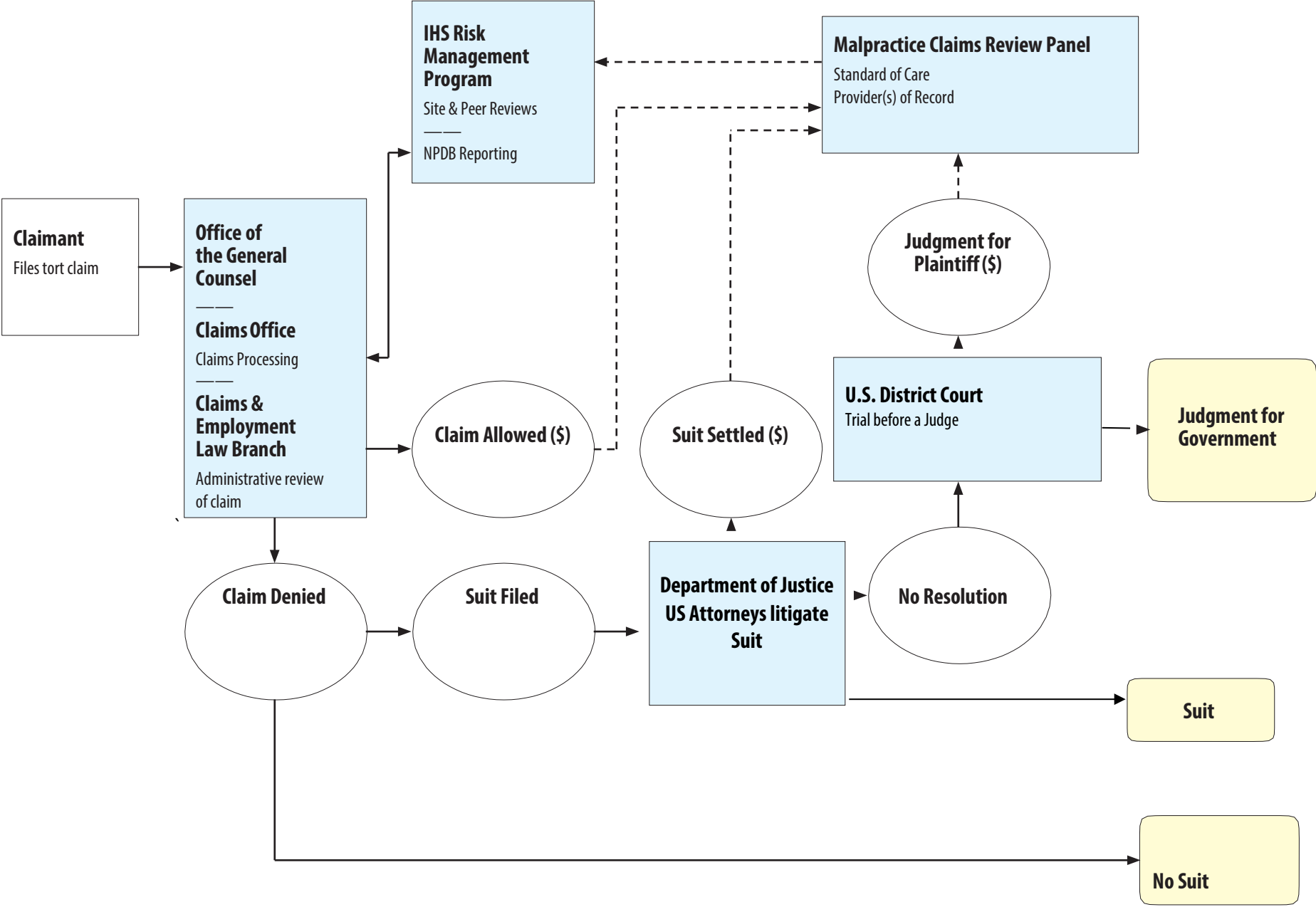
- 1) A person who believes she has suffered an injury due to the negligence of an IHS/Tribal health care provider or facility must first file a tort claim with the OGC Claims Office. No attorney at this point is required, but most prospective claimants do seek legal advice. To submit the claim, a claimant 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). Furthermore, the HHS OGC issues a litigation hold to the hospital or service unit. 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 claim is disallowed by the OGC, and the claimant wishes to pursue further legal action; or the claim is disallowed by the OGC, the claimant requests reconsideration, and the OGC denies the reconsideration request.
- 8) When a suit occurs, the case becomes the responsibility of the Department of Justice. If the DOJ determines that the case is not defensible in court or there are liability risks associated with proceeding to trial, 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.
- 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 or her order which practitioners were, in the judge's opinion, negligent. Please note, however, that if there are additional non-federal government defendants who are not covered by the FTCA, the plaintiff has the right to have a jury determine whether those defendants are liable.
- 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).

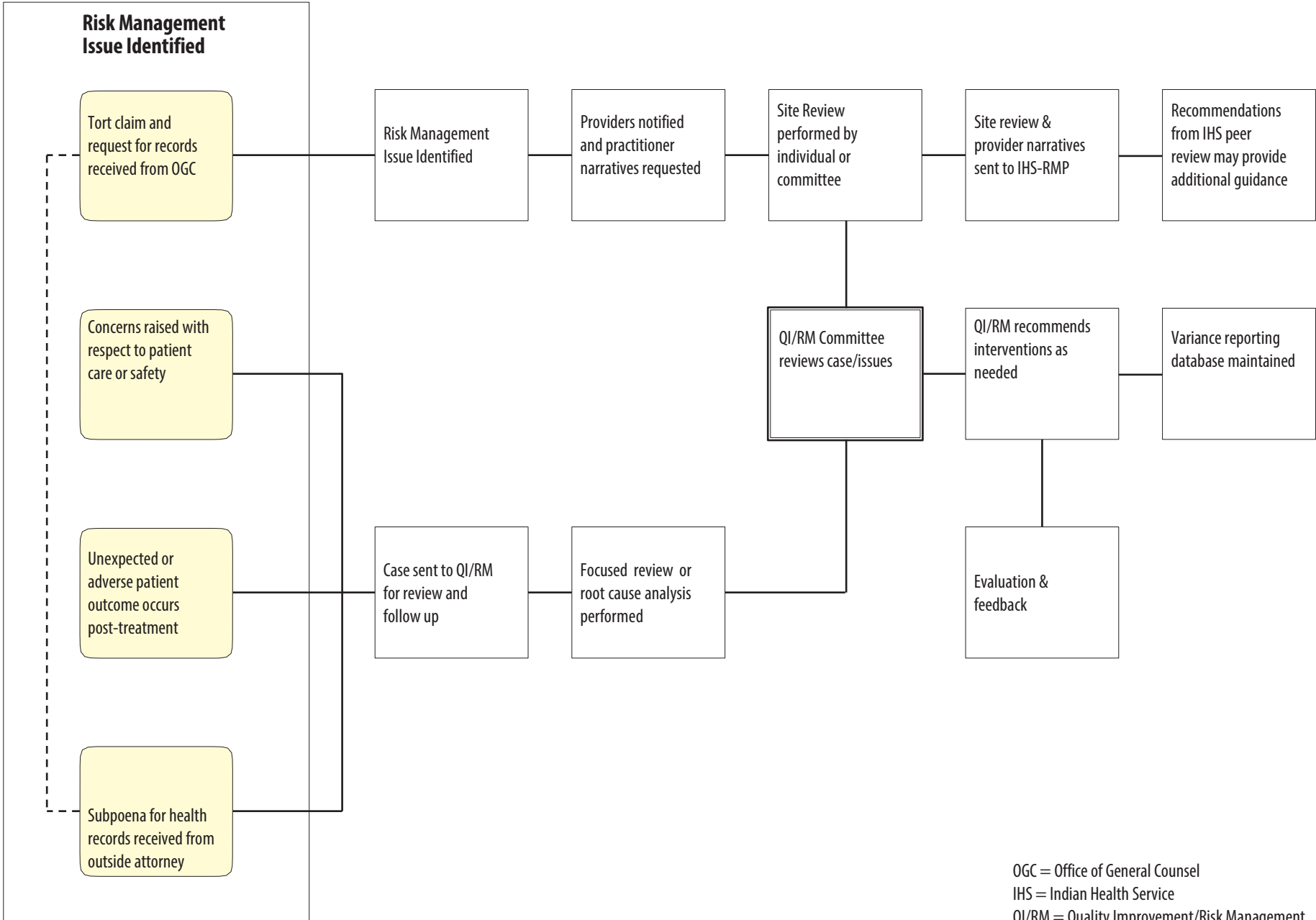
The service unit's response is key to the tort claim evaluation and risk management follow-up. The site evaluation of an incident may be triggered by the event itself (e.g., sentinel event analysis), when a claimant's attorney requests a patient's records before a claim is filed, or in response to the 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 29 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



OGC = Office of General Counsel
IHS = Indian Health Service
QI/RM = Quality Improvement/Risk Management
RMP = Risk Management Program

IX. National Practitioner Data Bank

The National Practitioner Data Bank (NPDB), which opened in 1990, is a web-based repository of reports containing information on medical malpractice payments and certain adverse actions related to clinical privileges and licensure of physicians, dentists, and other licensed health care practitioners, providers and suppliers. Federal regulations authorize eligible entities to report to and/or query the NPDB. Individual and organizations who are subjects of these reports have access to their own information. The reports are confidential and not available to the public. Medical Malpractice Payment Reports to the NPDB 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 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 civilian practitioners are to be reported do not apply to the federal sector. In regards to practitioners working for operating divisions of the HHS (and Tribal organizations), practitioners involved in an FTCA medical malpractice claim settlement will only be reported to the NPDB if the MRCP finds that they did not meet the standard of care.

National Practitioner Data Bank Reporting—The IHS has been submitting reports only on cases where it was determined by the HHS Medical Claims Review Panel (MCRP) that the standard of care was not met. 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

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, DOJ and MCRP. This process often takes years to come to a conclusion. The IHS RM Program encourages the local site risk managers to make renewed effort to maintain contact with practitioners during the various stages of claim and suit negotiations.
- 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 MCRP 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.

It is the sole responsibility of the IHS and Tribal local sites to report directly themselves to the NPDB any other certain and final adverse actions taken against providers that do not involve FTCA medical malpractice payments.

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

X. 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(s). Medical malpractice payers (including the IHS) must report medical malpractice payments to the National Practitioner Data Bank who then forwards the report to 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 can request a copy of the medical records involved. 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. If the FOIA request is approved, the FOIA Officer is responsible for de-identifying the records prior to releasing them to the state board. Health care providers must never release such records on their own. 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.

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 separate osteopathic boards in the United States. 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 Physician Data Center 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 data center.

XI. 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.
- 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 he or she has received, refer the patient 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.

Do not discuss a tort claim with the involved patient or the patient's relatives; if the patient asks you questions about the 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 a lawyer may attempt to ask you to divulge information. Refer the caller to the government's legal counsel (i.e., the HHS Office of the General Counsel attorney or Assistant U.S. Attorney), and advise the government's legal counsel that you were contacted by the claimant's attorney.
- You should confidently discuss the case with an attorney from the HHS Office of General Counsel (OGC) 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. Furthermore, you must cooperate with the HHS OGC attorney or AUSA when contacted to assist in the defense of a 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 applicable rules and policies for releasing information.
- 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 his or her 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 IHS medical records. Please do not send any copies of medical records directly to your state board as the Privacy Act and the Indian Health Care Improvement Act do not permit releasing these documents unless they have been approved for release and 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.

XII. 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 (i.e., the government). The plaintiff’s attorney questions the witnesses under oath, trying to extract information vital to the plaintiff’s 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 health care 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 his/her 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.

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 health care 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.

XIII. What to Do If you are Sued Individually

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 or contract. 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.

The Public Health Service Act, the Indian Self-Determination and Education Assistance Act, and the Indian Health Care Improvement Act provide FTCA coverage for certain IHS or P.L. 93-638 health professionals when they are 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.

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, 330 C Street, S.W., Switzer Building, Suite 2600, Washington, D.C. 20201; Telephone (202) 619-2155

The following materials must be e-mailed as soon as possible to hhs-ftca-claims@hhs.gov (the HHS Office of General Counsel FTCA e-mail inbox):

- 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.

XIV. Risk Management *DO*s and *DON'T*s

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.

XV. Selected Resources

IHS Risk Management/Tort Claims

IHS Risk Management Program Office

Paul R. Fowler DO, JD, FCLM, FAAFP, FAOCOPM, Chief Risk Officer,
5600 Fishers Lane, Suite 8N01, Rockville, MD 20857; Tel: (301)443-6372

Paul.Fowler@ihs.gov

EY Hooper MD, MPH. Medical Risk Manager Tel: (602) 364-7750

Edwards.Hooper@ihs.gov

Legal Counsel/Tort Claims

- Claims Office, Office of General Counsel/General Law Division, 330 C Street SW, Switzer Building, Suite 2600, Washington, DC 20201, (202) 619-2155, e-mail: hhs-ftca-claims@hhs.gov.

Clinical Guidelines

- National Guideline Clearinghouse, Agency for Healthcare Research and Quality, at www.guideline.gov

Medical Staff Issues/Credentialing and Privileging

- Indian Health Manual, Part 3, Chapter 1, “Medical Credentials and Privileges Review Process.” at <https://www.ihs.gov>

NATIONAL PRACTITIONER DATA BANK

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