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Patient Safety, Peer Review, and Credentialing: Navigating Sovereign Immunity and Balancing State and Federal Law in your Quality Department

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Navigating Sovereign Immunity And Balancing State And Federal Law In Your Quality Department

Eighth Annual Native American Healthcare Conference
November 5 - 7, 2017

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Quality Oversight at Healthcare Facilities

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Laws Governing Quality Oversight at Healthcare Facility

- Federal Law
  - IHS
  - Medicare
  - CMS
- State Law

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Indian Health Service

- Medical Staff is responsible for ensuring that practitioners who provide direct patient care are appropriately credentialed and privileged
- Medical Staff members are also required to participate in the measurement, assessment, and improvement of the clinical activities of those individuals with delineated medical staff privileges (e.g. peer review).
  - *Section 8: Issues of Provider Competence, Risk Management and Medical Liability,* ***A Manual for Indian Health Service and Tribal Health Care Professionals*** *(Second Edition)*

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Responsibility for Quality of Care Oversight

- Governing Body
  - 42 C.F.R. 482.12 - the governing body is legally responsible for the conduct of the hospital as an institution
- Medical Staff
  - 42 C.F.R. 482.22 - the medical staff operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital
- Traditionally
  - Medical staff responsible for oversight of quality of care

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Federal Law- Health Care Quality Improvement Act ("HCQIA")

- Requires that every hospital have an organized medical staff operating under bylaws approved by governing body that is responsible for the quality of care rendered to patients in the healthcare facility
  - 42 USC Section 11101 *et seq*.
  - 42 CFR 482.22 Conditions of Participation for Medicare

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California Law

- Requires that every hospital have an organized medical staff responsible to the governing body
  - California Health & Safety Code Section 1250(a)
  - Title 22 California Code of Regulations § 70703

Sovereign Immunity

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What is Sovereign Immunity?

- The idea that the sovereign or government is immune from lawsuits or other legal actions except when it consents to them
  - Allows distinct, independent political communities to make their own laws and be ruled by them
    - ***Williams v. Lee***, 358 U.S. 217 (1959)

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What is Sovereign Immunity? (cont.)

- It is the "general law" that "[l]ike other governments…[tribes are] free from liability for injuries to persons or property . . . ."
  - ***Turner v. United States***, 28 U.S. 354 (1919)
- Sovereignty means that practically tribes can only be sued if Congress has "unequivocally" authorized the suit or the tribe has "clearly" waived its immunity.
  - ***Kiowa Tribe v. Manufacturing Technologies***, 523 U.S. 757 (1998)

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Who Enjoys Sovereign Immunity?

- Indian tribes possess sovereign immunity, as does any "arm of the tribe."
- Tribal immunity generally extends to tribal officials in their official capacity and tribal businesses within and beyond the boundaries of the tribe's reservation.
- U.S. Supreme Court rejected attempts to limit sovereign immunity to the governmental activities of a tribe or even to activities taking place on reservations.
  - ***Kiowa Tribe v. Manufacturing Technologies***, 523 U.S. 751, 755 (1998)

Who Enjoys Sovereign Immunity? (cont.)

- Courts have held that sovereign immunity should be conferred to certain Native American quasi-governmental agencies whose functions are clearly governmental, rather than commercial or corporate in nature, including:
  - Tribal schools;
  - Housing authorities;
  - Utilities; and
  - Health agencies

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How does Sovereign Immunity Impact Health Agencies?

- *Pink v. Modoc Indian Health Project, Inc.,* 157 F.3d 1185 (9th Circuit, 1998)
  - Modoc was a nonprofit corporation created and controlled by the Alturas and Cedarville Rancherias, both federally recognized tribes.
  - Modoc was "organized for charitable, educational, and scientific purposes and such other related purposes … relative to the delivery of certain services pursuant to [the Indian Self-Determination Act]."
  - IHS awarded Modoc an Indian self-determination contract to provide health services to tribe members.

Pink v. Modoc

- Pink, a Native American, was hired by Modoc in November 1983 as the coordinator of the Indian Child Welfare Act Program.
- Pink alleged that from July 1991 until her termination in October 1993, her former supervisor subjected her to sexual harassment, sexual assault and a hostile workplace environment. Pink brought suit under federal and state law in tort, for employment discrimination and breach of contract
- Also brought claims against Modoc pursuant to the Civil Rights Act

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Pink v. Modoc (cont.)

- Case turned on whether Modoc was a “tribe” and whether it qualified for an exception pursuant to the Civil Rights Act
  - Although the Ninth Circuit had not specifically addressed whether a nonprofit organization incorporated by two Indian tribes is a "tribe" for purposes of Title VII exemption, the Tenth Circuit had addressed a similar question.
    - In *Dille v. Council of Energy Resource Tribes*, 801 F.2d 373 (10th Cir.1986), the court held that a council comprised of thirty-nine Indian tribes that had joined together to collectively manage energy resources was a "tribe" within the scope of Title VII's Indian tribe exemption. The *Dille* Court held that Congress intended to exempt individual Indian tribes as well as *collective* efforts by Indian tribes.

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How is *Pink v. Modoc* Applicable in the Healthcare Context?

- Healthcare agencies may be considered tribes by the federal government and may enjoy sovereign immunity
  - If healthcare agency is a “tribe” state laws may not apply
- Healthcare agencies may also be an “arm of sovereign tribe(s)”
  - Look for factors like who is on the Board of Directors of the healthcare agency (e.g. tribal representatives) or the purpose of the healthcare entity (e.g. solely for business? Other purpose?)

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If Healthcare Agency is a "Tribe" Does State Law Apply?

- Depends if there is applicable federal or tribal law
  - If there is an applicable federal or tribal law, that law applies and preempts any state law
  - If there is not an applicable federal or tribal law, then state law could apply
- Federal laws may also require compliance with state laws
  - For example, physician assistant Medicare reimbursement rules require compliance with certain state licensure and supervision laws

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Credentialing & Privileging of Healthcare Providers

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Indian Health Services (IHS)

- Indian Health Manual- Part 3: Professional Services
  - Chapter 1- Medical Credentials and Privileges Review Process
    - Policy of the IHS that all licensed independent practitioners and other practitioners who provide direct patient care be credentialed and privileged through the medical staff
  - The medical staff credentialing and privileging process for health care providers is one of the critical tasks of IHS and is directly related to the provision of quality medical care that is provided at IHS facilities.
  - An ineffective credentialing and privileging process has a negative effect on the quality of health care provided to patients treated at the facilities.

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Indian Health Manual- Part 3: Professional Services

- Credentialing. A ongoing process whereby a facility's medical staff obtains, verifies, and assesses an individual's professional credentials. This information is utilized by the medical staff and governing body to evaluate competency and appropriately grant medical staff membership and/or clinical privileges.
- Credentials. Credentials are the attestation of qualification, competence, or authority issued to an individual by a third party with the authority or assumed competence to do so. Examples of credentials include the documents that constitute evidence of practitioner training, licensure, experience, and expertise.

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Accreditation Body Guidelines

- Credentialing, Privileging, and Peer Review also governed by Accreditation Body
  - Require ongoing physician peer review
  - Also require development of peer review policies and procedures
  - Examples
    - Joint Commission
    - Accreditation Association for Ambulatory Health Care, Inc. (AAAHC)

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Credentialing Healthcare Providers

- Applicant for initial medical staff membership and/or clinical privileges must complete a comprehensive credentials review before delivering any healthcare services to any patient in an IHS facility
- Burden is on applicant to produce information for adequate evaluation of his/her qualifications and current competence
- Medical staff must verify that the practitioner has the appropriate credentials to provide healthcare services
  - Required to Verify:
    - ✓ Professional Education
    - ✓ Post-Graduate Training
    - ✓ Experience
    - ✓ Board Certification and Professional Affiliations
    - ✓ Licensure

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Credentialing Healthcare Providers (cont.)

- Also required to verify:
  - ✓ Professional Liability Claims, Suits, and/or Judgments
  - ✓ Denial or Revocation of Medical Staff Membership
  - ✓ Reduction, Suspension, Revocation, Relinquishment, or Non-renewal of Clinical Privileges
  - ✓ Drug Use
  - ✓ Loss, Suspension, Restriction, Denial, or Relinquishment of Professional Licensure or Professional Society Membership
  - ✓ Sanctions or Current Investigations
  - ✓ Convictions Involving Crimes Against Children
  - ✓ References
  - ✓ Heath Status

Procedures to Credential Healthcare Providers

- Verification
  - Verification is the process of validating all credentials and other information provided by an applicant for medical staff privileges.
  - Can verify medical credentials through primary and secondary source verification.
    - Primary source verification is the process of validating all credentials and other information provided by the applicant with the original sources of the credential.
    - Secondary source verification is the process of validating credentials and other information provided by the applicant through a third-party database and/or credentialing source.

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Procedures to Credential Healthcare Providers (cont.)

- Documentation
  - Every applicant requesting clinical privileges must be checked against the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank.
  - A query will be done on each provider at least every 2 years and when specified actions are requested by the applicant (e.g. reappointment to the medical staff, changes in privileges).

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Privileging Healthcare Providers

- Clinical Privileges. The specific clinical privileges a practitioner is permitted to perform in the facility, (e.g., diagnostic services, procedures, prescribe medications.)
  - Clinical privileges are based on the review of an individual practitioner's professional training, licensure, experience, and expertise.
  - Burden is on applicant to produce information for adequate evaluation of his/her current competence for clinical privileges in the areas requested
  - Every practitioner providing clinical services at a facility should only exercise those specific privileges granted to him/her
    - "Practitioner" includes physicians, physician assistants and nurse practitioners

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Privileging Healthcare Providers (cont.)

- Practitioners must demonstrate competency for specific clinical privileges
  - Granted by the governing body after consultation with discipline-specific staff or consultants, as appropriate.
  - The granting of privileges must reflect the training, experience, and qualifications of the applicant as they relate to the staffing, facilities, and capabilities of the facility.
  - Recommendation of privileges should be made by the medical staff to the chairperson of the governing body.
    - Governing Body must ultimately approve privileges

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Peer Review of Healthcare Providers

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What Is Peer Review?

- Evaluation of a provider's professional performance by his/her peers
  - Includes identification of opportunities to improve care
  - Consideration of compliance with general program expectations and clinical standards
  - Evaluates strengths and weaknesses of an individual provider's performance

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Why Peer Review Is Performed?

- Quality assurance
- Credentialing
- Education
- Utilization review

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Why are Healthcare Providers Required to Perform Peer Review?

- IHS
- Federal Law (HCQIA, CMS)
- Accreditation Body Requirements
  - AAAHC, Joint Commission
- Insurance Coverage
- State Law
  - Joint responsibility of both healthcare facility and staff

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IHS Peer Review Requirements

- 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
- Peer review consists of an evaluation by medical staff to retrospectively determine if a clinician's practice of medicine is within accepted standards of care

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IHS Peer Review Requirements (cont.)

- Peer reviews may be organized and conducted in response to specific issues by the appropriate authority
- If facility has bylaws, peer review should be conducted according to the bylaws
- A peer review inquiry may address any or all of the following:
  - an individual's personal and/or professional conduct;
  - the quality of the care provided;
  - the adequacy of the medical record documentation; and/or
  - any adverse patient outcome

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Different Types of Peer Review

- Ongoing Professional Practice Evaluation ("OPPE")
  - OPPE is defined as "a document summary of ongoing data collected for the purpose of assessing a practitioner's clinical competence and professional behavior. The information gathered during this process is factored into decisions to maintain, revise, or revoke existing privilege(s) prior to or at the end of the two-year license and privilege renewal cycle."
    - The routine monitoring and evaluation of current competency for current medical staff
    - The Joint Commission created in 2007
      - Example: quarterly chart review

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Different Types of Peer Review (cont.)

- Focused Professional Practice Evaluation (FPPE)
  - FPPE is "the time-limited evaluation of practitioner competence in performing a specific privilege. This process is implemented for all initially requested privileges and whenever a question arises regarding a practitioner's ability to provide safe, high-quality patient care."
  - FPPE can also be performed as an initial ongoing evaluation for new medical staff members or members requesting new privileges

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Healthcare Quality Improvement Act of 1986 (HCQIA)

- Congress enacted the Health Care Quality Improvement Act (HCQIA) in 1986 in order to solidify the role of peer review as a means of physician quality improvement across the United States
- Established national standards for the conduct of fair professional review action and peer review hearings
  - Part A: Provides immunity for those physicians and institutions conducting fair peer review
  - Part B: Created the National Practitioner Data Bank to track physicians
- Failure to Report can lead to sanctions, loss of peer review immunity

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Part A: Peer Review Process and Immunities

- 42 USC Sections 11112 *et seq*. provide immunity from civil damages if the peer review participants acted:
  - On the reasonable belief that the action was in furtherance of quality health care;
  - After reasonable effort to obtain the facts of the matter;
  - After adequate notice and fair hearing procedures; and
  - In the reasonable belief that the action was warranted.

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Part B: National Practitioner Data Bank

- National Practitioner Data Bank ("NPDB") is an electronic database that contains information about healthcare practitioners
- Healthcare facilities are required to report professional review actions which adversely affect the clinical privileges of a practitioner
  - "professional review action" means an action or recommendation of a professional review body which is based on the competence or professional conduct of an individual physician (which conduct affects or could affect adversely the health or welfare of a patient or patients)
  - "adversely affecting" includes reducing, restricting, suspending, revoking, denying, or failing to renew clinical privileges or membership in a health care entity

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What is Reportable to the National Practitioner Data Bank?

- A Report Must be Filed if the Medical Staff
  - takes a professional review action that adversely affects the clinical privileges of a physician for a period longer than 30 days;
  - accepts the surrender of clinical privileges of a physician
    - while the physician is under an investigation by the entity relating to possible incompetence or improper professional conduct, or
    - in return for not conducting such an investigation or proceeding;

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What is Reportable to the National Practitioner Data Bank?

- Definition of "Investigation"
  - NPDB considers an investigation to run from the start of an inquiry until a final decision on a clinical privileges action is reached
    - A routine, formal peer review process under which a health care entity evaluates, against clearly defined measures, the privilege-specific competence of all practitioners is **not** considered an investigation for the purposes of reporting to the NPDB.
    - However, if a formal, targeted process is used when issues related to a specific practitioner's professional competence or conduct are identified, this is considered an investigation for the purposes of reporting to the NPDB.

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2015 NPDB Guidebook

- NPDB Issues Final Revised Guidebook April 2015
  - Retains expansive definition of "investigation“
    - May look at healthcare entity's bylaws or
    - Other documents to assist determination of whether an investigation has started or is ongoing, ***but***
    - NPDB retains the ultimate authority to determine whether an “investigation” exists
  - Investigation is not limited to a healthcare entity's gathering of facts or limited to the manner in which the term “investigation” is defined in the entity’s bylaws

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California Law

- Requires reporting pursuant to California Business and Professions Code Section 805 of any of the following actions of a peer review body if based on “medical disciplinary cause or reason”:
  - Denial of application for Medical Staff Membership or Privileges
  - Termination or Revocation of Medical Staff Privileges, Membership
  - Restrictions Imposed for a Cumulative Total of 30 days for any 12 Month Period
    - Restrictions include proctoring *only* if proctor may overrule proctored physician’s treatment decision
  - Summary Suspension greater that 14 days

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California Law (cont.)

- How does sovereign immunity affect reporting in California?
  - Under 805, a "peer review body" is defined as a medical staff or peer review body of a health care facility licensed under the Health and Safety code or "a facility certified to participate in the federal Medicare program as an ambulatory surgical center"
  - Is the medical staff of an IHS facility a "peer review body"?
  - Does the IHS entity have to comply with California reporting requirements?

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Peer Review Tips

- 1. Utilize External Reviewers
- 2. Follow Your Process
  - Consult Bylaws, Policies, HCQIA
  - Conduct internal investigation and review
- 3. Educate Your Board Regarding Their Role
  - Determine what materials are going to be provided to Board Members
- 4. Take Appropriate Action
  - Be mindful of reporting requirements and provider's rights

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Thank you!

Questions? Please feel free to contact us anytime for guidance.

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