



Credentialing, Corrective Action, HCQIA and NPDB

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(8.25)

Preliminaries

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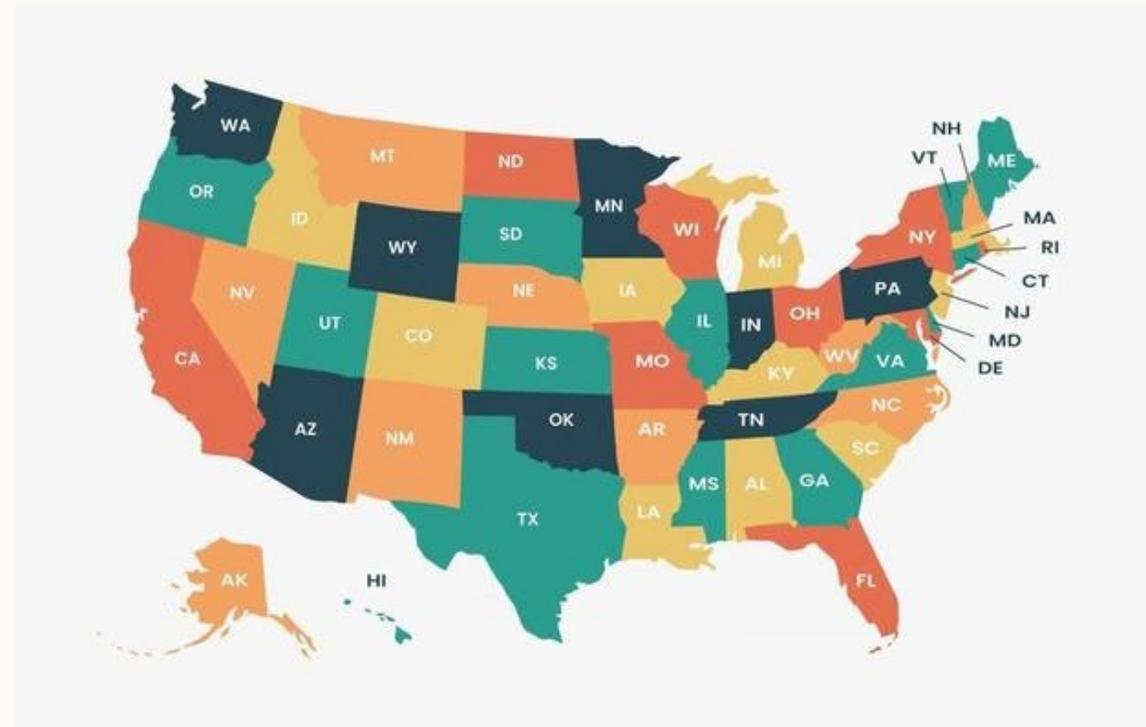
Overview

- Credentialing and privileging standards
 - Substantive
 - Procedural
- Corrective action
 - Informal
 - Investigations
 - Suspensions
 - Hearings
- Health Care Quality Improvement Act (HCQIA) requirements and protections
- National Practitioner Data Bank (NPDB) querying and reporting requirements
- Peer review privilege
- Defenses and protections

- *Standards and discussion generally defaults to hospitals, but principles may extend to other organizations, e.g.,*
 - *ASCs or similar facilities*
 - *Managed care*
 - *Large physician groups*

Disclaimer

- We'll be moving fast; may not cover all slides.
- I'll discuss federal laws and common standards, but...
- Standards may vary by:
 - State
 - Provider type
 - Accreditation standards
 - Contract requirements
 - Bylaws and policies
 - Other factors
- *Know and comply with the state laws and other applicable standards that apply in your situation!*



Housekeeping

- If you did not receive the .ppts, please contact Lisa at lbadelberg@hollandhart.com.
- The presentation will be recorded and available on our website, <https://hhhealthlawblog.com/2025-webinar-recordings/>.
- If you have questions, you may submit them using chat feature or e-mail me at kcstanger@hollandhart.com.

Written materials

- Sample credentialing checklist
- Sample Practitioner Application Addendum
- Sample Authorization to Disclose and Release of Liability
- Sample Disruptive Member Policy
- Sample Physician Behavior Contract

Credentialing



Who must be credentialed?

- All licensed independent practitioners (“LIP”), i.e., those who may order tests or procedures at the hospital, e.g.,
 - Physicians (e.g., MDs and DOs)
 - Podiatrists
 - Dentists and oral surgeons
 - Advance practice providers (APPs)
 - NPs, CRNAs, CNMs, etc.
 - Physician assistants
 - Psychologists
 - Therapists
 - Chiropractors
 - Others?
- “Credentialing” may not apply to others (e.g., nurses, techs, etc.), but must ensure they are qualified or face liability.

Sometimes referred to in bylaws
as “Limited License Practitioners”

Sometimes referred to in bylaws
as “Allied Health Professionals”

What does credentialing address?

Medical staff membership

(“part of the club”)

- Group of practitioners with privileges at facility.
- Membership = certain rights and responsibilities.
- Must apply for membership.
- Facility’s governing board may grant or deny membership.

Clinical privileges

(“what they can do at hospital”)

- Privileges = privilege to perform specified services or procedures at facility.
- Must apply for privileges.
- Facility’s governing board may grant or deny privileges.

Why credentialing?

- Proper credentialing = preventive medicine
 - Promotes quality health care.
 - Avoids problem practitioners.
 - Incompetent.
 - Disruptive.
 - Poor fit for organization.
 - Facilitates a professional workplace.
 - Increasingly important for reimbursement in healthcare reform.
 - Value-based care models.
 - Prevents liability to patients, practitioners, employees, and the government.

Effective credentialing

Liability to Practitioner

- Due process violation
- Breach of contract
- Emotional distress
- Discrimination
- Defamation
- Antitrust
- Other?

**Proper Credentialing:
Initial and Ongoing Review**

Liability to Patient

- Malpractice
- Respondeat superior
- Negligent credentialing

**Quality Care
Quality Workplace**

Liability to Govt

- State licensure
- COPs
- Accreditation

Credentialing: Liability to Practitioner

- Practitioners who are denied medical staff membership or privileges may sue.
 - Denial may inhibit the practitioner's ability to practice in the community if cannot provide services at local facility or contract with certain payers.
 - Reported denials may adversely affect practitioner's privileges at other facilities, ability to get a job, or ability to contract with certain payers.
 - Adverse action against privileges may be reported to:
 - National Practitioners Data Bank
 - State medical or other licensing boards
 - Future employers through application or background checks
 - Payer or services contracts may be conditioned on privileges.

Credentialing: Liability to Practitioner

- Courts usually do not second guess facility's credentialing decision if:
 - Followed standards in bylaws and statutes.
 - Based on legitimate, documented reasons
 - Patient care or facility operations
 - NOT arbitrary or capricious
 - NOT improper motive, *e.g.*, discrimination, anti-competition, retaliation, *etc.*
- From legal liability standpoint, the process is usually more important than the decision.



Miller v. St. Alphonsus (Idaho 2004)



- *Facts:* St. Alphonsus denied medical staff privileges due to physician's alleged history of disruptive behavior.
- *Held:* Court upheld St. Alphonsus' decision.
 - Bylaws do not constitute a contract.
 - Hospital must comply with statutes and bylaws.
 - Hospital gave the process due in statute and bylaws.

Credentialing Standards

- United States Constitution
- State statutes, regulations, and cases
 - Hospital or facility licensure requirements, professions, *etc.*
 - Cases concerning obligations to providers, status of bylaws as contract, negligent credentialing, *etc.*
- Hospital/CAH COPs, 42 CFR 482.12, 482.22, and 42 CFR 485.601 *et seq.*
- Health Care Quality Improvement Act (HCQIA), 42 USC 11101 *et seq.*
- Medical staff bylaws, rules and regulations
- Practitioner contracts
- Accreditation standards
- Others?

Credentialing Standards

- United States Constitution
 - Practitioner does not have a constitutional right to privileges at a public hospital. *Hayman v. Galveston*, 273 U.S. 414 (1927)
 - Once privileges granted at a public hospital, practitioner may have a property or liberty interest requiring due process before they are denied.
 - Hospital may not deny privileges for reasons prohibited by the Constitution, *e.g.*, discrimination based on race, *etc.*

Credentialing Standards

Substantive Standards

- Factors that should or may be considered in determining whether to grant medical staff membership or privileges.

See requirements set forth in:

- State statutes, regulations, and cases
- 42 CFR 482.12(a) and 482.22(a), (c)
- Accreditation standards
- Contracts

Procedural Standards

- Process that must be followed in making credentialing decisions.

Credentialing Standards

Substantive

- Type of provider approved by governing body
- Qualified legally and professionally
- Physical and mental capability
- Character, competence, training, experience and judgment
- NOT solely certification, fellowship or membership in specialty body or society
- Scope of practice
- Med staff bylaws, rules and regs
- Capabilities of hospital
- Others

Procedural

- Application
- Agreement to abide by bylaws
- Delineation of privileges
- Recommendation by active med staff
- Decision by governing body
- Action w/in x days
- Periodic appraisal by med staff
- Periodic reappointment
- Written notice of denial
- Hearing and appeal for denial
- Maybe proxy for telemedicine
- Temporary/emergency privileges
- Others

Credentialing: Substantive Standards

REASONABLE CRITERIA

- Licensure, scope of practice, education, training, experience, physical and mental capability, judgment, character
- Professional conduct
- Capability of hospital
- Effective hospital operations (*e.g.*, need for services, exclusive contracts, etc.)
- Geographic proximity
- Any other reasonable, legal bases relevant to patient care, effective hospital operations, etc.

✓ *Check state statutes and regs, accreditation standards, bylaws, and policies.*

IMPERMISSIBLE CRITERIA

- Professional membership or certification alone.
- Credentialing done by others
 - Maybe limited exception for credentialing by proxy for telehealth providers.
- Illegal bases, *e.g.*,
 - Discrimination (*e.g.*, age, race, sex, disability, religion, etc.)
 - Antitrust or anti-competitive conduct
 - Union organizing or complaining about conditions
 - Whistleblowing or retaliation
 - Political speech (public entities)
 - Others?

Credentialing Standards: Substantive

What about economic or business reasons?

- Exclusive contracts
- Closed staff arrangements
- Competitors on medical staff

Most courts have upheld if legitimate reason and consistent with bylaws, but check state law.

- Utilization, *i.e.*, “economic credentialing”

- OIG has expressed some fraud and abuse concerns.

- (*See, e.g.*, OIG Supplemental Compliance Program Guidance, 70 FR 4869, n.59)

- Others?

✓ *Check state law and bylaws.*

Medical Staff Categories

- May have “tiers” or different types of medical staff members:
 - Physicians (MD, DO)
 - Limited license practitioners (DPM, DDS, DMD, etc.)
 - Allied health professionals (PA, NP, CRNA, CNW, others)
 - Medical staff privileges and rights may differ between types, e.g.,
 - Admissions
 - Clinical services
 - Voting
 - Medical staff offices
 - Full fair hearing rights

Med Staff Categories



Must assign medical staff members to a medical staff category, e.g.,

- Active
- Courtesy
- Provisional or probationary
- Consulting
- Honorary
- Telemedicine
- Allied health professional
- Other?

For each, identify:

- *Qualifications*
- *Rights or privileges*
- *Responsibilities*
- *Medical staff or board ability to modify*

Medical Staff Categories

Should APPs or similar limited license practitioners be granted full medical staff membership like physicians?

PROS

- Promotes unity on staff.
- May facilitate APP satisfaction and commitment to med staff functions.
- May spread med staff responsibilities and ease burden on physicians.
- Helps ensure smaller hospitals have critical mass.
- May facilitate accreditation.

CONS

- Physicians may not want to share or cede authority.
- May complicate bylaws as you distinguish APP's rights and roles.
- May give APPs rights that are not required or appropriate (*e.g.*, full voting, med staff officer, full hearing rights, *etc.*)

Privileges

Governing board must determine each practitioners' privileges, i.e., services they may perform at the facility.

- “Laundry list”
 - Contains list of clinical procedures available at facility.
 - Works well for small facilities with limited procedures.
 - Requires updating re practitioners and procedures.
- “Core privileging”
 - Identifies “core” qualifications to work in department.
 - Identifies privileges associated with the dept
 - allows for additional privileges.
- Others?

Ensure privileges are consistent with:

- *Capability of facility.*
- *Competency.*
- *Permissible scope of practice, e.g.,*
 - *APRNs*
 - *PAs*
 - *Others*

May require physician oversight
- *COPs*
- *Contract limitations, e.g., exclusive contracts.*

Health Care Quality Improvement Act (HCQIA)

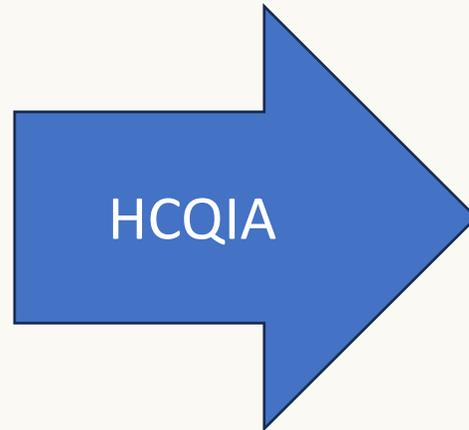


Health Care Quality Improvement Act (HCQIA)

If facility or other peer review body:

- Gives physician certain due process rights concerning peer review actions; and
- Reports certain adverse actions affecting clinical privileges to NPDB...

(42 USC 11101 et seq.)



- Then HCQIA grants immunity to peer review body and participants from lawsuits arising out of the action except:
 - Civil rights claims,
 - Claims for injunctive relief, or
 - Give info knowing the info was false.
- Defendant may recover costs and attorneys' fees.

HCQIA Application

- HCQIA applies to “professional review actions” against “physicians”, i.e.,
 - *Physician* = MD, DO, DDS, or DMD; not APPs or other non-physicians.
 - *Professional review action* =
 - an action or recommendation of a professional review body which is taken or made in the conduct of professional review activity,
 - based on the competence or professional conduct of a physician which conduct affects or could affect adversely the health or welfare of a patient, and
 - which action adversely affects the physician’s clinical privileges.

(42 USC 11151(9))

HCQIA

Due Process

- For HCQIA immunity, professional review action must be taken:
 - In reasonable belief that action furthered quality care,
 - After reasonable effort to obtain facts,
 - After adequate notice and hearing procedures, and
 - In reasonable belief that action warranted by the facts.
- Presumed to have met this standard unless physician rebuts it by preponderance of the evidence.

(42 USC 11112)

Process is deemed to satisfy HCQIA standards if:

- Entity gives notice of proposed action, reasons, witnesses, right to a hearing > 30 days, and summary of rights;
- Hearing before an arbitrator, officer or panel who is/are not in direct economic competition;
- Physician has right to be represented by attorney, have record made, call and cross-examine witnesses, present evidence, and present written statement.
- Physician receives written recommendation with reasons of the arbitrator, officer, or panel.
- Physician receives written decision of health care entity with basis for decision.

HCQIA

Precautionary Suspensions

- Entity may immediately suspend or restrict physician's privileges for up to 14 days while it investigates to determine need for professional review action.
 - Usually reserved for situations in which the failure to take action may result in an imminent danger to the health of any individual, but may be broader so long as satisfy due process requirements.
 - Within 14 days, investigate and determine need for formal action.
- If suspension/restriction \leq 14 days: no further due process is required by HCQIA.
- If suspension/restriction is $>$ 14 days: subsequent due process is required for HCQIA immunity.
- Suspensions $>$ 30 days must be reported to NPDB if related to professional competence or conduct that could affect patients.

(42 USC 11112(c))

Check standards and process in state law, bylaws and policies, and contracts.

HCQIA Immunity

Laurino v. Syringa Hospital (2005)



Physician with provisional staff membership denied privileges following fair hearing process involving independent hearing officer.

Physician sued hospital, trustees, and chief of staff for \$2,000,000.

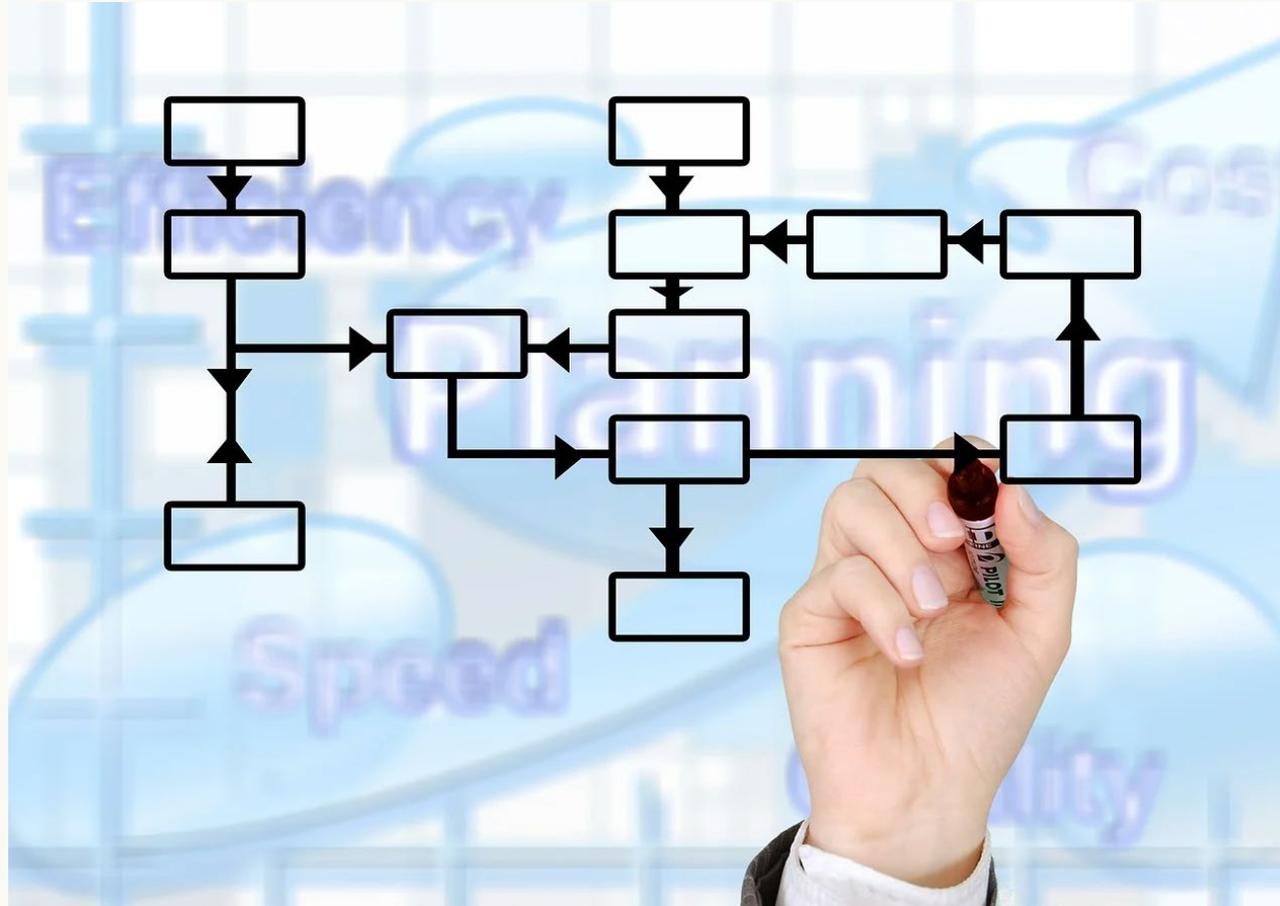
- Breach of contract
- Violation of due process
- Intentional infliction of emotional distress
- Intentional interference with contract
- Antitrust
- Defamation
- Injunction

(Laurino v. Syringa General (D. Idaho 2005))

Court dismissed all claims on summary judgment.

- HCQIA barred all claims except violation of due process.
 - Hospital's hearing satisfied due process.
 - Hospital awarded \$120,000 in attorneys fees.
- ✓ *Moral: document legitimate reasons and fair hearing process.*

Credentialing Process



Credentialing Process

- Process usually set out in medical staff bylaws and policies.
 - Application
 - Gather information
 - Verify information
 - Databank searches
 - Medical staff review
 - Review file
 - Interview practitioner
 - Recommendation to board
 - Hearing process, if required
 - Board review and decision
- Process may vary for physicians v. non-physicians
 - *Check state law and bylaws*

Administration
(e.g., Medical
Staff Services)

If recommendation—

- Would result in adverse action against a physician's privileges (e.g., reducing, restricting, suspending, revoking, denying or failing to renew clinical privileges or med staff membership, and
- Action based on competence or professional conduct that could adversely affect patient care, then HCQIA and due process requirements are usually triggered.

Credentialing: Process

- Consider 2-step process
 1. Screening for basic eligibility requirements (*e.g.*, education, licensure, geographic proximity, *etc.*).
 - Reviewed by medical staff office.
 - Application denied summarily if fail to meet basic objective qualifications.
 2. Review for competence and capability.
 - Reviewed by medical staff.
 - Only applies if satisfied basic qualifications.

Benefits

- *May weed out ineligible applicants.*
- *May save time and reduce burden on medical staff leadership.*
- *May avoid fair hearing process and NPDB reports.*
- *Check state law and bylaws.*

Credentialing Process

- See sample credentialing checklist.
- Make sure it complies with state law, bylaws, and credentialing policies before using.



Credentialing Process

- Put burden on applicant to produce relevant and required info and documents.
 - You should not be required to chase down info.
 - Notify applicant of deficiencies, *e.g.*, missing info or incomplete answers.
 - Notify applicant that you cannot process application until completed application is submitted.
- Confirm that misrepresentations in application are basis for automatic denial.

Credentialing Process: NPDB Queries

- Hospitals must query the NPDB about a health care practitioner:
 - At the time the practitioner applies for a position on its medical staff (courtesy or otherwise) or for clinical privileges.
 - Every 2 years for any practitioner who is on its medical staff (courtesy or otherwise) or has clinical privileges.

(45 CFR 60.17(a))
- “Health care practitioner” = an individual who is licensed or otherwise authorized by a state to provide health care services (or any individual who, without authority, holds himself or herself out to be so licensed or authorized). (45 CFR 60.3)
 - Not limited to physicians.
- Hospital that fails to query is presumed to have knowledge of any information reported to the NPDB. (45 CFR 60.17(b))

NPDB Queries

<https://www.npdb.hrsa.gov/hcorg/aboutQuerying.jsp>



About Querying the NPDB

[Help Center](#)

[Continuous Query](#)

[One-Time Query](#)

[Querying Infographics](#)

[How to...](#)

[Retrieve Historical Query and Report Summaries](#)

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Querying the NPDB

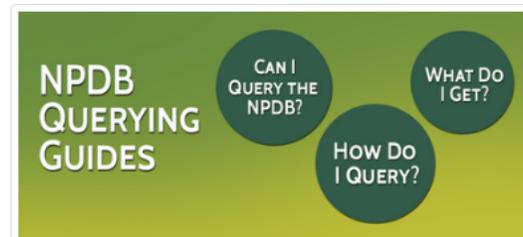
A query is a search for information in the NPDB regarding a health care practitioner or organization. The NPDB collects information on medical malpractice payments and certain adverse actions through reports submitted by [entities eligible to report](#). This information is disclosed to [entities eligible to query](#). Organizations must be [registered](#) with the NPDB and authorized to query for NPDB information. The ability of an organization to query, and the types of NPDB information they may receive through querying, is determined by [law](#). When an entity submits a query, the NPDB only releases the information they are lawfully allowed to access, based on their [NPDB registration](#).

How to Query

Organizations can request a query online through the [NPDB website](#), or through external systems using the NPDB's [Querying and Reporting XML Service \(QRXS\)](#).

There are two types of query services available through the NPDB website:

- [Continuous Query](#) allows you to receive a query response **and** all new or updated report notifications during the year-long enrollment for each practitioner.



Querying Infographics

Learn about more about querying the NPDB through infographics and a video about Continuous Query.

[See the infographics](#)

LEIE Queries: Federal Exclusion Statute

- Excluded person cannot order or prescribe items payable by federal healthcare program.
- Cannot submit claim for item ordered or furnished by an excluded person.
- Excluded owners cannot retain ownership interest in entity that participates in Medicare.
- Cannot hire or contract with excluded entity to provide items payable by federal programs.

(42 USC 1320a-7a(a)(8); 42 CFR 1003.200(a)(3), (b)(3)-(6))

Penalties

- \$24,947* per item or service ordered.
- 3x amount claimed.
- Repayment of amounts paid.
- Exclusion from Medicare and Medicaid

(42 USC 1320a-7a(a)(8); 42 CFR 1003.210; 45 CFR 102.3; OIG Bulletin, *Effect of Exclusion*,

<https://oig.hhs.gov/exclusions/files/sab-05092013.pdf>)

LEIE Queries

<https://oig.hhs.gov/exclusions/index.asp>

 An official website of the United States government [Here's how you know](#) ✓



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Exclusions Program

OIG has the authority to exclude individuals and entities from Federally funded health care programs.

*Check the
LEIE on
regular
basis!*

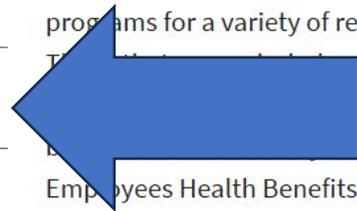
Exclusions Program

[Online Searchable Database](#)

[LEIE Downloadable Databases](#)

[Monthly Supplement Downloads](#)

This webpage provides information about OIG's exclusion authority and activities. The authority to exclude individuals and entities from Federally funded health care programs for a variety of reasons, including a conviction for Medicare or Medicaid fraud. Those who are excluded receive no payment from Federal health care programs for any services they furnish, order, or prescribe. This includes those that provide health care services directly or indirectly by the United States (other than the Federal Employees Health Benefits Plan).³⁸



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Credentialing Process

MEDICAL STAFF REVIEW

- Review application
- Consider relevant factors, *e.g.*, competence, professionalism, hospital needs, etc.
- Conduct additional investigation as needed, *e.g.*, interview candidate or others, evaluation, etc.
- Recommendation re med staff membership and privileges
 - Grant
 - **Limitations or conditions***
 - **Denial***



BOARD REVIEW AND DECISION

- Reviews recommendation:
 - Reasonable and supported by evidence.
 - Consistent with bylaws.
 - Substantive issues.
 - Procedure followed.
 - Not arbitrary, capricious, or illegal.
- Board may
 - Accept recommendation.
 - Return or conduct additional investigation.
 - **Deny or modify recommendation***

**Usually triggers hearing and/or appeal rights.*

Credentialing Process

- Beware warning signs, e.g.,
 - References indicate problems
 - Discrepancies in info submitted
 - Privileges requested vary from usual requests
 - Unexplained gaps in time
 - Loss or reduction in privileges, licensure, program participation, etc.
 - Prior disciplinary actions
 - Three or more malpractice claims in last five years
 - Numerous jobs or affiliations in last five years
 - More than five licenses across United States
 - Unexplained refusal to disclose info
 - Anything else that raises concerns
- It's easier to keep them off staff than to take adverse action against them later.



Credentialing: Telemedicine Privileges

- Hospital and CAH CoPs allow hospital to rely on credentialing done by remote hospital/entity if:
 - Have written agreement with distant site.
 - Distant site complies with CoP standards.
 - Practitioner privileged at distant site.
 - Practitioner licensed in state where services provided.
 - Hospital reviews practitioner's performance and provides results to distant site.

(42 CFR 482.12 and .22, and 485.616 and .635)

- *Confirm it is allowed by state law and consistent with bylaws.*
- *Confirm it does not trigger fair hearing rights.*
- *Consider exposure to negligent credentialing claim.*

Credentialing: Emergency or Temporary Privileges

- In limited circumstances, hospital may grant privileges on emergency or temporary basis, *e.g.*,
 - Practitioner needed but no time for full process.
 - Privileges temporarily granted while formal application processed.
 - Subject to expedited review.
 - Automatically expires within limited time period, *e.g.*, 60 days.
- *Be very careful and use sparingly.*
 - *Ensure bylaws allow for same.*
 - *Check—*
 - *State statutes and regs*
 - *Accreditation standards*

Credentialing: Reappointment

- Usually, must occur at least every 2/3 years.
 - COPs and Joint Commission allow every 3 years.
 - Many states and existing bylaws may require every 2 years.
- Process similar to initial appointment.
 - Application
 - Review by active staff
 - Governing body determination
- Process should be stated in bylaws, rules or regulations.
- Beware situations where reappointment process allowed to drag on or not completed.



May want to modify
your process.

Corrective Action



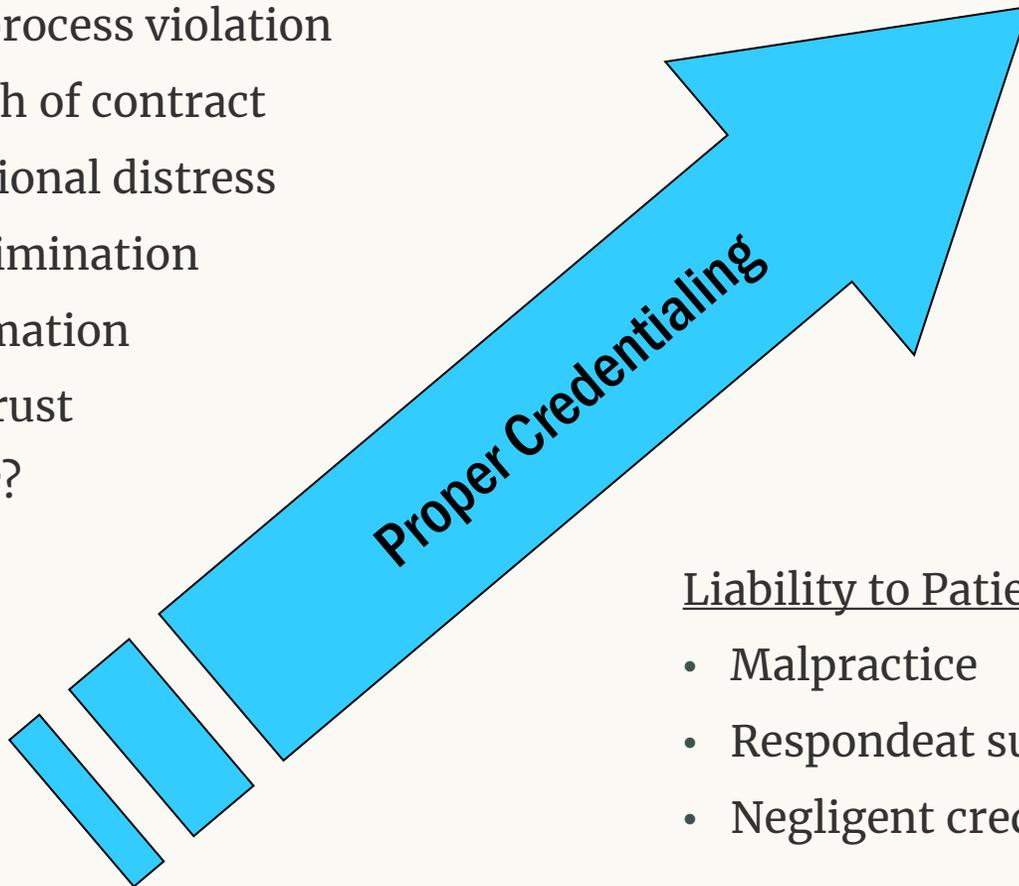
Corrective Action

- Organization has right to ensure effective operations.
- Organization has duty to protect patients and employees.
- Medical staff responsible for medical care, professional practices, and ethical conduct of members.
 - Clinical concerns
 - Ethical concerns
 - Behavioral concerns (*e.g.*, disruptive conduct)
 - Compliance (*e.g.*, laws, bylaws, rules, regulations)
 - Licensure, credentials, program participation
 - Other?

Remember...

Liability to Practitioner

- Due process violation
- Breach of contract
- Emotional distress
- Discrimination
- Defamation
- Antitrust
- Other?



Quality Care
Quality Workplace

Liability to Govt

- State licensure
- COPs
- Accreditation

Liability to Patient

- Malpractice
- Respondeat superior
- Negligent credentialing

Corrective Action: Med Staff v. Contract

ACTION ON CONTRACT FOR EMPLOYEES/CONTRACTORS

- **Pros**
 - More efficient.
 - Admin is skilled at handling.
- **Cons**
 - No HCQIA immunity.
 - Maybe no peer review immunity.
 - Med staff may want to be involved.
 - Depends on contract terms.
 - Exposed to contract claim.

✓ *Confirm state law requirements.*

ACTION BY MED STAFF

- **Pros**
 - HCQIA and peer review immunity.
 - Avoids breach of contract claim.
- **Cons**
 - Process is burdensome and expensive.
 - Med staff is inefficient and rarely adept.
 - Med staff may be conflicted.
 - Depends on bylaws terms and perhaps state law.

Corrective Action: Helpful Terms

CONTRACTS

- Condition contract on unrestricted med staff membership and privileges.
- Robust performance standards.
- Robust termination provisions, e.g., cause and no cause.
- Termination of contract = automatic resignation of privileges without bylaws hearing.
- If there is conflict between contract and bylaws, contract controls.

BYLAWS

- Confirm bylaws ≠ contract.
- Robust qualifications, responsibilities, standards.
- Confirm providers with a contract are subject to contract terms; contract trumps contrary bylaws.
- Automatic termination for certain items.
- Scaled back due process rights for certain providers or certain circumstances, e.g.,
 - Physicians v. non-physicians
- Precautionary suspensions.
- Exclusive contracts.
- Closed staffs.
- Restrict ability to reapply following adverse determination.

Corrective Action: Remember...

- Courts usually do not second guess an organization's corrective action if:
 - Decision is based on appropriate factors.
 - Valid patient care or business reason, not discrimination, retaliation, unfair competition, or other illegal reason.
 - Not arbitrary and capricious.
 - Practitioner given process required by contract, bylaws, or laws.
- ✓ *Remember: from legal liability perspective, the process is usually more important than the result.*

Corrective Action

- Make sure action is consistent with:
 - Practitioner's contract, if any
 - Bylaws, policies, and procedures
 - See sample Disruptive Practitioner Policy
 - State statutes, regulations and cases
 - Constitutional due process, if public entity
 - HCQIA, if action involves physicians
- If vary from bylaws or other required standards, seek and document a waiver from the physician.
 - Physician may waive standards, including HCQIA. (42 USC 11112(b))

Automatic Action e.g., Suspension or Termination

- Specify grounds in the bylaws and contracts, e.g.,
 - Loss of licensure or DEA number
 - Loss of liability insurance
 - Exclusion from Medicare/Medicaid
 - Conviction of felony or health care fraud
 - Failure to complete medical records
 - Termination of exclusive contract
 - Adverse action by other facility?
 - Specify process in bylaws
 - Identify entity who may terminate or suspend
 - Do not require full hearing process?
 - Coordinate with contracts
 - Termination of contract = termination of privileges
- *Consider expedited process if permitted by bylaws and state statutes, e.g.,*
 - *No full hearing*
 - *Written response*
 - *May not have HCQIA immunity if fail to provide required due process, but that is usually not an issue in these situations.*

Informal Response

- Facts may warrant informal response, e.g.,
 - Practitioner interview
 - Oral or written reprimand and warning
 - Chart review or proctoring
 - Counseling and treatment
 - Education and training
 - Voluntary remediation agreements
 - See sample Practitioner Behavior Agreement.
 - Focused professional practice evaluation (FPPE)
- *Document action in file.*
 - *May support future action.*
 - *May help avoid negligent credentialing claim.*
- *Ensure bylaws do not require progressive discipline.*
- *Informal response not reportable to NPDB if no action taken against privileges.*

Investigation

- Facts may require formal investigation.
- Define “investigation” in bylaw, rules or regulations.
 - “Investigation” may trigger obligation to report to NPDB if physician resigns or surrenders privileges during or to avoid investigation.
 - See discussion below re what constitutes and “investigation” under NPDB guidance.
- Consider notifying practitioner of investigation.
- Avoid identifying complainants.
- Warn against retaliation or improper contact.
- Remind practitioner of obligation to cooperate.
- If complaint involves serious allegations or difficult practitioner, consider involving attorney to ensure compliance with applicable standards.

Investigation

- Appoint investigating entity.
 - Specify process in bylaws, rules, and regulations.
 - Use fair and balanced professionals.
 - Use peers (*e.g.*, qualified physicians or providers in same or similar specialty) if possible.
 - Avoid using competitors or persons with conflict.
 - Avoid using anyone who may be needed to serve on a hearing panel if it goes that far.
 - Consider using outside reviewers, *e.g.*, peer review network.
 - May need business associate agreement.
 - Preserve peer review privilege.

Investigation

- Educate participants in investigation
 - Scope of investigation.
 - Relevant substantive standards that apply to misconduct and investigation.
 - Procedures found in bylaws, rules and regulations.
 - Importance of maintaining confidentiality and peer review privilege.
 - Statutory immunity if act in good faith, *e.g.*, HCQIA, state peer review statutes, others.

Investigation

- Conduct fair investigation.
 - HCQIA: entity must make “a reasonable effort to obtain the facts of the matter.”
 - Review documents
 - Interview witnesses
 - Consult experts
 - Require evaluations
 - Other?
- Scope depends on nature and seriousness of charges.
- Investigator should be careful not to unilaterally expand scope of investigation.
- If new matters are discovered, report back to appointing entity for action.
- Organization will be judged by investigative record.

Investigation

- Document legitimate actions, considerations, and conclusions in a written report to MEC or similar entity.
 - Will help ensure a well-reasoned conclusion.
 - Will support HCQIA immunity.
 - Will support decision on judicial review if it goes that far.
- Assume that report will be discoverable, *e.g.*,
 - To physician in proceeding
 - To board of medicine
 - To court in trial
- Beware improper considerations or motivations.
- Consider having legal counsel review before finalized.

Recommendation

- Determine recommendation to governing body.
- If recommend outcome favorable to practitioner, make recommendation to board.
- If recommend adverse action that would trigger hearing rights,
 - Notify practitioner of right to request hearing per bylaws, rules and regulations, if applicable.
 - Alert board, but do not make recommendation to board.
 - Implement hearing process, if applicable.

Ensure you comply with

- *State law*
- *Bylaws and policies*
- *Contracts*

Precautionary or Summary Suspension

- Appropriate where there is:
 - “Imminent danger to the health of any individual” or similar standard.
 - Adverse effect on hospital operations.
 - Immediate need to remove practitioner.
 - Other?
- Follow bylaws, rules and regulations if possible, including:
 - Standards for precautionary suspension.
 - Entity that can invoke precautionary suspension, *e.g.*, administrator, chief of staff, etc.
- Likely subject to subsequent notice and hearing if > 14 days.
 - Work to resolve or initiate formal proceedings within the 14 days.
- Report to NPDB if suspension of physician lasts > 30 days.

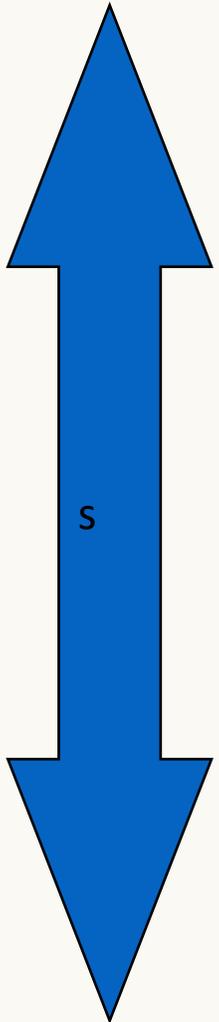
Precautionary Suspension

- Notice of suspension.
 - To subject practitioner.
 - To medical executive committee, chief of staff, administrator.
 - Others who need to know to ensure practitioner complies.
- Arrange to transfer care of patients to other practitioners.
 - Consider patient wishes.
 - Beware defamation issues.

Hearing Process

- Usually, must give due process (notice and hearing) if deny or reduce privileges based on practitioner's professional conduct that may adversely affect patient care, depending on:
 - State law,
 - Bylaws and policies,
 - Contracts, and/or
 - Accreditation standards.
- May have flexibility.
- Process that is “due” depends on circumstances.
 - Bylaws, rules and regulations.
 - Type of practitioners involved.
 - Severity of action.
 - Basis for action, *e.g.*, adversely affecting patient care or other consequences.
 - Contract requirements.
 - Other factors?

Hearing Process



- Full hearing and appeal process
 - Physicians
 - Denial, reduction, or termination of privileges
 - Competence or profession conduct related to patient care concerns
- ✓ *Check state law, bylaws and contracts. Hospitals and other entities have flexibility in establishing processes so long as they are consistent with applicable laws and regs.*
- May use alternative or expedited process.
 - Non-physicians
 - Temporary or limited restriction of privileges
 - Unrelated to patient care, e.g., administrative issues
 - Automatic action where there is no real dispute or need for hearing, e.g., loss of licensure.

If you want HCQIA immunity

Reporting Adverse Actions



National Practitioners Data Bank (NPDB)

Certain entities must report to NPDB.

- Insurers and other **entities making a payment to settle a medical malpractice claim.**
- Medical boards taking adverse action against a physician's or dentist's license.
- States taking adverse action against a practitioner.
- Federal licensing and certification agencies taking certain adverse actions against a practitioner.
- Peer review organizations and private accreditation taking negative or adverse action.
- Federal and state prosecutors obtaining judgment in healthcare cases.
- Federal and state agencies excluding practitioners from participating in healthcare programs.
- **“Health care entities” taking certain professional review actions against a physician's or dentist's privileges, including:**
 - **Hospitals, and**
 - **Other entities that provide health care services and engages in professional review activity through a formal peer review process for the purpose of furthering quality health care.**

(45 CFR 60.7-60.15)

NPDB Reports

<https://www.npdb.hrsa.gov/hcorg/aboutReporting.jsp>



About Reporting to the NPDB

[What You Must Report to the NPDB](#)

[Submitting a Narrative](#)

[MMPR Form \(MS Word - 183 KB\)](#)

[Reporting Through an External Application](#)

[Reporting Adverse Clinical Privileges Actions \(video - 4.34\)](#)

[Reporting Infographics](#)

[Policy Corner](#)

[Help Center](#)

[How to](#)

Reporting to the NPDB

Reports in the National Practitioner Data Bank are records of actions taken by authorized organizations regarding health care practitioners, entities, providers, and suppliers who do not meet professional standards. Health care organizations must register with the NPDB and be **authorized to report** to the NPDB in accordance with the [federal regulations](#). Reports are permanently stored in the NPDB unless modified or removed by the organization that submitted the report.

[Reportable actions](#) include medical malpractice payments and health care-related adverse actions. [Chapter E of the NPDB Guidebook](#) explains the NPDB reporting guidelines.

Reports are submitted online using the NPDB's secure system, either through the [NPDB website](#) or through external applications using the [Querying and Reporting XML Service \(QRXS\)](#).

Learn More

[> Which organizations are authorized to submit reports?](#)

NPDB REPORTING GUIDES

When to report...

CLINICAL PRIVILEGES ACTIONS

MEDICAL MALPRACTICE PAYMENTS

STATE LICENSURE ACTIONS

Questions About When to Report?

Our newest infographics guide you through what characteristics make these actions reportable.

[See the infographics](#)

NPDB Reports: Penalties

- If fail comply with NPDB reporting requirements:
 - Hospitals and healthcare entities: lose HCQIA immunity for 3 years, but...
 - NPDB gives notice and chance to correct.
 - May request hearing.

(42 USC 11111(b); 45 CFR 60.12(c))

 - Malpractice payers: civil penalty of \$27,894. (42 USC 11131(c); 42 CFR 1003.810)
- State medical boards must report health care entities who fail to report to the medical board. (45 CFR 60.12(a))

NPDB Reports

- Hospitals and other “healthcare entities” must (1) report to NPDB and (2) provide copy to state medical board of any action against physician or dentist if:
 - Action adversely affects clinical privileges for more than 30 days and is based on professional competence or conduct adversely affecting patient care;
 - Voluntary surrender or restriction of physician privileges
 - while physician is under investigation for incompetence or professional conduct, or
 - in return for not conducting an investigation;
 - Suspension in effect for more than 30 days; and/or
 - Revision or modification of such action.
- May report actions against other practitioners.
(42 USC 11133; 45 CFR part 60.12)

NPDB Guidebook

<https://www.npdb.hrsa.gov/resources/aboutGuidebooks.jsp>

Search the NPDB Guidebook for...



[For Health Care Professionals](#) [For Organizations](#) [NPDB Resources](#)

[Home](#) / [The NPDB Guidebook](#)

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NPDB Guidebook

Last Update October 2018



[Policy Corner](#)

[Legislation & Regulations](#)

[Updates](#)

See discussion beginning at E-31

NPDB Reports: Common Scenarios

REPORTABLE IF BASED ON COMPETENCE OR CONDUCT AFFECTING PATIENT CARE

- Denial of initial application.
- Denial of renewal application or requested privileges.
- Non-renewal, resignation or agreement not to exercise privileges while investigation is pending or to avoid investigation.
- Agreement not to exercise privileges > 30 days.
- Restriction on privileges > 30 days, e.g., mandatory proctoring during procedure.
- Termination or non-renewal of temporary or emergency privileges.

(See NPDB Guidebook at E-31 *et seq.*)

NOT REPORTABLE

- Withdrawal of initial application before final decision.
- Administrative action not involving a professional review action, e.g., failure to have liability coverage, geographic proximity, etc.
- Termination of employment or contract without professional review action.
- Adverse action unrelated to competence or professional conduct.
- Residents and interns acting within program.
- Investigation stopped before conclusion.

When does an “investigation” begin?

- “Investigation” is not controlled by bylaws, policies or procedures.
- In general, an investigation that triggers potential reporting is:
 - Focused on the practitioner in question.
 - Concerns the professional competence and/or professional conduct of the practitioner in question.
 - A precursor to a professional review action.
 - Ongoing until the health care entity’s decision-making authority takes a final action or formally closes the investigation.
- A routine or general review of cases is not an investigation.
- A routine review of a particular practitioner is not an investigation.

(NPDB Guidebook at E-37)

NPDB Reports: Timing

- Must report within 30 days following the action to be reported.
 - Generally, after peer review action becomes final, or
 - Suspension > 30 days even if not finally resolved.

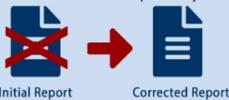
(45 CFR 60.5)

- If discover errors in info report, must send correction to NPDB as soon as possible.
- If revise action originally reported (*e.g.*, reverse action, reinstate privileges, terminate suspension, *etc.*), must report revision to NDPB within 30 days.

(45 CFR 60.6)

NPDB Reports

<https://www.npdb.hrsa.gov/hcorg/aboutReporting.jsp>

<p>Initial Report The first report submitted to and processed by the NPDB</p> 	<p>Initial Report An Initial Report is the first report of a medical malpractice payment, adverse action, or judgment or conviction submitted to and processed by the NPDB.</p> <p>Learn More</p>
<p>Correction A correction to an error or omission in a previously submitted report</p>  <p>Initial Report Corrected Report</p>	<p>Correction A Correction amends an error or omission in a previously submitted report. The reporting entity must submit a Correction as soon as they discover an error or omission is present.</p> <p>A Correction replaces the previously submitted report it is amending and can be submitted as often as necessary.</p> <p>Learn More</p>
<p>Revision-to-Action A report of an additional or continuing action related to a previously submitted report</p>  <p>Initial Report Revision Report</p>	<p>Revision-to-Action A Revision-to-Action is a modification to an action that has already been reported. In other words, it is a report of an additional or continuing action that is related to a previously reported action.</p> <p>A Revision-to-Action does not replace the preceding report(s), rather, it becomes an additional part of the disclosable record.</p> <p>Learn More</p>
<p>Void The withdrawal of a report in its entirety from the NPDB</p>  <p>Initial Report Initial and all related reports</p>	<p>Void A Void is the withdrawal of a report in its entirety from the NPDB. When a report is voided it is removed from the disclosable record of the report subject.</p> <p>A reporting entity may void a report at any time.</p> <p>Learn More</p>

NPDB has process for

- Initial Report
- Corrections to Report
- Revisions-to-Actions
- Voiding Report
- Provider's response or dispute

(See <https://www.npdb.hrsa.gov/hcorg/aboutReporting.jsp>)

NPDB Reports: Immunity

- Individuals, entities or their agents shall not be held liable in any civil action filed by the subject of a report unless the individual, entity, or authorized agent submitting the report **has actual knowledge of the falsity of the information contained in the report.** (42 USC 11137(c); 45 CFR 60.22)
- Hospital not immune where it improperly checked “incompetence/malpractice/negligence.” (*Brown v. Presbyterian Healthcare* (10th Cir. 1996))

Be careful about checking boxes or what you include in the report.

- *Ensure it is absolutely accurate.*
- *As a general rule, do not include more than is required.*
- *May want to check “other” and provide description.*

NPDB Reports: Confidentiality

- Persons and entities receiving info from the NPDB, either directly or from another party, must keep it confidential and use it solely for the purposes permitted under the NPDB, e.g., for credentialing, employment, check on reports about self, *etc.*
- Violations may result in civil penalties of up to \$27,894* per violation.

(42 USC 11137(b); 42 CFR 1003.810; 45 CFR 60.20)

- *Safeguard NPDB information.*
- *Ensure uses are consistent with NPDB reporting purposes.*

Additional Reporting Requirements

- Check state laws and regulations, *e.g.*,
 - Board of medicine as required by HCQIA and NPDB
 - Other licensing boards
- Reports may be broader than NDPB, *e.g.*,
 - Report practitioners in addition to physicians
 - Report additional adverse actions, including termination of employment
 - Report actions based on certain types of misconduct, *e.g.*,
 - Professional misconduct
 - Drug-related conduct
 - Others

Peer Review Privilege



Privileges and Immunities

PRIVILEGE

Ensures info from peer review actions remain confidential.

- Promotes full and frank discussion.
- May not be used in malpractice and maybe other actions.
- May limit claims by practitioners in litigation.

IMMUNITY

Protects participants in peer review actions from lawsuits so long as they act in good faith.

- Promotes participation.
- Promotes full and frank discussion.

✓ *Check your state laws, court rules, and cases.*

Protecting the Peer Review Privilege

- Designate peer review committees.
- Conduct peer review activities through designated committee or representative, including investigations, interviews, record reviews, reports.
 - *Check state law and cases to confirm protected organizations.*
- Retain outside experts or reviewers through committees.
- Educate participants and require that they maintain confidentiality.
 - Medical staff bylaws and policies
 - Agreements

Beware:

- *Inadvertent waivers.*
- *Disclosures or actions outside designated committee.*
- *Disclosures or actions outside designated process.*

Protecting the Peer Review Privilege

- Protect peer review documents.
 - Segregate peer review records from other records, *e.g.*, medical record.
 - Label privileged documents as “CONFIDENTIAL PEER REVIEW RECORD—DO NOT DISTRIBUTE WITHOUT AUTHORITY”
 - Designate appropriate custodians.
 - Beware copying and distributing them; require return.
- *Carefully consider before waiving the privilege.*
 - *May want to waive privilege to defend entity but be careful.*
 - *Privilege likely belongs to hospital, not subject practitioner or others.*

Always Assume the Records May Be Disclosed Despite Privilege

- Use qualified, trained persons to document.
 - More serious the issue → more important to document.
- Document accurately and professionally.
- Don't speculate or cast aspersions.
- Supplement the records as appropriate.
 - Use appropriate late entries.
 - Never falsify the record.
- Report up the chain.
- Follow through on whatever you write.

Credentialing Protections for Entities and Med Staff Leadership



Deference to Entities Making Credentialing Decisions

- Courts usually do not second guess facility's credentialing decision if:
 - Followed standards in bylaws and statutes.
 - Based on legitimate, documented reasons
 - Patient care or facility operations
 - NOT arbitrary or capricious
 - NOT improper motive, *e.g.*, discrimination, anti-competition, retaliation, *etc.*
- From legal liability standpoint, the process is usually more important than the decision.

Statutory Protections

- Health Care Quality Improvement Act (HCQIA), 42 USC 11101 *et seq.*
 - Protects peer review activity involving physicians.
- State peer review statutes.
 - Immunity for participants and protection of peer review info.
- Federal Volunteer Protection Act, 42 USC 14501
 - Protects volunteers paid < \$500/year
- State protections for non-profit officers and directors.
 - Protects for certain actions.
- Local Govt Antitrust Act, 15 USC 34
 - Protects govt hospitals from antitrust damages under federal act.
- State Tort Claims Act
 - Protects govt hospitals and actors.

Waivers and Releases

- Bylaws, policies or credentialing applications may (and should) contain a waiver or release from the practitioner relating to peer review activities.
- Whether it is enforceable may depend on state law and language.
- But better to have it than not.
 - Check application forms.
 - Check bylaws and policies.
- See sample Authorization and Release.

Indemnification Agreements

- Entities may sometimes agree to defend and indemnify medical staff leaders and other participants in peer review process.
- Check contracts, bylaws, policies, etc.

Director & Officers Insurance

- Facilities may purchase or provide D&O or similar insurance for medical staff leaders or others involved in the peer review process.
- May be subject to policy limits or conditions, e.g.,
 - May only reimburse defense costs.
 - Defense costs may reduce policy limits.
 - Usually coverage is on a “claims-made” basis.
 - May not apply if act outside course and scope of duties.
- May be subject to exclusions, *e.g.*, intentional misconduct; certain types of claims; *etc.*

Questions



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