

Utah Rural 9 Conference



**Corrective Action:
Managing the Process to
Protect Patients and
Minimize Liability**

**Kim C. Stanger
Jake Walker**
(10.25)

 **Holland & Hart**

Preliminaries

This presentation is similar to any other legal education materials designed to provide general information on pertinent legal topics. The statements made as part of the presentation are provided for educational purposes only. They do not constitute legal advice nor do they necessarily reflect the views of Holland & Hart LLP or any of its attorneys other than the speaker. This presentation is not intended to create an attorney-client relationship between you and Holland & Hart LLP. If you have specific questions as to the application of law to your activities, you should seek the advice of your legal counsel.

Overview

- Corrective Action
 - Standards
 - Process
- Waivers and Releases
- Mandatory reporting
 - NPDB
 - Utah law
- Peer review
 - Scope
 - Protection

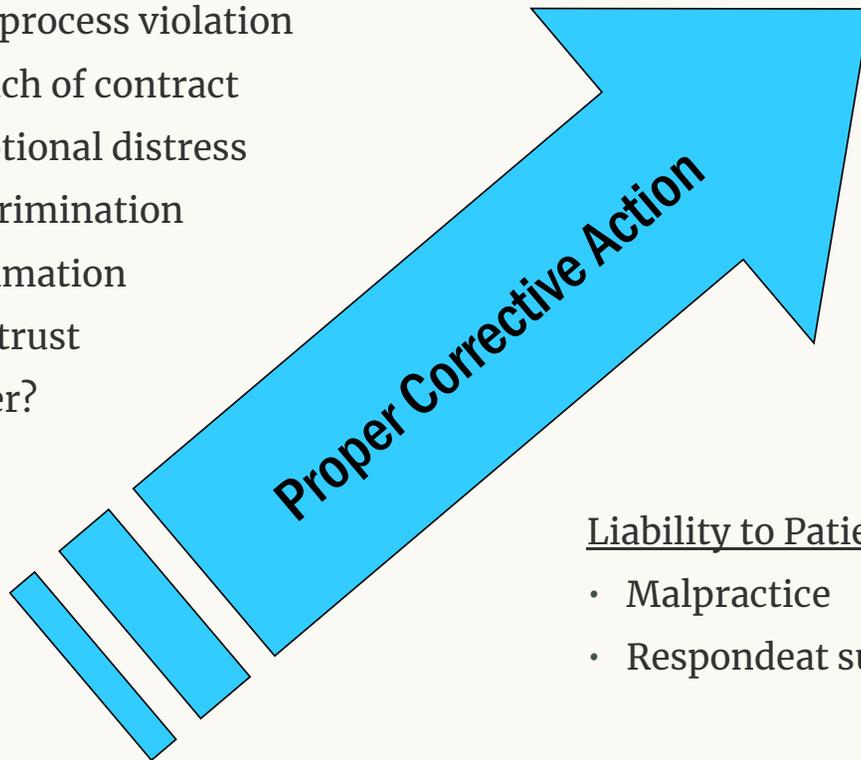


- Written Materials
 - Sample bylaws provisions re credentialing and corrective action.
 - Sample behavior agreement.
 - Sample authorization to disclose and release of liability.

Appropriate Corrective Action

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

Corrective Action

- 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.



Applicable Standards



Corrective Action Big Picture

- Hospital generally has the right to determine to whom it will grant privileges.
 - Private hospitals
 - Govt hospitals
- Hospital has right and obligation to take action if a provider is not living up to his/her obligations, is adversely affecting patient care, or is adversely affecting the hospital.



But...

- Subject to—
 - Utah law
 - Bylaws
 - Provider contract

Utah R432-100-7: Medical and Professional Staff

“(1) Each hospital shall have an organized medical and professional staff that operates under bylaws approved by the board.

“(2) The medical and professional staff shall advise and be **accountable to the board for the quality of medical care provided to patients.**

“(3) The medical and professional staff must adopt **bylaws and policies and procedures to establish and maintain a qualified medical and professional staff** including current **licensure, relevant training and experience, and competency** to perform the privileges requested. The bylaws shall address:

- (a) the appointment and re-appointment process;
- (b) the **necessary qualifications for membership**;
- (c) the delineation of privileges;
- (d) the participation and documentation of continuing education;
- (e) temporary credentialing and privileging of staff in emergency or disaster situations; and
- (f) a fair hearing and appeals process.”

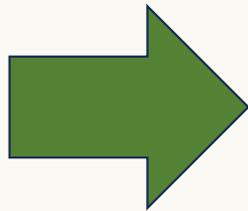
Corrective Action: Bases?

- ✓ Failure to satisfy qualifications in bylaws?
- ✓ Failure to comply with hospital policies, e.g., timely records?
- ✓ Disruptive conduct?
- ✓ Is aged 75?
- ✓ Competes with or is a member of an entity that competes with the hospital?
- ✓ Moved from geographic proximity to hospital?
- ✓ Is a podiatrist, psychologist, or has licensure not otherwise approved by the hospital board?
- ✓ Complains about hospital or medical staff leadership?
- ✓ Fails to have x number of admissions per year?
- ✓ Termination of employment?
- ✓ Other?

- *What do the bylaws say?*
- *Does it affect—*
 - *Patient care?*
 - *Hospital operations?*
- *Is the decision arbitrary or capricious?*

Bylaws and Policies

- Remember:
 - Bylaws constitute a contract.
 - Must substantially comply with bylaws.
- *Question: may you disclaim bylaws as a contract?*
- Ensure your bylaws address key terms, including—
 - Substantive standards.
 - Qualifications
 - Responsibilities
 - Consequences for failure to comply
 - Process for—
 - Credentialing (appointment, reappointment, etc.)
 - Corrective action
- *See sample bylaws terms.*



Utah R432-100-7: Medical and Professional Staff

“(3) The medical and professional staff must adopt bylaws and policies and procedures to establish and maintain a qualified medical and professional staff including current licensure, relevant training and experience, and competency to perform the privileges requested. The bylaws shall address:

- (a) the appointment and re-appointment process;
- (b) the necessary qualifications for membership;
- (c) the delineation of privileges;
- (d) the participation and documentation of continuing education;
- (e) temporary credentialing and privileging of staff in emergency or disaster situations; and
- (f) **a fair hearing and appeals process.”**

What does this mean or require?

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
bylaws and
policies, and
contracts.*

HCQIA Application

- HCQIA only 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))

- **Question: Should you / may you limit the due process to non-physicians?**

HCQIA: “Based on professional conduct or competence”

- Failure to satisfy qualifications in bylaws (e.g., loss of license, loss of insurance, outside geographic area)?
- Failure to comply with hospital policies, e.g., timely records?
- Disruptive conduct?
- Is aged 75?
- Complains about hospital or medical staff leadership?
- Fails to have x number of admissions per year?
- Termination of employment?
- Other?

- *Are or should they be entitled to due process if no “peer review action” under HCQIA?*
- *What do your bylaws say?*

To HCQIA or not to HCQIA?

- HCQIA process is not mandatory.
- In some cases, may decide NOT to go through full fair hearing process, e.g.,
 - Failure to satisfy basic qualifications where there is no real dispute as to issues, e.g., adverse licensure action, loss of malpractice insurance, exclusive contract, etc.
 - Non-physician providers.
 - Adverse action against contracted providers.
- But may be required to give some kind of due process per hospital licensing regulations.
 - Consider using expedited process, e.g., notice and chance to submit written response.
- Consider risk and need for HCQIA immunity.



Check—
✓ **Bylaws**
✓ **Policies**
✓ **Provider contracts**

Corrective Action: Helpful Terms

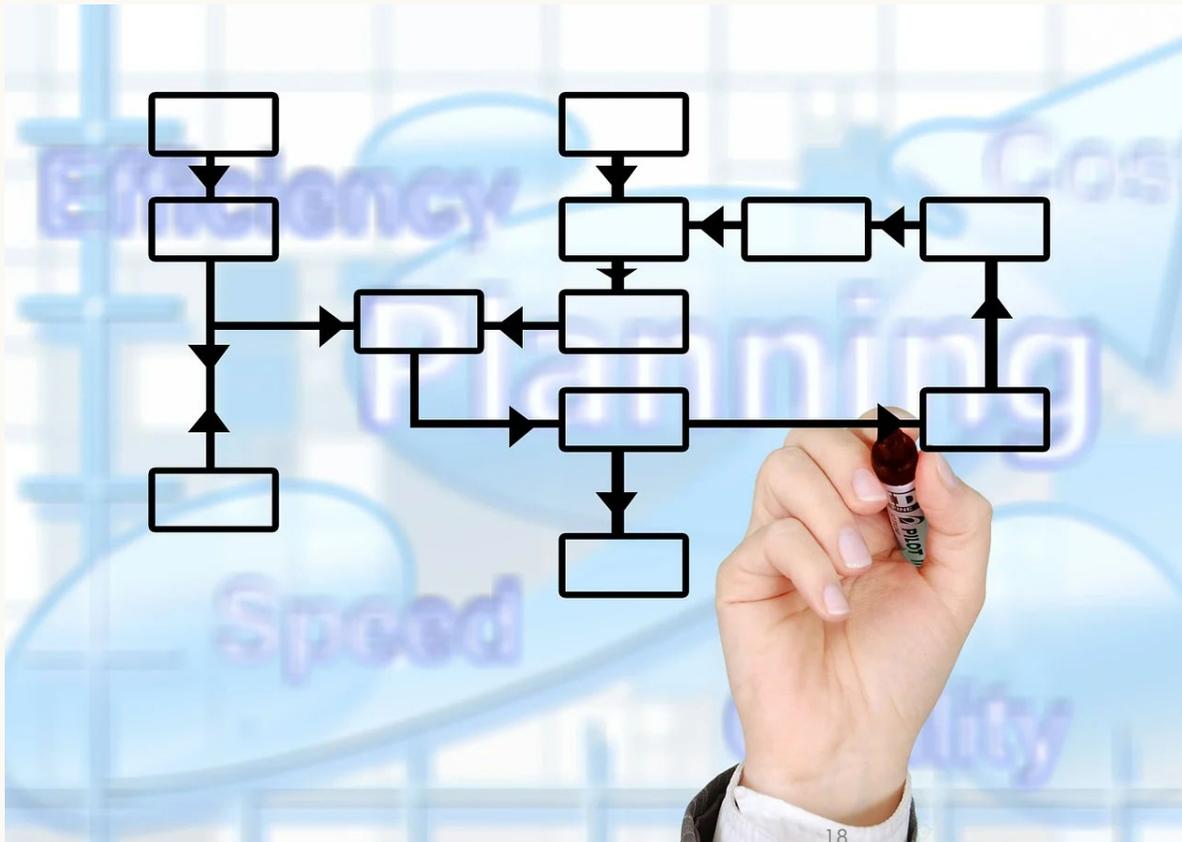
CONTRACTS

- 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.
- Restrictive covenants.
- Confidentiality.

BYLAWS

- Confirm bylaws \neq contract.
 - But see contrary Utah case.
- 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 Process



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.

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

If handle through medical staff--

- Make sure action is consistent with:
 - Practitioner's contract, if any
 - Bylaws, policies, and procedures
 - 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))

Corrective Actions

- Automatic action
 - Informal response
 - Formal response
 - Referral to MEC
 - Investigation
 - Recommendation to Board
 - Hearing consistent with HCQIA
 - Board decision
- *Ensure actions are consistent with bylaws and policies.*
 - *If vary, obtain agreement from provider.*

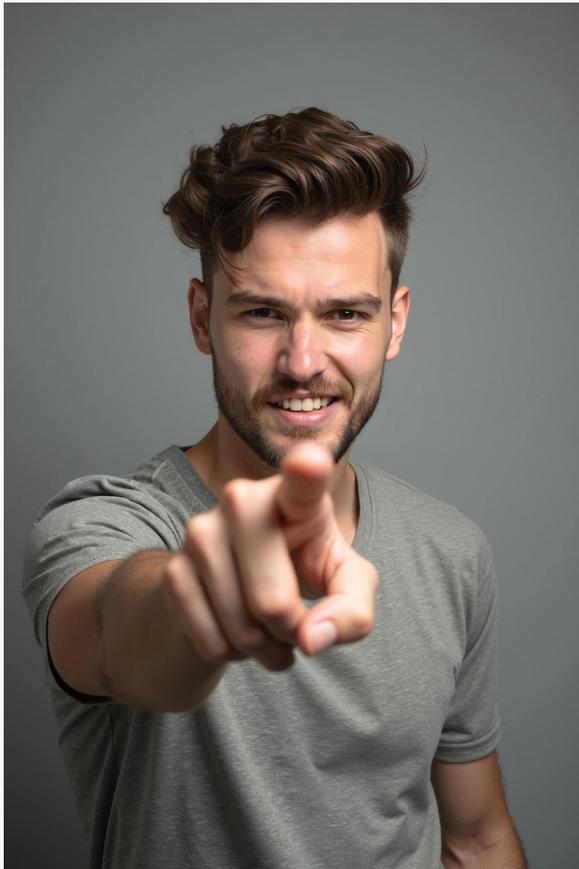
Automatic Action e.g., Suspension or Termination

- 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 regs, 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.*

Informal Response



- **Your job: make sure the action is documented in the file!**

- Complaints
- Discussions
- Warnings or reprimands
- OPPEs and FPPEs
- Response, e.g., failure to comply
- Appropriate minutes
- Reviews and privilege determinations
- Others?

**Maintain
the peer
review
privilege!**

Investigation

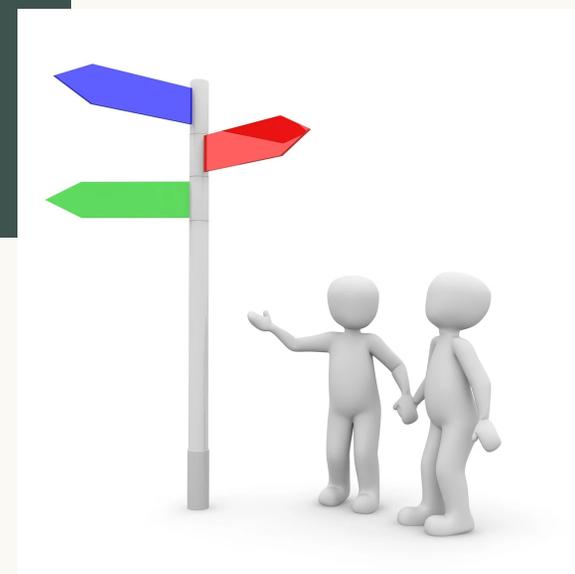
- Facts may require formal investigation.
- Define “investigation” in bylaws, rules or regulations.
 - “Investigation” may trigger obligation to report to NPDB if physician resigns or surrenders privileges during or to avoid investigation.
 - See discussion below re what constitutes and “investigation” 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

- Identify and/or 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
 - Complaint or concerns.
 - Scope of investigation.
 - Internal and external resources.
 - Relevant substantive standards that apply to misconduct and investigation.
 - Procedures found in bylaws, rules and regulations.
 - Desired product (not result), e.g., report
 - 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.

MEC 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*

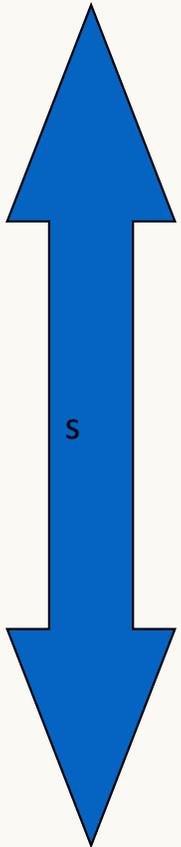
Precautionary or Summary Suspension

- 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.
- 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.
- Notify necessary persons and arrange for care of patients.
- 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.

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:
 - 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
- } If you want HCQIA immunity
- ✓ *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.

Due Process for Physicians

- Process is deemed to satisfy HCQIA standards if:
 - ✓ Entity gives notice of proposed action, reasons, witnesses, right to a hearing in no less than 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.
- Process may vary but be careful.

- *Be careful about adding or complicating process in your bylaws or policies.*
- *Retain authority to establish rules or process within general parameters of HCQIA.*
- *Confirm substantial compliance is sufficient.*

Due Process for Non-Physicians

- **Same process as physicians?** e.g.,
 - Formal hearing and appeal rights
- *Pros*
 - Consistency
 - Promotes equality among practitioners
- *Cons*
 - Additional cost and burden
 - No additional immunity
 - Greater chance of mistakes
- **Expedited process?** e.g.,
 - Written request for reconsideration to MEC or Board
- *Pros*
 - More efficient, less costly
 - Less chance for mistakes
- *Cons*
 - Non-physicians may feel second-class

Waivers and Release



Waivers and Releases

- Include in:
 - Bylaws
 - Credentialing applications
 - Contracts
- Address
 - Authorization to release records
 - Waiver and release of liability arising out of credentialing matters
 - Confidentiality of credentialing and peer review matters

➤ *See sample language.*

- *May not be enforceable*
- *But better than not having them.*
 - *May be enforced.*
 - *May dissuade physician from pursuing.*

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>

 U.S. Department of Health & Human Services

NPDB NATIONAL PRACTITIONER DATA BANK

[Home](#) [About Us](#) [Help Center](#) [Contact Us](#) [Sign In](#)

Search keywords or terms...

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

[Help Center - Organizations](#) / [Reporting](#) / [About Reporting the NPDB](#)

Text Size [AAA](#) [Print](#)

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>

- Guidebook Cover Page
- Table of Tables
- Table of Figures
- Chapter A: Introduction and General Information
- Chapter B: Eligible Entities
- Chapter C: Subjects of Reports
- Chapter D: Queries
- Chapter E: Reports
- Chapter F: Subject Statements and the Dispute Process
- Chapter G: Fees



- [Policy Corner](#)
- [Legislation & Regulations](#)
- [Updates](#)

This publication links to a nonfederal resource in order to provide additional information to consumers. The views and content in this resource has not been formally reviewed by the U.S. Department of Health and Human Services (HHS) or Health Resources and Services Administration.

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.



May create opportunity to settle with physician

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.

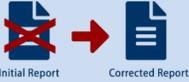
(45 CFR 60.5)

- 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</p> <p>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>Correction</p> <p>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>Revision-to-Action</p> <p>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>Void</p> <p>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.*

Utah Reporting Requirements

- Facilities (e.g., hospitals) are required to report certain events to DOPL within 60 days of the event occurring. These events include the following:
 - Terminating or restricting privileges for cause
 - Terminating, suspending, or restricting membership or privileges for unprofessional, unlawful, incompetent, or negligent conduct
 - Subjecting a licensed provider to disciplinary action for a period of more than 30 days
 - Finding that a provider has violated professional standards or ethics
 - Finding of incompetence in practice
- Utah Code Ann 58-13-5



Utah Reporting Requirements



DOPL has stated that precautionary suspensions that last less than 30 days while an investigation is pending do not need to be reported



But, if the investigation: (1) lasts longer than 30 days; or (2) is resolved with further action against the individual



Then, it needs to be reported

Utah Mandatory Reporting

- Facilities or persons providing information under the statute are immune from liability with respect to the information provided if it is provided in good faith and without malice
- This is true whether the information is provided voluntarily or upon request
- Also, individuals who are members of hospital administration, board, committee, department, medical staff, or professional organizations of providers, and facilities, are immune from liability arising from participation in review of a provider's ethics, competence, moral turpitude, or substance abuse

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.

Utah “Care Review Privilege”

- Utah law not only provides limited immunity for those involved in the review process but also establishes discovery and evidentiary privileges for the same
- This is different from UHCPILA

Utah Code Ann 26B-1-229

This authorizes any person, facility, or organization to provide certain persons and entities with a variety of information

The entities include peer review committees, professional review associations, any facility’s in-house staff committee

What Information?

- The following information can be disclosed and be protected:
 - Vital records as determined by the state registrar
 - Interviews
 - Reports
 - Statements
 - Memoranda
 - Familial information
 - Other data relating to the condition and treatment of a person

Utah “Care Review Privilege” Application

- The disclosing party can share information with such parties only for the following two purposes:
 - Study and advancing medical research, with the purpose of reducing incidence of disease, morbidity, and mortality
 - **Evaluation and improvement of hospital and health care rendered by hospitals, health facilities, or providers**

Information received must be held in strict confidence

Any use, release, or publication of such information is permitted only for the two purposes

All information is considered privileged communications; it is not subject to discovery, use, or admissibility in any legal proceeding

Any unauthorized use, release, or publication constitutes a Class B misdemeanor

Expansion of the Care Review Privilege; Utah Rules of Civil Procedure

- Utah Rules of Civil Procedure expanded the discovery and evidentiary privilege in 2022
- Essentially, the evidentiary privilege is broader than the original Care Review Privilege provided by the previous statute
- The expanded privilege applies to “all information in any form” related to peer review, care review, or quality assurance activities carried out by providers or entities
- Does not specify who the information must be provided to
- Such information is not discoverable or admissible in any proceeding of any kind or character

URCP 26(b)(2)

Care Review Privilege vs. URCP Rule 26

	Care Review Privilege	URCP Rule 26
What information is protected?	<p>(a) information as determined by the state registrar of vital records;</p> <p>(b) interviews;</p> <p>(c) reports;</p> <p>(d) statements;</p> <p>(e) memoranda;</p> <p>(f) familial information; and</p> <p>(g) other data relating to the condition and treatment of any person.</p> <hr/> <p>information, interviews, reports, statements, memoranda, or other information relating to the ethical conduct of any health care provider</p>	All information in any form <i>provided during and created specifically as part</i> of peer review, care review, or quality assurance processes (including investigations and requests for investigations).
Who can provide the information?	<p>any person, health facility*, or other organization.</p> <hr/> <p>any person</p>	Not specified.
To whom can the information be provided?	<p>(a) the department and local health departments;</p> <p>(b) the Division of Integrated Healthcare within the department;</p> <p>(c) scientific and health care research organizations affiliated with institutions of higher education;</p> <p>(d) the Utah Medical Association or any of its allied medical societies;</p> <p>(e) peer review committees;</p> <p>(f) professional review organizations;</p> <p>(g) professional societies and associations; and</p> <p>(h) any health facility's in-house staff committee.</p> <hr/> <p>peer review committees, professional societies and associations, or any in-hospital staff committee.</p>	Not specified.
For what purpose must the information be provided?	<p>(a) study and advancing medical research, with the purpose of reducing the incidence of disease, morbidity, or mortality; or</p> <p>(b) the evaluation and improvement of hospital and health care rendered by hospitals, health facilities, or health care providers.</p> <hr/> <p>intraprofessional society or association discipline.</p>	Evaluating care provided to reduce morbidity and mortality or to improve the quality of medical care, or for the purpose of peer review of the ethics, competence, or professional conduct of any health care provider.

*"Health care facility" means general acute hospitals, specialty hospitals, home health agencies, hospices, nursing care facilities, residential-assisted living facilities, birthing centers, ambulatory surgical facilities, small health care facilities, abortion clinics, facilities owned or operated by health maintenance organizations, end stage renal disease facilities, and any other health care facility which the committee designates by rule." However, it excludes "the offices of private physicians or dentists, whether for individual or group practice, except that it does include an abortion clinic." Utah Code Ann. § 26B-2-201(13).

Asserting the Privilege(s)

- The burden of establishing applicability of either privilege is on the party seeking to assert the privilege
- Must provide adequate evidence that demonstrates the item clearly falls within either privilege
- Utah courts have held that the privileges apply to documents that are specifically prepared, compiled, created, or submitted for the purpose of care or peer review
- Materials generated for other purposes, but could be used in care or peer review, do not fall within the scope of these privileges



Using the Privilege(s)

- Explicitly identify and document which committees and internal processes fall under either the peer review, care review, or quality assurance processes.
- Identify in meeting minutes the topics discussed and information reviewed that is considered to be protected
- Place prominent headers or footers on all documents provided during and created specifically as part of any review or quality assurance processes.
- Retain sufficient documentation to demonstrate that each document satisfies either privilege
- Establish safeguards to ensure that information discussed is not improperly disclosed.

Protecting the Peer Review Privilege

- Designate peer review committees.
- Conduct peer review activities through designated committee or representative, including investigations, interviews, record reviews, reports.
- 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.

Questions



Kim C. Stanger
kcstanger@hollandhart.com
(208) 383-3913

Jake Walker
jswalker@hollandhart.com
(303) 293-5254