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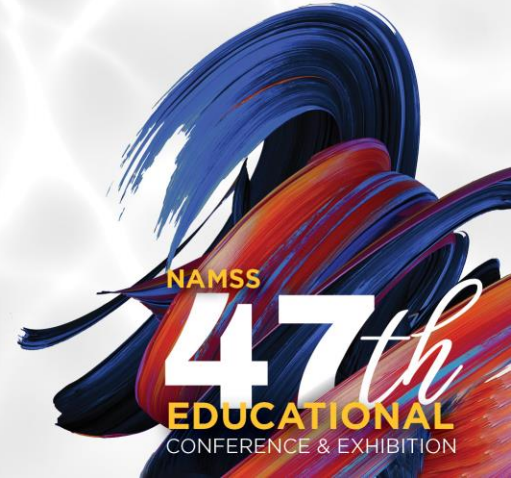
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Building Better:
Setting the Foundation
for the Future of the Profession

Made to Measure - Informal Remediation, Corrective Action, and Fair Hearings

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#NAMSS23





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Disclaimer



This presentation has been provided for informational purposes only and is not intended and should not be construed to constitute legal advice. Please consult your attorneys in connection with any fact-specific situation under federal, state, and/or local laws that may impose additional obligations on you and your company.

What We Will Cover

- Corrective action and alternatives to formal corrective action (i.e., informal remediation)
- Fair hearing foundational topics
- Regulatory influences on these processes



Sources of Physician Rights and Hospital Duties

- State statutes, regulations, and case law
- Medicare conditions of participation (COPs) (42 CFR § 482.22)
- Health Care Quality Improvement Act of 1986 (HCQIA) (42 USC §§ 11101, et seq.)
- Accreditation standards (TJC, HFAP, DNV)
- Medical staff bylaws, rules, and regulations

Medical Staff Accountability

The medical staff must be:



Organized in a manner approved by the governing body.



Accountable to the governing body for the quality of the medical care provided to patients.

Medical Staff Bylaws

- Medical Staff Bylaws are required by Medicare CoPs, content is determined by the applicable hospital accreditation standards and the CoPs, and content is approved by the Medical Executive Committee (MEC) and the hospital Board
- Bylaws should provide for procedural due process
- MS Bylaws contain:
 - Process for corrective action
 - Notice requirements
 - Hearing requirements



Medical Staff Documents Govern the Medical Staff

Medical Staff Bylaws: Provisions required by CoPs and accreditation standards. Associated details reside in applicable Medical Staff Policies.



Medical Staff Credentials Policy

Sets forth details with respect to credentialing, appointment, and privileging of Practitioners.



Medical Staff Organization Policy

Sets forth information regarding Medical Staff Departments/Sections, etc. (if any), standing Medical Staff committees, and meeting logistics.



Medical Staff Fair Hearing Policy

Sets forth the Medical Staff fair hearing and appeal process.



Practitioner/APC Conduct Policy

Sets forth the procedure for addressing unprofessional conduct by a Practitioner or Advanced Practice Clinician (APC).



Practitioner/APC Wellness (Impairment) Policy

Sets forth the procedure for addressing Practitioner or APC impairment.



Practitioner/APC Peer Review Policy

Sets forth the “peer” case review process for Practitioners and APCs granted clinical privileges.



Advanced Practice Clinician (APC) Policy

Sets forth details with respect to credentialing and privileging of APCs.



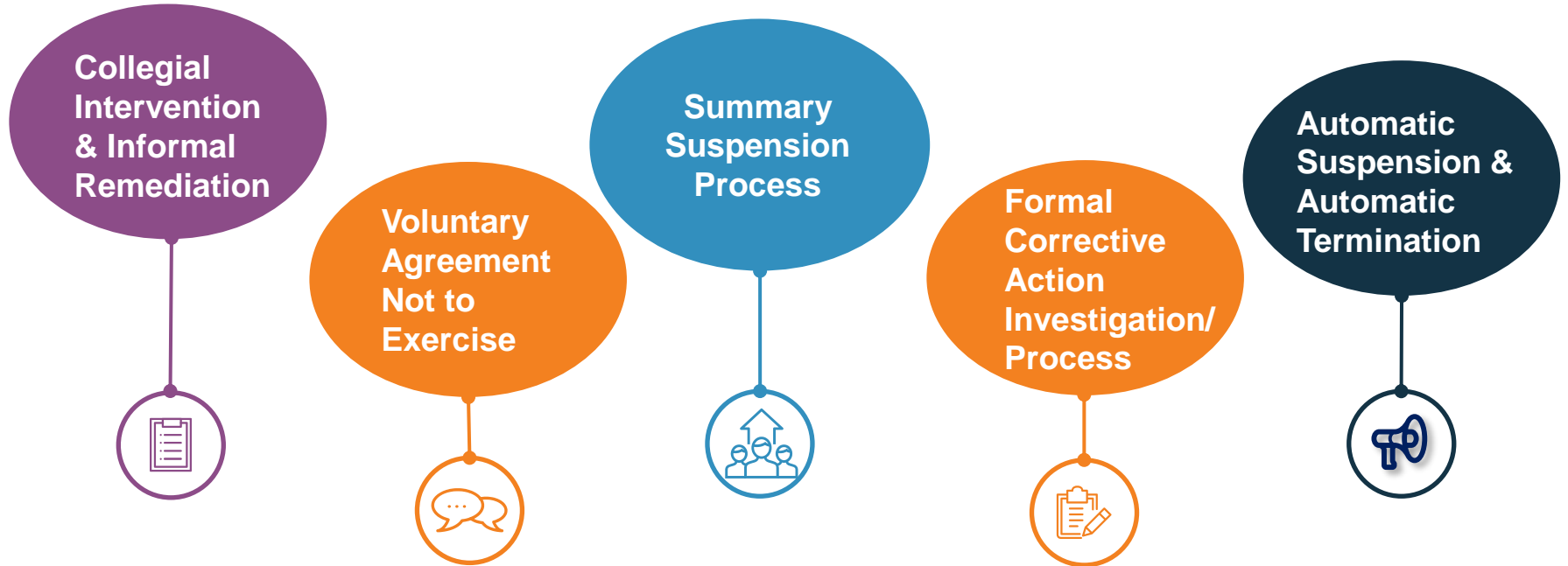
Other: Non-Privileged Allied Health Professional Policy (if needed); Initial FPPE/OPPE Policy (aligned with Peer Review Policy); Rules & Regulations (clinical in nature).

Peer Review Processes



- Best practice is for the PRC/MPRC to conduct all “routine peer review”
 - OPPE
 - Initial FPPE
 - Focused FPPE for purposes of informal remediation
 - Informal remediation
- Best practice is for the MEC to conduct all “investigations”
 - Formal corrective action process to determine whether to take or to initiate an adverse action

Tools of the Trade



Informal Remediation

General guideline: Seek to resolve the matter in a way that protects patients but is only as restrictive as necessary with respect to the practitioner.

- Considerations:
 - Patient safety
 - Work environment
 - Reporting obligations (State and Federal)
 - Medical Staff Governing Documents and Policies
- Informal remediation:
 - Resolve matters informally when possible
 - Document, document, document informal resolutions
 - Often undertaken prior to initiation of formal investigation



Corrective Action vs. Informal Remediation



Formal Corrective Action

- Mandatory in nature (the “stick”)
- Medical Executive Committee or Board level
- Focus on identifying necessary remedy (which may include action against privileges or appointment)
- Governed by Medical Staff governing documents



Informal Remediation

- Voluntary in nature (the “carrot”)
- Peer Review Committee or Practitioner Wellness Committee level
- Focus on identifying cooperative remedy
- Often governed by peer review policy

National Practitioner Data Bank (NPDB) History

The Health Care Quality Improvement Act (HCQIA) of 1986

HCQIA extends immunity from damages to individuals and entities who participate in the peer review process, in return for reporting “incompetent” physicians to the NPDB



NPDB Guidebook first issued in 2001; second edition in 2015; third edition in 2018

Contains HRSA’s interpretation of reporting obligations; does not have the force and effect of law

Very aggressive with respect to what constitutes an “investigation” and what constitutes a “reportable” event

Immunity from Damages Will Be Granted If a ‘Professional Review Action’ Is Found to Be Reasonable

If “reasonable,” then the immunity provision applies to:

- the professional review body,
- any person acting as a member or staff to the professional review body,
- any person under contract or other formal agreement with the professional review body, **and**
- any person who participates with or assists the professional review body
- Immunity provision applies to ALL claims except
 - Civil rights claims
 - Federal or state initiated antitrust action



The Quid Pro Quo

NPDB REPORTING

—— A Healthcare Entity Must Report ——

A professional review action that **adversely affects** the clinical privileges of a physician for a period of **more than 30 days, including:**

- Reduction, restriction, suspension or revocation of privileges
- Denial of privilege based on professional review (excluding denials based on failure to meet specific threshold criteria or an initial application withdrawal before a final professional revision decision)
- A practitioner's surrender of, or failure to renew, privileges while under or to avoid investigations
- Summary suspensions that are the result of a professional review (in effective for more than 30 days), regardless of whether the action is final

Standards for HCQIA Immunity

To be considered good faith peer review (to qualify for HCQIA protection), peer review should be carried out:

1. With a reasonable belief that the action was in furtherance of quality care
2. After a reasonable effort to obtain the facts of the matter
3. After adequate notice and hearing procedures or such other procedures as are fair to the practitioner under the circumstances
4. In the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirements of paragraph (3).

What Is Corrective Action, and Who Initiates It?

Generally, corrective action is the process whereby the Medical Staff examines a physician's professional competence or conduct under the procedure set out by the Medical Staff Bylaws, where there is a potential for action against the physician's clinical privileges or Medical Staff appointment.

Authority for initiating/requesting CA is defined by the bylaws, typically to include:

- Any Appointee,
- Any Medical Staff committee,
- The President,
- The chair of the Board of Directors, or
- The Board of Directors

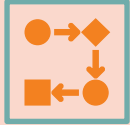
General Standard for Formal CA

Action is appropriate when a practitioner's clinical competence or professional behavior is:

- In violation of the standards or aims of the Medical Staff,
- Disruptive to the operations of the hospital, or
- Presents the threat of harm to a patient in the hospital

Employment is a relationship defined by contract. Employment related issues are not handled by the Medical Staff.

Who Handles the CA Investigation



Generally – CA starts with a request to the MEC and ends with the Board’s approval/adoption of recommendations



Typically, the investigation of whether to recommend/take CA will be handled by the MEC; the Board *may* handle an investigation if the MEC fails to act



If permitted by the Bylaws - The MEC may appoint an investigating committee to investigate the concerns identified by the request for CA, and to make a recommendation to the MEC on CA

Procedural Due Process

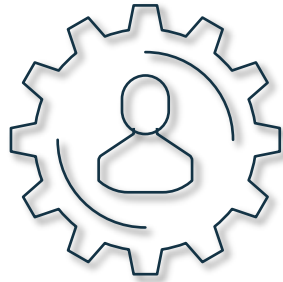
- Procedural due process is the key to all peer review activities
- The processes defined in the Bylaws should provide for procedural due process
- Considerations:
 - Was an ad hoc committee established?
 - Were the members advised of their responsibilities?
 - Did legal counsel provide assistance?
 - Who were the witnesses?
 - What information was reviewed?
 - How was the physician a part of the process?
 - Were participants cautioned about the importance of maintaining confidentiality?

External Reviews



- Why use an external reviewer?
 - Lack of internal expertise
 - Internal conflicts of interest, competition
 - Lack of consensus among internal reviewers
 - Other circumstances that could compromise review
- Where indicated, external reviews support a fair process (i.e., procedural due process)
- Notice provisions: Bylaws may require that physicians be notified when their cases are going to external review, and require that the physician be allowed to see the results

Options for Corrective Action

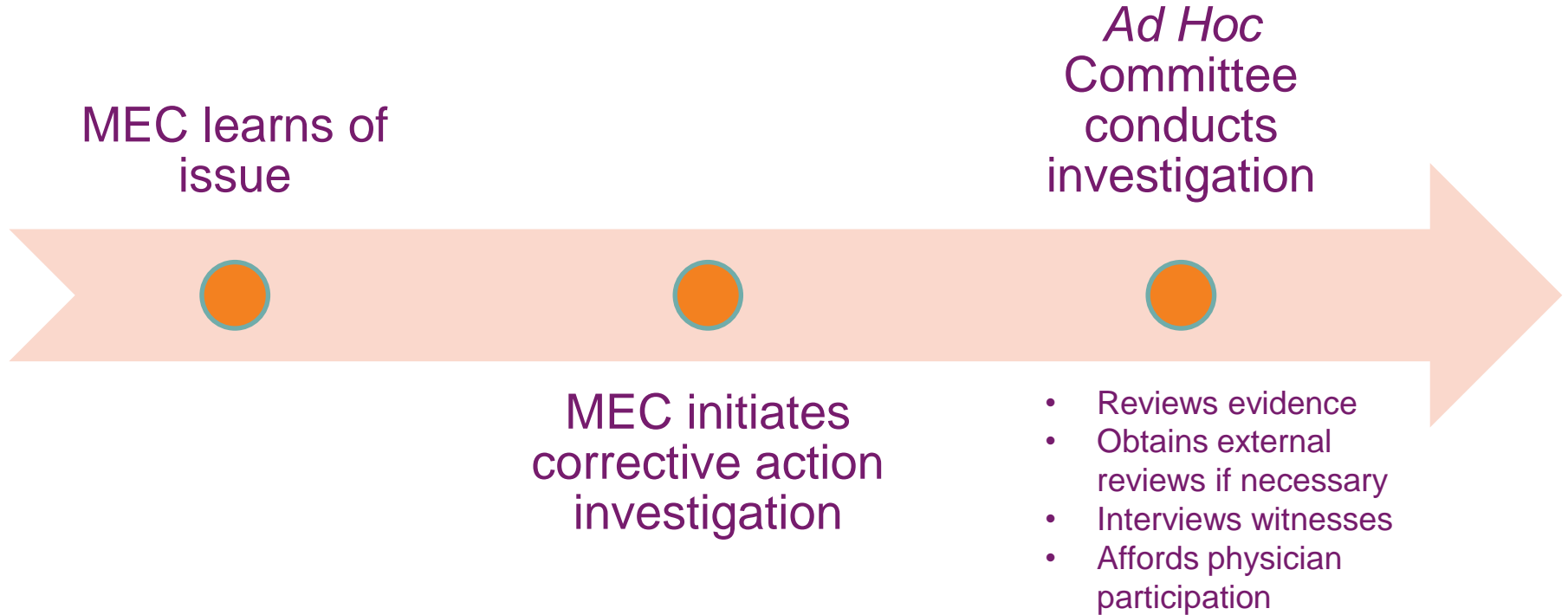


- Limitation, suspension, or revocation of privileges
- Summary suspension of privileges
- Reduction in staff category or revocation of appointment
- Requirements around proctoring/training/monitoring
- Warnings
- Closure without action
- Other options

Adverse Recommendations

- If the MEC recommends an action that is considered “adverse” as defined in the Bylaws, the physician can request a hearing.
- “Adverse actions” will generally include recommendations that limit privileges or appointment for specified time periods (aligned with HCQIA).
- Bylaws will include timing and documentation requirements around notices and requests.

Corrective Action – Timeline Recap



Corrective Action – Timeline Recap (continued)

Ad Hoc Committee
makes a
recommendation
and issues report

MEC notifies
physician of
recommendation

MEC adopts or
rejects the
recommendation

Fair Hearing Process Elements (Generally)

- Triggering event (e.g., an adverse action)
- Notice of adverse action to physician
 - Time limit to request a hearing
 - Manner to request a hearing
- Selection of hearing committee/officer
- Hearing procedures
 - Prehearing matters
 - Evidence standards
 - Opportunity to obtain legal representation
 - Right to cross-examine
 - Creation of the hearing record



Fair Hearing Process Elements (continued)

- Hearing committee/officer deliberation and decision
- Review of decision by the MEC (or other authority)
- Appellate review opportunity (if adverse)
- Procedures for appellate review
- Review of decision/appellate decision by Board







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