NAMSS Program

An Advanced Look at the new NPDB Guidebook

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Michael R. Callahan
Katten Muchin Rosenman LLP
Chicago, Illinois
+1.312.902.5634
michael.callahan@kattenlaw.com

Carol S. Cairns
President and Advisory Consultant
PRO-CON/ The Greely Company
+1.815.230.3543
carolcairns@sbcglobal.net

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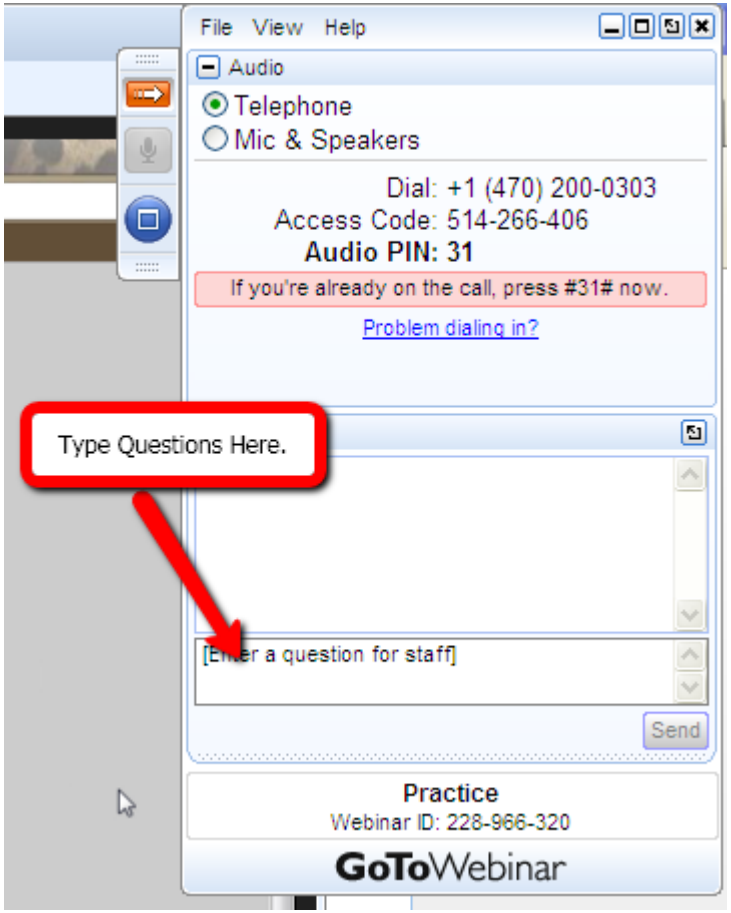
Overview of the Webinar Tool



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Michael R. Callahan

Michael R. Callahan assists hospital, health system and medical staff clients on a variety of health care legal issues related to accountable care organizations (ACOs), patient safety organizations (PSOs), health care antitrust issues, Health Insurance Portability and Accountability Act (HIPAA) and regulatory compliance, accreditation matters, general corporate transactions, medical staff credentialing and hospital/medical staff relations.

Michael's peers regard him as "one of the top guys […] for credentialing—he's got a wealth of experience" (*Chambers USA*). Additionally, his clients describe him as "always responsive and timely with assistance," and say he is "informed, professional and extremely helpful" and "would recommend him without reservation" (*Chambers USA*). Michael's clients also commend his versatility, and say "He is willing to put on the hat of an executive or entrepreneur while still giving legal advice," according to *Chambers USA.*

He is a frequent speaker on topics including ACOs, health care reform, PSOs, health care liability and peer review matters. He has presented around the country before organizations such as the American Health Lawyers Association, the American Medical Association, the American Hospital Association, the American Bar Association, the American College of Healthcare Executives, the National Association Medical Staff Services, the National Association for Healthcare Quality and the American Society for Healthcare Risk Management.

Michael was recently appointed as chair of the Medical Staff Credentialing and Peer Review Practice Group of the American Health Lawyers Association. He also was appointed as the public member representative on the board of directors of the National Association Medical Staff Services.

He was an adjunct professor in DePaul University's Master of Laws in Health Law Program, where he taught a course on managed care. After law school, he served as a law clerk to Justice Daniel P. Ward of the Illinois Supreme Court.

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Carol Cairns

Carol Cairns has been in the unique position of seeing and participating in the development of the medical staff services profession for more than 40 years. In 1996, she founded Plainfield, IL-based PRO-CON, a consulting firm specializing in credentialing, privileging, medical staff organization operations, and survey preparation.

Carol has counseled a variety of health care organizations on medical staff structure, bylaws content and revision, credentialing practices and procedures, privileging systems, medical staff law, allied health credentialing, medical staff leadership development, TJC survey preparation, medical staff office operations, role and creation of a CVO, etc. A recognized expert in the field, Carol is a frequent presenter at health care entities as well as state and national seminars.

In 1991, Carol became clinical faculty for The Joint Commission by collaborating in the development of an educational program on credentialing and privileging medical staff and allied health professionals. She served as faculty for this program from 1991 through 2000. During that time, she co-authored two books published by The Joint Commission that focused upon the medical staff credentialing and privileging standards.

Carol, a faculty member for the National Association Medical Staff Services (NAMSS) since 1990, has presented at numerous state and national conferences. Program subjects include basic and advanced credentialing and privileging, TJC standards and survey preparation, NCQA standards, AHPs, core privileging, and meeting management and documentation. She co-authored the initial NAMSS educational program for certification of provider credentialing specialists (CPCS) and the Credentials 101 seminar and is faculty for both programs.

In 1998, Carol also began consulting and presenting with The Greeley Company. As senior consultant, she serves as an information resource for HCPro, a division of BLR. She has written all 6 editions of *Verify and Comply: A Quick Reference Guide to Credentialing Standards,* an industry-favorite resource. She co-authored the third and fifth editions of *Core Privileges: A Practical Approach to Development and Implementation.* She has authored multiple books on credentialing AHPs among them *A Guide to AHP Credentialing*, *Core Privileges for AHPs*, and *Solving the AHP Conundrum: How to comply with HR standards related to nonprivileged practitioners.* Carol also coauthored *The FPPE Toolbox: Field-Tested Documents for Credentialing, Competency, and Compliance* and her latest effort *The Medical Staff's Guide to Overcoming Competence Assessment Challenges.*

From 1996-2006, Carol served the National Committee on Quality Assurance (NCQA) as a surveyor in the certification program for credentials verification organizations. During that time, she also presented programs as an NCQA faculty member on CVO Certification and the NCQA credentialing standards.

For the past eighteen years, Carol has been an advisor to health care attorneys including providing expert witness testimony regarding credentialing and privileging issues. In 2005 and 2012, Carol was invited by the American Osteopathic Association to provide input into the development of the medical staff and allied health professional standards for the *Healthcare Facilities Accreditation Program Manual.*

In 2005, the Illinois Association Medical Staff Services presented Carol with a Distinguished Member award. In the fall of 2013, The Greeley Company recognized her life-long professional contributions by establishing the Aspire Higher scholarship. The scholarship is managed by NAMSS and presented annually.

Carol Cairns' career in medical staff services began in Joliet, Illinois where she coordinated and directed medical staff services for two health care organizations (Presence Saint Joseph Medical Center and Silver Cross Hospital). Among her areas of responsibilities were credentialing, privileging, meeting management, quality improvement activities, medical staff orientation, CME programming, as well as serving as a liaison between medical staff and hospital administration and directors. In 2010, Carol "returned to the beginning" by accepting an appointment to the Board of Directors Bylaws and Credentialing Committee of Presence Saint Joseph Medical Center.

Areas to be Covered

- Investigation versus routine peer review
- Resignations while under an investigation
- Does the NPDB require that a practitioner needs to be informed that they are under an investigation?
- Is a leave of absence a reportable resignation?
- What is a professional review activity?
- What is a professional review action?
- When is the imposition of a proctoring requirement reportable?
- Do hospitals in a multi-hospital system need to make separate queries?
- Must a voided Data Bank report be destroyed?
- Is the payment of a medical malpractice claim raised in a patient's complaint letter reportable to the NPDB?
- Are all malpractice settlements reportable?

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Investigation Versus Routine Peer Review

Guidelines for Investigation

- Investigation must be focused on the practitioner in question and not the department or section as a whole – an example would be a routine OPPE review.
- It must concern the professional competence and/or professional conduct of the practitioner in question which has or may have an adverse impact on patients and is beyond routine peer review.
- The investigation generally should be a precursor to a professional review action.
- The NPDB will look at and defer to the hospital's Medical Staff Bylaws, Peer Review process and related Policies as to when an investigation is triggered.

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Investigation Versus Routine Peer Review (cont'd)

- If an FPPE plan, for example, is imposed as part of a normal, routine peer review process, then it probably would not be considered an investigation.
- If correspondence to the physician regarding the action imposed indicates that disciplinary action could follow if problems persist or the FPPE plan is not successful, this could be viewed as precursor to a professional review action.
- Another question which the NPDB may ask is whether the FPPE plan, proctoring or other similar action was extended based on a competency concern or based on insufficient data over a prescribed period of time.
- The NPDB found reasonable the position that an investigation does not commence until such time as an adverse recommendation is made to the MEC.
- Investigations begin with an inquiry but do not end until there is a final action or the investigation is closed – this is what the NPDB meant by its "expansive" view of investigations.

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Investigation Versus Routine Peer Review (cont'd)

Recommendations

- Bylaws and policies should broadly define routine peer review activities to include, but not be limited to, the following:
  - OPPE reviews
  - Routine case reviews based on quality and risk triggers and metrics
  - Retrospective and concurrent case reviews
  - Monitoring and proctoring (to be discussed in more detail)
  - FPPE plans

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Investigation Versus Routine Peer Review (cont'd)

- The term "investigation" should only be referenced in the bylaws in the context of a request for remedial/disciplinary action to the MEC when all other previously mentioned or identified remedial measures have failed.
- Communications with the practitioner regarding the imposition of a remedial measure should not include the reference to the possibility that disciplinary action will be taken if remedial efforts fail. To do so could give the impression that it is a "precursor" to a professional review action.

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Investigation Versus Routine Peer Review (cont'd)

Action Items

1. Educate medical staff leaders (MSL), senior management, governing body, and physician contracting staff regarding the revised NPDB Guidelines.
2. MSLs and management (MSP) review current documents for compliance to revised NPDB Guidelines with healthcare attorney input.
3. Revise governance documents as appropriate.
4. Implement resultant processes as needed.
5.
6.

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Resignations While Under an Investigation

- As a general rule, a resignation by a physician in lieu of conducting an investigation or during an investigation is reportable, even if the investigation later reveals no fault with the practitioner's professional competence or conduct.
- The imposition of an investigation in and of itself is not reportable.
- Reports are not required for investigations if no action was taken against the physician's clinical privileges.

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Resignations While Under an Investigation
(cont'd)

Recommendations

- Practitioner should always be informed as soon as an investigation is triggered under the Medical Staff Bylaws or Policies so that they can make an informed decision and understand the reporting implications of any decision to resign. Communication should further advise the practitioner that a resignation while under investigation is reportable.
- Practitioner should also be advised that the investigation shall continue until the investigation is closed or a final action taken by the Board of Directors.
- Out of fairness to the physician, if the hospital later determines after a report has been made that the investigation revealed no fault with respect to the practitioner's professional competence or conduct, the hospital should submit a revision to action report to the NPDB to identify this information for future queriers.

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Resignations While Under an Investigation
(cont'd)

- We strongly recommend the use of "collegial intervention" as part of a remedial action process so as to avoid the need for further actions in the peer review continuum which could lead to the imposition of an investigation.

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Resignations While Under an Investigation
(cont'd)

Action Items

1. Educate medical staff leaders (MSL), senior management, governing body, physician contracting & performance improvement staff regarding the revised NPDB Guidelines.
2. Review current or revised governance documents to assure compliance.
3. Assure MSSD, QI, and contracting departments have written procedures for implementation as needed with healthcare attorney input.
4.
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Does the NPDB require that a practitioner needs to be informed that they are under an investigation?

- Practitioners must be informed about an investigation before an action is taken by a licensing board based on current regulations governing the NPDB.
- Under the Guidebook, practitioners do not have to be informed by an investigation before action is taken by a hospital that could result in an adverse privileging action.
  - NPDB explanation for not requiring that a physician be informed of an investigation is based on the fact that notice is not statutorily required and its belief that most hospitals provide that this information be provided under their Medical Staff Bylaws and Policies.
- If a physician resigns while under investigation, irrespective of whether he or she knows about the investigation, the resignation is reportable.
- The NPDB takes the position that it is the final arbiter of whether an investigation was or was not triggered, although again it will defer to the hospital's Medical Staff Bylaws, Peer Review Policies and other related procedures.

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Does the NPDB require that a practitioner needs to be informed that they are under an investigation? (cont'd)

Recommendations

- See recommendations on slides 8-9.

Action Items

- See action items on slide 10.

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Is a leave of absence a reportable resignation?

- The NPDB at question 21 in the Guidebook (E-46) seemed to assume that a leave of absence ("LOA") should or could be considered a resignation.
- Some hospitals allow physicians to take a leave of absence in lieu of an investigation or even during an investigation. Some LOAs actually lead to a subsequent resignation.
- Under these circumstances, the NPDB would consider both situations as a reportable resignation.

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Is a leave of absence a reportable resignation?
(cont'd)

- If the LOA, on the other hand, was related to personal or professional reasons and physician's clinical privileges remain unaffected, then the LOA would not be reportable if the physician is not otherwise under an investigation or the threat of an investigation.
- The NPDB may look to whether the physician voluntarily requested an LOA as opposed to the hospital requesting the LOA based on the physician's competency or conduct which has or may adversely affect patient care.

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Is a leave of absence a reportable resignation?
(cont'd)

Recommendations

- When a physician generally requests an LOA which is not in lieu of corrective action or as a means of avoiding an investigation, it is never necessary to restrict clinical privileges because these cannot be exercised anyway while the physician is on the LOA.
- The reasons for requesting and granting an LOA should be clearly documented so as to clarify that it is not being granted in lieu of or during an investigation.
- Keep in mind that if an LOA is being requested so that the physician can participate in a drug/alcohol or similar rehab plan, this is not a reportable event as long as the physician is able to return with full privileges.
- If privileges, however, are reduced upon return, this action would be reportable if the reduction is affirmed after a final decision is rendered.

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Is a leave of absence a reportable resignation?
(cont'd)

Action Items

1. Educate medical staff leaders (MSL), senior management, governing body, physician contracting and performance improvement staff and the revised NPDB Guidelines re: reporting LOAs.
2. MSLs and management (MSP) review current documents related to LOAs for compliance to revised NPDB Guidelines with healthcare attorney input.
3. Revise governance documents as appropriate. Consider creating a LOA policy and procedure.
4. Implement resultant processes as needed.
5.
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What is a professional review activity?

- An activity of a health care entity with respect to an individual health care practitioner:
  - To determine whether the health care practitioner may have clinical privileges with respect to, or membership in, the health care entity;
  - To determine the scope or conditions of such privileges or membership; or
  - To change and modify such privileges or membership.

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What is a professional review action? (cont'd)

- An action or recommendation of a health care entity:
  - Taken in the course of a professional review activity;
  - Based on professional competence or professional conduct which affects or could adversely affect the health or welfare of patients;
  - Which adversely affects or may adversely affect the clinical privileges or membership in a professional society of the health care practitioner.

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What is a professional review action? (cont'd)

- A professional review action excludes actions based on any matter that does not relate to competence or professional conduct, including but not limited to:
  - Association with a professional society or association
  - Fees or advertising, or engaging in other competitive acts;
  - Participation in any manner of delivery health services, whether on a fee-for-service or other basis;
  - Association with a member or members or a particular class of health care practitioner or professional.
  - Failure to maintain adequate insurance.
  - Loss or failure to obtain or maintain board certification
  - Failure to meet other eligibility criteria.

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What is a professional review action? (cont'd)

Recommendations

- The NPDB has stated that it will defer to the hospital's decision as to whether action taken is a professional review action based on a professional review activity.
- Therefore, Bylaws and Policies and communications should clearly identify what actions are and are not a professional review action.
- Our recommendation is that professional review actions should be limited to those actions which trigger hearing rights under the Medical Staff Bylaws and/or Fair Hearing Plan.
- When an employed physician or physician under contract as part of an exclusive group with the hospital is terminated and no hearing or other professional review action has taken place, the loss of clinical privileges and membership resulting from termination is not reportable to the Data Bank.

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What is a professional review action? (cont'd)

- The NPDB, however, expressed some concern as to whether physicians being terminated based on competency or professional conduct are not being reported simply because there was no hearing or other professional review action or process provided.

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Professional Review Activity or Action Versus Routine Peer Review (cont'd)

Action Items

1. Educate medical staff leaders (MSL), senior management, and governing body regarding the definitions and differences between investigation and routine peer review
2. MSLs, senior management, and governing body determine an overall philosophy regarding reporting to NPDB
3. Philosophy is embedded in medical staff governance documents and P & Ps with healthcare attorney input as needed
4.
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When is the imposition of a proctoring requirement reportable?

- A question the NPDB will ask is whether the imposition of a proctoring requirement is the result of a professional review activity or is part of normal peer review. If included within the hospital's routine peer review procedures, it should not be a reportable event.
- The NPDB, however, considers the presence of a proctor as a restriction of privileges even if the proctor has no authority to intervene or otherwise terminate a procedure.
- If the proctor is physically present for more than 30 days and the physician cannot exercise all or certain clinical privileges unless the proctor is present, the NPDB takes the position that it is a reportable event.

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When is the imposition of a proctoring requirement reportable? (cont'd)

- If proctoring is not considered part of a professional review action under the hospital's medical staff bylaws and policies, then arguably proctoring which lasts more than 30 days is not reportable.
- Additional questions that could be asked include:
  - Can the physician admit with or without a proctor during the prescribed period of time?
  - Is proctoring a precursor to a professional review action?
  - Can the physician go forward and operate past the 30 days without a proctor?

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When is the imposition of a proctoring requirement reportable? (cont'd)

- Is there another step in the peer review process after proctoring, such as an FPPE plan, which is also part of normal peer review?
- How many levels of review has the physician been under by the time a proctoring requirement is imposed?

Recommendations

- As is true throughout the industry, proctoring should be characterized as part of the hospital's normal peer review process and not viewed as the last stage prior to a professional review action or as part of an investigation.
- Privileges should not be restricted during this time frame, such as a mandatory consultation requiring prior approval.

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When is the imposition of a proctoring requirement reportable? (cont'd)

- If proctoring is a precursor to a professional review action, consider a time frame of less than 30 days and/or not requiring that the proctor be present during all cases.
- If proctoring exceeds 30 days only because the physician has not met a defined number of cases that needed to be reviewed, as opposed to the need to extend based on identified competency concerns, you should document the reasons for the extension.

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When is the imposition of a proctoring requirement reportable? (cont'd)

Action Items

1. Identify & evaluate current medical staff documents that include reference to proctoring. Determine if revision is indicated based upon current practice re: proctoring and the revised NPDB regulations. Seek healthcare attorney input prn.
2. Implement resultant processes as needed.
3.
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Do hospitals in a multi-hospital system need to make separate queries?

- Under the Guidebook, if hospitals maintain separate medical staff credentialing procedures and have separate DBIDs, then they must query separately and cannot share Data Bank reports.
- On the other hand, if the peer review process is centralized and the institutions have a single decision making body, such as with a single unified medical staff under the Medicare Conditions of Participation, then query results can be shared because there is a single DBID.
- The NPDB's rationale for this standard is its goal of making sure to maintain the integrity of the information and that the information being shared is the most up to date information in its possession.

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Do hospitals in a multi-hospital system need to make separate queries? (cont'd)

- If shared, there is no way for the NPDB to know if all of the facilities received accurate information, especially if there has been corrections, updates, revision to action and void reports, etc.
- NPDB is open to receiving comments as to whether there are circumstances where sharing in a multi-hospital system with separate credentialing processes may be appropriate.
  - For example, if all of the hospitals are on the same reappointment process such that the information obtained through a query is up to date, then this might be a circumstance where the NPDB would allow sharing.

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Do hospitals in a multi-hospital system need to make separate queries? (cont'd)

Action Items

1. MSP in multi-hospital systems should evaluate current NPDB regulations. If cost savings can be achieved while protecting NPDB information, the MSP should discuss pursuing a single DBID with senior management and MSLs.
2. Provide comment to NPDB as invited and as applicable.
3.
4.
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Must a voided Data Bank report be destroyed?

- Where the reportable action taken by a health care entity and reported to the NPDB was overturned on appeal, was submitted in error, or was not reportable because it did not meet NPDB reporting requirements, the hospital is required to submit a void report.
- A copy of the void report is sent to the subject of the report as well as all queriers who received the previous version of the report within the past 3 years.
- The NPDB also directs the reporting facility “to destroy the prior report and any copies of it.”

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Must a voided Data Bank report be destroyed? (cont'd)

- Although the NPDB acknowledges that destruction of the initial report is not required under the statute, it expressed concern that it would be unfair to the practitioner to allow such reports to remain in files when the reportable action, i.e., a summary suspension, was reversed for whatever reasons.
- The NPDB is not aware of any circumstances in which a hospital has been subject to any liability based on its reliance on the initial report or its direction that such reports be destroyed but is open to any industry comments to the contrary.

Recommendations

- Keep voided report in file but note that hospital's decision on which the initial report was based was overturned.

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Must a voided Data Bank report be destroyed? (cont'd)

Action Items

1. Determine if the Medical Staff and/or MSSD has a policy on document retention (& document access) for practitioner credentials files.
    a. If so, including a procedure related to managing voided Data Bank reports.
    b. If not, create a policy on document retention including managing Data Bank reports.

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Is the payment of a medical malpractice claim raised in a patient's complaint letter reportable to the NPDB?

- Reportable medical malpractice claims must be in writing and demand monetary payment for damages. Payment need not be limited to an actual lawsuit being filed but can include pre-litigation written communications including a patient complaint letter.
- The NPDB determines whether a written claim has occurred but the claim must identify the practitioner in question and any payment must be made on behalf of the practitioner.
- The NPDB expects that the reporting entity will make the determination as to whether the reporting standards have been met.
- Questions have been raised as to whether an unsigned email communication from the patient, as an example, is a form of written claim.

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Are all malpractice settlements reportable?

- Settlements in which no findings or admissions of liability have been made are not reportable.
- Actions that occur in conjunction with settlements in which no findings or admissions of liability have been made but that meet other NPDB reporting requirements, must be reported.
- The NPDB has found no evidence that such reporting obligations have a chilling effect on negotiations with physicians but is open to industry comments.

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Other Questions Addressed During NAMSS Data Bank Webinar

- Is an agreement not to exercise privileges without actually relinquishing privileges considered a resignation while under investigation?
  - Yes, because the inability to exercise privileges is considered a surrender of privileges.
  - But what if the agreement is less than 30 days?

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Other Relevant and Important Questions (cont'd)

- Is the requirement that a surgeon can only operate with a surgical assistant considered a reportable restriction?
  - Questions that would be considered are the following:
    - Is this requirement the result of a professional review activity or is it part of hospital's routine process or procedure – i.e., applies to all new surgeons?
    - Is it the requirement a result of concerns about a physician's professional competency or competence?
    - Is the surgeon prohibited from operating unless the assistant is there?
    - Does the assistant have to be there for more than 30 days?
    - Is decision to extent beyond 30 days initially or later based on competency, or because surgeon has not performed the required number of cases?

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Other Relevant and Important Questions (cont'd)

- Is a resignation as a result of a quality assurance or improvement plan considered a resignation while under investigation?
  - If the plan results in the establishment of new qualification standards which the physician does not meet, a resignation would not be reportable.
  - If the plan is the result of a focused review of the physician that would qualify as an investigation and/or a professional review action, based on the physician's competency or conduct it is probably reportable.
- What if a physician's privileges lapse while under an investigation because his two year reappointment has expired before the physician can exercise his hearing rights? Is this reportable?
  - The Data Bank would consider this reportable.

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Other Relevant and Important Questions (cont'd)

- However, under most Bylaws or as a best practice, privileges remain in effect because the physician has not had hearing rights and no final decision has been reached. Therefore, no lapse has occurred.

- Is the review of outstanding or pending medical malpractice cases by an applicant during the application process an investigation?
  - If part of normal peer review for all applicants, probably not.
  - If the review goes further, it could be viewed as an investigation such that a resignation could be reportable.
    - But what about NPDB position that a voluntary resignation prior to a final decision is not reportable?

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Other Relevant and Important Questions (cont'd)

- Must the hospital query for physicians on the medical staff such as Honorary or Emeritus, even though they do not have clinical privileges?
  - Yes, because of statutory requirements.

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