

Katten

MAMSS 2022 VIRTUAL CONFERENCE

May 5, 2022

To Report to the Data Bank or Not

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Background

- Data Bank concerned about history of underreporting.
- Draft Guidebook issued in 2014 took the position that an FPPE Plan qualified as an “investigation” for reporting purposes.
- NAMSS, AHLA, the AHA and other associations and groups pushed back arguing that FPPE and similar remedial measures are effective tools in advancing “Just Culture” principles and assisting physicians in their efforts to improve patient care and reduce risk.

Background

- Treating an FPPE as an investigation will likely reduce reliance on this method as a remedial measure.
- Data Bank relented and indicated that it would look to a Hospital's Medical Staff Bylaws and policies to determine whether a physician was under investigation in the event of a dispute. Data Bank also stated, however, that these documents would be nonbinding in this determination as to whether an investigation was initiated.

What is Reportable?

- Professional review actions which result in an involuntary reduction, restriction, suspension, termination or denial of clinical privileges for greater than 30 days if based on professional competence or professional conduct.
- Acceptance of a surrender or restriction of clinical privileges while under investigation for possible professional incompetence or unprofessional conduct or in return for not conducting an investigation or taking a professional review action that otherwise would be reportable.

What is Reportable?

- Additional examples:
 - Mandatory consultations requiring prior approval before a practitioner can exercise clinical privileges for more than 30 days.
 - Mandatory proctoring requiring the physical presence of the proctor in order for the practitioner to exercise clinical privileges for more than 30 days.
- The decision is not reportable unless there is a final decision except for summary suspensions and other decisions which restrict privileges for more than 30 days.

What Is Not Reportable?

- Actions taken which do not involve professional competence or professional conduct.
- Administrative action/automatic suspensions for:
 - Failure to pay dues
 - Malpractice insurance reductions
 - Failure to obtain or maintain board certification
 - Failure to complete medical records
 - Failure to get vaccinated

What Is Not Reportable?

- Denial based on failure to satisfy eligibility criteria.
- Giving up privileges voluntarily.
- Resignation during routine peer review where there is no threat of an investigation or a professional review action.

Updated Data Bank Position on “Investigations”

- The Data Bank interprets the word “investigation” expansively.
- Not controlled by how the term is defined in Bylaws, policies or procedures.
- The investigation must be focused on the practitioner in question.
- Must concern the professional competence and/or professional conduct of the practitioner in question.
- The activity should be the precursor to a professional review action.

Updated Data Bank Position on “Investigations”

- The investigation is ongoing until the entity’s decision making authority makes a final decision or 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.
- There is no requirement that the practitioner be notified that they are under investigation.
- If conducting an investigation but privileges remain intact, there is nothing to report.

Updated Data Bank Position on “Investigations”

- Entity should be able to produce evidence (*e.g.*, minutes or excerpts from committee minutes or orders from hospital officials directing an investigation) that the investigation began before the practitioner took action.
- A practitioner’s decision to voluntarily relinquish privileges greater than 30 days in order to avoid an investigation or during an investigation is reportable. (Chapter E: Reports-Reporting Adverse Clinical Privileges Actions)

What Impact and What Problems?

- Confusion
- Over-reporting
- Failure to notify practitioner when under investigation
- Investigations after practitioner left without any notice that an investigation has been triggered
- Reports before consulting with legal counsel
- What is routine peer review versus what qualifies as an investigation

What Impact and What Problems?

- Hospital's failure to follow bylaws and policies before conducting an "investigation"
- Reporting before an investigation has been completed or an investigation has been triggered
- Medical staff education as to the proper procedures and promotion of collegial intervention and other routine peer review and related remedial measures in lieu of triggering an investigation

Data Bank Reports

- **Doe v. Rogers, Civil Action Criminal 12-01229 (TFH), 2020 U.S. Dist. Lexus 184719 (D.D.C. September 10, 2020)**

— Background

- Plaintiff physician is a surgeon who performed an emergency laparoscopic appendectomy on a 14 year old girl to remove an “inflamed band” which turned out to be the patient’s right fallopian tube.
- The hospital immediately filed a report on the incident to the New York Patient Incurrence Reporting and Tracking System.
- The report stated that, “the physician has been placed on suspension pending completion of the investigation and the family notified”.
- The physician subsequently executed a letter voluntarily suspending his surgical privileges for a period of two weeks. Shortly thereafter he submitted his resignation from the medical staff.

Data Bank Reports

- Two months later, the hospital submitted an adverse action report to the National Practitioner Data Bank.
- Although the hospital did not take further action regarding the physician's privileges or employment, it did include information that as a result of the investigation, the hospital concluded that the physician departed from the standard of care regarding the laparoscopic appendectomy in question.
- The physician subsequently sued the Secretary of HHS and the National Practitioner Data Bank arguing that the report was factually inaccurate and was not submitted in accordance with reporting requirements.

Data Bank Reports

— Court's Decision

- After reviewing the legal history leading up to the adoption, the Court noted that Data Bank reports can be as simple as a one sentence description. However, the report does “require ... action or surrender.”
- Furthermore, the Court stated that the language is broad enough to include the results of an investigation in order to enable “queriers to more fully understand the circumstances of the incident, and protect patients by providing entities with enough information to make informed hiring decisions.”
- The fact that the investigation had not been concluded by the time the physician resigned is irrelevant to the requirement that a hospital report a physician who resigns while under investigation.
- Even if the investigation resulted in a determination that the physician did not breach standard of care and no disciplinary action was going to be recommended, the resignation is still reportable.

Data Bank Reports

- **Jane Doe v. Community Memorial Hospital**

- **Background**

- This case involves a 16 year old patient who suffered a gun shot wound to his head, which resulted in the family's decision to have a procedure whereby his "organs were scheduled to be harvested for donation".
- The patient was otherwise healthy, but in order to control his pain, was given high doses of fentanyl and other pain relieving medications.
- When the procedure to harvest organs was scheduled, he was under the care of an advanced practice nurse who administered additional medications in order to keep him comfortable during the procedure.
- Because he had developed a high tolerance of the medication doses during his two-week stay at the hospital, the nurse had to give higher doses than usual order to relieve pain and keep him as comfortable as possible.

Data Bank Reports

- Because the patient did not expire within the 90 minute requirement, he was removed from the surgical suite and re-admitted to the hospital where he was subsequently discharged.
- The day in which the procedure occurred happened to be the last day of the nurse's employment. In fact, she had submitted her resignation 3 months previously in order to take a new job.
- Up until that point of time, she was in good standing and was not under any investigation.
- Moreover, as per the terms of her contract and the medical staff bylaws, her membership on the allied professional staff and her clinical privileges automatically expired on the last day of her employment.

Data Bank Reports

- One day after the procedure and after she had resigned, she received a call from the hospital's VPMA asking her if she would be willing to voluntarily participate in an interview to discuss her decisions to administer high doses of pain medication during the procedure. In response to the question of whether she was under investigation or whether she needed an attorney, the VPMA then responded by saying it was an informal interview and that legal counsel was not necessary.
- A few weeks later, the hospital reported her to the state nurse licensing board and to the National Practitioner Data Bank claiming that she resigned while under investigation.
- The Data Bank report was very specific about claims of breach of a standard of care in administering the high doses of pain medication.

Data Bank Reports

- After investigating the circumstances of the procedure, along with the medical records and information from the nurse's expert, the nursing board took no action against her.
- The nurse then challenged the basis of the hospital's report to the Data Bank arguing that she had not resigned while under investigation because no investigation had been triggered prior to her resignation and departure.
- The hospital had contended that she still retained privileges until such time as she was contacted by human resources to ask whether she wished to retain privileges two weeks after her resignation.

Data Bank Reports

—The Data Bank's Decision

- There were a number of communications back and forth between the nurse and the hospital as to whether the hospital had met all of the requirements for reporting to the Data Bank in light of the nurse's contention that she had already resigned, was never informed that she was under investigation, she had no clinical privileges at the time that she resigned, and furthermore, under the bylaws and under her employment contract, she no longer had clinical privileges.
- In addition, the Data Bank was given deposition testimony from the VPMA taken from litigation that was filed against the hospital which she conceded that the nurse really was not under investigation pursuant to the medical staff bylaws, but instead, was part of an interview which the hospital attempted to characterize as an investigation for reporting purposes.

Data Bank Reports

- The Data Bank specifically requested that the hospital provide “a copy of any written communication addressed directly to [Jane Doe] notifying her that a formal investigation into her professional competence or conduct had been initiated.”
- Although the hospital argued and the Data Bank acknowledged that there was no obligation to advise a practitioner that they were under investigation, it cited to the Guidebook, which provided that:
 - “The healthcare entity that submits a clinical privileges action based on surrender, restriction, or failure to renew a physician’s or dentist’s privileges while under investigation should have evidence of an ongoing investigation at the time of surrender, or evidence of a plea bargain.”
 - “Reporting entity should be able to produce evidence that an investigation was initiated prior to the surrender of clinical privileges.”

Data Bank Reports

“Examples of acceptable evidence may include minutes or excerpts from committee meetings, orders from hospital officials directing an investigation, or notices to practitioners of an investigation.”

- In its communication to the hospital, the Data Bank further stated that “such documentation must also include the effective date of the initiation of the investigation, the reason(s) the investigation was opened, and, if applicable, the timeframe by which this investigation was expected to be completed.
- The hospital was given 15 additional calendar days to provide such documentation to support its argument that the nurse was under investigation when she resigned.
- The hospital failed to provide such documentation in a timely manner. Its efforts to provide a response subject to the deadline was rejected by the Data Bank.
- Consequently, the Data Bank ordered the hospital to void the report which it submitted.

Data Bank Reports

- **Lessons Learned**

- Although the Data Bank initially backed off on its position that an FPPE constitutes an “investigation” for reporting purposes, a few years ago it reiterated its view that that term is interpreted broadly.
- This position has created confusion among hospitals and medical staffs in terms of what type of activity does or does not qualify as an investigation.
- The result, in part, is what I believe has been the unintended over-reporting to the Data Bank when physicians decide to resign even if there has been no formal request for disciplinary action.
- One way to address this issue is to in fact define the term “investigation” in the medical staff bylaws so that there is a clear standard and understanding as to when an investigation is triggered.

Data Bank Reports

- It is the recommendation of many attorneys and healthcare consultants that an investigation does not begin until such time as the MEC receives a formal request for disciplinary action and, after reviewing the request and any supporting information, decides to pursue an investigation, typically through an *ad hoc* committee.
- An example Bylaw definition would be as follows:
 - The term “Investigation”, for Data Bank reporting purposes, shall refer to that decision made by the Medical Executive Committee under Article ____, Section ____ of these Bylaws in response to a request for a formal request for (corrective)(disciplinary)(remedial) action under Article ____, Section ____ to initiate an investigation after reviewing the request and any supporting materials. All other remedial measures, including but not limited to collegial intervention, monitoring, re-education, and FPPE plans shall be considered routine Peer Review activities.

Data Bank Reports

place by an *ad hoc* committee. All other remedial measures including but not limited to, collegial intervention, monitoring, re-education and FPPE reviews are considered routine peer review.”

- Other than this defined term, you should avoid using the word “investigation” in any other section of the bylaws, policies or rules and regulations so as not to cause further confusion.
- Requests for disciplinary action which could trigger an investigation should only be submitted after all other efforts to address the quality of care, disruptive behavior or other similar actions have failed.
- The purpose is to create a “just culture” environment whereby physicians believe the hospital and the medical staff is there to assist them when problems arise rather than move towards disciplinary action.

Data Bank Reports

- This will encourage physicians to be more upfront and honest in acknowledging that issues or problems exist so that they can be addressed in a proactive and productive manner.
- It is important to identify what actions are and are not reportable to the Data Bank or to any state or governmental entity and therefore generally limit hearings to those disciplinary actions.
- Make sure you consult with in-house or outside legal counsel before determining whether a Data Bank report is required.

Recommendations

- Define when an “investigation” is triggered.
- An example Bylaw definition would be as follows:
 - The term “Investigation”, for Data Bank reporting purposes, shall refer to that decision made by the Medical Executive Committee under Article ____, Section ____ of these Bylaws in response to a request for a formal request for (corrective)(disciplinary)(remedial) action under Article __, Section ____ to initiate an investigation after reviewing the request and any supporting materials. All other remedial measures, including but not limited to collegial intervention, monitoring, re-education, and FPPE plans shall be considered routine Peer Review activities.
- Define “Peer Review” and utilize routine peer review and other remedial measures, including:
 - Collegial intervention
 - Inviting/requiring physician to respond to case reviews, adverse events, patient complaints, etc.
 - Monitoring

Recommendations

- Concurrent and/or retrospective case reviews
- Peer counseling/shadowing
- Re-education/re-training
- FPPE plans
- Mandatory consultation not requiring prior approval
- Require that routine peer review remedial measures be attempted first before requesting disciplinary action
- Educate leaders as to these measures

Recommendations

- Avoid communications, including decision to take action, if remedial measures fail
- Inform physicians when under investigation and educate about impact if they resign
- Disciplinary action should only be requested if seeking to impose a reportable action
- Eliminate the term “investigation” in policies, except for use in definitions and MEC’s action to trigger an investigation
- Educate medical staff on Just Culture principles
- Should you instead of be following Code of Conduct or Physician Wellness procedures?

Other Recommendations

- If a report is a required attempt to negotiate language in advance with practitioner and their legal counsel in order to limit or avoid litigation.
 - Expect third party inquiries and need to coordinate a unified response.
- Inform physician early on as to the progressive steps leading to possible disciplinary actions in order to encourage cooperation and participation.

Other Recommendations

- Who is the physician's "rabbi or confessor"?
- Consult with legal counsel.
- Reports need to be factual and objective. No need to include all of the gory details.

Questions?

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