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New National Practitioner Data Bank Guidebook Impact on Bylaw Standards

Strafford Webinars - Impact of Recent Regulatory Changes on Medical Staff Bylaws: Proposed Amendments and Best Practices

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NPDB Guidebook Revisions

- NPDB Established by Title IV of Public Law 99-60, the Health Care Quality Improvement Act of 1986- "HCQIA" 42 USC Sec. 11101
- The laws governing the NPDB are codified at 45 CFR Part 60, Title IV of the Health Care Quality Improvement Act of 1986 (HCQIA), Section 5 of the Medicare and Medicaid Patient and Program Protection Act of 1987, and Section 221(a) of the Health Insurance Portability and Accountability Act of 1996.

NPDB Guidebook Revisions

- The *National Practitioner Data Bank Guidebook* “is meant to serve as a resource for the users of the National Practitioner Data Bank (NPDB).”
 - Intent is to assist the health care community and authorized users understand the requirements established by Title IV of Public Law 99-660, the *Health Care Quality Improvement Act of 1986*, as amended.
 - Authorized users include state licensing authorities; medical malpractice payers; hospitals and other health care entities; and physicians, dentists, and other licensed health care practitioners.

NPDB Guidebook Revisions

- 2001 NPDB Guidebook was the first complete revision of the NPDB Guidebook since 1996.
 - Intended to incorporate regulatory changes issued previously
 - 2001 Guidebook edition superseded all previous versions.
- 2015 Revised Guidebook Published
 - Incorporates legislative and regulatory changes since the last draft and reflects the entire range of NPDB policies, including those that have changed or expanded since the NPDB opened in September 1990.

NPDB Guidebook Revisions

- NPDB Reporting Requirements
 - Medical Malpractice Payments
 - State Licensure Actions
 - Adverse Clinical Privilege Actions



NPDB Guidebook Revisions - Timeline

- Release of the Draft Guidebook was announced in November 2013 and the period to submit comments to the Draft was open until January 2014
- AHA, TJC, NAMSS, and NPDB Guidebook Work Group, among others, issued comments on Draft Guidebook January 2014
 - Many identify issues of concern regarding reporting of voluntary surrender and definition of investigation raised in NPDB responses to Examples 16 and 17

NPDB Guidebook Revisions - Adverse Clinical Privilege Actions

- Hospitals and Healthcare Entities Must Report:
 - Professional Review Actions
 - Based on a physician or dentist's professional competence or conduct that adversely affects or could adversely affect the health and welfare of any patient
 - That adversely affects the clinical privileges of a physician or dentist for more than 30 days
 - The acceptance of a physician's or dentist's surrender or restriction of clinical privileges, or the voluntary withdrawal of an application for renewal of a medical staff appointment or clinical privileges
 - While under investigation for possible professional incompetence or improper professional conduct, or
 - In return for not conducting an investigation, or
 - In return for not taking a professional review action

NPDB Guidebook Revisions - Investigation

- 2001 Guidebook Discussion of “Investigation”
 - “Investigations should not be reported to the NPDB; only the surrender or restriction of clinical privileges while under investigation or to avoid investigation is reportable. This would include a failure to renew clinical privileges while under investigation.”
 - A routine or general review of cases is not an investigation.
 - A routine review of a particular practitioner is not an investigation.
 - An investigation should be the precursor to a professional review action.

NPDB Guidebook Revisions - Investigation

- 2013 Draft Revisions re Investigations
 - NPDB Expands Definition
 - A *routine*, formal peer review process under which the health care entity evaluates, against clearly defined measures, the privilege-specific competence of all practitioners is **not** considered an investigation for the purposes of reporting to the NPDB.
 - If the formal peer review process is used when issues related to professional competence or conduct are identified or when a need to monitor a physician's performance is triggered based on a single event or pattern of events this is considered an investigation for the purposes of reporting to the NPDB.
 - The term "investigation" is "not controlled by how that term may be defined in a health care entity's bylaws or policies and procedures."

NPDB Guidebook Revisions- Investigation – cont'd

- NPDB Responses to Examples in Draft raise concerns regarding whether OPPE and FPPE constitute an “investigation”
 - TJC
 - “The Joint Commission does not consider OPPE or FPPE ‘investigations’... The Joint Commission has concerns with such a characterization...”
 - Work Group
 - “We submit that, if HRSA adopts the position in its Guidebook that the surrender of privileges while under a department review process such as an FPPE, that this will represent a substantial departure from prevailing interpretation...”
 - AHA
 - “A hospital should be able to define investigation in the Medical Staff bylaws consistent with the statute and regulations”

NPDB Guidebook Revisions - Investigation

- NPDB Issues Final Revised Guidebook April 2015
 - Retains expansive definition of "investigation"
 - may look at a health care entity's bylaws or
 - other documents to assist determination of whether an investigation has started or is ongoing, *but*
 - NPDB retains the ultimate authority to determine whether an "investigation" exists
 - "In other words, an investigation is not limited to a health care entity's gathering of facts or limited to the manner in which the term 'investigation' is defined in a hospital's by-laws."

NPDB Guidebook Revisions - Investigation

- Retains distinction between:
 - “routine” process which evaluates *all practitioners* against clearly defined measures - not reportable;

vs.

- “formal, targeted” process when issues related to a *specific practitioner's* professional competence or conduct - reportable.



NPDB Guidebook Revisions - Investigation

- When does an “investigation” begin and end, and does it matter if physician is aware?
 - “an investigation is not limited to a health care entity's gathering of facts. An investigation begins as soon as the health care entity begins an inquiry and does not end until the health care entity's decision making authority takes a final action or makes a decision to not further pursue the matter.”
 - A practitioner's awareness that an investigation is being conducted is not a requirement for reporting to the NPDB

NPDB Guidebook Revisions - Investigation

- Implications for Medical Staff Bylaws
 - The definition of “investigation” in your bylaws should be reviewed and clearly defined
 - Bylaws should differentiate “investigation” for corrective action or professional review action purposes vs. OPPE/FPPE
 - Department to perform OPPE/FPPE and Medical Executive Committee initiate investigation
 - Review OPPE/FPPE Policy to ensure consistency
 - State laws should be reviewed for definitions of investigation, if any.

NPDB Guidebook Revisions - Summary

Suspensions

- A summary suspension must be reported if it is:
 - In effect or imposed for more than 30 days
 - Based on the professional competence or professional conduct of the physician, dentist, or other health care practitioner that adversely affects, or could adversely affect, the health or welfare of a patient, and
 - The result of a professional review action taken by a hospital or other health
- 2015 Guidebook adds that summary suspensions that have not lasted more than 30 days *but are expected* to last more than 30 days, and that are otherwise reportable, *may* be reported to the NPDB.
 - If the summary suspension ultimately does not last more than 30 days, it must be voided.

NPDB Guidebook Revisions - Summary

Suspensions

- It does not matter what it is called
 - “The NPDB recognizes that suspensions are often called ‘immediate, summary, emergency, or precautionary’ in medical staff bylaws. Regardless of the name, the suspension is reportable if it is based on concerns for patient safety and it lasts more than 30 days.
- Voluntary Surrender of privileges during a suspension
 - must be reported even if that suspension has not been confirmed by the medical executive committee or other group that is required under the medical staff bylaws to review suspensions.

NPDB Guideline Revisions - Proctors

- 2001 Guidebook had no specific provision regarding when the assignment of a proctor was to be reported
 - Discussion was limited to Example 3
- 2015 Guidebook adds subsection regarding proctors
 - Whether the action must be reported to the NPDB depends on the role of the proctor. If, the physician cannot perform certain procedures without proctor approval or *without the proctor being present and watching the physician or dentist*, the action constitutes a restriction of clinical privileges and must be reported to the NPDB.
 - Question: does the assignment of a proctor to simply observe the subject physician constitute a reportable event?

NPDB Guidebook Revisions - Proctors

- Implications for Bylaws
 - Provisions regarding what type of action constitutes grounds for hearing state that hearing is required for imposition of “significant consultation or monitoring requirements”
 - See *Williams v. Columbus Clinic* (2015) 332 Ga.App. 714
 - “The [bylaws], however, identif[y] as an adverse action the [i]nvoluntary imposition of significant consultation requirements where the supervising Practitioner has the power to supervise, direct, or transfer care from the Practitioner under review.”
 - See also California Hospital Association Model Medical Staff Bylaws, 2011 edition, Sections 7.4-4 et seq.

Additional Issues/Best Practices

- California Appellate Court Case raises question of when bylaws language compels hearing for summary suspension
 - *Dhillon v. John Muir Health* (2015)- California Court of Appeal
 - Physician summarily suspended for 13 days for failure to comply with MEC directive to attend anger management
 - California Business and Professions Code Section 809 provides for hearing only if action is reportable under Section 805

Additional Issues/Best Practices

- Under California law, summary suspension reportable only if lasts more than 14 days.
- Bylaws say “suspension of Medical Staff privileges” is grounds for hearing - no reference to length of time
- Court of Appeal decision on technical legal grounds suggests that physician entitled to hearing because bylaws simply more generous than state laws in granting hearings for suspended physicians
- Case accepted for review by California Supreme Court
 - Has caused reviews of bylaws for any medical staff using similar wording

THANK YOU!!!!

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