January 29, 2014

Ernia Hughes  
Acting Director of the Division of Practitioner Data Banks  
Bureau of Health Professions  
Health Resources and Services Administration  
5600 Fishers Lane  
Rockville, MD 20852

Submitted electronically to: NPDBPolicy@hrsa.gov

Re: Revised NPDB Guidebook

Dear Ms. Hughes:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to provide input on the recently released proposed update to the Guidebook for the National Practitioner Data Bank (NPDB). We welcome the Health Resources and Services Administration’s (HRSA) decision to place a notice in the Federal Register as part of its efforts to advise hospitals and others that are affected by the NPDB of the opportunity to provide comments on the proposed revisions.

Every day in hospitals, teams of physicians, nurses, other clinicians and staff are engaged in quality improvement and patient safety activities to provide the best care possible for their communities. Hospitals support the goals of the Health Care Quality Improvement Act (HCQIA) and take seriously their responsibilities to report certain professional review actions to the NPDB, and to query the data base as part of the process for credentialing physicians to provide care in their facilities. Hospital staff involved with NPDB activities turn to the guidebook for practical information on reporting and querying consistent with the statute and regulations.

Attached to this letter is an Addendum with our detailed comments. As requested in the notice, each begins by identifying where in the document the relevant text, Q&A, etc. is located. However, we would like to highlight two issues of particular concern and provide context for reviewing the detailed comments: 1) minimizing unnecessary burden and expense for multi-hospital systems that utilize centralized credentialing by allowing for a single query regarding a physician on behalf of all of the hospitals to which the
physician is applying or at which the physician currently practices; and 2) eliminating the unnecessary confusion and uncertainty created about the meaning of “investigation” by continuing to permit hospitals to define when an investigation begins in the medical staff bylaws.

**SYSTEM IMPLICATIONS**

When a hospital is part of a system, some key functions related to the medical staff may be centralized, including the credentialing process. When that occurs, the duty to query the data bank regarding a physician should be satisfied for every hospital within the system by one query. We appreciate that the guidebook allows this for multi-hospital systems with one decision-making body; the same latitude should be provided for multi-hospital systems that have centralized credentialing, but do not have one decision-making body. Similarly, one query on behalf of all the hospitals in the system where the physician will or does practice should be permitted, even when credentialing is not centralized. It is an unreasonable duplication of effort to require that each hospital query about the same physician. Each hospital would, however, have to document that it received the appropriate information obtained through the centralized query.

**INVESTIGATION**

The proposed guidebook declares that a hospital’s medical staff by-laws do not control when an investigation begins. At the same time, however, the guidebook creates a patchwork of guidance-by-example to determine what constitutes an investigation. The result is confusion and uncertainty about the sufficiency of procedural protections for a physician. A hospital should be permitted to define investigation in the medical staff by-laws consistent with the statute and regulations.

The statute requires a hospital to report to the NPDB when it takes a professional review action that adversely affects the clinical privileges of a physician for more than 30 days; or if it accepts the surrender of clinical privileges by a physician while the physician is under investigation, or in return for not conducting such an investigation. The statute requires an opportunity for a physician to challenge an adverse action and details the procedures that must be followed. Hospitals have established policies to meet the standards of the statute and regulations. In doing so, they are careful to distinguish between an action that may give rise to a report and for which the procedural protections apply, and the many quality review and improvement activities that are outside the scope of a determination of “incompetence or improper professional conduct” under the statute. The medical staff by-laws are the vehicle through which these distinctions are made.

Many of the examples used to identify an investigation are out of step with common practices in hospitals and are not supported by the statute. Treating The Joint Commission-required Focused Professional Practice Evaluation (FPPE) as an investigation is one example; classifying peer review activities as an investigation is another. The collection and analysis of data required for the many quality improvement
efforts underway in hospitals enables them to identify areas to target for interventions that will improve care. If the data reveal concerns about a particular practitioner, then the hospital may educate and counsel the practitioner to resolve the problem rather than treat the situation as a disciplinary matter. The guidebook should not undermine the ability of hospitals and their medical leadership teams to use the many forms of early intervention to detect and address problems before they reach a level to be a reportable event by collapsing those efforts into investigations of incompetence or improper professional conduct.

The AHA welcomes the opportunity to discuss our comments further. Please feel free to contact me or Maureen Mudron, deputy general counsel, with any comments or questions at (202) 626-2301 or mmudron@aha.org.

Sincerely,

/s/

Melinda Reid Hatton
Senior Vice President and General Counsel
ADDENDUM
AMERICAN HOSPITAL ASSOCIATION DETAILED COMMENTS

Chapter B Eligible Entities
pp. B-17, -18 Q/A4 and Q/A5 address querying about a physician by multiple hospitals within a system and multiple departments within a hospital. It is redundant for multiple facilities within the same system to make multiple queries to obtain the same information. Health care systems should be able to make a single query and share the information with other owned or controlled hospitals. Each facility would have to document that it received the appropriate information so as to qualify as a “query.” Similarly, a hospital should be able to make one query and share the information with multiple departments.

Chapter D Queries
p. B-5 Residents and Interns: The discussion emphasizes that querying is not required. It is suggested that the text of the sentence describing the exception when querying is required be given more visibility so it is not missed.

p. B-9 Centralized Credentialing: This is another discussion regarding querying by multi-hospital systems. It should be possible for the system to make a single query regarding a physician and share that information with the individual hospitals, even if credentialing is not centralized. This would eliminate duplicative queries across the system.

Chapter E Reports
pp. E-15 through E-27 Reporting Malpractice Payments: The discussion in this section was clearly worded and helpful.

pp. E-27 through E-46 Reporting Adverse Clinical Privilege Actions:

p. E-27: The second and third paragraphs appear to say the same thing. If an important distinction was intended, it is not apparent.

p. E-28 Third Paragraph: The discussion regarding censures, reprimands and admonishments creates the incorrect impression that taking one of those actions may be a reportable event. The statute defines an adverse action and does not include those types of actions.

p. E-29 Multiple Adverse Actions: The use of “probation” in the discussion creates the incorrect impression that probation is a reportable event, although it is not included in the definition of an adverse action. A substitute should be included in the illustration.

p. E-30 Withdrawal of Application: The last two sentences of this paragraph should be deleted. Concluding that a physician’s lack of awareness that he or she is under
investigation is irrelevant to whether the physician has withdrawn the application for privileges while under investigation is at odds with the statute and unfair to the physician.

Nonrenewals: For the same reason, the last sentence in the paragraph should be deleted. The obligations to report the surrender of privileges while under investigation, or to avoid an investigation, assume a *quid pro quo*. If the physician is unaware of the investigation, that fails. Mandating a report to the data bank without the physician’s knowledge is also at odds with the procedural protections required by the statute.

**p. E-31 Investigations:** The guidebook’s discussion of investigations (in the narrative on pp. E-31-32 and the related QAs) will cause unnecessary confusion and uncertainty for hospitals and physicians about the sufficiency of procedural protections for physicians. Instead of declaring that a hospital’s medical staff by-laws do not control when an investigation begins, a hospital should be permitted to define investigation in the medical staff by-laws consistent with the statute and regulations.

Hospitals have established policies to meet the standards of the statute and regulations. In doing so they are careful to distinguish between an action that may give rise to a report and for which the procedural protections apply, and the many quality review and improvement activities that are outside the scope of a determination of “incompetence or improper professional conduct” under the statute. The medical staff by-laws are the vehicle through which these distinctions are made. The guidebook blurs those distinctions.

Using non-HCQIA terminology – routine formal peer review, formal peer review, need to monitor, routine review of practitioner, general review of care, Focused Professional Practice Evaluation, On-going Professional Practice Evaluation – sweeps in activities outside the scope of HCQIA. If the many quality improvement efforts underway in hospitals reveal concerns about a particular practitioner, the hospital may educate and counsel the practitioner to resolve the problem rather than treat the situation as a disciplinary matter. The guidebook should not undermine the ability of hospitals and their medical leadership teams to use the many forms of early intervention to detect and address problems before they reach a level to be a reportable event by collapsing those efforts into investigations of incompetence or improper professional conduct.

**p. E-32 Summary Suspension:** An edit to the first sentence in the first paragraph following the three bullets is recommended for greater clarity. “The NPDB treats summary suspensions differently than other professional review actions because the procedural rights of the practitioner are provided *following the imposition of a suspension*, rather than *preceding* it.”

**p. E-34 Proctor:** This provision is consistent with hospitals’ understanding of what the statute requires. Making explicit that requiring approval of procedures by a proctor is reportable only if it continues more than 30 days is a useful revision.
p. E-40 QA 11: For the same reasons previously discussed (see comment on p. E-30), concluding that a physician’s lack of awareness that he or she is under investigation is irrelevant to whether the physician’s failure to renew privileges was a surrender of privileges while under investigation is at odds with the statute and unfair to the physician.

p. E-41 Q16: This QA should be deleted; FPPE is incorrectly classified as an investigation. (See related discussion above regarding Investigations, p. E-31.)