



Michael D. Maves, MD, MBA, Executive Vice President, CEO

May 22, 2006

Ms. Betsy Ranslow
Associate Administrator
Bureau of Health Professions
Health Resources and Services Administration
Room 8-05 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Re: RIN 0906-AA43 National Practitioner Data Bank for Adverse Information on
Physicians and Other Health Care Practitioners: Reporting on Adverse and
Negative Actions

Dear Ms. Ranslow:

The American Medical Association (AMA) would like to comment on the proposed regulations expanding the scope of the National Practitioner Data Bank (NPDB) set forth in the Notice of Proposed Rulemaking published in the Federal Register, Vol. 71, No. 54, at page 14136 on Tuesday, March 21, 2006. The proposed amendments would revise existing regulations under Sections 410 through 432 of the Health Care Quality Improvement Act of 1986. The Department of Health and Human Services relies on Section 1921 of the Social Security Act, as amended by Section 5(b) of the Medicare and Medicaid Patient and Program Protection Act of 1987, and as amended by the Omnibus Budget Reconciliation Act of 1990 as statutory authorization for these changes. The proposed amendments would require each state to adopt a system of reporting adverse licensure actions against health care practitioners and health care entities to the NPDB and would require each state to report negative actions or findings by a state licensing authority, peer review organization, or private accreditation entity.

The AMA supports the purpose of the national data bank as envisioned in the NPDB's enabling legislation, the Health Care Quality Improvement Act of 1986, to assist states in protecting the public from health care practitioners crossing state lines to avoid the consequences of professional disciplinary proceedings or civil adjudications of negligence. However, the AMA persists in its objections to the establishment and

methodology employed by the NPDB on the basis that the Department of Health and Human Services exceeded its statutory authority in drafting the original regulations promulgating the NPDB. As a consequence, the NPDB ventured beyond its intended legislative purpose and has been structured in a way that prevents it from fulfilling its mission of flagging practitioners of questionable competence or conduct.

The NPDB was created as a national repository of information pertaining to the competence and conduct of practitioners, accessible by licensing authorities and facilities for licensing, credentialing, and privileging purposes. However, data collected by the NPDB is not reflective of the quality of care a practitioner provides. For example, a substantial portion of the NPDB's data consists of medical negligence verdict and settlement reports. It is recognized and documented, among NPDB constituents and within the medical community as a whole, that there is little correlation between findings of professional negligence by a trial jury and findings of negligence when the same actions are reviewed by individuals with training and experience in the same profession. Similarly, the report of a negligence settlement may provide a misleading impression of a practitioner's competence because it fails to note that the physician practices in a high-risk specialty and has a higher probability of being sued because of the nature of his or her practice. In a similar vein, physicians do not routinely exercise control over their professional liability insurance carriers, which may make the economic decision to settle a "nuisance" lawsuit rather than expend resources to defend the claim on its merits. As a result, the NPDB gathers data of dubious value in assessing a practitioner's competence.

Nonetheless, the professional and economic ramifications for a practitioner whose name appears in the National Practitioner Data Bank can be significant. It can result in denial of credentialing, loss or limitation of hospital privileges, exclusion from participation in health plans, loss or limitation of licensure, and increases in professional liability insurance premiums or exclusion from liability coverage altogether.

The AMA's concerns about the NPDB were heightened by the release of a 2000 GAO Report entitled "National Practitioner Data Bank: Major Improvements Are Needed to Enhance Data Bank's Reliability." The report catalogued troubling deficiencies in the data bank's accuracy and completeness of its data, among other things. However, to date there have not been adequate assurances or evidence that the NPDB's quality issues have been remedied.

The proposed amendments to the NPDB regulations represent a sweeping expansion to the kind of information the NPDB will warehouse. These changes represent a significant extension of data collection efforts on physicians and dentists beyond the NPDB's original directive to collect data on their competence and conduct. Requiring the reporting of loosely defined "adverse licensure actions" by a licensing agency will expand reporting requirements from those focused on competence or conduct to include lesser offenses that are not reflective of quality of care. Likewise, the reporting of "any negative finding or action" (emphasis added) by a state licensing authority, peer review

organization, or private accreditation entity will capture data that merely suggests quality of care issues may exist or that indicators of comparatively minor issues not reflective of quality have been identified. It is regrettable that the authorizing legislation permitting this expansion allows for the inclusion of a high volume of information that may indicate the mere possibility that a practitioner has delivered less than optimal care. The AMA is concerned that while the proposed regulations will considerably increase the scope and volume of reporting, the quality and accuracy of the data will be questionable and of negligible practical value for flagging questionable practitioners.

Expanded peer review reporting will have a chilling effect on quality improvement activities

Requiring any peer review organizations, QIO's or otherwise, to report to the National Practitioner Data Bank threatens their viability. In an inherently complex profession made more challenging by an exponentially increasing body of knowledge, peer review organizations are an essential tool for physician education and quality improvement. Confidentiality is the bedrock of peer review organizations. In the charged litigation environment in which physicians practice medicine, the confidential nature of peer review proceedings is an important mechanism to allow practitioners to discuss and learn from patient care events. Congress recognized the essential role that confidentiality plays in quality improvement activities when it passed the Patient Safety and Quality Improvement Act of 2005. The value of these proceedings is further evidenced by the fact that nearly all of the fifty states grant some protection against discovery of the deliberations of peer review committees in civil litigation. The public policy reasons for the existence of peer review protections are compelling. Physicians must be able to talk to one another and must be able to learn from their suboptimal outcomes so they are not repeated. Peer review also typically contains accountability measures, ensuring that findings that a patient was harmed through negligence are reported to appropriate state licensing agencies.

The kind of widespread peer review reporting envisioned by the proposed NPDB amendments contradicts Congress' intent expressed in the Patient Safety and Quality Improvement Act of 2005 to favor quality improvement activities and to encourage practitioners to come forward to participate in quality improvement activities without fear of aggressive reporting requirements or other reprisal. Likewise, this agency's rationale for precluding reporting of peer review activities by QIO's articulated in the preamble of the Notice of Proposed Rulemaking (Federal Register, Vol. 71, No. 54, p. 14136, Tuesday, March 21, 2006) is equally applicable to all peer review proceedings. Moreover, without tighter constraints on what data is reported, the NPDB will likely receive a large volume of reports of little practical value. Peer review organizations may make a wide variety of "negative findings," ranging from outright findings of negligence that may have harmed a patient to findings that a physician has been remiss in signing his

medical records within a hospital-imposed deadline. More serious findings are already obligated to be reported to state licensing agencies under state and federal peer review laws, which the NPDB will ultimately capture in subsequent reporting by the licensing agency. More innocuous findings will add volume to the NPDB, causing management and verification challenges for NPDB staff, without improving the quality of the data received. Moreover, the chilling effect that reporting all peer review findings to the NPDB will have on these essential quality improvement activities cannot be overstated.

§60.3 Definition of “Peer review organization”

We suggest a more restrictive definition of “peer review organization.” The definition in §60.3 of “Peer review organization” should be amended to include language assuring that PRO’s reporting to the NPDB are those that have demonstrated in their reporting that they provide due process to their physician participants and that a physician has had ample opportunity to appeal the peer review organization’s findings. These additional provisions will provide at least minimal assurance of the quality of information considered and the fairness of the fact-finding process.

§60.3 Definition of “Formal proceeding”

As stated in the preamble, the drafters’ intent in creating the definition of “Formal proceeding” under §60.3 was to allow State licensing authorities, peer review organizations and private accreditation entities maximum flexibility in determining the process they will follow in conducting such proceedings. However, defining a “formal proceeding” as “a formal or official proceeding held before a State licensing or certification authority, peer review organization or private accreditation entity” creates a circular definition and has the potential to create confusion for these organizations regarding their reporting responsibilities. Because these bodies operate by state law, in order for due process protections and statutory peer review protections to apply to these proceedings, all such actions will be “formal proceedings” and therefore reportable. As a result, the NPDB could receive a barrage of reports that have no appreciable merit in assessing a practitioner’s ability to practice and will further degrade the overall quality of the NPDB’s data.

If, in the alternative, the intended effect of this definition was to allow these entities to self-determine which events they would report to the NPDB, this will not accomplish that purpose. Informal proceedings do not provide licensing agencies full powers of subpoena, discovery, privilege, or confidentiality under state law. Likewise, informal proceedings of peer review organizations do not afford those peer review organizations protection against civil litigation. These practical constraints would prevent such organizations from initiating informal proceedings, and will not yield the overall flexibility the drafters anticipated.

§60.3 Definition of “Negative action or finding”

Not all negative actions or findings by PRO’s should be reported to the NPDB. The definition of “negative action or finding” under §60.3(1) only requires the reporting against a facility by a private accreditation entity “that indicates a substantial risk to the safety of a patient or patients or quality of health care services.” Likewise, §60.3(3) excludes reporting of administrative fines, citations, or corrective action plans absent an additional finding that a licensing authority took action against a license. In contrast, §60.3(2) requires the reporting of all findings by peer review organizations. We believe that only final actions or findings indicating a substantial risk of safety to a patient or quality of care should be reported by a peer review organization. This would create consistency among the actions that private accrediting organizations, peer review organizations, and State agencies must report.

Law enforcement agencies permitted to query

We similarly question the broad range of law enforcement agencies permitted to query under proposed regulation §60.13 (a)(2)(i), entitled “Requesting Information from the National Practitioner Data Bank.” Queries are permitted under this subsection for purposes of determining the fitness of individuals to provide health care services, protecting the health and safety of individuals receiving health care through programs administered by the requesting agency, and protecting the fiscal integrity of these programs. However, the list of law enforcement agencies permitted to query includes agencies with no such apparent jurisdiction over health care practitioners. For example, it is not immediately clear why the Nuclear Regulatory Commission or the United States Chief Postal Inspector should be granted access to the kind of information cataloged by the NPDB. Similarly, the need for state and local law enforcement agencies to have query rights is equally unclear.

The list of law enforcement agencies permitted to query should be no more expansive than those directly enumerated in the authorizing legislation. It is equally concerning that law enforcement agencies will be permitted to query the data bank without demonstrating the reason or need to query. Likewise, there is no requirement that parties who are the subject of these queries will be notified. The NPDB’s existence should not be permitted to vitiate law enforcement’s responsibilities to satisfy probable cause or due process requirements when investigating a health care practitioner. The NPDB should not be allowed to serve as a shortcut to appropriate independent criminal investigative procedures.

Retroactive data collection

While not explicitly addressed in the regulations, we recommend against the agency exercising operational discretion to authorize retroactive data collection. We recognize

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that the authorizing legislation for the expansion of the NPDB's data collection, section 1921 of the Social Security Act, as amended by the section 5(b) of the Medicare and Medicaid Patient Protection Act of 1987, and as amended by the Omnibus Reconciliation Act of 1990, will be nearly seventeen years old at the time of implementing these regulations. However, the integrity of older data on actions and proceedings newly reportable to the NPDB will be difficult to substantiate. Uneven reporting will unfairly prejudice those physicians who are the subject of such reporting. Because of the passage of time, physicians who have been the subject of a much earlier proceeding may lack the requisite documentation to effectively counter inaccuracies in reporting. Finally, the volume of data that expanded reporting requirements will most likely generate could prove unmanageable.

Practitioners' rights of rebuttal or correction

In light of the significant expansion of the volume and quality of information that the NPDB will collect regarding practitioners, much of it including actions or findings that do not afford physicians adequate rights to due process, it seems appropriate for the NPDB to exercise its statutory authority to permit physicians to rebut information the NPDB will report about them. However, no additional protections or safeguards for accuracy of the information reported have been included in the proposed regulations. The Secretary should exercise his statutory authority to afford physicians and other practitioners meaningful opportunities to dispute the accuracy of claims reported to the NPDB and to require the removal of inaccurate reports.

The AMA appreciates your consideration of the foregoing comments and respectfully suggests their incorporation into the final rules. Please do not hesitate to contact Christina Collins at (202) 789-4584 with any questions or comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Mike Maves", is written over a thin red horizontal line.

Michael D. Maves, MD, MBA