Burden-Related Comments and Responses
for
Section 1921 Clearance Package

1. **American Medical Association, Michael D. Maves, MD, MBA, Executive Vice President, CEO**

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

   Response: In §60.5, the NPDB regulations state that information must be submitted beginning with actions occurring on or after January 1, 1992, which is the date of the enactment of section 1921. We recognize the commenters' concerns. We strongly encourage each reporter to submit actions occurring on or after January 1, 1992, however, to assist in reducing the burden on State licensing agencies, we will be requesting permission to copy the eligible reports in the HIPDB (from August 21, 1996, forward) into the NPDB.

   We also recognize the report subjects' concerns regarding their ability to dispute reports of actions taken more than a decade ago. Secretarial reviews of disputes between reporting entities and subjects, however, address accuracy, completeness, timeliness and reportablity, issues typically based on information that is a matter of public record, such as board orders.

2. **National Council of State Boards of Nursing, Vickie Sheets, JD, RN, CAE, Director of Practice and Regulation**

   a. Comment: "A major concern voiced by boards of nursing has been the fear that the implementation of reporting other practitioners', including nurses, licensure actions to the NPDB would double the work required for reporting. We are pleased that the Secretary proposes to implement this regulation in a manner to avoid the need for an entity, that must report information to both the NPDB and HIPDB, to file two reports by providing a consolidated reporting mechanism that will sort the appropriate actions into the HIPDB, NPDB or both. We question the assertion in the supplementary information that the impact on reporting boards will only be electronic access and additional staff hours for transmission. The real drain on board staff time will be managing the increased calls

that will result from increased access to nursing discipline information."

Response: Because most of the licensing actions to be reported to the NPDB under section 1921 have already been or are required to be reported to the HIPDB, we do not believe that the volume of telephone calls resulting from these reports would constitute a burden to State licensing boards. We acknowledge there is a potential for increased phone calls from queriers, however, we do not anticipate the volume of calls to be significantly greater than that currently experienced by entities that report to the Data Banks.

b. Comment: "In reviewing the proposed rules, language in § 60.5 needs explanation. This section states that actions occurring after August 31, 1990, are to be reported. We realize this reflects the beginning of NPDB operation; however requiring boards to go back to 1990 is totally infeasible. An expectation that boards report old cases from the last sixteen years, it would pose a tremendous burden at a time when states are already struggling with financial crises resulting in decreased resources at a time of increased discipline demands. Reporting should begin when these proposed rules go into effect."

Response: In §60.5, the NPDB regulations state that information must be submitted beginning with actions occurring on or after January 1, 1992, which is the date of the enactment of section 1921. We recognize the commenters' concerns. We strongly encourage each reporter to submit actions occurring on or after January 1, 1992, however, to assist in reducing the burden on State licensing agencies, we will be requesting permission to copy the eligible reports in the HIPDB (from August 21, 1996, forward) into the NPDB.

3. Joint Commission, Trisha Kurtz, Director of Federal Relations

a. Comment: "The last part of the background section outlines the distinctions between the NPDB and the Healthcare Integrity and Protection Data Bank (HIPDB). Under this section, the Secretary of DHHS would ensure that those entities reporting to both databases would be required to only submit one report per action. The Joint Commission applauds this effort to reduce the regulatory and administrative burden on health care entities."

Response: We appreciate the Joint Commission's comments. HRSA has made every effort to ensure coordination between the NPDB and the HIPDB and to minimize the burden on those entities that must report to and/or query both of these data banks.

b. Comment: "Section 60.5 (c) would require that "peer review organizations or private accreditation entities must report any negative actions or findings to the State within 15 days from the date the action was taken or the finding was made." The section also stipulates that "each State, through the adopted system of reporting, must submit to the NPDB the information received from the peer review organization, or private accreditation entity within 15 days from the date on which it received this information."

c. Comment: The process by which private accreditation organizations will report to the states is unclear, and there is no provision to ensure consistency across the states. Private accreditation organizations should report directly to the NPDB or one

coordinating federal agency.

Although there is precedent for state reports to states, we believe that there should be a formal process for transmitting reports to the NPDB as referenced in Section 60.5(c). From the brief language in the proposed ruling, the process by which private accreditation bodies will report to the states is unclear and there is nothing to ensure consistency across states. For example, would there be a form letter, or what entity would create that letter? In addition, there is no mention as to how the appropriate authority in each state will be identified. This lack of clarity poses the risk of uneven, non-standardized reporting from the states as well as numerous other operational problems. We recommend that reports go directly from entities who report to the NPBD or a coordinating federal agency in a well prescribed fashion. Finally, we do not believe that 15 days is a reasonable time frame for reporting information. The Joint Commission would suggest a longer period of time."

Response: The NPDB has had a similar reporting process in place, and this has not posed a problem for reporting entities in the past. To be consistent with current NPDB regulations, we require reporting entities under section 1921 to report information within 15 days to the State, which then has 15 days to report that information to the NPDB. However, since the development of electronic reporting technology, entities now submit reports directly to the NPDB using the data bank's electronic reporting system. The reporting entity must report any actions or findings directly to the NPDB within 30 days from the date the action was taken or the finding was made. The data bank's electronic reporting system enables reporting entities to satisfy reporting obligations to other government agencies by making a print copy of the report available for separate submission via mail or fax.

4. American College of Radiology, Harvey L. Neiman, MD, FACR, Executive Director

a. Comment: "We also suggest that requiring private accreditation bodies to report to individual states is simply unworkable. For a national program that may have as few as a single accreditation applicant in a state to research and meet that state's individualized reporting requirements places an immense burden on the accreditation organization. It is the equivalent to reporting to 50 National Practitioner Data Banks (NPDB) and each with a different reporting format. If reporting must be required, direct reporting to the National Practitioner Data Bank is preferable."

Response: To be consistent with current NPDB regulations, we require reporting entities under section 1921 to report information within 15 days to the State, which then has 15 days to report that information to the NPDB. However, since the development of electronic reporting technology, entities now submit reports directly to the NPDB using the data bank's electronic reporting system. The reporting entity must report any actions or findings directly to the NPDB within 30 days from the date the action was taken or the finding was made. The data bank's electronic reporting system enables reporting entities to satisfy reporting obligations to other government agencies by making a print copy of the report available for separate submission via mail or fax.

b. Comment: "It is uncertain what specifically must be reported. The proposed rule

classifies data elements into "reported if known" and "discretionary data elements." Reporting requirements should not be oppressive or burdensome on accreditation organizations. The required information should only be that which the accrediting organization would collect during the course of its accreditation process. The collection should be as simple as possible to avoid costly software changes to the accreditation organization."

Response: The information that must be reported by private accreditation entities is listed in §60.9 (b). The electronic system will not accept a report that does not include the data elements listed in §60.9 (b). These data elements are mandatory. Data elements to be reported "if known" are listed in §60.9 (c). The inclusion of these data elements enhances matching between a query and a reported subject and provides additional information to aid users' understanding of the reported incident. These data elements, however, are not mandatory. We believe the data elements selected for inclusion under section 1921 are essential for users to properly identify entities that are subjects of reports in the data bank and to understand the nature of the actions taken against them. These data elements also are necessary to ensure the NPDB meets its requirements to ensure confidentiality of the information it collects.

We believe the required information should be available from information contained in existing records compiled during the review process. The NPDB makes available an electronic reporting format that can be completed online at the data banks' secure web-based reporting site. Reporting entities do not need to develop new software to report over the web-based electronic reporting system. Reporting entities also may elect to use an authorized agent to submit reports to the NPDB on their behalf. A reporting entity that makes information available in other public formats has not met its reporting obligations under section 1921.

5. American College of Surgeons, Thomas R. Russell, MD, FACS, Executive Director

a. Comment: We do not believe many peer review organizations have the authority to officially sanction providers. In addition, any formal actions would likely lead to a loss or restriction of clinical privileges and would already be captured in the NPDB. We believe adding peer review organizations to the list of groups that must report will be burdensome to these small, and often under funded, organizations and will lead to no additional meaningful information.

Response: Section 1921 requires that peer review organizations report negative actions or findings to the NPDB. However, information required to be reported by peer review organizations will be minimal. The regulations limit reporting by peer review organizations to recommendations to sanction a health care practitioner. We have received comments noting that peer review organizations generally recommend areas of improvement and do not recommend sanctions (the only type of reportable event for these organizations). Therefore, we believe their reporting requirements will not be overly burdensome. We estimate that 25 peer review organizations will each report a maximum of 4 negative actions or findings annually.

6. American Podiatric Medical Association, David M. Schofield, DPM, President

a. Comment: "Nevertheless, whether defined as physicians or as health care practitioners,

APMA believes DPMs would be subject to new reporting requirements under the proposed rule. Any adverse action taken by the state licensing board for podiatric medicine would now be reported to the NPDB. APMA believes this requirement must not become a burden for state podiatric medical boards. Podiatric medical boards need resources to report this information without detracting from the mission of the boards to protect state residents from poor health care."

Response: Section 1921 does not create a new reporting burden for State boards. State licensure reporting requirements under section 1921 are essentially identical to those already being reported to the HIPDB. Because of the data bank's integrated reporting and querying system, State licensing boards and agencies will only need to submit a licensing action once. The system will subsequently store the report according to statutory requirements in the NPDB, the HIPDB or both data banks.

7. The Hospital and Healthsystem Association of Pennsylvania, Lynn G. Leighton, Vice President, Professional & Clinical Services

a. Comment: "It is HAP's understanding that since our state health department serves as a contractor to CMS, it leaves decision on what should be reported to the HIPDB to CMO rather then report separately to this data bank. As currently proposed, state agencies would be required to report this information to the NPDB. This is precisely the same information that is already being reported to CMS, which in turn makes determinations as to what should be reported to the HIPDB. Since HRSA would essentially locate the same information in both data banks, there should be allowances in the proposed rule to permit state and federal agencies to jointly agree what information should be reported by which agency to avoid reporting redundancy."

Response: Statutes governing the NPDB and the HIPDB specify who must report and what actions must be reported to each data bank. A State licensing authority that takes a reportable action must report the action directly to the NPDB and/or the HIPDB. On the other hand, if a Federal agency separately takes an action, such as a contract termination, based on the State's action, and that contract termination meets the reporting requirements for the HIPDB, the Federal agency would be responsible for reporting that contract termination to the HIPDB. There would be no reporting redundancies because each agency is required to report only the action it takes, and the statute will not alter existing reporting relationships between agencies. A reporting entity may designate another organization to serve as its authorized agent. The reporting, entity, however, is ultimately responsible for ensuring that its own reporting obligations to the data banks have been satisfied. Reporting actions to other government agencies or data banks does not satisfy a reporting entity's statutory obligations for reporting these actions to the NPDB and the HIPDB.

b. Comment: HAP supports the goals of the Health Care Quality Improvement Act, under which the NPDB was created and appreciates the opportunity to comment on this proposed rule. HAP also appreciates the responsibility that HRSA has taken to minimize reporting to both the HIPDB and NPDB, and believes that some of this burden could be further reduced in better understanding how CMS acts on information furnished by state agencies and accreditation organizations, both of which serve as contractors to the federal government in ensuring hospitals and other health care entities meet Medicare Conditions of Participation."

Response: HRSA understands the relationship between CMS and accreditation entities and state survey and certification agencies. We recognize that CMS itself may not always take an action based on a negative action or finding by an accreditation entity that serves as a CMS contractor. However, section 1921 requires that negative actions or findings by private accreditation entities be reported to the NPDB, regardless of how other agencies or organizations respond to those actions or findings. The reporting requirements for private accreditation entities published in the final rule are consistent with statutory requirements while also reflecting the input of these accreditation organizations and other public commenters. Private accreditation entities must report final determinations of denial or termination of accreditation status, which, we estimate, will account for a total of 100 reports annually. We believe this represents a minimal reporting burden for these entities.