

National Practitioner Data Bank for Adverse Information
on Physicians and Other Health Care Practitioners--45 CFR Part 60
Regulations and Forms

SUPPORTING STATEMENT

A. Justification

1. Circumstances of Information Collection

This is a request for an extension of OMB approval of the information collections contained in regulations found at 45 CFR Part 60 governing the National Practitioner Data Bank (NPDB) and the forms to be used in reporting information to, and requesting information from, the NPDB cleared under OMB No. 0915-0126. This approval expires May 31, 2007. The NPDB is authorized by title IV, Pub. L. 99-660, the *Health Care Quality Improvement Act of 1986* (title IV) (42 U.S.C. 11101). The regulations implementing title IV governing the operation of the NPDB are found at 45 CFR Part 60. The NPDB became operational September 1, 1990.

Part B of title IV requires that certain adverse data regarding physicians, dentists, and other licensed health care practitioners be reported to the Secretary of Health and Human Services (HHS) or the Secretary's designee and be made available to parties as specified in the Act. Hospitals are required to query the Data Bank at specified times. The Data Bank allows State licensing boards, hospitals and other health care entities, and professional societies to identify those who engage in unprofessional behavior; and it restricts the ability of physicians, dentists, and other licensed health care practitioners with a history of substandard practice to move from State-to-State without disclosure or discovery of their previous damaging or incompetent performance or conduct.

The NPDB is primarily an alert or flagging system intended to facilitate a comprehensive review of health care practitioners' professional credentials. The information contained in the NPDB is intended to direct discrete inquiry into, and scrutiny of, specific areas of a practitioner's licensure, professional society memberships, medical malpractice payment history, and record of clinical privileges. The NPDB contains information that should be considered together with other relevant data in evaluating a practitioner's credentials; it is intended to augment, not replace, traditional forms of credentials review.

Approval is requested for the following reporting information data collection requirements, NPDB forms and their instructions required in the regulations to implement the NPDB.

REPORTING REQUIREMENTS:

' 60.6 Reporting errors, omissions, and revisions.

60.6(a) If errors or omissions are found after information has been reported to the NPDB, the reporter must report the correction or addition.

60.6(b) If the individual's record changes, such as a reinstatement of a license, or the modification or reversal of a professional review action, the reporting entity must file a revised report using the same time frame as that required for the original report.

' **60.7 Reporting medical malpractice payments.**

60.7(b) This paragraph identifies what information insurers, and all others making payments on behalf of a physician, dentist, or other licensed health care practitioner as a result of a medical malpractice action or claim, must submit to the NPDB and to the appropriate licensing board in the State in which the claim arose.

' **60.8 Reporting licensure actions taken by Boards of Medical Examiners.**

60.8(b) This paragraph identifies the data elements to be reported to the NPDB by State medical and dental boards regarding the physician or dentist involved, the nature of the action, and the reason for the action. Reportable licensure actions related to professional competence or conduct include: revocation, suspension, probation, censure, reprimand or surrender.

' **60.9 Reporting adverse actions on clinical privileges.**

60.9(a)(3) This subparagraph specifies the information that must be reported to State medical or dental boards on professional review actions taken by health care entities with peer review processes, such as hospitals or health maintenance organizations, or professional societies, which adversely affect the clinical privileges of a physician or dentist for more than 30 days. Such information on other health care practitioners may be reported on a voluntary basis (subparagraph (a)(2)). (Note: with the advent of electronic reporting, entities now report these actions directly to the NPDB and then forward the information to the State boards.)

60.9(b) This paragraph requires State medical or dental boards to forward those reports received under ' 60.9(a)(3) to the NPDB and to report any known instances of a health care entity's failure to report. (As indicated above, boards are no longer required to forward these reports to the NPDB because health care entities report these actions directly.)

60.9(c) This paragraph identifies the hearing and review process that a health care entity must follow, including submission of an account to the Secretary regarding the facts of the dispute, in order to request a hearing because the Secretary found that the health care entity had failed to report as required under ' 60.9(a)(3).

' **60.10 Information which hospitals must request from the National Practitioner Data Bank.**

60.10(a) This paragraph identifies the times when hospitals must request information from the NPDB:

- (1) When a practitioner applies for clinical privileges, or employment, or affiliation with the medical staff 60.10(a) (1);
- (2) Every two years for all practitioners holding clinical privileges or who are on the medical staff 60.10(a) (2).

' **60.11 Requesting information from the National Practitioner Data Bank.**

60.11(a) This paragraph identifies entities and persons who, under specified conditions, may have access to individuals' records or aggregate data from the NPDB.

- (1) Hospitals for purposes of professional review
- (2) Individual practitioners checking their own records
- (3) State boards
- (4) Other health care entities for hiring or affiliating with practitioners
- (5) An attorney or individual who has a malpractice claim under legal review
- (6) A health care entity for purposes of professional review
- (7) Researchers (aggregate data stripped of identifying information only)

Paragraph (a) also provides for the use of authorized agents. Information can be requested from the NPDB either directly by the querying entity or by that entity's authorized agent.

' 60.14 How to dispute the accuracy of National Practitioner Data Bank information.

60.14(b) This paragraph describes the process to be followed by a practitioner in disputing the factual accuracy of a report to the NPDB.

FORMS

All NPDB forms are available on the Data Bank web site. Reporting and querying for the NPDB is accomplished electronically over a secure Internet connection.

Reporting Forms

(1) Malpractice Payment Information Form - Insurance companies and other insurers must submit a report to the NPDB using this form when they make a payment under an insurance policy, self-insurance or otherwise, in settlement in satisfaction of a claim or a judgment in a medical malpractice action against a physician, dentist, or other licensed health care practitioner. A copy of the report must be sent to the appropriate State licensing board(s) in the State in which the act or omission that was the cause of the medical malpractice claim occurred. This report must be submitted to the NPDB within 30 days following the payment [see ' 60.7(b)].

(2) Adverse Action Report Form - State medical and dental boards must submit a report using this form to the NPDB when they take a formal action against a physician or dentist. This report must be submitted within 30 days from the date the licensure action was taken [see ' 60.8(b) and 60.9(a) (3)].

Professional review actions taken by health care entities with peer review processes, such as hospitals or health maintenance organizations, are reported on this form if they (a) adversely affect the clinical privileges

or membership of a physician or dentist for more than 30 days, and (b) are based on a review of the practitioner's professional competence or conduct.

Also reported are similar actions by professional societies that result from peer review and that adversely affect membership in the society.

Information on revision to licensure, clinical privilege and professional society membership actions is reported to the NPDB as required under '60.6(b). Such revisions include the reversal of a professional review action or the reinstatement of a license.

Each time the NPDB receives a report, it generates a computer printout of the information it has received and entered into the NPDB. The NPDB automatically sends a printed copy of the report to the subject practitioner. In addition, the NPDB sends an electronic copy of the report back to the reporting entity. The reporting organization also enters electronically revisions or corrections to previously submitted reports.

Information Disclosure (Query) Forms

(3) Request for Information Disclosure (Query) – Individual Subject. This form is used to request information from the NPDB. Hospitals are required to query the NPDB using this form each time a physician, dentist, or other licensed health care practitioner applies to be on its medical staff or for clinical privileges ['60.10(a)(1)]. Hospitals are also required to query the NPDB every two years regarding the physicians, dentists, and other licensed health care practitioners who are on the medical staff or who hold clinical privileges [60.10(a) (2)]. Information received through these required queries may help hospitals in making hiring and/or privileging decisions and decisions relating to the initial award and subsequent retention of clinical privileges. Information received is not intended to be a substitute for other forms of credentials review. Rather, it is intended to draw attention to patient care incidents that may merit closer scrutiny. Besides these required inquiries, hospitals may query the NPDB at any time concerning a physician, dentist, or other health care practitioner who is on its medical staff or who has clinical privileges at the hospital ['60.11(a)(1)].

State Medical Boards, Dental Boards, and other licensing Boards may query the NPDB to screen applicants for licensure ['60.11(a) (3)]. Health care entities, as defined in '60.3, other than hospitals, may query the NPDB if they have entered or may be entering an employment or affiliation relationship with a physician, dentist, or other health care practitioner or if the physician, dentist, or other health care practitioner has applied for membership, clinical privileges, or appointment to the medical staff. They use the information in making hiring, affiliation, appointment, and reappointment decisions ['60.11(a) (4)].

An attorney or a *pro se* defendant who has filed a medical malpractice action or claim in a court or other adjudicative body against a hospital may query the NPDB regarding a specific physician, dentist, or health care practitioner who is also named in the action or claim. However, this can be done only if he or she can provide evidence that the hospital failed to request information from the NPDB as required by the Act. The plaintiff's attorney must obtain this information independently, not through the NPDB. Information so received can be used by the attorney but only in the litigation against the hospital ['60.11(a) (5)].

Hospitals and other health care entities may also query the NPDB when conducting professional review activities. This information may be used in making decisions related to professional competence ['60.11(a) (6)].

Persons or entities who request information in a form which does not allow the identification of any particular health care entity, physician, dentist, or other health care practitioner, may receive such information for research purposes. The Health Resources and Services Administration (HRSA) also uses such aggregate data for research and in the preparation of required reports, such as the required Report to Congress on small payments [' 60.11(a)(7)].

The information collected about failure to report and disputes of accuracy as specified at " 60.9(c) and 60.14(b) is used in the resolution of disputes about either compliance with a health care entity=s required reporting or by a practitioner who is disputing the factual accuracy of information reported to the NPDB.

(4) Individual Self-Query Form An individual physician, dentist, or other health care practitioner may query the NPDB at any time concerning himself or herself. The NPDB proactively notifies an individual each time he or she is the subject of a report. [see ' 60.11(a)(2)].

Access and Administrative Forms

(5) Entity Registration Form is used by entities to self-certify that they meet the regulatory requirements needed to interact with the NPDB. The completion of the Entity Registration document allows the entity to begin interacting with the NPDB. This document is now completed online. Online entity registration continues to enable entities to register with the Healthcare Integrity and Protection Data Bank (HIPDB) as well the NPDB simultaneously. The HIPDB is authorized by section 1128E of the *Social Security Act* (hereinafter referred to as section 1128E), as added by section 221(a) of the *Health Insurance Portability and Accountability Act of 1996*. Section 1128E directs the Secretary of Health and Human Services (the Secretary) to establish a national health care fraud and abuse data collection program for the reporting and disclosing of certain final adverse actions (excluding settlements in which no findings of liability have been made) taken against health care providers, suppliers, or practitioners. It also directs the Secretary to maintain a database of final adverse actions taken against health care providers, suppliers, or practitioners. In addition, this form allows entities to provide updated information to the NPDB when information changes, and to renew their eligible status to access the NPDB if they were removed for failure to interact with the Data Bank for two years [see '60.3].

(6) Authorized Agent Designation Form is used by eligible entities to designate an agent to interact with the NPDB on their behalf as well as to update that designation status. Since the last clearance this form has been made available electronically through the NPDB-HIPDB web site. Entities now complete and submit this form online. [see ' 60.11(a)].

(7) Account Discrepancy Report is used when a problem occurs in a billing transaction, e.g., an entity believes it has been overcharged for queries or the NPDB has incorrectly applied a credit to the entity=s account [see ' 60.12(c)].

(8) Electronic Transfer of Funds Authorization allows the entity to make payment of the user fee directly from its bank account to the NPDB [see ' 60.12(c)]. This form is now available and completed online through the NPDB/HIPDB web site.

(9) Subject Statement and Dispute Initiation Form enables practitioner or entity subjects of an NPDB report to dispute factual information in that report, add a statement to the report, and/or request secretarial review

of the report. [see 60.14(b)]. This report is now completed and submitted online using the Integrated Querying and Reporting Service (IQRS).

2. Purpose and Use of Information

As stated above, Part B of Title IV requires that certain adverse actions against physicians, dentists, and other licensed health care practitioners be reported to the Secretary or the Secretary's designee and be made available to parties as specified in the Act. Hospitals are required to query the NPDB when a practitioner applies for clinical privileges, or employment, or affiliation with the medical staff, and every two years for all practitioners holding clinical privileges or on the medical staff. The purpose of the NPDB is to restrict the ability of physicians, dentists, and other licensed health care practitioners with a history of substandard practice to move from State to State without disclosure or discovery of their previous damaging or incompetent performance or conduct.

The NPDB receives and releases information on: (1) payments made on behalf of physicians, dentists and other licensed health care practitioners because of medical malpractice actions or claims; (2) licensure disciplinary actions taken by State medical and dental boards; and (3) professional review actions taken by health care entities with peer review processes, such as hospitals or health maintenance organizations, or professional societies, which adversely affect the clinical privileges or membership of a physician or dentist for more than 30 days, if these actions are based on a review of the practitioner's professional performance or conduct.

Changes to Forms and Instructions

There have been minor changes only to the NPDB data collection forms since the last OMB renewal. These changes were done to provide further convenience and/or clarification for users.

3. Use of Improved Technology

The NPDB forms are completely automated to allow easy completion and processing. Among these forms are the Entity Registration Form, the Authorized Agent Designation Form and the Subject Response and Dispute Initiation Form. Further, the reporting and querying forms (including the Medical Malpractice Payment Report, the Adverse Action Report and the Request for Information Disclosure Forms) are completely electronic. In addition, the Electronic Funds Transfer Form also is completed and submitted online. The program has eliminated the use of paper forms for these functions.

The NPDB has increased its use of the Internet and all administrative and access forms are available on the website for downloading.

Entities complete and submit the above listed forms over a secure Internet connection from the Data Bank web site. They may also submit reports via diskette; however, the NPDB continues to discourage reporting by this method.

A number of security features are employed to assure the confidentiality of the information transmitted as well as to prevent unauthorized access. These features include data encryption of all submissions across the Internet, entry of usernames and passwords by all registered users, and firewall protection of the NPDB network and server to prevent unauthorized access from the Internet. The system security plan is reviewed and updated annually to address changes in guidance or industry standards needed to continue providing secrecy and privacy for the system. In addition, every three years the NPDB-HIPDB is required under the

Federal Information System Management Act (FISMA) to conduct and renew the system's Certification and Accreditations (C&A). The C&A process involves convening a panel of information technology professionals who conducts a security review risk assessment, security test and evaluation, technical vulnerability assessment, and a Continuity of Operation Plan (COOP) exercised.

Self-query forms for individuals and organizations are also submitted via the Internet at the Data Bank website. Individuals or organizations complete query information and submit self-query online. The computer system automatically verifies that the online form has been completed correctly, reducing the chance for errors or missing data fields. Self-queriers need only to print the form for signature and notarization. In addition to online reporting and querying, entities may update certain registration information e.g., address, telephone number, directly via the Internet. These updates have replaced updates submitted via paper forms.

4. Efforts to Identify Duplication

Prior to 1990, when the NPDB began operations, a single, consolidated, national repository of information on medical malpractice payments, State licensure disciplinary actions, adverse actions on clinical privileges and professional society membership did not exist.

The Federation of State Medical Boards has maintained a Data Bank of information on State Medical Board licensure actions. Although all States report, participation in this Data Bank is voluntary. The majority of States require some form of reporting of medical malpractice payments, usually to State Medical Boards, but such information is not routinely compiled on a national basis. In some States, information on adverse actions taken by health care entities is reported to the State licensing board, but it has never been collected systematically or been generally available. Similarly, there has been no centralized reporting of professional society membership adverse actions.

HRSA drew on the experience of similar existing information collection systems to the extent feasible when developing the NPDB. For example, the classification system used in reporting licensure disciplinary actions is a modification of the system used by the Federation of State Medical Boards. The classification system used for acts or omissions that resulted in a medical malpractice insurance payment is adapted from a coding system developed by the Harvard Risk Management Foundation. We have worked with members of the malpractice insurance industry to update the coding schemes used to collect medical malpractice payment information for the NPDB. However, standardized methods of collecting the required information typically do not exist.

To the greatest extent possible, information collected by the NPDB is coordinated with the development and implementation of the HIPDB as required by section 1128E of the *Social Security Act*, as amended. The implementation of the HIPDB was proposed by regulatory action as a Notice of Proposed Rulemaking and was published in the Federal Register on October 30, 1998 (63 FR 58341). The HIPDB Final Rule was published in the Federal Register on October 26, 1999 (64 CFR 57740). Those entities that are eligible to receive information from the NPDB and the HIPDB are able to do so with a single query submission. Likewise, reporters that must submit reports to both Data Banks can do so with a single submission.

5. Involvement of Small Entities

The information collected is not expected to have a significant effect on small businesses. The electronic forms incorporate the data elements found in the regulations. Attempts are made to keep data collections to the minimum needed to differentiate adequately among individuals with similar names and to comply with statutory requirements. The use of an authorized agent to report to, and request information from (query), the NPDB at the behest of an eligible entity is at the discretion of that entity.

6. Consequences If Information Collected Less Frequently

Title IV provides that information on medical malpractice payments, State Medical or Dental Board licensure disciplinary actions, and adverse actions on clinical privileges or memberships are to be reported to the NPDB "regularly (but not less often than monthly)." Title IV requires frequent reporting to the NPDB to increase its capacity to provide current information on health care providers to its users. Less frequent collection would place HHS in non-compliance with title IV. In addition, less frequent collection could allow substandard practitioners to remain in practice without detection for longer periods of time, increasing the risk to patient safety.

7. Consistency with the Guidelines in 5 CFR 1320.6

(a) Requiring responses more than quarterly: As noted, title IV provides that information on medical malpractice payments, State Medical and Dental Board licensure disciplinary actions, and adverse actions on clinical privileges or membership is to be reported to the NPDB, "regularly (but not less often than monthly)." Timely information is essential to title IV=s purpose of protecting the public.

(b) Requiring responses within 30 days: The regulations require that reports be submitted to the NPDB within 30 days of the payment or official Board action. Electronic reporting has facilitated this process by allowing entities to transmit reports immediately to the NPDB.

8. Consultation Outside the Agency

The notice required by 5 CFR 1320.8(d) was published in the Federal Register on February 28, 2007 (72 FR 39). No comments were received.

In preparing this request for extension, HRSA consulted with users of the NPDB to detect any problems they may have had with electronic querying and reporting. We have invited comments at conferences of the National Association of Medical Staff Services B an organization whose constituents have mandatory querying and reporting under title IV as their primary responsibility in hospitals, managed care organization as well other health care entities. In addition, we have conducted a Policy and IQRS User Group adjacent to NAMMS' Annual Conference each year since 2005 to elicit feedback on the system and suggestions for changes. Other user group activities are conducted annually in the D. C. area. These meetings are comprised of approximately 50 representative users of the NPDB=s Internet-based reporting and querying service.

Also, HRSA has interacted extensively with users in the insurance industry and have obtained feedback and recommendations from the Harvard=s Risk Management Group, the Physicians Insurance Association of

America as well as members of the NPDB's Executive Committee. Finally, we continue to solicit comments from members of the NPDB Executive Committee as they receive information from their constituents on problems related to the NPDB.

9. Remuneration of Respondents

There will be no remuneration of respondents.

10. Assurance of Confidentiality

Title IV provides, at section 427(b) (1), that information reported to the NPDB is considered confidential and sets forth the circumstances under which it may be disclosed. The regulations at ' 60.10 further specify that the violators of this confidentiality provision are subject to a civil money penalty not to exceed \$11,000 for each violation. The Office of the Inspector General (OIG), Department of Health and Human Services, will impose and collect these penalties. The OIG Final Rule codifying these provisions at 42 CFR 1003 was published June 21, 1991.

Section 60.13, Confidentiality of National Practitioner Data Bank Information, implements title IV's statutory provisions for protecting NPDB information. These provisions state specifically that persons and entities that receive information from the NPDB must use it solely for the purposes for which it was provided. In accordance with the requirements of the *Privacy Act*, a system of records was established for the NPDB on March 17, 1997, with system number 09-15-0054 and system name, "National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners, HHS/HRSA/BHPr.

11. Questions of a Sensitive Nature

The purpose of title IV is to facilitate the exchange of information on medical malpractice payments, licensure disciplinary actions and adverse actions on clinical privileges, information that by its nature may be considered sensitive. The questions on these forms that solicit sensitive information result from requirements of title IV and are necessary to achieve its purposes. Collection of the Social Security Number of report subjects will take place only in accordance with section 7 of the *Privacy Act*. The Social Security Number will be used as an identifier to distinguish among practitioners with similar names. _

12. Estimates of Annualized Hour Burden

The following table, Distribution of Burden by Regulatory Citation, illustrates the burden hours and dollar expenditures associated with the NPDB regulations. The second table, Response Burden Associated with Data Collection and Disclosure Forms, shows the combined burden associated with the forms. It should be noted that the second table totals eight (8) less hours than the first table, which is associated with the regulations. The reason for the difference is that there is not a form associated with the hearing process for entities found in noncompliance [60.9(c)].

Several improvements to the system have reduced the amount of time it takes to report or query. Entities can now maintain a subject database of information on practitioners that they query or report to the NPDB. This allows entities to click on a name stored in their subject database and the subject's information will automatically populate the report or query form. This simplifies reporting and querying processes by eliminating the need for an entity to retype subject information each time they report or query.

Other improvements include the ability to save credit card payment information in the system eliminating the need for users to input this information with each query.

In several cases, burden and expenditure estimates for certain activities are captured as part of the burden for the HIPDB. This is because title IV and section 1128E (the statute governing the HIPDB) have several areas of overlap with respect to reporting and querying requirements. Specifically, the burdens associated with: 1) reports submitted by State licensing boards [including those licensure actions required under 60.8(b)]; 2) self queries by health care practitioners [60.11(a)(2)]; and 3) practitioner disputes, secretarial reviews and subject statements [60.14(b)] submitted for licensure actions are no longer included in the NPDB. Certain burden hour and dollar expenditure estimates are already accounted for in the HIPDB estimates for clearance, and, based on recent operational statistics, these estimates more than accommodate the combined NPDB and HIPDB burdens. More information about each of these specific estimates is provided in the burden descriptions by regulatory section.

There are several cases in which the overlap between title IV and section 1128E requirements are more difficult to separate. Title IV and section 1128E have both unique and common entity types that may query and or report information. The common entities include health care practitioner licensing boards; certain managed care organizations; and, Federal and State hospitals as well as other health care entities. These entities may register to query one or both Data Banks. If they choose to query both, they need to submit only one query via the Internet, and the system automatically will query both Data Banks for them.

The decision to query one or both Data Banks is up to each eligible entity. Because entities sometimes change their preferences during the course of a year, it is difficult to estimate the percentage of queries for both the NPDB and the HIPDB. Therefore, we have decided to estimate the query burden for each Data Bank based on the number of queries each receives, recognizing that a certain percentage of these entities query both Data Banks, which result in a potential overestimate of burden hours and expenditures. We anticipate that with more experience in the querying habits of entities eligible to query both Data Banks, we may be able to refine these estimates in the future.

Distribution of Burden by Regulatory Citation

| Regulation Citation | No. of Respondents | Responses per Respondent | Total Responses | Hours per Response | Total Burden Hours | Wage Rate | Total Cost |
|--|---------------------------|---------------------------------|------------------------|---------------------------|---------------------------|------------------|-------------------|
| 60.6(a) Errors & Omissions | 315 | 4 | 1,260 | 15 min. | 315 | \$25 | \$7,875.00 |
| 60.6(b) Revisions to Action | 109 | 1 | 109 | 30 min. | 54.5 | \$25 | \$1,362.50 |
| 60.7(b) Medical Malpractice Payment Report | 519 | 29 | 15,051 | 45 min. | 11,288.25 | \$25 | \$282,206.25 |
| 60.8(b) Adverse Action Reports-State Boards | 0 ¹ | 0 | 0 | 0 | 0 | 0 | 0 |
| 60.9(a)3 Adverse Action - Clinical Privileges & Professional Society | 480 | 2 | 960 | 45 min. | 720 | \$25 | \$18,000 |
| Requests for Hearings by Entities | 0 | 0 | 0 | 480 min. | 0 | \$200 | 0 |
| 60.10(a)(1) & (2) Queries by Hospital- Practitioner Applications and 2 year cycle | 5,996 | 213 | 1,277,148 | 5 min. | 106,429 | \$25 | \$2,660,725 |
| 60.11(a)(1) Disclosure to Hospitals | 0 ² | 0 | 0 | 0 | 0 | 0 | 0 |
| 60.11(a)(2) Disclosure to Practitioners (Self Query) | 0 ³ | 0 | 0 | 0 | 0 | 0 | 0 |
| 60.11(a)(3) Disclosure to Licensure Boards | 87 | 645 | 56,115 | 5 min. | 4,676.25 | \$25 | \$116,906.25 |
| 60.11(a)(4) Queries by Non- Hospital Health | 7,305 | 322 | 2,352,210 | 5 min. | 196,017.5 | \$25 | \$4,900,437.50 |

¹Included in estimate for reporting adverse licensure actions to the HIPDB in 45 CFR Part 61.

²³ Included in estimate for self queries to the HIPDB in 45 CFR Part 61.

³ Included in estimate for hospital queries under '60.11(a)(4).

| Regulation Citation | No. of Respondents | Responses per Respondent | Total Responses | Hours per Response | Total Burden Hours | Wage Rate | Total Cost |
|---|--------------------|--------------------------|-----------------|--------------------|--------------------|-----------|--------------|
| Care Entities | | | | | | | |
| 60.11(a)(5) Queries by Plaintiffs = Attorneys | 5 | 1 | 5 | 30 min. | 2.5 | \$200 | \$500.00 |
| 60.11(a)(6) Queries by Non-Hospital Health Care Entities-Peer Review | 0 ⁴ | 0 | 0 | 0 | 0 | 0 | 0 |
| 60.11(a)(7) Requests by Researchers for Aggregate Data | 20 | 1 | 20 | 30 min. | 10 | \$38 | \$380.00 |
| 60.14(b) Practitioner Places a Report in Disputed Status | 404 | 1 | 404 | 15 min. | 101 | \$45 | \$4,545.00 |
| 60.14(b) Practitioner Statement | 1,415 | 1 | 1,415 | 45 min. | 1,061.25 | \$100 | \$106,125.00 |
| 60.14(b) Practitioner Requests for Secretarial Review | 27 | 1 | 27 | 480 min. | 216 | \$200 | \$43,200.00 |
| 60.3 Entity Registration – Initial | 1,447 | 1 | 1,447 | 60 min. | 1,447 | \$25 | \$36,175 |
| 60.3 Entity Registration – Update | 13,115 | 1 | 13,115 | 5 min. | 1,092.92 | \$25 | \$27,323 |
| 60.11(a) Authorized Agent Designation – Initial | 717 | 1 | 717 | 15 min. | 179.25 | \$25 | \$4,481.25 |
| 60.11(a) Authorized Agent - Update | 139 | 1 | 139 | 5 min. | 11.58 | \$25 | \$289.50 |
| 60.12(c) Account Discrepancy Report | 5 | 1 | 5 | 15 min. | 1.25 | \$25 | \$31.25 |
| 60.12(c) Electronic Funds Transfer Authorization | 284 | 1 | 284 | 15 min. | 71 | \$25 | \$1,775.00 |
| 60.3 Entity Reactivation | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

⁴ Voluntary queries—not required by law.

| Regulation Citation | No. of Respondents | Responses per Respondent | Total Responses | Hours per Response | Total Burden Hours | Wage Rate | Total Cost |
|---------------------|--------------------|--------------------------|-----------------|--------------------|--------------------|-----------|---------------|
| Total | 32,389 | | 3,720,431 | | 323,694.25 | | \$8,212,337.5 |

Response Burden Associated with Data Collection and Disclosure Forms

| 45 CFR 60 Subpart B | Number of Respondents | Frequency of Response | Number of Responses | Hours per Response | Burden Hours |
|---|-----------------------|-----------------------|---------------------|--------------------|--------------|
| 60.6(a) Adverse Action/Medical Malpractice | 315 | 5 | 1,260 | 15 min. | 315 |
| 60.6(b) Adverse Action | 109 | 1 | 109 | 30 min. | 54.5 |
| 60.8(b) Adverse Action | 0 ¹ | 0 | 0 | 0 | 0 |
| 60.9(a)3 Adverse Action | 480 | 2 | 960 | 45 min. | 720 |
| 60.7(b) Medical Malpractice | 519 | 29 | 15,051 | 45 min. | 11,288.25 |
| 60.10(a)(1) & (2) Hospital Queries | 5,996 | 213 | 1,277,148 | 5 min. | 106,429 |
| 60.11(a)(3) Disclosure to Licensure Boards | 87 | 645 | 56,115 | 5 min. | 4,676.25 |
| 60.11(a)(4) Entity Queries | 7,305 | 322 | 2,352,210 | 5 min. | 196,017.5 |
| 60.11(a)(5) Queries by Plaintiffs' Attorneys | 5 | 1 | 5 | 30 min. | 2.5 |
| 60.11(a)(7) Researcher Requests for Aggregate Data | 20 | 1 | 20 | 30 min. | 10 |
| 60.11(a)(2) Self-Query | 0 ² | 0 | 0 | 0 | 0 |
| 60.14(b) Practitioner Disputes | 404 | 1 | 404 | 15 min. | 101 |
| 60.14(b) Practitioner Statement | 1,415 | 1 | 1,415 | 45 min. | 1,061.25 |
| 60.14(b) Practitioner Requests for Secretarial | 27 | 1 | 27 | 480 min. | 216 |

¹Included in estimate for reporting adverse licensure actions to the HIPDB in 45 CFR Part 61.

²Included in estimate for self queries to the HIPDB in 45 CFR Part 61.

| 45 CFR 60 Subpart B | Number of Respondents | Frequency of Response | Number of Responses | Hours per Response | Burden Hours |
|---|------------------------------|------------------------------|----------------------------|---------------------------|---------------------|
| Review | | | | | |
| 60.3 Entity Registration - Initial | 1,447 | 1 | 1,447 | 60 min. | 1,447 |
| 60.3 Entity Registration – Update | 13,115 | 1 | 13,115 | 5 min. | 1092.92 |
| 60.11(a) Authorized Agent Designation – Initial | 717 | 1 | 717 | 15 min. | 179.25 |
| 60.11 (a) Authorized Agent Designation – Update | 139 | 1 | 139 | 5 min. | 11.58 |
| 60.12(a) Account Discrepancy Reports | 5 | 1 | 5 | 15 min. | 1.25 |
| 60.12(c) Electronic Transfer of Funds Authorization | 284 | 1 | 284 | 15 min. | 71 |
| Total | 32,389 | | 3,722,202 | | 323,694.25 |

These estimates were arrived at in the following manner:

' **60.6(a) Correction of errors and omissions:** Reports made under " 60.7(b), 60.8(b) and 60.9(a) (3) sometimes contain omissions or errors that will be noted by the reporting entity and a correction reported. The corrections require less time than the original report because corrections can be made on an electronic copy of the original report via the NPDB web site, enabling the reporter to change only those elements of the report that require correction. This estimate is based on current operational statistics for the NPDB. Currently, between 9 and 10 percent of reports require correction. As described below, this estimate includes corrections submitted by reporters of medical malpractice payments, and clinical privileges and professional society membership actions. However, this estimate excludes corrections submitted by licensure boards under 60.8(b). These licensure corrections are included in burden estimates for the HIPDB. (1,260 responses x 15 min. = 315 hrs.)

' **60.6(b) Revisions to original report action:** Of the Adverse Action Reports filed by health care entities and professional societies, approximately 150 reports will require revisions to the original reported action. (This new estimate excludes NPDB licensure actions, which are now included in HIPDB estimates.) Revisions are not filed on medical malpractice payments. To file a revision to action report, the reporter must prepare a new report; however, the reporter no longer has to complete an entire reporting form. The web-based reporting system enables the reporter to retrieve a copy of the report to be revised with the subject-related information pre-populated. If this information is unchanged since the last report submission, the entity does not need to complete that section. As a result, the time to complete the revision report is less than that of an initial report. The estimate to prepare a report of a revised action is 30 minutes. (109 responses x 30 min. = 54.5 hrs.)

' **60.7(b) Reporting medical malpractice payments:** Approximately 18,981 Medical Malpractice Reports are filed annually according to current operational statistics. The time burden estimates are based on the 2000 NPDB Users and Non-Users Surveys, which surveyed approximately 650 NPDB reporters, including approximately 160 medical malpractice insurers regarding report preparation time. The Medical Malpractice Payment Report is used for making these reports. (15,051 responses X 45 min. = 11,288.25 hrs.)

' **60.8(b) Reporting licensure actions by Boards of Medical and Dental Examiners:** Dental, medical, osteopathic, and composite boards in the United States submit to the NPDB approximately 4,000 licensure actions taken against physicians and dentists each year. The HIPDB, (which became operational in November 1999) collects these same licensure reports as well as reports of licensure actions taken against other health care practitioners, providers and suppliers. Because reporters that are required to submit reports to both the NPDB and the HIPDB can do so with a single report submission via the web-based reporting system, estimating the burden in both sets of Data Bank regulations would result in double-counting. Therefore, we have discontinued accounting for this reporting burden [60.8(b)] under title IV. Instead, these reports are now included in the HIPDB estimates.

' **60.9(a) (3) Adverse actions on clinical privileges and professional memberships:** This estimate covers reporting by health care entities of adverse actions on clinical privileges and professional memberships. Potential reporters include hospitals, HMOs, medical group practices, professional societies and other organizations that meet the definition of Ahealth care entity@ found in title IV. These estimates were developed from recent operational statistics and input from the NPDB Users and Non-Users Surveys. Current operational statistics demonstrate that approximately 1,046 clinical privileges actions will reported

annually to the NPDB. Each report takes 45 minutes to complete. The Adverse Action Report Form is used for these reports. (960 responses x 45 min. = 720 hrs.)

' **60.9(c) Requests for hearings by health care entities found in noncompliance:** To date, no hearings have been requested nor have there been any cases of clear noncompliance. It is believed that there will not be many such requests for hearings. There are no forms associated with Hearing Requests.

' **60.10(a) (1) Hospital requests for information on applicants:** The burden associated with the querying by hospital for the purpose of granting privileges to physicians and other health care practitioners increased by 3,623.94 hours. This is due to an increase in the number of queries submitted by hospitals annually. Current operational statistics show that hospitals submitted 1,277,148 total queries in the 2006 year. It is our estimate that approximately 20.6 percent (266,872) of these queries are submitted for the purpose of granting privileges to physicians and other healthcare practitioners. We have not changed the original estimate of 5 minutes required to complete the information required on an individual practitioner per query. (266,872 queries x 5 min= 22,239.33 hours)

' **60.10(a)(2) Hospitals must request information on current staff every 2 years:** The burden associated with the requirement that all hospitals query the NPDB on their licensed and/or privileged medical staff every two years has increase due to the increases in the number of queries submitted by hospitals during the 2006 year. Current operational data estimates that hospitals submitted 1,010,276 queries as part of their two year query cycle. Hospitals require approximately 5 minutes per practitioner to prepare a request for information. The Request for Information Disclosure Form (Query) - Individual Subject is used to make these requests. (1,010,276 queries x 5 min. = 84,189.67 hrs.)

' **60.11(a)(1) Disclosure to hospitals:** It is estimated that hospitals will seldom query under this section of the regulation, since they must query the bank for new hires under ' 60.10(a)(1) and review staff in accordance with ' 60.10(a)(2), and query for peer review reasons under ' 60.11(a)(6). We also have no way to distinguish these queries from queries made under ' 60.10(a) (1). The number of requests under this section is included with the number of queries received less than 60.10(a) (1).

' **60.11(a)(2) Disclosure to individual practitioners:** Individuals who submit a self-query automatically have their results sent for both the NPDB and the HIPDB. The Internet-based querying system was designed in this manner to ensure that practitioners received all reports concerning themselves that may be maintained in either Data Bank. As a result, estimating separate self-query burdens for both the NPDB and the HIPDB results in double counting the actual burden imposed on practitioners. To eliminate this problem, we are accounting for all self-query estimates in the HIPDB regulations. The current HIPDB self-query estimate (51,198 self-queries annually) more than accounts for all self queries received by both the NPDB and the HIPDB during the last year, including submissions by practitioners, providers and suppliers.

' **60.11(a)(3) Disclosure to licensure boards:** This section allows medical and dental boards to query the NPDB prior to renewing a license or granting a new license. Operational statistics show that approximately 125 State boards query each year. Based on these statistics, we estimate that there will be 17,996 requests made to the NPDB annually from the 125 boards. (56,115 requests x 5 minutes per request = 4,676.25 hrs.)

' **60.11(a)(4) Disclosure to health care entities (non-hospitals for hiring or granting clinical privileges):** Based on current operational statistics, there are approximately 7,305 non-hospital health care entities that meet the definition of Ahealth care entity@ found in the regulations at '60.3. The major groups of entities included are outpatient departments, group practices, managed care organizations, and

skilled nursing facilities. The NPDB receives about 2,352,210 queries annually from these entities. Managed care organizations now account for more than half of all queries made to the NPDB. (2,352,210 queries x 5 min. = 196,017.50 hrs.)

' **60.11(a)(5) Disclosures to attorneys or individuals who have a malpractice claim under legal review:** During the last three years, we have received approximately five requests per year from plaintiffs= attorneys. However, only two requests have been approved since the NPDB opened in 1990. It appears, that given the severe restrictions on attorney access, few attorneys or plaintiffs see the NPDB as a source of information. Therefore, we have maintained a small amount of time in the request for this type of disclosure. (5 queries x 30 min. = 2.5 hrs.)

' **60.11(a)(6) Disclosure for professional review actions by health care entities:** We are not able to distinguish queries made for the purposes of professional review from other single name queries made under " 60.10(a)(1) and 60.11(a)(4). Queries made for professional review are included in " 60.10(a) (1) and 60.11(a) (4).

' **60.11(a)(7) Disclosure of aggregate information:** Current operational statistics show that approximately 20 individuals, entities, or research organizations request aggregate information from the NPDB for research purposes. We estimate that each researcher requires approximately 30 minutes to prepare a request. (20 requests x 30 minutes = 10 hrs.)

' **60.14(b) Procedures for filing a dispute (to the Data Bank):** A health care practitioner may dispute factual information reported to the NPDB. The subject of a report may initiate a dispute to the NPDB by logging in to the Report Response Service on the IQRS with a special password provided on the Subject Notification form and checking the dispute box on the screen. Although the subject cannot change the report, the NPDB will notify the reporting entity that the subject has disputed the report. If a report is maintained in both the NPDB and the HIPDB, the subject only needs to submit one dispute form, and the system automatically will initiate the dispute in both Data Banks. This estimate, therefore, accounts for all disputes of NPDB reports required to be reported in 45 CFR 60 (excluding licensure actions), regardless of whether the report resides in both Data Banks. Disputes of licensure reports and reports residing only in the HIPDB are accounted for in HIPDB estimates. Based on operational statistics, we estimate that there will be 404 disputes of reports in the NPDB. We estimate that subjects will require approximately 15 minutes to complete the form. (404 disputes x 15 minutes = 101 hrs.)

' **60.14(b) Procedures for requesting a review of a disputed report by the Secretary of the Department of Health and Human Services (Department):** If a health care practitioner subject of a report is unable to resolve a dispute with a reporting entity, the subject may request that the Department review his or her dispute. We estimate, based on discussions with disputants that it takes approximately 8 hours (480 minutes) to prepare their dispute for review. Current operational statistics show that approximately 27 secretarial reviews are requested annually. Requests for Secretarial reviews of licensure actions are accounted for in HIPDB estimates, so this number is inclusive of requests for secretarial review on NPDB reports that are not licensure actions. The current estimate shows a slight increase in the amount of reports placed in Secretarial review. This increase may be attributable to the introduction of the Report Response Service, which provides an easier mechanism for practitioners to elevate their reports to secretarial review. (27 disputes x 480 min. = 216 hrs.)

' **60.14(b) Practitioner Statements:** In response to previous practitioner requests, and in the belief that permitting such a statement might reduce the total number of disputed reports, a practitioner that is the

subject of a report may submit a 2,000-character statement at any time after the NPDB has received a report. A subject may choose to: 1) enter a statement only, 2) initiate a dispute without a statement, or 3) make a statement and have the report entered into dispute status. If the report resides in both the NPDB and the HIPDB, a subject only needs to submit a single statement for that report. We estimate that it will take approximately forty-five minutes to prepare the statement. Based on operational statistics from the Data Bank, we estimate that approximately 1,415 subjects annually will choose to enter a statement into their NPDB report. This estimate applies to reports that reside only in the NPDB and that receive statements. This estimate excludes statements submitted for NPDB licensure reports, which are accounted for in HIPDB estimates. (1,415 statements x 45 minutes = 1061.25 hrs.)

' **60.3 Entity Registration Form Initial:** All entities must register as users of the NPDB and self-certify that they meet the requirements to interact with the Data Bank. Based on current operational statistics we estimate that approximately 1,447 new entities will register annually with the NPDB. We estimate that it takes approximately 60 minutes to complete an initial registration form. (1,447 registrations x 60 minutes = 1,447 hrs.)

' **60.3 Entity Information - Update:** When a registered entity changes status, staff, or location, it must update its registration information. For certain information, such as phone number or address, the entity can now make these updates via the Internet. For other information, the changes must be made on a paper form. (The update function is now included in the Entity Registration form online and the Entity Update form has been eliminated.) Since the last clearance, updates have decreased slightly below the estimate in the last clearance package. Based on current operational statistics, we estimate that there will be approximately 13,115 updates per year for current NPDB users. Because the majority of these updates will occur via the Internet (nearly 2 out of every 3 this year), we estimate that each update will take approximately 5 minutes to complete. (13,115 updates x 5 minutes = 1092.92 hrs.)

' **60.11(a) Authorized Agent Designation - Initial:** For an entity to use an agent to interact with the NPDB on its behalf, the entity must officially designate the agent. The entity does this by completing the designation form. Since the NPDB completely eliminated paper reporting and established an all electronic payment system, many more users have elected to designate agents to handle their reporting and querying activities. Based on current trend information from the NPDB, we estimate that approximately 717 entities registered with the NPDB will enter into agreements with agents in each of the next three years. We estimate that it takes approximately 15 minutes to complete the designation form. (717 designations x 15 minutes = 179.25 hrs.)

' **60.11(a) Authorized Agent - Update:** When an entity changes its relationship with an agent, it must notify the NPDB. Since before the last clearance this function has been included in the Authorized Agent Designation form and the previous Authorized Agent Designation Update Form was eliminated. We estimate that the NPDB will receive 139 agent designation updates each year and that the updates will take approximately 5 minutes. (139 responses x 5 minutes = 11.58 hrs.)

' **60.12(c) Account Discrepancy Report:** The account discrepancy report is used when an entity cannot reconcile its credit card statement or debit notification with the number of queries for which it paid. The Data Bank staff uses this notification to begin its research into whether the entity should receive a refund or additional payment is required. Based on operational statistics from the NPDB, we project that entities will file the discrepancy report approximately 5 times in a year. We estimate that the form requires approximately 15 minutes to complete. (5 discrepancy reports x 15 minutes = 1.25 hrs)

' **60.12(c) Electronic Transfer of Funds Authorization Form:** If an entity wishes to use the electronic transfer of funds mechanism to pay for its queries, it must complete this authorization. The change to all-electronic payments has significantly increased the number of electronic transfer requests that the NPDB receives. Based on Data Bank operational statistics, we project that approximately 284 entities per year will complete this form. We estimate that it takes approximately 15 minutes to complete the form. (284 authorization requests x 15 minutes = 71 hrs.)

' **60.3 Entity Reactivation:** If an entity fails to interact with the NPDB for two years it will be removed from the list of entities eligible to access the NPDB. If such an entity wishes to renew interaction with the Data Bank it must complete an Entity Registration form and indicate that it intends to reactivate its status with the NPDB. Entities that wish to reactivate must complete the entire registration form to ensure that their statutory authorities to interact with either the NPDB, the HIPDB or both Data Banks have not changed. The estimate for this activity is included in §60.3, Entity Information –Update, above.

13. Estimates of Annualized Cost Burden to Respondents

There are no capital and start-up costs because the NPDB became operational on September 1, 1990.

Operation and Maintenance Costs: Since 1990, the NPDB has operated entirely on user fees. The regulations at '60.12 describe the user fees that will be assessed on requests for information from the Data Bank. On July 24, 1990, the National Practitioner Data Bank’s user fee was published in the Federal Register. The user fee was initially established at \$2.00 per named practitioner for the costs of processing requests and disclosing information (except for self queries). Since that time there have been several changes in the fee structure. On July 1, 2003 the query fee was decrease to \$4.25. Most recently, this fee was raised from \$4.25 to \$4.75 per query to the NPDB. This change took effect as of May 9, 2006. This fee was published in the Federal Register on March 10, 2006 (71 FR 12368). The cost to perform a self query is \$8 for the NPDB. This fee was decreased from \$10 on July 1, 2004 and was published in the Federal Register on May 24, 2004 (69 FR 29565). Practitioner self-queries are automatically assessed for both Data Banks.

| NPDB User Fee Data (FY 2006) | |
|-------------------------------------|------------------------|
| Queries from Entities: | \$16,330,460.25 |
| Self-Queries: | \$ 409,588.00 |
| Total | \$16,740,048.00 |

14. Estimate of Annualized Cost to the Federal Government

The NPDB does not receive any appropriations and is required by statute to recover the full costs of operations through user fees, which are charged for the disclosure of information.

15. Changes in Burden

There are currently 293,589 hours in the OMB Inventory for this program. This request is for 323,694 hours for an increase of 30,105 hours. This increase is the primarily the result of an increase in the number of requests for information (queries) by non-hospital health care entities—mainly managed care organizations. These requests for information are voluntary and not required by law as in the case of hospitals; however, the number of respondents overall for the data bank has increased since the last

clearance request. This increase is a program adjustment from 293,589 hours to 323,694 hours for a **30,105 hour increase.**

16. Time Schedules, Publication and Analysis Plans

There are no plans for publication of the data to be collected on these forms. Ultimately, data, stripped of identifiers, will be available to HRSA for use in preparation of required Reports to Congress, and to HRSA and others for research purposes.

17. Exemption for Display of Expiration Date

The expiration date will be displayed.

18. Certifications

This information collection fully complies with 5 CFR 1320.9. The certifications are included in the package.