Expansion of the National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Section 1921 of the Social Security Act

Notice of Final Rule
SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances of Information Collection

The Health Resources and Services Administration (HRSA) is requesting Office of Management and Budget (OMB) approval of the information collection requirements contained in the attached final rule. This final rule implements section 1921 of the Social Security Act (section 1921), as amended by Section 5(b) of the Medicare and Medicaid Patient and Program Protection Act of 1987,Public Law 100-93, and as amended by the Omnibus Budget Reconciliation Act of 1990, Public Law 101-508. The 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 are cleared under OMB No. 0915-0126. The NPDB is authorized by Title IV, Pub. L. 99-660, the Health Care Quality Improvement Act of 1986 (HCQIA) (42 U.S.C. 11101). The NPDB became operational on September 1, 1990.[1]

The section 1921 legislation modifies the existing regulations governing the NPDB at CFR 45 part 60 and expands the type of information collected by the NPDB. Specifically, section 1921 authorizes the collection of adverse actions taken by State licensing authorities against all health care practitioners and health care entities (currently the HCQIA authorizes only collection of information on licensure actions taken against physicians and dentists) as well as any negative action or finding taken by a private accreditation entity and peer review organizations. The Notice of Proposed Rule Making (NPRM) proposed to exclude the Center for Medicare and Medicaid Services' Quality Improvement Organizations (QIOs) from the proposed definition of "peer review organization" because of the unique role these Federal contractors play in quality improvement efforts. Commenters generally agreed with this proposal, so this clearance request does not contain burden estimates for the collection of negative actions or findings from QIOs. Section 1921 also makes this information available to a broader group of organizations than are able to request HCQIA information from the NPDB. Additionally, section 1921 is the only legislative mechanism through which private-sector hospitals can request licensure information on non-physician and non-dentist health care practitioners who are employed by hospitals.

Specifically, approval is requested for the following reporting administrative information and data collection burden required in Section 1921.

1 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.

1.2 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 addition or correction.

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

§ **60.9 Reporting licensure actions taken by States (New)**

(New) 60.9 This paragraph identifies the data elements to be reported to the NPDB by State licensing authorities regarding adverse actions taken against health care practitioners, physicians, dentists, or health care entities. Reportable actions include any adverse licensure action taken as the result of a formal proceeding, including revocation or suspension; any dismissal or closure of a formal proceeding due to the practitioner's or entity's surrender of licensure; any other loss of licensure (excluding nonpayment of renewal fees, retirement, or change to inactive status); and any negative action or finding that is publicly available, excluding administrative fines and citations, and corrective action plans, unless they meet the requirements as stated in the regulations.

§ **60.10 Reporting negative actions or findings taken by a peer review organization or private accrediting entity (New)**

(New) 60.10 This paragraph specifies the information to be reported by each State regarding any negative action or finding taken against a health care practitioner, physician, dentist, or health care entity by a peer review organization or private accreditation entity. Only peer review organizations that are not QIOs are eligible to report to the NPDB.

§ **60.11 Reporting adverse actions on clinical privileges**

Re-designated - formerly §60.9

60.11(a)(3) This subparagraph specifies the information that must be reported to the NPDB regarding 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. Such information on other health care practitioners may be reported on a voluntary basis (subparagraph (a) (2)). (Note that, with the advent of electronic reporting, entities now report these actions directly to the NPDB and then forward the information to the State boards.)

60.11 (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.)

60.11 (c) This paragraph identifies the hearing and review process 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 the health care entity had failed to report as required under §60.9(a)(3).

§ **60.12 Information which hospitals must request from the National Practitioner Data Bank**

Re-designated - formerly §60.10

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

(1) When a physician, dentist or other practitioner applies for clinical privileges or affiliation with the medical staff 60.10(a) (1); and

(2) Every two years for physicians, dentists and other practitioners holding clinical privileges or who are on the medical staff 60.10(a) (2).

§ **60.13 Requesting information from the National Practitioner Data Bank**

Redesignated – formerly §60.11

60.13(a) (1) This paragraph identifies entities that and persons who, under specified conditions, may have access to practitioners' records or statistical data from the NPDB reported under the HCQIA.

(i) Hospitals to review medical staff,

(ii) Individual physicians, dentists and other practitioners checking their own records,

(iii) State licensing boards,

(iv) Other health care entities for hiring or affiliating with practitioners,

(v) An attorney or individual who has a malpractice claim under legal review,

(vi) A health care entity for purposes of professional review, and

(vii) Researchers (statistical data stripped of identifying information only).

(New) 60.13(a) (2) This paragraph identifies entities that and individuals who, under specific conditions, may have access to practitioners' or entities' records or statistical data reported under §§60.9 and 60.10 from the NPDB (authority for querying only on information collected under section 1921).

(i) Agencies administering Federal health care programs, including private entities administering such programs under contract;

(ii) Authorities of States (or political subdivisions thereof) which are responsible for licensing health care practitioners and entities;

(iii) State agencies administering or supervising the administration of State health care programs;

(iv) State Medicaid Fraud Control Units;

(v) Law enforcement officials and agencies;

(vi) Utilization and quality control Quality Improvement Organizations (QIOs) under contract with the Centers for Medicare and Medicaid Services (CMS);

(vii) Hospitals and other health care entities;

(viii) Individual practitioners, physicians, dentists, and entities checking their own records; and

(ix) Researchers (statistical data stripped of identifying information).

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.

§ **60.16 How to dispute the accuracy of National Practitioner Data Bank information**.
Re-designated – formerly 60.14

60.16(b) This paragraph describes the process to be followed by a physician, dentist or other practitioner or a health care entity that is the subject of a NPDB report in disputing the factual accuracy of a report to the NPDB. This includes the subject's rights to enter a statement into the report and to request review of the report by the Secretary of the Department of Health and Human Services.

1.3 Reporting

The following information (Adverse Action Report, Request for Information Disclosure, Entity Registration, and Subject Statement and Dispute) is required to implement section 1921. Users complete all NPDB forms electronically over a secure Internet connection when reporting or querying.

Online forms have not been changed substantively since the OMB numbers were issued. However, some minor editorial changes have been made to the online forms since the NPRM in March 2006 and were approved under OMB Number 0915-0126 in 2007. These changes are not substantive; they did not result in the addition of new data elements. The changes were implemented to:

- Increase user convenience,
- Provide user clarification, or
- Provide additional instructions.

Further, when comparing the NPRM Self-Query form to the final rule Self-Query form, the fee for self-querying has changed since December 2005. The fee change for the NPDB took place May 6, 2004 and the fee change for the HIPDB took place May 24, 2004. At that time, the fee changed from $10 to $8 for self-querying.

a. **Adverse Action Report Form** This form accommodates the reporting of adverse actions and negative actions or findings specified under §§60.8(b) through 60.11. The form accommodates report subjects: health care practitioners, physicians, dentists and entities. Because the requirements are slightly different for each type of action, there are differences in the information required.

1. State medical and dental licensing authorities and, under section 1921, other State licensure or certification authorities must submit a report using this form to the NPDB when they take a formal action against a health care practitioner, physician, dentist or entity. 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)].

2. A peer review organization or private accreditation organization must report any negative action or finding by using this form.

In addition, this form is used to report information concerning errors, omissions, or revisions-to-action to reports of adverse actions against:

i. Licensure,
ii. Clinical privileges, and
iii. Professional society membership.

Finally, as required under §§60.6(a) and 60.6(b), peer review organizations, and private accreditation organizations will use this form to report revisions to reported actions against health practitioners and entities.

Such revisions include the extension of a practitioner's period of licensure suspension or the reinstatement of a license. It should be noted that both the current NPDB regulations as well as section 1921 regulations require States to establish a central location through which all reports to the NPDB would be sent by the reporting entities. Since the development of electronic reporting technology, however, reporting entities have submitted reports directly to the NPDB.

b. **Information Disclosure (Query) Forms**

1. Request for Information Disclosure (Query) on an Individual. These forms are used to request information from the NPDB that was reported under the HCQIA and section 1921. Any information received from the NPDB is not intended to be a substitute for other information that maybe used in verifying the credentials of healthcare practitioners. Rather, it is intended to draw attention to patient care or conduct incidents that may merit closer scrutiny. In addition, this includes several additional optional data elements for querying entities to include. These data elements will enhance matching of queries with section

1921 reports that may contain additional information. The following types of entities may receive information from the NPDB as reported under §§60.7 through 60.11 (i.e., under both the HCQIA and section 1921):

(i) A hospital to review medical staff or for clinical privileges [§60.12(a), §60.13(a)(2)(vii)], a health care entity with respect to professional review activity [§60.13(a)(1)(vi), §60.13(a)(2)(vii)], and a hospital or health care entity when entering into an employment or affiliation relationship [§60.13(a)(1)(i), §60.13(a)(1)(iv), and §60.13(a)(2)(vii)]; and

(ii) A State medical or dental board or other State health care practitioner licensing authority [§60.13(a)(1)(iii)].

2. The following entity types may request from the NPDB information collected only under §§60.9 and 60.10 (i.e., information collected under section 1921 only) for the 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 those programs.

(i) Agencies administering Federal health care programs, including private entities under contract [§60.13(a)(2)(i)];

(ii) State authorities that license health care entities [§60.13(a)(2)(ii)];

(iii) State agencies administering or supervising the administration of State health care programs (as defined in 42 U.S.C. 1128(h)[§60.13(a)(2)(iii)]:

(iv) State Medicaid Fraud Control Units (as defined in 42 U.S.C. 1903(q))[§60.13(a)(2)(iv)]:

(v) Law enforcement officials and agencies [§60.13(a)(2)(v)]; and

(vi) Utilization and quality control Quality Improvement Organizations described in part B of Title XI and to appropriate entities with contracts under Section 1154 (a)(4)(C) of the Social Security Act with respect to eligible organizations reviewed under the contracts [§60.13(a)(vi)].

3. Individual Self-Query Form. Individual self-queries are submitted automatically to both the NPDB and the HIPDB, and practitioners pay a self-query fee for both Data Banks. This form contains the same data elements as those submitted for clearance approval for the HIPDB program as well as section 1921 NPRM. However, the following change has been made for user clarification. In the "Home or Work Address" section the following is added before the "Street Address" field: *"Note: If specifying a work address, be sure to include the employer name in the first line of the address."* Additionally, it may appear that the fee for an individual self-query has changed since 2005. The fee change for the NPDB actually took place May 6, 2004 and the fee change for the HIPDB took place May 24, 2004. At that time, the fee changed from $10 to $8 for self-querying.

4. Request for Information Disclosure (Query) – organizations. This form enables entities, eligible under section 1921, to request information concerning health care entities.

5. Organization Self-Query Form. For the NPDB, this form is intended to accommodate self-queries made by health care entities that may be the subjects of new reports collected by the NPDB under Section 1921. This is the same form as was submitted and approved for the HIPDB program. With the implementation of section 1921, new respondents will use the form.

c. Access and Administrative Forms

1. Entity Registration Form is used by entities to self-certify to the NPDB that they meet the regulatory requirements needed to interact with the Data Bank. The completion of the Entity Registration document allows the entity to begin interacting with the Data Bank. This document is completed online. Online registration continues to enable entities to register with the NPDB as well as the Healthcare Integrity and Protection Data Bank (HIPDB) simultaneously. In addition, this form allows entities to provide updated information to the NPDB when information changes, and to renew their eligibility status to access the NPDB biennially [see §60.3].

   As mentioned above, the Entity Registration form is used to register entities for the NPDB and the HIPDB. In addition, it will be used to register eligible entities to interact with section 1921.

2. 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 [§60.16(b)]. This report is now completed and submitted online using the 3/13/20073/13/2007. The information collected about failure to report and disputes of accuracy as specified at §§60.11(c) and 60.16(b) is used in the resolution of disputes regarding either compliance with a health care entity's required reporting or by a practitioner disputing of the factual accuracy of information reported to the NPDB.
   A change has been made to this form that provides convenience to the users. Immediately after the Public Burden Statement is the following statement: *"Check here if you wish to remove your statement from the referenced report. (If you have a statement on file, it will appear below.)"*

2. Purpose and Use of Information

The HCQIA requires that certain adverse data regarding physicians, dentists, and other licensed health care practitioners be reported to the Secretary of Health and Human Services, or to the Secretary's designee, and be made available to parties as specified in the Act. Hospitals are required to query the NPDB at specified times. 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) medical malpractice payments made on behalf of physicians, dentists and other licensed health care practitioners; and (2) disciplinary licensure actions taken by State medical and dental boards. The NPDB also receives and releases information on the professional review actions taken by health care entities with peer review processes, such as hospitals, other health care entities (e.g. 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 process that includes a peer review of the practitioner's professional competence or conduct.

Section 1921 expands the role of the NPDB to collect new types of adverse action reports as well as to make that information available to a larger group of entities. These entities may query the NPDB to receive section 1921 information for the 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.

Specifically, section 1921 requires each State to adopt a system of reporting to the Secretary certain adverse licensure actions taken against a health care practitioner or health care entity by any authority of the State responsible for the licensing of such practitioners or entities. It also requires each State to report to the Secretary any negative action or finding that a private accreditation entity, peer review organization, or State licensing authority has concluded against a health care practitioner or a health care entity. The State licensing authorities, peer review organizations, and private accreditation entities will report directly to the NPDB, as do all other reporting entities currently interacting with the NPDB.

Section 1921 expands the scope of the NPDB by permitting queries from additional entities, such as agencies administering Federal health care programs, State Medicaid Fraud Control Units, QIOs and law enforcement officials to query the NPDB for adverse licensure actions and other negative actions or findings on health care practitioners or health care entities reported under section 1921.

HRSA selected System Research Applications International Incorporated (SRA) to operate the NPDB. The contract is monitored by HRSA's Division of Practitioner Data Banks Branch, Bureau of Health Professions.

3. Use of Improved Information Technology

The implementation of section 1921 will be fully automated and will fit within the structure of the existing NPDB. Forms can be accessed and completed online and are therefore electronic.

4. Efforts to Identify Duplication

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.

With respect to the section 1921 information, private accreditation entities such as the Joint Commission and the National Committee for Quality Assurance (NCQA), and some State Boards maintain websites where summary information on their negative actions or findings can be accessed. We know of no similar web sites that peer review organizations maintain.

Until this time, there has been no single, consolidated, national repository of information on medical malpractice payments, State licensure and certification disciplinary actions, adverse actions on clinical privileges and professional society membership, and negative actions or findings by accreditation entities and peer review organizations to which reporting is required.

The automated system allows entities to submit one report for incidents where more than one adverse action is taken against a practitioner or organization. This eliminates the need for entities to submit more than one report on a single incident. The NPDB and the Healthcare Integrity and Protection Data Bank (HIPDB)[2] share many data collection forms so that some entities (licensure and certification agencies) that report to or query both Data Banks may do so without duplication of effort. The content of the Adverse Action Report for clinical privileges and professional society actions remains unchanged.

The Authorized Agent Designation form includes the function of both agent designation and agent designation update. The online version of the Authorized Agent Designation form enables entities to update agent designation status on file with the NPDB and also enables entities to designate new agents to interact on their behalf with the Data Bank. Since the last NPRM clearance, a change that provides convenience to the user has been added. In the section, "Agent Information," immediately after the fields for agent city, state and zip code is the following question: *"Allow Agent to:* ☐ *Query* ☐*Report."* This question allows entities to specify the duties of their selected agent.

There is no other data collection activity that collects and maintains the information required under section 1921.

2 The HIPDB was created to combat fraud and abuse in health insurance and health care delivery. The HIPDB is primarily a flagging system that may serve to alert users that a comprehensive review of a practitioner's, provider's or supplier's past actions may be prudent.

5. Involvement of Small Entities

Section 1921 information collection is not expected to have a significant effect on small businesses. The forms incorporate data elements found in the regulations. Attempts were made to keep data collections to the minimum needed to differentiate adequately between individuals and entities with similar names and to comply with statutory confidentiality requirements. Entities are eligible to use an authorized agent to report to and query the NPDB if they do not have the needed equipment.

6. Consequences If Information Collected Less Frequently

The HCQIA 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)." The HCQIA requires frequent reporting to the NPDB to increase its capacity to provide current information on health care practitioners to its users. Less frequent collection would place HHS in non-compliance with the HCQIA. In addition, less frequent collection could allow substandard practitioners to remain in practice without detection for longer periods of time, increasing the risk to patients.

7. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

(a) Requiring responses more than quarterly: As noted, the HCQIA 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 the HCQIA'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 Data Banks.

Section 1921 requires that each State adopt a system of reporting to the NPDB for reports to be filed in accordance with the requirements of the statute. However, under the proposed regulations for section 1921, we anticipate that States will be responsible for reporting to the NPDB only those actions which the State authorities and agencies take themselves. We will require that private accreditation entities and peer review organizations report their negative actions or findings directly to the NPDB. The reports from State licensing and certification authorities, peer review organizations, and private accreditation entities will be submitted within 30 days of the action. This conforms to requirements for the current HCQIA reporters.

8. Consultation Outside the Agency

The Notice of Proposed Rulemaking was published in the *Federal Register* on March 21, 2006 (Vol. 71, No. 54, pages 14135-14149). In preparing the Notice of Proposed Rulemaking, HRSA consulted current and potential users of section 1921 information in the NPDB, including 17 professional associations for State licensing boards and three of the major private accreditation entities, including the Joint Commission, the National Committee for Quality Assurance (NCQA), and the Utilization Review Accreditation Commission (URAC). The input from these entities was used to develop the NPDB reporting format for these entities.

In addition, HRSA consulted with the Centers for Medicare and Medicaid Services (CMS) concerning requirements regarding QIOs with which CMS contracts and peer review organizations

in general. As previously noted, these discussions led to the determination that QIOs under contract with CMS would not be required, by the regulations, to report to the NPDB. The QIOs are eligible to query the NPDB for section 1921 information.

All of these entities were invited to comment on various implementation issues, such as potential reporting data elements and the feasibility of requiring electronic transmission. They also had an opportunity to comment again on the NPRM.

In preparing this request for the expansion of the NPDB under section 1921, we consulted with users of the NPDB to detect any current problems they may have had with electronic querying, reporting, and payment. We received feed-back from a sample of current NPDB reporters and current NPDB queriers.

Since the beginning of the NPDB, we have routinely attended and exhibited at the annual conference of the National Association of Medical Staff Services (NAMSS) this is an organization whose constituents have mandatory querying requirements under the HCQIA and could play a significant role in querying under section 1921.

A users group was formed comprised of approximately 20 representative users of the NPDB's Internet-based reporting and querying service. This group convenes approximately twice per year and provides input to HRSA concerning issues of reporting and querying. We will be incorporating users and potential users of section 1921 into this group after publication of this final rule.

Finally, we received comments from members of the NPDB Executive Committee who have received information from their constituents on problems related to the NPDB. The NPDB Executive Committee meets twice annually to discuss issues related to NPDB operations. Because section 1921 is part of the NPDB, the contractor will be able to utilize the resources of the NPDB Executive Committee as the program is implemented.

After the publication of the NPRM, HRSA received a total of seven comments related to information collection under section 1921. The comments we received supported the continued exclusion of QIOs from reporting under section 1921. These comments and HRSA's responses are included as a separate attachment.

9. Remuneration of Respondents

Respondents will not be remunerated.

10. Assurance of Confidentiality

The HCQIA 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 §60.13 (redesignated as §60.15 of the final rule), 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 assurance of confidentiality provided by the HCQIA, applies to section 1921. 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.

This provision, §60.15 Confidentiality of National Practitioner Data Bank Information, implements the HCQIA's statutory provisions concerning confidentiality. The section states specifically that persons who and entities that receive information from the NPDB must use it solely for the purposes for which it was provided.

11. Questions of a Sensitive Nature

The purpose of the HCQIA is to facilitate the exchange of information on medical malpractice payments, licensure disciplinary actions and adverse actions on clinical privileges and professional society membership, information that by its nature may be considered sensitive. The purpose of section 1921 is to expand the type of information that the NPDB collects and to expand disclosure to existing NPDB users, as well as give new organizations such as government health care programs and law enforcement agencies access to section 1921 information. The questions on these forms which solicit sensitive information result from requirements of these two authorizing statutes and are necessary to achieve their 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 only as an identifier to distinguish among practitioners with similar names.

12. Estimates of Annualized Hour Burden

The following table illustrates the burden hours and dollar expenditures associated with the section 1921 expansion of the NPDB regulations.

There are several cases in which overlap among the HCQIA and section 1128E of the Social Security Act (HIPDB) requirements are difficult to identify solely under one set of legislative requirements. Certain types of entities may query under the current NPDB, section 1921 and section 1128E. These include health care practitioner licensing boards, managed care organizations, and government hospitals. Also, section 1921 and section 1128E both authorize law enforcement agencies and Federal and State government health care programs to request information. 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 will automatically submit the query to both Data Banks.

Response Burden Associated with Section 1921

Section Number	Number of Respondents	Frequency of Response	Number of Responses	Hours per Response	Burden Hours	Hourly Cost	Total Cost
Errors and Omissions 60.6 (a)	23	1	23	15 min.	5.75	$25	$144
Revisions to Actions 60.6 (b)	7	1	7	30 min.	3.5	$25	$88
Licensure Actions 60.9	0[1]	0	0	0	0	0	0
Adverse Action 60.10 Private Accreditation Entities	11	1	11	45 min.	8.25	$25	$206
Adverse Action 60.10 Peer Review Organizations	25	2	50	45 min.	37.50	$25	$938
Queries: Agencies administering Federal health care programs 60.13 (a)(2)(i)	10	26	260	5 min.	21.66	$25	$542
Queries: State Licensing Authorities 60.13(a)(2)(ii)	0	0	0	0	0	0	0
Queries: State Agencies 60.13 (a)(2)(iii)	51	20	1020	5 min.	85	$25	$2,125
Queries: State Medicaid 60.13 (a)(2)(iv)	51	20	1020	5 min.	85	$25	$2,125
Queries: Law Enforcement 60.13 (a)(2)(v)	262	1	262	5 min.	21.83	$25	$546
Queries: QIOs 60.13 (a)(2)(vi)	51	5	255	5 min.	21.25	$25	$531
Queries: Hospitals and other health care entities 60.13 (a)(2)(vii)*	10,930	11	120,230	5 min.	10,019.16	$25	$250,479
Self-Query 60.11(a)(2)	0[2]	0	0	0	0	0	0
Entity Registration 60.3	50	1	50	60 min.	50	$25	$1,250

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

[2]Included in estimate for self queries to the HIPDB in 45 CFR part 61.

* Included as eligible to query under current NPDB 45 CFR part 60 regulations.

Section Number	Number of Respondents	Frequency of Response	Number of Responses	Hours per Response	Burden Hours	Hourly Cost	Total Cost
Entity Update 60.3	25	1	25	5 min.	2.08	$25	$52
Initial Request for Dispute of Report 60.16(b)	18	1	18	15 min.	4.5	$45	$203
Practitioner Requests for Secretarial Review 60.16(b)	3	1	3	8 hours	24	$200	$4,800
Subject Statements 60.16(b)	40	1	40	60 min.	40	$100	$4,000
Total	**11,557**		**123,274**		**10,429**		**$268,029**

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. As described below, this estimate excludes corrections submitted by licensure boards under 60.8(b). These licensure corrections are included in burden estimates for the HIPDB. Section 1921 will only add a small burden of reports filed requiring corrections or additions by private accreditation entities and peer review organizations, since there are so few initial reports under the authority. (23 Responses x 15 min. = 5.75 hours)

§ **60.6(b) Revisions to original report action:** Of the Adverse Action Reports filed by peer review organizations and private accreditation entities, approximately 7 reports are expected to require revisions to the original reported action. (This new estimate excludes NPDB licensure actions, which are now included in HIPDB estimates.) To file a revision to the 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. (7 reports x 30 min. = 3.5 hours)

(New) 60.9 Reporting Licensure Actions Taken by States
This is a new reporting requirement associated with the implementation of section 1921. State agencies that license or certify health care practitioners, physicians, dentists or health care entities are required to report to the NPDB disciplinary licensure actions and negative actions or findings. The same licensing agencies are responsible for reporting these actions to the HIPDB. Therefore, we calculate the annual reporting burden for State licensing agencies under the HIPDB. Reporting burden for State licensing agencies is not included in the section 1921 regulations.

(New) 60.10 Reporting of negative actions or findings of private accrediting organizations:
This is a new reporting requirement associated with the implementation of section 1921. Such accreditation organizations include, but are not limited to: the Joint Commission, the National Committee for Quality Assurance (NCQA), and the Utilization Review Accreditation Commission (URAC). These organizations will report final determinations of denial or termination of accreditation status that indicate a risk to patient safety or the quality of health care services. Because of the limited range of reportable actions, we estimate that 11 private accreditation organizations will file an average of one report each per year and that each of these 11 reports will take approximately 45 minutes to complete. (11 reports X 45 min. = 8.25 hours)

(New) 60.10 Reporting of negative findings of peer review organizations: This is a new reporting requirement associated with the implementation of section 1921. These are organizations who evaluate the quality of patient care or services ordered or performed by health care practitioners. As previously noted, the NPRM currently does not require reporting by QIOs that contract with CMS. We requested public comments regarding the number and activities of the non-QIO peer review organizations. While commenters did not offer specific volume estimates, they indicated that these reports would be infrequent. It is noteworthy that we did not receive comments from the QIO or peer review organization community. Based on our research and comments received, we estimate that there are approximately 25 peer review organizations that will report an average of two (2) actions per year. (50 reports X 45 minutes = 37.50 hours)

§ **60.13(a)(2)(i) Agencies that administer Federal health care programs, including private entities administering such programs under contract:** It is estimated that the number of queries will be small as these entities can query the HIPDB with no fee. Query fees under the HIPDB are not charged to Federal agencies. Additionally, by querying the HIPDB these entities will receive criminal conviction information not available in the NPDB. (260 requests x 5 minutes = 21.66 hours).

§ **60.13(a)(2)(ii) Authorities of States (or political subdivisions thereof) that are responsible for licensing health care practitioners and entities:** The query burden for these licensing authorities is included in the HIPDB clearance. There is no reason to believe that Section 1921 will increase queries from the State licensing Boards. Zero burden under section 1921.

§ **60.13(a)(2)(iii) State agencies administrating or supervising the administration of State health care programs (as defined in 42 U.S.C. 1128(h)):** Since querying is voluntary, the number of queries from State agencies is expected to be limited because the agencies can already receive State licensing actions from the HIPDB, in addition to other adverse actions reported to that Data

Bank. The only new information available to these agencies under section 1921 would be peer review organization and private accreditation action reports. (1020 requests x 5 min. = 85 hours)

§ **60.13(a)(2)(iv) State Medicaid fraud control units (MFCU) (as defined in 42 U.S.C. 1903(q)):** Since querying is voluntary, a limited number of queries are expected to be received from MFCUs. They have been active in querying HIPDB, but there is little new information for them to receive by querying NPDB. (1020 requests x 5 min. = 85 hours)

§ **60.13(a)(2)(v) Law enforcement officials and agencies such as: United States Attorney General, United States Chief Postal Inspector, United States Inspector General, United States Attorneys, United States Comptroller General, Drug Enforcement Administration, United States Nuclear Regulatory Commission, State law enforcement agencies such as State Attorneys General:** This regulatory provision is expected to require limited burden. The Federal officials and agencies have access to HIPDB without paying the query fee. There has been little querying of HIPDB by the State entities, and it is anticipated that this will continue for access to NPDB. We estimate that law enforcement entities will only file 262 requests with the NPDB. (262 requests x 5 min. = 21.83 hours)

§ **60.13(a)(2)(vi) Utilization and quality control Quality Improvement Organizations (QIOs):** We have estimated a small burden for queries from QIOs. The QIOs do not have access to HIPDB. The needs of the QIOs for the information collected under 1921 is not clear, so it is estimated that there will be approximately 255 annual queries from these entities.
(255 requests x 5 min. = 21.25 hours)

§ **60.13(a)(2)(vii) Hospitals and other health care entities as (defined in the NPDB):** Managed care organizations, which are the bulk of other health care entities, as well as other types of health care entities already have access to HIPDB information. Therefore, these entities are included in the HIPDB burden estimates and are not include in the burden estimates for section 1921.

While querying under section 1921 is voluntary for hospitals, we anticipate that these entities are most likely to query for the information collected under section 1921. Private-sector hospitals and some other health care entities do not have access to HIPDB. Thus, they currently have no access to information regarding State licensure information on practitioners who are not physicians or dentists. This group of practitioners constitutes a large part of a hospital's staff and may be the majority of staff in such entities as nursing homes. It appears that the volume of non-mandatory (voluntary) querying is dependent on the price of a query and the availability of entity resources to query. Recent well-publicized problems with apparent failures by health care entities to review the backgrounds of applicants may lead to greater use of this information by these entities. If hospitals queried on all initial applicants and recredentialed even 50% of their non-physician/ non-dentist staff the number of queries would far exceed our estimate. We estimate that these entities will query the NPDB, for section 1921 information, 120,230 times per year.
(120,230 requests x 5 min. = 10,019.16 hours)

§ **60.13(a)(2)(ix) Disclosure of aggregate information:** Estimates for this category of queries is contained in the burden shown in **§**60.(a)(1)(vii). Because these individuals generally ask for the entire NPDB file, we estimate that there will be no increase in the number of requests due to the implementation of section 1921.

§ **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 under the HCQIA and section 1921. Current entities have already certified the eligibility for section 1921. Based on current operational statistics and our estimates of anticipated new registrations required for section 1921, approximately 50 new entities will register annually with the NPDB over the next three (3) years. It takes approximately 60 minutes to complete an initial registration form.
(50 registrations x 60 minutes = 50 hours)

§ **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.) Updates have decreased slightly below the estimate in the last approval for NPDB (0915-0126). Based on current operational statistics, we estimate that there will be approximately 25 updates per year for the new users for section 1921. Because the overwhelming majority of these updates will occur via the Internet, each update will take approximately five (5) minutes to complete. (25 Updates x 5 minutes = 2.08 hours)

§ **60.16(b) Procedures for filing a dispute (to the NPDB):** A health care practitioner, physician, dentist, or health care entity (subject) may dispute factual information reported to the NPDB. The subject of a report may initiate a dispute to the NPDB by logging into the Report Response Service on the Integrated Querying and Reporting Service (IQRS)[3] 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. Disputes of State 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 18 disputes of reports under section 1921, and that subjects will require approximately 15 minutes to complete the form. (18 disputes x 15 minutes = 4.50 hours)

§ **60.16(b) Procedures for requesting a review of a disputed report by the Secretary of the Department of Health and Human Services (the 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. Based on discussions with disputants, it takes approximately 8 hours (480 minutes) to prepare a dispute for review. It is estimated that approximately three (3) Secretarial Reviews will be received annually. Requests for Departmental review of licensure actions are accounted for in HIPDB estimates, so this number is limited to requests for Secretarial review on peer review organization and private accreditation organization actions and findings.
(3 Secretarial Review Requests x 8 hours = 24 hours)

§ **60.16(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

3 The IQRS is an electronic, web-based system for querying and reporting. It is part of an ongoing effort to improve the efficiency and responsiveness of the NPDB-HIPDB.

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. It is estimated that it will take approximately forty-five minutes to prepare the statement and that approximately 30 additional subjects annually will choose to enter a statement into their NPDB report. This estimate excludes statements submitted for State licensure reports, which are accounted for in HIPDB estimates.
(40 statements x 60 minutes = 40 hours)

13. Estimates of Annualized Cost Burden to Respondents

The NPDB became operational in 1990 and the HIPDB became fully operational in 2000. Entities previously interacting with either Data Bank will have no capital start up expense. The only new entities that have not interacted with either the NPDB or the HIPDB are the private accrediting organizations, peer review organizations and the QIOs. These organizations have the computer capacity to interact with the NPDB.

Operation and Maintenance Costs: Since 1992, the NPDB has operated entirely on user fees. The regulations at §60.14 describe the user fees that will be assessed on requests for information from the data bank. On July 24, 1990, the NPDB's user fee was published in the *Federal Register*. The user fee was initially established at $2.00 per practitioner's name for the costs of processing requests and providing information (except for self queries). Since that time there have been several changes in the fee structure. Most recently, this fee was changed to $4.75 per query to the NPDB. This change took effect as of May 9, 2006. It is estimated that, with the implementation of section 1921, the additional annual amount of users' fees collected from entities will be approximately $560,000.

14. Estimate of Annualized Cost to the Federal Government

The NPDB does not receive any appropriations and is required by annual appropriations act language to be self-sufficient through the collection of user fees for information provided to users.

15. Changes in Burden

This is a new activity.

16. Time Schedules, Publication and Analysis Plans

There are no immediate plans for publication of the data to be collected on these forms for statistical purposes.

17. Exemption for Display of Expiration Date

No exemption is requested.

18. Certifications

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