Supporting Statement A

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

OMB Control No. 0915-0126

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Terms of Clearance: Revision

A. Justification

1. Circumstances Making the Collection of Information Necessary

This is a request for revision of OMB approval of the information collections contained in the Code of Federal Regulations (CFR) for Title 45 CFR Part 60 governing the National Practitioner Data Bank (NPDB) and the forms to be used in registering with, reporting information to, and requesting information from, the NPDB. HRSA published a Notice of Proposed Rulemaking (NPRM) in the Federal Register on February 15, 2012 (77 FR 9137) to merge the Healthcare Integrity and Protection Data Bank (HIPDB) with the NPDB. The NPDB Final Rule was published in the Federal Register on April 5, 2013 (78 FR 20473). This rule becomes effective on May 6, 2013. This rule revises existing regulations governing the NPDB to incorporate statutory requirements under section 6403 of the Patient Protection and Affordable Care Act of 2010, Public Law 111-148. The purpose of this Information Collection Review (ICR) clearance package is to get approval on all of the forms that will be used after publication of the Final Rule. The Final Rule does not alter current reporting or querying requirements, but merely consolidates information under the NPDB and eliminates any duplication between the HIPDB and NPDB. The approved NPDB and HIPDB forms will expire on December 31, 2012 and May 31, 2014, respectively. Data collection will not change, however, the merger will consolidate forms from OMB No. 0915-0239 for HIPDB under OMB No. 0915-0126 for NPDB. (Note that OMB No. 0915-0331 has been discontinued because the data collection merged into OMB No. 0915-0126). Once this consolidation takes place the HIPDB will cease operations and the OMB No. 0915-0239 will be retired.

The circumstances making the collection of information necessary are divided into four sections: (I) Legal Authorities Governing the Data Banks, (II) Reporting Requirements, (III) Query Requirements, and (IV) Data Collection Forms.

I. Legal Authorities Governing the Data Banks

1. The Health Care Quality Improvement Act of 1986 (42 U.S.C. 11101 et seq.)

HCQIA Final Regulations

The NPDB was established by the Health Care Quality Improvement Act of 1986 (HCQIA), as amended (42 U.S.C. 11101 et seq.). The HCQIA authorizes the NPDB to collect reports of adverse licensure actions against physicians and dentists (including revocations, suspensions, reprimands, censures, probations, and surrenders); adverse clinical privileges actions against physicians and dentists; adverse professional society membership actions against physicians and dentists; Drug Enforcement Administration (DEA) certification actions; Medicare/Medicaid exclusions; and medical malpractice payments made for the benefit of any health care practitioner. Organizations that have access to this data system include hospitals, other health care entities that have formal peer review processes and provide health care services, State medical or dental boards and other health care practitioner State boards. Individual practitioners may self-query. Information under the HCQIA is reported by medical malpractice payers, State medical and dental boards, professional societies with formal peer review, and hospitals and other health care entities (such as health maintenance organizations).

2. Section 1921 of the Social Security Act (42 U.S.C. 1396r-2) (Prior to the Passage of the Affordable Care Act)

Section 1921 Final Rule

Section 1921 of the Social Security Act (herein referred to as 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, expanded the scope of the NPDB. Section 1921 requires each State to adopt a system for reporting to the Secretary certain adverse licensure actions taken against health care practitioners and entities by any authority of the State responsible for the licensing of such practitioners or entities. It also requires each State to report any negative action or finding that a State licensing authority, a peer review organization, or a private accreditation entity had taken against a health care practitioner or health care entity. Groups with access to this information include all organizations eligible to query the NPDB under the HCQIA (hospitals, other health care entities that have formal peer review and provide health care services, State medical or dental boards, and other health care practitioner State boards), other State licensing authorities, agencies administering Federal health care programs (including private entities administering such programs under contract), State agencies administering or supervising the administration of State health care programs, State Medicaid fraud control units, certain law enforcement agencies, and utilization and quality control Quality Improvement Organizations (QIOs). Individual health care practitioners and entities may self-query. Information under section 1921 is reported by State licensing and certification authorities, peer review organizations, and private accreditation entities. Final regulations implementing section 1921 were issued on January 28, 2010 (75 FR 4656). The NPDB began collecting and disclosing section 1921 information on March 1, 2010.

3. **Section 1128E of the Social Security Act (42 U.S.C. 1320a-7e) (Prior to the Passage of the Affordable Care Act)**
   Section 1128E Final Regulations

Section 1128E of the Social Security Act (herein referred to as section 1128E), as added by section 221(a) of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, directed the Secretary to establish and maintain a national health care fraud and abuse data collection program for the reporting and disclosing of certain final adverse actions taken against health care practitioners, providers, or suppliers. This data bank is known as the HIPDB. Section 1128E required Federal and State government agencies and health plans to report to the HIPDB the following final adverse actions: Licensing and certification actions; criminal convictions and civil judgments related to the delivery of health care services; exclusions from Federal or State health care programs; and other adjudicated actions or decisions. Federal and State government agencies and health plans have access to this information. Individual practitioners, providers, and suppliers may self-query the HIPDB. The HIPDB began collecting reports in November 1999. Requirements of both HCQIA and section 1921 overlap with the requirements under section 1128E, although each law has unique characteristics, including differences in the types of reportable actions and the types of agencies, entities, and officials with access to information. For example, all three reporting schemes require the reporting of State licensure actions. The HCQIA, however, only requires the reporting of licensure actions taken against physicians and dentists that are based on professional competence or conduct. In contrast, sections 1921 and 1128E do not have a requirement that reportable adverse licensure actions be based on professional competence or conduct and also differ in the types of subjects reported. In addition, sections 1921 and 1128E authorize access to many of the same types of agencies, organizations, and officials. For example, both statutes authorize access by law enforcement agencies, agencies that administer or pay for health care services or programs, and State licensing authorities. Private-sector hospitals and health care service providers are only able to access information reported under the HCQIA and section 1921, but not under section 1128E.

4. **Section 6403 of the Patient Protection and Affordable Care Act of 2010**
   Section 6403 NPRM

Section 6403 of the Patient Protection and Affordable Care Act of 2010 (hereinafter referred to as section 6403), Public Law 111-148, amends sections 1921 and 1128E to eliminate duplication between the HIPDB and the NPDB, and requires the Secretary to establish a transition period for transferring data collected in the HIPDB to the NPDB and to cease HIPDB operations. Information previously collected and disclosed through the HIPDB will then be collected and disclosed through the NPDB. No new data elements have been added as a result of section 6403. All actions currently reported in the NPDB and HIPDB will be reported to the NPDB.

Although data collection will not change, the regulatory citation numbers will be updated to incorporate the HIPDB regulations into the NPDB. We seek approval of the revised NPDB package after publication of the Final Rule, so the regulatory citations in this document will correspond with the post-merge regulations. See Table 1 for a comparison of the current and updated regulatory citation numbers before and after the passage of section 6403. Additional

information on the data collection activities for each regulatory citation is discussed in the following sections: (II) Reporting Requirements, (III) Query Requirements, and (IV) Data Collection Forms.

Table 1: Comparison of Data Collection Regulatory Citations Before and After Passage of Section 6403.

Before Passage of Section 6403 Regulatory Citations (pre-merge)		After Passage of Section 6403 Regulatory Citations (post-merge)
NPDB	**HIPDB**	**NPDB**
§ 60.6	§ 61.6	§ 60.6: Reporting errors, omissions, revisions or whether an action is on appeal.
§ 60.7	N/A	§ 60.7: Reporting medical malpractice payments.
§ 60.8	N/A	§ 60.8: Reporting licensure actions taken by Boards of Medical Examiners
§ 60.9	§ 61.7	§ 60.9: Reporting licensure and certification actions taken by States.
N/A	§ 61.7	§ 60.10: Reporting Federal licensure and certification actions.
§ 60.10	N/A	§ 60.11: Reporting negative actions or findings taken by peer review organizations or private accreditation entities.
§ 60.11	N/A	§ 60.12: Reporting adverse actions taken against clinical privileges.
N/A	§ 61.8	§ 60.13: Reporting Federal or State criminal convictions to the delivery of a health care item or service.
N/A	§ 61.9	§ 60.14: Reporting civil judgments related to the delivery of a health care item or service
N/A	§ 61.10	§ 60.15: Reporting exclusions from participation in Federal or State health care programs
N/A	§ 61.11	§ 60.16: Reporting other adjudicated actions or decisions
§ 60.12	N/A	§ 60.17: Information which hospital must request from the NPDB
§ 60.13	§ 61.12	§ 60.18 Requesting Information from the NPDB
§ 60.16	§ 60.15	§ 60.21: How to dispute the accuracy of NPDB information

II. Reporting Requirements

After publication of the Final Rule, information must be reported to the NPDB as required under §§ 60.7, 60.8, 60.9, 60.10, 60.11, 60.12, 60.13, 60.14, 60.15 and 60.16. Information required under §§ 60.7, 60.8, and 60.12 must be submitted to the NPDB within 30 days following the action to be reported, beginning with actions occurring on or after September 1, 1990; information required under § 60.11 must be submitted to the NPDB within 30 days following the action to be reported, beginning with actions occurring on or after January 1, 1992; and

information required under §§ 60.9, 60.10, 60.13, 60.14, 60.15, and 60.16 must be submitted to the NPDB within 30 days following the action to be reported, beginning with actions occurring on or after August 21, 1996. Below is the list of reportable actions:

1. Malpractice payments (§ 60.7);
2. Licensure and certification actions (§§ 60.8, 60.9, and 60.10);
3. Negative actions or findings (§ 60.11);
4. Adverse actions (§ 60.12);
5. Health care-related criminal convictions (§ 60.13);
6. Health care-related civil judgments (§ 60.14);
7. Exclusions from Federal or State health care programs (§ 60.15); and
8. Other adjudicated actions or decisions (§ 60.16).

Persons or entities responsible for submitting reports of malpractice payments (§ 60.7), negative actions or findings (§ 60.11), or adverse actions (§ 60.12) must additionally provide to their respective State authorities a copy of the report they submit to the NPDB.

§ 60.6 Reporting errors, omissions, revisions or whether an action is on appeal.

If errors or omissions are found after information has been reported, the reporter must send an addition or correction to the NPDB. A reporter that reports information on licensure or certification, negative actions or findings, clinical privileges, criminal convictions, civil or administrative judgments, exclusions, or adjudicated actions or decisions under §§ 60.8, 60.9, 60.10, 60.11, 60.12, 60.13, 60.14, 60.15, or 60.16 must also report any revision of the action originally reported. Revisions include, but are not limited to, reversal of a professional review action or reinstatement of a license. In the case of actions reported under §§ 60.9, 60.10, 60.13, 60.14, 60.15 or 60.16, revisions also include whether an action is on appeal.

§ 60.7 Reporting medical malpractice payments.

This section 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.

This section identifies the data elements to be reported to the NPDB by State medical and dental boards regarding the physician or dentist, 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 licensure and certification actions taken by States

The title of this section will be revised to include licensure and certification actions, as required under section 6403(b)(1)(A)(i). Currently, the title is “Reporting licensure actions taken by

Federal or State licensing and certification agencies." This section requires State licensing and certification agencies to report actions taken as a result of formal proceedings (as defined in section 60.3) against a health care practitioners, physicians, dentists, health care entities, providers and suppliers. Reportable actions include:

1. Any adverse action (e.g., revocation, reprimand, censure, suspension, probation)
2. Any dismissal or closure of the proceedings by reason of surrendering the license or leaving the State or jurisdiction
3. Any other loss of, or loss of the right to apply for, or renew a license
4. Any negative action or finding by a State licensing or certification authority, peer review organization, or private accreditation entity

§ 60.10 Reporting licensure and certification actions taken by Federal agencies

This section requires Federal licensing and certification agencies to report certain final adverse actions taken against a health care practitioner, physician, dentist, provider, or supplier (regardless of whether the final adverse action is the subject of a pending appeal). Reportable actions include:

1. Any formal or official actions (e.g., revocation, reprimand, censure, suspension, probation)
2. Any dismissal or closure of the proceedings by reason of surrendering the license or leaving the State or jurisdiction
3. Any other loss of, or right to apply for, or renew, a license, whether by voluntary surrender, non-renewability, or otherwise
4. Any negative action or finding that is publicly available information

§ 60.11 Reporting Negative Actions or Findings Taken by Peer Review Organizations or Private Accreditation Entities

This section requires peer review organizations and private accreditation entities to report any negative actions or findings (as defined in § 60.3) which are taken against a health care practitioner, physician, dentist, health care entity, provider, or supplier to the NPDB and provide a copy to the appropriate State licensing or certification agency. The reportable actions include:

1. Any final determination of denial or termination of an accreditation status from a private accreditation entity
2. Any recommendation by a peer review organization to sanction a health care practitioner, physician, or dentist
3. Any negative action or finding that is publicly available (e.g., limitations to scope of practice, liquidations, injunctions, forfeitures), including final adverse actions (e.g., exclusions, revocations, or suspension of license or certification)

§ 60.12 Reporting Adverse Actions Taken Against Clinical Privileges.

This section requires that health care entities report to the NPDB and provide a copy of the report to the Board of Medical Examiners in the State in which the health care entity is located. Reportable actions include 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. This section also 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 § 60.12(b)(1).

§ 60.13 Reporting Federal or State Criminal Convictions Related to the Delivery of a Health Care Item or Service.

Federal and State prosecutors must report criminal convictions against health care practitioners, physicians, dentists, providers, and suppliers related to the delivery of health care items or services (regardless of whether the conviction is the subject of a pending appeal). Criminal convictions unrelated to the delivery of health care items or services are not reported under this section.

§ 60.14 Reporting Civil Judgments Related to the Delivery of a Health Care Item or Service.

Federal and State attorneys and health plans must report civil judgments against health care practitioners, physicians, dentists, providers, and suppliers related to the delivery of health care items or services (regardless of whether the conviction is the subject of a pending appeal).

§ 60.15 Reporting Exclusions from Participation in Federal or State Health Care Programs.

Federal government agencies and State law and fraud enforcement agencies must report health care practitioners, physicians, dentists, providers, or suppliers excluded from participating in Federal or State health care programs. This includes exclusions that were made in a matter in which there was also a settlement that is not reported because no findings or admissions of liability have been made (regardless of whether the exclusion is the subject of a pending appeal).

§ 60.16 Reporting Other Adjudicated Actions.

Federal government agencies, State law or fraud enforcement agencies, and health plans must report other adjudicated actions or decisions as defined in § 60.3 related to the delivery, payment or provision of a health care item or service against health care practitioners, physicians, dentists, providers, and suppliers (regardless of whether the other adjudicated action or decision is subject to a pending appeal).

Although not specifically required by the statute, the Department believes that the term *"other adjudicated actions or decisions"* should relate to the delivery of health care items or services, as do criminal convictions and civil judgments collected under this statute. In addition, the Department requires that a due process mechanism be associated with all adjudicated actions or

decisions. Examples of an adjudicated action or decision include, but are not limited to, orders by an administrative law judge, civil monetary penalties and assessments, revocations, debarments or other restrictions from participating in Federal or State government contracts or programs, liquidation, dissolution, license cancellation or revocations, and health plan contract terminations. The Department believes that this definition encompasses actions that are consistent with the characteristics of the specific final adverse actions already defined in the statute.

III. Requesting for Information (Querying) Requirements

§ 60.17 Information which hospitals must request from the National Practitioner Data Bank.

This section 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
2. Every two years for all practitioners holding clinical privileges or who are on the medical staff

§ 60.18 Requesting information from the National Practitioner Data Bank.

This section 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, providers, or suppliers 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)
8. Federal and State government agencies
9. Health plans

This section also provides an option 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.

§ 60.21 How to dispute the accuracy of National Practitioner Data Bank Information.

This section describes the process that a health care practitioner, physician, dentist, provider, or supplier must follow to dispute the accuracy of a report in the NPDB. The subject of the report or a designated representative may dispute the accuracy of a report concerning himself, herself, or itself.

IV. Data Collection Forms

All forms used to collect the required information outlined in the aforementioned statutes are available on the Data Bank website (http://www.npdb-hipdb.hrsa.gov/). After publication of the Final Rule, the new URL will be www.npdb.hrsa.gov. Reporting and querying is accomplished electronically over a secure internet connection. The Data Bank offers two methods to submit queries and reports. Eligible entities may submit information electronically through the Integrated Query and Reporting Service (IQRS) on the NPDB website or through an XML-based application programming interface called the Querying and Reporting XML Service (QRXS). As an alternative to querying and reporting via the website, QRXS is an ideal choice for entities who store and manage practitioner data within their own information or credentialing systems or if they submit a large number of queries and reports to the Data Bank. QRXS makes it easy to integrate Data Bank information into an entity's established information systems. This ICR package will cover the burden to entities that submit reports and queries online using the IQRS and does not include entities that use QRXS to submit data using an alternate format specified by the NPDB.

The reporting and querying forms are available at the individual level (e.g., physicians, dentists, other health care practitioner) and organization level (e.g., provider or supplier of medical goods or services). In addition, variations of the initial form will be available to report errors, omissions, revisions, or whether actions are on appeal, as noted in § 60.6. The types of reports are described below.

1. **Initial:** The first record of an adverse action that is submitted to and processed by the Data Bank. An Initial Report is the current version of the report until a Revision to Action, Correction, Void, or Notice of Appeal is submitted.
2. **Correction:** A report that corrects an error or omission in an existing report. The Correction will supersede the contents of the current version of a report in the Data Bank. It should be submitted as soon as possible after a reporting error or omission is discovered. Corrections may be submitted as often as necessary.
3. **Revision to Action:** A new action that relates to and modifies a previously reported adverse action, (e.g., reinstatement of a license, extension of an exclusion from a Government program, restrictions of clinical privileges lifted, previously stayed license revocation imposed). A correction of a Revision to Action Report may be submitted via the IQRS.
4. **Correction of Revision to Action:** A report that corrects a previously submitted Revision to Action Report. This correction will supersede the contents of the current version of the Revision to Action Report in the Data Bank. It should be submitted as soon as possible after a reporting error or omission is discovered. Corrections may be submitted as often as necessary.
5. **Void:** the retraction of a report in its entirety to from the Data Bank. The report is removed from the subject's disclosable record.
6. **Notice of Appeal:** a report notifying that a subject has formally appealed a previously reported adverse action. Reporting entities must submit a Notice of Appeal whenever a previously reported adverse action is on appeal. A Notice of Appeal is separate and distinct from a subject's dispute of a Data Bank report.

Reporting Forms

Initial reports are submitted using one of the following three formats: (A) Adverse Action Reports, (B) Judgment or Conviction Reports, and (C) Medical Malpractice Payment Reports. Variations of the initial report are available to report errors, omissions, revisions, or whether actions are on appeal, as noted in § 60.6. Table 2 provides a summary of the fifteen reporting forms, types of submission, and burden time associated with completing each form.

A. Adverse Action Reports (AAR): There are nine categories of AAR forms that must be submitted to the NPDB within 30 days of the date the action was taken.

1. **State Licensure:** State Licensure actions are adverse actions taken by State licensing authorities related to the license, certification, or registration of health care practitioners, providers, and suppliers. State licensing actions include State professional and health care facility licensing sanctions. State licensing actions against physicians and dentists that are based upon the subject's professional competence or conduct.
2. **Federal Licensure**: Federal Licensure actions are adverse actions taken by Federal licensing authorities related to the license, certification, or registration of health care providers, practitioners, and suppliers. Federal licensure actions include Clinical Laboratory Improvement Amendments (CLIA) certification actions; Drug Enforcement Administration (DEA) registration actions; and Food and Drug Administration (FDA) licensing, certification, and registration actions.
3. **Clinical Privilege:** Clinical Privilege actions are adverse actions taken by hospitals and other health care entities related to the authorization of health care practitioners to provide health care services, including actions related to a practitioner's membership on the medical staff or panel, and based upon the subject's professional competence or conduct.
4. **Health Plan**: Health Plan actions are adverse actions that are taken by a health plan against a health care practitioner, provider or supplier. These actions must meet the regulatory definition of "other adjudicated actions," which requires that they: 1) be formal or official actions; 2) include the availability of a due process mechanism; and 3) be based on acts or omissions that affect or could affect the payment, provision or delivery of a health care item or service. The definition specifically excludes clinical privileging actions or paneling decisions (which normally are the result of a formal peer review process). However, quality actions that include the availability of due process are reportable. An example of a reportable health plan action would be the termination of a practitioner's contract to provide health care services, as long as it meets the three specified criteria.
5. **Exclusion/Debarment:** The exclusion or debarment of a health care practitioner, provider, or supplier from participating in and/or contracting with a Federal or State health care program is reportable. Exclusion of a practitioner from the Medicare and Medicaid programs is reportable to the NPDB under a Memorandum of Understanding with the Office of Inspector General, and the Centers for Medicare & Medicaid Services.

6. **Professional Society:** Professional Society actions are adverse actions taken by associations of health care practitioners that follow formal peer review processes for the purpose of furthering quality health care and that are based upon the subject's professional competence or conduct.
7. **Peer Review Organization:** Peer Review Organization actions include any recommendation by a peer review organization to sanction a health care practitioner.
8. **Accreditation:** Private accreditation organization actions include final determinations of denial or termination of an accreditation status from a private accreditation entity that indicates a risk to the safety of a patient(s) or quality of health care services. These actions are taken against health care entities that have received or are attempting to receive accreditation.
9. **Government Administrative:** Government Administrative actions are reportable adverse actions that are not classified elsewhere. This category includes any publicly available negative action or finding by Federal or State agencies that certify health care practitioners, providers, and suppliers for participation in a government health care program. In addition, other Government Administrative actions include any other adjudicated action or decision by an authorized Federal or State agency against a health care practitioner, provider, or supplier. These adjudicated actions or decisions may include, for example, personnel actions, employment disqualifications, and contract terminations.

B. **<u>Judgment or Conviction Reports (JOCR):</u>** There are five categories of JOCR forms that must be submitted to the NPDB within 30 days of the date the action was taken.

10. **Criminal Conviction (Guilty Plea or Trial):** Federal or State criminal convictions against health care practitioners, providers, and suppliers. Convictions must be related to the delivery of a health care item or service. Convictions include guilty pleas and findings of guilt by either a judge or a jury.
11. **Deferred Conviction/Pre-Trial Diversion:** Federal or State court actions in which a healthcare practitioner, provider, or supplier has entered into participation in a first offender, or other program or arrangement where the conviction has been deferred or held in abeyance. These actions must be related to the delivery of a health care item or service.
12. **Nolo Contendere (No Contest) Plea:** Acceptance by a Federal or State court of a nolo contendere or no contest plea by a health care practitioner, provider, or supplier in a matter related to the delivery of a health care item or service.
13. **Civil Judgment:** Civil judgments against health care practitioners, providers, and suppliers in Federal or State courts. Judgments must be related to the delivery of a health care item or service. This reporting requirement does not include settlements in which no findings of liability have been made.
14. **Injunction:** Civil actions taken against health care practitioners, providers, and suppliers that seek to stop a specific activity, such as the continued production or distribution of a violative product or the provision of a service.

C. <u>Medical Malpractice Payment Reports (MMPR):</u> This MMPR form must be submitted to the NPDB within 30 days of the date the payment was issued.

15. **Medical Malpractice Payment**: 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.

Table 2: Reporting Forms, Submission Types, and Burden Time

Report Format	Form Name	Individual	Organi-zation	Initial	Correction	Revision to Action	Correction of Revision to Action
Adverse Action Report (AAR)	State Licensure	X	X	45 min	15 min	15 min	15 min
	DEA/Federal Licensure	X	X	45 min	15 min	15 min	15 min
	Title IV Clinical Privileges	X		45 min	15 min	15 min	15 min
	Health Plan Action	X	X	45 min	15 min	15 min	15 min
	Exclusion/Debarment	X	X	45 min	15 min	15 min	15 min
	Professional Society	X		45 min	15 min	15 min	15 min
	Peer Review Organization	X		45 min	15 min	15 min	15 min
	Accreditation		X	45 min	15 min	15 min	15 min
	Government Administrative	X	X	45 min	15 min	15 min	15 min
Judgment or Conviction Report (JOCR)	Criminal Conviction (Guilty Plea Or Trial)	X	X	45 min	15 min	15 min	15 min
	Deferred Conviction Or Pre-Trial Diversion	X	X	45 min	15 min	15 min	15 min
	Nolo Contendere (No Contest) Plea	X	X	45 min	15 min	15 min	15 min
	Civil Judgment	X	X	45 min	15 min	15 min	15 min
	Injunction	X	X	45 min	15 min	15 min	15 min
Medical Malpractice Payment Report (MMPR)	Medical Malpractice Payment	X		45 min	15 min		

Information Disclosure (Query) Forms

Query forms are used to request information from the NPDB (see Table 3). Individuals and entities can perform the following types of queries:

1. **One-Time Query:** Authorized users submit the name of a practitioner or organization and receive a one-time query response that includes the information that the Data Bank has received on the practitioner or organization.
2. **Continuous Query:** Authorized users enroll the name of a practitioner and subscribe to receive continuous query responses on that practitioner. Continuous Query allows for on-going monitoring of a practitioner's credentials and automatically alerts you to any new reports or changes to reports on your enrolled practitioners for a 12-month period, on a 24/7 basis. Users will be informed whenever there are new adverse licensure actions, adverse clinical privilege actions, Medicare/Medicaid exclusions, or malpractice payments during the 12-month enrollment.
3. **Self-Query:** An individual physician, dentist, other health care practitioner, and organization that is the provider or supplier of medical goods or services may query the NPDB at any time concerning himself, herself, or itself. The NPDB proactively notifies an individual each time he or she is the subject of a report (see § 60.18).

Hospitals, either directly or through an authorized agent, are required to query the NPDB each time a physician, dentist, or other licensed health care practitioner applies to be on its medical staff or for clinical privileges, as noted in § 60.17. 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. 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, as noted in § 60.18.

Based on section 6403 amendments, State licensing or certification agencies and Federal agencies responsible for the licensing and certification of health care practitioners, physicians, dentists, providers and suppliers are authorized to query the NPDB under section 1921 and 1128E. Also, as noted in § 60.18, 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. 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. 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.

Table 3: Query Forms, Submission Types, and Burden Time

Query Forms	Individual	Organization
One-Time Query	5 min	5 min
Continuous Query	5 min	N/A
Self-Query	25 min	25 min

Dispute Accuracy of NPDB Information Forms

The subject of the report will receive a copy of all reports, including revisions and corrections to the report. Upon receipt of the report, the subject can accept the report as written, provide a statement to the NPDB that will be permanently appended to the report, or follow the dispute process in accordance with section 60.21 to ensure the information reported is accurate. The procedure for filing a dispute with the Data Bank is specified in § 60.21. See Table 4 for the dispute related forms. The health care practitioner, physician, dentist, provider, or supplier must follow this process to dispute the accuracy of a report in the NPDB. The subject of the report or a designated representative may dispute the accuracy of a report concerning himself, herself, or itself.

1. **Subject Statement and Dispute Initiation:** This form allows the practitioner or entity subjects of an NPDB report to dispute factual information in that report by adding, modifying, or removing a statement of the report.
2. **Request for Secretarial Review:** This form allows the practitioner or entity subjects of an NPDB report to place the report in "disputed status" and request the Secretary to review the report for accuracy. The subject must return this request to the NPDB along with appropriate materials that support the subject's position. The Secretary will only review the accuracy of the reported information, and will not consider the merits or appropriateness of the action or the due process that the subject received.

Table 4: Dispute Forms, Submission Types, and Burden Time

Dispute Forms	Individual	Organization
Subject Statement and Dispute Initiation	45 min	45 min
Request for Secretarial Review	8 hours	8 hours

Administrative Forms

Table 5 provides a summary of the administrative forms, types of submission, and burden time associated with completing each form.

1. **Entity Registration:** This form is used by entities to self-certify that they meet the regulatory requirements needed to interact with the NPDB. These forms meet identity proofing and e-authentication requirements stipulated in the *E-Authentication Guidance for Federal Agencies* (OMB M-04-04) and National Institutes of Standards and

Technology's (NIST) Draft Special Publication 800-63-1, *Electronic Authentication Guidelines.* The completion of the Entity Registration document allows the entity to begin interacting with the NPDB. 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.

2. **Authorized Agent Designation:** This form is used by eligible entities to select an authorized agent to interact with the NPDB on their behalf. This form is available on the Data Bank website and meets the aforementioned identity proofing and e-authentication requirements.
3. **Agent Registration:** This form is used by an authorized agent to register as an authorized agent to query and/or report to the NPDB on behalf of the eligible, registered entities as well as to update that designation status. This form is available on the Data Bank website and meets the aforementioned identity proofing and e-authentication requirements.
4. **Account Discrepancy:** This form 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. Fees applicable to requests for information is noted in § 60.19.
5. **Electronic Transfer of Funds (EFT) Authorization:** This form allows the entity to make payment of the user fee directly from its bank account to the NPDB. Fees applicable to requests for information is noted in § 60.19.

Table 5: Administrative Forms, Submission Types, and Burden Time

Administrative Forms	Initial	Update	Renewal
Entity Registration	60 min	5 min	5 min
Authorized Agent Designation	5 min		
Agent Registration	15 min	5 min	15 min
Account Discrepancy	15 min		
Electronic Transfer of Funds (EFT) Authorization	15 min		

2. Purpose and Use of Information Collection

Information is collected from, and disseminated to, eligible entities (entities that are entitled to query and/or report to the NPDB and HIPDB under the three aforementioned statutory authorities). The statutes require the Secretary to assure that information is provided and utilized in a manner that appropriately protects the confidentiality of the information and the privacy of subjects in the Data Bank reports. The HIPDB and NPDB are vital sources of information for the effective evaluation of health care practitioners and entities and play an important role in improving the quality of health care. Information in the Data Bank reports should be considered with other relevant information in evaluating credentials of health care practitioners, providers, and suppliers.

Once the HIPDB data and operations transfer to the NPDB, the NPDB will serve as a single a flagging system; its principal purpose is to facilitate comprehensive review of health care practitioners' professional credentials and background. The intent of the NPDB is to improve the quality of health care by encouraging hospitals, state licensing boards, professional societies, and other entities providing health care services, to identify and discipline those who engage in unprofessional behavior; and to restrict the ability of incompetent health care practitioners, providers, or suppliers to move from state to state without disclosure of previous damaging or incompetent performance. It also serves as a fraud and abuse clearinghouse 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 practitioners, providers, or suppliers by health plans, federal agencies, and state agencies.

Table 6 provides a summary of the reporting and querying requirements based on: (1) the current statutory requirements (before the merger of NPDB and HIPDB forms) and (2) reporting/querying requirements after the passage of section 6403 (when NPDB and HIPDB forms consolidate into NPDB). Users of the Data Bank include: (1) Reporters (entities that are required to submit reports) and (2) Queriers (entities that are authorized to request for information). The list of reportable actions collected by reporters and disclosed to queriers allow the Data Bank to fulfill its mission “to collect and provide complete, accurate, timely, and reliable information on the nation’s health care practitioners, providers, and suppliers to improve health care quality, promote patient safety, and deter fraud and abuse.”

Congress's mandate that the Secretary provide for the maximum appropriate coordination among the statutes makes it necessary, in certain cases, to make slight modifications when combining sometimes overlapping statutory requirements. Therefore, Table 6 also highlights the following: (1) additional terms added by section 6403, and (2) modifications to existing terms. No new data elements have been added to the previously approved NPDB and HIPDB forms.

Table 6 Data Banks Statutory Requirements Before and After Passage of Section 6403*

Statutory Requirements before Passage of Section 6403	Reporting/Querying Requirements after Passage of Section 6403
WHO REPORTS? **HCQIA (NPDB)** ▪ Medical malpractice payers ▪ Boards of Medical/Dental Examiners ▪ Hospitals and other healthcare entities ▪ Professional societies with formal peer review ▪ Drug Enforcement Administration ▪ Health and Human Services-Office of Inspector General **SECTION 1921 (NPDB)** ▪ Peer review organizations ▪ Private accreditation organizations ▪ State authorities that license practitioners and entities **SECTION 1128E (HIPDB)** ▪ Federal and State government agencies (including State law or fraud enforcement agencies) ▪ Health plans	**WHO REPORTS?** **HCQIA (NPDB)** ▪ Medical malpractice payers ▪ Boards of Medical/Dental Examiners ▪ Hospitals and other health care entities ▪ Professional societies with formal peer review ▪ Drug Enforcement Administration ▪ Health and Human Services-Office of Inspector General **SECTION 1921 (NPDB)** ▪ Peer review organizations ▪ Private accreditation organizations ▪ State authorities that license or certify practitioners, entities, providers, suppliers ▪ State law or fraud enforcement agencies(1128E HIPDB) **SECTION 1128E (NPDB)** ▪ Federal government agencies ▪ Health plans
WHAT INFORMATION IS REPORTED? **HCQIA (NPDB)** ▪ Medical malpractice payments ▪ Adverse licensure actions (physicians/dentists): -- revocation, suspension, reprimand, probation, surrender, censure ▪ Adverse clinical privileges actions (primarily physicians/dentists) ▪ Adverse professional society membership (primarily physicians/dentists) ▪ DEA certification actions ▪ Medicare/Medicaid exclusions **SECTION 1921 (NPDB)** ▪ Licensing actions (practitioners and entities): -- revocation, reprimand, censure, suspension, probation -- any dismissal or closure of the proceedings by reason of surrendering the license or leaving the State or jurisdiction -- any other loss of the license --any negative action or finding by a State licensing authority, peer review organization, or private accreditation entity **SECTION 1128E (HIPDB)** ▪ Licensing and certification actions (practitioners, providers, and suppliers): -- revocation, reprimand, suspension, censure, probation;	**WHAT INFORMATION IS REPORTED?** **HCQIA (NPDB)** ▪ Medical malpractice payments ▪ Adverse licensure actions (physicians/dentists): -- revocation, suspension, reprimand, probation, surrender, censure ▪ Adverse clinical privileges actions (primarily physicians/dentists) ▪ Adverse professional society membership (primarily physicians/dentists) ▪ DEA certification actions ▪ Medicare/Medicaid exclusions **SECTION 1921 (NPDB)** ▪ Licensing or certification actions (practitioners, entities, providers, and suppliers): -- revocation, reprimand, censure, suspension, probation -- any dismissal or closure of the proceedings by reason of surrendering the license or leaving the State or jurisdiction --any other loss of, or right to apply for, or renew a license -- any negative action or finding by a State licensing or certification authority, peer review organization, or private accreditation entity ▪ Health care-related civil judgments in State court (practitioners, providers, suppliers) ▪ Health care-related State criminal convictions (practitioners, providers, suppliers) ▪ Exclusions from State health care programs (practitioners, providers, suppliers) ▪ Other adjudicated actions or decisions (practitioners, providers, suppliers)(1128E HIPDB) **SECTION 1128E (NPDB)** ▪ Federal licensing/certification actions (practitioners, providers, and suppliers): -- revocation, reprimand, censure, suspension, probation -- any dismissal or closure of the proceedings by reason of

Statutory Requirements before Passage of Section 6403	Reporting/Querying Requirements after Passage of Section 6403
-- any other loss of license, or right to apply for, or renew, a license, whether by voluntary surrender, non-renewability, or otherwise -- any other negative action or finding that is publicly available Information ▪ Health care-related civil judgments in Federal or State court (practitioners, providers, suppliers) ▪ Health care-related Federal or State criminal convictions (practitioners, providers, suppliers) ▪ Exclusions from Federal or State health care programs (practitioners, providers, suppliers) ▪ Other adjudicated actions or decisions (practitioners, providers, suppliers)	surrendering the license or leaving the State or jurisdiction -- any other loss of, or right to apply for, or renew, a license, whether by voluntary surrender, non-renewability, or otherwise -- any negative action or finding that is publicly available information ▪ Health care-related civil judgments in Federal or State court (practitioners, providers, suppliers) ▪ Health care-related Federal or State criminal convictions (practitioners, providers, suppliers) ▪ Exclusions from Federal health care programs (practitioners, providers, suppliers) ▪ Other adjudicated actions or decisions (practitioners, providers, suppliers)
WHO CAN QUERY? **HCQIA (NPDB)** ▪ Hospitals ▪ Other health care entities with formal peer review ▪ Professional societies with formal peer review ▪ Boards of Medical/Dental Examiners ▪ Other health care practitioner State licensing boards ▪ Plaintiff's attorney/*pro se* plaintiffs (limited circumstances) ▪ Health care practitioners (self-query) ▪ Researchers (statistical data only) **SECTION 1921 (NPDB)** ▪ Hospitals and other health care entities (HCQIA) ▪ Professional societies with formal peer review ▪ Quality Improvement Organizations ▪ State licensing agencies that license practitioners and entities ▪ Agencies administering Federal health care programs, as well as their contractors ▪ State agencies administering State health care programs ▪ State Medicaid Fraud Control Units ▪ U.S. Comptroller General ▪ U.S. Attorney General and other law enforcement ▪ Health care practitioners/entities (self-query) ▪ Researchers (statistical data only) **SECTION 1128E (HIPDB)** ▪ Federal and State Government Agencies ▪ Health Plans ▪ Health care practitioners/providers/ suppliers (self-query) ▪ Researchers (statistical data only)	**WHO CAN QUERY?** **HCQIA (NPDB)** ▪ Hospitals ▪ Other health care entities with formal peer review ▪ Professional societies with formal peer review ▪ Boards of Medical/Dental Examiners ▪ Other health care practitioner State licensing boards ▪ Plaintiff's attorney/*pro se* plaintiffs (limited circumstances) ▪ Health care practitioners (self-query) ▪ Researchers (statistical data only) **SECTION 1921 and SECTION 1128E (NPDB)** ▪ Hospitals and other health care entities (HCQIA)** ▪ Professional societies with formal peer review** ▪ Quality Improvement Organizations** ▪ State licensing or certification agencies that license or certify practitioners, entities, providers or suppliers ▪ Agencies administering (including those providing payment for services) Federal health care programs as well as their contractors ▪ State agencies administering State health care programs ▪ Federal agencies(1128HIPDB) that license or certify practitioners, providers, suppliers ▪ Health plans ▪ State law or fraud enforcement agencies(1128HIPDB) (including State Medicaid Fraud Control Units) ▪ U.S. Comptroller General ▪ U.S. Attorney General and other Federal law enforcement ▪ Health care practitioners, entities, providers, suppliers (self-query) ▪ Researchers (statistical data only) .

*For NPDB requirements, the term "practitioners" is used throughout this table to mean "practitioners, physicians, dentists."

** Under Section 1921, these entities only have access to reported licensing or certification actions, which is consistent with these entities' access prior to passage of the Affordable Care Act.

3. Use of Improved Information Technology and Burden Reduction

The reporting forms and request for information forms (query forms), are accessed, completed, and submitted online at http://www.npdb-hipdb.hrsa.gov/. After publication of the Final Rule, the new URL will be www.npdb.hrsa.gov. All reporting and querying is performed through this secure website. Responsibility for NPDB implementation and operation resides in the Bureau of Health Professions, Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

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 user names and passwords by all registered users, and firewall protection of the NPDB network and server to prevent unauthorized access from the internet.

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-queries 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 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.

After passage of section 6403, all security standards that are currently in place to protect the confidentiality of information in the Data Bank will be retained. HRSA follows the National Institute of Standards and Technology (NIST) security guidelines. More specifically, the Data Bank has extensive operational, management, and technical controls that ensure the security of the system and protect the data in the system. The Data Bank contains information classified under the Privacy Act that is considered personally identifiable information (PII). On an annual basis, the Data Bank conducts a detailed security review process that tests the effectiveness of the security controls to ensure the PII in the system remains safe. In accordance with HHS policy, a Privacy Impact Assessment (PIA) has been completed for the Data Bank. Finally, every three years, the Data Bank is Certified and Accredited (C&A) as a requirement to have an Authority to Operate (ATO), in order to function as a Federal system.

Transferring Healthcare Integrity and Protection Data Bank (HIPDB) data and operations to the NPDB will minimize the burden on reporters. Reporters previously responsible for reporting adverse actions to both the NPDB and HIPDB only needed to submit one report per action, provided that reporting was done through the Department's web-based system that sorted the appropriate actions into the HIPDB, the NPDB, or both. Similarly, under the section 6403 regulations, reporters will only need to submit one report per action.

This merge is technical in nature. It involves transferring data reporting requirements under 45 CFR part 61 for the HIPDB to 45 CFR part 60 for the NPDB, another data bank receiving like reports. The result of this transfer does not increase the regulatory burden on affected entities; it

alleviates duplication. The only impact of merging the HIPDB with the NPDB is to eliminate duplication and streamline internal operations. By combining two data banks into a single data bank, the need to capture like information in two data bases is eliminated.

4. Efforts to Identify Duplication and Use of Similar Information

There is a large amount of confidential information in the NPDB and HIPDB that is not available from any other source. Currently, coordination is required between the closely related and overlapping requirements of the HIPDB and NPDB. Section 6403 will eliminate duplication between the HIPDB and the NPDB. The NPDB will serve as the sole repository for all information previously captured in the HIPDB.

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 (FSMB) 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 FSMB. 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.

In developing the HIPDB, we have contacted numerous public and private sector agencies regarding existing databases that contain health care fraud-related information. Although various sources such as National Crime Information Center, Provider Indexing Network System, Financial Crimes Enforcement Network and National Practitioner Data Bank contain disciplinary licensure actions, criminal convictions, or civil judgments, there is no centralized source of comprehensive health care fraud information accessible to law enforcement officials, regulatory agencies, or health insurance plans. According to the May 1996 GAO report on Healthcare Fraud, “There is no centralized national data bank to track criminal activity in the health care system that would assist Federal, State, and industry anti-fraud enforcement efforts.” The HIPDB is the first to track such information and make it available in a centralized location for law enforcement officials, regulatory agencies, and health plans.

5. Impact on Small Businesses or Other 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. An eligible entity may use an authorized agent to report to and request information from (query) the HIPDB and NPDB at the discretion of that entity. Section 6403 will not substantially alter reporting requirements. Therefore the Secretary certifies that these regulations will not have a significant impact on a substantial number of small entities.

6. Consequences of Collecting the Information Less Frequently

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)." HCQIA 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 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 patient safety.

Information on licensing and certification actions, criminal convictions, civil judgments and other adjudicated actions must be submitted to the HIPDB within 30 calendar days from the date when the reporting entity became aware of the final adverse action or by the close of the entity's next monthly reporting cycle. If information is reported to the HIPDB less frequently, the HIPDB will not be able to provide accurate and timely information to law enforcement officials, regulatory agencies, or health insurance plans for their investigations.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the aforementioned regulations.

8. Comments in Response to the Federal Register Notice/Outside Consultation

8A: A 60-day Federal Register Notice was published in the *Federal Register* on January 8, 2013, Vol. 78, No. 5; pp. 1214-16 (see 60-Day FRN). A 30-day Federal Register Notice was published in the Federal Register on April 8, 2013, Vol. 78, No. 67; pp. 20929-20931 (see 30-Day FRN). There were no public comments.

8B: In preparing this request for revision, the Data Bank consulted with users of the NPDB and HIPDB to detect any problems they may have had with electronic querying and reporting. As part of this effort, we collected feedback from over 450 users in various settings, including 3 webinars, 4 user forums, and 3 usability evaluation sessions. See Table 7 for specific event details. The consultation activities conducted from 2011-2013 allowed the Data Bank to gather feedback from users of the IQRS and get suggestions on areas for improvement. In addition, 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.

Table 7: User Feedback Gathering Events

Event	Topic	Date/Time Frame	Number of Attendees/Participants
Webinar	Compliance	September 20, 2011	Over 180
	Compliance	June 14, 2011	45
	Report Forwarding	January 17, 2012 & January 19, 2012	44
User Forum	General	October 20, 2011	16
	General	January 12, 2013	69
	General	September 26, 2012	37
	General	October 11, 2012	24
Usability Evaluation	Continuous Query	September & November, 2011	14
	One-Time Query	July-August, 2011	16
	Reporting	January-March, 2011	14
TOTAL			459

A summary of the comments received are provided below. As noted, the Data Bank has resolved some of the problems identified by users and plan to implement future enhancements to reduce burden on users.

Suggestions that have been implemented:

- Create Report Forwarding to State Boards as a feature to reduce the users' burden of mailing a copy to state boards where required by law
- Make it easier to find reports that require modification without using the Document Control Number
- Reduce or hide extra fields on the form
- Make it easier to find an error on the form
- Make date validation more flexible to allow for slashes and other punctuation

Suggestions that have been prioritized for future system enhancements:

- Expand Report Forwarding to include all states where practitioner is licensed, not just those where the incident occurred
- Prevent previous actions from carrying over to Revision to Actions
- Make data fields less confusing for Date of Action, Length of Action, and Specialty
- Allow reporters to save all data in the reporting workflow, instead of losing the data when they go back to a previous step
- Make it easier to copy and paste content from MS Word to the Narrative of the form
- Make the "Automatic Reinstatement" question a required field
- Provide contextual help closer to the field where it is needed
- Improve form formatting to make it easier to see how field labels match up to data
- Include an incident date as a field so that more related reports can be linked together – further study is required to implement this

9. Explanation of any Payment/Gift to Respondents

There will be no compensation to respondents.

10. Assurance of Confidentiality Provided to Respondents

Section 60.20 provides information on the confidentiality of the NPDB. Information reported to the NPDB is considered confidential and shall not be disclosed outside the Department of Health and Human Services, except as specified in §§ 60.17, 60.18, and 60.21. Persons and entities receiving information from the NPDB, either directly or from another party, must use it solely with respect to the purpose for which it was provided. Nothing in this section will prevent the disclosure of information by a party from its own files used to create such reports where disclosure is otherwise authorized under applicable State or Federal law. Any person who violates NPDB confidentiality shall be subject to a civil money penalty of up to $11,000 for each violation. This penalty will be imposed pursuant to procedures at 42 CFR Part 1003.

11. Justification for Sensitive Questions

The purpose of HCQIA 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 HCQIA 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. A new registration process has been implemented to improve the security posture of the NPDB-HIPDB system and bring the system into compliance with new identity proofing and e-authentication requirements.

The purpose of section 1128E is to facilitate the exchange of health care fraud-related information among law enforcement agencies, regulatory agencies, and health plans. The Department has determined that the reporting of Social Security Numbers and/or Federal Employer Identification Numbers is mandatory to differentiate between health care providers, suppliers and practitioners with similar names. However, the Department discloses these numbers only to individuals or organizations permitted by the statute to obtain such information from the HIPDB.

Section 6403 involves transferring data reporting requirements under HIPDB to NPDB, another data bank receiving like reports. This will eliminate duplication and streamline internal operations. Data collection will not change.

12. Estimates of Annualized Hour and Cost Burden

This section summarizes the total burden hours for information collection and the cost associated with those hours. Table 8 provides the estimated annualized burden hours and Table 9 provides the estimated annualized cost burden. Note that the “number of respondents” in Table 8 includes only IQRS users who will manually complete the forms available on the NPDB website. Entities that use QRXS are not included in the burden table because they submit queries and reports through an external application.

12A. Estimated Annualized Burden Hours

Table 8: Estimated Annualized Burden Hours

Regulation Citation	Form Name	Number of Respondents	Responses per Respondent	Total Responses	Hours per Response	Total Burden Hours
§ 60.6: Reporting errors, omissions, revisions or whether an action is on appeal.	Correction, Revision to Action, Correction of Revision to Action, Void, Notice of Appeal	38,785	1	38,785	15/60	9,696
§ 60.7: Reporting medical malpractice payments.	Medical Malpractice Payment	14,193	1	14,193	45/60	10,645
§ 60.8: Reporting licensure actions taken by Boards of Medical Examiners & § 60.9: Reporting licensure and certification actions taken by States.	State Licensure	28,700	1	28,700	45/60	21,525
§ 60.10: Reporting Federal licensure and certification actions.	DEA/Federal Licensure	499	1	499	45/60	374
§ 60.11: Reporting negative actions or findings taken by peer review organizations or private accreditation entities.	Peer Review Organization	10	1	10	45/60	8
	Accreditation	10	1	10	45/60	8
§ 60.12: Reporting adverse actions taken against clinical privileges.	Title IV Clinical Privileges Actions	962	1	962	45/60	722
	Professional Society	71	1	71	45/60	53
§ 60.13: Reporting Federal or State criminal convictions to the delivery of a health care item or service.	Criminal Conviction (Guilty Plea or Trial)	1,023	1	1,023	45/60	767
	Deferred Conviction or Pre-Trial Diversion	126	1	126	45/60	95
	Nolo Contendere (No Contest) Plea	63	1	63	45/60	47
	Injunction	10	1	10	45/60	8

Regulation Citation	Form Name	Number of Respondents	Responses per Respondent	Total Responses	Hours per Response	Total Burden Hours
§ 60.14: Reporting civil judgments related to the delivery of a health care item or service	Civil Judgment	10	1	10	45/60	8
§ 60.15: Reporting exclusions from participation in Federal or State health care programs	Exclusion/Debarment	2,402	1	2,402	45/60	1,802
§ 60.16: Reporting other adjudicated actions or decisions	Government Administrative	2,682	1	2,682	45/60	2,012
	Health Plan Action	561	1	561	45/60	421
§ 60.18 Requesting Information from the NPDB	One Time Query for an Individual	986,552	1	986,552	5/60	78,924
	One Time Query for an Organization	18,892	1	18,892	5/60	1,511
	Self-Query on an Individual	154,824	1	154,824	25/60	65,026
	Self-Query on an Organization	1,095	1	1,095	25/60	460
	Continuous Query	387,767	1	387,767	5/60	31,021
§ 60.21: How to dispute the accuracy of NPDB information	Subject Statement and Dispute	3,347	1	3,347	45/60	2,510
	Request for Secretarial Review	83	1	83	8	664
Administrative	Entity Registration (Initial)	35,915	1	35,915	1	35,915
	Entity Registration (Renewal & Update)	15,461	1	15,461	5/60	1,237
	Agent Registration (Initial)	100	1	100	15/60	25
	Agent Registration (Renewal & Update)	100	1	100	15/60	25
	Electronic Transfer of Funds (EFT)Authorization	562	1	562	15/60	141
	Authorized Agent Designation	1,290	1	1,290	15/60	323
	Account Discrepancy	20	1	20	15/60	5

Regulation Citation	Form Name	Number of Respondents	Responses per Respondent	Total Responses	Hours per Response	Total Burden Hours
TOTAL		1,696,115		1,696,115	……	**265,978**

12B. Estimated Annualized Cost Burden

The Department of Labor website was used to determine appropriate wage rates for respondents (http://www.bls.gov/bls/blswage.htm). The mean hourly wages for the following professions were selected from the website:

- Education and training occupations ($24.46)
- Insurance appraisers ($28.41)
- Business and financial operations occupations ($33.05)
- Health care practitioners and technical occupations ($34.97)
- Administrative services managers ($41.69)
- Management occupations ($51.64)
- Family and general practitioners ($85.26)

Table 9: Estimated Annualized Cost Burden

Regulation Citation	Form Name	Total Burden Hours	Wage Rate	Total Respondent Costs
§ 60.6: Reporting errors, omissions, revisions or whether an action is on appeal.	Correction, Revision to Action, Correction of Revision to Action, Void, Notice of Appeal	9,696	$51.64	$500,714.35
§ 60.7: Reporting medical malpractice payments.	Medical Malpractice Payment	10,645	$28.41	$302,417.35
§ 60.8: Reporting licensure actions taken by Boards of Medical Examiners & § 60.9: Reporting licensure and certification actions taken by States.	State Licensure	21,525	$41.69	$897,377.25
§ 60.10: Reporting Federal licensure and certification actions.	DEA/Federal Licensure	374	$41.69	$15,602.48
§ 60.11: Reporting negative actions or findings taken by peer review organizations or private accreditation entities.	Peer Review Organization	8	$41.69	$312.68
	Accreditation	8	$33.05	$247.88
§ 60.12: Reporting adverse actions taken against clinical privileges.	Title IV Clinical Privileges Actions	722	$24.46	$17,647.89

Regulation Citation	Form Name	Total Burden Hours	Wage Rate	Total Respondent Costs
	Professional Society	53	$24.46	$1,302.50
§ 60.13: Reporting Federal or State criminal convictions to the delivery of a health care item or service.	Criminal Conviction (Guilty Plea or Trial)	767	$41.69	$31,986.65
	Deferred Conviction or Pre-Trial Diversion	95	$41.69	$3,939.71
	Nolo Contendere (No Contest) Plea	47	$41.69	$1,969.85
	Injunction	8	$41.69	$312.68
§ 60.14: Reporting civil judgments related to the delivery of a health care item or service	Civil Judgment	8	$41.69	$312.68
§ 60.15: Reporting exclusions from participation in Federal or State health care programs	Exclusion/Debarment	1,802	$41.69	$75,104.54
§ 60.16: Reporting other adjudicated actions or decisions	Government Administrative	2,012	$41.69	$83,859.44
	Health Plan Action	421	$41.69	$17,541.07
§ 60.18 Requesting Information from the NPDB	One Time Query for an Individual	78,924	$34.97	$2,759,977.88
	One Time Query for an Organization	1,511	$34.97	$52,852.26
	Self-Query on an Individual	65,026	$34.97	$2,273,959.22
	Self-Query on an Organization	460	$34.97	$16,086.20
	Continuous Query	31,021	$34.97	$1,084,816.96
§ 60.21: How to dispute the accuracy of NPDB information	Subject Statement and Dispute	2,510	$85.26	$214,023.92
	Request for Secretarial Review	664	$85.26	$56,612.64
Administrative	Entity Registration (Initial)	35,915	$33.05	$1,186,990.75
	Entity Registration (Renewal & Update)	1,237	$33.05	$40,878.88
	Agent Registration (Initial)	25	$33.05	$826.25
	Agent Registration (Renewal &	25	$33.05	$826.25

Regulation Citation	Form Name	Total Burden Hours	Wage Rate	Total Respondent Costs
	Update)			
	Electronic Transfer of Funds (EFT)Authorization	141	$33.05	$4,643.53
	Authorized Agent Designation	323	$33.05	$10,658.63
	Account Discrepancy	5	$33.05	$165.25
TOTAL	**…..**	265,978	**…..**	**$9,653,967.57**

13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

There are no capital and start-up costs because the NPDB became operational on September 1, 1990 and HIPDB became operational on November 22, 1999.

Operation and Maintenance Costs: Since 1990, the NPDB has operated entirely on user fees. The regulations at 60.19 describe the user fees that will be assessed on requests for information from the Data Bank. Since May 9, 2006, the fee is $4.75 per query to the NPDB and HIPDB. This fee was published in the Federal Register on March 10, 2006 (71 FR 12368). Since July 1, 2004, the cost to perform a self-query is $8.00 for each data bank. This fee was published in the Federal Register on May 24, 2004 (69 FR 29565). Fees are charged to practitioners, providers or suppliers who wish to self-query to obtain any reports that are contained on themselves. Practitioner self-queries are automatically assessed for both data banks. In addition, the annual charge to use continuous query is $3.25 for each practitioner for each data bank.

Based on 2011 data, the estimated annual cost to IQRS users will be:

Queries from Entities	$ 4,775,859.00
Self-Queries	$ 2,485,944.00
Continuous Query	$ 1,260,242.75
Total	$ 8,522,045.75

Note that this total does not include query fees collected from QRXS users.

14. Annualized Cost to Federal Government

The annual cost to the federal government is estimated at $18,041,000. This is based on

government staff involvement at 100% x 6 FTEs = $804,000. The annual cost of the contract (FY13) is $17,237,000. This estimate is consistent with the OMB Exhibit 300 submission for FY13.Note that the 6 FTEs are the COR, the Investment Manager, and 4 IT specialists that directly oversee the NPDB IT system operations and contract.
Also note that the contract cost above includes the costs for the actual operation, maintenance, and enhancement of the NPDB IT system, as well as costs for the help desk call center, maintenance of the public NPDB website, and other related IT support. All of those costs are rolled into 1 contract.

15. Explanation for Program Changes or Adjustments

There are currently a total of 469,844 hours in the OMB inventory for both data banks (323,694 hours for the NPDB and 146,190 hours for the HIPDB). As indicated by Table 8, this request will be 265,978 hours. The result of the HIPDB-NPDB merger alleviates duplication and streamlines internal operations, resulting in a decrease of burden to users by 203,866 hours.

16. Plans for Tabulation, Publication, and Project Time Schedule

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

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.