

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 Office of Management and Budget (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. The purpose of this Information Collection Review (ICR) clearance package is to get approval on all of the forms contained herein. The circumstances making the collection of information necessary are divided into four sections: (I) Legal Authorities Governing the NPDB, (II) Reporting Requirements, (III) Query Requirements, and (IV) Data Collection Forms.

Responsibility for NPDB implementation and operation resides in the Division of Practitioner Data Bank (DPDB), Bureau of Health Workforce, Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

I. Legal Authorities Governing the NPDB

As discussed below, there are multiple legal authorities governing the NPDB. NPDB regulations are applicable to entities in all 50 States, the District of Columbia, and the U.S. territories of American Samoa, Guam, Northern Marianas, Puerto Rico, and Virgin Islands. For simplicity, any reference to a state or entity in this Supporting Statement should be interpreted to include the District of Columbia and the five U.S. territories.

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

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). The NPDB began collecting reports in 1990.

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

[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. 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.

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

[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. Formerly known as the Healthcare Integrity and Protection Data Bank (HIPDB), the HIPDB began collecting reports in 1999. Congress amended Sections 1921 and 1128E with Section 6403 of the Patient Protection and Affordable Care Act of 2010 (Public Law 111-148), which merged the NPDB and HIPDB

operations into one data bank: the NPDB. Section 1128E required Federal and State government agencies and health plans to report to the NPDB 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 NPDB. The NPDB 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.

d) Section 6403 of the Patient Protection and Affordable Care Act of 2010

[Section 6403](#) of the Patient Protection and Affordable Care Act of 2010 (hereinafter referred to as section 6403), Public Law 111-148, amended sections 1921 and 1128E to eliminate duplication between the former HIPDB and the NPDB, and required the Secretary to establish a transition period for transferring data collected in the HIPDB to the NPDB and to cease HIPDB operations, which occurred on May 6, 2013.

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 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 NPDB reports. The NPDB is a vital source 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 NPDB reports should be considered with other relevant information in evaluating credentials of health care practitioners, providers, and suppliers.

The NPDB serves as a single 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.

Users of the NPDB include reporters (entities that are required to submit reports) and queriers (entities that are authorized to request for information). The list of reportable actions collected by reporters and disclosed to queriers allow the NPDB 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.”

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.hrsa.gov>. All reporting and querying is performed through this secure website.

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 NPDB 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.

HRSA follows the National Institute of Standards and Technology security guidelines. More specifically, the NPDB has extensive operational, management, and technical controls that ensure the security of the system and protect the data in the system. The NPDB contains information classified under the Privacy Act that is considered personally identifiable information (PII). On an annual basis, the NPDB 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 has been completed for the NPDB. Finally, every three years, the NPDB is Certified and Accredited as a requirement to have an Authority to Operate, in order to function as a Federal system.

4. Efforts to Identify Duplication and Use of Similar Information

There is a large amount of confidential information in the NPDB that is not available from any other source. 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.

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 NPDB at the discretion of that entity.

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 NPDB 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 NPDB less frequently, the NPDB 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 December 8, 2014, Vol. 79, No. 235; pp. 72690-92 (see [60-Day FRN](#)). There were no public comments.

8B: In preparing this request for revision, DPDB consulted with users of the NPDB to detect any problems they may have had with electronic querying and reporting. As part of this effort, we collected feedback from 88 users in various usability evaluation sessions (approved through HRSA generic clearance, OMB 0915-0212, exp. 7/31/15). See [Table 1](#) for specific event details. These sessions have allowed DPDB to gather feedback from users of the IQRS and get suggestions on areas for improvement. In addition, we continue to solicit comments from the NPDB Stakeholder Engagement Group as they receive information from their constituents on problems related to the NPDB.

Table 1: User Feedback Gathering Events

Usability Event Topic	Date/Time Frame	Number of Attendees/Participants
Continuous Query	December 2012 – February 2013	12
Continuous Query	December 2012 – January 2013	15
One-Time Query	January – February 2013	8
Reporting	December 2013	15
Continuous Query	April 2014	9
Continuous Query	May – June 2014	9
Query Prepayment	July 2014	5
Self-Query	August – September 2014	15
TOTAL		88

A summary of the comments received are provided below. As noted, the NPDB 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:

- Created Report Forwarding to State Boards as a feature to reduce the users’ burden of mailing a copy to state boards where required by law and included all states where practitioner is licensed, not just those where the incident occurred

- Made it easier to find reports that require modification without using the Document Control Number
- Reduced or hide extra fields on the form
- Made it easier to find an error on the form
- Allowed reporters to save all data in the reporting workflow, instead of losing the data when they go back to a previous step
- Made it easier to copy and paste content from MS Word to the Narrative of the form
- Made the “Automatic Reinstatement” question a required field
- Improved form formatting to make it easier to see how field labels match up to data
- Created paperless registration renewal to minimize burden that allows entities to renew entirely online without mailing in notarized forms as long as the Certifying Official is the same
- Streamlined practitioner enrollment screens for agents to eliminate the need to log in and out multiple times
- Streamlined self-query screens to enable better self-service, reduce errors, and enable faster transactions with fewer steps
- New flexible payment options for high-volume users to streamline or eliminate billing paperwork

Suggestions that have been discussed for future system enhancements:

- Make date validation more flexible to allow for slashes and other punctuation to be included in reports
- Re-design the screens with more intuitive workflows and better instructions for reporting malpractice settlements, state license actions, and other adverse actions so users can complete transactions faster and with fewer errors
- Re-design and simplify the registration screens to reduce the time and burden of registering, to reduce errors, and to reduce the volume of new registrations that are rejected for minor technicalities
- Re-design and simplify the output and response intake for query users to improve self-service and reduce users’ need to call the help desk

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 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 NPDB.

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 2](#) provides the estimated annualized burden hours and [Table 3](#) shows the estimated annualized cost burden.

12A. Estimated Annualized Burden Hours

Table 2: Estimated Annualized Burden Hours

Regulation Citation	Form Name	Number of Respondents	Responses per Respondent	Total Responses	Average Burden per Response (in hours)	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 (manual)	20,482	1	20,482	.25	5,121
	Correction, Revision to Action, Correction of	17,185	1	17,185	.0003	5

Regulation Citation	Form Name	Number of Respondents	Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
	Revision to Action, Void, Notice of Appeal (automated)					
§ 60.7: Reporting medical malpractice payments.	Medical Malpractice Payment (manual)	12,613	1	12,613	.75	9,460
	Medical Malpractice Payment (automated)	250	1	250	.0003	.1
§ 60.8: Reporting licensure actions taken by Boards of Medical Examiners & §60.9: Reporting licensure and certification actions taken by States.	State Licensure (manual)	16,770	1	16,770	.75	12,578
	State Licensure (automated)	17,422	1	17,422	.0003	5
§ 60.10: Reporting Federal licensure and certification actions.	DEA/Federal Licensure	114	1	114	.75	86
§ 60.11: Reporting negative actions or findings taken by peer review organizations or private accreditation entities.	Peer Review Organization	10	1	10	.75	8
	Accreditation	12	1	12	.75	9
§ 60.12: Reporting adverse actions taken against clinical privileges.	Title IV Clinical Privileges Actions	671	1	671	.75	503
	Professional Society	50	1	50	.75	38
§ 60.13: Reporting Federal or State criminal convictions related to the delivery of a health care item or service.	Criminal Conviction (Guilty Plea or Trial) (manual)	1,308	1	1,308	.75	981
	Criminal Conviction (Guilty Plea or Trial) (automated)	937	1	937	.0003	.3

Regulation Citation	Form Name	Number of Respondents	Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
	Deferred Conviction or Pre-Trial Diversion	50	1	50	.75	38
	Nolo Contendere (No Contest) Plea	80	1	80	.75	60
	Injunction	10	1	10	.75	8
§ 60.14: Reporting civil judgments related to the delivery of a health care item or service.	Civil Judgment	14	1	14	.75	11
§ 60.15: Reporting exclusions from participation in Federal or State health care programs.	Exclusion/Debarment (manual)	1,185	1	1,185	.75	889
	Exclusion/Debarment (automated)	5,094	1	5,094	.0003	2
§ 60.16: Reporting other adjudicated actions or decisions.	Government Administrative	2,233	1	2,233	.75	1,675
	Health Plan Action	524	1	524	.75	393
§ 60.18 Requesting Information from the NPDB.	One-Time Query for an Individual (manual)	1,980,825	1	1,980,825	.08	158,466
	One-Time Query for an Individual (automated)	2,163,208	1	2,163,208	.0003	649
	One-Time Query for an Organization (manual)	39,920	1	39,920	.08	3,194
	One-Time Query for an Organization (automated)	2,266	1	2,266	.0003	1
	Self-Query on an Individual	77,318	1	77,318	.42	32,474
	Self-Query on an Organization	427	1	427	1	427
	Continuous Query (manual)	508,203	1	508,203	.08	40,656
	Continuous Query (automated)	121,718	1	121,718	.0003	37

Regulation Citation	Form Name	Number of Respondents	Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours	
§ 60.21: How to dispute the accuracy of NPDB information.	Subject Statement and Dispute	3,501	1	3,501	.75	2,626	
	Request for Dispute Resolution	94	1	94	8	752	
Administrative	Non-Hospital Entity Registration (Initial)	524	1	524	1	524	
	Non-Hospital Entity Registration (Renewal)	6,383	1	6,383	.25	1,596	
	Hospital Registration (Initial)	37	1	37	1	37	
	Hospital Registration (Renewal)	3,198	1	3,198	.25	800	
	Licensing Board Data Request	140	1	140	10.5	1,470	
	Reporting Entity Discrepancy Letter	389	1	389	4	1556	
	Licensing Board Attestation	354	1	354	1	354	
	Corrective Action Plan	10	1	10	.08	1	
	Reconciling Missing Actions	2,176	1	2,176	0.8	174	
	Agent Registration (Initial)	30	1	30	1	30	
	Agent Registration (Renewal)	194	1	194	.08	16	
	Electronic Transfer of Funds (EFT) Authorization	566	1	566	.08	45	
	Authorized Agent Designation	788	1	788	.25	197	
	Account Discrepancy	41	1	41	.25	10	
		TOTAL	5,012,335	5,012,335	278,753

12B. Estimated Annualized Cost Burden

The Department of Labor website was used to determine appropriate wage rates for respondents. The mean hourly wages for the following professions were selected from the website (wage rates accurate as of 3/26/15):

- Education, Training, and Library Occupations (<http://www.bls.gov/oes/current/oes250000.htm>; \$25.10)
- Claims Adjusters, Appraisers, Examiners, and Investigators (<http://www.bls.gov/ooh/business-and-financial/claims-adjusters-appraisers-examiners-and-investigators.htm>; \$28.78)
- Business and Financial Operations Occupations (<http://www.bls.gov/oes/current/oes130000.htm>; \$34.81)
- Healthcare Practitioners and Technical Occupations (<http://www.bls.gov/oes/current/oes290000.htm>; \$36.54)
- Administrative Services Managers (<http://www.bls.gov/ooh/management/administrative-services-managers.htm>; \$38.98)
- Management Occupations (<http://www.bls.gov/oes/current/oes110000.htm>; \$54.08)
- Family and General Practitioners (<http://www.bls.gov/oes/current/oes291062.htm>; \$89.58)

Table 3: 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	5,126	\$54.08	\$277,214.08
§ 60.7: Reporting medical malpractice payments.	Medical Malpractice Payment	9,460.1	\$28.78	\$272,261.68
§ 60.8: Reporting licensure actions taken by Boards of Medical Examiners & § 60.9: Reporting licensure and certification actions taken by States.	State Licensure	12,583	\$38.98	\$490,485.34
§ 60.10: Reporting Federal licensure and certification actions.	DEA/Federal Licensure	86	\$38.98	\$3,352.28
§ 60.11: Reporting negative actions or findings taken by peer review organizations or private accreditation entities.	Peer Review Organization	8	\$38.98	\$311.84
	Accreditation	9	\$34.81	\$313.29

Regulation Citation	Form Name	Total Burden Hours	Wage Rate	Total Respondent Costs
§ 60.12: Reporting adverse actions taken against clinical privileges.	Title IV Clinical Privileges Actions	503	\$25.10	\$12,625.30
	Professional Society	38	\$25.10	\$953.80
§ 60.13: Reporting Federal or State criminal convictions to the delivery of a health care item or service.	Criminal Conviction (Guilty Plea or Trial)	981.3	\$38.98	\$38,251.07
	Deferred Conviction or Pre-Trial Diversion	38	\$38.98	\$1,481.24
	Nolo Contendere (No Contest) Plea	60	\$38.98	\$2,338.80
	Injunction	8	\$38.98	\$311.84
§ 60.14: Reporting civil judgments related to the delivery of a health care item or service.	Civil Judgment	11	\$38.98	\$428.78
§ 60.15: Reporting exclusions from participation in Federal or State health care programs.	Exclusion/Debarment	891	\$38.98	\$34,731.18
§ 60.16: Reporting other adjudicated actions or decisions.	Government Administrative	1,675	\$38.98	\$65,291.50
	Health Plan Action	393	\$38.98	\$15,319.14
§ 60.18 Requesting Information from the NPDB.	One-Time Query for an Individual	159,115	\$36.54	\$5,814,062.10
	One-Time Query for an Organization	3,195	\$36.54	\$116,745.30
	Self-Query on an Individual	30,201	\$36.54	\$1,103,544.54
	Self-Query on an Organization	427	\$36.54	\$15,602.58
	Continuous Query	40,693	\$36.54	\$1,486,922.22
§ 60.21: How to dispute the accuracy of NPDB information.	Subject Statement and Dispute	2,626	\$89.58	\$235,237.08
	Request for Dispute Resolution	752	\$89.58	\$67,364.16
Administrative	Non-Hospital Entity Registration (Initial)	524	\$34.81	\$18,240.44
	Non-Hospital Entity Registration (Renewal)	1,596	\$34.81	\$55,556.76
	Hospital Registration (Initial)	37	\$34.81	\$1,287.97
	Hospital Registration (Renewal)	800	\$34.81	\$27,848.00
	Licensing Board Data Request	1,470	\$34.81	\$51,170.70

Regulation Citation	Form Name	Total Burden Hours	Wage Rate	Total Respondent Costs
	Reporting Entity Discrepancy Letter	1,556	\$34.81	\$54,164.36
	Licensing Board Attestation	354	\$34.81	\$12,322.74
	Corrective Action Plan	1	\$34.81	\$34.81
	Reconciling Missing Actions	174	\$34.81	\$6,056.94
	Agent Registration (Initial)	30	\$34.81	\$1,044.30
	Agent Registration (Renewal)	16	\$34.81	\$556.96
	Electronic Funds Transfer (EFT) Authorization	45	\$34.81	\$1,566.45
	Authorized Agent Designation	197	\$34.81	\$6,857.57
	Account Discrepancy	10	\$34.81	\$348.10
TOTAL	278,753	\$10,292,205.24

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

There are no capital and start-up costs.

Operation and Maintenance Costs: Since 1990, the NPDB has operated entirely on user fees and is statutorily required to operate through the collection of fees and does not receive federal appropriations. As of October 1, 2014, the fee is \$3.00 for Continuous and One-Time Query and \$5.00 for Self-Query. The annual collection from query fees is estimated to be \$18,606,760. This estimate was derived from the monthly average query volume (\$1,550,563) and multiplying it by 12 months, as shown in [Table 4](#) below:

Table 4: Estimated Query Volume and Fee Collection

Query Type	Fee	Quantity	Value
One-Time Query (10/1/14-12/31/14)	\$3.00	1,058,565	\$3,175,695.00
Continuous Query (10/1/14-12/31/14)	\$3.00	457,050	\$1,371,150.00
Self-Query (10/1/14-12/31/14)	\$5.00	20,969	\$104,845.00
Total for Quarter		1,536,584	\$4,651,690
Average per month		512,195	\$1,550,563

14. Annualized Cost to Federal Government

The annual cost to the federal government is estimated at \$20.5 million. [Table 5](#) details the specific items that were included in the calculation of this estimate.

Table 5: Estimated Annualized Cost to Federal Government

Item	Details	Annual Value
NPDB Program Staff	43 government full-time equivalent staff involved in various aspects of support contract management and oversight, IT investments, disputes, compliance, policy, and general oversight and management of DPDB operations.	\$7,500,000
NPDB Support Contract	Support contract for the operation, maintenance, and enhancement of the NPDB IT system, customer service center, maintenance of the public NPDB website, and related technical services.	\$13,000,000
Estimated Annualized Cost to Federal Government		\$20,500,000

15. Explanation for Program Changes or Adjustments

The total burden hours increased by approximately 9,700 hours and the total number of respondents increased by approximately 3.3 million respondents since our last approved burden (as shown in [Table 6](#)):

Table 6: Explanation for Burden Changes

Item	Number of Respondents	Total Burden Hours
Requested Burden (2015)	5,009,285	275,689
Approved Burden (2013)	1,696,115	265,978
Difference	3,313,170	9,711

In the previous submission, we only counted individual transactions that were manually processed through the IQRS system. We did not account for batch transactions that were processed through an automated system called QRXS because there is no direct user burden. This time, we decided to include the number of batch queries and reports due to the large volume of automated transactions. For this reason, the burden table provides a more complete picture of our respondent numbers because it reflects manual (IQRS) and automatic (QRXS) transactions.

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 OMB number and Expiration date will be displayed on every page of every form/instrument.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.