

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

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.

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

Legal Authorities Governing the NPDB

As discussed below, there are multiple legal authorities governing the NPDB. The NPDB regulations are applicable to entities in all 50 States, the District of Columbia, and the U.S. territories of American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the 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. The NPDB regulations implementing these laws are codified at [45 CFR Part 60](#).

a.) [Title IV of Public Law 99-660, Health Care Quality Improvement Act \(HCQIA\) of 1986](#)

The intent of Title IV is to improve the quality of health care by encouraging State licensing boards, professional societies, hospitals, and other health care entities to restrict the ability of incompetent physicians, dentists, and other health care practitioners to move from State to State without disclosure or discovery of previous medical malpractice payment and adverse action history. These adverse actions include certain licensure, clinical privileges, and professional society membership actions, as well as Drug Enforcement Administration (DEA) controlled-substance registration actions and exclusions from participation in Medicare, Medicaid, and other Federal health care programs.

b.) [Section 1921 of the Social Security Act](#)

Section 1921 was enacted to provide protection from unfit health care practitioners to beneficiaries participating in Medicare and State health care programs and to improve the anti-fraud provisions of these programs. Information collected and disclosed by the NPDB under Section 1921 includes State licensure and certification actions against health care practitioners, entities, providers, and suppliers; negative actions or findings by peer review organizations and private accreditation organizations; and certain final adverse actions taken by certain State Agencies, including State law enforcement agencies, State Medicaid fraud control units, and State agencies administering or supervising the administration of State health care programs. These final adverse actions include exclusions from a State health care program, health care-related criminal convictions and civil judgments in State court, and other adjudicated actions or decisions specified in regulations.

c.) [Section 1128E of the Social Security 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: Licensure 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

NPDB is a web-based repository of reports containing information on medical malpractice payments and certain adverse actions related to health care practitioners, providers, and suppliers. Established by Congress in 1986, it is a workforce tool that prevents practitioners from moving state-to-state without disclosure or discovery of previous damaging performance.

Information is collected from, and disseminated to, eligible entities (entities that are entitled to query and/or report to the NPDB under Title IV, Sections 1921, 1128E, and 6403). 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. 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 improve health care quality, protect the public, and reduce health care fraud and abuse in the U.S.

The NPDB is a vital source of information for the effective evaluation of health care practitioners and entities and plays 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 majority of the proposed revisions in this package were made to forms that are used for registering or renewing/updating registration with the NPDB. Revisions include:

- *Allow users to create an account before providing entity data and save incomplete forms. Users can return later to complete the registration form that will decrease the number of abandoned registrations. This change increases the potential to collect more accurate data since the user is not pressured to complete the form in one session.*
- *Implementation of paperless registration renewal process that allows users to upload registration paperwork directly to NPDB and to shorten the renewal workflow, which saves time and mailing costs.*
- *Start registration renewal/update by showing users the summary page instead of the current process that sends the user through each page of the registration form. If the data is correct on the summary page, users can just submit it and be done. If not, users can navigate to the appropriate section(s) and update the data before submitting to the NPDB.*

- *Clarified statutory authority to ensure entities register correctly with the NPDB and clearly communicate the entity’s reporting and querying requirements.*
- *Added text early in the registration process to redirect users, if necessary, to the correct paths for their requests.*

Other minor changes include:

- *Reworded text to use “plain language.”*
- *Changed “Data Bank” references to the National Practitioner Data Bank or NPDB.*
- *Reordered response choices based on most common usage.*
- *Added modal windows to provide context for completing fields.*
- *Deleted Reporting Entity Discrepancy Letter because it is not a data collection form.*

As a result, these proposed revisions will eliminate redundant and unnecessary forms, improve user error recovery, and improve overall data integrity.

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 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 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 NPDB website.

HRSA follows the National Institute of Standards and Technology (NIST) security guidelines. The HRSA IT Security Policy outlines high-level security requirements for both HRSA IT systems and management processes, encompassing Management, Operational, and Technical controls as defined in NIST Special Publication 800-53, Revision 4, Recommended Security Controls for Federal Information Systems and Organizations. Any subsequent documentation (e.g., procedures, standards or other operational guidance) must comply with the HRSA IT Security Policy. In addition to NIST guidance, the HRSA IT Security Policy incorporates standards established by HHS, existing HRSA documentation and information obtained from

interviews with Personnel Security, Office of Information Technology staff, and other HRSA stakeholders.

The protection level of NPDB program data is commensurate with a moderate level of sensitivity as defined by the guidelines set forth in Federal Information Processing Standard 199, “Standards for Security Categorization of Federal Information and Information Systems.” The NPDB contains information classified under the Privacy Act that is considered personally identifiable information (PII). In accordance with HHS policy, a Privacy Impact Assessment (PIA) has been completed for the NPDB. 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.

Finally, a critical aspect of the Security Assessment and Authorization (SA&A) process is the post-authorization period involving the continuous monitoring of security controls in the information system over time. An effective continuous monitoring program requires configuration management and configuration control processes; security impact analyses on changes to the information system; and assessment of selected security controls in the information system and security status reporting to appropriate agency officials. For the NPDB, continuous monitoring is conducted, whereby one-third of the controls are tested each year. At the end of the third year, and once all the controls have been tested, an Authority to Operate (ATO) is issued. Additionally, if enhancements to a system are made which change the system’s security posture, an updated authorization to operate is required before deployment, regardless of where the system is in the 3-year cycle.

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.

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. 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 September 12, 2017, Vol. 82, No. 175; pp. 42821- 42822 (see [60-Day FRN](#)). There was a public comment from one organization. The NPDB had a preliminary discussion with this organization to address questions related to NPDB reporting policy and offered an opportunity for a formal meeting, as they desire.

8B: In preparing this request for revision, the NPDB consulted with its users to detect any problems they may have had with electronic querying and reporting. As part of this effort, we collected feedback from over 60 users via six usability sessions (approved through HRSA generic clearance, OMB 0915-0212, exp. 5/31/18) and a user education forum. See Table 1 for specific event details. The consultation activities conducted from 2015-2017 allowed the NPDB

to gather feedback from users of the Integrated Querying and Reporting Service (IQRS) and solicit suggestions on areas for improvement. In addition, HRSA continues to solicit comments from stakeholder organizations as they receive information from their constituents on problems related to the NPDB.

Table 1: User Feedback Gathering Events

Topic	Date/Time Frame	Number of Attendees/Participants
Compliance	April 7, 2015	5
Reporting	May 29 - July 10, 2015	24
Report Response Service	June 3 - July 24, 2015	8
Query Responses	June 17 - July 24, 2015	5
Health Center Attestation	January 12 - February 1, 2016	6
Hospital Profile	June 9 - 23, 2016	8
Entity Registration	April 24 - May 3, 2017	6
Total		62

A summary of the comments received are provided below.

Suggestions that have been implemented:

- Added display for the number of saved draft reports
- Added functionality to delete a draft report
- Added functionality to print a draft report
- Hospital profile design released 2017 incorporating enhancements from user evaluations
- Changed font treatment for report narratives from block case to mixed case
- Added display of "Not provided" to indicate information that was not collected (e.g., blank text entry form fields)
- Added SMS 2nd factor authentication to allow credentials recovery for user accounts
- Prevent previous actions from carrying over to Revision to Actions
- Implemented Tiny Moxiecode Content Editor (MCE) to make it easier to copy and paste content from MS Word to report form narrative text entries

Suggestions that have been prioritized for future system enhancements:

- Streamline reporting workflow
- Redesign and simplify report documents for increased readability
- Streamline and simplify identity proofing documents

- Increase functionality to store a draft report
- Enhance search for subjects to include prior reports and queries to reuse data elements
- Evaluate forms for opportunities to remove or consolidate data collection elements
- Enhance autocomplete/autosuggest for elements with selections > 10
- Indicate form elements that are mandatory for form completion
- Enhance report response service and self-query to allow SMS 2nd factor authentication
- Enhance forms to allow users to clearly specify data they do not have
- Enhance functionality to allow continuous monitoring for practitioners (continuous Self-Query)
- Add option to opt out of paper Subject Notification Document by the subject
- Allow single sign-in for report response for practitioners with multiple reports (e.g. create a unique user name or use primary email address)
- Streamline initial entity registration and renewal workflow
- Streamline and simplify content and form element labels to support plain language initiative
- Add a review summaries to report submission and registration workflows
- Clarify and simplify verbiage regarding definitions that are NPDB's "terms of art"
- Add more contextual help on all forms
- Streamline forms to hide elements that are used infrequently
- Increase opportunities for paperless transactions

9. Explanation of any Payment/Gift to Respondents

Respondents will not receive any payments or gifts.

10. Assurance of Confidentiality Provided to Respondents

45 CFR 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 of HHS, except as specified in Sections 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. This penalty will be imposed pursuant to procedures at 42 CFR Part 1003. The penalty amounts in this section are adjusted for inflation annually. Adjusted amounts are published at 45 CFR Part 102. The NPDB has system of record notice number 09-15-0054 (<https://www.hrsa.gov/about/privacy-act/09-15-0054.html>).

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 (SSN) of report subjects will take place only in accordance with Section 7 of the Privacy Act. The SSN will be used as an identifier to distinguish among practitioners with similar names.

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. HHS has determined that the reporting of SSN and/or Federal Employer Identification Numbers is mandatory to differentiate between health care providers, suppliers and practitioners with similar names. However, HHS 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 provides the estimated annualized cost burden. Note that the “number of respondents” in Table 2 includes IQRS users who will manually complete the forms available on the NPDB website and entities that use Querying and Reporting XML Service (QRXS) to query and reports through an external application.

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,	Correction, Revision to	11,114	1	11,114	.25	2,779

Regulation Citation	Form Name	Number of Respondents	Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
omissions, revisions or whether an action is on appeal.	Action, Correction of Revision to Action, Void, Notice of Appeal (manual)					
	Correction, Revision to Action, Correction of Revision to Action, Void, Notice of Appeal (automated)	17,966	1	17,966	.0003	6
§ 60.7: Reporting medical malpractice payments.	Medical Malpractice Payment (manual)	11,993	1	11,993	.75	8,995
	Medical Malpractice Payment (automated)	242	1	242	.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)	19,160	1	19,160	.75	14,370
	State Licensure (automated)	25,980	1	25,980	.0003	8
§ 60.10: Reporting Federal licensure and certification actions.	DEA/Federal Licensure	698	1	698	.75	524
§ 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	10	1	10	.75	8
§ 60.12: Reporting adverse actions taken against clinical privileges.	Title IV Clinical Privileges Actions	698	1	698	.75	524
	Professional Society	49	1	49	.75	37
§ 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)	1,140	1	1,140	.75	855
	Criminal Conviction (Guilty Plea or Trial) (automated)	688	1	688	.0003	1
	Deferred Conviction or Pre-Trial Diversion	54	1	54	.75	41

Regulation Citation	Form Name	Number of Respondents	Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
	Nolo Contendere (No Contest) Plea	85	1	85	.75	64
	Injunction	10	1	10	.75	8
§ 60.14: Reporting civil judgments related to the delivery of a health care item or service.	Civil Judgment	10	1	10	.75	8
§ 60.15: Reporting exclusions from participation in Federal or State health care programs.	Exclusion/Debarment (manual)	1,624	1	1,624	.75	1,218
	Exclusion/Debarment (automated)	3,180	1	3,180	.0003	1
§ 60.16: Reporting other adjudicated actions or decisions.	Government Administrative	2,062	1	2,062	.75	1,547
	Health Plan Action	335	1	335	.75	252
§ 60.18 Requesting Information from the NPDB.	One-Time Query for an Individual (manual)	2,054,381	1	2,054,381	.08	164,351
	One-Time Query for an Individual (automated)	2,813,341	1	2,813,341	.0003	844
	One-Time Query for an Organization (manual)	39,695	1	39,695	.08	3,176
	One-Time Query for an Organization (automated)	10,201	1	10,201	.0003	4
	Self-Query on an Individual	131,481	1	131,481	.42	55,223
	Self-Query on an Organization	1,545	1	1,545	.42	649
	Continuous Query (manual)	643,860	1	643,860	.08	51,509
	Continuous Query (automated)	226,838	1	226,838	.0003	69
§ 60.21: How to dispute the accuracy of NPDB information.	Subject Statement and Dispute	3,547	1	3,547	.75	2,661
	Request for Dispute Resolution	99	1	99	8	792

Regulation Citation	Form Name	Number of Respondents	Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Administrative	Entity Registration (Initial)	1,073	1	1,073	1	1,073
	Entity Registration (Renewal & Update)	14,060	1	14,060	.25	3,515
	Entity Profile	9,000	1	9,000	.25	2,250
	Licensing Board Data Request	146	1	146	10.5	1,533
	Licensing Board Attestation	301	1	301	1	301
	Corrective Action Plan	10	1	10	.08	1
	Reconciling Missing Actions	7,981	1	7,981	0.8	6,385
	Agent Registration (Initial)	85	1	85	1	85
	Agent Registration (Renewal)	278	1	278	.08	23
	Electronic Transfer of Funds (EFT) Authorization	654	1	654	.08	53
	Authorized Agent Designation	213	1	213	.25	54
	Account Discrepancy	10	1	10	.25	3
	New Administrator Request	3,016	1	3,016	.08	242
	Query Credit Purchase	789	1	789	.08	64
	Educational Request	10	1	10	.08	1
	Account Balance Transfer	10	1	10	.08	1
	Missing Report Form	29	1	29	.08	3
		TOTAL	6,059,761	6,059,761

12B. Estimated Annualized Burden Costs

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 as samples from the website:

- Education, Training, and Library Occupations (\$26.21)
- Claims Adjusters, Appraisers, Examiners, and Investigators (\$30.61)
- Business and Financial Operations Occupations (\$36.09)
- Healthcare Practitioners and Technical Occupations (\$38.06)
- Administrative Services Managers (\$43.29)
- Management Occupations (\$56.74)
- Family and General Practitioners (\$96.54)

Table 3: Estimated Annual Burden Costs

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 (manual)	2,779	\$56.74	\$157,680.46
	Correction, Revision to Action, Correction of Revision to Action, Void, Notice of Appeal (automated)	6	\$56.74	\$340.44
§ 60.7: Reporting medical malpractice payments.	Medical Malpractice Payment (manual)	8,995	\$30.61	\$275,336.95
	Medical Malpractice Payment (automated)	1	\$30.61	\$30.61
§ 60.8: Reporting licensure actions taken by Boards of Medical Examiners & §60.9: Reporting licensure and certification actions taken by States.	State Licensure (manual)	14,370	\$43.29	\$622,077.30
	State Licensure (automated)	8	\$43.29	\$346.32
§ 60.10: Reporting Federal licensure and certification actions.	DEA/Federal Licensure	524	\$43.29	\$22,683.96
§ 60.11: Reporting negative actions or findings taken by peer review organizations or private accreditation entities.	Peer Review Organization	8	\$43.29	\$346.32
	Accreditation	8	\$43.29	\$346.32
§ 60.12: Reporting adverse actions taken against clinical privileges.	Title IV Clinical Privileges Actions	524	\$43.29	\$22,683.96
	Professional Society	37	\$26.21	\$969.77

Regulation Citation	Form Name	Total Burden Hours	Wage Rate	Total Respondent Costs
§ 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)	855	\$43.29	\$37,012.95
	Criminal Conviction (Guilty Plea or Trial) (automated)	1	\$43.29	\$43.29
	Deferred Conviction or Pre-Trial Diversion	41	\$43.29	\$1,774.89
	Nolo Contendere (No Contest) Plea	64	\$43.29	\$3,410.56
	Injunction	8	\$43.29	\$346.32
§ 60.14: Reporting civil judgments related to the delivery of a health care item or service.	Civil Judgment	8	\$43.29	\$346.32
§ 60.15: Reporting exclusions from participation in Federal or State health care programs.	Exclusion/Debarment (manual)	1,218	\$43.29	\$52,727.22
	Exclusion/Debarment (automated)	1	\$43.29	\$43.29
§ 60.16: Reporting other adjudicated actions or decisions.	Government Administrative	1,547	\$43.29	\$66,969.63
	Health Plan Action	252	\$43.29	\$10,909.08
§ 60.18 Requesting Information from the NPDB.	One-Time Query for an Individual (manual)	164,351	\$38.06	\$6,255,199.06
	One-Time Query for an Individual (automated)	844	\$38.06	\$32,122.64
	One-Time Query for an Organization (manual)	3,176	\$38.06	\$120,878.56
	One-Time Query for an Organization (automated)	4	\$38.06	\$152.24
	Self-Query on an Individual	55,223	\$38.06	\$2,101,787.38
	Self-Query on an Organization	649	\$38.06	\$24,700.94
	Continuous Query (manual)	51,509	\$38.06	\$1,960,432.54
	Continuous Query (automated)	69	\$38.06	\$2,626.14
§ 60.21: How to dispute the accuracy of NPDB	Subject Statement and Dispute	2,661	\$96.54	\$256,892.94

Regulation Citation	Form Name	Total Burden Hours	Wage Rate	Total Respondent Costs	
information.	Request for Dispute Resolution	792	\$96.54	\$76,459.68	
Administrative	Entity Registration (Initial)	1,073	\$36.09	\$38,724.57	
	Entity Registration (Renewal & Update)	3,515	\$36.09	\$126,856.35	
	Entity Profile	2,250	\$36.09	\$81,202.50	
	Licensing Board Data Request	1,533	\$36.09	\$55,325.97	
	Licensing Board Attestation	301	\$36.09	\$10,863.09	
	Corrective Action Plan	1	\$36.09	\$36.09	
	Reconciling Missing Actions	6,385	\$36.09	\$230,434.65	
	Agent Registration (Initial)	85	\$36.09	\$3,067.65	
	Agent Registration (Renewal)	23	\$36.09	\$830.07	
	Electronic Transfer of Funds (EFT) Authorization	53	\$36.09	\$1,912.77	
	Authorized Agent Designation	54	\$36.09	\$1,948.86	
	Account Discrepancy	3	\$36.09	\$108.27	
	New Administrator Request	242	\$36.09	\$8,733.78	
	Query Credit Purchase	64	\$36.09	\$2,309.76	
	Education Request	1	\$36.09	\$36.09	
	Account Balance Transfer	1	\$36.09	\$36.09	
	Missing Report Form	3	\$36.09	\$108.27	
	TOTAL		326,120	\$12,670,213

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

There are no capital or 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. The NPDB does not receive

Federal appropriations. Since October 1, 2016, the fee cost of both the one-time query and continuous query is \$2.00. The cost of a self-query is \$4.00. These fees were published in the Federal Register on July 20, 2016 (81 FR 47173). For fiscal year 2017, the collection from query fees was approximately \$15.8 million shown in Table 4 below.

Table 4: Fiscal Year 2017-Estimated Query Volume and Fee Collection

Query Type	Fee	Query Count	Net Revenue
One-Time Query	\$2.00	4,631,000	\$9,262,000
Continuous Query	\$2.00	2,702,000	\$5,404,000
Self-Query	\$4.00	156,000	\$624,000
Query Credit Purchase	\$2.00	283,500	\$567,000
Estimated Total			\$15,857,000

14. Annualized Cost to Federal Government

The annual cost to the Federal government is estimated at \$19.5 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	34 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 NPDB operations.	\$ 5,540,000.00
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.	\$ 14,000,000.00
Estimated Annualized Cost to Federal Government		\$19,540,000

15. Explanation for Program Changes or Adjustments

The total burden hours increased by approximately 47,347 hours and the total number of

respondents increased by approximately 1,047,426 million respondents since our last approved burden as shown in Table 6. This is primarily attributable to increases in use of the “One-Time Query for an Individual” and “Continuous Query” forms.

Table 6: Explanation for Burden Changes

Item	Number of Respondents	Total Burden Hours
Requested Burden (2017)	6,059,761	326,120
Approved Burden (2016)	5,012,335	278,753
Difference	1,047,426	47,367

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

Aggregate data and data that are stripped of identifiers are made available on the NPDB website for statistical purposes. In addition, de-identified data may be made available 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.