

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 approval from the Office of Management and Budget (OMB) for this *revised* information collection request (ICR) 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. Administrative forms are also included to aid in monitoring compliance and ensure all eligible entities are meeting their Federal reporting, querying, and confidentiality requirements.

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

The statutes and regulations that govern and maintain NPDB operations include:

- Title IV of the Health Care Quality Improvement Act of 1986 (HCQIA), Public Law 99-660 (referred to as “[Title IV](#)”);
- Section 5 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93, codified as Section 1921 of the Social Security Act (referred to as “[Section 1921](#)”);
- Section 221(a) of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, codified as Section 1128E of the Social Security Act (referred to as “[Section 1128E](#)”); and
- [Section 6403](#) of the Patient Protection and Affordable Care Act of 2010 (Public Law 111-148).

The NPDB regulations implementing these laws are codified at [45 CFR Part 60](#).

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.

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

The original purpose of [Section 1128E](#) was to establish a national data collection program, formerly known as the HIPDB, to combat health care fraud and abuse. Section 1128E information is now collected and disclosed by the NPDB and includes certain final adverse actions taken by Federal agencies and health plans against health care practitioners, providers, and suppliers. These actions consist of Federal licensure and certification actions, exclusions from participation in a Federal health care program, health care-related criminal convictions and civil judgments, and other adjudicated actions or decisions specified in regulations.

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). 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 quierers (entities that are authorized to request for information). The list of reportable actions collected by reporters and disclosed to quierers 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.

This (ICR) proposes the following revisions:

- ***Consolidate all NPDB forms into one OMB ICR by including the five Attestation forms that were approved in OMB No. 0906-0028: National Practitioner Data Bank (NPDB) Attestation of Reports by Hospitals, Medical Malpractice Payers, Health Plans, and Certain Other Eligible Entities. HRSA will request to discontinue OMB No. 0906-0028 upon approval of this ICR.***
- ***Further clarify the statutes and regulations that govern and maintain NPDB operations to ensure entities register correctly with the NPDB and comply with their reporting and querying requirements.***
- ***Enhance the State Licensing Board workflows to collect an entity's current list of regulated professions and streamline their report submission process.***
- ***Add dynamic field labels that correspond to the reporting entity's selections on the Medical Malpractice Payer Report, making it more user-friendly.***
- ***Add contextual help on forms where needed to improve data integrity.***

3. Use of Improved Information Technology and Burden Reduction

As part of the Burden Reduction Initiative, 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.

Additionally, NPDB has been able to reduce input form error and enhance the overall user experience by implementing the technologies listed below:

- Offering the Experian Precise ID option for Self-Queriers to identity proof online as an alternative option in addition to using a legacy lengthy paper and notary process.
- Provision of electronic, browser based uploads for supporting documents for Self-Query, entity/agent registration and dispute resolution requests instead of mailing the forms via the United States Postal Service.
- Redesigned the agent and entity registration forms to streamline the workflow and reduce errors caused by incorrect selection (e. g. , self-queriers completing entity registration, entities incorrectly completing an agent form)
- Redesigned the self-query and the compliance review workflows to provide more information to users selecting organization self-query to reduce errors and to allow users to see their compliance status for all professions in real time and resolve missing actions.
- Incorporated autocomplete features for certifying user information, addresses, school names, including autosuggest features for licensure professions when users save incomplete forms.

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

The NPDB contains a large amount of confidential information 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 memberships 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

The request fully complies with the regulation.

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 October 16, 2020, Vol. 85, No. 201; pp. 65834-65837. There were two public comments from two organizations.

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 via 29 usability sessions and a user education forum. See Table 1 for specific event details. These consultation activities conducted from 2018 to 2020 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 problems related to the NPDB arise.

Table 1: User Feedback Gathering Events

Topic	Date/Time Frame	Number of Attendees/Participants
<u>Usability Session:</u> Compliance Summary	January 19 - February 5, 2018	9
<u>Usability Session:</u> Website Compliance Posting	November 29, 2018 - December 5, 2018	5
<u>Usability Session:</u> Limit FOL on Reporting	May 21 - June 3, 2019	6
<u>Usability Session:</u> Revisions and Corrections	January 13 - February 4, 2020	9
2019 NPDB Education Forum	April 9, 2019	56
Total		85

Suggestions that have been implemented:

- Clarified definitions for compliance status and actions needed for compliance activities.
- Streamlined required self-query identity proofing documents reducing paper use from four to one page.
- Streamlined entity registration renewal process to allow users to review a summary and renew in one step if they have no changes or navigate directly to the appropriate section if edits are needed.
- Added a review summary to report submission and registration workflows allowing users to review entries prior to submission, reducing potential errors.
- Extended length of time draft reports can be saved in the NPDB system from 45 days to 60 days.
- Implemented compliance summary page for state licensing boards selected for NPDB Compliance Reviews.

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 the 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	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours (rounded up)
§ 60.6: Reporting errors, omissions, revisions or whether an action is on appeal.	Correction, Revision-to-Action, Void, Notice of Appeal (manual)	11,918	1	11,918	.25	2,980
	Correction, Revision-to-Action, Void, Notice of Appeal (automated)	18,301	1	18,301	.0003	5
§ 60.7: Reporting medical malpractice payments.	Medical Malpractice Payment (manual)	11,481	1	11,481	.75	8,611
	Medical Malpractice Payment (automated)	296	1	296	.0003	1
§ 60.8: Reporting licensure actions taken by Boards of Medical Examiners	State Licensure or Certification (manual)	19,749	1	19,749	.75	14,812
	State Licensure or Certification (automated)	17,189	1	17,189	.0003	5
§60.9: Reporting licensure and certification actions taken by States.						
§ 60.10: Reporting Federal licensure and certification actions.	DEA/Federal Licensure	600	1	600	.75	450
§ 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	978	1	978	.75	734
	Professional Society	41	1	41	.75	31
§ 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)	1,174	1	1,174	.75	881
	Criminal Conviction (Guilty Plea or Trial) (automated)	683	1	683	.0003	1
	Deferred Conviction or Pre-Trial Diversion	70	1	70	.75	53
	Nolo Contendere (no contest plea)	127	1	127	.75	95

Regulation Citation	Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours (rounded up)
	Injunction	10	1	10	.75	8
§ 60.14: Reporting civil judgments related to the delivery of a health care item or service.	Civil Judgment	9	1	9	.75	7
§ 60.15: Reporting exclusions from participation in Federal or State health care programs.	Exclusion or Debarment (manual)	1,707	1	1,707	.75	1,280
	Exclusion or Debarment (automated)	2,506	1	2,506	.0003	1
§ 60.16: Reporting other adjudicated actions or decisions.	Government Administrative (manual)	1,750	1	1,750	.75	1,313
	Government Administrative (automated)	39	1	39	.0003	1
	Health Plan Action	488	1	488	.75	366
§ 60.17 Information which hospitals must request from the National Practitioner Data Bank. § 60.18 Requesting Information from the NPDB.	One-Time Query for an Individual (manual)	1,958,176	1	1,958,176	.08	156,654
	One-Time Query for an Individual (automated)	3,349,778	1	3,349,778	.0003	1,005
	One-Time Query for an Organization (manual)	50,681	1	50,681	.08	4,054
	One-Time Query for an Organization (automated)	25,610	1	25,610	.0003	8
	Self-Query on an Individual	168,557	1	168,557	.42	70,794
	Self-Query on an Organization	1,059	1	1,059	.42	445
	Continuous Query (manual)	806,971	1	806,971	.08	64,558
	Continuous Query (automated)	619,001	1	619,001	.0003	186
§ 60.21: How to dispute the accuracy of NPDB information.	Subject Statement and Dispute	3,264	1	3,264	.75	2,448
	Request for Dispute Resolution	74	1	74	8	592
Administrative	Entity Registration (Initial)	3,484	1	3,484	1	3,484
	Entity Registration (Renewal & Update)	13,245	1	13,245	.25	3,311
	State Licensing Board Data Request	60	1	60	10.5	630

Regulation Citation	Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours (rounded up)
	State Licensing Board Attestation	325	1	325	1	325
	Authorized Agent Attestation	350	1	350	1	350
	Health Center Attestation	722	1	722	1	722
	Hospital Attestation	3,416	1	3,416	1	3,416
	Medical Malpractice Payer, Peer Review Organization, or Private Accreditation Organization Attestation	274	1	274	1	274
	Other Eligible Entity Attestation	1,884	1	1,884	1	1,884
	Corrective Action Plan (Entity)	10	1	10	.08	1
	Reconciling Missing Actions	1,491	1	1,491	.08	1193
	Agent Registration (Initial)	44	1	44	1	44
	Agent Registration (Renewal & Update)	304	1	304	.08	24
	Electronic Funds Transfer (EFT) Authorization	644	1	644	.08	52
	Authorized Agent Designation	183	1	183	.25	46
	Account Discrepancy	85	1	85	.25	21
	New Administrator Request	600	1	600	.08	48
	Purchase Query Credits	1,786	1	1786	.08	143
	Education Request	40	1	40	.08	3
	Account Balance Transfer	10	1	10	.08	1
	Missing Report From Query Form	10	1	10	.08	1
	TOTAL	7,101,274	7,101,274	348,368

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:

- Educational Instruction and Library Occupations (\$28.37)
- Claims Adjusters, Appraisers, Examiners, and Investigators (\$29.17)

- Business and Financial Operations Occupations (\$30.74)
- Healthcare Practitioners and Technical Occupations (\$36.01)
- Administrative Services and Facilities Managers (\$44.41)
- Management Occupations (\$44.40)
- Family and General Practitioners (\$101.82)

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, Void, Notice of Appeal (manual)	2,980	\$44.40	\$132,312.00
	Correction, Revision-to-Action, Void, Notice of Appeal (automated)	5	\$44.40	\$222.00
§ 60.7: Reporting medical malpractice payments.	Medical Malpractice Payment (manual)	8,611	\$29.17	\$251,182.87
	Medical Malpractice Payment (automated)	1	\$29.17	\$29.17
§ 60.8: Reporting licensure actions taken by Boards of Medical Examiners §60.9: Reporting licensure and certification actions taken by States.	State Licensure or Certification (manual)	14,812	\$44.41	\$657,800.92
	State Licensure or Certification (automated)	5	\$44.41	\$222.05
§ 60.10: Reporting Federal licensure and certification actions.	DEA/Federal Licensure	450	\$44.41	\$19,984.50
§ 60.11: Reporting negative actions or findings taken by peer review organizations or private accreditation entities.	Peer Review Organization	8	\$44.41	\$355.28
	Accreditation	8	\$44.41	\$355.28
§ 60.12: Reporting adverse actions taken against clinical privileges.	Title IV Clinical Privileges Actions	734	\$44.41	\$32,596.94
	Professional Society	31	\$28.37	\$879.47

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)	881	\$44.41	\$39,125.21
	Criminal Conviction (Guilty Plea or Trial) (automated)	1	\$44.41	\$44.41
	Deferred Conviction or Pre-Trial Diversion	53	\$44.41	\$2,353.73
	Nolo Contendere (no contest plea)	95	\$44.41	\$4,218.95
	Injunction	8	\$44.41	\$355.28
§ 60.14: Reporting civil judgments related to the delivery of a health care item or service.	Civil Judgment	7	\$44.41	\$310.87
§ 60.15: Reporting exclusions from participation in Federal or State health care programs.	Exclusion or Debarment (manual)	1,280	\$44.41	\$56,844.80
	Exclusion or Debarment (automated)	1	\$44.41	\$44.41
§ 60.16: Reporting other adjudicated actions or decisions.	Government Administrative (manual)	1,313	\$44.41	\$58,310.33
	Government Administrative (automated)	1	\$44.41	\$44.41
	Health Plan Action	366	\$44.41	\$16,254.06
§ 60.17 Information which hospitals must request from the National Practitioner Data Bank. § 60.18 Requesting Information from the NPDB.	One-Time Query for an Individual (manual)	156,654	\$36.01	\$5,641,110.54
	One-Time Query for an Individual (automated)	1,005	\$36.01	\$36,190.05
	One-Time Query for an Organization (manual)	4,054	\$36.01	\$145,984.54
	One-Time Query for an Organization (automated)	8	\$36.01	\$288.08
	Self-Query on an Individual	70,794	\$36.01	\$2,549,291.94
	Self-Query on an Organization	445	\$36.01	\$16,024.45
	Continuous Query (manual)	64,558	\$36.01	\$2,324,733.58
	Continuous Query (automated)	186	\$36.01	\$6,697.86

Regulation Citation	Form Name	Total Burden Hours	Wage Rate	Total Respondent Costs
§ 60.21: How to dispute the accuracy of NPDB information.	Subject Statement and Dispute	2,448	\$101.82	\$249,255.36
	Request for Dispute Resolution	592	\$101.82	\$60,277.44
Administrative	Entity Registration (Initial)	3,484	\$30.74	\$107,098.16
	Entity Registration (Renewal & Update)	3,311	\$30.74	\$101,780.14
	State Licensing Board Data Request	630	\$30.74	\$19,366.20
	State Licensing Board Attestation	325	\$30.74	\$9,990.50
	Authorized Agent Attestation	350	\$30.74	\$10,759.00
	Health Center Attestation	722	\$30.74	\$22,194.28
	Hospital Attestation	3,416	\$30.74	\$105,007.84
	Medical Malpractice Payer, Peer Review Organization, or Private Accreditation Organization Attestation	274	\$30.74	\$8,422.76
	Other Eligible Entity Attestation	1,884	\$30.74	\$57,914.16
	Corrective Action Plan (Entity)	1	\$30.74	\$30.74
	Reconciling Missing Actions	119	\$30.74	\$3,658.06
	Agent Registration (Initial)	44	\$30.74	\$1,352.56
	Agent Registration (Renewal & Update)	24	\$30.74	\$737.76
	Electronic Funds Transfer (EFT) Authorization	52	\$30.74	\$1,598.48
	Authorized Agent Designation	46	\$30.74	\$1,414.04
	Account Discrepancy	21	\$30.74	\$645.54
	New Administrator Request	48	\$30.74	\$1,475.52
	Purchase Query Credits	143	\$30.74	\$4,395.82
	Education Request	3	\$30.74	\$92.22
	Account Balance Transfer	1	\$30.74	\$30.74
Missing Report From Query Form	1	\$30.74	\$30.74	
TOTAL		347,294	\$12,761,696

13. Estimates of other Total Annual Cost Burden to Respondents or Record keepers/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. The one-time query and continuous query fee 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 2019, the collection from query fees was approximately \$18.7 million as shown in Table 4 below.

Table 4: Fiscal Year 2019-Estimated Query Volume and Fee Collection

Query Type	Fee	Query Count	Net Revenue
One-Time Query	\$ 2.00	4,583,202	\$ 9,166,404.00
Continuous Query	\$ 2.00	3,351,294	\$ 6,702,588.00
Self-Query	\$ 4.00	178,795	\$ 715,180.00
Query Credit Purchase	\$ 2.00	1,065,141	\$ 2,130,282.00
Estimated Total			\$ 18,714,454.00

14. Annualized Cost to Federal Government

The annual cost to the Federal government for fiscal year 2019, was approximately \$19.1 million. Table 5 below details the specific items that were included in the calculation of this estimate.

Table 5: Fiscal Year 2019-Estimated Annualized Cost to Federal Government

Item	Details	Annual Value
NPDB Program Staff	27 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.	\$ 5,800,000
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.	\$ 13,300,000
Estimated Annualized Cost to Federal Government		\$ 19,100,000

15. Explanation for Program Changes or Adjustments

There is no change to the average burden per response, but the total burden hours and number of respondents increased. Total burden hours increased by approximately 21,174 hours. The total number of respondents increased by approximately 1,041,513 million respondents. The increase is mainly attributable to the addition of Attestation forms from OMB 0906-0028 and higher use of Query forms (i.e., Continuous Query, Self-Query on an Individual, One-Time Query for an Individual, and One-time Query for an Organization).

Table 6: Explanation for Burden Changes

Item	Number of Respondents	Total Burden Hours
Approved Burden (2017)	6,059,761	326,120
Requested Burden (2019)	7,101,274	347,294
Difference	1,041,513	21,174

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, data stripped of identifiers will be available to HRSA for use in preparation of 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.