

## **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**

**Note:** OMB control number prefix should change to 0906-, it was previously 0915-.

#### **A. Justification**

##### **1. Circumstances Making the Collection of Information Necessary**

This is a request for revision of Office of Management and Budget (OMB) 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. 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 in [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 actions regarding physicians and dentists, clinical privileges actions, and professional society membership actions, as well as Drug Enforcement Administration (DEA) controlled-substance registration actions.

**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 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. This Information Collection Request (ICR) proposes revisions to improve navigation through the secure portal.

- The proposed revisions will 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. HHS will request to discontinue OMB No. 0906-0028 upon approval of this ICR. Further, the revisions 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. The revisions also add dynamic field labels that correspond to the reporting entity's selections on the Medical Malpractice Payer Report, making it more user-friendly. Finally, the revisions 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](http://www.npdb.hrsa.gov). Reporting and querying are performed through this secure website. Additionally, the NPDB has been able to reduce input form error and enhance the overall user experience in recent years by implementing the technologies listed below:

- Offered 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.

- Provided 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, and 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 August 22, 2023, Vol. 88, No. 161; pp. 57118-57120. There were no public comments.

**8B:** HRSA held a virtual Education Forum in 2021 and 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 |
|---------------------------|-----------------|----------------------------------|
| 2021 NPDB Education Forum | May 20-21, 2021 | 378                              |
| <b>Total</b>              |                 | <b>378</b>                       |

#### **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>).

*Data will be kept private to the extent allowed by law.*

#### **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) |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|-----------------------|------------------------------------|-----------------|----------------------------------------|------------------------------|
| § 60.6: Reporting errors, omissions, revisions or whether an action is on appeal.                                                                     | Correction, Revision-to-Action, Void, Notice of Appeal (manual)    | 8,897                 | 1                                  | 8,897           | .25                                    | 2,225                        |
|                                                                                                                                                       | Correction, Revision-to-Action, Void, Notice of Appeal (automated) | 14,982                | 1                                  | 14,982          | .0003                                  | 5                            |
| § 60.7: Reporting medical malpractice payments.                                                                                                       | Medical Malpractice Payment (manual)                               | 11,080                | 1                                  | 11,080          | .75                                    | 8,310                        |
|                                                                                                                                                       | Medical Malpractice Payment (automated)                            | 447                   | 1                                  | 447             | .0003                                  | 1                            |
| § 60.8: Reporting licensure actions taken by Boards of Medical Examiners<br><br>§60.9: Reporting licensure and certification actions taken by States. | State Licensure or Certification (manual)                          | 13,996                | 1                                  | 13,996          | .75                                    | 10,497                       |
|                                                                                                                                                       | State Licensure or Certification (automated)                       | 14,636                | 1                                  | 14,636          | .0003                                  | 5                            |
| § 60.10: Reporting Federal licensure and certification actions.                                                                                       | DEA/Federal Licensure                                              | 555                   | 1                                  | 555             | .75                                    | 416                          |
| § 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                               | 782                   | 1                                  | 782             | .75                                    | 587                          |
|                                                                                                                                                       | Professional Society                                               | 27                    | 1                                  | 27              | .75                                    | 20                           |
| § 60.13: Reporting Federal or State criminal                                                                                                          | Criminal Conviction (Guilty Plea or Trial) (manual)                | 979                   | 1                                  | 979             | .75                                    | 735                          |



| Regulation Citation                                                                                                                             | Form Name                                              | Number of Respondents | Number of Responses per Respondent | Total Responses | Average Burden per Response (in hours) | Total Burden Hours (rounded) |
|-------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|-----------------------|------------------------------------|-----------------|----------------------------------------|------------------------------|
| convictions related to the delivery of a health care item or service.                                                                           | Criminal Conviction (Guilty Plea or Trial) (automated) | 406                   | 1                                  | 406             | .0003                                  | 1                            |
|                                                                                                                                                 | Deferred Conviction or Pre-Trial Diversion             | 60                    | 1                                  | 60              | .75                                    | 45                           |
|                                                                                                                                                 | Nolo Contendere (no contest plea)                      | 75                    | 1                                  | 75              | .75                                    | 56                           |
|                                                                                                                                                 | Injunction                                             | 10                    | 1                                  | 10              | .75                                    | 8                            |
| § 60.14: Reporting civil judgments related to the delivery of a health care item or service.                                                    | Civil Judgment                                         | 6                     | 1                                  | 6               | .75                                    | 5                            |
| § 60.15: Reporting exclusions from participation in Federal or State health care programs.                                                      | Exclusion or Debarment (manual)                        | 1,287                 | 1                                  | 1,287           | .75                                    | 966                          |
|                                                                                                                                                 | Exclusion or Debarment (automated)                     | 2,610                 | 1                                  | 2,610           | .0003                                  | 1                            |
| § 60.16: Reporting other adjudicated actions or decisions.                                                                                      | Government Administrative (manual)                     | 1,367                 | 1                                  | 1,367           | .75                                    | 1,026                        |
|                                                                                                                                                 | Government Administrative (automated)                  | 632                   | 1                                  | 632             | .0003                                  | 1                            |
|                                                                                                                                                 | Health Plan Action                                     | 391                   | 1                                  | 391             | .75                                    | 293                          |
| § 60.17 Information which hospitals must request from the National Practitioner Data Bank.<br><br>§ 60.18 Requesting Information from the NPDB. | One-Time Query for an Individual (manual)              | 1,790,355             | 1                                  | 1,790,355       | .08                                    | 143,229                      |
|                                                                                                                                                 | One-Time Query for an Individual (automated)           | 3,945,360             | 1                                  | 3,945,360       | .0003                                  | 1,184                        |
|                                                                                                                                                 | One-Time Query for an Organization (manual)            | 77,095                | 1                                  | 77,095          | .08                                    | 6,168                        |
|                                                                                                                                                 | One-Time Query for an Organization (automated)         | 33,993                | 1                                  | 33,993          | .0003                                  | 11                           |
|                                                                                                                                                 | Self-Query on an Individual                            | 223,589               | 1                                  | 223,589         | .42                                    | 93,907                       |
|                                                                                                                                                 | Self-Query on an Organization                          | 879                   | 1                                  | 879             | .42                                    | 369                          |
|                                                                                                                                                 | Continuous Query (manual)                              | 1,030,917             | 1                                  | 1,030,917       | .08                                    | 82,474                       |
|                                                                                                                                                 | Continuous Query (automated)                           | 900,661               | 1                                  | 900,661         | .0003                                  | 271                          |
| § 60.21: How to                                                                                                                                 | Subject Statement and                                  | 4,015                 | 1                                  | 4,015           | .75                                    | 3,011                        |

| Regulation Citation                       | Form Name                                                                                              | Number of Respondents | Number of Responses per Respondent | Total Responses  | Average Burden per Response (in hours) | Total Burden Hours (rounded) |
|-------------------------------------------|--------------------------------------------------------------------------------------------------------|-----------------------|------------------------------------|------------------|----------------------------------------|------------------------------|
| dispute the accuracy of NPDB information. | Dispute                                                                                                |                       |                                    |                  |                                        |                              |
|                                           | Request for Dispute Resolution                                                                         | 83                    | 1                                  | 83               | 8                                      | 664                          |
| Administrative                            | Entity Registration (Initial)                                                                          | 3,252                 | 1                                  | 3,252            | 1                                      | 3,252                        |
|                                           | Entity Registration (Renewal & Update)                                                                 | 12,990                | 1                                  | 12,990           | .25                                    | 3,248                        |
|                                           | State Licensing Board Data Request                                                                     | 87                    | 1                                  | 87               | 10.5                                   | 914                          |
|                                           | State Licensing Board Attestation                                                                      | 360                   | 1                                  | 360              | 1                                      | 360                          |
|                                           | Authorized Agent Attestation                                                                           | 171                   | 1                                  | 171              | 1                                      | 171                          |
|                                           | Health Center Attestation                                                                              | 724                   | 1                                  | 724              | 1                                      | 724                          |
|                                           | Hospital Attestation                                                                                   | 3,238                 | 1                                  | 3,238            | 1                                      | 3,238                        |
|                                           | Medical Malpractice Payer, Peer Review Organization, or Private Accreditation Organization Attestation | 267                   | 1                                  | 267              | 1                                      | 267                          |
|                                           | Other Eligible Entity Attestation                                                                      | 4,790                 | 1                                  | 4,790            | 1                                      | 4,790                        |
|                                           | Corrective Action Plan (Entity)                                                                        | 10                    | 1                                  | 10               | .08                                    | 1                            |
|                                           | Reconciling Missing Actions                                                                            | 1,371                 | 1                                  | 1,371            | .08                                    | 110                          |
|                                           | Agent Registration (Initial)                                                                           | 78                    | 1                                  | 78               | 1.00                                   | 78                           |
|                                           | Agent Registration (Renewal & Update)                                                                  | 318                   | 1                                  | 318              | .08                                    | 25                           |
|                                           | Electronic Funds Transfer (EFT) Authorization                                                          | 734                   | 1                                  | 734              | .08                                    | 59                           |
|                                           | Authorized Agent Designation                                                                           | 183                   | 1                                  | 183              | .25                                    | 46                           |
|                                           | Account Discrepancy                                                                                    | 4                     | 1                                  | 4                | .25                                    | 1                            |
|                                           | New Administrator Request                                                                              | 215                   | 1                                  | 215              | .08                                    | 17                           |
|                                           | Purchase Query Credits                                                                                 | 5,590                 | 1                                  | 5,590            | .08                                    | 447                          |
|                                           | Education Request                                                                                      | 10                    | 1                                  | 10               | .08                                    | 1                            |
|                                           | Account Balance Transfer                                                                               | 10                    | 1                                  | 10               | .08                                    | 1                            |
|                                           | Missing Report From Query Form                                                                         | 10                    | 1                                  | 10               | .08                                    | 1                            |
|                                           | <b>TOTAL</b>                                                                                           | <b>8,114,604</b>      | <b>.....</b>                       | <b>8,114,604</b> | <b>.....</b>                           | <b>374,258</b>               |

## 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 median hourly wages for the following professions were selected as samples from the website:

- Educational Instruction and Library Occupations (\$27.64)
- Claims Adjusters, Appraisers, Examiners, and Investigators (\$34.73)
- Business and Financial Operations Occupations (\$36.95)
- Healthcare Practitioners and Technical Occupations (\$37.38)
- Administrative Services and Facilities Managers (\$49.68)
- Management Occupations (\$51.62)
- General Internal Medicine Physicians (\$103.11)

The median hour wage rate listed above is multiplied by two in Table 3 below to account for overhead costs.

**Table 3: Estimated Annual Burden Costs**

| Regulation Citation                                                                                                   | Form Name                                                          | BLS Profession Classification                              | Total Burden Hours | Median Wage Rate (x2) | 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)    | Management Occupations                                     | 2,225              | \$103.24              | \$229,709.00           |
|                                                                                                                       | Correction, Revision-to-Action, Void, Notice of Appeal (automated) | Management Occupations                                     | 5                  | \$103.24              | \$516.20               |
| § 60.7: Reporting medical malpractice payments.                                                                       | Medical Malpractice Payment (manual)                               | Claims Adjusters, Appraisers, Examiners, and Investigators | 8,310              | \$69.46               | \$577,212.60           |
|                                                                                                                       | Medical Malpractice Payment (automated)                            | Claims Adjusters, Appraisers, Examiners, and Investigators | 1                  | \$69.46               | \$69.46                |
| § 60.8: Reporting licensure actions taken by Boards of Medical Examiners                                              | State Licensure or Certification (manual)                          | Administrative Services and Facilities Managers            | 10,497             | \$99.36               | \$1,042,981.92         |
| §60.9: Reporting licensure and certification actions taken by States.                                                 | State Licensure or Certification (automated)                       | Administrative Services and Facilities Managers            | 5                  | \$99.36               | \$496.80               |
| § 60.10: Reporting Federal licensure and certification actions.                                                       | DEA/Federal Licensure                                              | Administrative Services and Facilities Managers            | 416                | \$99.36               | \$41,333.76            |
| § 60.11: Reporting negative actions or findings taken by peer review organizations or private accreditation entities. | Peer Review Organization                                           | Administrative Services and Facilities Managers            | 8                  | \$99.36               | \$794.88               |
|                                                                                                                       | Accreditation                                                      | Administrative Services and Facilities Managers            | 8                  | \$99.36               | \$794.88               |
| § 60.12: Reporting adverse actions taken against clinical                                                             | Title IV Clinical Privileges Actions                               | Administrative Services and Facilities Managers            | 587                | \$99.36               | \$58,324.32            |

| Regulation Citation                                                                                                                             | Form Name                                              | BLS Profession Classification                      | Total Burden Hours | Median Wage Rate (x2) | Total Respondent Costs |
|-------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|----------------------------------------------------|--------------------|-----------------------|------------------------|
| privileges.                                                                                                                                     | Professional Society                                   | Educational Instruction and Library Occupations    | 20                 | \$55.28               | \$1,105.60             |
| § 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)    | Administrative Services and Facilities Managers    | 735                | \$99.36               | \$73,029.60            |
|                                                                                                                                                 | Criminal Conviction (Guilty Plea or Trial) (automated) | Administrative Services and Facilities Managers    | 1                  | \$99.36               | \$99.36                |
|                                                                                                                                                 | Deferred Conviction or Pre-Trial Diversion             | Administrative Services and Facilities Managers    | 45                 | \$99.36               | \$4,471.20             |
|                                                                                                                                                 | Nolo Contendere (no contest plea)                      | Administrative Services and Facilities Managers    | 56                 | \$99.36               | \$5,564.16             |
|                                                                                                                                                 | Injunction                                             | Administrative Services and Facilities Managers    | 8                  | \$99.36               | \$794.88               |
| § 60.14: Reporting civil judgments related to the delivery of a health care item or service.                                                    | Civil Judgment                                         | Administrative Services and Facilities Managers    | 5                  | \$99.36               | \$496.80               |
| § 60.15: Reporting exclusions from participation in Federal or State health care programs.                                                      | Exclusion or Debarment (manual)                        | Administrative Services and Facilities Managers    | 966                | \$99.36               | \$95,981.76            |
|                                                                                                                                                 | Exclusion or Debarment (automated)                     | Administrative Services and Facilities Managers    | 1                  | \$99.36               | \$99.36                |
| § 60.16: Reporting other adjudicated actions or decisions.                                                                                      | Government Administrative (manual)                     | Administrative Services and Facilities Managers    | 1,026              | \$99.36               | \$101,943.36           |
|                                                                                                                                                 | Government Administrative (automated)                  | Administrative Services and Facilities Managers    | 1                  | \$99.36               | \$99.36                |
|                                                                                                                                                 | Health Plan Action                                     | Administrative Services and Facilities Managers    | 293                | \$99.36               | \$29,112.48            |
| § 60.17 Information which hospitals must request from the National Practitioner Data Bank.<br><br>§ 60.18 Requesting Information from the NPDB. | One-Time Query for an Individual (manual)              | Healthcare Practitioners and Technical Occupations | 143,229            | \$74.76               | \$10,707,800.04        |
|                                                                                                                                                 | One-Time Query for an Individual (automated)           | Healthcare Practitioners and Technical Occupations | 1,184              | \$74.76               | \$88,515.84            |
|                                                                                                                                                 | One-Time Query for an Organization (manual)            | Healthcare Practitioners and Technical Occupations | 6,168              | \$74.76               | \$461,119.68           |
|                                                                                                                                                 | One-Time Query for an Organization (automated)         | Healthcare Practitioners and Technical Occupations | 11                 | \$74.76               | \$822.36               |
|                                                                                                                                                 | Self-Query on an Individual                            | Healthcare Practitioners and Technical Occupations | 93,907             | \$74.76               | \$7,020,487.32         |
|                                                                                                                                                 | Self-Query on an                                       | Healthcare Practitioners and                       | 369                | \$74.76               | \$27,661.20            |

| Regulation Citation                                       | Form Name                                                                                              | BLS Profession Classification                      | Total Burden Hours | Median Wage Rate (x2) | Total Respondent Costs |
|-----------------------------------------------------------|--------------------------------------------------------------------------------------------------------|----------------------------------------------------|--------------------|-----------------------|------------------------|
|                                                           | Organization                                                                                           | Technical Occupations                              |                    |                       |                        |
|                                                           | Continuous Query (manual)                                                                              | Healthcare Practitioners and Technical Occupations | 82,474             | \$74.76               | \$6,165,756.24         |
|                                                           | Continuous Query (automated)                                                                           | Healthcare Practitioners and Technical Occupations | 271                | \$74.76               | \$20,259.96            |
| § 60.21: How to dispute the accuracy of NPDB information. | Subject Statement and Dispute                                                                          | General Internal Medicine Physicians               | 3,011              | \$206.22              | \$620,928.42           |
|                                                           | Request for Dispute Resolution                                                                         | General Internal Medicine Physicians               | 664                | \$206.22              | \$136,930.08           |
| Administrative                                            | Entity Registration (Initial)                                                                          | Business and Financial Operations Occupations      | 3,252              | \$73.90               | \$240,322.80           |
|                                                           | Entity Registration (Renewal & Update)                                                                 | Business and Financial Operations Occupations      | 3,248              | \$73.90               | \$240,027.20           |
|                                                           | State Licensing Board Data Request                                                                     | Business and Financial Operations Occupations      | 914                | \$73.90               | \$67,544.60            |
|                                                           | State Licensing Board Attestation                                                                      | Business and Financial Operations Occupations      | 360                | \$73.90               | \$26,604.00            |
|                                                           | Authorized Agent Attestation                                                                           | Business and Financial Operations Occupations      | 171                | \$73.90               | \$12,636.90            |
|                                                           | Health Center Attestation                                                                              | Business and Financial Operations Occupations      | 724                | \$73.90               | \$53,503.60            |
|                                                           | Hospital Attestation                                                                                   | Business and Financial Operations Occupations      | 3,238              | \$73.90               | \$239,288.20           |
|                                                           | Medical Malpractice Payer, Peer Review Organization, or Private Accreditation Organization Attestation | Business and Financial Operations Occupations      | 267                | \$73.90               | \$19,731.30            |
|                                                           | Other Eligible Entity Attestation                                                                      | Business and Financial Operations Occupations      | 4,790              | \$73.90               | \$353,981.00           |
|                                                           | Corrective Action Plan (Entity)                                                                        | Business and Financial Operations Occupations      | 1                  | \$73.90               | \$73.90                |
|                                                           | Reconciling Missing Actions                                                                            | Business and Financial Operations Occupations      | 110                | \$73.90               | \$8,129.00             |
|                                                           | Agent Registration (Initial)                                                                           | Business and Financial Operations Occupations      | 78                 | \$73.90               | \$5,764.20             |
|                                                           | Agent Registration (Renewal & Update)                                                                  | Business and Financial Operations Occupations      | 25                 | \$73.90               | \$1,847.50             |
|                                                           | Electronic Funds Transfer (EFT) Authorization                                                          | Business and Financial Operations Occupations      | 59                 | \$73.90               | \$4,360.10             |
|                                                           | Authorized Agent Designation                                                                           | Business and Financial Operations Occupations      | 46                 | \$73.90               | \$3,399.40             |
|                                                           | Account Discrepancy                                                                                    | Business and Financial Operations Occupations      | 1                  | \$73.90               | \$73.90                |
|                                                           | New Administrator Request                                                                              | Business and Financial Operations Occupations      | 17                 | \$73.90               | \$1,256.30             |
|                                                           | Purchase Query Credits                                                                                 | Business and Financial Operations Occupations      | 447                | \$73.90               | \$33,033.30            |
|                                                           | Education Request                                                                                      | Business and Financial Operations Occupations      | 1                  | \$73.90               | \$73.90                |
|                                                           | Account Balance Transfer                                                                               | Business and Financial Operations Occupations      | 1                  | \$73.90               | \$73.90                |
|                                                           | Missing Report From                                                                                    | Business and Financial                             | 1                  | \$73.90               | \$73.90                |

| Regulation Citation | Form Name    | BLS Profession Classification | Total Burden Hours | Median Wage Rate (x2) | Total Respondent Costs |
|---------------------|--------------|-------------------------------|--------------------|-----------------------|------------------------|
|                     | Query Form   | Operations Occupations        |                    |                       |                        |
|                     | <b>TOTAL</b> |                               | <b>374,258</b>     | <b>.....</b>          | <b>\$28,827,111.78</b> |

### **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 fees are \$2.50. The cost of a digitally certified self-query is \$3.00. The cost of a mailed paper copy of the self-query is \$3.00. These fees were published in the Federal Register on July 21, 2021 (86 FR 173). For fiscal year 2022, the collection from query fees was approximately \$28.9 million as shown in Table 4 below.

**Table 4: Fiscal Year 2022-Estimated Query Volume and Fee Collection**

| Query Type                          | Query Count | Net Revenue          |
|-------------------------------------|-------------|----------------------|
| One-Time Query                      | 5,425,621   | \$7,549,170          |
| Continuous Query                    | 5,852,922   | \$11,290,612         |
| Digitally Certified Self-Query      | 230,163     | \$690,489            |
| Mailed Paper Copy of the Self-Query | 127,335     | \$357,972            |
| Query Credit Purchase               | 3,755,357   | \$8,991,376          |
| <b>Estimated Total</b>              |             | <b>\$ 28,879,619</b> |

### **14. Annualized Cost to Federal Government**

The annual cost to the Federal government for fiscal year 2022, was approximately \$23.6 million. Table 5 below details the specific items that were included in the calculation of this estimate. The base annual value of \$6,400,000 for NPDB program staff was multiplied by 1.5 to account for overhead costs (e.g., benefits).

**Table 5: Fiscal Year 2022-Estimated Annualized Cost to Federal Government**

| Item               | Details                                                                                                                                                                                                  | Annual Value |
|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| NPDB Program Staff | 39 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 | \$ 9,600,000 |

| Item                                                   | Details                                                                                                                                                                                  | Annual Value         |
|--------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
|                                                        | NPDB operations.                                                                                                                                                                         |                      |
| 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        |
| <b>Estimated Annualized Cost to Federal Government</b> |                                                                                                                                                                                          | <b>\$ 23,600,000</b> |

### **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 responses increased. Total burden hours increased by approximately 25,890 hours. The total number of responses increased by 1,013,330 million. The increase is mainly attributable to the 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 Responses | Total Burden Hours |
|-------------------------|---------------------|--------------------|
| Approved Burden (2019)  | 7,101,274           | 348,368            |
| Requested Burden (2023) | 8,114,604           | 374,258            |
| <b>Difference</b>       | <b>1,013,330</b>    | <b>25,890</b>      |

### **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.