



Billing Code: 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; National Practitioner Data Bank Attestation of Reports by Hospitals, Medical Malpractice Payers, Health Plans, Health Centers, and Other Eligible Entities, OMB NO. 0906-0028 Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this Notice has closed.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: National Practitioner Data Bank Attestation of Reports by Hospitals, Medical Malpractice Payers, Health Plans, Health Centers, and Other Eligible Entities, OMB No. 0906-0028 – Revision

Abstract: The National Practitioner Data Bank (NPDB) proposes to continue collecting data from entities, such as hospitals, medical malpractice payers, health plans, and health centers that are subject to NPDB reporting requirements during registration renewal.¹ This will allow the NPDB to continue to assist these entities in understanding and meeting their reporting requirements.

NPDB plans to expand its population of focus to include other eligible entities², including ambulatory surgery centers, group medical practices, skilled nursing facilities, mental health centers, and other registered entities. Beyond attesting to meeting NPDB reporting requirements, entities will also attest to querying and confidentiality compliance.

¹ Unless otherwise noted, the term “health centers” refers to health centers whose access and reporting obligations are addressed in the NPDB statutory and regulatory requirements for health care entities. In this document, “health center” refers to organizations that receive grants under the HRSA Health Center Program as authorized under section 330 of the Public Health Service Act, as amended (referred to as “grantees”) and FQHC Look-Alike organizations, which meet all the Health Center Program requirements but do not receive Health Center Program grants. It does not refer to FQHCs that are sponsored by tribal or Urban Indian Health Organizations, except for those that receive Health Center Program grants.

² “Other eligible entities” that participate in the NPDB are defined in the provisions of Title IV, Section 1921, Section 1128E, and implementing regulations. In addition, a few federal agencies also participate with the NPDB through federal memorandums of understanding. Eligible entities are responsible for complying with all reporting and/or querying requirements that apply; some entities may qualify as more than one type of eligible entity. Each eligible entity must certify its eligibility in order to report to the NPDB, query the NPDB, or both. Information from the NPDB is available only to those entities specified as eligible in the statutes and regulations. Not all entities have the same reporting requirements or level of query access.

NPDB began operation on September 1, 1990. The statutory authorities establishing and governing the NPDB are Title IV of Public Law (P.L.) 99-660, the Health Care Quality Improvement Act of 1986, as amended, Section 5 of the Medicare and Medicaid Patient and Program Protection Act of 1987, P.L. 100-93, codified as Section 1921 of the Social Security Act, and Section 221(a) of the Health Insurance Portability and Accountability Act of 1996, P. L. 104-191, codified as Section 1128E of the Social Security Act. Final regulations governing the NPDB are codified at 45 CFR Part 60. Responsibility of the NPDB implementation and operation resides in the Bureau of Health Workforce, HRSA, HHS.

NPDB acts primarily as a flagging system; its principal purpose is to facilitate comprehensive review of practitioners' professional credentials and background. Information on medical malpractice payments, health-related civil judgments, adverse licensure actions, adverse clinical privileging actions, adverse professional society actions, and Medicare/Medicaid exclusions is collected from, and disseminated to, eligible entities such as licensing boards, hospitals, and other health care entities. It is intended that NPDB information should be considered with other relevant information in evaluating a practitioner's credentials.

NPDB outlines specific reporting requirements for hospitals, medical malpractice payers, health plans, health centers and other eligible entities; per 45 CFR part 60. These reporting requirements are further explained in Chapter E of the NPDB e-Guidebook, which can be found at <http://www.npdb.hrsa.gov/resources/aboutGuidebooks.jsp>.

Through a process called Attestation, hospitals, medical malpractice payers, health plans, health centers, and other eligible entities are required to attest that they understand and have met their responsibility to submit all required reports, queries, and maintain confidentiality adherence with NPDB compliance. The Attestation process is completely automated through the secure

NPDB system (<http://www.npdb.hrsa.gov>), using both secure email messaging and system notifications to alert entities registered with the NPDB of their responsibility to attest. All entities with reporting requirements and querying access to the NPDB must register with the NPDB before gaining access to the secure NPDB system for all reporting and querying transactions.

The secure NPDB system currently used by hospitals, medical malpractice payers, health plans, health centers, and other entities to conduct reporting and querying will not undergo any changes, ensuring that these entities are familiar with the interface needed to complete the Attestation process. NPDB asks these entities to attest to their reporting, querying, and confidentiality compliance every two years. If the organization is responsible for privileging or credentialing individuals who provide services for other sites, those sites are included in the Attestation process.

Users of the NPDB include reporters (entities that are required to submit reports) and quierers (entities that are authorized to request for information). Data collected through the Attestation process informs the NPDB operations and facilitate the structuring of compliance efforts in a manner that is the most effective. The Attestation process will also serve as a catalyst to collect meaningful data about reporting entities which can later be transformed into actionable information and serve as a platform for future initiatives. The Attestation forms collect the following information: information regarding sub-sites and entity relationships; contact information for the Attesting official; and a statement attesting whether the organization adhered to all reporting, querying, and confidentiality requirements.

A 60-day notice published in the **Federal Register** on December 19, 2019, vol. 84, No. 244; pp. 69751- 69753. There were no public comments.

Need and Proposed Use of the Information: The NPDB engages in compliance activities to ensure the accuracy and completeness of the information in the NPDB. Through the Attestation process, the NPDB can better determine which, hospitals, medical malpractice payers, health plans, health centers and other eligible entities, are meeting the reporting, querying, and confidentiality requirements, and which of these entities may require additional outreach and assistance. The biennial Attestation process strengthens the robustness of the data in the NPDB, improving the accuracy of the query responses for entities with access to NPDB reports.

Below is a summary of the proposed revisions:

1. Add Query and Confidentiality language to the instruments. Beyond attesting to meeting NPDB reporting requirements, entities will also attest to querying and confidentiality compliance.

2. Change Title of ICR

Current Title: National Practitioner Data Bank Attestation of Reports by Hospitals, Medical Malpractice Payers, Health Plans, and Certain Other Health Care Entities

Proposed New Title: National Practitioner Data Bank Attestation of Reports by Hospitals, Medical Malpractice Payers, Health Plans, Health Centers, and Other Eligible Entities

3. Add NPDB Guidebook definition for **Eligible Entities** in footnote.
4. Discontinue use of the Generic Form. Currently Hospitals, Medical Malpractice Payers, and Health Plans use the Generic Form to attest. This revision includes making each attestation

form specific to entity type based on reporting/querying requirements.

5. Revise attestation question so that all entities will receive the same question.

A. Current question for health centers

Has your organization reported all adverse actions taken from Month DD, YYYY to Month DD, YYYY affecting the clinical privileges of a physician or dentist as defined above?

- Yes, all required reports are submitted
- No, some required reports have not been submitted

If “no”, why not? _____

B. Current question for hospitals, health plans, medical malpractice payers

Has your organization submitted all reports, as required by law, from <MM DD, YYYY>, to <MM DD, YYYY> ?

- Yes, all required reports are submitted
- No, some required reports have not been submitted

If “no”, why not? _____

C. New question for all registered entities

Has your organization complied with all NPDB regulatory requirements as outlined above?

- Yes
- No

If “no”, why not? _____

Likely Respondents: Hospitals, Medical Malpractice Payers, Health Plans, Health Centers, and Other Eligible Entities.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours ³
Authorized Agent Attestation	350	1	350	1	350
Health Center Attestation	650	1	650	1	650
Hospital Attestation	3,250	1	3,250	1	3,250
Medical Malpractice, Peer Review Organization, or Private Accreditation Organization Attestation	250	1	250	1	250
Other Eligible Entity Attestation <ul style="list-style-type: none"> • Agencies administering federal programs, including contract entities • Federal law enforcement officials and agencies (including DEA, HHS OIG, and federal prosecutors) • Federal licensing or certification agencies • Health Plans • Other health care entities with formal peer review • Other Health care service providers • Professional Societies with formal peer review • State agencies administering or supervising state programs • State law or fraud enforcement agencies (including Medicaid fraud control units & state prosecutors) 	7,100	1	7,100	1	7,100
Total	11,600		11,600		11,600

Maria G. Button,

Director, Executive Secretariat.

³ There are approximately 700 authorized agents; 1,300 health centers; 6,500 hospitals; 500 medical malpractice payers, peer review organizations, and private accreditation organizations; and 14,200 other eligible entities, for an estimated total of 23,200 registered entities currently in attestation or scheduled for attestation with the NPDB. However, the reporting entities may include multiple sites that are registered independently in the system, thereby increasing the total number of respondents. Given that entities will only be required to complete attestation biennially, these estimates are divided in half for the annualized burden hours.

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