Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for investigational new drug applications and 21 CFR part 314 for new drug applications have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information in 21 CFR part 601 for biologics license applications have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 814, subparts A through E, for premarket approval applications have been approved under OMB control number 0910–0231. The collections of information in section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), subpart E for 510(k) notifications, have been approved under OMB control number 0910–0120. The collections of information in the guidance for industry and FDA staff entitled ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844. The collection of information in 21 CFR part 4 has been approved under the underlying current good manufacturing process regulations for drugs, devices, and biological products, including current good tissue practices for human cells, tissues, and cellular and tissue-based products, found at parts 211, 820, 600 through 680, and 1271 (21 CFR parts 211, 820, 600 through 680, and 1271), which have already been approved and are in effect. The provisions of part 211 are approved under OMB control number 0910–0139. The provisions of part 820 are approved under OMB control number 0910–0073. The provisions of parts 606, 640, and 660 are approved under OMB control number 0910–0116. The provisions of part 610 are approved under OMB control numbers 0910–0116 and 0910–0338 (also for part 680). The provisions of part 1271, subparts C and D, are approved under OMB control number 0910–0543.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products,* or *https://www.regulations.gov.*

Dated: December 13, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–27354 Filed 12–18–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: National Practitioner Data Bank Attestation of Reports by Hospitals, Medical Malpractice Payers, Health Plans, Health Centers, and Other Eligible Entities

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than February 18, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

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

Abstract: 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 entities,[2] 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.

NPDB began operation on September 1, 1990. The statutory authorities establishing and governing the NPDB are Title IV of Public Law (Pub. 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, Public Law 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, Public Law 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.

[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 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 queriers (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.

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 • 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

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2019–27395 Filed 12–18–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Council on the National Health Service Corps

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Secretary's National Advisory Council on the National Health Service Corps (NACNHSC) will hold public meetings for the 2020 calendar year (CY). Information about NACNHSC, agendas, and materials for these meetings can be found on the NACNHSC website at: *https://nhsc.hrsa.gov/nac/meetings.html*.

DATES:

- January 14, 2020, 9:00 a.m.–5:00 p.m.; January 15, 2020, 9:00 a.m.–2:00 p.m. Eastern Time (E.T.)—In-Person and Webinar;
- March 10, 2020, 9:00 a.m.–5:00 p.m.; March 11, 2020, 9:00 a.m.–2:00 p.m. E.T.—Webinar;
- June 16, 2020, 9:00 a.m.–5:00 p.m.; June 17, 2020, 9:00 a.m.–2:00 p.m. E.T.—In-Person and Webinar;
- November 5, 2020, 9:00 a.m.–5:00 p.m.; November 6, 2020, 9:00 a.m.–2:00 p.m. E.T.—In-Person and Webinar.

ADDRESSES: Meetings may be held in-person, by teleconference, and/or Adobe Connect webinar. In-person NACNHSC meetings will be held at 5600 Fishers Lane, Rockville, Maryland 20857. Instructions for joining the meetings either in person or remotely will be posted on the NACNHSC website 30 business days before the date of the meeting. For meeting information updates, go to the NACNHSC website meeting page at *https://nhsc.hrsa.gov/nac/meetings.html*.

FOR FURTHER INFORMATION CONTACT: Diane Fabiyi-King, Designated Federal Official (DFO), Division of National Health Service Corps, HRSA. Address: 5600 Fishers Lane, Room 14N110, Rockville, Maryland 20857; phone (301) 443–3609; or *BHWNACNHSC@hrsa.gov*.

SUPPLEMENTARY INFORMATION: The NACNHSC consults, advises, and makes annual recommendations to the Secretary of HHS and the Administrator of HRSA with respect to their NHSC related responsibilities under Subpart II, Part D of Title III of the Public Health Service Act (42 U.S.C. 254d–254k), as amended, to designate areas of the United States with health professional shortages and assign National Health Service Corps clinicians to improve the delivery of health services in health professional shortage areas. Since priorities dictate meeting times, be advised that times and agenda items are subject to change. CY 2020 meetings and agenda items may include, but are not limited to, the identification of NHSC priorities for future program issues and concerns; proposed policy changes by using the varying levels of expertise represented on NACNHSC to advise on specific program areas; updates from clinician workforce experts; and education and practice improvement in the training development of primary care clinicians. More general items may include presentations and discussions on the current and emerging needs of health workforce; public health priorities; healthcare access and evaluation; NHSC-approved sites; HRSA priorities and other federal health workforce and education programs that impact the NHSC.

[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.