communication campaigns and (2) to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. We will use these methods to test and refine our ideas and to help develop messages and other communications but will generally conduct further research before making important decisions, such as adopting new policies and allocating or redirecting significant resources to support these policies. We will use this mechanism to test messages about regulated drug products on a variety of subjects related to consumer, patient, or healthcare professional perceptions and about use of drug products and related materials, including but not limited to, direct-to-consumer prescription drug promotion, physician labeling of prescription drugs, medication guides, over-the-counter drug labeling, emerging risk communications, patient labeling, online sale of medical products, and consumer and professional education.

Annually, we project about 45 communication studies using the variety of test methods listed in this document. We are requesting an extension of these burden hours so as not to restrict our ability to gather information on public sentiment for FDA's proposals in its regulatory and communications programs.

In the **Federal Register** of June 17, 2020 (85 FR 36591), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Interviews/Surveys	43,875	1	43,875	0.21925 (12 minutes)	9,620

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: January 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–01030 Filed 1–15–21; 8:45 am]

BILLING CODE 4164–01–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; Information Collection Request Title: National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners—45 CFR Part 60 Regulations and Forms, OMB No. 0915–0126—Revision

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

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 February 18, 2021.

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 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 for Adverse Information on Physicians and Other Health Care Practitioners—45 CFR Part 60 Regulations and Forms, OMB No. 0915–0126—Revision.

Abstract: This is a request for OMB's approval for a revision to the information collection contained in regulations found at 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 with federal reporting and querying requirements. Responsibility for NPDB implementation and operation resides in HRSA's Bureau of Health Workforce.

The intent of the NPDB is to improve the quality of health care by encouraging entities such as hospitals, State licensing boards, professional societies, and other eligible entities [1] providing health care services to identify and discipline those who engage in unprofessional behavior, and to restrict the ability of incompetent health care practitioners, providers, or suppliers to move from state to state without disclosure or discovery of previous damaging or incompetent performance. It also serves as a fraud and abuse clearinghouse for the reporting and disclosing of certain final adverse actions (excluding settlements in which no findings of liability have been made) taken against health care practitioners, providers, or suppliers by health plans, federal agencies, and state agencies. Users of the NPDB include reporters (entities that are required to

[1] ''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.

submit reports) and queriers (entities and individuals that are authorized to request for information).

The reporting forms, request for information forms (query forms), and administrative forms (used to monitor compliance) are accessed, completed, and submitted to the NPDB electronically through the NPDB website at *https://www.npdb.hrsa.gov/.* All reporting and querying is performed through the secure portal of this website.

This revision proposes changes to improve overall data integrity. In addition, this revision contains the five NPDB forms that were originally approved in: ''NPDB Attestation of Reports by Hospitals, Medical Malpractice Payers, Health Plans, and Certain Other Health Care Entities, OMB No. 0906–0028'' which will be discontinued upon approval of this ICR.

A 60-day notice published in the **Federal Register** on October 16, 2020, vol. 85, No. 201; pp. 65834–65837. There were two public comments that addressed ways to enhance the quality, utility, and clarity of the information to be collected by the NPDB.

Need and Proposed Use of the Information: The NPDB acts primarily as a flagging system; its principal purpose is to facilitate comprehensive review of practitioners' professional credentials and background. Information is collected from, and disseminated to, eligible entities (entities that are entitled to query and/or report to the NPDB as authorized in Title 45 CFR part 60 of the Code of Federal Regulations) on the following: (1) Medical malpractice payments, (2) licensure actions taken by Boards of Medical Examiners, (3) State licensure and certification actions, (4) Federal licensure and certification actions, (5) negative actions or findings taken by peer review organizations or private accreditation entities, (6) adverse actions taken against clinical privileges, (7) federal or state criminal convictions related to the delivery of a health care item or service, (8) civil judgments related to the delivery of a health care item or service, (9) exclusions from participation in Federal or State health care programs, and (10) other adjudicated actions or decisions. It is intended that NPDB information should be considered with other relevant information in evaluating credentials of health care practitioners, providers, and suppliers.

Likely Respondents: Eligible entities or individuals that are entitled to query and/or report to the NPDB as authorized in regulations found at 45 CFR part 60.

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

Regulation citation	Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours (rounded up)
§ 60.6: Reporting errors, omissions, revisions or whether an action is on appeal.	Correction, Revision-to-Action, Void, Notice of Appeal (manual).	11,918	1	11,918	.25	2,980
	Correction, Revision-to-Action, Void, Notice of Appeal (automated).	18,301	1	18,301	.0003	5
§ 60.7: Reporting medical malpractice payments.	Medical Malpractice Payment (manual).	11,481	1	11,481	.75	8,611
	Medical Malpractice Payment (automated).	296	1	296	.0003	1
§ 60.8: Reporting licensure actions taken by Boards of Medical Examiners.	State Licensure or Certification (manual).	19,749	1	19,749	.75	14,812
§ 60.9: Reporting licensure and certification actions taken by States.	State Licensure or Certification (automated).	17,189	1	17,189	.0003	5
§ 60.10: Reporting Federal licensure and certification actions.	DEA/Federal Licensure	600	1	600	.75	450
§ 60.11: Reporting negative actions or findings taken by peer review organizations or private accreditation entities.	Peer Review Organization.	10	1	10	.75	8
	Accreditation	10	1	10	.75	8
§ 60.12: Reporting adverse actions taken against clinical privileges.	Title IV Clinical Privileges Actions.	978	1	978	.75	734
	Professional Society	41	1	41	.75	31
§ 60.13: Reporting Federal or State criminal convictions related to the delivery of a health care item or service.	Criminal Conviction (Guilty Plea or Trial) (manual).	1,174	1	1,174	.75	881

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Regulation citation	Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours (rounded up)
	Criminal Conviction (Guilty Plea or Trial) (automated).	683	1	683	.0003	1
	Deferred Conviction or Pre-Trial Diversion.	70	1	70	.75	53
	Nolo Contendere (no contest plea).	127	1	127	.75	95
	Injunction	10	1	10	.75	8
§ 60.14: Reporting civil judgments related to the delivery of a health care item or service.	Civil Judgment	9	1	9	.75	7
§ 60.15: Reporting exclusions from participation in Federal or State health care programs.	Exclusion or Debarment (manual).	1,707	1	1,707	.75	1,280
	Exclusion or Debarment (automated).	2,506	1	2,506	.0003	1
§ 60.16: Reporting other adjudicated actions or decisions.	Government Administrative (manual).	1,750	1	1,750	.75	1,313
	Government Administrative (automated).	39	1	39	.0003	1
	Health Plan Action	488	1	488	.75	366
§ 60.17 Information which hospitals must request from the National Practitioner Data Bank.	One-Time Query for an Individual (manual).	1,958,176	1	1,958,176	.08	156,654
	One-Time Query for an Individual (automated).	3,349,778	1	3,349,778	.0003	1,005
	One-Time Query for an Organization (manual).	50,681	1	50,681	.08	4,054
	One-Time Query for an Organization (automated).	25,610	1	25,610	.0003	8
§ 60.18 Requesting Information from the NPDB.	Self-Query on an Individual.	168,557	1	168,557	.42	70,794
	Self-Query on an Organization.	1,059	1	1,059	.42	445
	Continuous Query (manual).	806,971	1	806,971	.08	64,558
	Continuous Query (automated).	619,001	1	619,001	.0003	186
§ 60.21: How to dispute the accuracy of NPDB information.	Subject Statement and Dispute.	3,264	1	3,264	.75	2,448
	Request for Dispute Resolution.	74	1	74	8	592
Administrative	Entity Registration (Initial).	3,484	1	3,484	1	3,484
	Entity Registration (Renewal & Update).	13,245	1	13,245	.25	3,311
	State Licensing Board Data Request.	60	1	60	10.5	630
	State Licensing Board Attestation.	325	1	325	1	325
	Authorized Agent Attestation.	350	1	350	1	350
	Health Center Attestation.	722	1	722	1	722
	Hospital Attestation	3,416	1	3,416	1	3,416
	Medical Malpractice Payer, Peer Review Organization, or Private Accreditation Organization Attestation.	274	1	274	1	274
	Other Eligible Entity Attestation.	1,884	1	1,884	1	1,884

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Regulation citation	Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours (rounded up)
	Corrective Action Plan (Entity).	10	1	10	.08	1
	Reconciling Missing Actions.	1,491	1	1,491	.08	119
	Agent Registration (Initial).	44	1	44	1	44
	Agent Registration (Renewal & Update).	304	1	304	.08	24
	Electronic Funds Transfer (EFT) Authorization.	644	1	644	.08	52
	Authorized Agent Designation.	183	1	183	.25	46
	Account Discrepancy ...	85	1	85	.25	21
	New Administrator Request.	600	1	600	.08	48
	Purchase Query Credits.	1,786	1	1786	.08	143
	Education Request	40	1	40	.08	3
	Account Balance Transfer.	10	1	10	.08	1
	Missing Report From Query Form.	10	1	10	.08	1
Total	.....	7,101,274	.....	7,101,274	.....	347,294

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. 2021–00989 Filed 1–15–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before February 18, 2021.

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: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795–7714. When submitting comments or requesting information, please include the document identifier 0990–New–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (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.

Title of the Collection: Incident Report Form.

Type of Collection: New.

OMB No. 0990–NEW—Office of the Assistant Secretary for Health, Office for Human Research Protections.

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections is requesting approval for three years of a new information collection on the OHRP Incident Report Form. This form will facilitate prompt reporting of specific human subject protection incidents to OHRP by organizations and institutions conducting or reviewing human subjects research, and will provide a simplified standardized format for the reports. The information collected on the form will help OHRP to ensure the safety of human research subjects involved in non-exempt HHS-conducted or -supported research and to ensure that the research is conducted in accordance with the HHS Protection of Human Subjects regulations at 45 CFR part 46.

Likely Respondents: Institutions or organizations conducting non-exempt HHS-conducted or -supported human subjects research.