

presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 24, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Stephanie L. Begansky at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 5, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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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

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has 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.

DATES: Comments on this ICR should be received no later than March 12, 2015.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202-395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email 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 a revision of OMB approval of 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 the Bureau of Health Workforce, Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

The intent of the NPDB is to improve the quality of health care by encouraging hospitals, state licensing boards, professional societies, and other entities 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 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.

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 Web site at <http://www.npdb.hrsa.gov/>. All reporting and querying is performed through this secure Web site.

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 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 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	Responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
§ 60.6: Reporting errors, omissions, revisions, or whether an action is on appeal.	Correction, Revision to Action, Correction of Revision to Action, Void, Notice of Appeal (manual).	20,482	1	20,482	.25	5,121
	Correction, Revision to Action, Correction of Revision to Action, Void, Notice of Appeal (automated).	17,185	1	17,185	.0003	5
§ 60.7: Reporting medical malpractice payments.	Medical Malpractice Payment (manual).	12,613	1	12,613	.75	9,460
	Medical Malpractice Payment (automated).	250	1	250	.0003	.1
§ 60.8: Reporting licensure actions taken by Boards of Medical Examiners & § 60.9: Reporting licensure and certification actions taken by States.	State Licensure (manual)	16,770	1	16,770	.75	12,578
	State Licensure (automated).	17,422	1	17,422	.0003	5
§ 60.10: Reporting Federal licensure and certification actions.	DEA/Federal Licensure	114	1	114	.75	86
§ 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	12	1	12	.75	9
§ 60.12: Reporting adverse actions taken against clinical privileges.	Title IV Clinical Privileges Actions.	671	1	671	.75	503
	Professional Society	50	1	50	.75	38
§ 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).	1,308	1	1,308	.75	981
	Criminal Conviction (Guilty Plea or Trial) (automated).	937	1	937	.0003	.3
	Deferred Conviction or Pre-Trial Diversion.	50	1	50	.75	38
	Nolo Contendere (No Contest) Plea.	80	1	80	.75	60
	Injunction	10	1	10	.75	8
	Civil Judgment	14	1	14	.75	11
§ 60.14: Reporting civil judgments related to the delivery of a health care item or service.						
§ 60.15: Reporting exclusions from participation in Federal or State health care programs.	Exclusion/Debarment (manual).	1,185	1	1,185	.75	889
	Exclusion/Debarment (automated).	5,094	1	5,094	.0003	2
§ 60.18 Requesting Information from the NPDB.	Health Plan Action	524	1	524	.75	393
	One Time Query for an Individual (manual).	1,980,825	1	1,980,825	.08	158,466
	One Time Query for an Individual (automated).	2,163,208	1	2,163,208	.0003	649
	One Time Query for an Organization (manual).	39,920	1	39,920	.08	3,194
	One Time Query for an Organization (automated).	2,266	1	2,266	.0003	1
	Self-Query on an Individual.	77,318	1	77,318	.42	30,201

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Regulation citation	Form name	Number of respondents	Responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
§ 60.21: How to dispute the accuracy of NPDB information.	Self-Query on an Organization.	427	1	427	1	427
	Continuous Query (manual).	508,203	1	508,203	.08	40,656
	Continuous Query (automated).	121,718	1	121,718	.0003	37
	Subject Statement and Dispute.	3,501	1	3,501	.75	2,626
	Request for Dispute Resolution.	94	1	94	8	752
Administrative	Non-Hospital Entity Registration (Initial).	524	1	524	1	524
	Non-Hospital Entity Registration (Renewal).	6,383	1	6,383	.25	1,596
	Hospital Registration (Initial).	37	1	37	1	37
	Hospital Registration (Renewal).	3,198	1	3,198	.25	800
	Licensing Board Data Request.	140	1	140	10.5	1,470
	Reporting Entity Discrepancy Letter.	389	1	389	4	1556
	Licensing Board Attestation.	354	1	354	1	354
	Corrective Action Plan	10	1	10	.08	1
	Reconciling Missing Actions.	2,176	1	2,176	0.8	174
	Agent Registration (Initial)	30	1	30	1	30
	Agent Registration (Renewal).	194	1	194	.08	16
	Electronic Transfer of Funds (EFT) Authorization.	566	1	566	.08	45
	Authorized Agent Designation.	788	1	788	.25	197
	Account Discrepancy	41	1	41	.25	10
	Total	5,009,324	5,009,324	275,689

Jackie Painter,

Director, Division of the Executive Secretariat.

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BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Food and Drug Administration (FDA) and the National Cancer Institute (NCI) Health Communication Survey (FDA-NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in

the **Federal Register** on December 4, 2014 (Vol. 79, No. 233, pages 72003-4) and allowed 60 days for public comment. A total of five public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Bradford W. Hesse, Ph.D., Health Communication and Informatics Research Branch, 9609 Medical Center Drive, MSC 9761, Room 3E610, Rockville, MD 20850 or call non-toll free number 240-276-6721 or Email your request, including your address, to *hesseb@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Health Information National Trends Survey (HINTS) 0925-0538, Reinstatement with Change, National Cancer Institute (NCI), National Institutes of Health (NIH).