agencies to provide a 60-day notice in the **Federal Register** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, FDA invites comment on the following topics: (1) Whether the proposed information collected is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimated burden of the proposed information collected, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Under the draft guidance, sponsors of certain medical countermeasure product applications submitted under section 505(b)(1) of the FD&C Act and section 351 of the PHS Act may request a priority review voucher. Based on inquiries FDA has received on section 565A and related discussions with sponsors, we estimate that we will receive annually approximately 2 requests from 2 sponsors, and that each request will take approximately 8 hours to prepare and submit to FDA.

The draft guidance also states that sponsors should notify FDA of their intent to use a priority review voucher, including the date on which the sponsor intends to submit the application, at least 90 days before use. We estimate that we will receive annually approximately 2 notifications of intent to use a voucher from 2 sponsors, and that each notification will take approximately 8 hours to prepare and submit to FDA. The draft guidance also permits the transfer of a priority review voucher from one sponsor to another, and states that each transfer should be documented with a letter of transfer. We estimate that we will receive approximately 1 letter indicating the transfer of a voucher from 1.5 application holders, and 1 letter acknowledging the receipt of a transferred voucher from 1.5 new voucher owners acknowledging the transfer, and that it will take approximately 8 hours to prepare and submit each letter to FDA.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Reporting under Section 3086 of the Cures Act	Number of respondents	Number of responses per respondent	Total responses	Hours per response	Total hours
Priority review voucher request	2	1	2	8	16
Notifications of intent to use a voucher	2	1	2	8	16
Letters indicating the transfer of a voucher	1.5	1	1.5	8	12
Letters acknowledging the receipt of a transferred voucher	1.5	1	1.5	8	12
Total					56

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

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/RegulatoryInformation/Guidances/default.htm, https://www.regulations.gov,* or *https://www.fda.gov/medicalcountermeasures.*

Dated: January 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00900 Filed 1–17–18; 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—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 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 February 20, 2018.

ADDRESSES: Submit your comments, including the ICR 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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

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 HRSA's Bureau of Health Workforce.

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 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 eliminate redundant and unnecessary forms, improve user error recovery, and improve overall data integrity. There is no change to the average burden per response. The total estimated number of respondents has increased from 5 million in 2015 to over 6 million in 2017, primarily attributable to increases in use of the ''One-Time Query for an Individual'' and ''Continuous Query'' forms. The increase in total respondents resulted in an estimated increase of approximately 47,000 total burden hours.

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) 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	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).	11,114	1	11,114	.25	2,779
	Correction, Revision to Action, Correction of Revision to Action, Void, Notice of Appeal (automated).	17,966	1	17,966	.0003	6
§ 60.7: Reporting medical malpractice payments.	Medical Malpractice Payment (manual).	11,993	1	11,993	.75	8,995
	Medical Malpractice Payment (automated).	242	1	242	.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) ...	19,160	1	19,160	.75	14,370
	State Licensure (automated).	25,980	1	25,980	.0003	8
§ 60.10: Reporting Federal licensure and certification actions.	DEA/Federal Licensure	698	1	698	.75	524

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
§ 60.11: 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.	698	1	698	.75	524
	Professional Society	49	1	49		37
§ 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).	1,140	1	1,140	.75	855
	Criminal Conviction (Guilty Plea or Trial) (automated).	688	1	688	.0003	1
	Deferred Conviction or Pre-Trial Diversion.	54	1	54	.75	41
	Nolo Contendere (No Contest) Plea.	85	1	85	.75	64
	Injunction	10	1	10	.75	8
§ 60.14: Reporting civil judgments related to the delivery of a health care item or service.	Civil Judgment	10	1	10	.75	8
§ 60.15: Reporting exclusions from participation in Federal or State health care programs.	Exclusion/Debarment (manual).	1,624	1	1,624	.75	1,218
	Exclusion/Debarment (automated).	3,180	1	3,180	.0003	1
§ 60.16: Reporting other adjudicated actions or decisions.	Government Administrative	2,062	1	2,062	.75	1,547
	Health Plan Action	335	1	335	.75	252
§ 60.18 Requesting Information from the NPDB.	One-Time Query for an Individual (manual).	2,054,381	1	2,054,381	.08	164,351
	One-Time Query for an Individual (automated).	2,813,341	1	2,813,341	.0003	844
	One-Time Query for an Organization (manual).	39,695	1	39,695	.08	3,176
	One-Time Query for an Organization (automated).	10,201	1	10,201	.0003	4
	Self-Query on an Individual	131,481	1	131,481	.42	55,223
	Self-Query on an Organization.	1,545	1	1,545	.42	649
	Continuous Query (manual)	643,860	1	643,860	.08	51,509
	Continuous Query (automated).	226,838	1	226,838	.0003	69
§ 60.21: How to dispute the accuracy of NPDB information.	Subject Statement and Dispute.	3,547	1	3,547	.75	2,661
	Request for Dispute Resolution.	99	1	99	8	792
Administrative	Entity Registration (Initial)	1,073	1	1,073	1	1,073
	Entity Registration (Renewal & Update).	14,060	1	14,060	.25	3,515
	Entity Profile	9,000	1	9,000	.25	2,250
	Licensing Board Data Request.	146	1	146	10.5	1,533
	Licensing Board Attestation	301	1	301	1	301
	Corrective Action Plan	10	1	10	.08	1
	Reconciling Missing Actions	7,981	1	7,981	0.8	6,385
	Agent Registration (Initial)	85	1	85	1	85
	Agent Registration (Renewal).	278	1	278	.08	23
	Electronic Transfer of Funds (EFT) Authorization.	654	1	654	.08	53
	Authorized Agent Designation.	213	1	213	.25	54
	Account Discrepancy	10	1	10	.25	3
	New Administrator Request	3,016	1	3,016	.08	242
	Query Credit Purchase	789	1	789	.08	64
	Educational Request	10	1	10	.08	1
	Account Balance Transfer	10	1	10	.08	1

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
	Missing Report Form	29	1	29	.08	3
Total	.....	6,059,761	.....	6,059,761	.....	326,120

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.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–00825 Filed 1–18–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment

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

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Centers for Disease Control and Prevention (CDC)/ Health Resources and Services Administration (HRSA) Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment will hold a public meeting.

DATES: February 22, 2018, 2:00 p.m. to 4:00 p.m. ET.

ADDRESSES: This teleconference meeting will accommodate up to 100 attendees. Parties may access the teleconference by dialing 888–989–6421 and using participant code 9874492. Participants should call and connect 15-minutes prior to the start of the meeting.

FOR FURTHER INFORMATION CONTACT: Anyone requesting information regarding the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment should contact CDR Holly Berilla, Senior Public Health Analyst, Division of Policy and Data (DPD), HIV/AIDS Bureau (HAB), HRSA, in one of three ways: (1) Mail a request to CDR Holly Berilla, Senior Public Health Analyst, HRSA/HAB/ DPD, 5600 Fishers Lane, 09N156, Rockville, Maryland 20857; (2) call 301–443–9965; or (3) send an email to *hberilla@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The CDC/ HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment was established under Section 222 of the Public Health Service (PHS) Act, [42 U.S.C. Section 217a], as amended.

The purpose of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment is to advise the Secretary, HHS; the Director, CDC; and the Administrator, HRSA regarding objectives, strategies, policies, and priorities for HIV, viral hepatitis, and other STDs; prevention and treatment efforts including surveillance of HIV infection, AIDS, viral hepatitis, and other STDs, and related behaviors; epidemiologic, behavioral, health services, and laboratory research on HIV, viral hepatitis, and other STDs; identification of policy issues related to HIV/viral hepatitis/STD professional eduction, patient healthcare delivery, and prevention services; Agency policies about prevention of HIV, viral hepatitis and other STDs; treatment, healthcare delivery, and research and training; strategic issues influencing the ability of CDC and HRSA to fulfill their missions of providing prevention and treatment services; programmatic efforts to prevent and treat HIV, viral hepatitis, and other STDs; and support to the Agencies in their developoment of responses to emerging health needs related to HIV, viral hepatitis, and other STDs. Information about the Committee and the meeting agenda is available by contacting CDR Holly Berilla at the contact information above.

During the meeting, the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment will discuss workgroup reports and updates, information regarding the National Ryan White HIV/ AIDS Program Conference, and Committee business-related items. Agenda items are subject to change as priorities dictate.

Due to the nature and time limitations of the meeting, members of the public will not have an opportunity to provide oral comments, although written comments may be submitted to CDR Holly Berilla at the contact information listed above at least 10 days prior to the meeting. Individuals who need special assistance should notify CDR Holly Berilla at the contact information listed above at least 10 days prior to the meeting.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–00824 Filed 1–18–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Office for Civil Rights, Office of the Secretary, HHS.

SUMMARY: This notice establishes the Conscience and Religious Freedom Division in the Office for Civil Rights of the Department of Health and Human Services.

SUPPLEMENTARY INFORMATION: In accordance with Executive Order 13798 Promoting Free Speech and Religious Liberty (May 4, 2017), 82 FR 21675, and the Attorney General's Guidance on Federal Law Protections for Religious Liberty (October 6, 2017), Part A, Office of the Secretary, Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (HHS), as last amended at 81 FR 95622 (December 28, 2016), is being amended at Chapter AT, Office for Civil Rights (OCR) to reflect the restructuring of OCR as follows:

I. Under Chapter AT, Office for Civil Rights (OCR), in the outline section