Studies.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500626 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). These collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; the collections of information in 21 CFR part 822 have been approved under OMB control number 0910–0449; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

V. References

The following references are on display in the Dockets Management Staff office (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. *FDA Report:* Collection, Analysis, and Availability of Demographic Subgroup Data for FDA-Approved Medical Products, issued August 2013, required under FDASIA section 907, available at *http://www.fda.gov/downloads/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAct/FDASIA/UCM365544.pdf.*
2. FDA's Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data (August, 2014), available at *https://www.fda.gov/downloads/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAct/FDASIA/UCM410474.pdf.*
3. FDA's guidance entitled ''Evaluation of Sex-Specific Data in Medical Device Clinical Studies'' (August 22, 2014), available at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM283707.pdf.*

Dated: September 7, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–19259 Filed 9–11–17; 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 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 (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 must be received no later than November 13, 2017.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail to the HRSA Information Collection Clearance Officer, 14N39, 5600 Fishers Lane, Rockville, MD 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 the HRSA Information Collection Clearance Officer at (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 Web site at *https://www.npdb.hrsa.gov/.* All reporting and querying is performed through the secure portal of this Web site. 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 has 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 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

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours (rounded up)
Accreditation	10	1	10	.75	8
Civil Judgment	10	1	10	.75	8
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
DEA/Federal Licensure	698	1	698	.75	524
Deferred Conviction or Pre-Trial Diversion	54	1	54	.75	41
Exclusion/Debarment (manual)	1,624	1	1,624	.75	1,218
Exclusion/Debarment (automated)	3,180	1	3,180	.0003	1
Government Administrative	2,062	1	2,062	.75	1,547
Health Plan Action	335	1	335	.75	252
Injunction	10	1	10	.75	8
Medical Malpractice Payment (manual)	11,993	1	11,993	.75	8,995
Medical Malpractice Payment (automated)	242	1	242	.0003	1
Nolo Contendere (No Contest) Plea	85	1	85	.75	64
Peer Review Organization	10	1	10	.75	8
Professional Society	49	1	49	.75	37
State Licensure (manual)	19,160	1	19,160	.75	14,370
State Licensure (automated)	25,980	1	25,980	.0003	8
Title IV Clinical Privileges Actions	698	1	698	.75	524
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
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
Continuous Query (manual)	643,860	1	643,860	.08	51,509
Continuous Query (automated)	226,838	1	226,838	.0003	69
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
Entity Registration (Initial)	1,073	1	1,073	1	1,073
Entity Registration (Renewal & Update)	14,060	1	14,060	.25	3,515
Agent Registration (Initial)	85	1	85	1	85
Agent Registration (Renewal & Update)	278	1	278	.08	23
Entity Profile	9,000	1	9,000	.25	2,250
Licensing Board Attestation	301	1	301	1	301
Licensing Board Data Request	146	1	146	10.5	1,533
Reconciling Missing Actions	7,981	1	7,981	0.8	6,385
Corrective Action Plan	10	1	10	.08	1

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours (rounded up)
Missing Report Form	29	1	29	.08	3
Subject Statement and Dispute	3,547	1	3,547	.75	2,661
Request for Dispute Resolution	99	1	99	8	792
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	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. 2017–19252 Filed 9–11–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group; Developmental Biology Subcommittee.

Date: October 2, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda Downtown, 7335 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Cathy J. Wedeen, Ph.D., Scientific Review Officer, Division of Scientific Review, OD, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, DHHS, 6710 B Rockledge Drive, Bethesda, Maryland 20892, 301–435–6878, *wedeenc@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: September 6, 2017.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–19232 Filed 9–11–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: Government owned intellectual property covering imaging agents with improved renal clearance available for licensing and commercialization.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the patent applications listed below may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive, Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing. A description of the technology available for licensing follows.

Evans Blue Dye Derivatives for Serum Albumin Labeling

Description of Technology: The invention is an imaging agent and method of its use for imaging blood pools and the lymphatic system. The imaging agent binds with high affinity to serum albumin, the most abundant serum protein, and can be tagged with several isotopes making it suitable for magnetic resonance imaging or positron emission tomographic imaging. To date, only very few blood-pool tracers have been introduced for positron emission tomography. The existing ones have short half-lives (20.4 min for ^{11}C and 2.05 min for ^{15}O) and thus can only be used in centers with an in-house cyclotron. Compared with these radiometals, ^{18}F has the advantages of being a pure position emitter with ideal half-life. It is the dominant radioisotope used for PET imaging for both clinical applications and preclinical investigations. Evans blue dye has been an important tool in many physiological and clinical investigations because of its