estimates or any other aspect of this collection of information, including:

(1) whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The State Councils on Developmental Disabilities (Councils) are authorized by Subtitle B of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act), as amended, [42 U.S.C. 15001 *et seq.*] (The DD Act). The DD Act requires Councils to submit an annual Program Performance Report. Section 125(c)(7) (42 U.S.C. 15025), states that: *Beginning in fiscal year 2002, the Council shall annually prepare and transmit to the Secretary a report. Each report shall be in a form prescribed by the Secretary by regulation under section 104(b). Each report shall contain information about the progress made by the Council in achieving the goals of the Council as specified in section 124(c)(4)).*

The Council is responsible for the development and submission of the PPR, and for reporting on performance measure data related to its progress in carrying out the goals and objectives of the State Plan. The data collected in the PPR and submitted to ACL is also used to comply with the GPRA Modernization Act of 2010 (GPRAMA). Performance measure results are reported to Congress under GPRAMA.

This is a revision of a currently approved information collection that expires in 2023. To ensure the DD Council PPR is consistent with the Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government and the Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals, ACL intends to determine whether the sexual orientation and gender identity (SOGI) data elements need to be adapted prior to adding them to ensure accessibility of the questions for individuals with intellectual and developmental disabilities.

This IC will also include elements needed to account for the activities supported by funding from the Centers for Disease Control and Prevention (CDC) to support access to vaccines for people with disabilities as well as the funds awarded under the American Rescue Plan to increase the Public Health Workforce (PHWF). All other elements of the template remain consistent with previously approved performance measures and corresponds to requirements in the DD Act.

The information collected from the DD Councils is used for multiple purposes:

(1) To develop and submit at least every two years a report to the President, Congress, and the National Council on Disability that describes the goals and outcomes of programs supported under the DD Act.

(2) As a tool for DD Councils to measure and report on progress in reaching goals and identify areas for which revisions are indicated;

(3) To enhance the Federal project officers' monitoring of DD Council progress in reaching projected outcomes;

(4) As a set of performance measures that will yield a national portrait of DD Council program impact; and

(5) For Congress and the Administration in making funding and appropriation decisions with regard to the DD Council program.

The proposed data collection tools may be found on the ACL website for review at: *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden: Based on DD Council reporting experience, current data and reporting efforts constitute approximately 238 burden hours per grantee for a total of 1,556 hours. The table below outlines the estimate for the hours of burden associated with the collection of information. Estimated Total Annual Burden Hours: 13,328.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Total annual burden hours
State Councils on Developmental Disabilities, Annual Program Performance Report (PPR)	56	1	172	9,632
DDC CDC Report	56	1	52	2,912
DDC PHWF Report	56	1	14	784
Total	56		238	13,328

Date: September 20, 2022.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2022–20796 Filed 9–23–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0738]

Ethical Considerations for Clinical Investigations of Medical Products Involving Children; Draft Guidance for Industry, Sponsors, and Institutional Review Boards; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry, sponsors, and institutional review boards (IRBs) entitled ''Ethical Considerations for Clinical Investigations of Medical Products Involving Children.'' This draft guidance describes FDA's current thinking regarding ethical considerations for clinical investigations of drugs, biological products, and medical devices (collectively referred to as ''medical products'' in this notice) involving children. The draft guidance is intended to assist industry, sponsors,

and IRBs when considering the enrollment of children in clinical investigations of medical products.

DATES: Submit either electronic or written comments on the draft guidance by December 27, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–0738 for ''Ethical Considerations for Clinical Investigations of Medical Products Involving Children.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Pediatric Therapeutics, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5126, Silver Spring, MD 20993–0002; the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling the Center for Biologics Evaluation and Research at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Donna Snyder, Office of Pediatric Therapeutics, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5121, Silver Spring, MD 20993–0002, 301–796–1397; or John J. Alexander, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5490, Silver Spring, MD 20993–0002, 301–796–0665; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Ouided Rouabhi, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G221, Silver Spring, MD 20993–0002, 240–402–2672.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry, sponsors, and IRBs entitled ''Ethical Considerations for Clinical Investigations of Medical Products Involving Children.'' This draft guidance describes FDA's current thinking regarding ethical considerations for clinical investigations of drugs, biological products, and medical devices (collectively referred to as ''medical products'' herein) involving children.

Clinical investigations involving children are essential for obtaining data on the safety and effectiveness of medical products in children and to protect children from the risks associated with exposure to medical products that may be unsafe or ineffective. Children are a vulnerable population who cannot consent for themselves and who therefore are afforded additional safeguards when

participating in a clinical investigation. Such safeguards are an essential requirement for the initiation and conduct of pediatric investigations as part of a medical product development program.

This draft guidance describes the ethical framework in FDA's regulations, including the principle of scientific necessity, the risk categories for interventions or procedures without the prospect of direct benefit, considerations regarding the prospect of direct benefit, the assessment of risk for interventions or procedures with a prospect of direct benefit, evaluations for the different components of a clinical investigation using component analysis of risk, the potential for review of a protocol under 21 CFR 50.54, and the necessity of obtaining parental/guardian permission and child assent. The draft guidance also describes the application of 21 CFR part 50, subpart D to pediatric clinical investigations, including the data to support conducting pediatric clinical investigations, design considerations for clinical investigations, and study procedures in pediatric clinical investigations.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Ethical Considerations for Clinical Investigations of Medical Products Involving Children.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130, the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014, and the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *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, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 20, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20720 Filed 9–23–22; 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 Bureau of Health Workforce Program Specific Form OMB No. 0915–XXXX–New

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

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 October 26, 2022.

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 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 Samantha Miller, the acting HRSA Information Collection Clearance Officer, at (301) 443–9094.

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

Information Collection Request Title: Bureau of Health Workforce (BHW) Program Specific Form OMB No. 0915–XXXX–New.

Abstract: HRSA seeks to collect disparity related data on two forms, the BHW Program Specific Form and the Scholarships for Disadvantaged Students (SDS) Application Program Specific Form. This clearance request is for approval of both forms. The SDS Application Program Specific Form is currently approved under OMB Approval No. 0915–0149 with the expiration date of November 30, 2022. For programmatic efficiency, HRSA is consolidating this previous separate ICR with this new ICR and will be discontinuing OMB No. 0915–0149.

A 60-day notice published in the **Federal Register** on May 25, 2022 (87 FR 31893). There were no public comments.

Need and Proposed Use of the Information: Historically, only the SDS Program collects disparity related data from applicants. In addition to the SDS data, HRSA seeks to obtain general demographic data for its other health workforce programs to assess the experience and performance of applicants in strengthening the health workforce and the populations in which they serve. Examples of this data include but are not limited to:

- Demographic Information: Students/trainees gender, race, and ethnicity;
- Class Enrollment Information: Student/trainees from disadvantaged backgrounds; and
- Graduate Service Information: Graduates or program completers serving in Medically Underserved Communities, rural communities and in primary care.

Collecting disparity related data from BHW applicants would close a data gap in program performance.

The Public Health Service (PHS) Act authorizes the Secretary to collect data for workforce information and analysis activities for BHW's Title VII and VIII programs in sections 799(c) and 806(b) and (f) (42 U.S.C. 295o–1(c); 42 U.S.C 296e(b) and (f)). PHS Act section 799(c) specifically authorizes the Secretary to ensure that such data collection takes