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This draft guidance describes the ethical framework in FDA's regulations, including the principle of scientific necessity, the risk categories for interventions or procedures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 The draft guidance also describes the application of 21 CFR part 50, subpart D to pediatric clinical investigations, including the data to support conducting pediatric clinical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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Ethical Considerations for Clinical Investigations of Medical Products Involving Children.''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Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,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

into account age, sex, race, and ethnicity and sections 806(b) and (f) specifically provide the Secretary with authority to collect information and carry out workforce analytical activities. Collecting these data in the HRSA Electronic Handbook will help grant reviewers, policy makers and HRSA staff make decisions that expand the workforce and help increase access to health care.

The SDS Application Program Specific Form seeks to assist HRSA in assessing applicants for the SDS Program, which is to make grant awards to eligible schools to provide scholarships to full-time, financially needy students from disadvantaged backgrounds enrolled in health professions programs. To qualify for participation in the SDS program, a school must be carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including students who are members of racial and ethnic minority groups, as required by section 737(d)(1)(B) of the PHS Act (42 U.S.C 293a(d)(1)(B)). To meet this requirement, a school must provide data via the SDS Application Program Specific Form that at least 20 percent of the school's full-time enrolled students and graduates are from a disadvantaged background.

The SDS Application Program Specific form previously approved under OMB Control No. 0915–0149 does not include substantive changes. Both forms will be used to collect three years of student and participant data from BHW program applicants only.

Likely Respondents: Respondents vary by the specific program and are determined by each program's eligibility, to include but are not limited to the following: Accredited schools of nursing with advanced education nursing programs; accredited allopathic schools of medicine; accredited schools of osteopathic medicine, dentistry, pharmacy, and graduate programs in behavioral or mental health; schools of nursing; nurse managed health clinics/centers; academic health centers; state or local governments; public or private nonprofit entities determined appropriate by the Secretary; and consortiums and partnerships of eligible entities when applicable.

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
BHW Program Specific Form	2,069	1	2,069	14	28,966
SDS Application Program Specific Form	323	1	323	31	10,013
Total	2,392	.....	2,392	.....	38,979

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. 2022–20717 Filed 9–23–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier 0945–0002]

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 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 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) 264–0041. When submitting comments or requesting information, please include the document identifier 0945–0002–30D 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: Complaint Forms for Discrimination; Health Information Privacy Complaints and Civil Rights Discrimination.

Type of Collection: Extension.

OMB No.: 0945–0002.

Abstract: The Office for Civil Rights (OCR) is requesting an extension of the previously approved collection 0945–0002 that is expiring in November 2022, titled: Complaint Forms for Discrimination; Health Information Privacy Complaints and Civil Rights Discrimination. This request revises the OCR Civil Rights Discrimination