

guidance on June 21, 2018, with the intention of issuing future draft guidance on the evaluation of analytical data to support a demonstration that a proposed biosimilar product is highly similar to a reference product.

This draft guidance revises the guidance issued on April 30, 2015. FDA has adjusted the title of this draft guidance to more clearly communicate that this draft guidance includes the Agency's recommendations on the design and evaluation of comparative analytical studies intended to support a demonstration that a proposed therapeutic protein product is biosimilar to a reference product. In addition to editorial and clarifying edits, the draft guidance includes a section that fulfills the Biosimilar User Fee Act II commitment to publish a revised draft or final guidance, describing statistical considerations for the analysis of analytical similarity data intended to support a demonstration of "highly similar" for biosimilar biological products within 18 months after the close of the public comment period for the withdrawn guidance, "Statistical Approaches to Evaluate Analytical Similarity."

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality-Related Considerations." 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.

## II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations, which are not expected to change as a result of the guidance. 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). The collections of information related to the submission of: (1) An investigational new drug application, which is covered under 21 CFR part 312 and approved under OMB control number 0910–0014; (2) a new drug application, which is covered under 21 CFR 314.50 and approved under OMB control number 0910–0001; (3) a biologics license application (BLA) under section 351(a) of the PHS Act, which is covered under

part 601 (21 CFR part 601) and approved under OMB control number 0910–0338; and (4) a BLA under section 351(k), which is covered under part 601 and approved under OMB control number 0910–0719.

## III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov>.

Dated: May 16, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Proposed Changes to the Scholarships to Disadvantaged Students Program

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

**ACTION:** Request for public comment on the Scholarships for Disadvantaged Students program.

**SUMMARY:** The Scholarships for Disadvantaged Students (SDS) program is authorized by the Public Health Service Act (PHS Act) and administered by HRSA. The program promotes diversity among the health professions and nursing workforce by providing awards to eligible health professions and nursing schools for use in awarding scholarships to students from disadvantaged backgrounds. This notice seeks public comment to inform and guide policy and planning associated with the SDS program.

**DATES:** Individuals and organizations interested in providing information must submit written comments no later than 11:59 p.m. Eastern Time on June 21, 2019.

**ADDRESSES:** Interested parties should submit their comments to Denise Sorrell, SDS Project Officer, via email at [SDSProgram@HRSA.gov](mailto:SDSProgram@HRSA.gov). Please include the title of this notice, "Request for Comment: SDS Program" in the subject line of the email. Response to this request is voluntary. Responders are free to address any or all of the proposals listed below. This request is for

information and planning purposes only and should not be construed as a solicitation or as an obligation on the part of the federal government. All submitted comments will be available to the public in their entirety.

#### FOR FURTHER INFORMATION CONTACT:

Denise Sorrell, SDS Project Officer, Division of Health Careers and Financial Support, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Room 15N78, Rockville, Maryland 20857, phone (301) 443–2909, or email [SDSProgram@HRSA.gov](mailto:SDSProgram@HRSA.gov).

**SUPPLEMENTARY INFORMATION:** HRSA is considering updating the SDS program to increase the impact of the program. The authorizing statute allows the Secretary of HHS to make grants to certain health professions and nursing schools that are carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including students who are members of racial and ethnic minority groups, to provide scholarships to eligible students (PHS Act, Sec. 737(a), (d)(1)). Grantees provide scholarships to individuals who meet the following requirements: (1) are from disadvantaged backgrounds; (2) have a financial need for a scholarship; and (3) are enrolled (or accepted for enrollment) at an eligible health professions or nursing school as a full-time student in a program leading to a degree in a health profession or nursing (PHS Act, Sec. 737(d)(2)(A–C)). Under the statute, priority is given to eligible entities based on the proportion of graduating students practicing in primary care settings, the proportion of underrepresented minority student enrollees and graduates, and the proportion of graduates working in medically underserved communities (MUCs) (PHS Act, Sec. 737(c)). The PHS Act requires HRSA to award at least 16 percent of the available funds to schools of nursing (PHS Act, Sec. 740(a)).

Eligible applicants are public or non-profit private accredited schools of allopathic medicine, osteopathic medicine, dentistry, nursing, pharmacy, podiatric medicine, optometry, veterinary medicine, public health, chiropractic, or allied health; a school offering a graduate program in behavioral and mental health practice; or an entity providing programs for the training of physician assistants as determined in Section 737(d)(1)(A) of the PHS Act. Faith-based and community-based organizations, tribes, and tribal organizations are eligible to apply if all other eligibility requirements are met. Additionally, Section 737(d)(2) requires "a school must be carrying out a recruitment and

retention program for students from disadvantaged backgrounds.”

As explained in the most recent Notice of Funding Opportunity (HRSA–16–069), published on November 25, 2015, HRSA determined at least 20 percent of a school’s enrollees and graduates must be disadvantaged individuals. For the purposes of the SDS program, an individual from a disadvantaged background is defined as one who: (1) comes from an environment that has inhibited the individual from obtaining the knowledge, skills, and abilities required to enroll in and graduate from a health profession or nursing school, or from a program providing education or training in allied health professions; or (2) comes from a family with an annual income below the established Census Bureau low-income thresholds, adjusted by the Secretary of HHS for health professions and nursing programs eligibility.

As explained in the most recent Notice of Funding Opportunity, (HRSA–16–069), scholarship awards equal an amount no less than 50 percent of the student’s annual tuition costs, up to a maximum amount of \$30,000 to cover the cost of attendance. Scholarships may be expended only for a recipient’s cost of tuition expenses, other reasonable educational expenses, and reasonable living expenses incurred by attendance at the participant’s school of enrollment, as described in Section 737(a) of the PHS Act. The project period for this program may be altered within the range of one to five years. HRSA will announce any future changes to the project period for the SDS program through the relevant Notice of Funding Opportunity.

#### **Scholarships for Disadvantaged Students Program in FY 2020—Proposal for Public Comment**

HRSA is seeking comments from interested parties, including current and former grant recipients and former applicants to the program, on the following proposed changes. In your comments, please address one or more of the following proposals. Please reference the section number in your comments.

1. In an effort to combat workforce shortages, HRSA will distribute SDS funding to award recipients consistent with promoting health professions careers projected to experience the most severe shortages as determined by the National Center for Health Workforce Analysis. Section 740(a) of the PHS Act requires HRSA to distribute at least 16 percent of the SDS funding to nursing schools. Precise distributions for each competition will be announced in the

relevant Notice of Funding Opportunity. This adjustment of funding would allow HRSA to strategically target SDS funding for the health professions with a current or projected workforce shortage.

2. At least 20 percent of the school’s full-time enrolled students and graduates must be from a disadvantaged background. Institutions are required to provide 1 year of data to demonstrate this eligibility requirement. The proposal is to require schools to provide the average for the most recent 3-year period to demonstrate their eligibility. A 3-year average is a more accurate portrayal of school enrollment patterns than 1 year. This change would allow SDS to support the grantees who have demonstrated a commitment over time to serving students from disadvantaged backgrounds. Any future changes to the disadvantaged student percentage or data collection period will be announced through the SDS Notice of Funding Opportunity for the relevant grant funding cycle.

3. HRSA has analyzed SDS award data, compared it with performance measures, and discovered providing amounts to students to cover a substantial portion of their education costs positively correlates with better graduation rates, consistent with the statutory aims. Data suggests the availability of scholarships, especially for disadvantaged students, continues to limit educational opportunities for students. SDS last increased its scholarship amount in 2016. Without sufficient financial support, disadvantaged students are much more likely to be unable to successfully complete their education. Based on this understanding and the steady increase in tuition nationally, HRSA proposes to increase the maximum scholarship award to \$40,000 per student, to ensure the SDS program will continue to impact students who receive the awards and ensure their success in completing the program. HRSA also reserves the right to adjust the scholarship award amount as necessary to accommodate any rise in tuition and will announce any such changes in the Notice of Funding Opportunity for the relevant funding cycle.

HRSA will announce any future administrative changes to the SDS program through the relevant Notice of Funding Opportunity.

Dated: May 16, 2019.

**George Sigounas,**  
*Administrator.*

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

#### **Establishment of the Interdepartmental Substance Use Disorders Coordinating Committee and Solicitation of Nominations for Committee Members; Correction**

**AGENCY:** U.S. Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

**ACTION:** Notice; correction.

**SUMMARY:** The U.S. Department of Health and Human Services (HHS) published a document in the **Federal Register** of May 15, 2019, concerning the establishment of the Interdepartmental Substance Use Disorders Coordinating Committee and Solicitation of Nominations for Committee Members. The document contained an inadvertent omission of the following membership category from the list of non-federal members that the Secretary of HHS will appoint to the committee: Public safety officer with extensive experience in interacting with adults with a substance use disorder.

**FOR FURTHER INFORMATION CONTACT:** Roula K. Sweis, Psy.D., M.A., Chief, Operations and Management, Office of the Assistant Secretary for Health; U.S. Department of Health and Human Services; Telephone: 202–260–6619; Fax: 202–690–4631; Email address: [SUDCommittee@hhs.gov](mailto:SUDCommittee@hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### *Correction*

In the **Federal Register** of May 15, 2019, in FR Doc. 2019–09969, on page 21793 under the header Membership and Designation the following category was inadvertently omitted from the list of non-federal members that the Secretary of HHS will appoint to the committee: “at least one such member will be a public safety officer with extensive experience in interacting with adults with a substance use disorder.”

Dated: May 16, 2019.

**Roula K. Sweis,**

*Designated Federal Official.*

[FR Doc. 2019–10679 Filed 5–21–19; 8:45 am]

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