

I. Comments

FDA invites comment on all matters relating to topics for consideration regarding DMD drug development. This request is not limited to comments on the proposal described in the submission by PPMD.

Interested persons may submit either electronic comments to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

II. Electronic Access

Persons with access to the Internet may obtain the proposed draft guidance document at <http://www.regulations.gov>.

Dated: August 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-21051 Filed 9-3-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Ryan White HIV/AIDS Program, Special Projects of National Significance (SPNS), the Albert Einstein College of Medicine, Enhancing Access to and Retention in Quality HIV Care for Women of Color Initiative

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

ACTION: Notice of a deviation from competition requirements to award a program expansion supplement for the HIV/AIDS Bureau's (HAB's) Ryan White HIV/AIDS Program, Special Projects of National Significance (SPNS), the Albert Einstein College of Medicine, Enhancing Access to and Retention in Quality HIV Care for Women of Color Initiative.

SUMMARY: HRSA will be issuing a non-competitive award under the SPNS Program to current grantee, the Albert Einstein College of Medicine (Grant #5 H97HA15152-05-00), for approximately \$55,000 during the budget period September 1, 2014, to August 31, 2015. This will allow the Albert Einstein College of Medicine to cover the costs

associated with the publication of a special supplemental issue of the journal *AIDS Patient Care and STD's*, which will feature eight articles on findings from the Special Projects of National Significance (SPNS) Program Enhancing Access to and Retention in Quality HIV Care for Women of Color Initiative. A program expansion supplement will allow SPNS wider dissemination of the most current best practices and lessons learned for the care of women of color living with HIV. The journal *AIDS Patient Care and STD's* has a combined 18,200 print and online subscribers, and the publisher will also extend online distribution to readers of the *Journal of Women's Health* (approximately 32,000 additional subscribers) and to attendees of the Congress on Women's Health (approximately 800 physicians and nurses).

SUPPLEMENTARY INFORMATION: Intended Recipient of the Award: Albert Einstein College of Medicine (Grant #5 H97HA15152-05-00). The amount of the noncompetitive award is \$55,000.

Authority: Section 2692 of the Public Health Service Act, 42, U.S.C. 300ff-111.

CFDA Number: 93.145.

Period of Supplemental Funding: September 1, 2014, through August 31, 2015.

Justification: SPNS Program is charged with the development of innovative models of HIV treatment, in order to respond to emerging needs of those with HIV/AIDS, including clients served by the Ryan White HIV/AIDS Program. A major goal of the SPNS Program is to disseminate findings and innovative models of care and treatment to the broader HIV provider community and encourage replication of successful models/interventions.

The SPNS Women of Color Initiative began September 1, 2009, and involved 11 demonstration site grantees and an Evaluation and Technical Assistance Center—the Albert Einstein College of Medicine. The Initiative enrolled 921 women of color living with HIV/AIDS in its multi-site evaluation; the findings from this initiative can improve the care of women living with HIV through the identification of best practices and lessons learned. The Albert Einstein College of Medicine has served as the Evaluation and Technical Assistance Center for the SPNS Women of Color Initiative from September 1, 2009, to the present. As such, this grantee has been tasked to lead and coordinate all dissemination activities for this initiative, and is best-positioned to lead and facilitate the publication process. This program expansion would allow

for the publication of findings from the Women of Color Initiative in the journal of *AIDS Patient Care and STD's* in support of HRSA's and HAB's commitment to ensuring that comprehensive and effective models of care and treatment are available to underserved, un/under-insured populations, including those from communities of color.

FOR FURTHER INFORMATION CONTACT:

Adan Cajina, MSc, Branch Chief, Special Programs of National Significance (SPNS), Division of Training and Capacity Development, HAB/HRSA, 5600 Fishers Lane, Rockville, Maryland 20857, by email at acajina@hrsa.gov, or by phone at (301) 443-3180.

Dated: August 27, 2014.

Mary K. Wakefield,

Administrator.

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BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Ryan White HIV/AIDS Program, AIDS Education and Training Centers, The University of Washington, Northwest AIDS Education and Training Center

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

ACTION: Notice of a deviation from competition requirements to award a program expansion supplement for the HIV/AIDS Bureau's (HAB) Ryan White HIV/AIDS Program, AIDS Education and Training Centers (AETC) (H4A), The University of Washington, Northwest AIDS Education and Training Center (NWAETC).

SUMMARY: HRSA will be issuing a non-competitive award under the AETC Program, to current grantee, the University of Washington NWAETC, for approximately \$250,239 during the budget period July 1, 2014, to June 30, 2015. This will allow the University of Washington NWAETC to develop a unique and flexible HIV distance learning curriculum that can be used in a variety of health care settings by a variety of health care providers. This on-line curriculum will enhance our ability to reach and so increase the numbers of health care providers skilled in delivering HIV/AIDS care and treatment at a time when there is a greater demand for these professionals—especially primary care physicians.

SUPPLEMENTARY INFORMATION: Intended Recipient of the Award: The University of Washington, NWAETC (Grant # H4AHA00051). The amount of the noncompetitive award is \$250,239.

Authority: Section 2692 of the Public Health Service Act, 42, U.S.C. 300ff-111.

CFDA Number: 93.145

Period of Supplemental Funding: July 1, 2014, through June 30, 2015.

Justification: With the implementation of the Affordable Care Act, more people, including those living with HIV/AIDS, are able to access care and are being seen by providers in a variety of settings, including community health care centers. This has resulted in an increased need for primary care providers to receive training in HIV care. A program expansion supplement will allow the NWAETC to develop a comprehensive portfolio of web-based, HIV primary care distance learning and assessment resources and tools that will reach greater numbers of health care providers across the nation. This free, state-of-the-art HIV care and treatment curriculum will be evidence-based and aligned with up-to-date federal guidelines. Further, the curriculum would be accessed in an online environment that is effective at assessing HIV training needs, providing relevant, tailored training to meet those needs, and will monitor and evaluate individual and group progress throughout the curriculum.

The University of Washington NWAETC, now in the fifth year of a 5-year project ending on June 30, 2015, is uniquely positioned to rapidly develop and deliver the national HIV care and treatment distance curriculum, having the necessary infrastructure for implementation already developed and in place, and having previously demonstrated the capacity to develop similar products. A distance HIV curriculum is consistent with the goals of the AETC program—to provide HIV treatment education, clinical consultation, capacity building, and technical assistance to health care professionals and agencies. An on-line HIV care and treatment training curriculum will help to better meet the HIV training needs of the current health care workforce that is working to achieve the goals of the National HIV/AIDS Strategy (NHAS).

FOR FURTHER INFORMATION CONTACT:

Rupali K. Doshi, MD, MS, Acting Branch Chief, HIV Education Branch, Division of Training and Capacity Development, HAB/HRSA, 5600 Fishers Lane, Rockville, Maryland 20857, by email at rdoshi@hrsa.gov, or by phone at (301) 443-5313.

Dated: August 27, 2014.

Mary K. Wakefield,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at Vol. 79, FR 31952-31956 dated June 3, 2014).

This notice reflects organizational changes to the Health Resources and Services Administration. This notice updates the functional statement for the Healthcare Systems Bureau (RR). Specifically this notice: (1) Renames the Division of Vaccine Injury Compensation to the Division of Injury Compensation Programs (RR4); (2) transfers the Countermeasures Injury Compensation Program function from the Office of the Associate Administrator (RR) to the newly named Division of Injury Compensation Programs (RR4); (3) updates the functional statement for the Office of the Associate Administrator (RR); and (4) updates the functional statement for the Division of Injury Compensation Programs (RR4).

Chapter RR—Healthcare Systems Bureau

Section RR-10, Organization

Delete the organization for the Healthcare Systems Bureau (RR) in its entirety and replace with the following: The Healthcare Systems Bureau (RR) is headed by the Associate Administrator, who reports directly to the Administrator, Health Resources Services Administration.

- (1) Office of the Associate Administrator (RR);
- (2) Division of Transplantation (RR1);
- (3) Division of Injury Compensation Programs (RR4);
- (4) Office of Pharmacy Affairs (RR7);
- (5) Division of Poison Control and Healthcare Facilities (RR9); and
- (6) Division of National Hansen's Disease Program (RRH).

Section RR-20, Functions

Delete the functional statement for the Office of the Associate Administrator (RR), and the functional statement for the Division of Vaccine Injury Compensation (RR4), and replace in its entirety.

Office of the Associate Administrator (RR)

The Healthcare Systems Bureau leads the agency in providing health care programs to eligible organizations around the country. Specifically, (1) administers the Organ Transplantation Program to include the Organ Procurement and Transplantation Network (OPTN) to facilitate the allocation of donor organs to patients waiting for an organ transplant, and the Scientific Registry of Transplant Recipients that provides analytic support to the OPTN in the development and assessment of organ allocation and other OPTN policies; (2) administers the C.W. Bill Young Cell Transplantation Program to increase the number of unrelated blood stem cell transplants and improve the outcomes of blood stem cell transplants; (3) administers the National Cord Blood Inventory to increase the number of high quality cord blood units available for transplantation; (4) develops and maintains a national program of grants and contracts to organ procurement organizations and other entities to increase the number of organs made available for transplantation; (5) manages the national program for compliance with the Hill-Burton uncompensated care requirement and other assurances; (6) directs and administers a congressionally-directed grant program for the construction/renovation/equipping of health care and other facilities; (7) directs and administers the National Vaccine Injury Compensation Program; (8) manages and promotes the 340B Drug Pricing Program; (9) directs and administers the Poison Center Support, Enhancement, and Awareness Act; (10) implements and administers the Countermeasures Injury Compensation Program; (11) provides professional and administrative support for the HHS Medical Review Claims Panel; and (12) manages the National Hansen's Disease Program in accordance with regulations of the Public Health Service.

Division of Injury Compensation Programs (RR4)

The Division of Injury Compensation Programs, on behalf of the Secretary of Health and Human Services (HHS), administers and implements all