

The guidance represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively, and the collection of information under the guidance for industry "Special Protocol Assessment" has been approved under OMB control number 0910–0470.

III. Comments

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: November 22, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–29796 Filed 11–26–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Health Center Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Noncompetitive Replacement Awards to Upper Room AIDS Ministry, Inc.

SUMMARY: The Health Resources and Services Administration (HRSA) will transfer Health Center Program (section 330 of the Public Health Service Act) Increased Demand for Services (IDS) and Capital Improvement Project (CIP) funds, awarded under the American Recovery and Reinvestment Act (ARRA), originally awarded to Harlem United Community AIDS Center, Inc. (HUCAC) to Upper Room AIDS Ministry, Inc. to ensure the provision of critical primary health care services and continuity of services to low-income, underserved homeless patients in New York City.

SUPPLEMENTARY INFORMATION:

Former Grantee of Record: Harlem United Community AIDS Center, Inc.

Original Period of Grant Support: March 27, 2009, to March 26, 2011 (IDS) and June 29, 2009, to June 28, 2011 (CIP).

Replacement Awardee: Upper Room AIDS Ministry, Inc.

Amount of Replacement Award: \$103,317 (IDS) and \$262,740 (CIP).

Period of Replacement Award: The period of support for the replacement awards is March 27, 2009 to March 26, 2011 (IDS) and June 29, 2009 to June 28, 2011 (CIP).

Authority: Section 330(h) of the Public Health Service Act, 42 U.S.C. 245b.

CDDA Number: 93.703

Justification for Exception to Competition: Under the original grant applications approved by HRSA, Harlem United Community AIDS Center, Inc. (HUCAC) was identified as the grantee of record. HUCAC had a subrecipient agreement in place with Upper Room AIDS Ministry, Inc., a HUCAC-subsidiary organization. Through this arrangement, Upper Room AIDS Ministry, Inc. provided all services and carried out the full scope of project for the homeless program. Instead of continuing this agreement, both organizations decided that Upper Room AIDS Ministry, Inc. should become the direct grantee recipient for the ARRA IDS and CIP grants. Upper Room AIDS Ministry, Inc. competed successfully for fiscal year 2010 Service Areas Competition funding and has become the direct grant recipient of the health center homeless grant. HUCAC and the Upper Room AIDS Ministry, Inc. requested that full responsibility for the grants be transferred from HUCAC to Upper Room AIDS Ministry. Upper Room AIDS Ministry has provided documentation to HRSA that it meets Section 330 statutory and regulatory requirements as well as applicable grant management requirements.

The transfer of these grants will ensure critical primary health care services continue and remain available to low income, underserved homeless populations with no interruption in services to the target population. Transferring the funds to Upper Room AIDS Ministry, Inc. does not materially change the projects as originally proposed and funded. Upper Room AIDS Ministry, Inc. will fulfill the expectations of the former grantee's originally funded IDS and CIP grant applications. In order to ensure that critical primary health care services continue to be available to the original target population in a timely manner, these ARRA CIP and IDS awards will not be competed.

FOR FURTHER INFORMATION, CONTACT:

Marquita Cullom-Stott via e-mail at MCullom-Stott@hrsa.gov or 301–594–4300.

Dated: November 19, 2010.

Mary K. Wakefield,
Administrator.

[FR Doc. 2010–29866 Filed 11–26–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Part C Early Intervention Services Grant under the Ryan White HIV/AIDS Program

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

ACTION: Notice of a non-competitive one-time replacement award from Ryan White HIV/AIDS Program, Part C funds for the Louisiana State University, Health Sciences Center, Viral Disease Clinic in Shreveport, Department of Medicine, Shreveport, Louisiana.

SUMMARY: HRSA will be giving a non-competitive one-time replacement award to support comprehensive primary care services for persons living with HIV/AIDS, including primary medical care, laboratory testing, oral health care, outpatient mental health and substance abuse treatment, specialty and subspecialty care, referrals for health and support services and adherence monitoring/education services to the Louisiana State University, Health Sciences Center, Viral Disease Clinic to ensure continuity of critical HIV medical care and treatment services, to clients in Shreveport, Louisiana.

SUPPLEMENTARY INFORMATION: