

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]

BILLING CODE 4165–15–P

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:

Grantee of record: Premier Care and Learning Center, Shreveport, Louisiana.

Intended recipient of the award: Louisiana State University, Health Sciences Center, Shreveport, Louisiana.

Amount of the award: \$268,377 to ensure ongoing clinical services to the target population.

Authority: Section 2651 of the Public Health Service Act, 42 U.S.C. 300ff-51.

CFDA Number: 93.918.

Project period: July 1, 2010, to June 30, 2011. The period of support for this non-competitive one-time replacement award is from July 1, 2010, to June 30, 2011.

Justification for the Exception to Competition

Critical funding for HIV medical care and treatment services to clients in Shreveport, Louisiana, will be continued through a non-competitive replacement award to an existing grant award to the Louisiana State University, Health Sciences Center, Viral Disease Clinic. This is a non-competitive one-time replacement award because the previous grant recipient serving this population notified HRSA that it would not continue in the program after the fiscal year (FY) 2010 award was made. Louisiana State University, Health Sciences Center, Viral Disease Clinic is the best qualified grantee for this supplement, since it serves many of the former grantee's patients and is the closest Part C Program to the former grantee. Further funding beyond

June 30, 2011, for this service area will be competitively awarded during the Part C HIV Early Intervention Service competing application process for FY 2011.

FOR FURTHER INFORMATION CONTACT: Kathleen Treat, by e-mail ktreat@hrsa.gov, or by phone, 301-443-7602.

Dated: November 19, 2010.
Mary K. Wakefield,
Administrator.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Customer and Other Partners Satisfaction Surveys

SUMMARY: In compliance with the requirement of Section 3507(A)(1)(D) of the Paperwork Reduction Act of 1995 for the opportunity for public comment on the proposed data collection projects, the Clinical Center (CC) of the National Institutes of Health, (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on September 21, 2010, pages 57470-57472 and allowed 60 days for public comments. One comment regarding the use of government resources to conduct surveys was received during the 60-day comment period. The purpose of this notice is to provide an additional 30 days for public comment.

5 CFR 1320.5 Respondents to this request for information collection should not respond unless the request displays a currently valid OMB control number.

Proposed Collection: Title: Generic Clearance for Satisfaction Surveys of Customer and Other Partners. *Type of Information Collection Request:* Extension (OMB Control Number: 0925-0458). *Need and Use of Information Collection:* The information collected in these surveys will be used by Clinical Center personnel: (1) To evaluate the satisfaction of various Clinical Center

customers and other partners with Clinical Center services; (2) to assist with the design of modifications of these services, based on customer input; (3) to develop new services, based on customer need; and (4) to evaluate the satisfaction of various Clinical Center customers and other partners with implemented service modifications. These surveys will almost certainly lead to quality improvement activities that will enhance and/or streamline the Clinical Center's operations. The major mechanisms by which the Clinical Center will request customer input is through surveys and focus groups. The surveys will be tailored specifically to each class of customer and to that class of customer's needs. Surveys will either be collected as written documents, as faxed documents, mailed electronically or collected by telephone from customers. Information gathered from these surveys of Clinical Center customers and other partners will be presented to, and used directly by, Clinical Center management to enhance the services and operations of our organization. *Frequency of Response:* The participants will respond yearly. *Affected Public:* Individuals and households, businesses and other for profit, small businesses and organizations. *Types of Respondents:* These surveys are designed to assess the satisfaction of the Clinical Center's major internal and external customers with the services provided. These customers include, but are not limited to, the following groups of individuals: Clinical Center patients, family members of Clinical Center patients, visitors to the Clinical Center, NIH intramural collaborators, private physicians or organizations who refer patients to the Clinical Center, volunteers, vendors and collaborating commercial enterprises, small businesses, regulators, and other organizations. The annual reporting burden is as follows:

Customer	Number of respondents	Frequency of response	Average time per response	Annual hour burden
FY 2010				
Clinical Center Patients	5000	1	.5	2500
Family Members of Patients	2000	1	.5	1000
Visitors to the Clinical Center	1000	1	.17	170
NIH Intramural Collaborators	2000	1	.17	340
Vendors and Collaborating Commercial Enterprises	2500	1	.33	833
Professionals and Organizations Referring Patients	2000	1	.33	833
Regulators	30	1	.33	10
Volunteers	275	1	.5	138
Total	14,805	5,824