

electronic format using the electronic Common Technical Document (eCTD) specifications: “The eCTD Backbone Files Specification for Module 1, version 2.1” (which includes the U.S. regional document type definition, version 3.1), and “Comprehensive Table of Contents Headings and Hierarchy, version 2.1.” Technical files that support these documents are also available on the Agency Web site. A complete summary of the revisions made is included in the updated documents. FDA estimates it will be able to receive submissions utilizing Module 1 Specifications 2.1 by September 2013 and will give 30 days advanced notice to industry.

ADDRESSES: Submit written requests for single copies of the documents to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002 or Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the documents.

FOR FURTHER INFORMATION CONTACT: Constance Robinson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1105, Silver Spring, MD 20993, 301-796-1065, constance.robinson@fda.hhs.gov; or Joseph Montgomery, Center for Biologics Evaluation and Research, Food and Drug Administration, 11400 Rockville Pike, HFM-165, rm. 4155, Rockville, MD 20857, 301-827-1332, joseph.montgomery@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The eCTD is an International Conference on Harmonisation (ICH) standard based on specifications developed by ICH and its member parties. FDA’s Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) have been receiving submissions in the eCTD format since 2003; the eCTD has been the standard for electronic submissions to CDER and CBER since January 1, 2008. The majority of new electronic submissions are now received in eCTD format. Since adoption of the eCTD standard, it has become necessary to update the

administrative portion of the eCTD (Module 1) to reflect regulatory changes, provide clarification of business rules for submission processing and review, refine the characterization of promotional marketing and advertising material, and facilitate automated processing of submissions. FDA announced availability of final versions of technical documentation in the **Federal Register** of August 6, 2012 (77 FR 46763). FDA has revised the final documentation and is making available revised versions of the following documents:

- “The eCTD Backbone Files Specification for Module 1, version 2.1,” which provides specifications for creating the eCTD backbone file for Module 1 for submission to CDER and CBER. It should be used in conjunction with the guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Applications and Related Submissions,” which will be revised as part of the implementation of the updated eCTD backbone files specification.
- “Comprehensive Table of Contents Headings and Hierarchy, version 2.1,” which reflects updated headings that are specified in the document entitled “The eCTD Backbone Files Specification for Module 1, version 2.1.”

Supporting technical files are also being made available on the Agency Web site. A complete summary of the revisions made are included in the updated documents. The revisions include the following:

- The 1.16 heading regarding risk management was modified and subheadings were added.
- The application-type attribute file was modified to include PMA and 510(k).
- Attribute files were modified to allow the version, date, and number to be machine readable.

FDA is not prepared at present to accept submissions utilizing this new version, because eCTD software vendors need time to update their software to accommodate this information and because its use will require software upgrades within the Agency. FDA estimates it will be able to receive submissions utilizing Module 1 Specifications 2.1 by September 2013 and will give 30 days advanced notice to industry.

II. Electronic Access

Persons with access to the Internet may obtain the documents at either <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/>

<http://www.regulations.gov>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: February 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-03319 Filed 2-12-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

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

ACTION: Notice of Ryan White HIV/AIDS Program (Part C) Early Intervention Services One-Time Noncompetitive Award to Ensure Continued HIV Primary Medical Care.

SUMMARY: To prevent a lapse in comprehensive primary care services for persons living with HIV/AIDS, HRSA will provide one-time noncompetitive Part C funds to the Hoboken Community Healthcare, Inc., Hoboken, New Jersey.

SUPPLEMENTARY INFORMATION: The amount of the award to ensure ongoing HIV medical services is \$327,166.

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

CFDA Number: 93.918.

Project period: The period of support for this award is from January 1, 2013, through June 30, 2013.

Justification for the Exception to Competition: Hoboken Municipal Hospital Authority (HMHA), Hoboken, NJ; H76HA07886 announced the December 31, 2012, relinquishment of their Part C grant to Hoboken Community Healthcare, Inc., a nonprofit 501(c)(3) organization that purchased the hospital and associated clinics. Hoboken Community Healthcare, Inc. has been identified as an interim provider of the Part C grant. The amount of \$327,166 will be awarded to Hoboken Community Healthcare, Inc., which represents a proportional share of the last award to HMHA. This funding will support HIV medical care until the start of a new funding cycle under HRSA-13-168 with a July 1, 2013, start date.

FOR FURTHER INFORMATION CONTACT: John Fanning; by email at jfanning@hrsa.gov or by phone, 301-443-0493.

Dated: February 6, 2013.

Mary K. Wakefield,
Administrator.

[FR Doc. 2013-03295 Filed 2-12-13; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

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

ACTION: Notice of Ryan White HIV/AIDS Program Part C Early Intervention Services One-Time Noncompetitive Award to Ensure Continued HIV Primary Medical Care.

SUMMARY: To prevent a lapse in comprehensive primary care services for persons living with HIV/AIDS, HRSA will provide one-time noncompetitive Ryan White HIV/AIDS Program (Part C) funds to the University of Pittsburgh Medical Center, Presbyterian Shadyside, Pittsburgh, Pennsylvania.

SUPPLEMENTARY INFORMATION: The amount of the award to ensure ongoing HIV medical services is \$543,037.

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

CFDA Number: 93.918.

Project period: The period of support for this award is January 1, 2013, through June 30, 2013.

Justification for the Exception to Competition: The University of Pittsburgh School of Medicine, Pittsburgh, PA; H76HA00079 announced the December 31, 2012, relinquishment of their Part C grant in order to transfer it to another entity within their organization; the University of Pittsburgh Medical Center, Presbyterian Shadyside, a nonprofit 501(c)(3) organization. The transfer will more closely align the administrative responsibilities with the clinical entity and simplify accounting and reporting for the Part C grant. An award of \$543,037 represents a proportional share of the last award to the University of Pittsburgh School of Medicine. The funding will support services to Presbyterian Shadyside until the service

area is competed under HRSA-13-168 with a July 1, 2013, start date.

FOR FURTHER INFORMATION CONTACT: John Fanning; by email at jfanning@hrsa.gov or by phone at 301-443-0493.

Dated: February 6, 2013.

Mary K. Wakefield,
Administrator.

[FR Doc. 2013-03291 Filed 2-12-13; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

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

ACTION: Notice of Ryan White Part C Early Intervention Services One-Time Noncompetitive Award to Ensure Continued HIV Primary Medical Care.

SUMMARY: To prevent a lapse in comprehensive primary care services for persons living with HIV/AIDS, HRSA will provide one-time noncompetitive Part C funds to the Aaron E. Henry Community Health Center (AEHCHC), Clarksville, Mississippi.

SUPPLEMENTARY INFORMATION: The amount of the award to ensure ongoing HIV medical services is \$178,579.

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

CFDA Number: 93.918

Project period: The period of support for this award varies according to the circumstances and is explained in further detail below.

Justification for the Exception to Competition: The Tutwiler Clinic, Tutwiler, MS; H76HA21225 announced the December 31, 2012, relinquishment of their Part C grant due to the loss of administrative and clinical resources. To prevent a lapse in HIV medical services, the grant for \$178,579 will be awarded to AEHCHC, Clarksdale, MS, to provide HIV medical care. The \$178,579 represents a proportional share of the last award to Tutwiler Clinic. AEHCHC has been identified as an interim provider for the Part C grant and is currently a HRSA-funded community health center which offers HIV medical care. The 6 months of funding will ensure continued service until the service area is competed under HRSA-13-168 with a July 1, 2013, start date.

FOR FURTHER INFORMATION CONTACT: John Fanning; by email at jfanning@hrsa.gov or by phone at 301-443-0493.

Dated: February 6, 2013.

Mary K. Wakefield,
Administrator.

[FR Doc. 2013-03292 Filed 2-12-13; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

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

ACTION: Notice of One-Time Noncompetitive Award of Part C Funds for the District Four Health Services (DFHS), Lagrange, Georgia.

SUMMARY: To prevent a lapse in comprehensive primary care services for persons living with HIV/AIDS, HRSA will be providing a one-time noncompetitive Part C funds award to DFHS, Lagrange, Georgia.

SUPPLEMENTARY INFORMATION: The amount of the award is \$104,218 to ensure ongoing clinical services to this rural population.

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

CFDA Number: 93.918.

Project period: The period of support for this award is from April 1, 2013, to June 30, 2013.

Justification for the Exception to Competition: Since 2000, DFHS has provided critical Ryan White HIV/AIDS Program (Part C) Early Intervention Services for over 427 persons living with HIV/AIDS in the twelve county public health service areas. DFHS will continue to provide critical HIV medical care and treatment services during the three-month extension from April 1, 2013, until June 30, 2013, until the start of the July 1 funding cycle. This service area will be included in the upcoming competition for the Part C HIV Early Intervention Services Grant under the funding opportunity announcement HRSA-13-168.

FOR FURTHER INFORMATION CONTACT: John Fanning; by email at jfanning@hrsa.gov or by phone at 301-443-0493.