

oral presentation do not need to register. Seating is limited and will be on a first-come, first-served basis.

If you would like to make an oral presentation during the public session on November 17, 2010, you must register and provide an abstract of your presentation by the close of business on October 15, 2010. To speak, submit your name, title, business or organization affiliation (if applicable), address, telephone number, fax number, and email address to Sharon Bakayoko (see **FOR FURTHER INFORMATION CONTACT**). FDA has included areas of interest in section II of this document. Please indicate the topic area you wish to address in your presentation. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interest are urged to consolidate or coordinate their presentations and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. Persons registered to make an oral presentation should check in at the registration desk before the workshop. Time will be allowed during the scheduled agenda for attendees to ask questions of panelists. In addition, we strongly encourage electronic or written comments to the docket (see section IV of this document).

If you need special accommodations because of a disability, please contact Sharon Bakayoko at least 7 days before the workshop.

#### IV. Comments

Regardless of attendance at the workshop, interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document, including suggestions for workshop topics. 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.

#### V. Electronic Access

Information about the Safe Use Initiative, including the Safe Use Report, is available on the Internet at <http://www.fda.gov/safeuseinitiative>. Information about the workshop will be posted on this Web site when it is available.

#### VI. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.fda.gov/safeuseinitiative> and <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: September 16, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Health Resources and Services Administration

##### Part D Grant for Coordinated HIV Services and Access to Research for Women, Infants, Children, and Youth Part D Funds Under the Ryan White HIV/AIDS Program

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

**ACTION:** Notice of Non-competitive Award of Part D Funds for the University of Utah.

**SUMMARY:** HRSA will be awarding, non-competitively, Part D Funds to support family-centered primary medical care, treatment, and support services (directly or through contracts) for women, infants, children, and youth with HIV/AIDS, to the University of Utah in order to ensure continuity of critical HIV medical care and support services, to women, infants, children and youth in Salt Lake City, Utah and the surrounding counties.

##### SUPPLEMENTARY INFORMATION:

*Grantee of record:* Utah Department of Health, Salt Lake City, Utah.

*Intended recipient of the award:* University of Utah, Salt Lake City, Utah.

*Amount of the award:* \$350,000 to ensure continuity of medical care and support services to the target population.

**Authority:** Section 2671 of the Public Health Service Act, 42 U.S.C. 300ff-71.

*CFDA Number:* 93.918.

*Project period:* August 1, 2010, to July 31, 2011. The period of support for this award is from August 1, 2010, to July 31, 2011.

#### Justification for the Exception to Competition

Funding for critical HIV medical care and support services to women, infants, children and youth in Salt Lake City, Utah and the surrounding areas will be continued through a non-competitive award to the University of Utah. The Utah Department of Health is currently contracting all of these services to the University of Utah. The University of Utah has the clinical, fiscal, and administrative infrastructure to administer the Part D Grant since it is currently the Part C Early Intervention Services Grant recipient. This is a temporary replacement award, as the previous grant recipient serving this population notified HRSA that it could not continue as the grantee of record after July 31, 2010. HRSA's HIV/AIDS Bureau identified the University of Utah as the best qualified entity for this temporary grant. Since the grant's inception, the Utah Department of Health has contracted with the University of Utah to provide all Part D services, and the University can continue to ensure family-centered care involving outpatient or ambulatory care (directly or through contracts) for women, infants, children, and youth living with HIV/AIDS. The University is able to provide critical services with the least amount of disruption to the service population while the service area is re-competed.

This supplement will cover the time period from August 1, 2010, through July 31, 2011. This service area will be included in the upcoming competition for the Part D Coordinated HIV Services and Access to Research for Women, Infants, Children, and Youth for project periods starting August, 2011.

**FOR FURTHER INFORMATION CONTACT:** Dora Ober, by e-mail [dober@hrsa.gov](mailto:dober@hrsa.gov), or by phone, 301-443-0759.

Dated: September 15, 2010.

**Mary K. Wakefield,**

*Administrator.*

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