

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.293]

Announcing the Award of a Single-Source Cooperative Agreement to the American Public Human Services Association for the Association of Administrators of the Interstate Compact on the Placement of Children (AAICPC) in Washington, DC

AGENCY: Children's Bureau, Administration on Children, Youth and Families, ACF, HHS.

ACTION: Notice of the award of a single-source cooperative agreement to the American Public Human Services Association to support the development and implementation of a national inter-jurisdictional Interstate Compact on the Placement of Children (ICPC) electronic system.

SUMMARY: The Administration for Children and Families (ACF), Administration on Children, Youth and Families (ACYF), Children's Bureau (CB), Division of Capacity Building announces the award of a single-source cooperative agreement in the amount of \$1,250,000 to the American Public Human Services Association for its affiliate the Association of Administrators of the Interstate Compact on the Placement of Children (AAICPC), Washington, DC, for the development and implementation of an inter-jurisdictional electronic system to improve administrative efficiency in the interstate process of the ICPC. The ICPC ensures safe and suitable interstate placements for children in foster care.

Award funds will support the development and implementation of a national inter-jurisdictional Interstate Compact on the Placement of Children (ICPC) electronic system to improve administrative efficiency in the interstate process via the ICPC.

This pilot, "Supporting Permanent Placement of Foster Care Children Through Electronic Records Exchange," implements real-time, on-line data exchange for States to share records and other information to support permanent placements of foster care children in homes across state lines. The Association of Administrators of the Interstate Compact on the Placement of Children (AAICPC) has identified current paper-based processes as causing excessive delays. Children may wait an unnecessarily long time for the paperwork for placement in a permanent home to be executed

manually. The pilot will test whether an automated system reduces the time to process such cross-state exchanges to determine whether a placement is safe and suitable.

The pilot evaluation will measure timeliness of communication, expeditious exchange of case documentation and similar immediate outcomes as well as utilization and adherence to streamlined ICPC processes. Additional questions, such as those related to the permanency of child placements and the associated savings, may be addressed if it is feasible to do so within the project period. Results, which will be included in a final public report, will inform further adoption of the system across states.

The initial pilot will include at least 5 states and ultimately, beyond the pilot period, the system will be used by all 50 states, the District of Columbia and the U.S. Virgin Islands (ICPC Compact Members). The system will serve and benefit children, families, the public, private and tribal child welfare agencies nationwide and other multidisciplinary groups that work in support of the and throughout the child placement continuum.

DATES: The 17 month period of support for this award is September 30, 2013 through February 28, 2015.

FOR FURTHER INFORMATION CONTACT: June Dorn, National Adoption Specialist, Division of Capacity Building, 1250 Maryland Avenue SW., Suite 8150, Washington, DC 20024. Telephone: 202-205-9540; Email: June.Dorn@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: The Partnership Fund, administered by the Office of Management and Budget (OMB), supports pilot projects that test improvements in how Federal assistance programs are administered. The pilot projects address the four goals of improving service delivery, improving payment accuracy, improving administrative efficiency and reducing barriers to access for eligible people. Using \$32.5 million appropriation, the Partnership Fund allows Federal, state, and local government agencies to pilot innovative ideas in a controlled environment. Pilot projects funded by the Partnership Fund address Federal assistance programs that have a substantial State role in eligibility determination or administration, or where Federal-State cooperation could otherwise be beneficial. Ideas for pilots are developed through a collaborative process involving Federal, state, local, and private stakeholders. The OMB consults with a Federal Steering Committee to

select pilots for funding. Funds are then transferred to lead Federal agencies, which in turn select states and localities to implement each pilot. Based on careful evaluation, successful pilots serve as models for other states and agencies and inform future policy decisions by the Administration and Congress.

Statutory Authority: The transfer of funding from the Partnership Fund for Program Integrity Innovation by the OMB to Federal agencies is authorized by the Consolidated Appropriations Act, 2010 (Pub. L. 111-117) and the Consolidated Appropriations Act, 2012 (Pub. L. 112-74)

Joseph Bock,

*Associate Acting Commissioner,
Administration on Children, Youth and Families.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 8 and 9, 2013, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900.

Contact Person: Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-3063, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously

announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On both days the committee will discuss, make recommendations, and vote on devices indicated for use in patients with heart failure (HF). On October 8, 2013, the committee will discuss, make recommendations, and vote on information related to the premarket approval application regarding the expansion of indications supported by the BLOCK HF trial to apply to all market-approved Medtronic Cardiac Resynchronization Therapy-Pacemaker (CRT-P) and Cardiac Resynchronization Therapy-Defibrillator (CRT-D) devices. The devices are pulse generators either without (CRT-P) or with (CRT-D) defibrillation capabilities. The devices require the implantation of at least a right ventricular (RV) and a left ventricular (LV) lead for sensing and pacing functionality. The RV lead used with a CRT-D device also has the capability to deliver high voltage energy. The implantation of a right atrial (RA) lead is left to the discretion of the clinician for both devices.

The requested expansion in indications for use was studied under the BLOCK HF trial. The trial was a prospective, multisite, randomized, double-blinded, parallel-controlled investigational device exemption (IDE) study. The primary objective of the trial was to demonstrate that the time until the first event of all-cause mortality, heart-failure-related urgent care, or a significant increase in left ventricular end systolic volume index (LVESVI) for subjects programmed to biventricular pacing is superior to that of subjects programmed to right ventricular pacing.

On October 9, 2013, the committee will discuss, make recommendations, and vote on information related to the premarket approval application for CardioMEMS, Inc. Champion™ HF Monitoring System. The CardioMEMS HF System is a permanently implantable pressure measurement system designed to provide daily pulmonary arterial pressure measurements including systolic, diastolic, and mean pulmonary arterial (PA) pressure. These measurements are used to guide treatment of congestive heart failure. The system consists of the following:

Implantable Sensor—The Pressure Sensor consists of a three-dimensional coil and pressure-sensitive capacitor encased between two wafers of fused silica. The coil (inductor) electromagnetically couples to the Sensor and allows the remote measurement of the resonant frequency of the inductive/capacitive (LC) circuit. This allows for wireless communication with the Sensor and eliminates the need for an onboard source of energy, such as a battery.

Delivery System—The Delivery System allows the placement of the Pressure Sensor within the distal pulmonary artery. There are two versions of the Delivery System. The first includes a hydrophilic coating on the distal portion of the catheter shaft and the second has no coating on the catheter shaft. Both delivery catheters are compatible with a guidewire. The Delivery System (with HF Sensor) is introduced over a guidewire through a sheath. Tether wires connect the Sensor to the Delivery System until the physician determines that the Sensor is properly positioned within the distal pulmonary artery. Once the Sensor is in position, the tether wires are withdrawn, releasing the Sensor.

Electronics Unit (Interrogator) and database—The Electronics Unit contains hardware and software to acquire and process signals from the sensor, provides a system interface for both patients and clinicians, and transfers PA measurements to a database for review by medical professionals. The database is a Web-based server that contains software, which receives data transmitted from the electronics unit, and presents the data for review by medical professionals.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 24, 2013. On October 8 and 9, 2013, oral presentations from the public will be

scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 16, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 18, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at AnnMarie.Williams@fda.hhs.gov or 301-796-5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 4, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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