

Qualified Health Centers mechanism, Migrant Health Centers, Primary Care Public Housing Health Centers, Healthcare for the Homeless Centers, and other community-based health centers.

**Comprehensive women's health services:** Services including, but going beyond traditional reproductive health services to address the health needs of underserved women in the context of their lives, including a recognition of the importance of relationships in women's lives, and the fact that women play the role of health providers and decision-makers for the family. Services include basic primary care services; acute, chronic, and preventive services including gender and age-appropriate preventive services; mental and dental health services; patient education and counseling; promotion of healthy behaviors (like nutrition, smoking cessation, substance abuse services, and physical activity); and enabling services. Ancillary services are also provided such as laboratory tests, X-ray, environmental, social referral, and pharmacy services.

**Coordinated care:** The formal linkages, case management services, partnering arrangements, and patient advocate support that enable better coordination of women's health resources and help underserved women to navigate systems to obtain the comprehensive health services they need. Community-based organizations are expected to coordinate with State and local health departments, nonprofit organizations, academic institutions, or other local organizations in the community as appropriate.

**Culturally competent:** Information and services provided at the educational level and in the language and cultural context that are most appropriate for the individuals for whom the information and services are intended. Additional information on cultural competency is available at the following Web site: <http://www.aoa.dhhs.gov/May2001/factsheets/Cultural-Competency.html>.

**Cultural perspective:** Recognizes that culture, language, and country of origin have an important and significant impact on the health perceptions and health behaviors that produce a variety of health outcomes.

**Enabling services:** Services that help women access health care, such as transportation, parking vouchers, translation, child care, and case management.

**Frontier Area:** Areas with low population density that is usually fewer than 6-7 persons per square mile.

**Gender-based Care:** Highlights inequalities between men and women in

access to resources to promote and protect health, in responses from the health sector, and in the ability to exercise the right to quality health care.

**Healthy People 2010:** A set of national health objectives that outlines the prevention agenda for the Nation. Healthy People 2010 identify the most significant preventable threats to health and establishes national goals for the next ten years. Individuals, groups, and organizations are encouraged to integrate Healthy People 2010 into current programs, special events, publications, and meetings. Businesses can use the framework, for example, to guide worksite health promotion activities as well as community-based initiatives. Schools, colleges, and civic and faith-based organizations can undertake activities to further the health of all members of their community. Health care providers can encourage their patients to pursue healthier lifestyles and to participate in community-based programs. By selecting from among the national objectives, individuals and organizations can build an agenda for community health improvement and can monitor results over time. More information on the Healthy People 2010 objectives may be found on the Healthy People 2010 Web site: <http://www.health.gov/healthypeople>.

**Holistic:** Looking at women's health from the perspective of the whole person and not as a group of different body parts. It includes dental, mental, as well as physical health.

**Integrated:** In the CCOE context, the bringing together of the numerous spheres of activity (6 CCOE components) that touch women's health, including clinical services, research, health training, public health outreach and education, leadership development for women, and technical assistance. The goal of this approach is to unite the strengths of each of these areas, and create a more informed, less fragmented, and efficient system of care for underserved women that can be replicated in other populations and communities.

**Lifespan:** Recognizes that women have different health and psychosocial needs as they encounter transitions across their lives and that the positive and negative effects of health and health behaviors are cumulative across a woman's life.

**Multi-disciplinary:** An approach that is based on the recognition that women's health crosses many disciplines, and that women's health issues need to be addressed across multiple disciplines, such as adolescent health, geriatrics, cardiology, mental

health, reproductive health, nutrition, dermatology, endocrinology, immunology, rheumatology, dental health, etc.

**Rural Community:** All territory, population, and housing units located outside of urban areas and urban cluster.

**Social Role:** Recognizes that women routinely perform multiple, overlapping social roles that require continuous multi-tasking.

**Sustainability:** An organization's or program's staying power; the capacity to maintain both the financial resources and the partnerships/linkages needed to provide the services demanded from a CCOE program. It also involves the ability to survive change, incorporate needed changes, and seize opportunities provided by a changing environment.

**Underserved Women:** In the context of the CCOE model, women who encounter barriers to health care that result from any combination of the following characteristics: poverty, ethnicity and culture, mental or physical state, housing status, geographic location, language, age, and lack of health insurance/under-insured.

**Women-centered/women-focused:** Addressing the needs and concerns of women (women-relevant) in an environment that is welcoming to women, fosters a commitment to women, treats women with dignity, and empowers women through respect and education. The emphasis is on working with women, not for women. Women clients are considered active partners in their own health and wellness.

Dated: June 9, 2004.

**Wanda K. Jones,**

*Deputy Assistant Secretary for Health (Women's Health), Office of Public Health and Science.*

[FR Doc. 04-13894 Filed 6-18-04; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Administration for Children and Families**

#### **Delegation of Authority**

Notice is hereby given that I have delegated to the Assistant Secretary for Children and Families, with the authority to redelegate to the Commissioner, Administration on Children, Youth and Families, which may be further redelegated, the authority vested in the Secretary of Health and Human Services to administer the Abstinence Education Program under Title V, section 510 of

the Social Security Act, and as amended, hereafter.

This delegation supersedes all previous delegations of authority to administer the Abstinence Education Program under Title V, section 510 of the Social Security Act. Except as provided above, the existing delegations of authority to officials within the Health Resources and Services Administration concerning Title V of the Social Security Act are unaffected.

This delegation shall be exercised under the Department's existing delegation and policy on regulations, and under financial and administrative requirements applicable to all Administration for Children and Families authorities.

I have ratified any actions taken by the Assistant Secretary for Children and Families, or any other Administration for Children and Families officials, which, in effect, involved the exercise of this authority prior to the effective date of this delegation.

This delegation is effective immediately.

Dated: June 9, 2004.

**Tommy G. Thompson,**  
Secretary.

[FR Doc. 04-13895 Filed 6-18-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): BECAUSE Kids Count (Building and Enhancing Community Alliances United for Safety and Empowerment), Program Announcement Number 04142

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

*Name:* Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): BECAUSE Kids Count (Building and Enhancing Community Alliances United for Safety and Empowerment), Program Announcement Number 04142.

*Times and Dates:* 4 p.m.-5:30 p.m., July 15, 2004 (Open), 9 a.m.-4:30 p.m., July 16, 2004 (Closed).

*Place:* Sheraton Buckhead, 3405 Lenox Road, NE, Atlanta, GA 30326, Telephone 404.261.9250.

*Status:* Portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of

the Director, Management Analysis and Services Office, CDC, pursuant to Pub. L. 92-463.

*Matters To Be Discussed:* The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement Number 04142.

*For Further Information Contact:* La Tanya Butler, Deputy Branch Chief, Program Implementation Branch, DVP/NCIPC, 4770 Buford Highway, NE, MS-K60, Atlanta, GA 30310, Telephone 770.488.4653.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 15, 2004.

**Alvin Hall,**

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 04-13913 Filed 6-18-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004N-0254]

#### Possible Barriers to the Availability of Medical Devices Intended to Treat or Diagnose Diseases and Conditions that Affect Children; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), is requesting comments concerning the possible barriers to the availability of medical devices intended to treat or diagnose diseases and conditions that affect children. This action is being taken to assist the agency in preparing a report to Congress required by the Medical Devices Technical Corrections Act of 2004 (MDTCA).

**DATES:** Submit written or electronic comments by August 20, 2004.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Joanne Less, Center for Devices and Radiological Health, Food and Drug

Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190.

**SUPPLEMENTARY INFORMATION:** The President signed MDTCA (Public Law 108-214) into law on April 1, 2004. Section 3 of the MDTCA was added to address potential difficulties in bringing pediatric devices to market. Over the last few months, several professional organizations representing pediatric interests expressed concern about the availability of safe and effective devices intended for this population. Representatives from CDRH and the Office of Pediatric Therapeutics met with these organizations to explore the issue. The agency has also received anecdotal reports suggesting there is an unmet need in the pediatric population, but additional information is needed to assess the accuracy of these reports.

By October 1, 2004, the new law requires FDA to submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report addressing the "barriers to the availability of devices intended for treatment or diagnosis of diseases and conditions that affect children." The law also states that the report must include "any recommendations of the Secretary of Health and Human Services for changes to existing statutory authority, regulations, or agency policy or practice to encourage the invention and development of such devices."

Through this notice, FDA is soliciting comments that will help the agency draft its report to Congress under section 3 of MDTCA. In particular, FDA seeks input in response to the following questions:

1. What are the unmet medical device needs in the pediatric population (neonates, infants, children, and adolescents)? Are they focused in certain medical specialties and/or pediatric subpopulations?

2. What are the possible barriers to the development of new pediatric devices? Are there regulatory hurdles? Clinical hindrances? Economic issues? Legal issues?

3. What could FDA do to facilitate the development of devices intended for the pediatric population? Are there changes to the law, regulation, or premarket process that would encourage clinical investigators, sponsors, and manufacturers to pursue clinical trials and/or marketing of pediatric devices?

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic