

awareness of the benefits and risks of new, existing, or combined uses of therapeutics through education and research and to reduce costs. The CERTs were to disseminate their findings to inform, among others, insurers and government agencies, patients and consumers. Under 42 U.S.C. 299b-1(b), CERTs grantees were to gather, develop and provide evidence related to comparative effectiveness, cost effectiveness and safety of therapeutics. Thus, the mission and work of the CERTs is consistent with and addresses identified priority research requirements of the MMA section 1013. Accordingly, the expedite the conduct of priority research related to health care services and items including prescription drugs, as mandated by section 1013, AHRQ is seeking to carry out the initial work on a competitive basis with the benefit of the existing collaborative organizational frameworks and therapeutics expertise and specialization developed by CERTs with prior AHRQ support.

Review

AHRQ will consider requests from current CERTs research center grantees to develop short term supplemental research projects specifically gathering, summarizing and assessing available therapeutics evidence with respect to subjects identified as priorities pursuant to MMA section 1013 or formulating and/or addressing methodological issues pertinent to the production of evidence that is needed with research to these priority subject areas. See <http://www.medicare.gov/MedicareReform/researchtopics.asp>. These competitive applications for supplemental grant awards will undergo scientific and technical review using regular AHRQ peer review processes. In addition to criteria set forth in 42 CFR part 67, subpart A, § 67.15(c), the peer review evaluations and recommendations, in particular, will be based on adherence to the agenda and priorities established in accordance with section 1013 of the MMA.

Each center may submit a single application for supplemental support of a research project that address clinical or methodological issues pertaining to a knowledge gap regarding the comparative effectiveness of therapeutics for one or more of the ten priority clinical areas of interest to the Medicare, Medicaid and SCHIP programs. Requests are to be limited to projects that can be completed in 12 months or less. Although each CERTs Research Center may be the primary applicant on any one application, AHRQ encourages partnerships between

existing CERTs. The actual number of applications that will be funded is dependent on the number of high quality applications.

Dated: February 24, 2005

Carolyn M. Clancy,

Director.

[FR Doc. 05-4444 Filed 3-7-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meeting of the ICD-9-CM Coordination and Maintenance Committee

National Center for Health Statistics (NCHS), Classifications and Public Health Data Standards Staff, announces the following meeting.

Name: ICD-9-CM Coordination and Maintenance Committee meeting.

Time and Date: 9 a.m.-4 p.m., March 31-April 1, 2005.

Place: Centers for Medicare and Medicaid Services (CMS) Auditorium, 7500 Security Boulevard, Baltimore, Maryland.

Status: Open to the public.

Purpose: The ICD-9-CM Coordination and Maintenance (C&M) Committee will hold its first meeting of the 2005 calendar year cycle on Thursday and Friday March 31-April 1, 2005. The C&M meeting is a public forum for the presentation of proposed modifications to the International Classification of Diseases, Ninth-Revision, Clinical Modification.

Matters to be Discussed: Agenda items include:

- Sleep disorders
- Epilepsy
- Transfusion related lung injury (TRALI)
- Failed hearing screening
- Myelitis
- Macrophage activation syndrome
- Subtalar joint arthroereisis
- 360 degree spinal fusion
- Implantation of interspinous process decompression device
- Hip arthroplasty "bearing surfaces
- External fracture fixation devices
- Endovascular implantation of graft in thoracic aorta
- Infusion of liquid radioisotope
- Radiofrequency Total Occlusion Crossing System
- ICD-10-Procedure Coding System (PCS) update Addenda

Contact Person for Additional Information: Amy Blum, Medical Systems Specialist, Classifications and Public Health Data Standards Staff, NCHS, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone

(301) 458-4106 (diagnosis), Amy Gruber, Health Insurance Specialist, Division of Acute Care, CMS, 7500 Security Blvd., Room C4-07-07, Baltimore, Maryland 21244 telephone (410) 786-1542 (procedures).

Notice: Because of increased security requirements, (CMS) has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show an official form of picture I.D., (such as a drivers license), and sign-in at the security desk upon entering the building.

Those who wish to attend a specific ICD-9-CM C&M meeting in the CMS auditorium must submit their name and organization for addition to the meeting visitor list. Those wishing to attend the March 31-April 1, 2005 meeting must submit their name and organization by March 29, 2005 for inclusion on the visitor list. This visitor list will be maintained at the front desk of the CMS building and used by the guards to admit visitors to the meeting. Those who attended previous ICD-9-CM C&M meetings will no longer be automatically added to the visitor list. You must request inclusion of your name prior to each meeting you attend. Register to attend the meeting on-line at: <http://cms.hhs.gov/events>.

Notice: This is a public meeting. However, because of fire code requirements, should the number of attendants meet the capacity of the room, the meeting will be closed.

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: March 2, 2005.

Alvin Hall,

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

[FR Doc. 05-4428 Filed 3-7-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Allergenic Products 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: Allergenic Products 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 April 7, 2005, from 8:30 a.m. to 4 p.m.

Location: Holiday Inn Select, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Gail Dapolito or Jane Brown, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512388. Please call the Information Line for up-to-date information on this meeting.

Agenda: On April 7, 2005, the committee will discuss a proposed strategy for the reclassification of Class IIIA allergenic products. The committee will also receive an update of the FDA Critical Path Initiative.

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 by March 31, 2005. Oral presentations from the public will be scheduled between approximately 11:15 a.m. and 12:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 31, 2005, 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.

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 Gail Dapolito at least 7 days in advance of the meeting.

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

Dated: March 2, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05-4484 Filed 3-7-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Health Resources and Services Administration (HRSA); Request for Public Comment on a HRSA Commissioned Report: Newborn Screening: Toward a Uniform Screening Panel and System

SUMMARY: The changing dynamics of emerging technology, and the complexity of genetics require an assessment of the state of the art in newborn screening and a perspective on the future directions such programs should take. In 1999, the American Academy of Pediatrics Newborn Screening Task Force recommended that "HRSA should engage in a national process involving government, professionals, and consumers to advance the recommendations of this Task Force and assist in the development and implementation of nationally recognized newborn screening system standards and policies." In response to this need, pursuant to 42 U.S.C. 701(a)(2), the Maternal and Child Health Bureau (MCHB) of HRSA commissioned the American College of Medical Genetics (ACMG) to conduct an analysis of the scientific literature on the effectiveness of newborn screening and gather expert opinion to delineate the best evidence for screening specified conditions and develop recommendations focused on newborn screening, including but not limited to the development of a uniform condition panel. It was expected that the analytical endeavor and subsequent recommendations be based on the best scientific evidence and analysis of that evidence. ACMG was specifically asked to develop recommendations to address:

- A uniform condition panel (including implementation methodology);
- Model policies and procedures for State newborn screening programs (with consideration of a national model);
- Model minimum standards for State newborn screening programs (with consideration of national oversight);
- A model decision matrix for consideration of State newborn screening program expansion; and

- The value of a national process for quality assurance and oversight.

The ACMG report is a response to the HRSA/MCHB request. The ACMG report, Newborn Screening: Toward a Uniform Screening Panel and System is available at <http://mchb.hrsa.gov/screening>.

In the report, 29 conditions were identified as primary targets or core panel conditions for screening; an additional 25 conditions were listed as conditions that could be identified in the course of screening for core panel conditions. Many of these 25 additional conditions are included in the differential diagnosis of the conditions including in the primary target list. With additional screening, an improvement in the infrastructure for appropriate follow-up and management throughout the lives of children who have been identified as having one of these rare conditions will be needed. A cost analysis for the State of California indicates newborn screening is beneficial to patients and may have some net costs or net savings over time depending on assumptions of expected lifetime costs of medical care.

HRSA is now seeking public comments on the report and its recommendations.

DATES: The public is encouraged to submit written comments on the report and its recommendations within 60 days of publication of this **Federal Register** notice.

ADDRESSES: The following mailing address should be used: Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Building, 18A-19, Rockville, MD 20857. HRSA/MCHB's facsimile number is 301-443-8604. Comments can also be sent via e-mail to screening@hrsa.hhs.gov. All public comments received will be available for public inspection at MCHB/HRSA's office between the hours of 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Questions about this request for public comment can be directed to Dr. Michele Lloyd-Puryear, MD, PhD, by e-mail (screening@hrsa.hhs.gov). The report will be posted on HRSA/MCHB's Web site at <http://mchb.hrsa.gov/screening>.

Dated: March 2, 2005.

Elizabeth M. Duke,
Administrator.

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