

Government Employees Participating in FDA Product Specific Advisory Committees,” and requested comments on the draft guidance (formerly Docket No. 02D-0049 now Docket No. FDA-2002-D-0094). The draft guidance was limited in application to special government employees (SGEs) participating in advisory committee meetings at which particular matters relating to particular products were discussed.

In August 2008, after an internal assessment of FDA’s advisory committee process and based on the comments submitted to the docket for the January 2002 draft guidance and a revised draft guidance published for public comment in October 2007, the agency issued guidance that expanded public availability of relevant information, brought additional transparency to FDA’s waiver process, and increased the consistency and clarity of the process (www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125647.pdf).

FDA is now making available for public comment revisions to the August 2008 guidance that provide even greater transparency. The agency has tentatively concluded that it is appropriate to request that individuals receiving a waiver of conflict of interest to participate in an FDA advisory committee meeting disclose the name of the company or institution when identifying the “nature” of the disqualifying financial interest.

In determining how much information to publicly disclose, FDA needs to provide enough detail so the public can understand the nature of the potential conflict and FDA’s decisionmaking regarding participation, while not disclosing so much detail that the agency would be unable to attract essential expertise to its advisory committees. Under the August 2008 guidance, the nature of the financial interest was identified only as sponsor, competitor, or other affected firm. This approach was informed, in part, by a survey in 2001 of active advisory committee members that asked whether members would decline to participate based on varying levels of disclosure.

FDA is now proposing to disclose more detail than it did under its August 2008 guidance. Specifically, the agency proposes to disclose the name of the company or institution associated with the financial interest. New information indicates that this additional detail would not be a deterrent to current and potential advisory committee members. For example, the agency notes that academic institutions, peer-reviewed journals, and scientific symposia,

among other entities/venues, have in recent years developed more rigorous policies for disclosure of potential conflicts of interest with the work that is being presented or discussed. (See “Conflict of Interest in Medical Research, Education, and Practice, Committee on Conflict of Interest in Medical Research, Education, and Practice, Board on Health Sciences Policy,” Institute of Medicine of the National Academies (see p. 62 at http://books.nap.edu/openbook.php?record_id=12598). While policies differ among organizations, many provide for disclosure of the name of the company or entity constituting the potential conflict of interest. (See “Uniform Format for Disclosure of Competing Interests in ICMJE Journals” that describes a disclosure policy and format that includes identification of the entity that is the source of the financial interest; adopted by all International Committee of Medical Journal Editors (ICMJE) journals (accessed at <http://content.nejm.org/cgi/content/full/361/19/1896>)). In addition, FDA informally polled several active advisory committee members. While not a representative sample, the survey indicated that disclosing the names of companies would not adversely affect FDA’s ability to attract and retain expert advisors. Accordingly, we have tentatively concluded that the public now expects this level of detail to help them understand the nature of a potential conflict and that individuals would accept this level of detail as a routine part of required disclosures.

To help us in issuing a final guidance, FDA is requesting comments on whether disclosing the name of the company or institution associated with the financial interest would: (1) Increase the transparency of FDA’s decisions regarding advisory committee member participation and (2) not significantly deter current and potential advisory committee members from service on those committees.

The draft guidance also includes a template for disclosing to the public the financial interests for which waivers are granted and a template for disclosing to the public all waivers that FDA grants. The draft guidance further describes FDA’s process for making these documents available on its Web site in advance of each advisory committee meeting.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on public availability of information regarding advisory committee members’

financial interests and waivers granted by FDA to permit participation in advisory committee meetings. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

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 comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

II. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/RegulatoryInformation/Guidances/ucm122045.htm> or <http://www.regulations.gov>.

Dated: April 19, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010-9313 Filed 4-21-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Health Center Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Noncompetitive Replacement Awards to Cornerstone Care, Inc.

SUMMARY: The Health Resources and Services Administration (HRSA) will be transferring Health Center Program (section 330 of the Public Health Service Act) New Access Point (NAP), Increased Demand for Service (IDS), and Capital Improvement Program (CIP) funds originally awarded to Community Medical Services to Cornerstone Care, Inc. to ensure the provision of critical primary health care services to underserved populations in Fayette County, Pennsylvania.

SUPPLEMENTARY INFORMATION:

Former Grantee of Record:
Community Medical Services.

Original Period of Grant Support:
March 1, 2009 to February 28, 2011 (NAP); March 27, 2009 to March 26, 2011 (IDS); and June 29, 2009 to June 28, 2011 (CIP).

Replacement Awardee: Cornerstone Care, Inc.

Amount of Replacement Awards:
\$391,306 (NAP), \$101,000 (IDS) and \$250,000 (CIP).

Period of Replacement Awards: The period of support for the replacement awards is March 1, 2009 to February 28, 2011 (NAP); March 27, 2009 to March 26, 2011 (IDS); and June 29, 2009 to June 28, 2011 (CIP).

Authority: Section 330 of the Public Health Service Act, 42 U.S.C. 245b.

CFDA Number: 93.703.

Justification for the Exception to Competition:

The former grantee, Community Medical Services (CMS), Inc., is unable to meet several Health Center Program statutory and regulatory requirements. CMS notified HRSA that it was unable to carry out the administrative and programmatic requirements to appropriately manage the grant funds and indicated that it would be relinquishing the grant funds. CMS's inability to meet these requirements has restricted it from providing necessary primary health care services in Fayette County, Pennsylvania, to the more than 10,500 low income, underserved and uninsured individuals in the service area, as had been proposed in their approved New Access Point grant application.

Cornerstone Care Inc. (CCI) is an experienced provider of care and is currently providing primary health care services under a contractual agreement with CMS to the original target population, has a demonstrated record of compliance with the Health Center Program statutory and regulatory requirements and is located in the same geographical area.

This underserved target population has an immediate need for vital primary health care services and would be negatively impacted by any delay or disruption of services caused by a competition. As a result, in order to ensure that critical primary health care services remain available to the original target population without disruption, this replacement award will not be competed.

FOR FURTHER INFORMATION CONTACT:
Marquita Cullom-Stott via e-mail at MCullom-Stott@hrsa.gov or 301-594-4300.

Dated: April 16, 2010.

Marcia K. Brand,

Deputy Administrator.

[FR Doc. 2010-9308 Filed 4-21-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Meeting: Secretary's Advisory Committee on Genetics, Health, and Society

Pursuant to Public Law 92-463, notice is hereby given of the twenty-second meeting of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), U.S. Public Health Service. The meeting will be held from 8:30 a.m. to approximately 5:30 p.m. on Tuesday, June 15, 2010, and from 8 a.m. to approximately 2:45 p.m. on Wednesday, June 16, 2010, at the Washington Plaza Hotel, 10 Thomas Circle, NW., Washington, DC 20005. The meeting will be open to the public with attendance limited to space available. The meeting will also be Web cast.

The main agenda item will be an exploratory session on the implications of affordable whole-genome sequencing. The meeting will also include updates and discussions on other issues SACGHS has been addressing, including the work of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children related to the retention and use of dried blood spot specimens from newborn screening.

As always, the Committee welcomes hearing from anyone wishing to provide public comment on any issue related to genetics, health and society. Please note that because SACGHS operates under the provisions of the Federal Advisory Committee Act, all public comments will be made available to the public. Individuals who would like to provide public comment should notify the SACGHS Executive Secretary, Ms. Sarah Carr, by telephone at 301-496-9838 or e-mail at carrs@od.nih.gov. The SACGHS office is located at 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892. Anyone planning to attend the meeting who needs special assistance, such as sign language interpretation or other reasonable accommodations, is also asked to contact the Executive Secretary.

Under authority of 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended, the Department of Health and Human Services established SACGHS to serve as a public forum for

deliberations on the broad range of human health and societal issues raised by the development and use of genetic and genomic technologies and, as warranted, to provide advice on these issues. The draft meeting agenda and other information about SACGHS, including information about access to the Web cast, will be available at the following Web site: http://oba.od.nih.gov/SACGHS/sacghs_meetings.html.

Dated: April 16, 2010.

Jennifer Spaeth,

Director, NIH Office of Federal Advisory Committee Policy.

[FR Doc. 2010-9311 Filed 4-21-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel, Drug Discovery, Chemoprevention and Targeted Therapy.

Date: May 25-27, 2010.

Time: 8 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Peter J. Wirth, PhD, Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8129, Bethesda, MD 20892-8328. 301-496-7565. pw2q@nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, Innovative and Early Stage Development of Emerging Technologies in Biospecimen Science.

Date: June 14, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.