

the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 26, 2009.

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 Elaine Ferguson 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/oc/advisory/default.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: February 4, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9-3089 Filed 2-12-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Final Policy Guidance

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

ACTION: Final Agency Guidance and Response to Public Comments.

SUMMARY: HRSA is publishing a final Agency Guidance ("Policy Information Notice" (PIN) 2009-02), to describe the policy and processes pertaining to requests from federally-funded health centers to change the scope of their Federal project. The PIN, "Specialty Services and Health Centers" Scope of Project," and the Agency's "Response to Public Comments" are available on the Internet at <http://bphc.hrsa.gov>.

DATES: The effective date of this final Agency guidance is December 18, 2008.

Background: The Health Resources and Services Administration administers the Health Center Program, as authorized by section 330 of the Public Health Service (PHS) Act as amended, (42 U.S.C. 254b). Health centers improve the health of the

Nation's underserved communities and vulnerable populations by assuring access to comprehensive, culturally competent, quality primary health care services. Health center grants support a variety of community-based and patient-directed public and private nonprofit organizations and continue to serve an increasing number of the Nation's underserved. Charges for health care services are set according to income. At the end of the 2007 calendar year, there were more than 1,000 federally-funded health centers with more than 7,000 primary health care delivery sites located in urban and rural underserved areas throughout the U.S. and its territories. In 2007, over 16 million medically underserved and uninsured patients received comprehensive, culturally competent, quality primary health care services through the federally-supported Health Center Program.

On August 10, 2007, HRSA made the draft PIN, "Specialty Services and Health Centers" Scope of Project," available for public comment on HRSA's Web site. HRSA also published a notice in the **Federal Register** of August 29, 2007, requesting comments on this draft PIN.

Sixty-five comments were received from 20 organizations and/or individuals. After review and careful consideration of all comments received, HRSA has amended the PIN to incorporate certain recommendations from the public. The final PIN reflects these changes.

In addition to making the final PIN available on HRSA's Web site, HRSA is also posting the Agency's "Response to Public Comments" at <http://bphc.hrsa.gov/policy/pin0902/pin0902comments.htm>. The purpose of that document is to summarize the major comments received and describe the Agency's response, including any corresponding changes made to the PIN. Where comments did not result in a revision to the PIN, explanations are provided. Any interested party that does not have access to HRSA's Web site can contact the HRSA point of contact to request that a hardcopy of the "Response to Public Comments" be mailed to their attention.

FOR FURTHER INFORMATION CONTACT: For questions regarding this notice, please contact the Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, at 301-594-4300.

Dated: February 6, 2009.

Elizabeth M. Duke,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Final Policy Guidance

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final Guidance.

DATES: The effective date of this final Agency guidance is January 5, 2009.

SUMMARY: HRSA has issued Policy Information Notice (PIN) 2009-04, "Revision to PIN 2003-21: Federally Qualified Health Center (FQHC) Look-Alike Guidelines and Application," to announce a technical revision to PIN 2003-21: FQHC Look-Alike Guidelines and Application, issued on August 26, 2003. Both PINs are available on HRSA's Web site at <http://bphc.hrsa.gov/policy/#lookalikes>.

Background: HRSA has issued PIN 2009-04, "Revision to PIN 2003-21: FQHC Look-Alike Guidelines and Application," to announce a technical revision to PIN 2003-21: FQHC Look-Alike Guidelines and Application, issued on August 26, 2003. PIN 2003-21 conveys eligibility and compliance requirements of the FQHC Look-Alike Program and instructions for submitting an application for FQHC Look-Alike designation, recertification, and change in scope of project. PIN 2009-04 updates the data submission requirements in PIN 2003-21.

Applicants and existing FQHC Look-Alikes should refer to both PINs when preparing applications. Both PINs are available on HRSA's Web site at <http://bphc.hrsa.gov/policy/#lookalikes>.

PIN 2009-04 reflects the Office of Management and Budget (OMB) approved extension of information collection (control number 0915-0142) to November 30, 2011. Furthermore, the race and ethnicity data is now collected as two separate data elements in Table 2, Part B, to meet OMB Standards for the Classification of Federal Data on Race and Ethnicity as well as Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (62 FR 36874-36946; 62 FR 58781-9; and OMB Bulletin #00-02). Please note that all information provided regarding race and/or ethnicity will be used only to ensure compliance with statutory and regulatory Governing Board requirements set forth in section 330 of the Public Health Service Act. Data on race and/or ethnicity collected on this form will not be used as a factor in recommending approval for FQHC