DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

General and Plastic Surgery 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: General and Plastic Surgery 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 August 26, 2010, from 8 a.m. to 6 p.m.

Location: Holiday Inn College Park, Grand Ballroom, 1000 Baltimore Ave., College Park, MD.

Contact Person: Margaret McCabe-Janicki, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 1535, Silver Spring, MD 20993–0002, 301–796–7029, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512519. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On August 26, 2010, the committee will discuss, make recommendations, and vote on premarket approval application for MelaFind, sponsored by MELA Sciences, Inc. MelaFind is a non-invasive computer vision system intended to assist in the evaluation of pigmented skin lesions, including atypical moles, which have one or more clinical or historical characteristics of melanoma, before a final decision to biopsy has been rendered. MelaFind acquires and displays multi-spectral (from blue to near infrared) digital images of pigmented skin lesions and uses automatic image analysis and statistical pattern recognition to help identify lesions to be considered for biopsy to rule out melanoma.

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 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 or before August 17, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make 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 August 5, 2010. 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 August 10, 2010.

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 accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, at 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: June 18, 2010.

Thinh Nguyen,
Acting Associate Commissioner for Special Medical Programs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, July 14, 2010, 8:30 a.m. to July 15, 2010, 5 p.m., State Plaza Hotel, 2117 E Street, NW., Washington, DC 20037 which was published in the Federal Register on June 14, 2010, 75 FR 33626–33627.

The meeting will be held July 13, 2010 to July 14, 2010. The meeting time and location remain the same. The meeting is closed to the public.

Dated: June 18, 2010.

Anna P. Snouffer,
Deputy Director, Office of Federal Advisory Committee Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Recruitment of Sites for Assignment of National Health Service Corps (NHSC) Personnel Obligated Under the NHSC Scholarship Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: General notice.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that the listing of entities, and their Health Professional Shortage Area (HPSA) scores, that will receive priority for the assignment of National...
Entities that receive assignment of NHSC personnel must assure that: (1) the position will permit the full scope of practice and that the clinic meets the credentialing requirements of the State and site; and (2) the NHSC member assigned to the entity is engaged in full-time clinical practice at the approved service location. For all health professionals except those noted below, “full-time clinical practice” means a minimum of 40 hours per week with at least 32 hours per week spent providing direct patient care. In outpatient ambulatory care setting(s) at the approved practice site(s), during normally scheduled office hours. The remaining 8 hours of the minimum 40 hours per week must be spent providing clinical services for patients in the approved practice site(s), or providing clinical services in alternative settings (e.g., hospitals, nursing homes, shelters) as directed by the approved practice site(s), or performing practice-related administrative duties not to exceed 8 hours per week. For obstetricians/gynecologists, certified nurse midwives (CNMs), family practitioners who practice obstetrics on a regular basis, psychiatrists, pediatric dentists, and providers of geriatric services, at least 21 of the minimum 40 hours per week must be spent providing direct patient care (direct patient counseling for psychiatrists) in the outpatient ambulatory care setting(s) at the approved practice site(s), during normally scheduled office hours. The remaining 19 hours of the minimum 40 hours per week must be spent providing clinical services for patients in the approved practice site(s), or providing clinical services in alternative settings (e.g., hospitals, nursing homes, shelters) as directed by the approved practice site(s), or performing practice-related administrative activities (not to exceed 8 hours per week). For all NHSC Scholars, time spent on-call does not count toward the 40 hours per week. In addition, sites receiving assignment of NHSC personnel are expected to: (1) Report to the NHSC all absences, including those in excess of the authorized number of days (up to 35 work days or 280 hours per service year); (2) report to the NHSC any change in the status of an NHSC clinician at the site; (3) provide the time and leave records, schedules, and any related personnel documents for NHSC assignees (including documentation, if applicable, of the reason(s) for the termination of an NHSC clinician’s employment at the site prior to his or her obligated service end date); and (4) submit a Uniform Data System (UDS) report. The UDS system allows the site to assess the age, sex, race/ethnicity of, and provider encounter records for, its user population. The UDS reports are site specific. Providers fulfilling NHSC commitments are assigned to a specific site or, in some cases, more than one site. The scope of activity to be reported in UDS includes all activity at the site(s) to which the NHSC member is assigned.

Evaluation and Selection Process

In order for a site to be eligible for placement of NHSC personnel, it must be approved by the NHSC following the site’s submission of a Multi-Year Recruitment and Retention (R&R) Assistance Application. The R&R Application approval is good for a period of 3 years from the date of approval.

In approving applications for the assignment of NHSC members, the Secretary shall give priority to any such application that is made regarding the provision of primary health services to a HPSA with the greatest shortage. For the program year July 1, 2010, through June 30, 2011, HPSAs of greatest shortage for determination of priority for assignment of NHSC scholarship-obligated NHSC personnel will be defined as follows: (1) Primary medical care HPSAs with scores of 17 and above are authorized for the assignment of NHSC scholarship recipients who are primary care physicians, family nurse practitioners (NPs), or CNMs; (2) mental health HPSAs with scores of 17 and above are authorized for the assignment of NHSC scholarship recipients who are psychiatrists; (3) primary medical care HPSAs with scores of 15 and above are authorized for the assignment of NHSC scholarship recipients who are physician assistants (PAs); (4) dental HPSAs with scores of 17 and above are authorized for the assignment of NHSC scholarship recipients who are dentists. The NHSC has determined that a minimum HPSA score of 15 for Physician Assistants, and 17 for all other eligible clinicians will enable it to meet its statutory obligation to identify a number of approved service sites at least equal to, but not greater than, twice the number of NHSC scholars available to serve in the 2010–2011 placement cycle.

The number of new NHSC placements through the Scholarship Program allowed at any one site is limited to the following:

1. **Primary Medical Care**

   No more than 1 physician (MD or DO); and no more than 1 NP, PA, or CNM.
The program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100).

(2) Dental

No more than 1 dentist.

(3) Mental Health

No more than 1 psychiatrist.

Application Requests, Dates and Address

The list of HPSAs and entities that are eligible to receive priority for the placement of NHSC personnel may be updated periodically. Entities that no longer meet eligibility criteria, including those whose NHSC 3-year approval has lapsed or whose HPSA designation has been proposed for withdrawal will be removed from the priority listing. New entities interested in being added to the high priority list must submit a Multi-Year NHSC R&R Assistance Application to: National Health Service Corps, 5600 Fishers Lane, Room 8A–30, Rockville, MD 20857, fax 301–594–9009.

Entities interested in receiving application materials may do so by calling the HRSA call center at 1–800–221–9393. They may also get information and download application materials at: http://nhsc.hrsa.gov/communities/apply.htm.

A listing of HPSAs and their scores is posted at http://hpsafind.hrsa.gov/.

Additional Information

Entities wishing to provide additional data and information in support of their inclusion on the proposed list of HPSAs and entities that would receive priority in assignment of scholarship-obligated NHSC members must do so in writing no later than July 26, 2010. This information should be submitted to: Lori Roche, Acting Director, Division of Site and Clinician Recruitment, Bureau of Clinician Recruitment and Service, 5600 Fishers Lane, Room 8A–55, Rockville, MD 20857 or faxed to: 301–480–4577, attention: Lori Roche. This information will be considered in preparing the final list of HPSAs and entities that are receiving priority for the assignment of scholarship-obligated NHSC personnel.

Paperwork Reduction Act: The R&R Assistance Application has been approved by the Office of Management and Budget under the Paperwork Reduction Act. The OMB clearance number is 0915–0230 and expires September 30, 2011.

The program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100).


Mary K. Wakefield,
Administrator

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BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 75 FR 12559 dated March 16, 2010).

This notice reflects organizational changes in the Health Resources and Services Administration. Specifically, this notice updates the functional statement for the Office of Acquisitions Management and Policy (RB3) within the Office of Operations (RB).

Chapter RB3, Office of Acquisitions Management and Policy

Section RB3–10, Organization

Delete in its entirety and replace with the following:

The Office of Acquisitions Management and Policy (RB3) is headed by the Director who reports directly to the Chief Operating Officer, Health Resources and Services Administration. The Office of Acquisitions Management and Policy (RB3) includes the following components:

(1) Immediate Office of the Director (RB3);
(2) Division of Contract Services for Primary Care, Health Systems and Clinician Recruitment and Retention (RB35);
(3) Division of Contract Services for Maternal and Child Health and Administrative Support Offices (RB36);
(4) Division of Contact Services for HIV/AIDS, Health Professions, Rural Health and Grants Management (RB37); and
(5) Division of Contracts Administration (RB38).

Section RB3–20, Functions

(1) Delete the functions for the Office of Acquisitions Management and Policy (RB3) in its entirety and replace with the following:

Office of Acquisitions Management and Policy (RB3)

(1) Provides leadership in the planning, development, and implementation of policies and procedures for contracts; (2) exercises the sole responsibility within HRSA for the award and management of contracts; (3) provides advice and consultation of interpretation and application of the Department of Health and Human Services’ policies and procedures governing contracts management and inter/intra agency agreements; (4) develops operating procedures and policies for the Agency’s contracts programs and inter/intra agency agreements; (5) establishes standards, guides and evaluation procedures for contract operations throughout the Agency; (6) coordinates the Agency’s positions and actions with respect to the audit of contracts; (7) maintains liaison directly with or through Agency Bureaus or Offices with contractors, other organizations, and various components of the Department; (8) provides leadership, guidance, and advice on the promotion of the activities in HRSA relating to procurement and material management governed by the Small Business Act of 1958, Executive Order 11625, other statutes and national policy directives for augmenting the role of private industry, small and minority businesses as sources of supply to the Government and Government contractors; and (9) plans, directs, and coordinates the Agency’s sourcing program.

Division of Contract Services for Primary Care, Health Systems and Clinician Recruitment and Retention (RB35)

(1) Responsible for providing comprehensive acquisition services including planning, soliciting, negotiating, awarding, and administering simplified and negotiated procurement actions tailored to the following functions in HRSA:

a. Funding health centers in communities, providing access to high quality, family oriented, comprehensive primary and preventive health care for people who are low income, uninsured, or living where health care is scarce;

b. Helping underserved communities and facilities experiencing critical shortages of health care providers, recruit and retain clinicians through scholarship and educational loan repayment opportunities in exchange for service; and

c. Protecting the public health and promoting practices that improve