4. What secondary efficacy endpoints might be considered clinically meaningful (e.g., subjective and objective assessments of memory, recall, anxiety, agitation, or delirium) if appropriately studied?

5. How should responses to rapid changes in procedural stimulation be considered in the evaluation of efficacy, e.g., the time of initial incision or negotiating a colonoscope around the splenic or hepatic flexure?

6. How do the responses for each of the previous questions differ for the evaluation of sedation products used in the operating room (OR), the intensive care unit (ICU), the emergency department (ED), and the gastrointestinal (GI) suite?

FDA will post the agenda and additional workshop background material approximately 5 days before the workshop at: http://www.fda.gov/Drugs/NewsEvents/ucm221185.htm.

II. Transcripts

Please be advised that approximately 30 days after the public workshop, a transcript will be available. It will be accessible at http://www.regulations.gov and may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.


Leslie Kux,
Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Lists of Designated Primary Medical Care, Mental Health, and Dental Health Professional Shortage Areas

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: This notice advises the public of the published lists of all geographic areas, population groups, and facilities designated as primary medical care, mental health, and dental health professional shortage areas (HPSAs) as of September 1, 2011, available on the Health Resources and Services Administration (HRSA) Web site at http://bhpr.hrsa.gov/shortage/index.html. HPSAs are designated or withdrawn by the Secretary of Health and Human Services (HHS) under the authority of section 332 of the Public Health Service (PHS) Act and 42 CFR part 5.

FOR FURTHER INFORMATION CONTACT: Requests for further information on the HPSA designations listed below and requests for additional designations, withdrawals, or reapplication for designation should be submitted to Leslie Kux, Office of Shortage Designation, Bureau of Health Professions, Health Resources and Services Administration, Room 9A–18, Parklawn Building, 5600 Fisher Lane, Rockville, Maryland 20857, (301) 594–0816, http://bhpr.hrsa.gov/shortage/index.html.

SUPPLEMENTAL INFORMATION:

Background

Section 332 of the PHS Act, 42 U.S.C. 254e, provides that the Secretary of HHS shall designate HPSAs based on criteria established by regulation. HPSAs are defined in section 332 to include (1) urban and rural geographic areas with shortages of health professionals, (2) population groups with such shortages, and (3) facilities with such shortages. Section 332 further requires that the Secretary annually publish a list of the designated geographic areas, population groups, and facilities. The lists of HPSAs are to be reviewed at least annually and revised as necessary.

HRSA’s Bureau of Health Professions (BHPr) has the responsibility for designating and updating HPSAs.

Public or private nonprofit entities are eligible to apply for assignment of National Health Service Corps (NHSC) personnel to provide primary health services in or to these HPSAs. NHSC health professionals with a service obligation may serve only in federally designated HPSAs. Entities with clinical training sites located in HPSAs are eligible to receive priority for certain training program grants administered by BHPr. Many other Federal programs also utilize HPSA designations. For example, under authorities administered by the Centers for Medicare and Medicaid Services, certain qualified providers in HPSAs are eligible for increased levels of Medicare reimbursement.

Development of the Designation and Withdrawal Lists

Criteria for designating HPSAs were published as final regulations (42 CFR part 5) in 1980. Criteria then were defined for each of seven health professional types (primary medical care, dental, psychiatric, vision care, podiatric, pharmacy, and veterinary care). The criteria for correctional facility HPSAs were revised and published on March 2, 1989, in the Federal Register (54 FR 8735). The criteria for psychiatric HPSAs were expanded to mental health HPSAs on January 22, 1992 (57 FR 2473). Currently funded PHS Act programs use only the primary medical care, mental health, or dental HPSA designations.

Individual requests for designation or withdrawal of a particular geographic area, population group, or a facility as a HPSA are received and reviewed continuously by BHPr. The majority of the requests come from the Primary Care Offices (PCOs) in the State Health Departments, who have access to the online application and review system. Requests that come from other sources are referred to the PCOs for their review and concurrence. In addition, applicants are expected to share copies of the requests with other interested parties, including the Governor, the State Primary Care Association and state professional associations for their comments and recommendations.

Annually, lists of designated HPSAs are provided to all PCOs, state medical and dental societies and others, with a request to review and update the data on which the designations are based. Emphasis is placed on updating those designations that are more than 3 years old or where significant changes relevant to the designation criteria have occurred.

Recommendations for possible additions, continuations, revisions or withdrawals from a HPSA list are reviewed by BHPr, and the review findings are provided by letter to the agency or individual requesting action or providing data, with copies to other interested organizations and individuals. These letters constitute the official notice of designation as a HPSA, rejection of recommendations for HPSA designation, revision of a HPSA designation, and/or advance notice of pending withdrawals from the HPSA list. Designations (or revisions of designations) are effective as of the date of the notification letter from BHPr.

Proposed withdrawals become effective only after interested parties in the area affected have been afforded the opportunity to submit additional information to BHPr in support of its continued or revised designation. If no new data are submitted, or if BHPr review confirms the proposed withdrawal, it becomes effective upon publication in the Federal Register of the lists of HPSAs that do not include...
the proposed withdrawals. In addition, lists of HPSAs are continuously available on the HRSA Web site, http://bhpr.hrsa.gov/shortage/index.html, so that interested parties can access the most accurate and timely information.

Publication and Format of Lists
Due to the volume of designations, this notice informs the public of the availability on the HRSA Web site of the published lists of designated shortage areas. The three lists of designated HPSAs are available at a link on the Office of Shortage Designation Web site at http://bhpr.hrsa.gov/shortage/index.html. Each list (primary medical care, mental health, and dental) includes all those geographic areas, population groups, and facilities that were designated HPSAs as of September 1, 2011. This notice incorporates the most recent annual reviews of designated HPSAs and supersedes the most recent annual reviews of this notice informs the public of the publication and format of lists of designated shortage areas. The three lists of designated HPSAs (primary medical care, mental health, and dental) is arranged by state. The lists are constantly changing based on the identification of new sites that meet the eligibility criteria or current sites that lose their eligibility and need to be removed. Each list of designated HPSAs (primary medical care, mental health, and dental) is arranged by state. Within each state, the list is presented by county. If only a portion (or portions) of a county’s rural health services, and dental) is arranged by state. Within each state, the list is presented by county. If only a portion (or portions) of a county is designated, or if the county is part of a larger designated service area, or if a population group residing in the county or a facility located in the county has been designated, the name of the service area, population group, or facility involved is listed under the county name. Counties that have a whole county geographic HPSA designation designated as of September 1, 2011, are available on the HRSA Web site at http://bhpr.hrsa.gov/shortage/index.html. Frequently updated information on HPSAs is also available at http://datawarehouse.hrsa.gov.

Electronic Access Address
The lists of HPSAs below consist of all those that were designated as of September 1, 2011. It should be noted that additional HPSAs may have been designated by letter since that date. The appropriate agencies and individuals have been notified of these actions by letter. These newly designated HPSAs will be included in the next publication of the HPSA list.

Any designated HPSA listed on the HRSA Web site below is subject to withdrawal from designation if new information received and confirmed by HRSA indicates that the relevant data for the area involved have significantly changed since its designation. The effective date of the withdrawal will be the next publication of a notice regarding this list in the Federal Register.

All requests for new designations, updates, or withdrawals should be based on the relevant criteria in regulations published at 42 CFR part 5.

Electronic Access Address
The complete lists of HPSAs designated as of September 1, 2011, are available on the HRSA Web site at http://bhpr.hrsa.gov/shortage/index.html. Frequently updated information on HPSAs is also available at http://datawarehouse.hrsa.gov.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

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 meeting. The meeting 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: Center for Scientific Review Special Emphasis Panel; Virology B: Overflow.

Date: November 17, 2011.

Time: 12 p.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: John C Pugh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1206, MSC 7808, Bethesda, MD 20892, (301) 435–2398, pughjohn@csr.nih.gov.


Jennifer S. Spaeth,
Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

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 meeting. The meeting will be closed to the public in accordance with the