

31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Kristina Toliver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: CRDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area).

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 at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On August 6, 2013, the committee will discuss new drug application (NDA) 204819, proposed trade name ADEMPAS (riociguat coated tablet), submitted by Bayer HealthCare Pharmaceuticals Inc., for the treatment of: (1) Chronic thromboembolic pulmonary hypertension World Health Organization (WHO) Group 4 to improve exercise capacity and WHO functional class and (2) pulmonary arterial hypertension (WHO Group 1) to improve exercise capacity, improve WHO functional class, and to delay clinical worsening.

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 meeting 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 on or before July 22, 2013. Oral presentations from the public will be scheduled between approximately 12:30 p.m. to 1:30 p.m. Those individuals interested in making 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 July 12, 2013. 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 July 15, 2013.

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 Kristina Toliver 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 21, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013-15332 Filed 6-26-13; 8:45 am]

BILLING CODE 4160-01-P

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 May 11, 2013, available on the Health Resources and Services Administration (HRSA) Web site at <http://www.hrsa.gov/shortage/>. 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 on the HRSA Web site below and requests for additional designations, withdrawals, or reapplication for designation should be submitted to Victoria Hux, Chief, Shortage Designation Branch, Bureau of Clinician Recruitment and Service, Health Resources and Services Administration, Room 9A-55, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 594-0816, <http://www.hrsa.gov/shortage/>.

SUPPLEMENTARY 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 Clinician Recruitment and Service (BCRS) 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 care,

dental, or mental health services in or to these HPSAs. NHSC health professionals with a service obligation may enter into service agreements to serve only in federally designated HPSAs. Entities with clinical training sites located in HPSAs are eligible to receive priority for certain residency training program grants administered by the Bureau of Health Professions. 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 geographic area 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 (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 BCRS. The majority of the requests come from the Primary Care Offices (PCO) in the State Health Departments, who have access to the on-line application and review system. Requests that come from other sources are referred to the PCOs for their review and concurrence. In addition, interested parties, including the Governor, the State Primary Care Association and state professional associations are notified of each request submitted for their comments and recommendations.

Annually, lists of designated HPSAs are made available 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 three 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 BCRS, 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 on the notification letter from BCRS. Proposed withdrawals become effective only after interested parties in the area affected have been afforded the opportunity to submit additional information to BCRS in support of its continued or revised designation. If no new data are submitted, or if BCRS review confirms the proposed withdrawal, the withdrawal becomes effective upon publication of the lists of designated HPSAs in the **Federal Register**. In addition, lists of HPSAs are updated daily on the HRSA Web site, <http://www.hrsa.gov/shortage/>, so that interested parties can access the most accurate and timely information.

Publication and Format of Lists

Due to the large volume of designations, a printed version of the list is no longer distributed. This notice serves to inform the public of the availability of the complete listings of designated HPSA on the HRSA Web site. The three lists (primary medical care, mental health, and dental) of designated HPSAs are available at a link on the HRSA Web site at <http://www.hrsa.gov/shortage/> and include a snapshot of all geographic areas, population groups, and facilities that were designated HPSAs as of May 11, 2013. This notice incorporates the most recent annual reviews of designated HPSAs and supersedes the HPSA lists published in the **Federal Register** on June 29, 2012 (77 FR 38838). The lists also include automatic facility HPSAs, designated as a result of the Health Care Safety Net Amendments of 2002 (Pub. L. 107–251), not subject to update requirements. 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 is (are) 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 are indicated by the “Entire

county HPSA” notation following the county name. Further details on the snapshot of HPSAs listed can be found on the HRSA Web site: <http://www.hrsa.gov/shortage/>.

In addition to the specific listings included in this notice, all Indian Tribes that meet the definition of such Tribes in the Indian Health Care Improvement Act of 1976, 25 U.S.C. 1603(d), are automatically designated as population groups with primary medical care and dental health professional shortages. The Health Care Safety Net Amendments of 2002 also made the following entities eligible for automatic facility HPSA designations: all federally qualified health centers (FQHCs) and rural health clinics that offer services regardless of ability to pay. These entities include: FQHCs funded under section 330 of the PHS Act, FQHC Look-Alikes, and Tribal and urban Indian clinics operating under the Indian Self-Determination and Education Act of 1975 (25 U.S.C. 450) or the Indian Health Care Improvement Act. Many, but not all, of these entities are included on this listing. Exclusion from this list does not exclude them from HPSA designation; any facilities eligible for automatic designation will be included in the database as they are identified.

Future Updates of Lists of Designated HPSAs

The lists of HPSAs on the HRSA Web site below consist of all those that were designated as of May 11, 2013. It should be noted that HPSAs are currently updated on an ongoing basis based on the identification of new areas, population groups, and facilities and sites that meet the eligibility criteria or that no longer meet eligibility criteria and/or are being replaced by another type of designation. As such, additional HPSAs may have been designated by letter since that date. The appropriate agencies and individuals have been or will be notified of these actions by letter. These newly designated HPSAs will be included in the next publication of the HPSA list and are currently included in the daily updates posted on the HRSA Web site at <http://www.hrsa.gov/shortage/find.html>.

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 such a 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 list of HPSAs designated as of May 11, 2013, are available on the HRSA Web site at <http://www.hrsa.gov/shortage/>. Frequently updated information on HPSAs is also available at <http://datawarehouse.hrsa.gov>.

Dated: June 21, 2013.

Mary K. Wakefield,
Administrator.

[FR Doc. 2013-15380 Filed 6-26-13; 8:45 am]

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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 78 FR 32404-32405 dated May 30, 2013).

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA). Specifically, this notice abolishes the Office of Special Health Affairs (OSHA) (RA1) and transfers functions to other areas throughout HRSA. (1) The Office of Health Equity (RAB) function will transfer from OSHA to the Office of the Administrator (RA); (2) the Office of Global Health Affairs (RPJ) function will transfer from OSHA to the Bureau of Health Professions (RP); (3) the Office of Strategic Priorities will be abolished, the oral and behavioral health function will transfer to the Bureau of Health Professions (RP); (4) the Office of Emergency Preparedness and Continuity of Operations function will transfer to the Office of Information Technology (RB5); (5) the Office of Health Information Technology and Quality will be abolished and functions will transfer to (a) the Healthcare Systems Bureau (RR); (b) the Office of Rural Health Policy (RH); and (c) the Office of Planning, Analysis and Evaluation (RA5); (6) establishes the Office of Performance and Quality Measurement (RA58) within the Office of Planning, Analysis and Evaluation (RA5). HRSA

will benefit from the improvements and efficiencies gained through this reorganization.

Chapter RA—Office of the Administrator

Section RA-10, Organization

Delete in its entirety and replace with the following:

The Office of the Administrator (RA) is headed by the Administrator, Health Resources and Services Administration, who reports directly to the Secretary. The Office of the Administrator includes the following components:

- (1) Immediate Office of the Administrator (RA);
- (2) Office of Equal Opportunity, Civil Rights, and Diversity Management (RA2);
- (3) Office of Planning, Analysis and Evaluation (RA5);
- (4) Office of Communications (RA6);
- (5) Office of Legislation (RAE);
- (6) Office of Women's Health (RAW); and
- (7) Office of Health Equity (RAB).

Section RA-20, Functions

Delete the functional statement for the Office of Special Health Affairs (RA1). Establish the functional statement for the Office of Health Equity (RAB) within the Office of the Administrator (RA).

Office of Health Equity (RAB)

Serves as the principal advisor and coordinator to the Agency for the special needs of minority and disadvantaged populations, including: (1) Providing leadership and direction to address HHS and HRSA Strategic Plan goals and objectives related to improving minority health and eliminating health disparities; (2) establishing and managing an Agency-wide data collection system for minority health activities and initiatives including the White House Initiatives for Historically Black Colleges and Universities, Educational Excellence for Hispanic Americans, Tribal Colleges and Universities, Asian Americans and Pacific Islanders, and departmental initiatives; (3) implementing activities to increase the availability of data to monitor the impact of Agency programs in improving minority health and eliminating health disparities; (4) participating in the formulation of HRSA's goals, policies, legislative proposals, priorities, and strategies as they affect health professional organizations and institutions of higher education and others involved in or concerned with the delivery of culturally-appropriate, quality health services to minorities and disadvantaged populations; (5)

consulting with federal agencies and other public and private sector agencies and organizations to collaborate in addressing health equity, including enhancing cultural competence in health service providers; (6) establishing short-term and long-range objectives; and (7) participating in the focus of activities and objectives in assuring equity in access to resources and health careers for minorities and the disadvantaged.

Chapter RP—Bureau of Health Professions

Section RP-10, Organization

Delete in its entirety and replace with the following:

The Bureau of Health Professions is (RP) is headed by the Associate Administrator, Bureau of Health Professions, who reports directly to the Administrator, Health Resources and Services Administration (RA). The Bureau of Health Professions includes the following components:

- (1) Office of the Associate Administrator (RP);
- (2) Office of Administrative Management Services (RP1);
- (3) Office of Global Health Affairs (RPJ);
- (4) Office of Policy Coordination (RP3);
- (5) Office of Performance Measurement (RP4);
- (6) Division of Public Health and Interdisciplinary Education (RPF);
- (7) Division of Medicine and Dentistry (RPC);
- (8) Division of Nursing (RPB);
- (9) Division of Practitioner Data Banks (RPG);
- (10) Division of Student Loans and Scholarships (RPD); and
- (11) National Center for Health Workforce (RPW).

Section RP-20, Functions

Delete and replace the functional statement for (1) the Bureau of Health Professions (RP); (2) the Office of the Associate Administrator; (3) the Division of Public Health and Interdisciplinary Education; (4) the Division of Medicine and Dentistry; and (5) establish the functional statement for the Office of Global Health Affairs (RPJ).

Bureau of Health Professions (RP)

The Bureau of Health Professions' programs are designed to improve the health of the nation's underserved communities and vulnerable populations by assuring a diverse, culturally competent workforce that is ready to provide access to quality health care services. Bureau of Health Professions' program components