

timely and effective conduct of such meetings.

Section 119(a) of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) (Public Law 105-115) amends section 505(b) of the act (21 U.S.C. 355(b)) and directs FDA to meet with sponsors and applicants, provided certain conditions are met, for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effectiveness claim in a new drug application submitted under section 505(b) of the act or in a biologics license application submitted under section 351 of the Public Health Service Act (21 U.S.C. 355(b)(4)(B)). Moreover, in conjunction with the reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA) in November 1997, FDA agreed to specific performance goals for the management of meetings with sponsors and applicants for PDUFA products. The performance goals are summarized in an enclosure to a letter dated November 12, 1997, from the Secretary of Health and Human Services, Donna E. Shalala, to Senator James M. Jeffords.

The procedures and policies described in this guidance are designed to promote efficient, well-managed meetings between sponsors, applicants, and CDER or CBER. These procedures will implement section 119(a) of the Modernization Act and are consistent with the timeframes described in the performance goals.

In the notice announcing the availability of the draft version of this guidance (64 FR 13591), FDA published notice of the proposed collection of information related to the draft guidance. The **Federal Register** notice also requested comments on the burden estimates for the guidance. In the **Federal Register** of August 26, 1999 (64 FR 46684), the agency announced that it was submitting the collection of information to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. The information collection provisions related to this guidance have been approved under OMB control number 0910-0429. This approval expires December 31, 2002. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

This Level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The guidance represents the agency's current thinking on formal meetings with sponsors and applicants

for PDUFA products. 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 statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 20, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00-5464 Filed 3-6-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Graduate Medical Education Advisory Council; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of April 2000.

Name: Council on Graduate Medical Education (COGME).

Date and Time: April 5, 2000; 8:30 a.m.—5:30 p.m.; April 6, 2000; 8:30 a.m.—12 p.m.

Place: The Latham Hotel, Georgetown-Residential Ballroom, 3000 M Street, N.W., Washington, D.C. 20007.

The meeting is open to the public.

Agenda: The agenda will include: Welcome and opening comments from the Administrator, Health Resources and Services Administration, the Associate Administrator for Health Professions, and the Acting Executive Secretary of COGME; a presentation on the Minimum Requirements for Physicians Enrolled in US Post-Graduate Training Programs; a panel of speakers discussing the Role of Labor in Graduate Medical Education; a legislative update on Graduate Medical Education; a presentation on the History of COGME's 110:50/50 Ratio; and a discussion of COGME Resource Papers. The Council will hear the reports of its work groups on GME Financing, and Physician Workforce.

Anyone requiring information regarding the subject should contact Stanford M. Bastacky, D.M.D., M.H.S.A., Executive

Secretary, Council on Graduate Medical Education, Division of Medicine, Bureau of Health Professions, Room 9A-27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-6326.

Agenda items are subject to change as priorities dictate.

Dated: February 29, 2000.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00-5420 Filed 3-6-00; 8:45 am]

BILLING CODE 4160-15-U

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 (DHHS), Health Resources and Services Administration (60 FR 56605 as amended November 6, 1995, as last amended at 65 FR 8375-6 dated February 18, 2000).

This notice reflects the organizational and functional changes in the Bureau of Health Professions (RP).

Make the following changes:

A. Delete the opening functional statement for the Bureau of Health Professions in its entirety and replace with the following:

Bureau of Health Professions (RP)

Provides national leadership in coordinating, evaluating, and supporting the development and utilization of the Nation's health personnel. Specifically: (1) Assess the Nation's health personnel supply and requirements and forecasts supply and requirements for future time periods under a variety of health resources utilization assumptions; (2) collects and analyzes data and disseminates information on the characteristics and capacities of the Nation's health personnel production systems; (3) proposes new or modifications of existing Departmental legislation, policies, and programs related to health personnel development and utilization; (4) develops, tests and demonstrates new and improved approaches to the development and utilization of health personnel within various patterns of health care delivery and financing systems; (5) provides financial support to institutions and individuals for health professions education programs; (6) administers Federal programs for

targeted health personnel development and utilization; (7) provides leadership for promoting equity and diversity in access to health services and health careers for under-represented minority groups; (8) provides technical assistance, consultation, and special financial assistance to national, State, and local agencies, organizations, and institutions for the development, production, utilization, and evaluation of health personnel; (9) provides linkage between Bureau headquarters and HRSA Field Office activities related to health professions education and utilization by providing training, technical assistance, and consultation to Field Office staff; (10) coordinates with the programs of other agencies within the Department, and in other Federal Departments and agencies concerned with health personnel development and health care services; (11) provides liaison and coordinates with non-Federal organizations and agencies concerned with health personnel development and utilization; (12) in coordination with the Office of the Administrator, Health Resources and Services Administration, serves as a focus for technical assistance activities in the international aspects of health personnel development, including the conduct of special international projects relevant to domestic health personnel problems; (13) administers the National Vaccine Injury Compensation Program; and (14) administers the National Practitioner Data Bank Program.

B. Delete the functional statement for the Office of the Bureau Director in its entirety and replace with the following:

Office of the Bureau Director (RP)

The Office of the Director, BHPr, provides national leadership in coordinating, evaluating, and supporting the development and utilization of the Nation's health personnel. Specifically: (1) Directs the national health professions education, student assistance and development programs and activities; (2) provides policy guidance and staff direction to the Bureau; (3) maintains liaison with other Federal and non-Federal organizations and agencies with health personnel development interests and responsibilities; (4) provides guidance and direction for technical assistance activities in the international aspects of health personnel development; (5) provides guidance and assistance to the Field Director or field staff as appropriate; and (6) directs and coordinates Bureau programs in support of Equal Employment Opportunity.

C. Delete the functional statement for the Office of Research and Planning and replace with the following:

Office of Planning and Project Development

Serves as the Bureau focal point for program planning, evaluation, and legislation. Maintains liaison with governmental, professional, voluntary, and other public and private organizations, institutions, and groups for the purpose of providing information exchange. Specifically (1) stimulates, guides, and coordinates program planning, reporting, and evaluation activities of the Divisions and staff offices; (2) provides staff services to the Bureau Director for program and strategic planning and its relation to the budgetary, legislative and regulatory processes, the development of issue papers, congressional reports, and coordination of OMB information clearance requests for forms and regulations; (3) coordinates the development and implementation of the Bureau's evaluation program; (4) provides staff services and coordinates activities pertaining to legislative policy development, interpretation, and implementation, including the development of legislative proposals, the analysis of existing and pending legislation with other agencies, and distribution of legislative materials; (5) reviews and interprets program award policies and authorities for incorporation into the development and implementation of the Bureau's program and award procedures; (6) coordinates the development, clearance, and dissemination of legislative implementation plans, regulations, **Federal Register** notices, application guidelines and operating procedures; (7) identifies issues and coordinates the resolution of program award policy and procedural questions that arise; and (8) coordinates public relations and media communications in conjunction with the Agency and Department.

D. Delete the functional statement for the Division of Associated, Dental and Public Health Professions and replace with the following:

Division of Public Health and Allied Health

The Division of Public Health and Allied Health serves as the principal Federal focus for the development and improvement of basic professional education and continuing professional development of public health, including preventive medicine and school health educators; environmental health, including undergraduate preparation for entry level positions; health

administration, including hospitals, ambulatory primary care settings, such as health maintenance organizations, community/migrant health centers, and community based organizations; the associated health professions, including veterinary medicine, optometry, and pharmacy; allied health professions, including physical therapy, occupational therapy, medical technology, dental hygiene, respiratory therapy, radiography, radiation therapy, emergency medical technicians, and a long list of similar professionals; chiropractic health care; social workers, especially in medical settings; clinical psychology; mental health workers; and other new and developing health disciplines. Specifically, the Division: (1) Provides professional direction and leadership for planning, evaluating and supporting the development and utilization of the health professionals in these fields; (2) provides leadership in maintaining contact with the employers of health professionals in these fields to monitor educational relevance to current and future needs in the work place; (3) develops contractual and staff studies concerning the future education needs of the health professions in these fields and supports the development of specialized curricula to encourage progress in basic and continuing professional development; (4) provides leadership to the grant programs administered by the Division to meet the legislated intent of the authorizations; (5) provides professional technical assistance to educational institutions and other potential applicants concerning the grant programs managed by the Division; (6) monitors awarded grants and provides professional technical assistance to assist grantees in the accomplishment of their project objectives within the context of national strategies for the health professionals in these fields; (7) monitors and assists in the credentialing process for the health professionals in these fields, including accreditation, certification by professional organizations, and licensure; (8) maintains liaison with professional associations concerned with the quality of education for the health professionals in these areas; (9) coordinates activities with other Bureau, HRSA, Department, and Federal educational activities for the health professionals in these fields to encourage cooperation and accomplish national health objectives; (10) conducts special initiatives including the development of management information systems; and (11) monitors data collection activities in the Bureau and professional

associations to assure timely and accurate information is available concerning the supply and quality of education of the health professionals in these areas and information is available concerning the grant programs and training activities of the Division.

E. Delete the functional statement for the Division of Medicine and replace with the following:

Division of Medicine and Dentistry

Serves as the principal focus with regard to education, practice, and research of medical personnel; with special emphasis on allopathic and osteopathic physicians, podiatrists, dentists and physician assistants. Specifically: (1) Provides professional expertise in the direction and leadership required by the Bureau for planning, coordinating, evaluating, and supporting development and utilization of the Nation's health personnel for these professions; (2) supports and conducts programs with respect to the need for and the development, use, credentialing, and distribution of such personnel; (3) engages with other Bureau programs in cooperative efforts of research, development, and demonstration on the interrelationships between the members of the health care team, their tasks, education requirements, and training modalities, credentialing and practice; (4) conducts and supports studies and evaluations of physician, dentist, physician assistant, and podiatric personnel requirements, distribution and availability, and cooperates with other components of the Bureau and Agency in such studies; (5) analyzes and interprets physician, dental, physician assistant, and podiatric programmatic data collected from a variety of sources; (6) conducts, supports, or obtains analytical studies to determine the present and future supply and requirements of physicians, dentists, physician assistants, and podiatrists by specialty and geographic location, including the linkages between their training and practice characteristics; (7) conducts and supports studies to determine potential national goals for the training and distribution of physicians in graduate medical education programs and develops alternative strategies to accomplish these goals; (8) supports and conducts programs with respect to activities, associated with the international migration, domestic training, and utilization of foreign medical graduates and U.S. citizens studying abroad; (9) maintains liaison with relevant health professional groups and others, including consumers, having common interest in the Nation's

capacity to deliver health services; (10) provides consultation and technical assistance to public and private organizations, agencies, and institutions, including Field Offices, other agencies of the Federal Government, and international agencies and foreign governments, on all aspects of the Division's functions; (11) provides administrative and staff support for the Advisory Committee on Training and Primary Care Medicine and Dentistry, and for the Council on Graduate Medical Education; and (12) represents the Bureau, Agency and Federal Government, as designated, on national committees and as the Accreditation Council on Graduate Medical Education (ACGME) and the Accreditation Council for Continuing Medical Education (ACCME).

F. Delete the functional statement for the Division of Student Assistance in its entirety and replace with the following:

Division of Student Assistance (RP6)

Serves as the focal point for the Health Professions and Nursing Student Loan and Scholarship Programs, the Exceptional Financial Need Scholarship Program, the Federal Assistance to Disadvantaged Health Professions Scholarship Program, the Health Educational Assistance Loan Program, the Health Professions and Nursing Educational Loan Repayment and Loan Cancellation Programs. Specifically: (1) Directs and administers these student assistance, training and support programs, including the awarding of loan and scholarship funds; (2) develops and implements program plans and policies and operating and evaluation plans and procedures in coordination with the Office of Program Development; (3) monitors and assesses educational and financial institutions with respect to capabilities and management of Federal support for students; (4) develops and conducts training activities for staff of educational and financial institutions; (5) maintains liaison with and provides assistance to program-related public and private professional organizations and institutions; (6) maintains liaison with the Office of the General Counsel, and the Office of the Inspector General, DHHS, components of the Department of Education and the Department of Defense, and State agencies concerning student assistance; (7) in coordination with the Office of Program Development, develops legislative proposals and related administrative and management information and control documents; (8) coordinates financial aspects of programs with educational institutions; and (9)

develops program data needs, formats, and reporting requirements, including collection, collation, analysis and dissemination of data.

G. Delete the functional statement for the Division of Disadvantage Assistance in its entirety and replace with the following:

Division of Health Professions Diversity

Provides the Bureau focal point and leadership for assuring equity in access to health resources and health careers for diverse and disadvantaged populations. Specifically: (1) Provides technical assistance to groups that represent and seek to improve the health status of diverse and disadvantaged populations, and facilitates the access of such groups to Bureau and other Federal programs and resources; (2) provides leadership and direction for the development and implementation of Bureau objectives as they relate to diverse and disadvantaged populations; (3) develops and recommends health resources and health career opportunities for diverse and disadvantaged populations; (4) initiates, stimulates, supports, coordinates, and evaluates Bureau programs for improving the availability and accessibility of health careers for diverse and disadvantaged populations; (5) initiates, stimulates, supports, coordinates, and evaluates in conjunction with other Bureau units, comprehensive data systems and analyses on requirements, resources, accessibility, and accountability of the health delivery system for diverse and disadvantaged populations; (6) conducts special studies and collects baseline data to identify specific factors contributing to the health and health-related problems of diverse and disadvantaged populations, and to develop strategies for improving health services and career opportunities for diverse and disadvantaged populations; (7) conducts extramural programs, including the use of grants and contracts, specifically designed to promote equity in access to health careers; (8) assures contract compliance and implementation of the Policy Statement on Civil Rights in the Bureau; (9) in coordination with the Bureau's divisions and in collaboration with other HRSA entities, provides leadership for and assures implementation of Presidential, Departmental, and other special initiatives addressing the needs of diverse and disadvantaged populations; (10) conducts and coordinates Bureau programs in health careers for women; (11) provides leadership to develop and coordinate Bureau program support to

student health organizations; and (12) provides advice and consultation on policy and other matters related to assuring equity in access to health resources and health careers for diverse and disadvantaged populations.

H. Delete the functional statement for the Division of Quality Assurance in its entirety and replace with the following:

Division of Quality Assurance (RPA)

Serves as the focal point within DHHS/HRSA for medical, dental, nursing and other health professions quality assurance efforts. Specifically in coordination with the Department and other Federal entities, State licensing boards, and national, State and local professional organizations: (1) administers the National Practitioner Data Bank (NPDB) as authorized under Title IV of the Health Care Quality Improvement Act of 1986 and Section 5 of the Medicare and Medicaid Patient and Program Protection Act of 1987; (2) on behalf of the Inspector General, DHHS, administers the Healthcare Integrity and Protection Data Bank (HIPDB) under Title II Subsection C of the Health Insurance Portability and Accountability Act of 1996; (3) conducts and supports research based on NPDB and HIPDB information; (4) maintains active consultative relations with professional organizations, societies, and Federal and state agencies involved in the NPDB and HIPDB; (5) proposes and monitors guidelines for (a) credentials assessment, granting of privileges, and monitoring and evaluating programs for physicians, dentists, and other health care professionals; (b) professional review of specified medical liability and malpractice; (7) works with the Secretary's office to provide technical assistance to States undertaking malpractice reform; (8) provides staff to and coordinates the activities of the PHS interagency Advisory Council on Quality Assurance and Risk Management; and (9) undertakes other quality assurance and risk management development efforts.

I. Establish the Division of Interdisciplinary and Community Based Programs (RPA)

Division of Interdisciplinary and Community Based Programs

Serves as the principal focal point for specialized DHHS interagency projects, HRSA initiatives and Bureau of Health Professions interdivisional activities. Specifically: (1) promotes, designs, supports and administers activities relating to the planning and development of nationally integrated health professions education programs;

(2) administers special projects of the Office of the Secretary, such as the primary Care Policy Fellowship Program and the Secretary's Award Program for Innovations in Health Promotion and Disease Prevention; (3) promotes, plans and develops collaborative, interdisciplinary activities in the specialty areas of behavioral/mental health, rural health and geriatrics; (4) promotes quality improvement in health professions education through collaboration and partnerships with national and international institutes and centers for quality improvement; (5) promotes and supports academic-community partnerships whose goal is the development of interdisciplinary, community-based programs designed to improve access to health care through improving the quality of health professions education and training; (6) collaborates with relevant offices of the Bureau, HRSA and the Department; and (7) maintains liaison with related professional groups, foundations, and other private and government organizations as needed.

Delegations of Authority

All delegations and redelegations of authority which were in effect immediately prior to the effective date herof have been continued in effect in them or their successors pending further redelegation.

This reorganization is effective upon date of signature.

Dated: February 18, 2000.

Claude Earl Fox,

Administrator.

[FR Doc. 00-5470 Filed 3-6-00; 8:45 am]

BILLING CODE 4160-15-P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Colorado River Irrigation Project— Irrigation Division, Arizona, Irrigation Rate Adjustment

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final Notice of Rate Adjustment.

SUMMARY: The Bureau of Indian Affairs (BIA) is adjusting irrigation rates for customers of Colorado River Irrigation Project, Irrigation Division for the 2000 irrigation season. The Notice of Proposed Rate Adjustment was published in the **Federal Register** on July 26, 1999, 64 FR 40387. The public and interested parties were provided an opportunity to submit written

comments during the 60-day period subsequent to July 26, 1999. No comments were received.

EFFECTIVE DATE: The new rates are effective for the 2000 irrigation season.

FOR FURTHER INFORMATION CONTACT:

Regional Director, Bureau of Indian Affairs, Western Region, P.O. Box 10, Phoenix, Arizona 85001, Telephone (602) 379-6956.

SUPPLEMENTARY INFORMATION: The authority to issue this document is vested in the Secretary of the Interior by 5 U.S.C. 301; the Act of August 14, 1914 (38 Stat. 583; 25 U.S.C. 385). The Secretary has delegated this authority to the Assistant Secretary-Indian Affairs pursuant to part 209 Departmental Manual, Chapter 8.1A and Memorandum dated January 25, 1994, from Chief of Staff, Department of the Interior, to Assistant Secretaries, and Heads of Bureaus and Offices. The new rates are specified in the following schedule.

Irrigation Rate Per Assessable Acre— 2000 Irrigation Season

1. When does this schedule apply to me?

This schedule applies to you if you irrigate lands within the CRIP/ID for the 2000 irrigation season.

2. What will BIA charge for the 2000 irrigation season?

The following table shows how we will bill you.

For . . .	We will bill you . . .
(1) Zero to 5 acre-feet/acre.	\$38.50 per assessable acre.
(2) Excess Water above 5 acre-feet.	\$17.00 per acre foot.

Executive Order 12988

The Department has certified to the Office of Management and Budget (OMB) that this rate adjustment meets the applicable standards provided in sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 12866

This rate adjustment is not a significant regulatory action and has been reviewed by the Office of Management and Budget under Executive Order 12866.

Regulatory Flexibility Act

This rate making is not a rule for the purposes of the Regulatory Flexibility Act because it is "a rule of particular applicability relating to rates." 5 U.S.C. 601(2).