

fees that require a cover sheet are certain animal drug application fees and certain supplemental animal drug application fees. The cover sheet (Form FDA 3546) is designed to provide the minimum necessary information to determine whether a fee is required for the review of an application or supplement, to determine the amount of the fee required, and to assure that each animal drug user fee payment and each animal drug application for which

payment is made is appropriately linked to the payment that is made. The form, when completed electronically, will result in the generation of a unique payment identification number used in tracking the payment. FDA will use the information collected to initiate administrative screening of new animal drug applications and supplements to determine if payment has been received. Inability to collect this information would delay the review process, and

would also delay receipt of revenue that is to be used to fund the review of animal drug applications during the current fiscal year. FDA is requesting this emergency processing under the PRA to implement these new statutory requirements of ADUFA (section 740(a)(1) and (e) of the act). FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Section of the act as amended by ADUFA	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
740(a)(1) FDA Form 3546 (cover sheet)	69	1 time for each application	69	1	69

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents to this collection of information are new animal drug applicants or manufacturers. Based on FDA's data base system, there are an estimated 140 manufacturers of products or sponsors of new animal drugs potentially subject to ADUFA. However, not all manufacturers or sponsors will have any submissions in a given year and some may have multiple submissions. The total number of annual responses is based on the number of submissions received by FDA in fiscal year 2003. The Center for Veterinary Medicine (CVM) estimates 69 annual responses that include the following: 28 new animal drug premarket approval applications and 41 supplements. The estimated hours per response are based on past FDA experience with the various submissions, and range from 30 minutes to 1 hour. The hours per response are based on the average of these estimates.

Dated: February 23, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on

proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Data Collection Tool for the Black Lung Clinics Program: In Use Without Approval

The Bureau of Primary Health Care (BPHC), Health Resources and Services Administration (HRSA), conducts an annual data collection of user information for the Black Lung Clinics Program. The purpose of the Black Lung Clinics Program is to improve the health

status of coal workers by providing services to minimize the effects of respiratory and pulmonary impairments of coal miners. Grantees provide specific diagnostic and treatment procedures required in the management of problems associated with black lung disease which improve the quality of life of the miner and reduces economic costs associated with morbidity and mortality arising from pulmonary diseases. The purpose of collecting this data is to provide HRSA with information on how well each grantee is meeting the needs of active and retired miners in the funded communities.

Data from the annual report will provide quantitative information about the programs, specifically: (a) The characteristics of the patients they serve (gender, age, disability level, occupation type), (b) the characteristics of services provided (medical, non-medical, or counseling), and (c) number of patients served and visits conducted (encounters). This assessment will provide data useful to the program and will enable HRSA to provide data required by Congress under the Government Performance and Results Act of 1993. It will also ensure that the organizations funded have demonstrated a need for services in their communities and that funds are being effectively used to provide services to meet those needs.

The estimated burden is as follows:

Form name	Number of respondents	Hours per response	Total burden hours
Database	15	10	150

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14-45, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: February 19, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Recruitment of Clinicians To Become Commissioned Officers; Recruitment of Sites for Assignment of Commissioned Officers

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

ACTION: General notice.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that applications will be accepted from clinicians seeking to be hired as commissioned officers in the U.S. Public Health Service and from sites seeking the assistance of these commissioned officers. These commissioned officers will be primary care clinicians who are physicians, dentists, family nurse practitioners, physician assistants, clinical psychologists, and clinical social workers. In support of other Presidential and Department of Health and Human Services Initiatives, a limited number of registered nurses (baccalaureate level) will be considered for placement in ambulatory community-based systems of care. These officers will be assigned by the National Health Service Corps (NHSC) to the neediest Health Professional Shortage Areas throughout the Nation. The NHSC will pay the salaries, moving expenses and benefits for these commissioned officers.

These officers will be part of a mobile cadre of health care professionals who, in addition to the services they will provide to patients at their assigned sites, may be called upon to respond to regional and/or national emergencies. The NHSC will assist the officers in acquiring, maintaining and enhancing

emergency response skills. Their initial assignments will be up to three years in duration, after which, should these clinicians choose to stay in the U.S. Public Health Service, they will progress to new assignments.

Eligible Applicants

Clinicians—Applicants must file a U.S. Public Health Service Commissioned Corps application and meet the requirements for such commissioning. For example, all clinicians must be U.S. citizens under 44 years of age (age may be offset by prior active duty Uniformed Service time and/or civil service work experience in a Public Health Service (PHS) agency at a PHS site at a level commensurate with the duties of a commissioned officer), and have served less than 8 years of active duty if the clinician is/was a member of another Uniformed Service. Also, applicants must meet medical requirements, and pass an initial suitability investigation.

In addition, prior to the start of their assignment at an NHSC site, clinicians must meet the following requirements:

(1) Physicians must have completed a residency in Family Practice, Internal Medicine, combined Internal Medicine and Pediatrics, General Psychiatry or Obstetrics and Gynecology and be a diplomate of their respective Allopathic or Osteopathic Specialty Boards;

(2) Dentists must have passed a state or regional dental board exam;

(3) Family Nurse Practitioners must have national certification by the American Nurses Credentialing Center or the American Academy of Nurse Practitioners;

(4) Physician Assistants must have national certification by the National Commission on Certification of Physician Assistants;

(5) Clinical Psychologists must have a doctoral degree in clinical psychology, have a minimum of 1 year of postgraduate supervised clinical experience, have passed the Examination for Professional Practice in Psychology, and be able to practice independently and unsupervised as a clinical psychologist;

(6) Clinical Social Workers must have a masters degree in social work, have passed the Association of Social Work Board's (ASWB) Clinical or Advanced licensing exam prior to July 1, 1998 or the ASWB Clinical exam on or after July 1, 1998, and be able to practice

independently and unsupervised as a clinical social worker; and

(7) All clinicians must possess a current, unrestricted, and valid license to practice their health profession in at least one of the 50 States, Washington, D.C., the Commonwealth of Puerto Rico, the U.S. Virgin Islands, or Guam.

Sites—Applicants must be located in a Health Professional Shortage Area (HPSA) and submit a Proposal for Use of a Commissioned Officer 2004. Applicants must also submit a Recruitment and Retention Assistance Application, if not yet approved as an NHSC site. Sites applying for a physician, family nurse practitioner, physician assistant or registered nurse must be located in a primary medical care HPSA; sites applying for a dentist must be located in a dental HPSA; and sites applying for a psychiatrist, a clinical psychologist, or a clinical social worker must be located in a mental health HPSA. All sites to which NHSC clinicians are assigned must accept assignment under Medicare, have appropriate agreements with the applicable State entity to participate in Medicaid and the State Children's Health Insurance Program, see all patients regardless of their ability to pay, and use and post a discounted fee plan. Sites must also understand and accept that these officers will periodically be away from their assigned locations as they train for, or respond to, a regional and/or national health emergency.

Application Requests, Dates and Addresses

Application materials are available for downloading via the Web at <http://nhsc.bhpr.hrsa.gov> or by calling the National Health Service Corps "Call Center" at 1-800-221-9393.

Clinicians—The original of the completed application must be mailed or delivered no later than March 31, 2004 to: Division of Commissioned Personnel, ATTN: Recruitment and Assignment Branch, 5600 Fishers Lane, Room 4A-18, Rockville, MD 20857-0001. A copy of the completed application must be mailed or delivered no later than September 30, 2004 to: HRSA Commissioned Corps Operations Office, Parklawn Building, Room 13A-22, 5600 Fishers Lane, Rockville, MD 20857. Clinicians are encouraged to submit an application early, as applications will be considered as soon