

Human Blood and Blood Components Intended for Transfusion or for Further Manufacture” dated January 2000 that was announced in the **Federal Register** of January 3, 2000 (65 FR 134).

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document represents the agency’s current thinking on reporting changes to an approved application for human blood and blood components that are intended for transfusion or for further manufacture. 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 requirement of the applicable statutes and regulations.

II. Comments

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

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: June 29, 2001.
Margaret M. Dotzel,
Associate 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) will publish periodic summaries of proposed projects 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 at (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: Healthy Schools, Healthy Communities User/Visit Surveys

The Bureau of Primary Health Care of HRSA is planning to conduct User/Visit Surveys of the Healthy Schools, Healthy Communities (HSHC) Program. The purpose of these surveys is to obtain nationally representative data about the patients of HSHC health centers and the services provided to them. The study consists of two parts. One is the User Survey, which involves interviewing HSHC patients or their parents about the patients’ health and health care. The second is the Visit Survey, in which patient visit data will be collected from medical records in order to find out what health services are being used by patients. The data collected will provide policymakers with a better understanding of the services students are receiving at HSHC health centers and how well these centers are meeting the needs of students. The surveys will provide new information about health care received in HSHC settings.

Data from the surveys will provide quantitative information on the population served by the HSHC program, specifically: (a) Sociodemographic characteristics, (b) health care access and utilization, (c) health status and morbidity, (d) health care experiences and risk behaviors, (e) content of medical encounters, (f) preventive care (g) and patient satisfaction. These surveys 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.

The estimated burden on respondents is as follows:

Respondents	Number of Respondents	Hours per Respondent	Total Hour Burden
Adolescent Users of HSHC Clinics	750	.5	375
Guardians (Proxies) of Users of HSHC Clinics	750	.5	375
Medical Records Copied by Health Center Personnel	* 1500	.25	385
Total	1500		1,135

* Medical records.

Send comments to Susan Queen, Ph.D., HRSA Reports Clearance Officer, Room 14-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: July 31, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

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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 (DHHS), Health Resources and Services Administration (HRSA) as last amended at (60 FR 56605, November 6, 1995 and most recently amended at 66 FR 35981, July 10, 2001).

This notice is to amend the functional statements for the Bureau of Health Professions and the Bureau of Primary Health Care. Specifically, this notice will move the functions of the Division of National Health Service Corps (RC5), the Division of Scholarships and Loan Repayment (RC6) and the Division of Shortage Designation (RC8) in the Bureau of Primary Health Care and place them in the Bureau of Health Professions. A statement outlining HRSA's reorganization aims is set forth at the end of this notice.

Section RP Function

A. Revise the functional statement for the Bureau of Health Professions (RP) as follows:

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) Assesses 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 to 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; (14) administers the National Practitioner Data Bank Program; (15) administers the Healthcare Integrity and Protection Data Bank Program; (16) administers the Ricky Ray Hemophilia Relief Fund Program; (17) administers the Children's Hospitals Graduate Medical Education (CHGME) Payment Program; (18) administers the National Health Service Corps Program which assures accessibility of health care in under-served areas; (19) plans the activities of the National Health Service Corps Advisory Council; (20) administers the Public Health Service Scholarship Training Program and the National Health Service Corps Scholarship Loan Repayment Program; and (21) administers the designation of

health professional shortage areas and medically under-served populations.

B. Revise the functional statements for the Bureau of Primary Health Care (RC) as follows:

Bureau of Primary Health Care (RC)

Provides national leadership in developing, coordinating, evaluating, and assuring access to comprehensive preventive and primary health care services and improving the health status of the Nation's under-served and vulnerable populations. Specifically: (1) Assesses the Nation's health care needs of under-served populations; (2) assists communities in providing quality health care services, demonstrating new and improved approaches for providing access to health care and improved health care delivery, and creating new access through community development, expansion and partnerships; (3) administers the Consolidated Health Center Program; (4) develops comprehensive integrated systems of care for under-served communities and populations; (5) decreases health disparities through the targeting of resources to those populations at increased risk of negative health outcomes; (6) promotes the integration of primary care services with mental health, counseling and dental health services; (7) develops innovative strategies for serving special populations and difficult to serve sub-populations; (8) provides leadership for promoting equity, diversity, and cultural competency in access to health care services for under-served populations; (9) coordinates with other Federal agencies and various other organizations involved in health care access and utilization, integrated systems of care, and improvement of health status for under-served populations; (10) supports national, State, local, community, voluntary, public and private entities to help primary health care and health-related organizations meet the needs of vulnerable, under-served, and special populations; (11) provides policy leadership, programmatic direction and consultation for HRSA Field Office staff on activities related to community-based primary health care; (12) administers the Black Lung Clinics Program and the Native Hawaiian Health Systems Program; (13) provides leadership and direction for the National Hansen's Disease Program; (14) administers a national health care program in support of the Immigration and Naturalization Service; and (15) administers the Section 340B Drug Pricing Program.