

the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Brenda R. Friend, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry and FDA Review Staff: Collection of Platelets by Automated Methods," dated December 2007. The guidance provides to blood establishments and FDA staff revised recommendations for the collection of Platelets by automated methods (plateletpheresis). In recent years, many improvements have been made in automated blood cell separator technology, platelet storage stability, and blood cell counting methods. Automated blood cell separator devices are now capable of various plateletpheresis collection procedures including, but not limited to, collection of double and triple platelet components obtained during a single procedure; use of in-process leukocyte reduction; collection of concurrent plasma components; and collection of concurrent Red Blood Cell components. This guidance replaces the draft guidance of the same title, and supersedes the guidance entitled "Revised Guideline for the Collection of Platelets, Pheresis," dated October 1988.

In the **Federal Register** of October 3, 2005 (70 FR 57609), FDA announced the availability of the draft guidance of the same title dated September 2005. FDA received numerous comments on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes includes: (1) Revised recommendations for donor selection and management, (2) revised recommendations for collection performance qualification criteria, and (3) revised recommendations on quality control monitoring. The guidance announced in this notice finalizes the draft guidance dated September 2005.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

The guidance represents FDA's current thinking on this topic. 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 statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 211 (21 CFR part 211), subpart J (Records and Reports) have been approved under OMB control number 0910-0139; the collections of information in part 606 (21 CFR part 606), subpart I (Records and Reports) have been approved under OMB control numbers 0910-0116 and 0910-0458; the collections of information in §§ 606.100(b) and (c), 606.110(a), 606.121, 606.122, 21 CFR 640.25, and 21 CFR 640.27 have been approved under OMB control number 0910-0116; the collections of information in §§ 211.22, 211.80, 211.100(b), and 211.160 have been approved under OMB control number 0910-0139; the collections of information in 21 CFR 610.2 have been approved under OMB control number 0910-0206; and the collections of information in 21 CFR 601.12 and 610.60 have been approved under OMB control number 0910-0338.

III. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will

publish a **Federal Register** notice announcing that date.

IV. Electronic Access

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

Dated: December 7, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-24385 Filed 12-14-07; 8:45 am]

BILLING CODE 4160-01-S

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 the 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 at (301) 443-1129.

Comments are invited on (a) whether the agency needs to collect the proposed information to properly perform its functions and whether the information has any practical utility; (b) whether the agency's estimate of the burden of the proposed collection of information is accurate; (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 for respondents (e.g., by using automated collection techniques or other forms of information technology).

Proposed Project: Ryan White HIV/AIDS Program Part F Dental Services Report (OMB No. 0915-0151)—Extension

The Dental Reimbursement Program (DRP) and the Community Based Dental Partnership Program under Part F of the Ryan White HIV/AIDS Program offer funding to accredited dental education programs to support the provision of

oral health services for HIV-positive individuals. Institutions eligible for these programs are accredited schools of dentistry, post-doctoral dental education programs and dental hygiene programs.

The DRP Application is the Dental Services Report that schools and programs use to apply for funding of non-reimbursed costs incurred in providing oral health care to patients with HIV, or to report annual program data. Awards are authorized under section 2692(b) of the Public Health Service Act (42 U.S.C. § 300ff-111(b)). The Dental Services Report collects data in four different areas: program information, patient demographics and services, funding, and training. It also

requests applicants to provide narrative descriptions of their services and facilities, as well as their links and collaboration with community-based providers of oral health services.

The primary purpose of collecting this information annually is to verify eligibility and determine reimbursement amounts for DRP applicants, as well as to document the program accomplishments of Community-Based Dental Partnership Program grant recipients. This information also allows HRSA to learn about (1) the extent of the involvement of dental schools and programs in treating patients with HIV, (2) the number and characteristics of clients who receive HIV/AIDS program-supported oral health services, (3) the

types and frequency of the provision of these services, (4) the non-reimbursed costs of oral health care provided to patients with HIV, and (5) the scope of grant recipients' community-based collaborations and training of providers. In addition to meeting the goal of accountability to Congress, clients, advocacy groups, and the general public, information collected in the Dental Services Report is critical for HRSA, State and local grantees, and individual providers, to help assess the status of existing HIV-related health service delivery systems.

The reporting burden for reviewing the Dental Services Report Instructions and completing the Report is estimated as:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Dental Services Report	80	1	80	20	1600

Send comments to Susan G. Queen, PhD, HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: December 11, 2007.

Alexandra Huttinger,

Acting Director, Division of Policy Review and Coordination.

[FR Doc. E7-24348 Filed 12-14-07; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Part C HIV Early Intervention Services Grant

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

ACTION: Notice of Noncompetitive Program Expansion Supplemental Award.

SUMMARY: HRSA will be providing temporary critical HIV medical care and treatment services through Chase Brexton Health Services to avoid a disruption of HIV clinical care to homeless populations in the Baltimore, Maryland, area.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Chase Brexton Health Services, Baltimore, Maryland.

Amount of the Award: \$73,125 (initial three month supplement) and \$300,000

(anticipated second 12 month supplement) to ensure ongoing clinical services to the target population.

Authority: Section 2651 of the Public Health Service Act, 42 U.S.C. 300ff-51.

CFDA Number: 93.918.

Project Period: The first period of supplemental support is from September 30, 2007, through December 31, 2007. The anticipated second period of supplemental support will be January 1, 2008, through December 31, 2008.

FOR FURTHER INFORMATION CONTACT:

Maria Rios, M.D, via e-mail: *mrios@hrsa.gov*, or via telephone: 301-443-0493.

Justification for the Exception to Competition

Funding critical HIV medical care and treatment services for homeless populations in Baltimore, MD area will be continued through a noncompetitive program expansion supplement to an existing grant award to Chase Brexton Health Services. This is a temporary award made because the previous grant recipient servicing this population is unable to satisfactorily meet legislative and program requirements. Chase Brexton, a currently funded Ryan White HIV/AIDS Program Part C grantee, is the best qualified and geographically positioned grantee able to provide the necessary continuity of HIV care and treatment for the targeted population. The initial supplemental funding will provide support for three months. Based on satisfactory performance, continued need, and availability of funds, a second and final supplemental award for these

services will be awarded for twelve months. Further funding beyond December 31, 2008, for this service area will be competitively awarded during the next Part C HIV Early Intervention Services (EIS) competing application process. The next available Part C EIS open competing cycle will occur in fiscal year 2009.

Dated: December 7, 2007.

Elizabeth M. Duke,
Administrator.

[FR Doc. E7-24437 Filed 12-14-07; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HOMELAND SECURITY

Office of the Chief Procurement Officer; Submission for Review; Information Collection Request for Various Contract Related Forms and Regulation on Agency Protests

AGENCY: Office of the Chief Procurement Officer, DHS.

ACTION: Notice; 30-day notice of information collections under review: Various contract related forms and Regulation on Agency Protests, OMB Control Number 1600-0002 and 1600-0004.

SUMMARY: The Department of Homeland Security (DHS) will submit the following proposed information collection request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995: 1600-0002 and 1600-0004. The