Because of the limited timeframes established by section 510(m) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation (21 CFR 10.115). The guidance represents the agency's current thinking on optical impression systems for CAD/CAM. 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 and regulations.

III. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**), written or electronic comments regarding this document. 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 brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The labeling provisions addressed in the guidance have been approved by OMB under the PRA under OMB control number 0910–0485.

V. Electronic Access

To receive a copy of ''Class II Special Controls Guidance Document: Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations; Guidance for Industry and FDA'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1203) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at http://www.fda.gov/cdrh. A search capability for all CDRH guidance documents is available at http://www.fda.gov/cdrh/guidance.html. Guidance documents are also available on the Dockets Management Branch Internet site at http://www.fda.gov/ohrms/dockets.

Dated: April 16, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–9870 Filed 4–21–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[HRSA–03–088]

Rural Access to Emergency Devices (RAED) Grant Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that of approximately $12,500,000 for fiscal year (FY) 2003 to provide grants for the purchase, placement and training in the use of automated external defibrillators (AEDs) and related activities in eligible rural areas. HRSA estimates that approximately 50 awards will be made to community partnerships, in collaboration with State Offices of Emergency Medical Services, for FY 2003. This is assuming one award per State. The project period will consist of three years, to include two non-competitive continuations for years two and three. All funding is subject to the availability of funds. These grants will be awarded under the authority of Pub. L. 106–505, Title IV—Cardiac Arrest Survival, Subtitle B—Rural Access to Emergency Devices, 42 U.S.C. 254c, note. The Office of Rural Health Policy will administer the Rural Access to Emergency Devices (RAED) Grant Program.

DATES: Applicants interested in applying for funding under this program are requested to fax or mail a letter of intent to the Office of Rural Health Policy by May 5, 2003, at fax number (301) 443–2803. Mailed letters of intent should be sent to Evan Mayfield, Office of Rural Health Policy, HRSA, Room 9A–55, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. A copy of this letter of intent should also be faxed or mailed to the appropriate State Office of Emergency Medical Services by this same date. The letter of intent need only include the lead applicant's organizational name, proposed number of AEDs requested and a proposed listing of those in their community partnership. The deadline for receipt of applications is June 18, 2003. Applications will be considered on time if they are either received on or before the deadline date in the HRSA Grants Application Center or postmarked on or before the deadline date.

ADDRESSES: To receive an application kit, applicants may telephone the HRSA Grants Application Center at (877) 477–2123 (877–HRSA–123) or the application forms can be downloaded via the Web at *http://www.ruralhealth.hrsa.gov/funding.htm.* The instructions for preparing the applications will be included with the grant guidance as part of the grant application kit. The RAED Grant Program uses PHS Forms 424 and 5161 for applications. Applicants must use the administrative code ''RAED,'' Catalog of Federal Domestic Assistance number 93.259 and HRSA Program Announcement number HRSA03–088 when requesting applications. The CFDA is a Government-wide compendium of enumerated Federal programs, projects, services and activities that provide assistance. All applications must be mailed or delivered to the Grants Management Officer, Office of Rural Health: HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg, MD 20879: telephone (877) 477–2123.

FOR FURTHER INFORMATION CONTACT: Evan Mayfield, Office of Rural Health Policy, HRSA, email address *ruralems@hrsa.gov,* telephone number

(301) 443–0835 and fax number (301) 443–2803.

SUPPLEMENTARY INFORMATION:

(1) Program Background and Objectives

The Rural Access to Emergency Devices Act, 42 U.S.C. 254c, note, authorizes grants to community partnerships to provide for the purchase, placement and training in the use of automated external defibrillators (AEDs) and related activities in eligible rural areas. An applicant must be a multi-county, regional or State-wide consortium of rural community organizations applying as a community partnership. Each community partnership must have a designated lead applicant to apply as the grantee of record and act as a fiscal agent for the partnership. Funding preference will be granted to applications that are State-wide in scope. Preference moves those approved applicants carrying the preference ahead of approved applicants without the preference. A funding priority will be given to State-wide community partnerships that identify their State Office of Emergency Medical Services as the lead applicant and include as partners emergency first response entities (*e.g.*, EMS, law enforcement and fire departments) that are currently operating without AEDs. Priority gives an application additional points during the scoring process of approved applications. In order to qualify as a State-wide community partnership, not every eligible county within the State need apply. However, a State-level office must be the lead applicant. Selected locations for AED placement around the State should be identified by the lead applicant to achieve fair geographical, organizational (*e.g.*, first response versus public access placement) and resource allocation.

The State Office of Emergency Medical Services is a logical lead applicant to administer funding to individual entities within the partnership, given its role in medical direction and regulation. Other State-level offices eligible to accept these Federal grant funds include the State Office of Rural Health or a division within the Department of Health. The State Office of Rural Health is a valuable resource for consulting in public access AED placement for those areas that lack EMS services, or are located too far away to be of practical benefit to a community. Community partnerships that apply without their State Office of Emergency Medical Services as the lead applicant are required to work with the State Office of Emergency Medical Services on issues related to medical direction and integration and placement of AEDs into existing EMS systems. Furthermore, such community partnerships must still demonstrate how they are State-wide in scope.

(2) Eligible Applicants

Applicants must apply in the form of a community partnership. Interested eligible entities are encouraged to collaborate with a wide range of other providers in developing a broad-based consortium that will make up their community partnerships. These partnerships will include local first response entities (*e.g.*, EMS, law enforcement and fire departments). In addition, local for- and non-profit entities that have a demonstrated concern about cardiac arrest survival rates may be included such as, but not limited to, community hospitals or clinics, nursing homes and senior citizen day care facilities, governmental facilities, athletic facilities, faith based and community based organizations and schools.

All services provided by the community partnership must be provided in an eligible rural county or Rural-Urban Commuting Area zip codes. Each State-level office, acting on behalf of the community partnership(s) within its State, will be required to demonstrate how its services will be directed to the eligible rural areas. A complete listing of these eligible rural areas is available on the Web. Eligible rural counties can be found at *http://www.ruralhealth.hrsa.gov/ruralcoI.htm* and Rural-Urban Commuting Area zip codes can be found at *http://www.ruralhealth.hrsa.gov/ruralcoZIPII.htm*. Each is sorted by State.

(3) Review Criteria

Applications should be no longer than 40 pages. Incomplete applications, applications in excess of the page limitation, or applications otherwise non-responsive will be returned without further review. Applications that are responsive will be evaluated for technical merit by an objective review panel convened specifically for this solicitation and in accordance with HRSA grants management policies and procedures. Applications will be assessed using the following criteria:

(a) Need for AED equipment and training with documentation using any local standard enumerating average response and transport times (or include a plan on how these times will be recorded if there are no pre-existing records of such) noting mileage to stabilizing and/or definitive care and cardiovascular mortality prevalence rates for the proposed response area(s);

(b) Plan for a need-based placement of AEDs and accessibility plan for those AEDs;

(c) Reasonableness of the proposed budget, including estimated AED purchasing, training and maintenance costs (include maintenance schedule);

(d) How the grant award will be distributed within the community partnership, with identified names of who will receive funding for each entity within the partnership;

(e) A listing of identified and approved CPR and AED training entities;

(f) A listing of who will use the AEDs, and a reference to State laws regulating AED usage;

(g) Integration into local EMS systems ensuring medical direction for documented protocols of care and legal oversight; and

(h) A well-defined data collection and reporting mechanism via their State Office of Emergency Medical Services or the State Office of Rural Health should the former be unable to participate.

A further explanation of these criteria will be included in the grant application guidance.

Use of Funds: RAED grant program funding shall be used to: (1) Purchase automated external defibrillators that have been approved, or cleared for marketing, by the Food and Drug Administration; and (2), provide defibrillator and basic life support training in automated external defibrillator usage through the American Heart Association, the American Red Cross, or other nationally recognized training courses.

Paperwork Reduction Act: The application form for the RAED Grant Program has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (Form–424). Should any of the data collection activities associated with this fall under the purview of the Paperwork Reduction Act of 1995, OMB clearance will be sought.

Public Health System Impact Statement: This program is subject to the Public Health System Reporting Requirements (approved under OMB No. 0937–0195). Under these requirements, the community-based non-governmental applicant must prepare and submit a Public Health System Impact Statement (PHSIS). The PHSIS is intended to provide information to State and local health officials to keep them apprized of proposed health services grant applications submitted by community-

based organizations within their jurisdictions.

Community-based non-governmental applicants are required to submit the following information to their local or State health authority, or State Office of Emergency Medical Services as appropriate, no later than the Federal application receipt due date of June 18, 2003:

(a) A copy of the face page of the application (SF 424)

(b) An abstract of the project not to exceed one page, which provides:

(1) A description of the population to be served,

(2) The proposed number of AEDs to be purchased and how many people will be trained within the community partnership,

(3) A description of the coordination planned with the appropriate State agencies (ranging from required notification of AED placement to such agency agreeing to being the lead applicant and/or fiscal agent of a State-wide community partnership should they choose to).

Executive Order 12372

This grant program is subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs by appropriate State and local officials as implemented by 45 CFR part 100. Executive Order 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. Applicants (other than Federally-recognized Indian tribal governments) should contact their State Single Point of Contact (SPOC), a list of which will be included in the application kit, as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. All SPOC recommendations should be submitted to Darren Buckner, Office of Grants Management, HIV/AIDS Bureau, 5600 Fishers Lane, Room 11A–16, Rockville, Maryland 20857, (301) 443–1913. The due date for State process recommendations is 60 days after the application deadline of June 18, 2003, for competing applications for the RAED Grant Program. The granting agency does not guarantee to ''accommodate or explain'' State process recommendations it receives after that date. See part 148 of the PHS Grants Administration Manual, Intergovernmental Review of PHS Programs under Executive Order 12372, and 45 CFR part 100 for a description of the review process and requirements.

Dated: February 4, 2003.

Elizabeth M. Duke,

Administrator.

[FR Doc. 03–9872 Filed 4–21–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Practitioner Data Bank: Change in User Fees

AGENCY: Health Resources and Services Administration, DHHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA), Department of Health and Human Services (DHHS), is announcing a seventy-five cent decrease in the fee charged to entities authorized to request information from the National Practitioner Data Bank (NPDB) for all queries. The new fee will be $4.25. There will be no change to the $10.00 self-query fee.

DATES: The new fee is effective on July 1, 2003.

FOR FURTHER INFORMATION CONTACT: John Heyob, Director, Division of Practitioner Data Banks, Bureau of Health Professions, Health Resources and Services Administration, 7519 Standish Place, Suite 300, Rockville, Maryland 20857. Tel: (301) 443–2300. Email: *policyanalysis@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The current fee structure ($5.00 per name) was announced in the **Federal Register** on July 11, 2001 (66 FR 36289) and became effective October 1, 2001. All entity queries are submitted and query responses received through the NPDB's Integrated Query and Reporting Service (IQRS) and paid via an electronic funds transfer or credit card.

The NPDB is authorized by the Health Care Quality Improvement Act of 1986 (the Act), Title IV of Pub. L. 99–660, as amended (42 U.S.C. 11101 *et seq.*). Section 427(b)(4) of the Act authorizes the establishment of fees for the costs of processing requests for disclosure and of providing such information.

Final regulations at 45 CFR part 60 set forth the criteria and procedures for information to be reported to and disclosed by the NPDB. Section 60.3 of these regulations defines the terms used in this announcement.

In determining any changes in the amount of the user fee, the Department uses the criteria set forth in § 60.12 (b) of the regulations, as well as allowable costs pursuant to Title II, Division G, Labor, Health and Human Services, Education, and Related Agencies Appropriation of the Consolidated Appropriations Resolution, 2003, Pub. L. 108–7, enacted on February 20, 2003. This Act requires that the Department recover the full costs of operating the Data Bank through user fees. Paragraph (b) of the regulations states:

''The amount of each fee will be determined based on the following criteria:

(1) Use of electronic data processing equipment to obtain information—the actual cost for the service, including computer search time, runs, printouts, and time of computer programmers and operators, or other employees, (2) Photocopying or other forms of reproduction, such as magnetic tapes—actual cost of the operator's time, plus the cost of the machine time and the materials used, (3) Postage—actual cost, and (4) Sending information by special methods requested by the applicant, such as express mail or electronic transfer—the actual cost of the special service.''

Based on analysis of the comparative costs of the various methods for filing and paying for queries, the Department is reducing all the entity query fees by $0.75 per name. The practitioner self-query fee remains at $10. This price decrease is justified after an evaluation of the Data Bank's operational costs. The implementation of the Data Bank's all-electronic process for querying, reporting, and payment, the Web-based IQRS system, has resulted in a decrease in the Data Bank operating expenditures. In keeping with the Act, and pursuant to the requirements of § 60.2 of the regulations, there are sufficient funds to recover the full costs of operating the Data Bank with a decrease in the user fee.

When a query is for information on one or more physicians, dentists, or other health care practitioners, the appropriate fee will be $4.25 multiplied by the number of individuals about whom information is being requested. For examples, see the table below.