

experience with the use of the 3500A for mandatory medical device reporting and the need to collect information found only on the baseline report led the agency in 1998 to propose a major modification to the medical device sections of the 3500A form.

Dated: April 24, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 03N-0158]

#### Specification for Annotated Electrocardiographic Waveform Data in Electronic Format; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting comments on proposed specifications for annotated electrocardiographic (ECG) waveform data in electronic format. The proposed specifications are described in a Health Level Seven (HL7) informative document.

**DATES:** Submit written or electronic comments on the specifications by May 29, 2003. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Copies of the specifications are available on the Internet at <http://www.hl7.org/V3AnnECG/index.htm>. Submit written comments on the specifications to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Norman Stockbridge, Center for Drug Evaluation and Research (HFD-110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5329, or e-mail: [stockbridgen@cdcr.fda.gov](mailto:stockbridgen@cdcr.fda.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA considers the results of ECG tests in evaluating the safety and efficacy of certain new drugs, biologics, and devices. Traditionally, FDA has reviewed only summary representations of ECG data for the analysis of the safety

and efficacy of products. The agency is interested in improving the evaluation of specific drug induced cardiac toxicity by reviewing ECG waveform data with detailed, sponsor generated annotations from the full spectrum of ECG devices, including 12-lead standard ECG, holter monitors, and implanted devices. On November 19, 2001, FDA held a public meeting to collect information regarding the content and format of annotated ECG waveform data that could be submitted to the agency in support of product applications.

Following the meeting, the Regulated Clinical Research Information Management Technical Committee (RCRIM) in HL7<sup>1</sup>, in association with the Clinical Data Interchange Standards Consortium (CDISC)<sup>2</sup>, investigated the technology necessary for the submission and review of this ECG data. The RCRIM then developed a model electronic format for the transportation of digital ECG waveform data, including annotations in the data message. The specifications on this annotated ECG waveform data message are provided in a proposed HL7 informative document. The document can be found on the HL7 Web site at <http://www.hl7.org/V3AnnECG/index.htm>.

##### II. Comments

We are interested in comments on the use of the proposed HL7 electronic format in providing annotated waveform ECG data to FDA in support of submissions for regulated products. Specifically, does the proposed message capture the appropriate level of detail about ECGs for assessment? Are there additions needed to the proposed controlled terminology? What are the issues concerning the creation of the HL7 message?

After FDA reviews any such comments concerning the HL7 proposal, the agency intends to issue a draft guidance setting forth its recommended electronic format for the submission of digital ECG waveform data. In those

<sup>1</sup>Founded in 1987, Health Level Seven, Inc., (HL7) ([www.hl7.org](http://www.hl7.org)), is a nonprofit, ANSI-Accredited Standards Developing Organization that provides standards for the exchange, management and integration of data that supports clinical patient care and the management, delivery and evaluation of healthcare services. Its 2,200 members represent over 400 corporate members, including 90 percent of the largest information systems vendors serving healthcare. HL7 international affiliates are active in Europe, Japan, Australia, Canada, New Zealand, and Southern Africa.

<sup>2</sup>CDISC, ([www.cdisc.org](http://www.cdisc.org)), is an open, multidisciplinary, nonprofit organization committed to the development of worldwide industry standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data and metadata for medical and biopharmaceutical product development.

instances when the agency requests that a regulated entity submit ECG data electronically concerning a product, the draft guidance would describe an appropriate electronic format for the submission. Interested parties would have an opportunity to submit comments on this recommended format in response to the draft guidance. FDA would consider any such comments before publishing a guidance.

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the proposed specification. Two paper copies of any mailed comments are to be submitted, 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. The proposed specifications 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 proposed specifications at <http://www.hl7.org/V3AnnECG/index.htm>.

Dated: April 21, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-10475 Filed 4-28-03; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### HRSA-03-097 Fiscal Year 2003 Competitive Application Cycle for the Nurse Education, Practice and Retention Grant Program Grants for Career Ladder Programs (CARL)—CFDA 93.359

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Health Resources and Services Administration (HRSA) announces that applications will be accepted for the Nurse Education, Practice and Retention Grant Program; Grants for Career Ladder Programs for Fiscal Year 2003.

*Purpose:* Grants will be awarded to eligible entities for programs—

(A) To promote career advancement for nursing personnel in a variety of training settings, cross training or specialty training among diverse

population groups, and the advancement of individuals including to become professional nurses, advanced education nurses, licensed practical nurses, certified nurse assistants, and home health aides;

(B) To assist individuals in obtaining education and training required to enter the nursing profession and to advance within such profession, such as by providing career counseling and mentoring.

**Authorizing Legislation:** These applications are solicited under the authority of title VIII, section 831 of the Public Health Service (PHS) Act, as amended.

**Statutory Matching or Cost Sharing Requirements:** None.

**Eligible Applicants:** The following are eligible entities: a school of nursing, a health care facility, or a partnership of such a school and facility, nursing centers, academic health centers, State or local governments, and other public and private non profit entities.

**Funding Priorities and/or Preferences:** As provided in section 805 of the Public Health Service Act, a funding preference will be applied to approved applications with projects that will substantially benefit rural or underserved populations, or help meet public health nursing needs in State or local health departments. This preference will be applied to applications that rank above the 20th percentile of applications recommended for approval.

**Administrative Funding Priority:** In making awards under this program a funding priority will be given to those projects that provide career paths leading to Registered Nurse licensure.

**Administrative Special Consideration:** Special consideration will be given to applicants that propose collaborative approaches for increasing the number of students in rural and underserved areas who can access educational opportunities through the use of electronic distance learning methodologies.

**Review Criteria:** Applications will be reviewed by a panel of peer reviewers using the following criteria:

- (a) A clearly stated project purpose;
- (b) A documented need for the proposed project;
- (c) The potential effectiveness of the proposed project;
- (d) A clearly articulated project plan including evaluation of project objectives;
- (e) A plan for addressing diversity and cultural competence;
- (f) A comprehensive plan for project management;
- (g) The reasonableness of the budget and fiscal plan;

(h) The presence of established and/or planned linkages with relevant entities.

Final review criteria are included in the application kit.

**Estimated Amount of Available Funds:** It is estimated that \$3 million will be available in fiscal year 2003.

**Estimated Number of Awards:** This is a new program; the estimated number of awards may range from 12 to 30 in fiscal year 2003.

**Estimated or Average Size of Each Award:** This is a new grant program; the estimated costs are expected to vary considerably with a range from \$100,000 to \$250,000.

**Estimated Project Period:** Applications may be submitted for 2 years, 10 months. The first budget period is September 1, 2003—June 30, 2004; the second and third budget periods are July 1, 2004—June 30, 2005 and July 1, 2005—June 30, 2006 respectively.

**Application Requests, Availability, Dates and Addresses:** Applicants for this program are encouraged to notify HRSA, Division of Nursing of their intent to apply. Notification can be made in one of three ways: call, e-mail or mail Dr. Madeline Turkeltaub of your intent. Telephone (301) 443-6334; e-mail [mturkeltaub@hrsa.gov](mailto:mturkeltaub@hrsa.gov); mail Division of Nursing, Bureau of Health Professions, HRSA, Parklawn Building, Room 9-36, 5600 Fishers Lane, Rockville MD 20857. Application materials will be available for downloading via the web at <http://bhpr.hrsa.gov/grants.htm> on April 29, 2003. Applicants may also request a hardcopy of the application material by contacting the HRSA Grants Application Center, 901 Russell Avenue, Suite 450, Gaithersburg, Maryland, 20879, by calling at 1-877-477-2123, or by fax at 1-877-477-2345. Applications may not be submitted electronically at this time. In order to be considered for competition, hard copy applications must be postmarked by the due date of June 6, 2003. Applicants should request a legibly dated U.S. Postal postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing. An application receipt will be provided. Applications submitted after the deadline date will be returned to the applicant and not processed.

**Projected Award Date:** September 1, 2003.

**FOR FURTHER INFORMATION CONTACT:** Madeline Turkeltaub, Division of Nursing, Bureau of Health Professions, HRSA, Room 9-36, Parklawn Building,

5600 Fishers Lane, Rockville, Maryland 20857. Central telephone is (301) 443-6193. E-mail: [mturkeltaub@hrsa.gov](mailto:mturkeltaub@hrsa.gov).

**Paperwork Reduction Act:** The Application for the Nurse Education, Practice and Retention Grant Program has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. The OMB clearance number is 00915-0060. The program is not subject to the provision of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100).

Dated: April 16, 2003.

**Elizabeth M. Duke,**  
Administrator.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### HRSA-03-096 Fiscal Year 2003 Competitive Application Cycle for the Nurse Education, Practice and Retention Grant Program Internship and Residency Programs (INRE)—CFDA 93.359

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Health Resources and Services Administration (HRSA) announces that applications will be accepted for the Nurse Education, Practice and Retention Grant Program; Grants for Internships and Residency Programs for Fiscal Year 2003.

**Purpose:** Grants will be awarded to eligible entities for programs to develop and implement internship and residency programs to encourage mentoring and the development of specialties.

**Authorizing Legislation:** These applications are solicited under the authority of title VIII, section 831 of the Public Health Service (PHS) Act, as amended.

**Statutory Matching or Cost Sharing Requirement:** None.

**Eligible Applicants:** The following are eligible entities: Schools of nursing, health care facilities, or a partnership of such a school and facility; academic health centers, State or local governments, and, other public and private non profit entities determined appropriate by the Secretary. Non profit (entities) means any school, agency, organization or institution which is a