

for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Joe McCallion, Office of Regulatory Affairs, Food and Drug Administration, (301) 443-6553 or Ted Poplawski, Office of Regulatory Affairs, Food and Drug Administration, (301) 443-6553.

#### SUPPLEMENTARY INFORMATION:

### I. Background

FDA is announcing the availability of CPG Sec. 110.310 entitled "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002." This guidance is issued jointly with CBP and explains to FDA and CBP staff the FDA and CBP policies on enforcement of section 307 of the Bioterrorism Act and its implementing regulations, which require, beginning on December 12, 2003, prior notice to FDA of all food imported or offered for import into the United States. (68 FR 58974 (Oct. 10, 2003) (to be codified at 21 CFR 1.276-1.285).)

FDA is issuing this document as level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The CPG Sec. 110.310 is being implemented immediately without prior public comment, under § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. Under section 307 of the Bioterrorism Act, the prior notice requirements are effective December 12, 2003, making it urgent that the agencies explain how they intend to enforce those requirements.

### II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance document. Submit two copies of written comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### III. Electronic Access

An electronic version of this guidance is available on the Internet at <http://www.fda.gov/ora> under "Compliance References."

Dated: December 10, 2003.

**John M. Taylor, III,**

*Associate Commissioner for Regulatory Affairs, Food and Drug Administration.*

**Jayson P. Ahern,**

*Assistant Commissioner, Office of Field Operations, U.S. Customs and Border Protection.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Recruitment of Sites for Assignment of Corps Personnel

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

**ACTION:** General notice.

**SUMMARY:** The Health Resources and Services Administration (HRSA) announces that the listing of entities, and their Health Professional Shortage Area (HPSA) scores, that will receive priority for the assignment of National Health Service Corps (NHSC) personnel (Corps Personnel) for the period July 1, 2003, through June 30, 2004, is posted on the NHSC Web site at <http://nhsc.bhpr.hrsa.gov/resources/fedreg-hpol/>. This list specifies which entities are eligible to receive assignment of Corps members who are participating in the NHSC Scholarship Program; the NHSC Loan Repayment Program; and Corps members who have become Corps members other than pursuant to contractual obligations under the Scholarship or Loan Repayment Programs. Please note that not all vacancies associated with sites on this list will be for Corps members, but could be for individuals serving an obligation to the NHSC through the Private Practice Option.

#### Eligible HPSAs and Entities

To be eligible to receive assignment of Corps personnel, entities must: (1) Have a current HPSA designation by the Shortage Designation Branch in the National Center for Workforce Analysis, Bureau of Health Professions, Health Resources and Services Administration; (2) enter into an agreement with the State agency that administers Medicaid, accept payment under Medicare 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; and (3) be determined by the Secretary to have (a) a need and demand for health

manpower in the area; (b) appropriately and efficiently used Corps members assigned to the entity; (c) general community support for the assignment of Corps members; (d) made unsuccessful efforts to recruit; and (e) a reasonable prospect for sound fiscal management by the entity with respect to Corps members assigned there. Priority in approving applications for assignment of Corps members goes to sites that (1) provide primary, mental or oral health services to a HPSA of greatest shortage; (2) are part of a system of care that provides a continuum of services, including comprehensive primary health care and appropriate referrals or arrangements for secondary and tertiary care; (3) have a documented record of sound fiscal management; and (4) will experience a negative impact on its capacity to provide primary health services if a Corps members is not assigned to the entity.

Entities that receive assignment of Corps personnel must assure that (1) the vacancy will permit the full scope of practice and that the clinician meets the credentialing requirements of the State and site; and (2) the Corps member assigned to the entity is engaged in full-time clinical practice for a minimum of 40 hours per week with at least 32 hours in the ambulatory care setting. Obstetricians/gynecologists and certified nurse midwives (CNMs) are required to engage in a minimum of 21 hours per week of outpatient clinical practice. The remaining hours, making up the 40-hour per week total, include delivery and other clinical hospital-based duties. Time spent on-call does not count toward the 40 hours per week. In addition, sites receiving assignment of Corps personnel are expected to (1) report to the NHSC all absences in excess of the authorized number of days (up to 35 days or 280 hours); (2) report to the NHSC any change in the status of an NHSC clinician at the site; (3) provide the time and leave records, schedules, and any related personnel documents (including documentation, if applicable, of the reason(s) for the termination of an NHSC clinician's employment at the site prior to his or her obligated service end date); and (4) submit a Uniform Data System (UDS) report. This system allows the site to assess the age, sex, race/ethnicity and provider encounter records for its user population. The UDS reports are site specific. Providers fulfilling NHSC commitments are assigned to a specific site or, in some cases, more than one site. The scope of activity to be reported in UDS includes all activity at the site(s) to which the Corps member is assigned.

### Evaluation and Selection Process

In approving applications for the assignment of Corps members, the Secretary shall give priority to any such application that is made regarding the provision of primary health services to a health professional shortage area with the greatest such shortage. For the program year July 1, 2003–June 30, 2004, HPSAs of greatest shortage for determination of priority for assignment of Corps personnel will be defined as follows: (1) Primary care HPSAs with a score of 14 and above are authorized for the assignment of Corps members who are family nurse practitioners or primary care physicians participating in the Scholarship Program; (2) mental health HPSAs with a score of 18 and above are authorized for the assignment of Corps members who are physician psychiatrists participating in the Scholarship Program; (3) dental HPSAs with a score of 18 and above are authorized for the assignment of Corps members who are dentists participating in the Scholarship Program; (4) all primary care HPSAs are authorized for the assignment of Corps members who are physician assistants (PAs) or CNMs participating in the Scholarship Program; and (5) HPSAs (appropriate to each discipline) with scores of 14 and above will receive authorization for the assignment of Corps members who are participating in the Loan Repayment Program. HPSAs with scores below 14 will be eligible to receive assignment of Corps personnel participating in the Loan Repayment Program only after assignments are made of those Corps members matching to those HPSAs receiving the priority for placement of Corps members through the Loan Repayment Program. Placements made through the Loan Repayment Program in HPSAs with scores 13 or below will be made by decreasing HPSA score, only to the extent funding remains available. All sites on the list are eligible sites for individuals wishing to serve in an underserved area but who are not contractually obligated under the Scholarship or Loan Repayment Program. A listing of HPSAs and their scores is posted at <http://belize.hrsa.gov/newhpsa/newhpsa.cfm>.

Sites qualifying for an automatic HPSA designation are currently unscored. A methodology to score these automatic HPSAs is currently being developed. Sites on the list with an unscored HPSA designation are authorized for the assignment of Corps personnel who are PAs or CNMs participating in the Scholarship Program. Unscored HPSAs are eligible to receive assignment of Corps

personnel participating in the Loan Repayment Program only after assignments are made of those Corps members matching to scored HPSAs. When automatic HPSAs receive scores, these sites will then be authorized to receive assignment of Corps members if they meet the criteria outlined above and their newly assigned scores are above the stated cutoffs.

The number of new NHSC placements through the Scholarship and Loan Repayment programs allowed at any one site are limited to the following:

#### (1) Primary Health Care

(a) *Loan Repayment Program*—no more than 2 physicians (MD or DO); and no more than a combined total of 2 nurse practitioners (NPs), PAs, or CNMs.

(b) *Scholarship Program*—no more than 2 physicians (MD or DO); and no more than a combined total of 5 NPs, PAs or CNMs.

#### (2) Dental

(a) *Loan Repayment Program*—no more than 2 dentists and 2 dental hygienists.

(b) *Scholarship Program*—no more than 1 dentist.

#### (3) Mental Health

(a) *Loan Repayment Program*—no more than 2 psychiatrists (MD or DO); and no more than a combined total of 2 clinical or counseling psychologists; licensed clinical social workers, licensed professional counselors, marriage and family therapists, or psychiatric nurse specialists.

(b) *Scholarship Program*—no more than 2 psychiatrists.

### Application Requests, Dates and Address

The list of HPSAs and entities that are eligible to receive priority for the placement of Corps personnel may be updated periodically. Entities that no longer meet eligibility criteria, including HPSA score, will be removed from the priority listing. Entities interested in being added to the high priority list must submit an NHSC Recruitment and Retention Assistance Application to: National Health Service Corps, 5600 Fishers Lane, Room 8A-55, Rockville, MD 20857, fax 301-594-2721. These applications must be submitted on or before the deadline date of March 26, 2004. Applications submitted after this deadline date will be considered for placement on the priority placement list in the following program year. Any changes to this deadline will be posted on the NHSC Web site at <http://nhsc.bhpr.hrsa.gov>.

### Additional Information

Entities interested in receiving application materials may do so by calling the NHSC call center at 1-800-221-9393. They may also get information and download application materials from: <http://nhsc.bhpr.hrsa.gov/applications/rraa.cfm>.

Entities wishing to provide additional data and information in support of their inclusion on the high priority placement list, must do so in writing no later than January 14, 2004. This information should be submitted to the National Health Service Corps, 5600 Fishers Lane, Room 8A-55, Rockville, MD 20857. This information will be considered in preparing the final list of HPSAs and entities eligible to receive priority for the assignment of Corps personnel.

*Paperwork Reduction Act:* The Recruitment & Retention Assistance Application has been approved by the Office of Management and Budget under the Paperwork Reduction Act. The OMB clearance number is 0915-0230.

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: December 9, 2003.

**Elizabeth M. Duke,**  
Administrator.

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### DEPARTMENT OF HOMELAND SECURITY

#### Coast Guard

[USCG-2003-16675]

#### Random Drug-Testing Rate for Covered Crewmembers; Calendar Year 2004

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of minimum random drug-testing rate.

**SUMMARY:** The Coast Guard has set the calendar year 2004 minimum random chemical drug-testing rate at 50 percent of covered crewmembers. An evaluation of the 2002 Management Information System (MIS) data collection forms submitted by marine employers showed that random drug testing on covered crewmembers for the calendar year 2002 resulted in positive test results 1.63 percent of the time. Therefore, we will maintain the minimum random drug-testing rate at 50 percent of covered