

be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: November 1, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-28722 Filed 11-4-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0690]

#### Product Shortage Report; Availability; Request for Comments

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

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

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a medical product shortage report entitled "A Review of FDA's Approach to Medical Product Shortages." The Agency is making the report available by placing it in the docket opened for a previous public workshop on drug shortages. The report discusses the Agency's approach to product shortages, particularly those products regulated by the FDA Center for Drug Evaluation and Research (CDER). FDA requests comments, until December 23, 2011, on the report and its recommendations, including whether there are additional suggestions for recommendations and how we should prioritize work on these recommendations.

**DATES:** Submit either electronic or written comments by December 23, 2011.

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

**FOR FURTHER INFORMATION CONTACT:** Peter Lurie, Office of Policy and Planning, Food and Drug

Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4220, Silver Spring, MD 20993-0002, (301) 796-4800.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the *Federal Register* of September 29, 2011 (76 FR 60505), FDA opened a comment period for a public workshop notice which published in the *Federal Register* of July 28, 2011 (76 FR 45268). This document announces the availability of a product shortage report by placing it in the docket of the public workshop on drug shortages. This report provides background information on product shortages, discusses four FDA product centers' various approaches to addressing product shortages, particularly those in CDER, and includes recommendations for FDA and others. FDA is requesting comment on the report and its recommendations, including whether there are additional suggestions for recommendations and how we should prioritize work on these recommendations.

##### II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. 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

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm275051.htm> or <http://www.regulations.gov>.

Dated: October 31, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-28723 Filed 11-4-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Proposed Eligibility Criteria for the Centers of Excellence Program in Health Professions Education for Under-Represented Minority Individuals

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

**ACTION:** Notice.

**SUMMARY:** This notice requests comments on proposed eligibility criteria for the Centers of Excellence (COE) program in health professions education for under-represented minority (URM) individuals (See Title VII, Section 736 of the Public Health Service Act, 42 U.S.C. 293 (2011) as amended by the Patient Protection and Affordable Care Act, Public Law 111-148, § 5401 (2010)). When finalized, these eligibility criteria will be used to determine the eligibility of designated health professions schools to apply for COE funding in fiscal year (FY) 2012 and subsequent fiscal years. Funding is dependent on the availability of appropriated funds for the COE program. The designated health professions schools are schools of allopathic medicine, osteopathic medicine, dentistry, pharmacy, and graduate programs in behavioral or mental health. This does not apply to Historically Black Colleges and Universities (HBCUs) eligible to establish a COE, under PHS Act section 736(c)(2).

**DATES:** Interested persons are invited to comment within 30 days of the publication of this notice. All comments received on or before those 30 days complete will be considered.

**ADDRESSES:** All written comments concerning this notice should be submitted to Dr. Joan Weiss, Director, Division of Public Health and Interdisciplinary Education, at the contact information below.

**FOR FURTHER INFORMATION CONTACT:** Anyone requesting additional details should contact Dr. Joan Weiss, Bureau of Health Professions, Health Resources and Services Administration. Dr. Weiss may be reached in one of three following methods: (1) Via written request to: Dr. Joan Weiss, Designated Federal Official, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 9-36, 5600 Fishers Lane, Rockville, Maryland 20852; (2) via

telephone at (301) 443-6950; or (3) via email at [jweiss@hrsa.gov](mailto:jweiss@hrsa.gov).

**SUPPLEMENTARY INFORMATION:**

*Purpose:* The COE program supports programs of excellence in health professions education for URM individuals in designated health professions schools. The categories of designated health professions schools subject to this notice are: (1) Hispanic, (2) Native American, and (3) "Other" health professions schools that meet the program requirements. Centers of Excellence provide academic enhancement programs to URM individuals; develop a large and competitive applicant pool to pursue health professions careers; and improve the capacity of schools to recruit, train, and retain URM faculty. The COE program facilitates faculty and student research on health issues particularly affecting URM groups. In addition, the program carries out activities to improve information resources, clinical education, curricula and cultural competence of schools' graduates relating to minority health issues. Training students to provide health services to a significant number of URM individuals at community-based health facilities and providing financial assistance, as available and appropriate, are also required.

*Eligibility Criteria:* To be eligible for funding, the PHS Act requires designated health professions schools to meet each of four criteria. The schools must: (1) Have a significant number of URM students enrolled, including individuals accepted for enrollment; (2) have been effective in assisting URM students to complete their educational program and receive the degree involved; (3) have been effective in recruiting URM students to enroll in and graduate from the school, including providing scholarships and other financial assistance and encouraging URM students at all levels of the educational pipeline to pursue health professions careers; and (4) have made significant recruitment efforts to increase the number of URM individuals serving in faculty or administrative positions at the school.

The COE program aims to support institutions with a commitment to URMs, which includes demonstrated effectiveness in recruiting, teaching, training, and retaining current and future URM health professionals, both as practitioners and as faculty. This announcement details the proposed approach that the Secretary will use to assess whether schools and other eligible entities meet the eligible criteria defined in statute. Beginning in FY

2012, the following approach will be used to assess whether applicants meet eligibility criteria.

*A. Criterion one:* The school must have a significant number of URM students enrolled in the designated health professions education program. The Secretary will determine the significant number for Hispanic and Native American COEs based on a percentage of the current number of URM students enrolled in these schools. This determination is unnecessary, however, for HBCUs because they meet the significant number condition by virtue of their definition. With respect to the eligible "Other" COE health professions schools, the PHS Act requires these schools to have a current enrollment of URMs above the national average.

*B. Criterion two:* The second criterion requires designated health professions schools to be effective in assisting its URM students to successfully complete the program of education and to receive the appropriate professional degree. Graduation rates are calculated, determined, and provided by health professions schools applying for COE funding. To account for varying class sizes across the health professions schools, the graduation rate eligibility thresholds for Hispanic, Native American, and "Other" COEs in the designated health professions will be determined using the following procedure:

1. Health professions schools and programs will be ranked according to the percentage of URMs (e.g., Hispanic, Native American, or "Other") successfully graduating from such health professions schools or programs with degrees each year, as calculated by the total number of URM students graduating from the health professions school with degrees divided by the total number of students graduating with degrees in a given health professions school.

2. The top quartile (75th percentile) will serve as the eligibility threshold for Hispanic, Native American, and "Other" COE applicants.

3. The Integrated Postsecondary Education Data System (IPEDS) Completions survey will provide the raw data for threshold analysis. IPEDS is a system of interrelated completed surveys conducted annually by the U.S. Department of Education's National Center for Education Statistics (NCES). The IPEDS collects data on postsecondary education in the United States, including the number of students who complete a postsecondary education program by type of program and level of award (certificate or

degree). The IPEDS is available at <http://nces.ed.gov/ipeds/datacenter/DataFiles.aspx>. Separate thresholds will be calculated and established for each of the following four categories: Allopathic and osteopathic medicine; pharmacy; dentistry; and, behavioral or mental health.

Individual schools will be responsible for calculating their percentage of URM graduates with degrees. Schools' graduation rate percentages will be compared to the thresholds established through the methodology described above. If a school meets or exceeds the threshold, it will meet the graduation eligibility criterion for the COE program. To calculate their URM graduation percentage, health professions schools would:

1. Sum the appropriate URM (Hispanic, Native American, or "Other") population that completed and successfully graduated from the health professions school with degrees across the most recent three years (A).

2. Sum the total student population that completed and successfully graduated from the health professions school with degrees across the most recent three years (B).

3. Divide A by B to arrive at the average designated URM percentage of successful graduates from the health professions schools with degrees across the past three years.

To be eligible for the COE program, Hispanic, Native American and "Other" applicants must meet or exceed the proposed graduation thresholds. The proposed graduation threshold in each of the eligible fields of study is the 75th percentile of URM graduation rates as reported to the IPEDS. The 75th percentile was determined based on an analysis of the IPEDS Completions survey of 2009 data within the appropriate field of study, as defined by the Classification of Instructional Program (CIP) code system. The CIP is the accepted federal government statistical standard on instructional program classifications. The "Total Programs" per discipline represents the number of programs reporting a completions rate for the given CIP code in the U.S. within the IPEDS system.

**Proposed Graduation Rate Eligibility Thresholds**

The analysis would be as follows:

*Allopathic And Osteopathic Medicine Programs (Doctors of Medicine, Doctors of Osteopathy)*

Total Programs Reported in IPEDS = 142.

Hispanic graduation rate eligibility threshold = 6.3 percent.

Native American graduation rate eligibility threshold = 1.0 percent.  
 "Other" COE graduation rate eligibility threshold = 14.1 percent.

*Dentistry (Doctors of Dental Surgery, Doctors of Dental Medicine)*

Total Programs Reported in IPEDS = 59.  
 Hispanic graduation rate eligibility threshold = 7.1 percent.  
 Native American graduation rate eligibility threshold = 1.4 percent.  
 "Other" COE graduation rate eligibility threshold = 13.5 percent.

*Pharmacy (Doctor of Pharmacy)*

Total Programs Reported in IPEDS = 94.  
 Hispanic graduation rate eligibility threshold = 3.5 percent.  
 Native American graduation rate eligibility threshold = 0.5 percent.\*  
 Other COE graduation rate eligibility threshold = 10.0 percent.

*Behavioral or Mental Health*

Total Programs Reported in IPEDS = 1928.  
 Hispanic graduation rate eligibility threshold = 7.7 percent.  
 Native American graduation rate eligibility threshold = 0.66 percent.\*  
 Other COE graduation rate eligibility threshold = 26.1 percent.

\* Due to the limited number of Native Americans graduating with a Doctor of Pharmacy or a graduate degree in Behavioral or Mental Health from the school of discipline, the proposed graduation rate eligibility threshold for these two disciplines is based on the mean percentage and not on the 75 percentile of Native Americans graduating with the required degree.

*C. Criterion three:* The third criterion requires designated health professions schools to have effectively recruited URMs, including providing scholarships and other financial assistance for individuals enrolled in the school, and encouraging URM students from all levels of the education pipeline to pursue health professions careers. Such schools are responsible for establishing criteria for financial assistance, selecting recipients within the Centers of Excellence program, and making reasonable determinations of need for the level of financial assistance for the recipients. Each school will independently develop the criteria to receive financial assistance, submit this information in their application, where it collectively will be objectively reviewed by the peer review panel. The availability of financial assistance, as formulated by the health professions school, is designed to assist in increasing the level of URM health professionals who successfully complete the program, as well as

increase their intent to practice in underserved areas.

*D. Criterion four:* The fourth criterion requires designated health professions schools to have made a significant recruitment effort to increase the number of URM individuals serving in faculty or administrative positions at the school. A major COE program focus is to improve the capacity of the school to train, recruit, and retain URM faculty and administrative personnel. A health professions school should demonstrate over a 5-year period a "significant effort" to recruit and retain URM faculty and administrative positions based on the number of URM faculty and new URM hires.

The catalog of Federal Domestic Assistance Number for the COE program is 93.157. This program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100). Further, these programs are not subject to the Public Health Systems Reporting Requirements. The Centers of Excellence Program application is approved under OMB No. 0915-0060.

Dated: November 1, 2011.

**Mary K. Wakefield,**  
*Administrator.*

[FR Doc. 2011-28670 Filed 11-4-11; 8:45 am]

**BILLING CODE 4165-15-P**

---

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[USCG-2011-1014]

#### Information Collection Requests to Office of Management and Budget

**AGENCY:** Coast Guard, DHS.

**ACTION:** Sixty-day notice requesting comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit Information Collection Requests (ICRs) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collections of information: 1625-0028, Course Approval and Records for Merchant Marine Training Schools and 1625-0069, Ballast Water Management for Vessels with Ballast Tanks Entering U.S. Waters. Our ICRs describe the information we seek to collect from the public. Before submitting these ICRs to OIRA, the

Coast Guard is inviting comments as described below.

**DATES:** Comments must reach the Coast Guard on or before January 6, 2012.

**ADDRESSES:** You may submit comments identified by Coast Guard docket number [USCG-2011-1014] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT). To avoid duplicate submissions, please use only one of the following means:

(1) *Online:* <http://www.regulations.gov>.

(2) *Mail:* DMF (M-30), DOT, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001.

(3) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 366-9329.

(4) *Fax:* (202) 493-2251. To ensure your comments are received in a timely manner, mark the fax, to attention Desk Officer for the Coast Guard.

The DMF maintains the public docket for this Notice. Comments and material received from the public, as well as documents mentioned in this Notice as being available in the docket, will become part of the docket and will be available for inspection or copying at room W12-140 on the West Building Ground Floor, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find the docket on the Internet at <http://www.regulations.gov>.

Copies of the ICRs are available through the docket on the Internet at <http://www.regulations.gov>. Additionally, copies are available from: Commandant (CG-611), Attn Paperwork Reduction Act Manager, US Coast Guard, 2100 2nd St. SW Stop 7101, Washington DC 20593-7101.

**FOR FURTHER INFORMATION CONTACT:** Contact Ms. Kenlinishia Tyler, Office of Information Management, telephone (202) 475-3652, or fax (202) 475-3929, for questions on these documents. Contact Ms. Renee V. Wright, Program Manager, Docket Operations, (202) 366-9826 for questions on the docket.

**SUPPLEMENTARY INFORMATION:**

**Public Participation and Request for Comments**

This Notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains