

submissions may be made to the contact person on or before March 22, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 14, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 15, 2012.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kalyani Bhatt at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 3, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### 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:** Final Notice.

**SUMMARY:** The Centers of Excellence (COE) program in health professions education for under-represented minority (URM) individuals is authorized by section 736 of the Public Health Service Act (PHS Act), 42 U.S.C. 293 (2011). The purpose of this final notice is to inform interested individuals of the criteria that 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. The Supplementary Information in this Notice provides a brief synopsis of the public comments that the Health Resources and Services Administration (HRSA) received on the updates to the proposed eligibility criteria in response to the November 7, 2011 **Federal Register** Notice, specifically addressing: 1) the proposed graduation threshold eligibility criteria, 2) the COE eligibility criteria in general, and 3) the purpose of the COE program as authorized by the PHS Act.

**DATES:** *Effective Date:* February 9, 2012.

**FOR FURTHER INFORMATION CONTACT:** Dr. Joan Weiss, Director, Division of Public Health and Interdisciplinary Education, 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:

##### Background

For more than 20 years, the COE program has supported programs of excellence in health professions education for under-represented minority (URM) individuals in designated health professions schools. The authorized categories of designated health professions schools are: (1) Designated Historically Black Colleges and Universities (HBCUs), (2) Hispanic, (3) Native American, and (4) "other" health professions schools that meet the program requirements. COEs 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. COEs also train students to provide health services to URM individuals at community-based health facilities and provide financial assistance, as available and appropriate. To be eligible for funding, the PHS Act requires designated schools to meet each of four general conditions. The schools must: (1) Have a significant number of URM individuals enrolled in the school, including individuals accepted for enrollment in the school; (2) have been effective in assisting URM students of the school to complete the program of education and receive the degree involved; (3) have been effective in recruiting URM individuals to enroll in and graduate from the school, including providing scholarships and other financial assistance to such individuals and encouraging URM students from 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 (See PHS Act, Section 736(c)(1)(B)(i)-(iv)).

##### 1. Proposed Graduation Threshold Eligibility Criteria

The **Federal Register** Notice (FRN), published November 7, 2011, updated the eligibility criteria and requires eligible health professions schools to demonstrate effectiveness in assisting URM students to successfully complete the program of education and receive the appropriate degree. The eligibility criteria requires applicants to meet or exceed a specified minimum number of URM students graduating with appropriate degrees. Graduation rates are calculated and provided by health professions schools applying for COE funding. To account for varying class sizes across the landscape of health professions schools, the threshold percentage for Hispanic, Native American, and "Other" COEs within the designated health professions will be determined 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. The percentage representing the cut-off point for the top quartile (75th percentile) will serve as the minimum percentage that Hispanic, Native American, and "Other" COEs must meet.

One commenter requested removing the graduation rate as an eligibility requirement, and instead using it as one factor to evaluate a school's qualifications for a COE grant due to the number of medical schools that have recently opened and are undergoing accreditation and do not yet have a graduating class to meet the graduation threshold. However, section 736(c)(1)(B)(ii) of the PHS Act requires health professions schools to demonstrate that they have "been effective in assisting under-represented minority students of the school to complete the program of education and receive the degree involved." Newly opened health professions schools that are undergoing accreditation may be unable to meet this statutory requirement.

Another commenter expressed concern that the graduation threshold gives preference to institutions in the top quartile nationally for graduating URM students and may encourage institutions that have data below the threshold to inappropriately expand the number. The previous COE funding opportunity announcement (FY 2009) provided that, "[t]he reviewers will determine if the health professions school has been effective in assisting URM students of the school to complete the program of education and receive the degree involved. Reviewers will verify that the applicant school meets the required URM graduation rate of at least 85% over 4 or 5 years. If the applicant is a Native American COE, reviewers will verify that the applicant school has a URM graduation rate of at least 75%." The criterion implements a statutory provision requiring effectiveness in assisting URM students to complete their degree programs, and we believe that the current formulation serves to standardize the minimum threshold by setting it at 75 percent. If the result is an increase in the graduation rate, that would be consistent with the goals of the program.

One commenter noted that the word "its" that was in the 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" disconnects the intent of the criterion from the calculation. To avoid miscommunication on the intent of graduation threshold criteria and calculation, the word "its" is not used in this context in this Final Notice and will not be used when this criteria is reiterated in the COE funding opportunity announcement.

## 2. COE Eligibility Criteria in General

The general conditions of a designated health professions school to be eligible for COE funding, as authorized by the PHS Act, Title VII, Section 736, include meeting the four criteria mentioned previously in the Background section. A public comment recommended deleting part or all of the first, third, and fourth eligibility criteria. Because the statute clearly states these four conditions are required for eligible applicants to receive COE funding, none can be deleted, partially or in full.

## 3. Authorized Purpose and Intent of COE Program

Another commenter raised concern about the underlying statute, rather than the proposed criteria; these concerns are beyond the scope of this notice. The COE program, first authorized by Public Law 100-97 ("Excellence in Minority Health Education and Care Act") in 1987, funds minority health professions schools to recruit, retain, and graduate URM students to increase the supply and quality of URM students in the health professions workforce. As demonstrated by national data sources, there continues to be a low number of URM students applying to U.S. medical schools (<https://www.aamc.org/download/161338/data/table15.pdf>) and a low number in the physician workforce (AAMC, *Diversity in the Physician Workforce, Facts and Figures 2010*; Figure 14, p. 30). Due to the challenges in recruiting and graduating a critical mass of URM students to increase diversity in the health professions workforce, the eligibility criteria for eligible health professions schools for COE funding remains as defined in the authorizing statute.

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: February 2, 2012.

**Mary K. Wakefield,**

*Administrator, Health Resources and Services Administration.*

For the reasons stated above, the Health Resources and Services Administration (HSRA) is adopting the Proposed Notice, published at 76 FR 0215 on Monday, November 7, 2011, as

a Final Notice with the change to clarify Criterion Two.

**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. COEs also train students to provide health services to URM individuals at community-based health facilities and provide financial assistance, as available and appropriate.

**Eligibility Criteria:** To be eligible for funding, the Public Health Service Act requires designated 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 URM students, including having 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 would 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 Act requires these schools to have a current enrollment of URM students above the national average.

*B. Criterion two:* The second criterion requires designated health professions schools to be effective in assisting 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 URM students (*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 threshold and eligibility percentage for Hispanic, Native American, and "Other" COE applicants.

3. The Integrated Postsecondary Education Data System Completions survey will provide the raw data for threshold analysis. The Integrated Postsecondary Education Data System (IPEDS) is a system of interrelated completed surveys conducted annually by the U.S. Department of Education's National Center for Education Statistics (NCES). 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. Each school's graduation rate percentage 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 completion 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 75th percentile of Native Americans graduating with the required degree.

*C. Criterion three:* The third criterion requires designated health professions schools to have effectively recruited URM students, 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.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Proposed Collection; Comment Request: Information Program on Clinical Trials; Maintaining a Registry and Results Databank**

*Summary:* In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) to provide opportunity for public comment on proposed data collection projects, the National Library of Medicine (NLM), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

#### **Proposed Collection**

*Title:* Information Program on Clinical Trials: Maintaining a Registry and Results Databank.

*Type of Information Collection Request:* Revision of OMB No. 0925-0586, expiration date April 30, 2012.

*Form Number:* NA.

*Need and Use of Information Collection:* The National Institutes of Health operates ClinicalTrials.gov, which was established as a clinical trial registry under section 113 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) and was expanded to include a results data bank by Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA). ClinicalTrials.gov collects registration and results information for clinical trials and other types of clinical studies (e.g., observational studies and patient

registries) with the objectives of enhancing patient enrollment and providing a mechanism for tracking subsequent progress of clinical studies, to the benefit of public health. It is widely used by patients, physicians, and medical researchers; in particular those involved in clinical research. While many clinical studies are registered voluntarily, FDAAA requires the registration of certain applicable clinical trials of drugs and devices and the submission of results information for completed applicable clinical trials of drugs and devices that are approved, licensed, or cleared by the Food and Drug Administration. Beginning in 2009, results information was required to include information about serious and frequent adverse events. As the existing PRA clearance for this information collection nears expiration, we are making a limited number of revisions to include additional data elements that may be voluntarily submitted to describe and aid in the interpretation of any submitted adverse event information and to facilitate the registration of patient registries.

*Frequency of Response:* For clinical trials that are subject to FDAAA, responsible parties must submit the required registration information not later than 21 days after enrolling the first subject. Results information is to be submitted not later than 12 months after the completion date (as defined in the law), but can be delayed under certain circumstances. Updates to most submitted information are required at least once a year, if there are changes to report, but changes in recruitment status and completion of a trial must be reported not later than 30 days after such events. Other clinical studies register once, at their inception, and are requested to update information annually, as necessary.

*Description of Respondents:* Respondents include sponsors or principal investigators of clinical studies. Those subject to FDAAA are referred to as "responsible parties," which are defined as sponsors of the clinical trial (as defined in 21 CFR 50.3) or designated principal investigators who meet requirements specified in the law.

*Estimate of Burden:* The burden associated with this information collection consists of the burden associated with registration of clinical studies and the burden associated with the submission of results information (including adverse events). These information collections will occur at different times, but submitted information is integrated into a single record for each clinical trial. To estimate

the annual reporting burden for registration, we examined the number of clinical studies registered annually with ClinicalTrials.gov and found an average of 17,000 registrations per year since the enactment of FDAAA. From this total, we estimate that approximately 5,000 studies would be applicable clinical trials of drugs (including biological products) and 500 would be applicable trials of devices subject to FDAAA. The remaining 11,500 studies would be registered voluntarily. We estimate the time to complete an initial registration to be 7 hours (including time to extract, reformat and submit information which has already been produced for other purposes). This estimate is consistent with that used on the previous PRA clearance and incorporates 4 hours for data extraction and 3 hours for reformatting. Based on previous experience, we estimate that each registration record will be updated an average of eight times and that each update takes approximately 2 hours. Applying these figures to the estimated number of trials to be registered per year produces an annual burden estimate of 391,000 hours. Of this total, 126,500 hours are associated with the mandatory registration of trials subject to FDAAA, and 264,500 hours are associated with voluntary registrations.

The burden of results submission consists of the time and effort needed to summarize information from a clinical trial, format it, and enter it into the databank. We estimate that of the 5,500 applicable clinical trials that are registered each year, approximately 1,845 will be required to submit results each year (1,500 trials of drugs and biological products, and 345 trials of devices). We estimate that each results record will be submitted once and updated twice to reflect changes in the data analysis, additional results of subsequent pre-specified outcome measures, or additional adverse event information. Based on information available from various organizations about results submission times, comments made at a public meeting held in April 2009, responses to estimates in previous OMB clearance documents (73 FR 58972, Oct. 8, 2008), and feedback from respondents who have submitted results to ClinicalTrials.gov, we have increased our estimate of the average response time to 25 hours from the 10 hour estimate included in the previous OMB clearance request. We estimate that updates take 8 hours, an increase over the 5 hour estimate included in the previous OMB clearance request for adverse event information. In addition,