

§ 866.3372 Nucleic acid-based in vitro diagnostic devices for the detection of *Mycobacterium tuberculosis* complex in respiratory specimens.

(a) *Identification.* Nucleic acid-based in vitro diagnostic devices for the detection of *Mycobacterium tuberculosis* complex in respiratory specimens are qualitative nucleic acid-based in vitro diagnostic devices intended to detect *Mycobacterium tuberculosis* complex nucleic acids extracted from human respiratory specimens. These devices are non-multiplexed and intended to be used as an aid in the diagnosis of pulmonary tuberculosis when used in conjunction with clinical and other laboratory findings. These devices do not include devices intended to detect the presence of organism mutations associated with drug resistance. Respiratory specimens may include sputum (induced or expectorated), bronchial specimens (e.g., bronchoalveolar lavage or bronchial aspirate), or tracheal aspirates.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA document entitled "Class II Special Controls Guideline: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of *Mycobacterium tuberculosis* Complex in Respiratory Specimens." For availability of the guideline document, see § 866.1(e).

Dated: May 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF EDUCATION

34 CFR Chapter VI

[Docket ID ED-2014-OPE-0038; CFDA Number 84.015A]

Final Priorities; National Resource Centers Program

AGENCY: Office of Postsecondary Education (OPE), Department of Education.

ACTION: Final priorities.

SUMMARY: The Acting Assistant Secretary for Postsecondary Education announces two priorities for the National Resource Centers (NRC) Program administered by the International and Foreign Language Education Office. The Assistant Secretary may use these priorities for competitions in fiscal year (FY) 2014 and later years.

We take this action to focus Federal financial assistance on an identified

national need. We intend these priorities to address a gap in the types of institutions, faculty, and students that have historically benefited from the resources available at NRCs and to address a shortage in the number of teachers entering the teaching profession with global competency and world language training, certification, or credentials.

DATES: *Effective Date:* These priorities are effective June 30, 2014.

FOR FURTHER INFORMATION CONTACT:

Cheryl E. Gibbs, U.S. Department of Education, 1990 K Street NW., Room 6083, Washington, DC 20006, K-OPE-6078. Telephone: (202) 502-7634 or by email: cheryl.gibbs@ed.gov.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service, toll free, at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:

Purpose of Program: The NRC Program provides grants to institutions of higher education or consortia of such institutions to establish, strengthen, and operate comprehensive and undergraduate foreign language and area or international studies centers that will be national resources for (a) teaching of any modern foreign language; (b) instruction in fields needed to provide full understanding of areas, regions, or countries in which the modern language is commonly used; (c) research and training in international studies and the international and foreign language aspects of professional and other fields of study; and (d) instruction and research on issues in world affairs that concern one or more countries.

Program Authority: 20 U.S.C. 1122.

Applicable Program Regulations: 34 CFR parts 655 and 656.

We published a notice of proposed priorities for this program in the **Federal Register** on March 18, 2014 (79 FR 15077). That notice contained background information and our reasons for proposing the particular priorities.

There are differences between the proposed priorities and these final priorities as discussed in the *Analysis of Comments and Changes* section elsewhere in this notice.

Public Comment: In response to our invitation in the notice of proposed priorities, 25 parties submitted comments on the proposed priorities.

We discuss substantive issues under the number of the item to which they pertain. Generally, we do not address technical and other minor changes.

Analysis of Comments and Changes: An analysis of the comments and any changes in the priorities since

publication of the notice of proposed priorities follows.

Priority 1—Applications that propose significant and sustained collaborative activities with one or more Minority-Serving Institutions (MSIs) or one or more community colleges

Comment: Several commenters stated that by defining an MSI for the purpose of this priority using eligibility under the programs authorized by Title III or Title V of the Higher Education Act of 1965, as amended (HEA), the Department unduly limits the pool of institutions with which NRCs could potentially collaborate. They also observed that opportunities to reach and impact substantially more underrepresented and underserved populations will be missed if NRC institutions only collaborate with institutions that are eligible to receive assistance under Title III or Title V of the HEA. The commenters suggested alternative strategies to give NRC institutions more flexibility in achieving the access and diversity goals of the priority. For example, one institutional commenter noted that there are no Title III or V institutions in its State, but, to fulfill its urban access mission, it serves high enrollments of low-income, underrepresented, and minority students through a long-standing partnership with the local public school system. When students from the local public school system are admitted as undergraduate students, they are familiar with, and more likely to participate in, area studies and world language courses and study abroad opportunities. The same commenter also noted that to support underrepresented, low-income, and underserved students, the institution has established valuable partnerships with local agencies so that a continuum of resources is available to low-income and minority students before and after they are admitted to the institution. The commenter suggested that encouraging grantees to devise innovative strategies and partnerships that respond to local circumstances in order to reach more low-income and minority students is more consistent with the Department's emphasis on outcome-based performance measures than is requiring grantees to respond to a proscribed priority.

A rural institution commented that it does not have an MSI or a community college in its geographic locale. It observed that partnerships with MSIs and community colleges should not be prioritized over a rural institution's capacity to provide area studies courses and less commonly taught language

training to undergraduate students who are underrepresented minorities. The commenter also suggested that, instead of requiring collaborative activities with MSIs or community colleges, an NRC should be able to meet the priority by incorporating international dimensions into the NRC institution's undergraduate curriculum. According to the commenter, this would serve to attract and retain minority students and permit the NRC to focus its instruction and outreach efforts on underrepresented undergraduates on its campus, with the goal of increasing diversity in area studies programs.

Two commenters observed that many NRC institutions independently serve high numbers of underrepresented, underserved, or minority students, and if they have to allocate limited financial resources to support external collaborative activities, this will further strain their budgets and divert institutional resources from their students who are equally deserving of international education training opportunities. Another commenter noted that although it is both an MSI and an NRC institution, its internal activities and programming to support underrepresented and underserved groups do not meet the intent of the priority because the priority focuses on proposing collaborative activities with other MSIs. The commenter suggested that, in cases where an NRC institution is also a Title III- or Title V-eligible MSI, this priority should allow such an institution to focus on intra-campus collaborative activities as well as on collaborative activities with other MSIs and community colleges.

Discussion: We appreciate the commenters' concern that the definition of MSI is too narrow for the purpose of the priority and the alternative strategies they offered. However, we do not believe that the suggested strategies would achieve an important goal of this priority, which is to provide Title III and Title V institutions opportunities to access the resources available at Title VI institutions, through collaboration among Title III, Title V, and Title VI institutions. Further, institutions that are eligible to receive assistance under Title III, part A, Title III, part B, and Title V include Historically Black Colleges and Universities (HBCUs), predominately black institutions, Hispanic-serving institutions, and tribal colleges, among others. Accordingly, NRC institutions have a variety of options for collaboration, covering a wide range of underrepresented and underserved populations. Considering that community colleges are also included in this priority, we believe that

there is sufficient opportunity for applicants to meet this priority. We, therefore, do not agree that the definition of an MSI for the purposes of this priority is too narrow.

We also believe that there are sufficient opportunities for collaboration between an NRC institution that is not in close proximity to MSIs or community colleges. For example, the institution may, among other things, use technology to connect with other institutions or offer faculty travel grants to bring faculty to the institution.

In regard to the concerns about using limited NRC grant funds to conduct the collaboration activities described in the priority, we do not think that the activities, if planned cost-effectively, will require significant portions of grant funds. In addition, the goal is not only to reach underserved students but to support collaboration with Title III and Title V institutions to improve international education on their campuses.

For an applicant that meets the definition of an MSI, we agree that it is appropriate to allow that institution to meet the priority by conducting intra-campus collaborative activities instead of, or in addition to, collaborative activities with other MSIs or community colleges. An example of an intra-campus collaborative activity would be a project involving the faculty in the Department of Social Sciences and the Portuguese language instructors to develop a language across the curriculum course about food security issues in Latin America.

Changes: We have revised the priority language to permit institutions that are eligible under Title III or Title V to propose intra-campus collaborative activities instead of, or in addition to, collaborative activities with other MSIs or community colleges.

Comment: One commenter suggested that it would be helpful if we provide a list of eligible Title III, part A, Title III, part B, and Title V institutions.

Discussion: We agree that making this information readily available to applicants will help them in addressing and meeting this priority.

Changes: None. We will provide the information on the institutions that currently meet this definition in the notice inviting applications.

Comment: One commenter recommended that we remove the singular modifier before MSI and before community college to clarify that collaborative activities may be proposed with more than one MSI or more than one community college.

Discussion: We agree with the commenter's suggestion and are making this change to ensure we do not limit the number of entities that are able to collaborate under this priority.

Changes: We have revised the priority to make it clear that an institution can collaborate with multiple MSIs or community colleges.

Priority 2—Collaborative activities with schools or colleges of education

Comment: All commenters expressed concern about priority 2 because many institutions of higher education do not have a school or college of education or do not provide pre-service teacher certification training. They further observed that at many institutions, pre-service teacher training is offered through the schools of social sciences, liberal arts, or natural sciences, or the college of arts and sciences or through emerging models in teacher credential programs that are decentralized outside of the schools or colleges of education. The same commenters recommended that we revise the proposed priority to include options such as teacher credentialing programs, programs of teacher education, or post-baccalaureate programs. Three commenters recommended that we revise the priority to permit institutions that do not have schools or colleges of education to collaborate with institutions in their geographical location that have schools or colleges of education. Similarly, all commenters recommended that we expand the priority to allow applicants to propose collaborative activities with colleges or schools of education on or off the NRC campus.

Discussion: We agree with these suggestions. We believe that these revisions will offer more flexibility and reflect how different institutions of higher education operate in practice, while ensuring that the intent and objectives of the priority are still met. In addition, we note that the units listed in the final priority are not exhaustive, meaning that an institution could also collaborate with similar types of units that are not specifically mentioned in the priority and institutions that are on or off the NRC campus.

Changes: We have revised the priority to allow collaboration with units such as schools or colleges of education, schools of liberal arts and sciences, post-baccalaureate teacher education programs, and teacher preparation programs. We also have expanded the priority to permit collaborative activities with units or institutions that are on or off the NRC campus.

Comment: Several commenters raised concerns that the priority does not take into consideration that there is a limited job market for new teachers with credentials to teach less commonly taught languages (LCTLs), partly because LCTLs are not integrated into kindergarten through grade 12 (K–12) education or supported by the States.

Specifically, one commenter noted that giving priority to NRCs that contribute to the training and credentialing of new teachers is particularly problematic for NRCs that focus on languages and world areas such as Southeast Asia (SEA), because world areas like SEA are almost entirely absent from State-mandated K–12 curricula. The commenter further noted that through the training of Ph.D., Master of Arts, and Bachelor of Arts students, an NRC institution that focuses on SEA is educating the future post-secondary teachers of Southeast Asian Studies, thereby meeting a vital national interest. Similarly, another commenter cited the discontinuance of its Russian language teaching program due to low enrollment in the face of a weak job market. The commenter argued against encouraging students to pursue a teaching certification when there is no market for the credential.

Another commenter recommended that we either eliminate the portion of the priority regarding credentialing more foreign language teachers or tailor the priority to those specific LCTLs that require additional teachers to meet existing and expected future instructional needs within the K–12 system.

Another commenter suggested that we remove the last clause in the proposed priority relating to the credentialing of foreign language teachers because the commenter believed that LCTL instruction is adequately addressed by the first clause regarding the integration of world languages into teacher education. The commenter stated that teachers who are hired to teach other content courses but who also have foreign language training often have the opportunity to expose students to LCTLs in conjunction with other teaching activities. The commenter further noted that the first part of the priority already addresses this indirect path by which the NRCs can support and encourage the inclusion of more language instruction in elementary through secondary school classrooms. Encouraging teachers in training to study LCTLs has the potential to increase the overall availability of instruction in LCTLs in regular classroom activities.

Discussion: We do not agree that the portion of the priority relating to the credentialing of foreign language teachers is adequately addressed by the first part of the priority regarding the integration of world languages into teacher education. The preparation and credentialing of foreign language teachers in LCTLs is a distinct and formal process that might not necessarily occur under the broader collaboration categories in the first clause. We wish to encourage preparation and credentialing of foreign language teachers in LCTLs to the extent that there is demand for teachers of those languages, and therefore will maintain that option in the priority. Nonetheless, this activity is not required to meet this priority.

However, the commenters have provided a sound rationale to revise the priority as it relates to the credentialing of foreign language teachers in LCTLs. We agree that, due to limited State support and the lack of integration of language teaching into elementary and secondary education nationwide, there is low or no demand for teachers of some LCTLs. Accordingly, we agree with the suggestion that we limit the priority to LCTLs for which there is a demand for additional teachers to meet existing and expected future K–12 language program needs.

Changes: We have revised the priority to allow applicants to focus their teacher preparation and credentialing efforts on those specific LCTLs for which there is a demand for additional teachers to meet existing and expected future K–12 language program needs.

Final Priorities

Priority 1

Applications that propose significant and sustained collaborative activities with one or more Minority-Serving Institutions (MSIs) (as defined in this notice) or with one or more community colleges (as defined in this notice). These activities must be designed to incorporate international, intercultural, or global dimensions into the curriculum at the MSI(s) or community college(s), and to improve foreign language, area, and international studies or international business instruction at the MSI(s) or community college(s). If an applicant institution is an MSI or a community college (as defined in this notice), that institution may propose intra-campus collaborative activities instead of, or in addition to, collaborative activities with other MSIs or community colleges.

For the purpose of this priority:

Community college means an institution that meets the definition in section 312(f) of the Higher Education Act of 1965, as amended (HEA) (20 U.S.C. 1058(f)); or an institution of higher education (as defined in section 101 of the HEA (20 U.S.C. 1001)) that awards degrees and certificates, more than 50 percent of which are not bachelor's degrees (or an equivalent) or master's, professional, or other advanced degrees.

Minority-Serving Institution means an institution that is eligible to receive assistance under sections 316 through 320 of part A of Title III, under part B of Title III, or under Title V of the HEA.

Priority 2

Applications that propose collaborative activities with units such as schools or colleges of education, schools of liberal arts and sciences, post-baccalaureate teacher education programs, and teacher preparation programs on or off the national resource center campus. These collaborative activities are designed to support the integration of an international, intercultural, or global dimension and world languages into teacher education and/or to promote the preparation and credentialing of more foreign language teachers in less commonly taught languages (LCTLs) for which there is a demand for additional teachers to meet existing and expected future kindergarten through grade 12 language program needs.

Types of Priorities

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a

preference over other applications (34 CFR 75.105(c)(1)).

This notice does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This notice does *not* solicit applications. In any year in which we choose to use one or more of these priorities, we invite applications through a notice in the **Federal Register**.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is “significant” and, therefore, subject to the requirements of the Executive order and subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of \$100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities in a material way (also referred to as an “economically significant” rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles stated in the Executive order.

This final regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this final regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things

and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency “to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.” The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include “identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.”

We are issuing these final priorities only on a reasoned determination that their benefits justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that this regulatory action is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action does not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department’s programs and activities.

Intergovernmental Review: This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: www.gpo.gov/fdsys. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site. You may also access documents of the Department published in the **Federal Register** by using the article search feature at: www.federalregister.gov.

Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: May 27, 2014.

Lynn B. Mahaffie,

Senior Director, Policy Coordination, Development, and Accreditation Service, delegated the authority to perform the functions and duties of the Assistant Secretary for Postsecondary Education.

[FR Doc. 2014–12583 Filed 5–29–14; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

34 CFR Chapter VI

[Docket ID ED–2014–OPE–0035]

Final Priority; Foreign Language and Area Studies Fellowships Program

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Final priority.

[CFDA Number: 84.015B.]

SUMMARY: The Acting Assistant Secretary for Postsecondary Education announces a priority under the Foreign Language and Area Studies Fellowships (FLAS) Program administered by the International and Foreign Language Education (IFLE) Office. The Assistant Secretary may use this priority for competitions in fiscal year (FY) 2014 and later years.

We take this action to lower postsecondary education costs for