

- d. In newly designated paragraph (a), by removing from the first sentence the phrase “(see mailing addresses in § 600.2)”; and
- e. By adding new paragraph (b) to read as follows:

§ 600.81 Distribution reports.

(a) *Reporting requirements.* * * *
 (b)(1) *Electronic format.* Except as provided for in paragraph (b)(2) of this section, the distribution reports required under paragraph (a) of this section must be submitted to the Agency in an electronic format that FDA can process, review, and archive. FDA will issue guidance on how to provide the electronic submission (e.g., method of transmission, media, file formats, preparation and organization of files).

(2) *Waivers.* An applicant may request, in writing, a temporary waiver of the requirements in paragraph (b)(1) of this section. These waivers will be granted on a limited basis for good cause shown. FDA will issue guidance on requesting a waiver of the requirements in paragraph (b)(1) of this section. Requests for waivers must be submitted in accordance with § 600.90.

§ 600.90 [Amended]

- 11. Section 600.90 is amended by removing the phrase “licensed manufacturer” or “licensed manufacturer’s” each time it appears and by adding in its place the word “applicant” or “applicant’s” respectively.

Dated: June 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF EDUCATION

34 CFR Chapter III

[Docket ID: ED-2014-OSERS-0013]

Final Priority. National Institute on Disability and Rehabilitation Research—Rehabilitation Research and Training Centers

[CFDA Number: 84.133B-4.]

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Final priority.

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services announces a priority for the Rehabilitation Research and Training Center (RRTC) Program administered by the National Institute on Disability and

Rehabilitation Research (NIDRR). Specifically, we announce a priority for an RRTC on Health and Function of Individuals with Physical Disabilities. The Assistant Secretary may use this priority for competitions in fiscal year (FY) 2014 and later years. We take this action to focus research attention on an area of national need. We intend the priority to contribute to improved outcomes of health and function of individuals with physical disabilities.

DATES: This priority is effective July 10, 2014.

FOR FURTHER INFORMATION CONTACT: Patricia Barrett, U.S. Department of Education, 400 Maryland Avenue SW., Room 5142, Potomac Center Plaza (PCP), Washington, DC 20202-2700. Telephone: (202) 245-6211 or by email: patricia.barrett@ed.gov.

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

SUPPLEMENTARY INFORMATION: Purpose of Program: The purpose of the Disability and Rehabilitation Research Projects and Centers Program is to plan and conduct research, demonstration projects, training, and related activities, including international activities, to develop methods, procedures, and rehabilitation technology that maximize the full inclusion and integration into society, employment, independent living, family support, and economic and social self-sufficiency of individuals with disabilities, especially individuals with the most severe disabilities, and to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended (Rehabilitation Act).

Rehabilitation Research and Training Centers

The purpose of the RRTCs, which are funded through the Disability and Rehabilitation Research Projects and Centers Program, is to achieve the goals of, and improve the effectiveness of, services authorized under the Rehabilitation Act through well-designed research, training, technical assistance, and dissemination activities in important topical areas. These activities are designed to benefit rehabilitation service providers, individuals with disabilities, family members, policymakers, and other research stakeholders. Additional information on the RRTC program can be found at: <http://www2.ed.gov/programs/rrtc/index.html>.

Program Authority: 29 U.S.C. 762(g) and 764(b)(2).

Applicable Program Regulations: 34 CFR part 350.

We published a notice of proposed priority (NPP) for this program in the **Federal Register** on March 3, 2014 (79 FR 11738). That notice contained background information and our reasons for proposing the particular priority.

There are no differences between the proposed priority and this final priority.

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

Generally, we do not address technical and other minor changes, or suggested changes the law does not authorize us to make under the applicable statutory authority. In addition, we do not address general comments that raised concerns not directly related to the proposed priority.

Analysis of Comments and Changes: An analysis of the comments and of any changes in the priority since publication of the NPP follows.

Comment: One commenter questioned the need for this priority.

Discussion: This priority, creating an RRTC on Health and Function of Individuals with Physical Disabilities, would help achieve the goals of, and improve the effectiveness of services authorized under, the Rehabilitation Act. By creating an RRTC on Health and Function for Individuals with Physical Disabilities, we are fulfilling the purposes established in NIDRR’s Long-Range Plan for Fiscal Years 2013–2017 (Plan), which was published in the **Federal Register** on April 4, 2013 (78 FR 20299). More specifically, as we discuss in the NPP, there is a need to better understand how specific health problems are interrelated with optimal health and function; how they may affect community participation, work productivity, and quality of life; and how they may be prevented or mitigated. We believe this priority will focus research attention on this area of national need.

Changes: None.

Comment: One commenter recommended that the RRTC should focus on technology-based interventions to improve health and function outcomes of individuals with disabilities.

Discussion: NIDRR agrees that technology can be used to improve the health and function outcomes of individuals with physical disabilities. This is one of five broad areas described in the priority, under which applicants can propose research and related activities. NIDRR does not wish to limit applicants’ ability to address the other areas in the priority by requiring a focus

on technology, as recommended by the commenter. The peer review process will determine the merits of each proposal.

Changes: None.

Comment: One commenter noted that several research centers working in the area of health and function for individuals with physical disabilities have focused their efforts on analysis of existing data. The commenter recommended that NIDRR revise the priority to require the RRTC to collect new data in order to advance the field.

Discussion: Nothing in the priority precludes an applicant from proposing to engage in the collection and analysis of new data. However, NIDRR does not wish to revise the research requirements in the way suggested by the commenter because we believe the revisions would limit the number and breadth of applications submitted under this priority. The peer review process will determine the merits of each proposal.

Changes: None.

Comment: One commenter recommended that NIDRR revise the priority to require the RRTC to focus on at least two study populations or diagnostic groups, thereby promoting the generalizability of the RRTC's findings.

Discussion: Paragraph (a) of the proposed priority states that the RRTC can focus on individuals with physical disabilities as a group or on specific disability or demographic subpopulations of individuals with physical disabilities. NIDRR purposely does not require a minimum number of target populations because we do not want to limit the breadth and number of applications that can be submitted under this priority.

Changes: None.

Comment: One commenter asked NIDRR to further define and specify the limits of the term "physical disability." The commenter noted that people with traumatic brain injury (TBI) or stroke, for example, have acquired cognitive or intellectual impairments, as well as physical impairments, and often receive clinical services from rehabilitation professionals with expertise in physical disabilities. The commenter requested clarification of the term "physical disability" to help applicants determine whether their proposed target population(s) are an appropriate fit within the priority.

Discussion: We agree that some individuals with disabling conditions such as TBI or stroke could be considered in multiple target populations, including individuals with physical disabilities. NIDRR purposely outlines broad categories of target

populations in its Plan and its priorities to allow applicants the flexibility to choose the disability category that is most relevant to their research questions and purposes. With this priority, we allow applicants to define and justify their target population within the broad category of individuals with physical disabilities. The peer review process will determine the merits of each proposal.

Changes: None.

Comment: One commenter noted that paragraph (c)(ii) of the priority requires the RRTC to provide training to rehabilitation providers and other disability service providers in order to facilitate more effective delivery of services. The commenter suggested that by limiting the recipients of the required training to service providers, NIDRR may be limiting the knowledge that is available to consumers and reinforcing the knowledge barrier between service providers and consumers. The commenter suggested that NIDRR modify paragraph (c)(ii) to require the RRTCs to provide training to consumers and service providers.

Discussion: The requirements in paragraph (c)(ii) are based directly on the Federal regulations that govern administration of the RRTC program. The regulations in 34 CFR 350.22(b)(1) require that training be provided to rehabilitation personnel or rehabilitation research personnel. At the same time, nothing in the regulations or in the priority precludes applicants from proposing to provide training to individuals with disabilities in addition to rehabilitation or rehabilitation research providers (who may also have disabilities). It is up to the applicant to designate and justify training targets. The peer review process will determine the merits of each proposal.

Changes: None.

Final Priority

The Assistant Secretary for Special Education and Rehabilitative Services establishes a priority for an RRTC on Health and Function of Individuals with Physical Disabilities.

The RRTC must contribute to maximizing the health and function outcomes of individuals with physical disabilities by:

(a) Conducting research activities in one or more of the following priority areas, focusing on individuals with physical disabilities as a group or on individuals in specific disability or demographic subpopulations of individuals with physical disabilities:

(i) Technology to improve health and function outcomes for individuals with physical disabilities.

(ii) Individual and environmental factors associated with improved access to rehabilitation and health care and improved health and function outcomes for individuals with physical disabilities.

(iii) Interventions that contribute to improved health and function outcomes for individuals with physical disabilities. Interventions include any strategy, practice, program, policy, or tool that, when implemented as intended, contributes to improvements in outcomes for the specified population.

(iv) Effects of government practices, policies, and programs on health care access and on health and function outcomes for individuals with physical disabilities.

(v) Practices and policies that contribute to improved health and function outcomes for individuals with physical disabilities.

(b) Focusing its research on one or more specific stages of research. If the RRTC is to conduct research that can be categorized under more than one of the research stages, or research that progresses from one stage to another, those stages must be clearly specified. The research stages and their definitions are in the final priorities and definitions published in the **Federal Register** on May 7, 2013 (78 FR 26513).

(c) Serving as a national resource center related to health and function for individuals with physical disabilities, their families, and other stakeholders by conducting knowledge translation activities that include, but are not limited to:

(i) Providing information and technical assistance to service providers, individuals with physical disabilities and their representatives, and other key stakeholders.

(ii) Providing training, including graduate, pre-service, and in-service training, to rehabilitation providers and other disability service providers, to facilitate more effective delivery of services to individuals with physical disabilities. This training may be provided through conferences, workshops, public education programs, in-service training programs, and similar activities.

(iii) Disseminating research-based information and materials related to health and function for individuals with physical disabilities.

(iv) Involving key stakeholder groups in the activities conducted under paragraph (a) in order to maximize the relevance and usability of the new knowledge generated by the RRTC.

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 this priority, 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 this final priority only on a reasoned determination that its benefits justify its 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.

The benefits of the Disability and Rehabilitation Research Projects and Centers Program have been well established over the years, as projects similar to the one envisioned by the final priority have been completed successfully. The new RRTC will generate and promote the use of new knowledge that is intended to the health and function of individuals with disabilities.

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.

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Dated: June 5, 2013.

Michael K. Yudin,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

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