

number 0910–0485; the collections of information in 21 CFR part 807 have been approved under OMB control number 0910–0387.

VIII. 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. 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.

IX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday and are available electronically at <http://www.regulations.gov>. (FDA has verified the Web site addresses of the following references, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. Transcript from the Food and Drug Administration Ophthalmic Devices Panel Meeting, January 22, 1996.
2. Chang, Stanley, "LXII Edward Jackson Lecture: Open Angle Glaucoma After Vitrectomy," *American Journal of Ophthalmology*, vol. 141(6): pp. 1033–1043, June 2006, available at <http://www.sciencedirect.com/science/article/pii/S0002939406002546>.
3. Stewart, M. W., "Intraoperative Radiographic Detection of a 'Lost' Scleral Plug," *Retina*, vol. 25(4): pp. 526–527, June 2005.
4. Bovino, J. A. and D. F. Marcus, "Intraocular Foreign-Body Hazard During Vitrectomy," *American Journal of Ophthalmology*, vol. 93 (3): p. 366, March 1982.

List of Subjects in 21 CFR Part 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA proposes to amend part 886 as follows:

PART 886—OPHTHALMIC DEVICES

- 1. The authority citation for 21 CFR part 886 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

- 2. In subpart E, add § 886.4155 to read as follows:

§ 886.4155 Scleral plug.

(a) *Identification.* A scleral plug is a prescription device intended to provide temporary closure of a scleral incision during an ophthalmic surgical procedure. These plugs prevent intraocular fluid and pressure loss when instruments are withdrawn from the eye. Scleral plugs include a head portion remaining above the sclera, which can be gripped for insertion and removal, and a shaft that fits inside the scleral incision. Scleral plugs are removed before completing the surgery.

(b) *Classification.* Class II (special controls). The special controls for the scleral plug are:

(1) The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9 if the material is a surgical grade stainless steel with or without a gold, silver, or titanium coating. The special controls for the surgical grade stainless steel scleral plug (with or without a gold, silver, or titanium coating) are:

- (i) The device must be demonstrated to be sterile during the labeled shelf life;
- (ii) The device must be demonstrated to be biocompatible; and

(iii) Labeling must include all information required for the safe and effective use of the device, including specific instructions regarding the proper sizing, placement, and removal of the device.

(2) The device is not exempt from premarket notification procedures if it is composed of a material other than surgical grade stainless steel (with or without a gold, silver, or titanium coating). The special controls for scleral plugs made of other materials are:

- (i) The device must be demonstrated to be sterile during the labeled shelf life;
- (ii) The device must be demonstrated to be biocompatible;
- (iii) Characterization of the device materials must be performed;

(iv) Performance data must demonstrate acceptable mechanical properties under simulated clinical use conditions including insertion and removal of the device;

(v) Performance data must demonstrate adequately low levels of the extractables or residues from manufacturing (or processing) of the device; and

(vi) Labeling must include all information required for the safe and effective use of the device, including specific instructions regarding the proper sizing, placement, and removal of the device.

Dated: January 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–01447 Filed 1–24–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF EDUCATION

34 CFR Chapter III

Proposed Priorities and Definitions—NIDRR DRRP—Community Living and Participation, Health and Function, and Employment of Individuals With Disabilities

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

ACTION: Proposed priorities and definitions.

CFDA Numbers: 84.133A–3, 84.133A–4, and 84.133A–5.

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services proposes funding priorities and definitions for the Disability and Rehabilitation Research Projects and Centers Program administered by the National Institute on Disability and Rehabilitation Research (NIDRR). Specifically, this document proposes priorities for a Disability and Rehabilitation Research Project (DRRP) on Community Living and Participation of Individuals with Disabilities (Proposed Priority 1), a DRRP on Health and Function of Individuals with Disabilities (Proposed Priority 2), and a DRRP on Employment of Individuals with Disabilities (Proposed Priority 3). If an applicant proposes to conduct research under these priorities, the research must be focused on one of the four stages of research. This document proposes definitions for the four stages of research: exploration and discovery, intervention development, intervention efficacy, and scale-up evaluation. The Assistant Secretary may use one or more of these priorities and definitions for competitions in fiscal year (FY) 2013 and later years. We take this action to focus research attention on areas of national need. We intend these priorities and definitions to contribute to improved employment and independent living outcomes for individuals with disabilities.

DATES: We must receive your comments on or before February 25, 2013.

ADDRESSES: Address all comments about this document to Marlene Spencer, U.S. Department of Education, 400 Maryland Avenue SW., Room 5133, Potomac

Center Plaza (PCP), Washington, DC 20202–2700.

If you prefer to send your comments by email, use the following address: marlene.spencer@ed.gov. You must include the phrase “Proposed Priorities for Combined RRTC Notice” in the subject line of your electronic message.

FOR FURTHER INFORMATION CONTACT:

Marlene Spencer. Telephone: (202) 245–7532 or by email:

marlene.spencer@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: This notice of proposed priorities and definitions is in concert with NIDRR’s currently approved Long-Range Plan (Plan). The currently approved Plan, which was published in the **Federal Register** on February 15, 2006 (71 FR 8165), can be accessed on the Internet at the following site: <http://www2.ed.gov/legislation/FedRegister/other/2006-1/021506d.pdf>.

Through the implementation of the currently approved Plan, NIDRR seeks to: (1) Improve the quality and utility of disability and rehabilitation research; (2) foster an exchange of expertise, information, and training to facilitate the advancement of knowledge and understanding of the unique needs of traditionally underserved populations; (3) determine best strategies and programs to improve rehabilitation outcomes for underserved populations; (4) identify research gaps; (5) identify mechanisms of integrating research and practice; and (6) disseminate findings.

This document proposes three priorities and four definitions that NIDRR intends to use for a DRRP competition in FY 2013 and possibly later years. However, nothing precludes NIDRR from publishing additional priorities and definitions, if needed. Furthermore, NIDRR is under no obligation to make an award using any of these priorities. The decision to make an award will be based on the quality of applications received and available funding.

Invitation to Comment: We invite you to submit comments regarding this document. To ensure that your comments have maximum effect in developing the notice of final priorities, we urge you to identify clearly the specific priority or definition that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and its overall requirement of reducing

regulatory burden that might result from these proposed priorities and definitions. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this document in Room 5133, 550 12th Street SW., PCP, Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this document. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

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).

Disability and Rehabilitation Research Projects

The purpose of NIDRR’s DRRPs, which are funded through the Disability and Rehabilitation Research Projects and Centers Program, is to improve the effectiveness of services authorized under the Rehabilitation Act by developing methods, procedures, and rehabilitation technologies that advance a wide range of independent living and employment outcomes for individuals with disabilities, especially individuals with the most severe disabilities. DRRPs carry out one or more of the following types of activities, as specified and defined in 34 CFR 350.13 through 350.19: Research, training, demonstration, development, dissemination, utilization, and technical assistance.

An applicant under this program must demonstrate in its application how it will address, in whole or in part, the needs of individuals with disabilities from minority backgrounds (34 CFR 350.40(a)). The approaches an applicant may take to meet this requirement are found in 34 CFR 350.40(b). Additional information on the DRRP program can be found at: www.ed.gov/rschstat/research/pubs/res-program.html#DRRP.

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

Applicable Program Regulations: 34 CFR part 350.

Proposed Priorities

This document contains three proposed priorities. Each priority reflects a major area or domain of NIDRR’s research agenda. These domains include community living and participation, health and function, and employment of individuals with disabilities.

If the applicant proposes to conduct research under these priorities, the research must be focused on a specific stage of research. If the DRRP is to conduct research that can be categorized under more than one stage, or research that progresses from one stage to another, those stages must be clearly specified. For purposes of these priorities, the stages of research (i.e., exploration and discovery, intervention development, intervention efficacy, and scale-up evaluation) are defined in the DEFINITIONS section of this document.

Proposed Priority 1—Disability Rehabilitation Research Project on Community Living and Participation of Individuals With Disabilities

Background

The United States Supreme Court’s *Olmstead* decision, 527 U.S. 581 (1999), requires States to provide services “in the most integrated setting appropriate to the needs of qualified individuals with disabilities,” except in the rare instances where the individual objects or competent professionals consider it inappropriate. *Id.* at 607. Federal efforts to support the implementation of this decision have included, among others, the New Freedom Initiative, the Year of Community Living, Community First Choice, and the Money Follows the Person demonstration program. Despite these national efforts, individuals with disabilities of all ages continue to experience significant barriers to living in the community and participating in the typical educational, employment, recreational, and civic and social activities (Reinhart, et al., 2011;

Houtenville et al., 2011; Brault, 2008; National Council on Disability (NCD), 2004; Rimmer et al., 2004; Gibson, 2003). Barriers to community living and participation include, but are not limited to, insufficient affordable home and community-based long-term services and supports (LTSS), such as personal assistance, assistance for family caregivers, assistive technologies and devices, and home modifications; shortages of affordable and accessible housing; inadequate transportation services; limited personal knowledge of community resources; and poor health status (Cooper, O'Hara & Zovistoski, 2011; Reinhart et al., 2011; NCD, 2004; Rimmer, et al., 2004; Gibson, 2003).

U.S. Census Bureau data indicate that an estimated 8 million adults in the non-institutionalized population need personal assistance with activities of daily living (e.g., bathing, dressing, and toileting) (U.S. Census Bureau, 2009). By 2030, this number is estimated to increase to between 8.8 million and 12.3 million (U.S. Census Bureau, 2009). In addition, while studies show that most adults requiring assistance with daily activities prefer to live with support in their own homes (Salomon, 2010; Gibson, 2003), there is a growing disparity between the need for and supply of paid and informal direct care workers and family caregivers (Paraprofessional Healthcare Institute (PHI), 2008; Hewitt et al., 2008; U.S. Department of Health and Human Services, 2003). In a 2007 national survey, 86 percent of States considered the shortage of direct care workers to be a serious issue affecting their ability to meet the growing demand for long-term services and supports among adults with disabilities (PHI, 2009).

Individuals with disabilities, especially those with more significant disabilities, report feeling socially isolated and lonely in their communities (Price, Stephenson, Krantz & Ward, 2011). They are less satisfied with their community participation than their counterparts without disabilities (National Organization on Disability, 2000; Sheppard-Jones, Prout & Kleinert, 2005), and participate in fewer community activities than their counterparts without disabilities. For example, despite the evidence of benefits of regular physical activity for health and functioning, individuals with disabilities are far less likely to engage in physically active lifestyles than are individuals without disabilities (Rimmer, et al., 2004; Spivock, et al., 2008). Similarly, individuals with disabilities are much less likely than those without disabilities to be actively engaged in the workforce.

Approximately 18 percent of individuals with disabilities who are age 16 or older are employed, compared to 64 percent of those without disabilities (U.S. Department of Labor, 2012). To address disparities in community participation, and to improve the opportunities and abilities of individuals with disabilities to live as integrated members of their communities, NIDRR proposes to fund one or more Disability Rehabilitation Research Project(s) (DRRPs) on Community Living and Participation for Individuals with Disabilities.

NIDRR has funded a wide range of disability research and development projects related to the community living and participation of individuals with disabilities. In accordance with NIDRR's Plan, NIDRR seeks to build on these investments by supporting innovative and well-designed research and development projects that fall under one or more of NIDRR's general "community living and participation" priority areas, as described in the following proposed priority. NIDRR hopes to increase competition and innovation by allowing applicants to specify the research topics under the broad priority areas within the community living and participation domain. If an applicant proposes to conduct research activities, the applicant must identify the relevant priority area or areas, indicate the stage or stages of the proposed research (i.e., exploration and discovery, intervention development, intervention efficacy, and scale-up evaluation), justify the need and rationale for research at the proposed stage or stages, and describe fully an appropriate methodology or methodologies for the proposed research.

References

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- Brault, M.W. (2008) Americans with Disabilities. Current Population Reports. Washington, DC: U.S. Department of Commerce, U.S. Census Bureau.
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Proposed Priority 1

The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority for a Disability Rehabilitation Research Project (DRRP) on Community Living and Participation of Individuals with Disabilities. The DRRPs must contribute to the outcome of maximizing the community living and participation outcomes of individuals with disabilities.

(1) To contribute to this outcome, the DRRP must—

- (a) Conduct either research activities or development activities, in one or more of the following priority areas:
 - (i) Technology to improve community living and participation outcomes for individuals with disabilities, generally or within specific disability or demographic groups.
 - (ii) Individual and environmental factors associated with improved community living and participation outcomes for individuals with disabilities generally or within specific disability or demographic groups.
 - (iii) Interventions that contribute to improved community living and participation outcomes for individuals with disabilities generally or within specific disability or demographic groups. Interventions include any strategy, practice, program, policy, or tool that, when implemented as intended, contributes to improvements in outcomes for individuals with disabilities.

(iv) Effects of government policies and programs on community living and participation outcomes for individuals with disabilities generally or in specific disability or demographic groups.

(v) Research, knowledge translation, and capacity building for improved community living and participation outcomes for individuals with disabilities generally or within specific disability or demographic groups.

(vi) Practices and policies that contribute to improved community living and participation outcomes for transition-aged youth with disabilities;

(b) If conducting research under paragraph (1)(a) of this priority, focus its research on a specific stage of research. If the DRRP is to conduct research that can be categorized under more than one stage, including research that progresses from one stage to another, those stages must be clearly specified. These stages, exploration and discovery, intervention development, intervention efficacy, and scale-up evaluation, are defined in this document;

(c) Conduct knowledge translation activities (i.e., training, technical assistance, utilization, dissemination) in order to facilitate stakeholder (e.g., individuals with disabilities, employers, policymakers, practitioners) use of the interventions, programs, technologies, or products that resulted from the research or development activities conducted under paragraph (1)(a) of this priority; and

(d) Involve key stakeholder groups in the activities conducted under paragraph (1)(a) of this priority in order to maximize the relevance and usability of the research or development products to be developed under this priority.

Proposed Priority 2—Disability Rehabilitation Research Project on Health and Function of Individuals With Disabilities

Background

In the United States, approximately 56.7 million individuals have a disability, including 38.3 million who have a severe disability (Brault, 2012). Research has contributed to a wide variety of policies, programs, services, interventions, and products to enhance the health and function of individuals with disabilities. Despite this work, a large number of individuals with disabilities with significant health conditions and functional limitations lack adequate access to health care, personal assistance services, and rehabilitation services (National Council on Disability, 2009). Maximizing the health and function of individuals with disabilities is critical to their general

well-being and their fulfillment of personal aspirations in areas such as employment and community participation (Henry et al., 2007; Waghorn et al., 2008).

Adults with disabilities are substantially more likely than adults without disabilities to be in fair or poor health (as opposed to excellent, very good, or good health), and to experience a wide variety of diseases and chronic conditions (Bureau for Health Information, Statistics, Research, and Evaluation, 2011). Health risks often vary by condition. For example, individuals with significant vision loss or with an intellectual disability have a greater prevalence of obesity, hypertension, and heart disease than individuals without disabilities (Capella-McDonnell, 2007; Stancliffe et al., 2011). Such risks often have major adverse health outcomes, including reduced longevity. For example, 60 percent of individuals with serious mental illness die 25 or more years earlier than the general population due to preventable or treatable chronic diseases (Colton, Manderschied, 2006). Despite their substantial health needs and elevated risk of adverse health outcomes, individuals with disabilities are at a substantial disadvantage in obtaining access to needed health care services compared to those without disabilities (National Council on Disability, 2009; Yee, 2011).

In addition to health impairments, individuals with disabilities experience a wide range of functional limitations that jeopardize their access to employment and other forms of community participation. According to the U.S. Census Bureau 5 million adults need assistance from another person to perform one or more activities of daily living, such as getting around inside the home, getting into or out of bed, bathing, dressing, eating, and toileting. Approximately 15 million individuals have difficulty with one or more instrumental activities of daily living such as going outside the home, managing money, preparing meals, doing housework, taking prescription medication, and using the phone (Brault, 2012). As the number of individuals with disabilities in the United States continues to grow (Institute on Medicine, 2007), it will be necessary to improve the Nation's capacity to meet their needs and access their talents. This will require the development and refinement of policies, programs, practices, and technologies that reduce functional limitations and improve health outcomes for these individuals.

NIDRR has funded a wide range of disability research and development projects related to the health and functional outcomes of individuals with disabilities. In accordance with NIDRR's Plan, NIDRR seeks to build on these investments by supporting innovative and well-designed research and development projects that fall under one or more of NIDRR's general "health and function" priority areas, as described in the following proposed priority. NIDRR hopes to increase competition and innovation by allowing applicants to specify the research topics under the broad priority areas within the health and function domain. If an applicant proposes to conduct research activities, the applicant must identify the relevant priority area or areas, indicate the stage or stages of the proposed research in its application (i.e., exploration and discovery, intervention development, intervention efficacy, and scale-up evaluation), justify the need and rationale for research at the proposed stage or stages, and describe fully an appropriate methodology or methodologies for the proposed research.

References

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Proposed Priority 2

The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority for a Disability and Rehabilitation Research Project (DRRP) on Health and Function of Individuals with Disabilities. The DRPs must contribute to the outcome of maximizing health and function outcomes of individuals with disabilities.

(1) To contribute to this outcome, the DRRP must—

(a) Conduct either research activities or development activities in one or more of the following priority areas:

(i) Technology to improve health and function outcomes for individuals with disabilities, generally or within specific disability or demographic groups.

(ii) Individual and environmental factors associated with improved access to rehabilitation and healthcare and improved health and function outcomes for individuals with disabilities generally or within specific disability or demographic groups.

(iii) Interventions that contribute to improved health and function outcomes for individuals with disabilities generally or within specific disability or demographic groups. Interventions include any strategy, practice, program, policy, or tool that, when implemented as intended, contributes to improvements in outcomes for individuals with disabilities.

(iv) Effects of government policies and programs on health care access and on health and function outcomes for individuals with disabilities generally or within specific disability or demographic groups.

(v) Research, knowledge translation, and capacity building for improved health and function outcomes for individuals with disabilities generally or within specific disability groups.

(vi) Practices and policies that contribute to improved health and function outcomes for transition-aged youth with disabilities;

(b) If conducting research under paragraph (1)(a) of this priority, focus its research on a specific stage of research. If the DRRP is to conduct research that can be categorized under more than one stage, including research that progresses from one stage to another, those stages must be clearly specified. These stages, exploration and discovery, intervention development, intervention efficacy, and scale-up evaluation, are defined in this document;

(c) Conduct knowledge translation activities (i.e., training, technical assistance, utilization, dissemination) in order to facilitate stakeholder (e.g., individuals with disabilities, employers, policymakers, practitioners) use of the interventions, programs, technologies, or products that resulted from the research or development activities conducted under paragraph (1)(a) of this priority; and

(d) Involve key stakeholder groups in the activities conducted under paragraph (1)(a) of this priority in order to maximize the relevance and usability of the research or development products to be developed under this priority.

Proposed Priority 3—Disability Rehabilitation Research Project on Employment of Individuals With Disabilities

Background

Despite the enactment of legislation and the implementation of a variety of policy and program efforts at the Federal and State levels to improve employment outcomes for individuals with disabilities, the employment rate for individuals with disabilities remains substantially lower than the rate for those without disabilities.

Approximately 18 percent of individuals with a disability aged 16 years and older are employed, compared to 64 percent of individuals of the same age without a disability. The unemployment rate for these two populations is 13.5 percent, and 7.3 percent, respectively (U.S. Department of Labor, 2012). The economic downturn in recent years has disproportionately impacted employment outcomes of individuals with disabilities; among individuals 25 to 54 years of age during the recent recession, the unemployment rate of

individuals with a disability ranged from 2.0 to 2.3 times that of individuals without a disability (Fogg, Harrington, McMahon, 2010). Not only are individuals with a disability much less likely to be employed, the median earnings for individuals with a disability who are employed are \$19,735 per year as compared to \$30,285 per year earned by persons without a disability (U.S. Census Bureau, 2011).

NIDRR has funded a wide range of disability research and development projects related to the employment outcomes of individuals with disabilities. In accordance with NIDRR's Plan, NIDRR seeks to build on these investments by supporting innovative and well-designed research and development projects that fall under one or more of NIDRR's general employment priority areas as described in the following proposed priority. NIDRR hopes to increase competition and innovation by allowing applicants to specify the research topics under the broad priority areas within the employment domain. If an applicant proposes to conduct research activities, the applicant must identify the relevant priority area or areas, indicate the stage or stages of the proposed research in its application (i.e., exploration and discovery, intervention development, intervention efficacy, and scale-up evaluation), justify the need and rationale for research at the proposed stage or stages and describe fully an appropriate methodology or methodologies for the proposed research.

References

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Proposed Priority 3

The Assistant Secretary for Special Education and Rehabilitative Services announces a priority for a Disability and Rehabilitation Research Project (DRRP) on Employment of Individuals with Disabilities. The DRRPs must contribute to the outcome of maximizing employment outcomes of individuals with disabilities.

(1) To contribute to this outcome, the DRRP must—

(a) Conduct either research activities or development activities, in one or more of the following priority areas:

(i) Technology to improve employment outcomes for individuals with disabilities, generally or within specific disability or demographic groups.

(ii) Individual and environmental factors associated with improved employment outcomes for individuals with disabilities generally or within specific disability or demographic groups.

(iii) Interventions that contribute to improved employment outcomes for individuals with disabilities generally or within specific disability or demographic groups. Interventions include any strategy, practice, program, policy, or tool that, when implemented as intended, contributes to improvements in outcomes for individuals with disabilities.

(iv) Effects of government policies and programs on employment outcomes for individuals with disabilities generally or in specific disability or demographic groups.

(v) Research, knowledge translation, and capacity building for improved employment outcomes for individuals with disabilities generally or within specific disability groups.

(vi) Practices and policies that contribute to improved employment outcomes for transition-aged youth with disabilities.

(vii) Vocational rehabilitation (VR) practices that contribute to improved employment outcomes for individuals with disabilities;

(b) If conducting research under paragraph(1)(a) of this priority, focus its research on a specific stage of research. If the DRRP is to conduct research that can be categorized under more than one stage, including research that progresses from one stage to another, those stages must be clearly specified. These stages, exploration and discovery, intervention development, intervention efficacy, and scale-up evaluation, are defined in this document;

(c) Conduct knowledge translation activities (i.e., training, technical assistance, utilization, dissemination) in order to facilitate stakeholder (e.g., individuals with disabilities, employers, policymakers, practitioners) use of the interventions, programs, technologies, or products that resulted from the research activities, development activities, or both, conducted under paragraph (1)(a) of this priority; and

(d) Involve key stakeholder groups in the activities conducted under

paragraphs (1)(a) of this priority in order to maximize the relevance and usability of the research or development products to be developed under this priority.

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)).

Proposed Definitions

Background

For the purpose of NIDRR's DRRPs and other programs that NIDRR uses to sponsor research activities, definitions of the four stages of research (i.e., exploration and discovery, intervention development, intervention efficacy, and scale-up evaluation) are proposed in this document.

Proposed Definitions

The Assistant Secretary for Special Education and Rehabilitative Services proposes the following definitions for this program. We may apply one or more of these definition in any year in which this program is in effect.

Exploration and discovery means the stage of research that generates hypotheses or theories by conducting new and refined analyses of data, producing observational findings, and creating other sources of research-based information. This research stage may include identifying or describing the barriers to and facilitators of improved outcomes of individuals with disabilities, as well as identifying or describing existing practices, programs, or policies that are associated with important aspects of the lives of

individuals with disabilities. Results achieved under this stage of research may inform the development of interventions or lead to evaluations of interventions or policies. The results of the exploration and discovery stage of research may also be used to inform decisions or priorities.

Intervention development means the stage of research that focuses on generating and testing interventions that have the potential to improve outcomes for individuals with disabilities. Intervention development involves determining the active components of possible interventions, developing measures that would be required to illustrate outcomes, specifying target populations, conducting field tests, and assessing the feasibility of conducting a well-designed interventions study. Results from this stage of research may be used to inform the design of a study to test the efficacy of an intervention.

Intervention efficacy means the stage of research during which a project evaluates and tests whether an intervention is feasible, practical, and has the potential to yield positive outcomes for individuals with disabilities. Efficacy research may assess the strength of the relationships between an intervention and outcomes, and may identify factors or individual characteristics that affect the relationship between the intervention and outcomes. Efficacy research can inform decisions about whether there is sufficient evidence to support “scaling-up” an intervention to other sites and contexts. This stage of research can include assessing the training needed for wide-scale implementation of the intervention, and approaches to evaluation of the intervention in real world applications.

Scale-up evaluation means the stage of research during which a project analyzes whether an intervention is effective in producing improved outcomes for individuals with disabilities when implemented in a real-world setting. During this stage of research, a project tests the outcomes of an evidence-based intervention in different settings. It examines the challenges to successful replication of the intervention, and the circumstances and activities that contribute to successful adoption of the intervention in real-world settings. This stage of research may also include well-designed studies of an intervention that has been widely adopted in practice, but that lacks a sufficient evidence-base to demonstrate its effectiveness.

Final Priorities and Definitions

We will announce the final priorities and definitions in a notice in the **Federal Register**. We will determine the final priorities and definitions after considering responses to this document and other information available to the Department. This document does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This document does *not* solicit applications. In any year in which we choose to use one or more of these priorities and definitions, 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 proposed 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 proposed 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 on 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 proposed priorities and definitions only on a reasoned determination that their benefits would 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 would 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 Programs have been well established over the years in that similar projects have been completed successfully. These proposed priorities and definitions would generate new

knowledge through research and development. Another benefit of these proposed priorities and definitions is that the establishment of new DRRPs would improve the lives of individuals with disabilities. The new DRRPs would generate, disseminate, and promote the use of new information that would improve outcomes for individuals with disabilities.

Intergovernmental Review: This program is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotope, 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: January 18, 2013.

Michael Yudin,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2013-01418 Filed 1-24-13; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

34 CFR Chapter II

[Docket ID ED-2012-OESE-0033]

Proposed Priorities, Requirements, Definitions, and Selection Criteria—Enhanced Assessment Instruments

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Proposed priorities, requirements, definitions, and selection criteria.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.368

SUMMARY: The Assistant Secretary for Elementary and Secondary Education proposes priorities, requirements, definitions, and selection criteria under the Enhanced Assessment Instruments Grant program, also called the Enhanced Assessment Grants (EAG) program. The Assistant Secretary may use one or more of these priorities, requirements, definitions, and selection criteria for competitions using funds from fiscal year (FY) 2012 and later years. The Department takes these actions in order to establish priorities, requirements, definitions, and selection criteria that are likely to recognize high-quality proposals and to help focus Federal financial assistance on the pressing needs of, and promising developments in, developing or enhancing assessments under the Elementary and Secondary Education Act of 1965, as amended (ESEA).

DATES: We must receive your comments on or before February 25, 2013, and we encourage you to submit comments well in advance of this date.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments by fax or by email. To ensure we do not receive duplicate comments, please submit your comments only once. In addition, please include the Docket ID and the term “Enhanced Assessment Grants—Comments” at the top of your comments.

Federal eRulemaking Portal: Go to www.regulations.gov to submit your comments electronically. Information on using Regulations.gov, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under “How To Use This Site.”

Postal Mail, Commercial Delivery, or Hand Delivery: If you mail or deliver your comments about these proposed priorities, requirements, definitions, and selection criteria, address them to the Office of Elementary and Secondary Education (Attention: Enhanced Assessment Grants—Comments), U.S. Department of Education, 400 Maryland Avenue SW., room 3w110, Washington, DC 20202-6132.

Privacy Note: The Department’s policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at www.regulations.gov. Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Erin Shackel. Telephone: (202) 453-6423 or by email: erin.shackel@ed.gov.

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

SUPPLEMENTARY INFORMATION:

Invitation to Comment: We invite you to submit comments regarding this notice. To ensure that your comments have maximum effect in developing the notice of final priorities, requirements, definitions, and selection criteria, we urge you to identify clearly the specific proposed priority, requirement, definition, or selection criterion that each comment addresses.

Please note that we have included existing requirements and selection criteria in this document to provide context and to make it easier to comment on the requirements and selection criteria we are proposing. We seek comment only on the proposed priorities, requirements, definitions, and selection criteria.

We invite you to assist us in complying with the specific requirements of Executive Order 12866 and its overall requirement of reducing regulatory burden that might result from these proposed priorities, requirements, definitions, and selection criteria. Please let us know of any further ways the Department could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this notice in room 3W110, 400 Maryland Avenue SW., Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request the Department will provide an appropriate accommodation or auxiliary to aid an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Purpose of Program: The purpose of the EAG program is to enhance the quality of assessment instruments and systems used by States for measuring the academic achievement of elementary and secondary school students.