

NIDILRR-funded grantees, including knowledge translation grantees and grantees involved with employment research.

#### Final Priority

We will announce the final priority in a notice in the **Federal Register**. We will determine the final priority after considering responses to this notice and other information available to the Department. 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** or in a Funding Opportunity Announcement posted at [www.grants.gov](http://www.grants.gov).

#### 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 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 proposed priority only upon a reasoned determination that its benefits would justify its costs. In choosing among alternative regulatory approaches, we selected those approaches that would maximize net benefits. Based on the analysis that follows, the Department believes that this proposed priority 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 Program have been well

established over the years. Projects similar to one envisioned by the proposed priority have been completed successfully, and the proposed priority would generate new knowledge through research. The new RRTC would generate, disseminate, and promote the use of new information that would improve outcomes for individuals with disabilities in the area of employment.

*Intergovernmental Review:* This program is not subject to Executive Order 12372.

*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](http://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](http://www.federalregister.gov). Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: February 19, 2015.

**Kathy Greenlee,**  
Administrator.

[FR Doc. 2015–03882 Filed 2–24–15; 8:45 am]

BILLING CODE 4154–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

[CFDA Number: 84.133A–7]

#### Proposed Priority—National Institute on Disability, Independent Living, and Rehabilitation Research—Disability and Rehabilitation Research Projects Program

**AGENCY:** Administration for Community Living, HHS.

**ACTION:** Notice of proposed priority.

**SUMMARY:** The Administrator of the Administration for Community Living proposes a priority for the Disability and Rehabilitation Research Projects (DRRPs) Program administered by the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR). Specifically, this notice proposes a priority for Promoting

Universal Design in the Built Environment. We take this action to focus research attention on an area of national need. We intend this priority to contribute to improved access to the built environment by individuals with disabilities.

**DATES:** We must receive your comments on or before March 27, 2015.

**ADDRESSES:** Submit your comments through the Federal eRulemaking Portal or via postal mail or commercial delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to [www.regulations.gov](http://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 "Are you new to the site?"

- *Postal Mail or Commercial Delivery:* If you mail or deliver your comments about these proposed regulations, address them to Patricia Barrett, U.S. Department of Health and Human Services, 400 Maryland Avenue SW., Room 5142, Potomac Center Plaza (PCP), Washington, DC 20202-2700.

*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](http://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:** Patricia Barrett. Telephone: (202) 245-6211 or by email: [patricia.barrett@ed.gov](mailto: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:** This notice of proposed priority is in concert with NIDRR's currently approved Long-Range Plan (Plan). The Plan, which was published in the **Federal Register** on April 4, 2013 (78 FR 20299), can be accessed on the Internet at the following site: [www.ed.gov/about/offices/list/ose/nidrr/policy.html](http://www.ed.gov/about/offices/list/ose/nidrr/policy.html).

The Plan identifies a need for research and training regarding employment, community living and participation,

and health and function of individuals with disabilities. To address this need, NIDILRR seeks to: (1) Improve the quality and utility of disability and rehabilitation research; (2) foster an exchange of research findings, expertise, and other information to advance knowledge and understanding of the needs of individuals with disabilities and their family members, including those from among traditionally underserved populations; (3) determine effective practices, programs, and policies to improve community living and participation, employment, and health and function outcomes for individuals with disabilities of all ages; (4) identify research gaps and areas for promising research investments; (5) identify and promote effective mechanisms for integrating research and practice; and (6) disseminate research findings to all major stakeholder groups, including individuals with disabilities and their family members in formats that are appropriate and meaningful to them.

This notice proposes one priority that NIDILRR intends to use for one or more competitions in fiscal year (FY) 2015 and possibly later years. NIDILRR is under no obligation to make an award under this priority. The decision to make an award will be based on the quality of applications received and available funding. NIDILRR may publish additional priorities, as needed.

*Invitation to Comment:* We invite you to submit comments regarding this proposed priority. To ensure that your comments have maximum effect in developing the final priority, we urge you to identify clearly the specific topic within the priority that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866 and 13563 and their overall requirement of reducing regulatory burden that might result from this proposed priority. 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 by following the instructions found under the "Are you new to the site?" portion of the Federal eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov). Any comments sent to NIDILRR via postal mail or commercial delivery can be viewed in Room 5142, 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 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 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 NIDILRR'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 significant 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, utilization, dissemination, and technical assistance.

An applicant for assistance 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](http://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 Priority:* This notice contains one proposed priority.

*Promoting Universal Design (UD) in the Built Environment*

*Background:* Universal Design is generally defined as the “design of products and environments that are usable by all people, to the greatest extent possible, without the need for adaptation or specialized design” (Mace, 1985; Ostroff, 2011). UD proponents seek to improve human performance, health and wellness, and social participation for the entire population including individuals with disabilities (Steinfeld & Maisel, 2012).

NIDILRR grantees have substantially contributed to the development, refinement, and application of UD principles. In particular, the NIDILRR-funded Center for Universal Design at North Carolina State University (in collaboration with other researchers and practitioners) developed the seven “Principles of Universal Design” (The Principles of Universal Design, 1997). These principles (equitable use, flexibility in use, simple and intuitive use, perceptible information, tolerance for error, low physical effort, and appropriate size and space for approach and use regardless of users’ body size, posture, and mobility) have increasingly guided designers, builders, developers, and other stakeholders in the provision of accessible housing and built environments. Examples of UD found in the built environment include: curb cuts, building ramps, automatic door openers, fully accessible restrooms, moving walkways, and wayfinding systems that facilitate user access and orientation.

All NIDILRR-funded Rehabilitation Engineering Research Centers (RERCs) must incorporate UD principles in their research and development activities. Funded for the past 15 years, the RERC on Universal Design and the Built Environment is specifically charged with advancing the implementation of UD principles in the built environment. Center outcomes include a tool set for UD research and practice, prototypes for built environments, and UD standards. NIDILRR funding has contributed to the development of 35 state and local visitability ordinances and initiatives across the U.S, which require or encourage affordable and sustainable integration of basic accessibility features into all newly-built homes. NIDILRR funding also supported the inclusion of UD principles in a building manual which the New York City Department of Design and Construction adopted as the

official reference for all architects working in the city (Center for Inclusive Design and Universal Access, 2003).

Despite these notable outcomes, application of UD principles to the built environment has not become a mainstream practice (Ostroff, 2011; Dong 2011). Practical demonstrations of UD applications for buildings, homes, and outdoor environments, as well as a strengthened evidence-base for UD standards and strategies are yet needed. These needs will only increase as the baby boom generation ages while seeking to live and thrive in their own homes and communities (Federal Interagency Forum on Aging-Related Statistics, 2012). Making research-based knowledge about UD accessible to designers, developers, architects, and builders will help to advance UD implementation and realize the goals of improving human performance, health and wellness, and social participation for the entire population, including individuals with disabilities. Accordingly, NIDILRR aims to sponsor a DRRP on Promoting UD in the Built Environment to conduct research, knowledge translation, technical assistance, and training activities aimed at continued implementation of UD principles in the built environment.

**References**

- Center for Inclusive Design and Universal Access, 2003. *Universal Design New York 2: The NYC Guidebook to Accessibility and Universal Design*. Buffalo New York: Idea Publications.
- Dong, H (2011). Global Perspectives and Reflections. In *Trends in Universal Design*. Tonsberg, Norway: The Delta Centre.
- Federal Interagency Forum on Aging-Related Statistics, (2012). *Older Americans 2012: Key Indicators of Well-Being*. (Washington, DC: U.S. Government Printing Office).
- Mace, R. (1985). *Universal design, barrier free environments for everyone*. Los Angeles: Designers West.
- Ostroff, E. (2011). Universal design: An evolving paradigm. In Preiser, W. & Smith K. (Eds.). *Universal Design Handbook*. New York, McGraw Hill.
- The Principles of Universal Design (1997). Version 2.0—4/1/97*. Compiled by advocates of universal design, listed in alphabetical order: Bettye Rose Connell, Mike Jones, Ron Mace, Jim Mueller, Abir Mulkick, Elaine Ostroff, Jon Sanford, Ed Steinfeld, Molly Story, and Gregg Vanderheiden. NC State University, The Center for Universal Design.
- Steinfeld, E. & Maisel, J.L. (2012). *Universal Design: Creating Inclusive Environments*. Hoboken, NJ: Wiley and Sons, Inc.

*Proposed Priority:* The Administrator of the Administration for Community Living proposes a priority for a Disability and Rehabilitation Research

Project on Promoting Universal Design in the Built Environment. The intended outcome of the DRRP on Universal Design is further adoption of universal design principles into mainstream architecture and the development and construction of built environments. The DRRP must contribute to this outcome by:

- (a) Conducting research activities toward developing evidence-based practices for UD implementation in commercial and private facilities, outdoor environments, and housing.
- (b) Creating measurable UD standards and guidelines to facilitate the implementation of UD principles in commercial and private facilities, outdoor environments, and housing.
- (c) Developing and promoting curricula on UD for university-level architecture, engineering, and design students.
- (d) Providing training and technical assistance to designers, architects, and builders to incorporate UD principles and features into their buildings, projects, and communities.
- (e) Providing training and technical assistance to NIDILRR’s engineering and assistive technology grantees to incorporate UD strategies and standards into development projects serving the needs of individuals with disabilities and the broader population.
- (f) Partnering with relevant stakeholders in carrying out all DRRP activities. Stakeholders include but are not limited to: Individuals with disabilities, professional organizations that teach design principles, researchers, engineers, planners, designers, developers, architects, and builders.

*Final Priority:* We will announce the final priority in a notice in the **Federal Register**. We will determine the final priority after considering responses to this notice and other information available to the Department. 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** or in a Funding Opportunity Announcement posted at [www.grants.gov](http://www.grants.gov).

**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 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 proposed priority only upon a reasoned determination that its benefits would justify its costs. In choosing among alternative regulatory approaches, we selected those approaches that would maximize net benefits. Based on the analysis that follows, the Department believes that this proposed priority 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 Program have been well established over the years. Projects similar to one envisioned by the proposed priority have been completed successfully, and the proposed priority would generate new knowledge through research. The new DRRP would generate, disseminate, and promote the use of new information that would improve accessibility of the built environment for individuals with disabilities.

*Intergovernmental Review:* This program is not subject to Executive Order 12372.

*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](http://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](http://www.federalregister.gov). Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: February 19, 2015.

**Kathy Greenlee,**  
*Administrator.*

[FR Doc. 2015–03888 Filed 2–24–15; 8:45 am]

**BILLING CODE 4154-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2011–N–0362]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by March 27, 2015.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910–0139. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.