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Dated: June 3, 2015.

Rose E. Gottemoeller,
*Under Secretary, Arms Control and
International Security, Department of State.*

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DEPARTMENT OF EDUCATION

34 CFR Chapter III

[Docket ID ED-2015-OSERS-0069]

Proposed Priority—Rehabilitation Training: Vocational Rehabilitation Workforce Innovation Technical Assistance Center

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

ACTION: Proposed priority.

[CFDA Number: 84.264G.]

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority to establish the Workforce Innovation Technical Assistance Center. The Assistant Secretary may use this priority for competitions in fiscal year (FY) 2015 and later years. We take this action to provide training and technical assistance (TA) to State vocational rehabilitation (VR) agencies to improve services under the State Vocational Rehabilitation Services program (VR program) and State Supported Employment Services program for individuals with disabilities, including those with the most significant disabilities, and to implement changes to the Rehabilitation Act of 1973, as amended by the Workforce Innovation and Opportunity Act (WIOA), signed into law on July 22, 2014.

DATES: We must receive your comments on or before July 17, 2015.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand 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 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, Commercial Delivery, or Hand Delivery:** If you mail or deliver your comments about the proposed priority, address them to Jerry Elliott, U.S. Department of Education, 400 Maryland Avenue SW., Room 5042, Potomac Center Plaza (PCP), Washington, DC 20202-2800.

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: Jerry Elliott. Telephone: (202) 245-7335 or by email: jerry.elliott@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:

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 priority, we urge you to identify clearly the specific section of the proposed 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 about this notice by accessing Regulations.gov. You may also inspect the comments in person in Room 5021, 550 12th Street SW., PCP, Washington, DC, 20202-2800, 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. Please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

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: Under the Rehabilitation Act of 1973 (Rehabilitation Act), as amended by WIOA, the Rehabilitation Services Administration (RSA) makes grants to States and public or nonprofit agencies and organizations (including institutions of higher education) to support projects that provide training, traineeships, and TA designed to increase the numbers of, and improve the skills of, qualified personnel (especially rehabilitation counselors) who are trained to provide vocational, medical, social, and psychological rehabilitation services to individuals with disabilities; assist individuals with communication and related disorders; and provide other services authorized under the Rehabilitation Act.

Program Authority: 29 U.S.C. 772(a)(1).

Proposed Priority:

This notice contains one proposed priority.

Workforce Innovation Technical Assistance Center. Background:

WIOA supersedes the Workforce Investment Act of 1998 and amends the Rehabilitation Act, making major changes that affect the management and performance of the VR program and Supported Employment program. Among the changes are: (a) A requirement that States reserve at least 15 percent of their Federal VR allotment for providing or arranging for the provision of pre-employment transition services to students with disabilities; (b) a requirement that States reserve at least 50 percent of their Federal Supported Employment allotment for the provision of supported employment services, including extended services, to youth with the most significant disabilities; (c) a requirement that States provide a 10 percent non-Federal share to match the 50 percent of Supported Employment allotment reserved for the provision of supported employment services to youth with the most significant disabilities; (d) a requirement that VR agencies provide documentation of the completion of certain specified activities to individuals with disabilities, including youth with disabilities, seeking or wanting to maintain employment at a subminimum wage; (e) a heightened emphasis on the achievement of competitive integrated employment by individuals with disabilities; (f) enhanced coordination

and integration of the VR program with other core programs of the workforce development system; and (g) new common performance accountability requirements for all core programs of the workforce development system, including the State VR program.

While some of these changes affect documentation or reporting requirements, others represent significant changes in the management and operation of the State VR program and the Supported Employment program. As such, RSA believes that it is appropriate to provide training and TA on the new statutory requirements imposed by WIOA.

RSA believes that a dedicated TA center would help collect and disseminate information about relevant existing, emerging, and evidence-based practices; assist in developing and disseminating new approaches and practices; and coordinate and share activities and approaches related to implementation of WIOA in the topic areas for this priority so that States have the benefit of learning from each other as WIOA implementation proceeds.

Proposed Priority:

The Assistant Secretary for Special Education and Rehabilitative Services proposes a priority to establish a cooperative agreement to create a Workforce Innovation Technical Assistance Center (WITAC) to assist VR agencies in implementing changes affecting the State Vocational Rehabilitation Services and State Supported Employment Services programs under WIOA, and to achieve, at a minimum, the following outcomes:

(a) Implementation of effective and efficient “pre-employment transition services” for students with disabilities, as set forth in section 113 of the Rehabilitation Act;

(b) Implementation by State VR agencies, in coordination with local and State educational agencies and with the Department of Labor, of the requirements in section 511 of the Rehabilitation Act that are under the purview of the Department of Education;

(c) Increased access to supported employment and customized employment services for individuals with the most significant disabilities, including youth with the most significant disabilities, receiving services under the State VR and Supported Employment programs;

(d) An increased percentage of individuals with disabilities who receive services through the State VR agency and who achieve employment outcomes in competitive integrated employment;

(e) Improved collaboration between State VR agencies and other core programs of the workforce development system; and

(f) Implementation of the new common performance accountability system under section 116 of WIOA.

Topic Areas.

The WITAC will develop and provide training and technical assistance (TA) to State VR agency staff and related rehabilitation professionals and service providers in five topic areas related to changes made by WIOA:

(a) Provision of pre-employment transition services to students with disabilities and supported employment services to youth with disabilities;

(b) Implementation of the requirements in section 511 of the Rehabilitation Act that are under the purview of the Department of Education;

(c) Provision of resources and strategies to help individuals with disabilities achieve competitive integrated employment, including customized employment and supported employment;

(d) Integration of the State VR program into the workforce development system; and

(e) Transition to the new common performance accountability system under section 116 of WIOA, including the collection and reporting of common data elements.

Project Activities.

To meet the requirements of this priority, the WITAC must, at a minimum, conduct the following activities:

Knowledge Development Activities.

(a) In the first year, collect information from the literature and from existing State and Federal programs about evidence-based and promising practices relevant to the work of the WITAC and make this information publicly available in a searchable, accessible, and useful format. The WITAC must review, at a minimum:

(1) Literature on evidence-based and promising practices relevant to the work of the WITAC;

(2) The results of State VR agency monitoring conducted by RSA;

(3) State VR agency program and performance data;

(4) Department of Education and Department of Labor policies and guidance on program changes made by WIOA and implementation of those changes; and

(5) Any existing State VR agency memoranda of understanding (MOUs) or agreement (MOAs) related to the work of the WITAC.

(b) In the first year, conduct a survey of relevant stakeholders and VR service

providers to identify workforce development TA needs and a process by which TA solutions can be offered to State VR agencies and their partners.

The WITAC must survey, at a minimum:

(1) State VR agency staff;

(2) Relevant RSA staff; and

(3) Other stakeholders, including stakeholders from the transition and special education community, the workforce development community, and the rehabilitation community.

(c) Develop and refine one or more curriculum guides for VR staff training for each of the topic areas listed in the Topic Areas section of this priority.

Technical Assistance and Dissemination Activities.

(a) Provide intensive, sustained TA¹ to a minimum of 23 State VR agencies and their associated rehabilitation professionals and service providers in the topic areas set out in this priority. The WITAC must provide intensive, sustained TA to a minimum of two agencies in the first year of the project and to a minimum of seven additional agencies per year in the second, third, and fourth years of the project. These are minimum requirements, and the expectation is that intensive, sustained TA will be provided, to the extent funds are available, to all of the State VR agencies that request intensive, sustained TA. This TA must include:

(1) For topic area (a), how to—

(i) Develop, manage, and implement effective pre-employment transition services to improve the transition of students with disabilities from secondary to postsecondary education and employment;

(ii) Coordinate pre-employment transition services with transition services provided under IDEA; and

(iii) Develop and implement supported employment services for youth with the most significant disabilities;

(2) For topic area (b):

(i) How to provide career-related counseling, information, and referral services to individuals entering and continuing employment at subminimum wages; and

(ii) How to implement documentation requirements for youth with disabilities seeking employment at subminimum wage, in accordance with section 511 of the Rehabilitation Act;

¹ For the purposes of this priority, “intensive, sustained technical assistance” means TA services often provided on-site and requiring a stable, ongoing relationship between the TA center staff and the TA recipient. “Technical assistance services” are defined as negotiated series of activities designed to reach a valued outcome. This category of TA should result in changes to policy, program, practice, or operations that support increased recipient capacity or improved outcomes at one or more systems levels.

(3) For topic area (c), how to design and implement new services and new roles and responsibilities among partner agencies to increase the percentage of individuals achieving competitive integrated employment and to meet the supported employment and customized employment requirements of the Rehabilitation Act;

(4) For topic area (d), how to develop model relationships between State VR agencies and other core programs of the workforce development system for purposes of implementing the requirements of title I of WIOA, especially those requirements related to integration of core programs into the workforce development system; and

(5) For topic area (e), how to effectively transition to the new common performance accountability system required in section 116 of WIOA and use performance results to implement programmatic changes to improve agency performance.

(b) Provide a range of targeted, specialized TA² and universal, general TA³ products and services on the topic areas in this priority. This TA must include, at a minimum, the following activities:

(1) Establishing and maintaining a state-of-the-art information technology (IT) platform sufficient to support Webinars, teleconferences, video conferences, and other virtual methods of dissemination of information and TA.

Note: All products produced by WITAC must meet government- and industry-recognized standards for accessibility, including section 508 of the Rehabilitation Act.

(2) Developing and maintaining a state-of-the-art archiving and dissemination system that—

²For the purposes of this priority, “targeted, specialized technical assistance” means TA services based on needs common to multiple recipients and not extensively individualized. A relationship is established between the TA recipient and one or more TA center staff. This category of TA includes one-time, labor-intensive events, such as facilitating strategic planning or hosting regional or national conferences. It can also include episodic, less labor-intensive events that extend over a period of time, such as facilitating a series of conference calls on single or multiple topics that are designed around the needs of the recipients. Facilitating communities of practice can also be considered targeted, specialized TA.

³For the purposes of this priority, “universal, general technical assistance” means TA and information provided to independent users through their own initiative, resulting in minimal interaction with TA center staff and including one-time, invited or offered conference presentations by TA center staff. This category of TA also includes information or products, such as newsletters, guidebooks, or research syntheses, downloaded from the TA center’s Web site by independent users. Brief communications by TA center staff with recipients, either by telephone or email, are also considered universal, general TA.

(i) Provides a central location for later use of TA products, including course curricula, audiovisual materials, Webinars, examples of emerging and best practices for the topic areas in this priority, and any other TA products; and

(ii) Is open and available to the public.

Note: In meeting the requirements for (b)(1) and (2) above, the WITAC may either develop new platforms or systems or may modify existing platforms or systems, so long as the requirements of this priority are met.

(3) Providing a minimum of two Webinars or video conferences over the course of the project on each of the topic areas in this priority to describe and disseminate information about emerging and best practices in each area.

Coordination Activities.

(a) Establish one or more communities of practice that focus on the topic areas in this priority and that act as vehicles for communication and exchange of information among State VR agencies and partners, including the results of TA projects that are in progress or have been completed;

(b) Communicate, collaborate, and coordinate, on an ongoing basis, with other relevant Department-funded projects and those supported by the Social Security Administration (SSA) and the Departments of Labor, Health and Human Services, and Commerce; and

(c) Maintain ongoing communication with the RSA project officer and other RSA staff as required.

Application Requirements.

To be funded under this priority, applicants must meet the application and administrative requirements in this priority. RSA encourages innovative approaches to meet these requirements, which are:

(a) Demonstrate, in the narrative section of the application under “Significance of the Project,” how the proposed project will address State VR agencies’ capacity to implement the requirements of WIOA. To meet this requirement, the applicant must:

(1) Demonstrate knowledge of current RSA guidance and State and Federal initiatives designed to improve engagement with the workforce development system and workforce development system partners;

(2) Demonstrate knowledge of current State VR agency and other efforts to improve engagement with secondary schools, youth programs, and other programs that provide services to youth with disabilities for the purpose of assisting such youth to enter postsecondary education or competitive integrated employment; and

(3) Demonstrate knowledge of current State VR agency efforts to engage with State Medicaid, developmental disability, and mental health agencies to develop agreements and provide services leading to competitive integrated employment, including supported employment and customized employment.

(b) Demonstrate, in the narrative section of the application under “Quality of Project Services,” how the proposed project will—

(1) Achieve its goals, objectives, and intended outcomes. To meet this requirement, the applicant must provide—

(i) Measurable intended project outcomes;

(ii) A plan for how the proposed project will achieve its intended outcomes; and

(iii) A plan for communicating, collaborating, and coordinating with key staff in State VR agencies; State and local partner programs; RSA partners, such as the Council of State Administrators of Vocational Rehabilitation, the National Association of State Directors of Special Education, the National Council of State Agencies for the Blind, and other TA centers; and relevant programs within SSA and the Departments of Education, Labor, Health and Human Services, and Commerce.

(2) Use a conceptual framework to develop project plans and activities, describing any underlying concepts, assumptions, expectations, beliefs, or theories, as well as the presumed relationships or linkages among these variables, and any empirical support for this framework.

(3) Be based on current research and make use of evidence-based practices. To meet this requirement, the applicant must describe—

(i) How the current research about adult learning principles and implementation science will inform the proposed TA; and

(ii) How the proposed project will incorporate current research and evidence-based practices in the development and delivery of its products and services.

(4) Develop products and provide services that are of high quality and sufficient intensity and duration to achieve the intended outcomes of the proposed project. To address this requirement, the applicant must describe—

(i) Its proposed activities to identify or develop the knowledge base on emerging and promising practices in the five topic areas listed in the Topic Areas section of this priority;

(ii) Its proposed approach to universal, general TA;

(iii) Its proposed approach to targeted, specialized TA, which must identify—

(A) The intended recipients of the products and services under this approach; and

(B) Its proposed approach to measure the capacity and readiness of State VR agencies to work with the proposed project, assessing, at a minimum, their current infrastructure, available resources, and ability to effectively respond to the TA, as appropriate;

(iv) Its proposed approach to intensive, sustained TA, which must identify—

(A) The intended recipients of the products and services under this approach;

(B) Its proposed approach to measure the readiness of the State VR agencies to work with the proposed project, including the State VR agencies' commitment to the initiative, fit of the initiative, current infrastructure, available resources, and ability to effectively respond to the TA, as appropriate;

(C) Its proposed plan for assisting State VR agencies to build training systems that include professional development based on adult learning principles and coaching; and

(D) Its proposed plan for developing agreements with State VR agencies to provide intensive, sustained TA. The plan must describe how the agreements will outline the purposes of the TA, the intended outcomes of the TA, and the measurable objectives of the TA that will be evaluated.

(5) Develop products and implement services to maximize the project's efficiency. To address this requirement, the applicant must describe—

(i) How the proposed project will use technology to achieve the intended project outcomes; and

(ii) With whom the proposed project will collaborate and the intended outcomes of this collaboration.

(c) Demonstrate, in the narrative section of the application under "Quality of the Evaluation Plan," how the proposed project will—

(1) Measure and track the effectiveness of the TA provided. To meet this requirement, the applicant must describe its proposed approach to—

(i) Collecting data on the effectiveness of each TA activity from State VR agencies, partners, or other sources, as appropriate; and

(ii) Analyzing data and determining effectiveness of each TA activity, including any proposed standards or targets for determining effectiveness.

(2) Collect and analyze data on specific and measurable goals, objectives, and intended outcomes of the project, including measuring and tracking the effectiveness of the TA provided. To address this requirement, the applicant must describe—

(i) Its proposed evaluation methodologies, including instruments, data collection methods, and analyses;

(ii) Its proposed standards or targets for determining effectiveness;

(iii) How it will use the evaluation results to examine the effectiveness of its implementation and its progress toward achieving the intended outcomes; and

(iv) How the methods of evaluation will produce quantitative and qualitative data that demonstrate whether the project and individual TA activities achieved their intended outcomes.

(d) Demonstrate, in the narrative section of the application under "Adequacy of Project Resources," how—

(1) The proposed project will encourage applications for employment from persons who are members of groups that have historically been underrepresented based on race, color, national origin, gender, age, or disability, as appropriate;

(2) The proposed key project personnel, consultants, and subcontractors have the qualifications and experience to provide TA to State VR agencies and their partners in each of the topic areas in this priority and to achieve the project's intended outcomes;

(3) The applicant and any key partners have adequate resources to carry out the proposed activities; and

(4) The proposed costs are reasonable in relation to the anticipated results and benefits;

(e) Demonstrate, in the narrative section of the application under "Quality of the Management Plan," how—

(1) The proposed management plan will ensure that the project's intended outcomes will be achieved on time and within budget. To address this requirement, the applicant must describe—

(i) Clearly defined responsibilities for key project personnel, consultants, and subcontractors, as applicable; and

(ii) Timelines and milestones for accomplishing the project tasks.

(2) Key project personnel and any consultants and subcontractors will be allocated to the project and how these allocations are appropriate and adequate to achieve the project's intended outcomes, including an assurance that

such personnel will have adequate availability to ensure timely communications with stakeholders and RSA;

(3) The proposed management plan will ensure that the products and services provided are of high quality; and

(4) The proposed project will benefit from a diversity of perspectives, including those of State and local personnel, TA providers, researchers, and policy makers, among others, in its development and operation.

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)).

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**.

Executive Orders 12866 and 13563

Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this proposed 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 this proposed priority only on 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 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.

We propose to fund through this priority TA to State VR agencies to improve the quality of VR services and of the competitive integrated employment outcomes achieved by individuals with disabilities, and ultimately to increase the percentage of individuals with disabilities who receive services through the State VR agencies who achieve competitive integrated employment outcomes. This proposed priority would promote the efficient and effective use of Federal funds.

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

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

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on

request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

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

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: June 12, 2015.

Michael K. Yudin,

Assistant Secretary for Special Education and Rehabilitative Services.

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BILLING CODE 4000–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906–AA89

340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Health Resources and Services Administration (HRSA) administers section 340B of the Public Health Service Act (PHSA), which is referred to as the “340B Drug Pricing Program” or the “340B Program.” This proposed rule will apply to all drug manufacturers that are required to make their drugs available to covered entities under the 340B Program. The proposed rule sets forth the calculation of the ceiling price and application of civil monetary penalties.

DATES: Submit comments on or before August 17, 2015.

ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN) 0906–AA89, by any of the following methods. Please submit your comments in only one of these ways to