

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 300

[Docket No. FDA-2019-N-5553]

RIN 0910-AI36

Annual Summary Reporting Requirements Under the Right To Try Act; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; correction.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is correcting a proposed rule that published in the **Federal Register** of

July 24, 2020. That proposed rule proposes to establish requirements for the deadline and contents of submission in an annual summary. We are placing a corrected copy of the proposed rule in the docket.

FOR FURTHER INFORMATION CONTACT:

Kathleen Davies, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3121, Silver Spring, MD 20993, 301-796-2205, *kathleen.davies@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 24, 2020, (85 FR 44803), FDA published the proposed rule “Annual Summary Reporting Requirements Under the Right to Try Act” with several errors.

In the **Federal Register** of July 24, 2020, FR Doc. 2020-16016, the following corrections are made:

On page 44804, in the third column, in section “*D. Costs and Benefits*” the first paragraph, the fourth and fifth sentences are corrected as follows: “The total estimated present value of this rule’s costs is \$39,991 at a seven percent discount rate and \$49,345 at a three percent discount rate (in 2018 dollars). The annualized cost of this rule over 10 years is \$5,694 at a seven percent discount rate and \$5,785 at a three percent discount rate.” On page 44808, in table 1, in column 2 (“Primary estimate”) rows 4 and 5 (“Costs” category) are corrected as follows: “\$5,694” and “\$5,785”, respectively, and the “7” in column 4 (“High estimate”) is removed. On pages 44808 and 44809, in column 6 (“Discount Rate (10%)”) is corrected to read as follows:

TABLE 1—SUMMARY OF BENEFITS AND COSTS IN 2018 DOLLARS OVER A 10-YEAR TIME HORIZON

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized Monetized \$/year.				2018	7	10	Disclosure of serious adverse events and outcomes related to investigational new drug treatments.
Annualized Quantified				2018	3	10	
Qualitative					7		
					3		
Costs:							
Annualized Monetized \$/year.	\$5,694			2018	7	10	
Annualized Quantified	\$5,785			2018	3	10	
Qualitative					7		
Transfers:					3		
Federal Annualized Monetized \$/year.					7		
From/To	From:			To:			
Other Annualized Monetized \$/year.					7		
From/To	From:			To:	3		
Effects:	State, Local or Tribal Government: Small Business: Wages: Growth:						

Dated: August 20, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-18777 Filed 9-20; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF EDUCATION

34 CFR Chapter III

[Docket ID ED-2020-OSERS-0056]

Proposed Priorities and Definitions—American Indian Vocational Rehabilitation Services—Training and Technical Assistance

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

ACTION: Proposed priorities and definitions.

SUMMARY: The Department of Education (Department) proposes priorities and definitions to fund an American Indian Vocational Rehabilitation Training and Technical Assistance Center (AIVRTTAC), Catalog of Federal Domestic Assistance (CFDA) number 84.250Z. The Department may use the priorities and definitions for competitions in fiscal year (FY) 2020 and later years. We take this action to focus Federal financial assistance on

identified national needs and to improve employment outcomes and raise expectations for American Indians with disabilities. We intend the AIVRTTAC to provide training and technical assistance (TA) to American Indian Vocational Rehabilitation Services (AIVRS) project personnel, especially vocational rehabilitation (VR) counselors, in order to improve their capacity to implement innovative and effective VR services and employment strategies and practices to increase the number and quality of employment outcomes for American Indians with disabilities served through the AIVRS program.

DATES: We must receive your comments on or before October 13, 2020.

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 "Help."

- *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments, address them to Jerry Elliott, U.S. Department of Education, 400 Maryland Avenue SW, Room 5097, Potomac Center Plaza, 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, U.S. Department of Education, 400 Maryland Avenue SW, Room 5097, Potomac Center Plaza, Washington, DC 20202-2800. Telephone: (202)245-7335. 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 the proposed priorities and definitions. To ensure that your comments have maximum effect in developing the notice of final priorities and definitions, we urge you to identify clearly the specific part of the priorities or definition that each comment addresses. In addition to your general comments and recommended clarifications, we seek input as to whether entities who may apply under this competition would have the ability to meet Proposed Priority 2, which is consistent with option (f) of the Secretary's Final Supplemental Priorities and Definitions for Discretionary Grant Programs, published in the **Federal Register** on March 2, 2018 (83 FR 9096), related to matching support, and if so, whether that priority should be included as an absolute priority, competitive preference priority, or an invitational priority and what the level of matching support should be.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866, 13563, and 13771 and their overall requirement of reducing regulatory burden that might result from the proposed priorities and definitions. Please let us know of any 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 the proposed priorities and definitions by accessing *Regulations.gov*. Due to the current COVID-19 pandemic, the Department buildings are currently not open. However, upon reopening, you may also inspect the comments in person in room 5059, 550 12th Street SW, Washington, DC, between the hours of 9:30 a.m. and 4:00 p.m., Eastern 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 the proposed priorities and definitions. 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 AIVRTTAC program is to provide training and TA to governing bodies of

Indian Tribes, or consortia of those governing bodies, that have received an AIVRS grant under section 121(a) of the Rehabilitation Act of 1973, as amended (Act). Under section 121(c)(2) of the Act, the Commissioner of the Rehabilitation Services Administration (RSA) makes grants to, or enters into contracts or other cooperative agreements with, entities that have experience in the operation of AIVRS projects to provide such training and TA on developing, conducting, administering, and evaluating these projects.

Program Authority: 29 U.S.C. 741(c).
Applicable Program Regulations: 34 CFR part 371.

Proposed Priorities

This notice contains two proposed priorities.

Background

Section 121(c)(1) of the Act requires the Commissioner of RSA to reserve not less than 1.8 percent and not more than 2 percent of the funds set aside for the AIVRS program under section 110(c)(1) from the amount appropriated to the State VR program under section 100(b)(1) of the Act to provide training and TA to governing bodies of Indian Tribes and consortia of those governing bodies that have received an AIVRS grant, as well as their personnel.

Under section 121(a) of the Act, the Department funds 92 active AIVRS projects that provide VR services to American Indians with disabilities who reside on or near a Federal or State reservation, consistent with each individual's strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice, so that they may prepare for, and engage in, high-quality competitive integrated employment that will increase opportunities for economic self-sufficiency. In FY 2015, the Department funded one grant under section 121(c) for an AIVRTTAC to provide training and TA to the AIVRS projects.

The AIVRTTAC funded in FY 2015 has provided intensive, sustained TA; targeted, specialized TA; and universal, general TA to governing bodies of Indian Tribes that have received an AIVRS grant and to the personnel of the AIVRS projects in the following topic areas:

(a) Applicable laws and regulations governing the AIVRS program.

(b) Promising practices for providing VR services to American Indians with disabilities.

(c) Delivering VR services to American Indians with disabilities, including the determination of

eligibility, case management, case record documentation, assessment, development of the individualized plan for employment (IPE), and placement into competitive integrated employment.

(d) Assistive technology (AT), including what AT is, how to evaluate the need for AT, use of AT, and access to AT.

(e) Implementing professional development practices to ensure effective project coordination, administration, and management.

(f) Implementing appropriate financial and grant management practices to ensure compliance with the Office of Management and Budget's (OMB) Uniform Guidance (2 CFR 200) and the Education Department General Administrative Regulations (EDGAR).

(g) Evaluating project performance, including data collection, data analysis, and reporting.

Also, in FY 2015, RSA used a different funding source, section 21 of the Act, to fund one grant for a Vocational Rehabilitation Training Institute for the Preparation of Personnel in American Indian Vocational Rehabilitation (the Institute). The Institute was designed to provide a structured program of VR training to personnel of the AIVRS projects to improve the delivery of VR services to American Indians with disabilities. The Institute included in its training a series of courses specifically geared toward building foundational skills that, when satisfactorily completed, led to a VR certificate awarded by the Institute. The Institute's training was intentionally different in scope and sequence than was the training and TA provided by the AIVRTTAC funded in FY 2015, which provided more concentrated short-term training in specific areas.

Together, the AIVRTTAC and the Institute comprise the totality of RSA-funded training and TA to the AIVRS projects to date.

Both projects funded in FY 2015 are now in their fifth and final year of operation, and both have proven to be successful in delivering training and TA to the AIVRS projects. For example, as of the second quarter of grant year five, the Institute provided outreach to 2,093 participants, almost seven times the outreach goal; and enrolled 226 personnel from 61 AIVRS programs in multiple offerings of thirteen different courses, exceeding their goal by more than 10 percent.

The AIVRTTAC has developed and delivered intensive TA to 23 AIVRS projects to date. Thirteen AIVRS projects have completed all intensive TA activities included in the intensive

TA agreement. Ten AIVRS projects are currently working on intensive TA activities. Additionally, there are four AIVRS projects currently developing requests for intensive TA. The AIVRTTAC has developed 41 products or tools to support the provision of intensive, targeted, and universal TA, with 21 more products and tools under development.

The grantees that participated in intensive TA are showing improvements in the documentation of service records and the provision of VR services to project participants. For example, among grantees that participated in intensive TA, documentation that participants had been notified of their rights and responsibilities increased from 33 percent to 100 percent. Similarly, external partnerships increased significantly, including partnerships with schools (increased from 0 to 6) and businesses (increased from 0 to 25), as well as training events with business partners (increased from 0 to 18).

Each intensive TA plan is customized to the individual needs of the AIVRS project and targets areas of improvement based on input and requests from the project staff and areas of need identified by the pre-TA service record review. During on-site and desk monitoring of the two TA centers and of the AIVRS projects conducted over several years, RSA has observed the need to continue to assist AIVRS personnel to work more effectively with American Indians with disabilities and to fulfill their roles as VR counselors, VR support personnel, and project administrators. There are four factors that contribute to this need. First, many of the personnel employed by AIVRS projects live in rural and remote communities. While many of these individuals have relevant experience in social service fields, they have not been able to obtain formal training in rehabilitation counseling.

Second, the remote locations of many AIVRS projects not only make it difficult for local personnel to obtain further training due to distance and cost, but they also make it difficult to recruit VR counselors from other locations to work for AIVRS projects.

Third, the AIVRS program requires projects to give a preference in hiring to American Indians, with a special priority being given to American Indians with disabilities. While American Indians may be knowledgeable of American Indian cultural practices and norms, this preference in hiring requirement makes it difficult to find VR counselors who have experience with VR and who are

also familiar with the Indian Tribe's particular cultural practices and norms.

Fourth, the AIVRS projects have historically had high personnel turnover rates. The need for basic training and skills development is ongoing as new personnel are hired.

Based on these factors, RSA determined that AIVRS personnel could benefit from a structured training program focused on the VR process and practices and the unique skills and knowledge necessary to improve employment outcomes for this population. For example, AIVRS personnel require a better understanding of how various disabilities affect an individual's ability to participate in competitive employment, how to interview and evaluate the eligibility of prospective AIVRS consumers respectfully and appropriately, how to develop a reasonable and achievable IPE, how to effectively manage the VR services and supports provided to the individual identified in the IPE, how to obtain and use accurate labor market information to understand the skill needs and demands of local employers, and how to develop employment opportunities to meet those demands that are at appropriate skill levels and consistent with the consumer's aspirations, as documented in the IPE. AIVRS personnel also need to understand how job training, reasonable accommodations, and assistive technology help individuals with disabilities to pursue, obtain, and retain competitive employment. In addition, project administrators would benefit from training in areas such as financial management and accountability, performance measurement, and case management.

To help determine funding priorities, section 121(c)(3) of the Act requires RSA to survey the governing bodies of Indian Tribes operating AIVRS projects to identify their training and TA needs. To do that, RSA considered the results of the needs survey each AIVRS project submitted as part of the most recent annual performance report (APR) and the results of the Tribal consultation on this competition undertaken by RSA. Analysis of APR survey results over four years showed continuing demand for almost all topics, even though the relative demand for various topics shifted somewhat from the initial survey conducted in 2015. Training is consistently requested on applicable laws, outreach to veterans, eligibility determination, and IPE development. In addition, there has recently been an increase in requests for training on Federal regulations applying to grants management, strategies for working with

individuals with physical and mental disabilities, budget management, case management, case record documentation, outreach to underserved populations regarding disability and institutionalized potential consumers, VR services, and AIVRS data collection and reporting.

Tribal Consultation: RSA conducted Tribal consultation on this competition in two primary ways. First, RSA conducted targeted consultation at a conference of the Consortia of Administrators for Native American Rehabilitation (CANAR) in December 2019. The conference is for AIVRS project directors—the personnel who had been served by both the AIVRTTAC and the Institute and would be served by the new training and TA grantee. RSA conducted an open Tribal input session on December 5, 2019 and invited a small focus group of AIVRS project directors to provide input on December 3, 2019.

Second, RSA issued a request for consultation to all Tribal leaders through the Department's Office of Indian Education's listserve on December 4, 2019. This request was open for 31 days and asked for responses by January 3, 2020. A second request for consultation was sent to the Tribal leaders and AIVRS project directors of Tribes operating AIVRS projects. This request was open from December 9, 2019, through January 9, 2020.

The Tribal requests for consultation consisted of a survey of the topics and methodologies used by the current TA providers—AIVRTTAC and the Institute—as well as open-ended questions about how training and TA could be improved or changed. The results of the Tribal consultation survey and the input from the Tribal consultation focus groups showed support for continuing both the activities of the AIVRTTAC and the Institute and for continuing the specific topics addressed by each entity. There was also support for continuing the training delivery models developed by both entities.

The structure of training and TA was also discussed during the Tribal consultation. The structural issue involved deciding whether to combine the types of training and TA provided by the AIVRTTAC and the Institute into a single project. There was no consensus on whether to change the structure of the AIVRTTAC project funded under a new competition. Tribal consultation input included support for combining the two projects and for retaining them separately.

Tribal consultation input indicated that some AIVRS project personnel wanted a single AIVRS website where AIVRS related material could be retained, archived, and accessed in a single location. The Tribal consultation also included suggestions for additional training and TA needs that will be incorporated into the final priority and the cooperative agreement.

Proposed Priority 1

Background

RSA proposes for the FY 2020 competition to continue to build upon the functions and activities of both the AIVRTTAC and the Institute but combine these functions into a single grant. RSA has noted some overlap and duplication in the content of the modules developed by the Institute and the tools, webinars, and on-site TA delivered by the AIVRTTAC, as well as duplication of overhead functions such as maintaining two websites. In addition, while funding available for training and TA under section 121(c) of the Act has increased, overall funding for training and TA for the AIVRS projects has decreased, because the Act's section 21 funds that were used for the Institute in FY 2015 will not be available as they have been redirected to other priorities in FY 2020. We believe that a single grantee will be able to work within funding limitations to reduce administrative inefficiencies and deliver effective training and TA using identified and potentially new methods and modules.

Proposed priority 1 is designed to assist AIVRS projects to implement—

- (1) efficient and effective project and resource management techniques to increase the numbers of, and improve the skills of, VR counselors and other service delivery personnel; and
- (2) innovative employment and support strategies provided by these personnel to improve employment outcomes and career advancement for individuals with disabilities. The AIVRTTAC funded under this priority would do this by—

- Developing current and, to the extent possible, evidence-based training modules for use with AIVRS projects, both for use as part of VR education programs and certificate programs, and as stand-alone modules;
- Providing on-site and other direct training and guidance to individual AIVRS projects and Tribal governments to implement best practices and training module content; and
- Through both academic content and direct TA, providing AIVRS project managers, professionals, and paraprofessionals with the knowledge to

meet the unique needs of American Indians with disabilities.

Consistent with the Secretary's priorities, proposed priority 1 is designed to implement strategies that ensure Department funds are spent in a way that increases their efficiency and cost effectiveness, including by reducing waste or achieving better outcomes.

Proposed Priority 1

American Indian Vocational Rehabilitation Services—Training and Technical Assistance Program

This priority would fund a five-year cooperative agreement to establish an American Indian Vocational Rehabilitation Training and Technical Assistance Center (AIVRTTAC) to provide four types of training and technical assistance (TA) for the personnel of the American Indian Vocational Rehabilitation Services (AIVRS) projects awarded under section 121(a) of the Rehabilitation Act of 1973, as amended (Act), to the governing bodies of Indian Tribes. The four types of training and TA are: (1) Intensive, sustained training and TA; (2) targeted, specialized training and TA; (3) universal, general training and TA; and (4) capacity-building for AIVRS project personnel through training modules that build foundational skills for the delivery of VR services to AIVRS project participants. The AIVRTTAC will develop and provide these types of training and TA for AIVRS projects in the following topic areas:

(a) Applicable laws and regulations governing the AIVRS program.

(b) Promising practices for providing VR services to American Indians with disabilities.

(c) The delivery of VR services to American Indians with disabilities, including the determination of eligibility, case management, case record documentation, assessment, development of the individualized plan for employment, and placement into competitive integrated employment.

(d) Knowledge of assistive technology (AT), including the definition of AT, how to evaluate the need for AT and what types of AT are available, use of AT, and access to AT.

(e) Implementing professional development practices to ensure effective project coordination, administration, and management.

(f) Implementing appropriate financial and grant management practices to ensure compliance with OMB's Uniform Guidance (2 CFR part 200) and the Education Department General Administrative Regulations.

(g) Evaluating project performance, including data collection, data analysis, and reporting.

Specific subjects for training and TA in each of these topic areas will be identified on an annual basis and in coordination with RSA.

Project Activities

To be considered for funding under this priority, applicants must conduct the following activities, or a subset of the following activities as determined by the Department, in a culturally appropriate manner:

(a) Maintain and build upon the 12 training modules and the fiscal tool kit developed by the Institute in the previous grant cycle, including maintaining the series of seven training modules that build foundational skills that, when satisfactorily completed, lead to a VR certificate to be awarded by the AIVRTTAC. To satisfy this activity requirement, the grantee—

(i) May determine whether the VR certificate awarded will be academic or non-academic, the requirements for obtaining such a certificate, and how the certificate may be used by the participants who earned it;

(ii) May offer the series of training modules in a traditional classroom setting, through distance learning, through week-long institutes, at regional trainings throughout the country as an extension of national conferences, and through other delivery methods, as appropriate, to meet the needs of the targeted audience;

(iii) May use grant funds to provide reasonable financial assistance for the cost of tuition and fees and training materials and to offset costs associated with travel for participants who may be in remote areas of the country;

(iv) Must conduct an assessment before and after providing training for each participant in order to assess strengths and specific areas for improvement, educational attainment and application of skills, and any issues or challenges to be addressed post-training to ensure improved delivery of VR services to American Indians with disabilities;

(v) Must provide follow-up TA to participants to address any issues or challenges that are identified post-training and to ensure that the training they received is applied effectively in their work setting, and such follow-up may be conducted as part of the provision of targeted or intensive TA as determined by the needs of the specific AIVRS project;

(vi) Must conduct an evaluation to obtain feedback on the training and follow-up TA and to determine whether

this training and TA contributed to increased employment outcomes for American Indians with disabilities; and

(vii) May develop additional training modules as negotiated through the cooperative agreement.

(b) Maintain and build upon the topics and tools the current AIVRRTAC has developed to provide intensive, sustained training and TA. To satisfy this activity requirement, the grantee must—

(i) Develop and provide intensive, sustained training and TA to a minimum of three AIVRS projects in the first year. For future years, the minimum number of AIVRS projects to receive intensive, sustained training and TA will be negotiated through the cooperative agreement;

(ii) Develop and implement training and TA consistent with AIVRS project activities and tailored to the specific needs and challenges of the AIVRS project receiving the intensive training and TA;

(iii) Provide training and TA under an agreement with each AIVRS project receiving intensive training and TA that, at a minimum, details the purpose of the training and TA, intended outcomes, and requirements for the subsequent evaluation of the training and TA; and

(iv) Assess the results of the training and TA 90 days after its completion to ensure that the recipient is able to apply effectively the training and TA, identify any issues or challenges in its implementation, and provide additional training and TA, either virtually or on-site, as needed.

(c) Maintain and build upon the topics and tools the current AIVRTTAC has developed to provide a range of targeted, specialized training and TA in the topic areas described in this priority based on needs common to multiple AIVRS projects. The new grantee must follow up with the recipients of targeted, specialized training and TA it provides in order to determine the effectiveness of the training and TA;

(d) Maintain and build upon the topics and tools the current AIVRTTAC has developed to provide universal, general training and TA in the topic areas in this priority;

(e) Provide a minimum of two webinars or video conferences in each of the topic areas in this priority to describe and disseminate up-to-date information, guides, examples, and emerging and promising practices in each area;

(f) Develop new information technology (IT) platforms and systems, or modify existing platforms and systems, as follows:

(i) Develop or modify, and maintain, a state-of-the-art IT platform capable and reliable enough to support webinars, teleconferences, video conferences, and other virtual methods of dissemination of information and TA;

(ii) Develop or modify, and maintain, a state-of-the-art archiving and dissemination system that is open and available to all AIVRS projects and that provides a central location for all AIVRS training and TA products for later use, including course curricula, audiovisual materials, webinars, examples of promising practices related to the topic areas in this priority, the primary areas identified through the annual surveys completed by AIVRS projects, other topics identified by RSA, and other relevant TA products (the possibility of collaborating with the National Clearinghouse of Rehabilitation Training Materials will be considered with the grantee and included in the cooperative agreement, as appropriate);

(iii) Ensure that all products produced by the AIVRTTAC meet government and industry-recognized standards for accessibility; and

(iv) Ensure that all products, resources, and materials developed by the AIVRTTAC are widely disseminated across the AIVRS projects and reflect the AIVRS population and diversity among its communities to the maximum extent possible.

(g) Establish a community of practice (or communities of practice) that will serve as a vehicle for communication, an exchange of information among AIVRS projects, and a forum for sharing the results of training and TA projects that are in progress or have been completed;

(h) Conduct outreach to AIVRS projects so that they are aware of, and can participate in, training and TA activities; and

(i) Conduct an evaluation to determine the quality, relevance, and usefulness of the AIVRTTAC's training and TA, including the impact of the AIVRTTAC's activities on the ability of AIVRS projects to effectively manage their projects and improve the delivery of VR services to American Indians with disabilities.

Application Requirements

To be funded under this priority, applicants must meet the application 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 Proposed Project" how the proposed project will—

(1) Use the applicant's knowledge and experience in the operation of AIVRS projects in order to provide training and TA for these projects;

(2) Address the AIVRS projects' capacity to effectively implement an AIVRS project. To meet this requirement, the applicant must—

(i) Demonstrate knowledge of emerging and promising practices in the topic areas in this priority;

(ii) Demonstrate knowledge of current RSA guidance and Federal initiatives designed to improve the functioning of grant projects in general and grant projects for American Indian Tribes in particular; and

(iii) Present information about the difficulties that AIVRS grantees have encountered in implementing effective AIVRS projects;

(b) Demonstrate in the narrative section of the application under "Quality of Project Design" 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;

(iii) A plan for communicating and coordinating with RSA and key personnel of AIVRS projects; and

(iv) A draft training module or outline for a targeted TA training presentation or an outline for intensive TA activities for one of the topic areas in this priority to demonstrate how participants would be trained in that area. The module or outline is a required attachment in the application and must include, at a minimum, the following:

(A) The goals and objectives of this training module, targeted training activity, or intensive TA activities;

(B) A specific list of what participants should know and be able to do as a result of successfully completing the module, targeted training activity, or intensive TA activities;

(C) Up-to-date resources, publications, applicable laws and regulations, and other materials that may be used to develop the module, targeted training activity, or intensive TA activities;

(D) Exercises that will provide an opportunity for application of the subject matter;

(E) A description of how participant knowledge, skills, and abilities will be measured; and

(F) In the case of an intensive TA intervention, how the outcomes and impact of the intensive TA intervention will be measured;

(2) Use a logic model to develop project plans and activities that includes, at a minimum, the goals, activities, outputs, and outcomes of the proposed project;

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

(i) The current research on the emerging and promising practices in the topic areas in this priority; and

(ii) How the AIVRTTAC will incorporate current research and promising and evidence-based practices, including research about adult learning principles and implementation science, in the development and delivery of its products and services;

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

(i) Its proposed approach to universal, general training and TA;

(ii) Its proposed approach to targeted, specialized training and TA, which must identify—

(A) The intended recipients of the products and services under this approach, including the categories of personnel that would be receiving the training and TA;

(B) Its proposed methods for providing targeted, specialized training and TA; and

(C) Its proposed methodology for determining topics for the targeted, specialized training and TA;

(iii) Its proposed approach to intensive, sustained training and TA, which must identify—

(A) Its proposed approach to identifying recipients for intensive, sustained training and TA;

(B) Its proposed methodology for providing intensive, sustained training and TA to recipients; and

(C) Its proposed approach to assessing the training and TA needs of recipients, including their ability to respond effectively to the training and TA; and

(iv) Its proposed approach to maintaining and building upon capacity-building modules, which must identify—

(A) Its proposed approach to maintaining the 12 training modules and the fiscal tool kit developed by the Institute in the previous grant cycle, including maintaining the series of seven training modules that build foundational skills that, when satisfactorily completed, lead to a VR

certificate to be awarded by the new grantee; and

(B) Its proposed approach to identifying, developing and delivering new capacity-building modules; and

(5) Develop products and implement services to maximize the proposed 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;

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

(iii) In particular, how the proposed project will coordinate and collaborate with other RSA-funded technical assistance centers to exchange and adapt relevant products and materials to avoid duplication and make effective use of grant funds to better manage the AIVRTTAC project and its available resources to improve service delivery to AIVRS projects;

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

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

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

(d) Demonstrate in the narrative section of the application under "Quality of Project Personnel" 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; and

(2) The proposed key project personnel, consultants, and subcontractors have the qualifications and experience to provide training and TA to AIVRS projects in each of the topic areas in this priority and to achieve the project's intended outcomes, including how the proposed project personnel have a high degree of knowledge and understanding of cultural factors that will be sufficient to ensure the delivery of training and TA in a culturally appropriate manner;

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

(1) Clearly defined roles and responsibilities for two full-time key

project personnel designated to the AIVRTTAC through the entire project period and for consultants and subcontractors, as applicable;

(2) Timelines and milestones for accomplishing the project tasks;

(3) Using a personnel loading chart, detailed project activities through the entire project period, key personnel and any consultants or subcontractors that will be allocated to each activity, and the designated level of effort for each of those activities;

(4) How the personnel allocations in the personnel loading chart are appropriate and adequate to achieve the project's intended outcomes, including an assurance that all personnel will communicate with stakeholders and RSA in a timely fashion;

(5) How the proposed management plan will ensure that the training and TA products developed through this cooperative agreement are complete, accurate, and of high quality; and

(6) How the proposed project will benefit from a diversity of perspectives, including AIVRS projects and consumers, State VR agencies, TA providers, and policy makers, in its development and operation; and

(f) Demonstrate in the narrative section of the application under "Quality of the Evaluation Plan" how the applicant proposes to collect and analyze data on specific and measurable goals, objectives, and intended outcomes of the project, including the effectiveness of the training and 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 training and TA activities achieved their intended outcomes.

Proposed Priority 2

Background

In this second priority, RSA proposes a matching requirement to increase the vested interest of the grantee in the success of the project and to maximize the Federal investment because additional funds provided through the match would allow the grantee to support more activities. In addition, this

matching requirement may provide an opportunity for grantees to identify and partner with other entities, resulting in cooperative partnerships that could ultimately improve sustainability of the projects.

Proposed Priority 2

Projects that are designed to demonstrate matching support for the proposed projects at one or more of the following levels:

(a) 10 percent of the Federal amount of the grant.

(b) 20 percent of the Federal amount of the grant.

(c) 30 percent of the Federal amount of the grant.

(d) 40 percent of the Federal amount of the grant.

(e) 50 percent of the Federal amount of the grant.

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)(a)); 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

We propose the following definitions for use with these proposed priorities to ensure that applicants have a clear understanding of how these terms are being used.

Intensive training and technical assistance means training and technical assistance provided to the governing bodies of Indian Tribes that have received an AIVRS grant and to the current personnel of the AIVRS projects primarily on-site over an extended period. Intensive training and technical assistance is based on an ongoing

relationship between the training and technical assistance center personnel and the governing bodies of Indian Tribes that have received an AIVRS grant and the current personnel of the AIVRS projects under the terms of a signed intensive training and technical assistance agreement.

Targeted training and technical assistance means training and technical assistance based on needs common to one or more governing bodies of Indian Tribes that have received an AIVRS grant and to the current personnel of the AIVRS projects on a time-limited basis and with limited commitment of training and technical assistance center resources. Targeted training and technical assistance are delivered through virtual or in-person methods tailored to the identified needs of the participating governing bodies of Indian Tribes that have received an AIVRS grant and to the current personnel of the AIVRS projects.

Universal training and technical assistance means training and technical assistance broadly available to governing bodies of Indian Tribes that have received an AIVRS grant and to the current personnel of the AIVRS projects and other interested parties through their own initiative, resulting in minimal interaction with training and technical assistance center personnel. Universal training and technical assistance include generalized presentations, products, and related activities available through a website or through brief contacts with the training and technical assistance center personnel.

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 the proposed priorities and definitions 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 the priorities or definitions, we invite applications through a notice in the **Federal Register**.

Executive Orders 12866, 13563, and 13771

Regulatory Impact Analysis

Under Executive Order 12866, the Office of Management and Budget (OMB) determines whether this regulatory action is "significant" and,

therefore, subject to the requirements of the Executive order and subject to review by 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.

OMB has determined that this proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

Under Executive Order 13771, for each new rule that the Department proposes for notice and comment or otherwise promulgates that is a significant regulatory action under Executive Order 12866 and that imposes total costs greater than zero, it must identify two deregulatory actions. For FY 2020, any new incremental costs associated with a new rule must be fully offset by the elimination of existing costs through deregulatory actions. However, Executive Order 13771 does not apply to “transfer rules” that cause only income transfers between taxpayers and program beneficiaries, such as those regarding discretionary grant programs. Because the proposed priorities and definitions would be utilized in connection with a discretionary grant program, Executive Order 13771 does not apply.

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

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

In accordance with these 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 costs would include the time and effort in responding to the priorities for entities that choose to respond.

In addition, we have considered the potential benefits of this regulatory action and have noted these benefits in the background section of this

document. The benefits include receiving comments regarding the need to continue to provide both TA and a structured training program focused on the VR process and practices and the unique skills and knowledge necessary to improve employment outcomes for American Indians with disabilities.

Clarity of the Regulations

Executive Order 12866 and the Presidential memorandum “Plain Language in Government Writing” require each agency to write regulations that are easy to understand. The Secretary invites comments on how to make the proposed priorities and definitions easier to understand, including answers to questions such as the following:

- Are the requirements in the proposed regulations clearly stated?
- Do the proposed regulations contain technical terms or other wording that interferes with their clarity?
- Does the format of the proposed regulations (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce their clarity?
- Would the proposed regulations be easier to understand if we divided them into more (but shorter) sections?
- Could the description of the proposed regulations in the **SUPPLEMENTARY INFORMATION** section of the preamble be more helpful in making the proposed regulations easier to understand? If so, how?
- What else could we do to make the proposed regulations easier to understand?

To send any comments that concern how the Department could make these proposed regulations easier to understand, see the instructions in the **ADDRESSES** section.

Regulatory Flexibility Act

Certification: The Secretary certifies that this proposed regulatory action would not have a significant economic impact on a substantial number of small entities. The U.S. Small Business Administration Size Standards define proprietary institutions as small businesses if they are independently owned and operated, are not dominant in their field of operation, and have total annual revenue below \$7,000,000. Nonprofit institutions are defined as small entities if they are independently owned and operated and not dominant in their field of operation. Public institutions are defined as small organizations if they are operated by a government overseeing a population below 50,000.

The small entities that this proposed regulatory action would affect are public or private nonprofit agencies and

organizations, including Indian Tribes and institutions of higher education that may apply. We believe that the costs imposed on an applicant by the proposed priorities and definitions would be limited to paperwork burden related to preparing an application and that the benefits of the proposed priorities and definitions would outweigh any costs incurred by the applicant. There are very few entities who could provide the type of TA required under the proposed priorities. For these reasons the proposed priorities and definitions would not impose a burden on a significant number of small entities.

Paperwork Reduction Act of 1995:

The proposed priorities and definitions contain information collection requirements that are approved by OMB under OMB control number 1820–0018.

Assessment of Educational Impact

In accordance with section 411 of the General Education Provisions Act, 20 U.S.C. 1221e–4, the Secretary particularly requests comments on whether these proposed regulations would require transmission of information that any other agency or authority of the United States gathers or makes available.

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**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at www.govinfo.gov. 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 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.

Mark Schultz,

Commissioner, Rehabilitation Services Administration. Delegated the authority to perform the functions and duties of the Assistant Secretary for the Office of Special Education and Rehabilitative Services.

[FR Doc. 2020–19925 Filed 9–8–20; 4:15 pm]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0053; FRL–10013–78]

Receipt of a Pesticide Petition Filed for Residues of Pesticide Chemicals in or on Various Commodities (July 2020)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing of petition and request for comment.

SUMMARY: This document announces the Agency’s receipt of an initial filing of a pesticide petition requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

DATES: Comments must be received on or before October 13, 2020.

ADDRESSES: Submit your comments, identified by docket identification (ID) number by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <https://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

Marietta Echeverria, Registration Division (7505P), main telephone number: (703) 305–7090, email address: RDFRNotices@epa.gov. The mailing address is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. As part of the mailing address, include the contact’s name, division, and mail code.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws,