

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:

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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.

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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