

441 G St. N.W.
Washington, DC 20548

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February 2, 2021

Chair
Ranking Member
Committee on Finance
United States Senate

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Cathy McMorris Rodgers
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Richard Neal
Chairman
The Honorable Kevin Brady
Republican Leader
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Food and Drug Administration, Public Health Service, Centers for Medicare & Medicaid Services, Office of the Inspector General, Office of the Secretary, Administration for Children and Families: Securing Updated and Necessary Statutory Evaluations Timely*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Health and Human Services, Food and Drug Administration, Public Health Service, Centers for Medicare & Medicaid Services, Office of the Inspector General, Office of the Secretary, Administration for Children and Families (Department) entitled “Securing Updated and Necessary Statutory Evaluations Timely” (RIN: 0991-AC24). We received the rule on January 19, 2021. It was published in the *Federal Register* as a final rule on January 19, 2021. 86 Fed. Reg. 5694. The effective date of the rule is March 22, 2021.

According to the Department, the Regulatory Flexibility Act (RFA) requires agencies to publish plans to conduct periodic reviews of certain regulations and multiple executive orders also require agencies to submit plans for periodic reviews of certain regulations. To further comply with the RFA and executive orders, and to ensure the Department’s regulations have appropriate impacts, the Department stated the final rule amends its regulations to set expiration dates for the Department’s regulations (subject to certain exceptions), unless the Department periodically assesses the regulations to determine if they are subject to the RFA, and if they are, performs a review that satisfies the criteria in the RFA.

Enclosed is our assessment of the Department's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. If you have any questions about this report or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rule, please contact Shari Brewster, Assistant General Counsel, at (202) 512-6398.

A handwritten signature in black ink that reads "Shirley A. Jones". The signature is written in a cursive, flowing style.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II
Regulations Coordinator
Department of Health and Human Services

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
FOOD AND DRUG ADMINISTRATION,
PUBLIC HEALTH SERVICE,
CENTERS FOR MEDICARE & MEDICAID SERVICES,
OFFICE OF THE INSPECTOR GENERAL,
OFFICE OF THE SECRETARY,
ADMINISTRATION FOR CHILDREN AND FAMILIES
ENTITLED
“SECURING UPDATED AND NECESSARY STATUTORY EVALUATIONS TIMELY”
(RIN: 0991-AC24)

(i) Cost-benefit analysis

The Department of Health and Human Services, Food and Drug Administration, Public Health Service, Centers for Medicare & Medicaid Services, Office of the Inspector General, Office of the Secretary, Administration for Children and Families (Department) estimated the final rule would lead to costs between \$60.2 million to \$177.2 million at a 7 percent discount rate and \$67.7 million to \$199.3 million at a 3 percent discount rate.

(ii) Agency actions relevant to the Regulatory Flexibility Act (RFA), 5 U.S.C. §§ 603-605, 607, and 609

The Department performed a Regulatory Impact Analysis and stated that analysis fulfilled the requirements of the RFA.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

The Department discussed the requirements of the Act in the final rule.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.*

On November 4, 2020, the Department published a proposed rule. 85 Fed. Reg. 70096. The Department received comments on the rule proposed rule and held a public hearing on November 23, 2020. The Department addressed the comments in the final rule.

Paperwork Reduction Act (PRA), 44 U.S.C. §§ 3501-3520

The Department determined the final rule contained no information collection requirements subject to the Act.

Statutory authorization for the rule

The Department promulgated the final rule pursuant to various sections of titles 5, 6, 8, 15, 18, 19, 20, 21, 22, 25, 26, 28, 29, 30, 31, 35, 40, 42, 44, 48, and 50, United States Code. The Department also promulgated the final pursuant to Public Laws 94-114, 97-248, 99-514, 99-603, 100-241, 100-259, 100-383, 100-707, 101-201, 101-239, 101-392, 101-426, 102-325, 105-115, 107-109; 107-188, 108-155, 109-171, 111-5, 111-31, 111-148, 111-152, 111-353, 112-202, 113-54, 114-10, 114-74, and 115-245.

Executive Order No. 12866 (Regulatory Planning and Review)

The Department stated the Office of Management and Budget determined the final rule was economically significant for purposes of the Order.

Executive Order No. 13132 (Federalism)

The Department determined that this final rule does not impose substantial direct costs on state and local governments or have federalism implications.