



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

B-334355

March 10, 2023

The Honorable Bernard Sanders
Chairman
The Honorable Bill Cassidy
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

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

Subject: *Department of Health and Human Services: Withdrawing Rule on 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 (HHS) titled “Withdrawing Rule on Securing Updated and Necessary Statutory Evaluations Timely” (RIN: 0991-AC24). We received the rule on May 26, 2022. It was published in the *Federal Register* as a final rule on May 27, 2022. 87 Fed. Reg. 32246. The effective date is July 26, 2022.

According HHS, it is issuing a final rule withdrawing another rule titled “Securing Updated and Necessary Statutory Evaluations Timely” (SUNSET final rule), which it published in the *Federal Register* on January 19, 2021. 86 Fed. Reg. 5694. HHS stated that the SUNSET final rule was originally scheduled to take effect on March 22, 2021. However, HHS also stated, after a lawsuit seeking to overturn the SUNSET final rule was filed on March 9, 2021, it issued an administrative delay of effective date, which postponed the effective date of the SUNSET final rule, pending judicial review, until March 22, 2022. 86 Fed. Reg. 15404 (Mar. 23, 2021). HHS stated further that it subsequently extended the effective date of the SUNSET final rule until September 22, 2022. 87 Fed. Reg. 12399 (Mar. 4, 2022). HHS stated it is now withdrawing the SUNSET final rule.

The Congressional Review Act (CRA) requires a 60-day delay in the effective date of a major rule from the date of publication in the *Federal Register* or receipt of the rule by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). This final rule was published in the *Federal Register* on May 27, 2022. The *Congressional Record* reflects that the Senate received the rule on July 14, 2022, and the House received the rule on June 28, 2022. 168 Cong. Rec. S3307,

3308 (daily ed. July 14, 2022); 168 Cong. Rec. 5921 (daily ed. June 28, 2022).¹ The rule has a stated effective date of July 26, 2022. Therefore, the final rule does not have the required 60-day delay in its effective date.

Enclosed is our assessment of HHS'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 style with a large, prominent "S" and "J".

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Samuel A. Shipley
Senior Policy & Regulations Coordinator
Department of Health and Human Services

¹ Due to an administrative tracking error in monitoring the *Congressional Record* to verify congressional receipt of this rule, we are delayed in releasing this report.

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
TITLED
“WITHDRAWING RULE ON SECURING UPDATED AND
NECESSARY STATUTORY EVALUATIONS TIMELY”
(RIN: 0991-AC24)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS) conducted an economic analysis of this final rule. HHS’s primary estimate for cost savings in 2020 dollars, annualized over 10 years, using a 3 percent discount rate, totals \$69.9 million. HHS also estimates \$75.5 million in annualized cost savings using a 7 percent discount rate. In addition to providing estimates of monetized costs and benefits, HHS stated that the final rule will also reduce anticipated regulatory uncertainty and regulatory confusion. HHS also stated that the final rule will also reduce the time spent by HHS on other activities that it has not monetized or quantified, such as the time developing Small Entity Compliance Guides, and it will reduce the time spent by the public monitoring regulations undergoing assessment or review and set to expire. Lastly, HHS stated that the final rule will also result in a disbenefit with respect to foregone information as a result of not performing the assessments and reviews.

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

HHS certified that the final rule will not have a significant economic impact on a substantial number of small entities. HHS also prepared a Final Regulatory Flexibility Analysis. HHS stated that its Final Small Entity Analysis, as well as other sections in the Regulatory Impact Analysis (RIA), serve as the Final Regulatory Flexibility Analysis. The Final Small Entity Analysis includes a description and number of affected small entities and a description of the potential impacts of the rule on small entities. The RIA includes: (1) an introduction, summary, and background of the final withdrawal rule; (2) reasons why federal regulatory action was required; (3) the purpose of the final withdrawal rule; (4) baseline against which the changes imposed by this final rule could be measured; (5) benefits of the final withdrawal rule; (6) costs of the final withdrawal rule; and (7) a final small entity analysis.

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

HHS determined that that this final rule will result in an expenditure in at least one year of \$165 million (\$100 million, adjusted for inflation) or more.

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

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

On January 19, 2021, HHS issued a final rule titled “Securing Updated and Necessary Statutory Evaluations Timely” (SUNSET final rule). 86 Fed. Reg. 5694. According to HHS, the SUNSET

final rule was scheduled to take effect on March 22, 2021. However, HHS stated, after a lawsuit seeking to overturn the SUNSET final rule was filed on March 9, 2021, it issued an Administrative Delay of Effective Date, effective as of March 19, 2021, which postponed the effective date of the SUNSET final rule, pending judicial review, until March 22, 2022. 86 Fed. Reg. 15404 (Mar. 23, 2021). HHS also stated that it subsequently extended the effective date of the SUNSET final rule until September 22, 2022. 87 Fed. Reg. 12399 (Mar. 4, 2022). On October 29, 2021, HHS issued a notice of proposed rulemaking to withdraw or repeal the SUNSET final rule (Withdrawal NPRM). 86 Fed. Reg. 59906. HHS stated that it received 80 public comments on the Withdrawal NPRM that it summarized and responded to in this final rule.

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

HHS determined that this final rule contains no information collection requirements under the Act.

Statutory authorization for the rule

HHS promulgated this final rule pursuant to section 301 of title 5; section 371 of title 21; and sections 216, 1302, 1395hh, and 2003 of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

HHS stated that it believes that this final rule is a significant regulatory action.

Executive Order No. 13132 (Federalism)

HHS determined that this final rule does not contain policies that have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.