



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

B-338802

October 19, 2026

The Honorable Mike Crapo
Chairman
The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Brett Guthrie
Chairman
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Jason Smith
Chairman
The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Global Benchmark for Efficient Drug Pricing (GLOBE) Model*

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, Centers for Medicare & Medicaid Services (CMS) entitled "Global Benchmark for Efficient Drug Pricing (GLOBE) Model" (RIN: 0938-AV66). We received the rule on October 2, 2026. It was published in the *Federal Register* on October 2, 2026. 91 Fed. Reg. 62936. The stated effective date of the rule is November 30, 2026.

According to CMS, the final rule implements the Global Benchmark for Efficient Drug Pricing Model (GLOBE Model), a new mandatory Medicare payment model under section 1115A of the Social Security Act. CMS stated the GLOBE Model will test whether a payment model that uses an alternative method for calculating Medicare Part B drug inflation rebate amounts for certain separately payable Medicare Part B drugs and biological products reduces costs for Original Medicare (OM) beneficiaries and the Medicare program while preserving quality of care. CMS also stated the term OM has the same meaning as Medicare fee-for-service and the traditional Medicare program.

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). The rule was published on October 2, 2026. 91 Fed. Reg. 62936. The *Congressional Record* does not reflect receipt of the rule by the House of Representatives or the Senate. The stated effective date of the rule is November 30, 2026. Therefore, the stated effective date is less than 60 days from the date of publication of the rule in the *Federal Register*.

Enclosed is our assessment of CMS'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 me at (202) 512-8156.

A handwritten signature in black ink, reading "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,
CENTERS FOR MEDICARE & MEDICAID SERVICES
ENTITLED
“GLOBAL BENCHMARK FOR EFFICIENT DRUG PRICING (GLOBE) MODEL”
(RIN: 0938-AV66)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) estimated the final rule would lead to transfers from manufacturers to the Medicare and Medicaid Trust Funds in the amount of \$80 million at the three percent discount rate and \$80.3 million at the seven percent discount rate per year for contract years 2027 to 2032. 91 Fed. Reg. 63087.

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

The Secretary concluded the final rule will not have a significant economic impact on a substantial number of small entities. 91 Fed. Reg. 63096. The Secretary additionally concluded the final rule would not have a significant economic impact on a substantial number of small rural hospitals. *Id. at.* 63099.

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

The Secretary has determined that this final rule will not impose a federal mandate that will result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, exceeding the \$193 million UMRA threshold in any one year. 91 Fed. Reg. 63100.

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

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

On December 23, 2025, CMS published in the *Federal Register*, 90 Fed. Reg. 60244, a proposed rule titled “Global Benchmark for Efficient Drug Pricing (GLOBE) Model”. CMS stated it solicited comments on the proposed rule. 91 Fed. Reg. 62944. In response to the final rule, CMS stated it received 20,168 pieces of correspondence, of which 157 were unique, timely correspondence from a variety of commenters, including, but not limited to, academia, consumer/patient advocacy organizations, consulting groups, distributors, health plans, health care companies or providers, professional associations, pharmaceutical manufacturers, and individuals. *Id. at* 62944–45. The other 20,011 pieces of correspondence were duplicative correspondence submitted by the same entity. *Id. at* 62945.

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

In its submission to us, CMS indicated this rule does not contain an information collection requiring Office of Management and Budget approval under the PRA.

Statutory authorization for the rule

CMS promulgated this rule pursuant to section 1315a of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated the Office of Information and Regulatory Affairs has determined this rulemaking is significant according the Order. 91 Fed. Reg. 63086.

Executive Order No. 13132 (Federalism)

CMS determined since this final rule does not impose any substantial costs on state or local governments, preempt state law or have federalism implications, the requirements of the Order are not applicable. 91 Fed. Reg. 63100.