



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

B-335355

June 15, 2023

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

The Honorable Cathy McMorris Rodgers
Chair
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: Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID-19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs-IID) to Provide COVID-19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long-Term Care Facility COVID-19 Testing Requirements*

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 "Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID-19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs-IID) to Provide COVID-19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long-Term Care Facility COVID-19 Testing Requirements" (RINs: 0938-AU75, 0938-AU57, 0938-AU33). We received the rule on May 25, 2023. It was published in the *Federal Register* as a final rule on June 5, 2023. 88 Fed. Reg. 36485. The effective date is August 4, 2023.

According to CMS, the final rule removes expired language addressing staff and patient COVID-19 testing requirements for LTC Facilities issued in the interim final rule with comment (IFC) “Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency,” published in the September 2, 2020 *Federal Register*. 85 Fed. Reg. 54820. The final rule also finalizes requirements for these facilities to provide education about COVID-19 vaccines and to offer COVID-19 vaccines to residents, clients, and staff. In addition, the final rule withdraws the regulations in the IFC “Omnibus COVID-19 Health Care Staff Vaccination,” published in the November 5, 2021 *Federal Register*, 86 Fed. Reg. 61555, and finalizes certain provisions of the “COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff” IFC, published in the May 13, 2021 *Federal Register*. 86 Fed. Reg. 26306.

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 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
Centers for Medicare & Medicaid Services
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

“MEDICARE AND MEDICAID PROGRAMS; POLICY AND REGULATORY CHANGES
TO THE OMNIBUS COVID-19 HEALTH CARE STAFF VACCINATION REQUIREMENTS;
ADDITIONAL POLICY AND REGULATORY CHANGES TO THE REQUIREMENTS
FOR LONG-TERM CARE (LTC) FACILITIES AND INTERMEDIATE CARE FACILITIES
FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES (ICFS-IID)
TO PROVIDE COVID-19 VACCINE EDUCATION AND OFFER VACCINATIONS
TO RESIDENTS, CLIENTS, AND STAFF; POLICY AND REGULATORY CHANGES
TO THE LONG-TERM CARE FACILITY COVID-19 TESTING REQUIREMENTS”
(RINS: 0938-AU75, 0938-AU57, 0938-AU33)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) estimated the final rule would create \$690 million in benefits per year at both the seven and three percent discount rates from 2023–2025. CMS stated the benefits come from reduction of costs.

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

CMS stated that HHS determined the final rule would not have a significant adverse economic impact on a substantial number of small entities. CMS also stated that HHS determined the final rule would not have a significant impact on the operations of a substantial number of rural hospitals.

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

CMS determined that the final rule contains no state, local, or tribal governmental mandates, nor any mandates on private sector entities.

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

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

CMS stated it did not issue a proposed rule. CMS noted the three interim final rules would have expired after three years if not finalized due to statutory limitations.

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

CMS stated the final rule contains no new information collection requirements and sunsets those implemented in the prior interim final rules.

Statutory authorization for the rule

CMS promulgated the final rule pursuant to sections 263a, 273, 1302, 1320a-7, 1320b-8, 1395, 1395i, 1395hh, 1395rr, 1395eee, 1396r, and 1396u-4 of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated the Office of Management and Budget determined the final rule was economically significant.

Executive Order No. 13132 (Federalism)

CMS determined the final rule was not subject to the requirements of the Order.