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B-333286

May 24, 2021

The Honorable Ron Wyden
Chairman
The Honorable Mike Crapo
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
Ranking Member
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare and Medicaid Services: Medicare and Medicaid Programs; 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*

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 and Medicaid Services (CMS) entitled "Medicare and Medicaid Programs; 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" (RIN: 0938-AU57). We received the rule on May 13, 2021. It was published in the *Federal Register* as an interim final rule with comment period on May 13, 2021. 86 Fed. Reg. 26306. The effective date is May 21, 2021.

According to CMS, the rule revises the infection control requirements that LTC facilities (Medicaid nursing facilities and Medicare skilled nursing facilities, also collectively known as "nursing homes") and ICFs-IID must meet to participate in the Medicare and Medicaid programs. CMS indicates that this rule aims to reduce the spread of SARS-CoV-2 infections, the virus that causes COVID-19, by requiring education about COVID-19 vaccines for LTC facility residents, ICF-IID clients, and staff serving both populations, and by requiring that such vaccines, when available, be offered to all residents, clients, and staff. CMS also states that the rule requires LTC facilities to report the COVID-19 vaccination status of residents and staff to

the Centers for Disease Control and Prevention (CDC). CMS explains these requirements as necessary to help protect the health and safety of ICF-IID clients and LTC facility residents. In addition, CMS solicits public comments via the rule on the potential application of these or other requirements to other congregate living settings over which CMS has regulatory or other oversight authority.

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 60-day delay in effective date can be waived, however, if the agency finds for good cause that delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued. 5 U.S.C. § 808(2). CMS states that the 60-day delay would be impracticable and contrary to the public interest, due to the nation's pressing need to address the on-going health impacts of COVID-19. Specifically, CMS cites to the higher mortality rate for LTC facility residents who contract COVID-19, and their subsequent prioritization in vaccination efforts; the need to continue supporting vaccination efforts in long-term care facilities; the increase in residents and facility staff who have recently overcome vaccine hesitancy; and the need for vaccination data from these facilities.

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.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Vanessa Jones
Regulations Coordinator
Department of Health and Human Services

ENCLOSURE

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; 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"
(RIN: 0938-AU57)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) conducted an economic analysis of the interim final rule. CMS included a final accounting table with the rule. CMS also included an estimation of first year and succeeding year costs for 11 cost categories, with a total first year cost estimate of $159,056,000 and a total succeeding year cost estimate of $104,705,000. The economic analysis discussed, in detail, anticipated benefits from the rule, including modified quality adjusted life years and value of a statistical life calculations for long-term care (LTC) and intermediate care facilities for individuals with intellectual disabilities (ICF-IID) residents and staff who will be vaccinated under the rule, but who otherwise would have contracted COVID-19. CMS noted the array of uncertainties with regards to the evolving COVID-19 vaccination situation, which affect the economic analysis of the rule.

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

CMS determined that this rule will not have a significant economic impact on a substantial number of small entities and that a final regulatory impact assessment is not required. CMS stated, because the rule has no direct effects on any hospitals, it has determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals. CMS also determined that this rule is exempt from section 1102(b) of the Social Security Act's regulatory impact assessment requirements, because that provision of law only applies to final rules for which a proposed rule was published.

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

CMS stated that this rule does contain mandates on private sector entities, and estimated the resulting amount to be about $158 million, which represents the $100 million threshold under the Unfunded Mandates Reform Act, adjusted for inflation, in the first year. However, because this rule was not preceded by a notice of proposed rulemaking, CMS specifies that the requirements of the Unfunded Mandates Reform Act do not apply.

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

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

CMS found good cause to waive the notice and comment rulemaking provisions of the Administrative Procedure Act, 5 U.S.C. § 553(b)(B). CMS stated that the continuing effects of and response to the nationwide health effects of COVID-19 made it impracticable and contrary to the public interest for CMS to undertake normal notice and comment rulemaking procedures.

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

CMS determined that this rule contains information collection requirements (ICRs) under the Act. CMS solicited comments on ICRs for the Office of Management and Budget's (OMB) future review and approval. The total burden estimate for the information collection burden in both LTC facilities and ICFs-IID in the first year is 1,277,874 hours at an estimated cost of $91,250,874, and, in subsequent years, the burden is estimated at 866,580 hours at a cost of $55,177,044. The requirements and burden will be submitted to OMB under OMB Control Number 0938-1363 for the LTC facilities and 0938-New for the ICFs-IID.

CMS estimated the burden of ICRs regarding the development of policies and procedures for:

- 42 C.F.R. § 483.80(d)(3) (OMB Control Number 0938-1363) at a first year cost of $38,360,400 and subsequent annual cost of $12,542,400;
- ICRs regarding developing education materials for staff members and residents and residents' representatives in 42 C.F.R. §§ 483.80(d)(3)(ii) and (iii) (OMB Control Number 0938-1363) at a first year cost of $4,180,800;
- ICRs regarding keeping vaccine information up-to-date and making necessary changes under 42 C.F.R. § 483.80(d)(3)(iv) (OMB Control Number 0938-1363) at an annual cost of $6,271,200;
- ICRs regarding the documentation requirements in 42 C.F.R. §§ 483.80(d)(3)(vi) and (vii) (OMB Control Number 0938-1363) at an annual cost of $3,837,600;
- ICRs regarding the reporting requirements to CMS and the Centers for Disease Control and Prevention (National Healthcare Safety Network) in 42 C.F.R. §§ 483.80(d)(3)(viii) and (ix) (OMB Control Number 0938-1363) at an annual cost of $27,175,200;
- ICRs regarding the development of policies and procedures for 42 C.F.R. § 483.460(a)(4) (OMB Control Number 0938-New) at a first year cost of $5,688,306 and a subsequent annual cost of $2,320,344;
- ICRs regarding the education requirements in 42 C.F.R. §§ 483.460(a)(4)(ii), (iii), and (iv) (OMB Control Number 0938-New) at a first year cost of $5,027,412 and a subsequent annual cost of $2,320,344;
- ICRs regarding the documentation requirements in 42 C.F.R. §§ 483.460(a)(4)(vi) and (f) (OMB Control Number 0938-New) at an annual cost of $709,956.

Statutory authorization for the rule

CMS promulgated this rule pursuant to sections 1302, 1320a-7, 1395i, 1395hh, and 1396r of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS determined that this rule is economically significant as measured by the $100 million threshold in the Order and submitted it to OMB for review.

Executive Order No. 13132 (Federalism)

CMS determined that nothing in this rule will have a substantial direct effect on state or local governments, preempt state laws, or otherwise have federalism implications.