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November 19, 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
Republican Leader
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 & Medicaid Services: Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination*

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; Omnibus COVID-19 Health Care Staff Vaccination" (RIN: 0938-AU75). We received the rule on November 8, 2021. It was published in the *Federal Register* as an interim final rule on November 5, 2021. 86 Fed. Reg. 61555. The effective date is November 5, 2021.

According to CMS, this interim final rule with comment period revises the requirements that most Medicare- and Medicaid-certified providers and suppliers must meet to participate in the Medicare and Medicaid programs. CMS stated that these changes are necessary to help protect the health and safety of residents, clients, patients, Programs of All-Inclusive care for the Elderly participants, and staff, and reflect lessons learned to date as a result of the coronavirus disease 2019 (COVID-19) public health emergency. CMS also stated that the revisions to the requirements establish COVID-19 vaccination requirements for staff of the included Medicare- and Medicaid-certified providers and suppliers.

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 a delay would be 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. §§ 553(b)(3)(B), 808(2). According to CMS, a combination of factors, including but not limited to failure to achieve sufficiently high levels of vaccination based on voluntary efforts and patchwork requirements, potential harm to patients from unvaccinated health-care workers, and continuing strain on the health care system and known efficacy and safety of available vaccines, have persuaded CMS that a vaccine mandate for health care workers is an essential component of the nation's COVID-19 response. CMS also stated that delaying the effective date would endanger the health and safety of patients, and be contrary to the public interest. Thus, CMS asserts that there is good cause to waive notice and comment rulemaking procedures and the delay in effective date under CRA.

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: Calvin E. Dukes II
Regulations Coordinator

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;
OMNIBUS COVID-19 HEALTH CARE STAFF VACCINATION"
(RIN: 0938-AU75)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) prepared an accounting statement and table for this interim final rule (IFR). According to CMS, the two largest benefit categories are 1) staff and patient lives extended through vaccinations for the coronavirus disease 2019 (COVID-19), and 2) reduced medical costs for vaccinated persons who would otherwise be hospitalized. CMS stated that patient benefits are larger than staff benefits, but it did not quantify, into annual totals, either the life-extending or medical cost-reducing benefits of the IFR. CMS did, however, quantify the cost associated with the IFR. CMS stated that the cost would stem from increased staff vaccinations. CMS's primary estimate of the annualized and monetized cost is $1,380,000,000 in 2020 dollars at a seven percent discount rate for 2021–2022, and $1,400,000,000 in 2020 dollars at a three percent discount rate for 2021–2022. CMS noted that its projection is limited to one year because of uncertainties surrounding the COVID-19 pandemic. Lastly, CMS indicated that there are no transfers associated with this IFR.

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

HHS has determined that this IFR will not have a significant economic impact on a substantial number of small entities. CMS estimates that this IFR would cost employers about $125 per employee and assuming a fully loaded average wage per employee of $90,000, the first-year cost would not approach the three percent threshold for increases in costs or a decrease in revenue that HHS uses to determine whether a rule would have a significant economic impact on small entities. Lastly, HHS also determined that this IFR will not have a significant impact on the operations of a substantial number of small 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 stated that this IFR contains no state, local, or tribal governmental mandates, but does contain mandates on private sector entities that would impose costs in excess of approximately $158 million ($100 million in 1995 dollars adjusted for inflation). CMS stated further that this IFR was not preceded by a notice of proposed rulemaking, therefore the requirements of the 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.*

According to CMS, a combination of factors, including but not limited to failure to achieve sufficiently high levels of vaccination based on voluntary efforts and patchwork requirements, potential harm to patients from unvaccinated health-care workers, and continuing strain on the health care system and known efficacy and safety of available vaccines, have persuaded CMS that a vaccine mandate for health care workers is an essential component of the nation's COVID-19 response. CMS also stated that undertaking the notice and comment rule process would endanger the health and safety of patients, and be contrary to the public interest. Thus, CMS asserted that there is good cause to waive the notice and comment procedures required under the Act.

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

CMS stated that there are information collection requirements (ICR) associated with this IFR. CMS also stated that the ICRs are included in an emergency revision of an information collection request currently approved under the appropriate Office of Management and Budget (OMB) Control Number. CMS stated further that, with respect to PRA-related comments received in response to this ICR, it will seek regular, non-emergency, approval. CMS stated the total burden for all ICRs in the IFR is 1,555,487 hours at an estimated cost of $136,088,221. CMS stated the ICRs are associated with OMB Control Numbers: 0938-0266, 0938-1067, 0938-1326, 0938-0328, 0938-1363, 0938-0833, 0938-1402, 0938-1299, 0938-1091, 0938-1043, 0938-0273, 0938-1245, 0938-855B, 0938-0334, and 0938-0386.

Statutory authorization for the rule

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

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated that this IFR is economically significant and that OMB has reviewed the rule.

Executive Order No. 13132 (Federalism)

CMS stated that this IFR would preempt some state laws that prohibit employers from requiring their employees to be vaccinated for COVID-19. CMS stated that it has considered other alternatives (for example, relying entirely on measures such as voluntary vaccination, source control alone, and social distancing) and has concluded that the mandate established by this IFR is the minimum regulatory action necessary to achieve the objectives of CMS's statutory health and safety authority. CMS stated further that it has invited, through this IFR, state and local comments on the substance as well as legal issues presented by this IFR, and on how it can fulfill the statutory requirements for health and safety protections of patients if it were to exempt any providers or suppliers based on state or local opposition to this IFR.