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March 10, 2021

The Honorable Patty Murray
Chair
The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

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

Subject: *Department of Health and Human Services: Control of Communicable Diseases; Foreign Quarantine: Suspension of Introduction of Persons Into United States From Designated Foreign Countries or Places for Public Health Purposes*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Centers for Disease Control and Prevention (CDC) within the U.S. Department of Health and Human Services (HHS) entitled "Control of Communicable Diseases; Foreign Quarantine: Suspension of Introduction of Persons Into United States From Designated Foreign Countries or Places for Public Health Purposes" (RIN: 0920-AA76). We received the rule on May 8, 2020.[1] It was published in the *Federal Register* as an interim final rule with request for comments on March 24, 2020. 85 Fed. Reg.16559. The effective date of this interim final rule was March 20, 2020.

According to HHS, CDC is issuing this interim final rule with request for comments to amend its Foreign Quarantine Regulations. HHS stated that this interim final rule provides a procedure for CDC to suspend the introduction of persons from designated countries or places, if required, in the interest of public health.

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. §§ 553(b)(3)(B), 808(2). Here, although HHS did not specifically mention CRA's 60-day delay in effective date requirement, HHS stated that notice

[1] This major rule report was due on June 30, 2020. Due to a processing error on our part, we are delayed in our issuance of this report.

and comment procedures were unnecessary for this interim final rule because it found good cause to waive such procedures under section 553(b)(3)(B) of the Administrative Procedure Act (APA). HHS also stated that given the national emergency caused by the Coronavirus Disease 2019, it would be impracticable and contrary to the public health—and, by extension, the public interest—to delay these implementing regulations until a full public notice-and-comment process is completed. HHS stated further, for the same reasons, it has determined, consistent with section 553(d) of APA, that there is good cause to make this interim final rule effective immediately.

Enclosed is our assessment of HHS's and CDC'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
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
ENTITLED
"CONTROL OF COMMUNICABLE DISEASES; FOREIGN QUARANTINE:
SUSPENSION OF INTRODUCTION OF PERSONS INTO UNITED STATES
FROM DESIGNATED FOREIGN COUNTRIES OR PLACES
FOR PUBLIC HEALTH PURPOSES"
(RIN: 0920-AA76)

(i) Cost-benefit analysis

In its submission to us, the Department of Health and Human Services (HHS) on behalf of the Centers for Disease Control and Prevention (CDC) indicated that it did not prepare an analysis of the costs and benefits of this interim final rule (IFR).

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

In its submission to us, HHS indicated that a regulatory flexibility analysis was not prepared for this IFR. However, according HHS, when a rule is promulgated in response to an emergency that makes timely compliance impracticable, the agency must publish a regulatory flexibility analysis within 180 days of publication of the final rule. 5 U.S.C. § 608(b). HHS stated that for the reasons set forth in this IFR pertaining to the Coronavirus Disease 2019 (COVID-19) outbreak, the Secretary found that this IFR was being promulgated in response to an emergency that made timely compliance with the provisions of section 604 impracticable. HHS also stated that it will assess the potential impacts—including economic effects—of this action on all small entities. HHS stated further, based on that assessment, the Secretary will either certify that the rule will not have a significant economic impact on a substantial number of small entities or publish a final regulatory flexibility 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 this IFR is not expected to result in expenditures by state, local, and tribal governments, or by the private sector, of $154 million ($100 million, adjusted for inflation) or more in any one year, because it only establishes a regulatory mechanism for the exercise of the Public Health Service Act's section 362 suspension authority, which applies against persons and not state, local, or tribal governments, or the private sector. 42 U.S.C. § 265.

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

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

HHS stated that notice and comment procedures were unnecessary for this IFR, and it found good cause to waive such procedures under section 553(b)(3)(B) of the Administrative Procedure Act (APA). HHS also stated that given the national emergency caused by COVID-19, it would be impracticable and contrary to the public health—and, by extension, the

public interest—to delay these implementing regulations until a full public notice-and-comment process was completed.

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

HHS determined that this IFR has no new collections of information for purposes of PRA.

Statutory authorization for the rule

HHS, on behalf of CDC, promulgated this IFR pursuant to sections 216, 243, and 264–272 of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

HHS determined that this IFR is economically significant under the Order. HHS stated that it is proceeding under the emergency provision of the Order at section 6(a)(3)(D) based on the need to move expeditiously during the current public health emergency to limit the number of new cases of COVID-19.

Executive Order No. 13132 (Federalism)

According to HHS, this IFR does not alter the relationship between the federal government and state/local governments as set forth in 42 U.S.C. § 264(e), which provides that federal public health regulations do not preempt state or local public health regulations, except in the event of a conflict with the exercise of federal authority. HHS stated that the longstanding provision on preemption in the event of a conflict with federal authority, 42 C.F.R. § 70.2, is left unchanged by this rulemaking. HHS stated further that there are no provisions in this IFR that impose direct compliance costs on state and local governments.