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November 17, 2009

The Honorable Tom Harkin
Chairman
The Honorable Michael B. Enzi
Ranking Minority Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Henry A. Waxman
Chairman
The Honorable Joe L. Barton
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

Subject: *Department of Health and Human Services, Centers for Disease Control and Prevention: Medical Examination of Aliens--Removal of Human Immunodeficiency Virus (HIV) Infection From Definition of Communicable Disease of Public Health Significance*

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 Disease Control and Prevention (CDC), entitled "Medical Examination of Aliens--Removal of Human Immunodeficiency Virus (HIV) Infection From Definition of Communicable Disease of Public Health Significance" (RIN: 0920-AA26). We received the rule on October 30, 2009. It was published in the *Federal Register* as a final rule on November 2, 2009, with an effective date of January 4, 2010. 74 Fed. Reg. 56,547.

The final rule removes HIV infection from the definition of communicable disease of public health significance and removes references to HIV from the scope of examinations for aliens because HIV infection does not represent a communicable disease that is a significant threat to the general U.S. population. As a result of the final rule, HIV infection will no longer be an inadmissible condition, and HIV testing will no longer be required for those aliens who are required to undergo a medical examination for U.S. immigration purposes. As a result of this final rule, CDC has also revised the Technical Instructions provided to panel physicians and civil surgeons to reflect the removal of the HIV testing requirement.

Prior to the enactment of the United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, CDC was required by statute to list HIV infection as a communicable disease of public health significance. Now that the statute provides discretion, CDC removed HIV infection from the definition to reflect current scientific knowledge and public health best practices, and to reduce stigmatization of people who are HIV infected. CDC also found it appropriate to remove HIV testing from the scope of examinations in the immigration process, since HIV infection has been removed as a communicable disease of public health significance. CDC notes that the regulations found at 42 C.F.R. part 34 do not specify testing for any illness that is not included in the definition of *communicable disease of public health significance*.

Enclosed is our assessment of the 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. Our review of the procedural steps taken indicates that CDC complied with the applicable requirements.

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 Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer
Managing Associate General Counsel

Enclosure

cc: Vivian Stallion
Program Manager
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 DISEASE CONTROL AND PREVENTION
ENTITLED
"MEDICAL EXAMINATION OF ALIENS--REMOVAL OF
HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION
FROM DEFINITION OF COMMUNICABLE DISEASE
OF PUBLIC HEALTH SIGNIFICANCE"
(RIN: 0920-AA26)

(i) Cost-benefit analysis

CDC analyzed the costs and benefits of the final rule. The benefits would allow roughly 4,275 persons to enter the United States annually who are otherwise admissible but are denied admission solely based on their HIV status, will bring family members together who had been barred from entry thus strengthening families, permit HIV-infected immigrants with skills in high demand to enter the U.S. to seek employment and contribute as productive members of U.S. society, remove stigmatization of HIV-infected people who have long been denied entry into the U.S. based only on a treatable and preventable medical condition, and bring the U.S. in line with current science and international standards of public health. The costs to the health care sector could range from an estimated \$19 million to \$173 million in the first year, depending on annual cost of treatment, available treatment options, and inclusion of direct medical costs. Though difficult to quantify with precision, the CDC also noted there will likely be some additional cases of HIV infection due to onward transmissions from HIV infected immigrants to others in the United States who are not currently infected. The costs associated with onward transmission include shortened lifespan and reduction in quality of life even with treatment, the health care costs associated with treating HIV infection, the costs of social services when individuals are unable to fully support themselves because of their illness, and decreased productivity when individuals become too sick to work.

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

CDC certifies that the rule will not have a significant impact on a substantial number of small entities and therefore did not provide an analysis under the Act.

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

CDC states that the rule does not contain federal mandates for state, local, or tribal governments, nor for the private sector. CDC also states the rule's provisions will not affect small governments.

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

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

The final rule was issued using the notice and comment procedures found at 5 U.S.C. § 553. On July 2, 2009, CDC published a notice of proposed rulemaking to remove HIV infection from the definition of communicable disease of public health significance and from the scope of examinations for immigration purposes. 74 Fed. Reg. 31,798. CDC received over 20,000 timely items of correspondence from the public which are addressed in the final rule. 74 Fed. Reg. 56,549.

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

There are no new data collection requirements. The Act applies to the data collection requirements found in 42 C.F.R. part 34. CDC states that currently, aliens determined to have a communicable disease of public health significance may request a waiver from the Department of Homeland Security to enter the United States under the Immigration and Nationality Act. 8 U.S.C. § 1182(d)(3)(a), (g). CDC has approval from the Office of Management and Budget (OMB) to collect data pertaining to the waiver. CDC will discontinue the use of this form, for a reduction of 67 burden hours for this approved data collection.

Statutory authorization for the rule

CDC states that the rule is promulgated under the authority of 42 U.S.C. § 252 and 8 U.S.C. §§ 1182, 1222.

Executive Order No. 12,866 (Regulatory Planning and Review)

The CDC states that the final rule is an economically significant action under the Order.

Executive Order No. 13,132 (Federalism)

CDC has determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.