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August 16, 2010

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

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

Subject: *Department of Health and Human Services: Pre-Existing Condition Insurance Plan Program*

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 (HHS), entitled "Pre-Existing Condition Insurance Plan Program" (RIN: 0991-AB71). We received the rule and it was published in the *Federal Register* as an interim final rule with comment period on July 30, 2010. 75 Fed. Reg. 45,014. The rule has a stated effective date of July 30, 2010, and comments due on or before September 28, 2010.

The interim final rule implements section 1101 of the Patient Protection and Affordable Care Act of 2010,[1] which requires HHS to establish, either directly or through contracts with states or nonprofit entities, a temporary high risk health insurance pool program to provide affordable health insurance coverage to uninsured individuals with pre-existing conditions. This program will continue until January 1, 2014. This rule addresses issues such as administration of the program, eligibility and enrollment, benefits, premiums, funding, and appeals and oversight rules.

[1] Pub. L. No. 111-148, § 1101, 124 Stat. 119, 141 (Mar. 23, 2010).

The Congressional Review Act requires major rules to have a 60-day delay in their effective date following their publication in the *Federal Register* or receipt by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). However, notwithstanding the 60-day requirement, any rule that an agency for good cause finds that the notice and public comment procedures are impractical, unnecessary, or contrary to the public interest is to take effect when the promulgating agency so determines. 5 U.S.C. § 808(2). HHS determined that it had good cause to waive prior notice and comment procedures in this case, noting that it would be impractical and contrary to the public interest to delay putting regulations into effect that are necessary to implement the program until the rules have been subject to prior notice and comment procedures. HHS further noted that the normal 60-day comment period would by itself consume two-thirds of the 90 days the statute provided for implementation. Therefore, the requirement to have a 60-day delay in the effective date does not apply to this rule.

Enclosed is our assessment of HHS'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 HHS 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: Ann 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
ENTITLED
"PRE-EXISTING CONDITION INSURANCE PLAN PROGRAM"
(RIN: 0991-AB71)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS) analyzed the costs and benefits of this interim final rule. In assessing the benefits of this rule, HHS stated that the Pre-existing Condition Insurance Plan (PCIP) will provide uninsured Americans with pre-existing conditions and that have been denied coverage or otherwise excluded from purchasing insurance coverage an opportunity to obtain coverage. HHS determined that providing this insurance option will increase access to health care and reduce financial strain for participants and will likely improve health outcomes and worker productivity. HHS found that individuals who are especially vulnerable as a result of existing health problems and financial status may receive the greatest benefit from this program.

HHS estimated that the annual reporting and recordkeeping costs associated with this interim final rule will be $1,939,020. HHS determined that, to the extent PCIP increases access to health care services, increased health care utilization and costs will result due to increased uptake. HHS also identified administrative costs of the rule, including the cost of contractors to apply, the time cost for individuals to apply, and the contractors' costs of complying with program rules (e.g., conducting appeals, preventing fraud). Finally HHS estimates that under this rule $5 billion in federal funds will be transferred to contractors to aid in administering the program.

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

HHS determined that this interim final rule will not have a significant impact on a substantial number of small entities.

(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 interim final rule does not impose an unfunded mandate on states or on the private sector.

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

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

HHS did not publish a notice of proposed rulemaking for this interim final rule. An agency may waive publishing a notice of proposed rulemaking if it finds for good cause that a notice-and-comment procedure is impractical, unnecessary, or contrary to the public interest. 5 U.S.C. § 553(b). HHS found that statutory deadlines provided good cause to waive the notice of proposed rulemaking as impracticable and contrary to the public interest. HHS issued this rule as final on an interim basis with a 60-day comment period.

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

HHS determined that this interim final rule contains six information collection requirements under the Act and submitted them to the Office of Management and Budget (OMB) for review. HHS estimates that these requirements will have 100,051 respondents submitting 101,887 responses annually, with a total burden of 103,244 hours and a total cost of $1,939,020.

Statutory authorization for the rule

HHS promulgated this interim final rule under the authority of section 1101 of the Patient Protection and Affordable Care Act of 2010.[2]

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

HHS determined that this interim final rule is an economically significant rule under the Order because it is likely to have an annual effect on the economy of $100 million in any one year. OMB reviewed the rule under the Order.

Executive Order No. 13,132 (Federalism)

HHS determined that this interim final rule does not impose any direct costs on state or local governments.

[2] Pub. L. No. 111-148, § 1101, 124 Stat. 119, 141 (Mar. 23, 2010).