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February 17, 2011

The Honorable Max Baucus
Chairman
The Honorable Orrin G. Hatch
Ranking Member
Committee on Finance
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Dave Camp
Chairman
The Honorable Sander M. Levin
Ranking Member
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services and Office of Inspector General: Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers*

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 (Department), Centers for Medicare & Medicaid Services and Office of Inspector General, entitled "Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers" (RIN: 0938-AQ20). We received the rule on January 24, 2011. It was published in the *Federal Register* as a final rule with comment period on February 2, 2011. 76 Fed. Reg. 5862.

The final rule with comment period will implement provisions of the Affordable Care Act (ACA) that establish procedures under which screening is conducted for providers of medical or other services and suppliers in the Medicare program and providers in the Medicaid or Children's Health Insurance Program (CHIP). The final rule with comment period also implements an application fee imposed on institutional providers and suppliers. Additional elements to be implemented include temporary moratoria that may be imposed if necessary to prevent or combat fraud, waste, and abuse under Medicare, Medicaid, and CHIP, and requirements for suspension of payments pending credible allegations of fraud in the Medicare and Medicaid programs.

The Department has identified specific provisions surrounding its implementation of fingerprinting for certain providers and suppliers for which it may make changes if warranted by the public comments received. The Department will consider public comments only on the Fingerprinting Requirements, contained in 42 C.F.R. §§ 424.518 and 455.434, no later than 5 p.m. on April 4, 2011.

The final rule with comment period has an effective date of March 25, 2011. 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). We received the rule on January 24, 2011, but it was not published in the *Federal Register* until February 2, 2011. Therefore the final rule does not have the required 60-day delay in its effective date.

Enclosed is our assessment of the Department'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 the Department 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,
CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF INSPECTOR GENERAL
ENTITLED
"MEDICARE, MEDICAID, AND CHILDREN'S HEALTH INSURANCE
PROGRAMS; ADDITIONAL SCREENING REQUIREMENTS,
APPLICATION FEES, TEMPORARY ENROLLMENT MORATORIA,
PAYMENT SUSPENSIONS AND COMPLIANCE PLANS
FOR PROVIDERS AND SUPPLIERS"
(RIN: 0938-AQ20)

(i) Cost-benefit analysis

The Department estimates that the annual reporting/recordkeeping burden for the final rule with comment period will be 1,248,082 hours and \$62.4 million dollars. The Department believes that this regulation will have a significant benefit by reducing the ability of potential providers to defraud taxpayers. In its conclusion, the Department also noted that the final rule contains provisions that are of critical importance in the transition of the Centers for Medicare and Medicaid Services' antifraud activities from "pay and chase" to fraud prevention.

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

The Department does not believe that its application fees or other screening provisions will have a significant impact on any small entities. According to the Department, this final rule with comment period could have a significant impact on a relatively small proportion of small businesses in terms of restrictions on federal health monies paid to small businesses participating in the Medicare or Medicaid programs or CHIP. Additionally, the Department believes the imposition of an enrollment moratorium would have an impact on a small business that is attempting to do business with any of the federal health programs, just as the suspension of payments to any small entity could create a significant impact on that entity. However, the Department has no basis for estimating how many entities might be affected by these provisions, but believes that this final rule with comment period will reduce fraud and abuse among potential providers.

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

In order to enforce the Medicaid-related provisions, the Department states that this final rule with comment period mandates expenditures by state and local governments, but believes that those expenditures will be relatively minor. According to the Department, the mandated costs on providers—primarily for application fees—may approach or exceed the threshold for the private sector.

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

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

The final regulations were issued using the notice and comment procedures found at 5 U.S.C. § 553. On September 23, 2010, the proposed rule on Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers was published. 75 Fed. Reg. 58,204. The Department received approximately 300 timely pieces of correspondence. Summaries of the public comments that were within the scope of the proposals and the Department's responses were set out in the final rule.

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

The Department states that the Paperwork Reduction Act of 1995 requires a 60-day notice in the *Federal Register* and solicitation of public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. The Department solicited public comment on each issue that contains information collection requirements. The Department notes that for this final rule with comment period it will be retaining the Collection of Information estimates in the proposed rule.

Statutory authorization for the rule

The Department states that the final rule is authorized by section 353 of the Public Health Service Act (42 U.S.C. § 263a) and sections 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. §§ 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k)).

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

The Department determined that the final rule with comment period is economically significant because it is likely to have an effect on the economy of \$100 million or more in any one year.

Executive Order No. 13,132 (Federalism)

The Department states that since this final rule with comment period would not impose any substantial direct requirement costs on state or local governments, preempt state law, or otherwise have federalism implication, the requirements of the order are not applicable.