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United States Government Accountability Office
Washington, DC 20548

B-321287

December 15, 2010

The Honorable Max Baucus
Chairman
The Honorable Charles E. Grassley
Ranking Member
Committee on Finance
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: Health Insurance Issuers
Implementing Medical Loss Ratio (MLR) Requirements Under the Patient
Protection and Affordable Care Act*

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 “Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act” (RIN: 0950-AA06). We received the rule on November 22, 2010. It was published in the *Federal Register* as an interim final rule with request for comments on December 1, 2010. 75 Fed. Reg. 74,864.

The interim final rule implements the medical loss ratio (MLR) requirements for health insurance issuers under the Public Health Service Act (PHS Act), as added by the Patient Protection and Affordable Care Act (Affordable Care Act). This interim final regulation adopts and certifies in full all of the recommendations in the model regulation of the National Association of Insurance Commissioners (NAIC) regarding MLRs. It is being published to implement section 2718(a) through (c) of the PHS Act, relating to bringing down the cost of health care coverage through a new MLR standard. Subpart A implements the requirements for reporting the data to be considered in determining that ratio. Subpart B addresses the requirements for health insurance issuers (issuers) in the group or individual market, including grandfathered health plans, to provide an annual rebate to enrollees, if the issuer’s

MLR fails to meet minimum requirements--generally, 85 percent in the large group market and 80 percent in the small group or individual market. In Subpart C, this interim final regulation provides a process and criteria for the Secretary of HHS (the Secretary) to determine whether application of the 80 percent MLR in the individual market in a state may destabilize that individual market. Finally, enforcement of the reporting and rebate requirements of section 2718(a) and (b) are addressed in Subparts D–F, as specifically authorized in section 2718(b)(3). This interim final regulation is generally applicable for plan years beginning on or after January 1, 2011. Self-insured plans are not a health insurance issuer, as defined by section 2791(b)(2) of the PHS Act, and thus are not subject to this interim final regulation.

The interim final regulations are effective on January 1, 2011. The Congressional Review Act (CRA) generally 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). However, notwithstanding the 60-day delay requirement, any rule that an agency for good cause finds that notice and public comment are impracticable, unnecessary, or contrary to the public interest is to take effect when the promulgating agency so determines. 5 U.S.C. §§ 553(d)(3), 808(2). HHS found good cause to forego the notice and comment procedures based on the fact that the provisions of the rule apply, by statute, on January 1, 2011.

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: Annie Lamb
Regulations Coordinator
Department of Health and
Human Services

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
ENTITLED
"HEALTH INSURANCE ISSUERS IMPLEMENTING
MEDICAL LOSS RATIO (MLR) REQUIREMENTS UNDER
THE PATIENT PROTECTION AND AFFORDABLE CARE ACT"
(RIN: 0950-AA06)

(i) Cost-benefit analysis

In developing this interim final regulation, HHS carefully considered its potential effects including both costs and benefits. Because of data limitations, HHS did not attempt to quantify the benefits of this regulation. Nonetheless, HHS was able to identify several potential benefits. HHS believes one potential benefit to this regulation is greater market transparency and improved ability of consumers to make informed insurance choices. In addition, HHS states that issuers that would not otherwise meet the MLR minimum defined by this regulation may increase spending on quality-promoting activities. According to HHS, these programs, which include case management, care coordination, chronic disease management and medication compliance, have the potential to create a societal benefit by improving outcomes and population health. HHS notes that issuers that would not otherwise meet the MLR minimum may also expand covered benefits or reduce cost sharing. HHS believes that to the extent that these changes result in increased consumption of effective health services, the regulation could result in improved health outcomes, thereby creating a societal benefit.

HHS has identified the primary sources of costs associated with this regulation as the costs associated with reporting, recordkeeping, rebate notifications and payments, and other costs. HHS estimates that issuers will incur approximately \$33 million to \$67 million in one-time administrative costs, and \$11 million to \$29 million in annual ongoing administrative costs related to complying with the requirements of this interim final regulation from 2011 through 2013. HHS notes that there are two other potential types of costs associated with this regulation: costs of potential increases in medical care use, the cost of additional quality-improving activities, and costs to consumers if some issuers decide to limit offered products as a result of this interim final regulation.

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

HHS states that the Regulatory Flexibility Act only requires an analysis to be conducted for those final rules for which a Notice of Proposed Rule Making (NPRM)

was required. Accordingly, HHS has determined that a regulatory flexibility analysis is not required for this interim final rule. However, HHS has considered the likely impact of this interim final rule on 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 states that this interim final regulation is not subject to the Unfunded Mandates Reform Act (UMRA), because it is being issued as an interim final regulation. However, consistent with the policy embodied in UMRA, this interim final regulation has been designed to be the least burdensome alternative for state, local, and tribal governments, and the private sector while achieving the objectives of the Affordable Care Act.

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

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

HHS issued this rule as an interim final rule. Under section 553(b) of the APA, a general NPRM is not required when an agency for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. Section 2792 of the PHS Act authorizes the Secretary to promulgate any interim final rules determined to be appropriate to carry out the provisions of Part A of title XXVII of the PHS Act. HHS states that the provisions of these interim final regulation requirements in section 2718, and the foregoing interim final rule authority applies to this interim final regulation. HHS states that although the provisions of the APA that ordinarily require a NPRM do not apply here because of the specific authority granted by section 2792 of the PHS Act, even if the APA were applicable, the Secretary has determined that it would be impracticable and contrary to the public interest to delay putting the provisions of this interim final regulation in place until a public notice and comment process was completed. Additionally, HHS states that prior notice and comment in this situation is impracticable because section 2718 of the PHS Act directs the NAIC, not later than December 31, 2010, and subject to certification by the Secretary, to establish uniform definitions. However, the reporting required by section 2718 of the PHS Act applies to plan years beginning not later than January 1, 2011. HHS states that there are fewer than 60 days between when HHS would be able to review the NAIC's recommendations, certify them, and issue an implementing regulation. Therefore, HHS finds good cause to waive the NPRM and to issue this final rule on an interim basis. HHS is providing a 60-day public comment period.

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

HHS is soliciting public comment for 60 days on each of the issues that contain information collection requirements. HHS has submitted a copy of these interim

final regulations to the Office of Management and Budget (OMB) in accordance with 44 U.S.C. § 3507(d) for review of the information collections.

Statutory authorization for the rule

HHS states that the interim final rule is authorized pursuant to the authority found in section 2718 of the Public Health Service Act. 42 U.S.C. §§ 300gg–18, as amended.

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

HHS concluded that this interim final rule is likely to have economic impacts of \$100 million or more in any one year. Accordingly, OMB has reviewed this interim final regulation pursuant to the Executive Order.

Executive Order No. 13,132 (Federalism)

In HHS's view, while this interim final rule does not impose substantial direct requirement costs on state and local governments, this interim final regulation has federalism implications due to direct effects on the distribution of power and responsibilities among the state and federal governments relating to determining and enforcing minimum MLR standards, reporting and rebate requirements relating to coverage that state-licensed health insurance issuers offer in the individual and group markets. However, HHS anticipates that the federalism implications (if any) are substantially mitigated because the Affordable Care Act does not provide any role for the states in terms of receiving or analyzing the data or enforcing the requirements of section 2718 of the PHS Act.