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The Honorable Tom Harkin
Chairman
The Honorable Lamar Alexander
Ranking Member
Committee on Health, Education, Labor, and Pensions
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: Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs*

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 Medicare & Medicaid Services (CMS) entitled “Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs” (RIN: 0938-AR69). We received the rule on May 21, 2013. It was published in the *Federal Register* as a final rule on May 23, 2013, with an effective date of July 22, 2013. 78 Fed. Reg. 31,284.

The final rule for the Medicare Advantage (Part C) and prescription drug (Part D) programs make changes as required by the Patient Protection and Affordable Care Act (Pub. L. No. 111–148), as amended by the Health Care and Education Reconciliation Act (Pub. L. No. 111–152) (Reconciliation Act), also known

collectively as the Affordable Care Act. The Affordable Care Act includes significant reforms to both the private health insurance industry and the Medicare and Medicaid programs. Provisions in the Affordable Care Act concerning the Part C Medicare Advantage (MA) and Part D Prescription Drug programs largely focus on beneficiary protections, MA payment reforms, and simplification of MA and Prescription Drug program processes for both programs.

The final rule implements section 1103 of Title I, Subpart B of the Reconciliation Act. This section of the Affordable Care Act amends section 1857(e) of the Social Security Act (the Act) to add new medical loss ratio (MLR) requirements. An MLR is expressed as a percentage, generally representing the percentage of revenue used for patient care, rather than for such other items as administrative expenses or profit. Because section 1860D–12(b)(3)(D) of the Act incorporates by reference the requirements of section 1857(e) of the Act, these new Affordable Care Act medical loss ratio requirements also apply to the Part D program. Under these new requirements, MA organizations and Part D sponsors are required to report their MLR and are subject to financial and other penalties for a failure to meet a new statutory requirement that they have an MLR of at least 85 percent. The Affordable Care Act requires several levels of sanctions for failure to meet the 85 percent minimum MLR requirement, including remittance of funds to the Secretary, a prohibition on enrolling new members, and ultimately contract termination. The final rule sets forth CMS's implementation of the new MLR requirements for the MA and Part D programs.

Enclosed is our assessment of CMS'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 CMS 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

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
ENTITLED
"MEDICARE PROGRAM; MEDICAL LOSS RATIO REQUIREMENTS
FOR THE MEDICARE ADVANTAGE AND THE MEDICARE
PRESCRIPTION DRUG BENEFIT PROGRAMS"
(RIN: 0938-AR69)

(i) Cost-benefit analysis

In developing the final rule, CMS carefully considered its potential effects, including both costs and benefits and identified several potential benefits. According to CMS, one potential benefit of the final rule is greater market transparency and improved ability of beneficiaries to make informed insurance choices. CMS states that the uniform reporting required under the final rule, along with other programs such as *www.Medicare.gov*, a Web site with plan-level information, will mean that beneficiaries will have better data to inform their choices, enabling the market to operate more efficiently. In addition, CMS notes that contracts that will not otherwise meet the MLR minimum defined by the final rule may opt to increase spending on quality-promoting activities. CMS explains that 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 beneficiary population health. Additionally, CMS states that MA organizations and Part D sponsors that will not otherwise meet the MLR minimum may also expand covered benefits or reduce cost-sharing for beneficiaries. To the extent that these changes result in increased consumption of effective health services, CMS believes that the final rule could result in improved beneficiary health outcomes, thereby creating a societal benefit.

CMS identified the direct costs associated with the final rule as the costs associated with reporting, recordkeeping, remittance payments, enrollment sanctions and termination, and other costs. CMS estimates that each MA organization and Part D sponsor will incur approximately \$16,000 in one-time administrative costs (per report), and about \$5,000 in annual ongoing administrative costs (per report) related to complying with the requirements of the final rule. CMS identified other potential costs as costs of potential increases in medical care use, the costs of additional quality-improving activities, and costs to beneficiaries if MA organizations and Part D sponsors decide to limit products offered as a result of the final rule. According to CMS, there may be increases in quality improving activities, provision of medical services, and Part D covered items due to the final rule. CMS believes that this is

likely to have some benefit to beneficiaries but also potentially represents an additional cost to MA organizations, Part D sponsors, and the federal government. CMS notes that it is also possible that some MA organizations and Part D sponsors in particular areas or markets will not be able to operate profitably when required to comply with the proposed requirements and they may respond by changing or reducing the number of products they offer. CMS believes that MA organizations and Part D sponsors are likely to consider whether they expect to be successful competitors in a given market. According to CMS, entire contracts or subsets of plans under contracts with low MLRs may be withdrawn from a given market entirely, while MA organizations and Part D sponsors with low MLR contracts (particularly those that are subsidiaries of larger organizations) may find ways to achieve higher MLRs through increased efficiencies. Additionally, CMS states that to the extent that MA organizations and Part D sponsors decide to limit product offerings in response to this final rule, individual enrollees in the plans under these contracts may bear some costs associated with searching for and enrolling in a new Medicare health plan. For Medicare beneficiaries, CMS believes that this may also lead to reduced choice, the inability to purchase similar coverage, and higher search costs related to finding affordable insurance coverage.

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

CMS believes that the final rule will have minimal impact on small entities. As a result, the Secretary of Health and Human Services has determined that this 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

CMS states that the final rule includes no mandates on state, local, or tribal governments.

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

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

On February 22, 2013, CMS published a proposed rule with revisions to the MA program (Part C) and prescription drug benefit program (Part D). 78 Fed. Reg. 12,428. CMS received approximately 51 items of timely correspondence containing comments in response to the proposed rule. According to CMS, these public comments addressed issues on multiple topics. CMS notes that commenters included health and drug plan organizations, insurance industry trade groups, provider associations, pharmacist and pharmacy associations, beneficiary advocacy groups, private citizens, and others. CMS states that it presents a summary of public comments received, as well as its responses to them in the applicable

section of the final rule. CMS also notes that regulations implementing most Affordable Care Act provisions pertaining to the MA and Prescription Drug program provisions were published on April 12, 2012 (77 Fed. Reg. 22,072) and a correction was published June 1, 2012 (77 Fed. Reg. 32,407).

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

CMS is soliciting public comment on information collection requirements (ICRs) regarding MLR and remittance reporting requirement and ICRs regarding retention of records. CMS states that it developed a preliminary burden estimate, but is not seeking Office of Management and Budget (OMB) approval at this time. CMS will seek OMB approval for the aforementioned recordkeeping requirements at the same time it seeks OMB approval for the information collection requirements associated with the proposed MLR remittance reporting requirements discussed in 42 C.F.R. §§ 422.2470 and 423.2470.

Statutory authorization for the rule

CMS states that section 1857(e)(4) of the Social Security Act, which establishes requirements for a minimum MLR, directly applies to the MA program. The requirements at section 1857(e)(4) of the Act also apply to the Medicare Prescription Drug Benefit Program, because section 1860D–12(b)(3)(D) of the Act requires that the contractual requirements at section 1857(e) of the Act apply to the Part D program.

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

CMS examined the effects of the final rule as required by the Order and states that the final rule is likely to have economic impacts of \$100 million or more in any one year, and therefore has been designated an “economically significant” rule. Therefore, CMS prepared a regulatory impact statement (RIA) that details the anticipated effects (costs, savings, and expected benefits), and alternatives considered in this final rule. Accordingly, OMB has reviewed the final rule pursuant to the Order. CMS notes that it did not receive any comments on the RIA and is therefore finalizing the analysis as proposed.

Executive Order No. 13,132 (Federalism)

Executive Order 13,132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. States generally regulate health insurance coverage. However in 2003, section 232(a) of the Medicare Modernization Act of 2003 amended section 1856 for MA plans by eliminating the general and specific preemption distinctions from section 1856 and expanded

federal preemption of state standards to broadly apply preemption to all state law or regulation (other than state licensing laws or state laws relating to plan solvency). In CMS's view, while this final rule does not impose substantial direct requirement costs on state and local governments, the final rule has minimal 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 remittance requirements relating to coverage that MA organizations and Part D sponsors offer. CMS 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 1857(e)(4) of the Act. The enforcement provisions of the final rule state that the Secretary has enforcement authority and does not require the states to do anything. CMS explains that in developing the final rule for the Medicare Advantage and the Medicare Prescription Drug Benefit programs, HHS used the commercial MLR regulation as a reference point for developing the Medicare MLR requirements. In compliance with the requirement of the Order that agencies examine closely any policies that may have federalism implications or limit the policymaking discretion of the states, HHS made efforts to consult with and work cooperatively with states during the development of the commercial MLR regulation, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with state insurance officials on an individual basis. Throughout the process of developing the commercial MLR regulation, to the extent feasible within the specific preemption provisions of HIPAA as it applies to the Affordable Care Act, the Department attempted to balance the states' interests in regulating health insurance issuers, and Congress' intent to provide uniform minimum protections to consumers in every state.

It is the Department's view that it complied with the requirements of Executive Order 13,132, and pursuant to the requirements set forth in section 8(a) of the Executive Order, the Department certifies that it has complied with the requirements for the final rule in a meaningful and timely manner.