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February 16, 2016

The Honorable Orrin G. Hatch
Chairman
The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Kevin Brady
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: Medicaid Program; Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health*

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 "Medicaid Program; Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health" (RIN: 0938-AQ36). We received the rule on January 28, 2016. It was published in the *Federal Register* as a final rule on February 2, 2016. 81 Fed. Reg. 5530.

The final rule revises the Medicaid home health service definition consistent with section 6407 of the Patient Protection and Affordable Care Act of 2010 (PPACA) and section 504 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) to add requirements that, for home health services, physicians document, and, for certain medical equipment, physicians or certain authorized non-physician practitioners (NPP) document the occurrence of a face-to-face encounter (including through the use of telehealth) with the Medicaid eligible beneficiary within reasonable timeframes. This rule also aligns the timeframes for the face-to-face encounter with similar regulatory requirements for Medicare home health services. In addition, this rule amends the definitions of medical supplies, equipment, and appliances. CMS expects minimal impact with the implementation of section 6407 of PPACA and section 504 of MACRA. CMS

recognizes that states may have budgetary implications as a result of the amended definitions of medical supplies, equipment, and appliances. Specifically, this rule may expand coverage of medical supplies, equipment, and appliances under the home health benefit. As stated in the rule, there will be items that had previously only been offered under certain sections of the Social Security Act that will now be covered under the home health benefit.

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
Deputy Director, ODRM
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
"MEDICAID PROGRAM; FACE-TO-FACE REQUIREMENTS
FOR HOME HEALTH SERVICES; POLICY CHANGES
AND CLARIFICATIONS RELATED TO HOME HEALTH"
(RIN: 0938-AQ36)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) described the costs and benefits of this final rule. A table summarizing the costs and benefits was included in the final rule. The provision was described to be for physician and certain non-physician practitioners (NPP) for durable medical equipment documentation of face-to-face encounters with the Medicaid eligible beneficiary within reasonable timeframes when ordering home health services. CMS stated that this provision applies to Medicaid in the same manner and to the same extent as the Medicare program, but no estimates (costs or savings) were noted for the Medicaid program as data to determine these estimates was unavailable. For Medicare, the overall economic impact of this provision is an estimated \$920 million in savings to the Medicare program from 2010–2014 and \$2.29 billion in savings from 2010–2019. CMS concluded that there may be an increase in costs, but the scope of the increases are not measurable due to state flexibilities.

CMS projects that the overall benefit of this rule is the expected increase in program integrity resulting in more quality home health services for Medicaid beneficiaries. Additionally, CMS states that the rule will potentially serve to provide individuals with disabilities a greater ability to engage in normal activities of daily living. CMS further noted that this provision may result in offsetting benefits to both beneficiaries and state budgets, including the ability for beneficiaries to return to or enter the workforce, thereby increasing the pool of taxpayers, and decreasing reliance on other Medicaid benefits, including institutional care. CMS concluded that while there is no specific estimate regarding the benefits, they nonetheless should be taken into account.

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

CMS acknowledged that most hospitals and most other providers and suppliers are small entities, but concluded that it need not prepare an analysis for the RFA because it has determined that the final rule will not have a significant economic impact on a substantial number of small entities. CMS stated that entities affected by this rule should already be administering these changes for Medicare purposes as the statutory change was effective in 2010. CMS believes that entities should already have systems in place to accommodate this change for the Medicaid population. In addition, CMS stated that section 1102(b) of the Social Security Act (the Act) requires CMS to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of RFA, but CMS concluded that it need not prepare an analysis for section 1102(b) of the Act because it has determined that the rule

would not have a significant impact on the operations of a substantial number of small rural hospitals.

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

CMS determined that this final rule will not impose a mandate that would result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of more than \$144 million (\$100 million adjusted for inflation) in any one year.

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

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

On July 12, 2011, CMS published a proposed rule. 76 Fed. Reg. 41,032. In addition, in the May 5, 2010, *Federal Register*, CMS issued the interim final rule entitled “Medicare and Medicaid Programs: Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements,” which was effective on July 6, 2010, and which requested comments. 75 Fed. Reg. 24,437. As section 6405(a) of the Patient Protection and Affordable Care Act (PPACA) was not applicable to title XIX of the Act, CMS did not incorporate changes in the proposed rule to the scope of providers that may order medical supplies, equipment, and appliances in the Medicaid program. However, CMS specifically solicited comments through the interim rule on the merits of doing so. CMS received a total of 94 timely items of correspondence from home health provider representatives and other professional associations, state Medicaid directors, states, beneficiaries, and other individuals. CMS responded to comments in the final rule.

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

In the proposed rule, CMS solicited public comment on each of the PRA-required issues for the information collection requirements (ICRs). The final rule summarized the PRA-related comments along with the CMS responses. CMS states that it solicited comments on: the need for the information collection and its usefulness in carrying out the proper functions of the agency; the accuracy of the CMS burden estimates; the quality, utility, and clarity of the information to be collected; and the effort to minimize the information collection burden on the affected public, including the use of automated collection techniques. Subsequent to the publication of the proposed rule, CMS revised its cost estimates by a factor of 100 percent using the most current U.S. Bureau of Labor Statistics wage estimates along with a fringe benefit adjustment factor. Other ICRs were carried over from the proposed rule including: ICRs regarding home health services--physician documentation of the face-to-face encounter; and ICRs regarding home health services--communication of clinical findings. A table of the annual recordkeeping and reporting requirements was included in the final rule. CMS stated that it has submitted a copy of the rule to the Office of Management and Budget (OMB) for its review of the rule's information collection and recordkeeping requirements, and noted that requirements are not effective until they have been approved by OMB.

Statutory authorization for the rule

CMS promulgated this final rule under the authority of section 6407 of PPACA (Pub. L. 111–148) (Mar. 23, 2010), and section 504 of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) (Apr. 16, 2015) which amended the underlying Medicare requirements at section 1834(a)(11)(B)(ii) of the Social Security Act.

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

CMS determined that, since the estimate of this final rule may likely have a financial impact of greater than \$100 million, this final rule is economically significant. This rule was reviewed by OMB.

Executive Order No. 13,132 (Federalism)

CMS concluded that since this regulation does not impose any costs on state or local governments, the requirements of the Executive Order on federalism are not applicable.