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B-327675

January 13, 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: Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies*

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; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies" (RIN: 0938-AR85). We received the rule on December 29, 2015. It was published in the *Federal Register* as a final rule on December 30, 2015, with an effective date of February 29, 2016. 80 Fed. Reg. 81,674.

The final rule establishes a prior authorization program for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items that are frequently subject to unnecessary utilization. According to CMS, this rule defines unnecessary utilization and creates a new requirement that billing claims for certain DMEPOS items must have prior authorization as a condition of payment. This rule also adds the decision regarding prior authorization of coverage to the list of actions that are not appealable.

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
"MEDICARE PROGRAM; PRIOR AUTHORIZATION PROCESS FOR
CERTAIN DURABLE MEDICAL EQUIPMENT,
PROSTHETICS, ORTHOTICS, AND SUPPLIES"
(RINs: 0938-AR85)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) summarized the costs, benefits, and transfers resulting from this final rule. CMS estimated that the overall economic cost of this final rule will be approximately \$1.3 million in the first year, the 5-year cost will be approximately \$57 million, and the 10-year cost will be approximately \$212 million, mostly driven by the increased number of items subjected to prior authorization after the first year. CMS also noted that additional administrative paperwork costs to private sector providers and suppliers and an increase in Medicare spending to conduct reviews combine to create the financial impact. However, CMS found that this impact will be offset by some savings. CMS believes there are likely to be other benefits and cost savings that result from the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) prior authorization requirement, but many of those benefits are difficult to quantify. For instance, as stated in the final rule, CMS expects to see savings in the form of reduced unnecessary utilization, fraud, waste, and abuse, including a reduction in improper Medicare fee-for-service payments.

CMS found that the overall benefits of this final rule include a change in billing practices that also enhances the coordination and collaboration of care between the primary care provider and the supplier to provide the most appropriate DMEPOS item to meet the needs of the beneficiary. According to CMS, the provider and supplier community will benefit from the increased education and outreach that is planned during year 1 of the prior authorization program. CMS estimated that savings, net of premium offsets, to the Medicare program due to reductions in payments to DMEPOS suppliers will be \$10 million in 2016, potentially rising over time to between \$10 million and \$110 million in 2025, yielding a 10-year annualized amount of \$10 to \$68.1 million with a 7 percent discount rate or \$10 to \$71.4 million with a 3 percent discount rate.

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

CMS acknowledged that many of the entities affected by this final rule are small entities. CMS prepared an analysis that explains the rationale for and purposes of this final rule, details the costs and benefits of the rule, and presents the measures CMS would use to minimize the burden on small entities. CMS stated it was unaware of any relevant federal rules that duplicate, overlap, or conflict with this final rule and that the relevant sections of this final rule contain a description of significant alternatives if applicable. CMS also determined that this final rule would not have a significant impact on the operations of a substantial number of small 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 May 28, 2014, CMS published a proposed rule. 79 Fed. Reg. 30,511. CMS received 1,009 comments from the prosthetics and orthotics community, beneficiaries (including amputees) and beneficiary advocacy groups, professional and trade organizations, physicians and other clinicians, suppliers, and other interested parties. CMS responded to comments in the final rule.

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

CMS determined that this final rule does not add or change any current documentation requirements. However, CMS also believes that this rule will initially increase the burden associated with collecting and submitting required documentation. CMS estimates that these information collection requirements will affect an average of 70,000 claims in 2016 through 2018 and that these claims will have an associated prior authorization request submission 2.25 times resulting in an average of 157,500 cases. CMS estimated the total average annual burden for 2016 through 2018 will be 78,750 hours per year at a cost of \$2.8 million per year. After adding average mailing costs, the burden rises to \$5.8 million per year for 2016 through 2018.

Statutory authorization for the rule

CMS promulgated this final rule under the authority of section 353 of the Public Health Service Act and sections 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act. 42 U.S.C. §§ 263a, 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

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

CMS determined that, since the effect of this final rule may redistribute more than \$100 million in certain years under its high estimates, this final rule is economically significant. This rule was reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

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