



441 G St. N.W.
Washington, DC 20548

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July 6, 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; Medicare Clinical Diagnostic Laboratory Tests Payment System*

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; Medicare Clinical Diagnostic Laboratory Tests Payment System" (RIN: 0938-AS33). We received the rule on June 21, 2016. It was published in the *Federal Register* as a final rule on June 23, 2016. 81 Fed. Reg. 41,036.

The final rule implements requirements of section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), which significantly revises the Medicare payment system for clinical diagnostic laboratory tests. This final rule also announces an implementation date of January 1, 2018, for the private payor rate-based fee schedule required by PAMA.

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: Agnes Thomas
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,
CENTERS FOR MEDICARE & MEDICAID SERVICES
ENTITLED
"MEDICARE PROGRAM; MEDICARE CLINICAL DIAGNOSTIC
LABORATORY TESTS PAYMENT SYSTEM"
(RIN: 0938-AS33)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) performed a cost-benefit analysis in conjunction with the regulatory impact analysis in the final rule. CMS stated that it is limited in its ability to estimate effects of the Medicare Clinical Laboratory Fee Schedule (CLFS) payment policies under different scenarios due to a lack of data. According to CMS, the effect on the Medicare program is expected to be \$390 million less in Part B program payments for CLFS tests furnished in FY 2018. The 5-year impact is estimated to be \$1.71 billion less and the 10-year impact is expected to result in \$3.93 billion less in program payments. Medicare pays approximately \$7 billion a year under the current CLFS for Clinical Diagnostic Laboratory Tests. Using the estimated amount of changes in CLFS spending, CMS estimated an overall percentage reduction in revenue of approximately -5.6 percent for FY 2018 ($-\$390 \text{ million}/\$7 \text{ billion} = -5.6 \text{ percent}$); a 5-year percentage reduction of about 4.9 percent ($-\$1.71 \text{ billion}/\$35 \text{ billion} = -4.9 \text{ percent}$) and a 10-year percentage reduction of approximately 5.6 percent ($-\$3.93 \text{ billion}/\$70 \text{ billion} = -5.61 \text{ percent}$). As such, CMS estimates that the revisions to the CLFS as authorized by Protecting Access to Medicare Act of 2014 (PAMA) will have a significant impact on small businesses.

CMS noted that the above estimates differ from the estimates indicated in the regulatory impact analysis section of the proposed rule. According to CMS, the difference is due to the move in implementation from January 1, 2017, to January 1, 2018. The move not only eliminated a year of potential savings but resulted in less future savings as another year of productivity adjustments will take effect and essentially narrow the gap between private payor rates and Medicare rates.

CMS states that it is creating a data collection system, developing Healthcare Common Procedure Coding System (HCPCS) codes for laboratory tests when needed, convening a Federal Advisory Committee Act (FACA) advisory committee to make recommendations on how to pay for new Clinical Diagnostic Laboratory Tests (CDLTs) including reviewing and making recommendations on applications for Advanced Diagnostic Laboratory Tests (ADLTs), and undertaking other implementation activities. To implement these new standards, CMS anticipates initial federal start-up costs to be approximately \$4 million per year. Once implemented, ongoing costs to collect data, review ADLTs, maintain data collection systems, and provide other upkeep and maintenance services will require an estimated \$3 million annually in federal costs. CMS states that it will continue to examine and seek comment on the potential impacts to both Medicare and Medicaid.

CMS further believes that each of the policies, which are finalized in this rule, will substantially reduce the reporting burden for reporting entities in general and small businesses in particular.

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

CMS states that for purposes of RFA, it estimated that most of the entities paid under CLFS are small entities as that term is used in the RFA (including small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration definition of a small business (having revenues of less than \$7.5 million to \$38.5 million in any 1 year). CMS found that the final rule will have a significant impact on a substantial number of small

businesses or other small entities even with an exception for low expenditure laboratories. A final regulation is generally deemed to have a significant impact on small businesses if the rule is estimated to have an impact greater than a 3 to 4 percentage change to their revenue. CMS provided an estimated accounting statement which it believes to be a reasonable representation of the impact of the changes to CLFS on small businesses.

According to CMS, the final rule will not have a significant impact on small rural hospitals because the majority of entities paid under CLFS and affected by the policies are independent laboratories and physician offices. To the extent that rural hospitals own independent laboratories and to the extent that rural hospitals are paid under CLFS, there could be a significant impact on those facilities. Since most payments for laboratory tests to hospitals are bundled in Medicare Severity Diagnosis Related Group payments under Part A, CMS determined that the final rule will not have a significant impact on the operations of a substantial number of small rural hospitals. CMS requested comment from small rural hospitals on (1) their relationships with independent clinical laboratories and (2) the potential impact of a reduction in CLFS payments on their revenues and profits. CMS received no comments.

In developing this final rule, CMS states that it considered numerous alternatives to the final policies. Key areas where CMS considered alternatives include the organizational level associated with an applicable laboratory, authority to develop a low volume or low expenditure threshold to reduce reporting burden for small businesses, whether to include coinsurance amounts as part of the applicable information, the definition of the initial reporting period for ADLTs, and how to set rates for CDLTs for which the agency receives no applicable information.

(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 Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2016, that is approximately \$146 million. CMS states that the final rule does not contain mandates that will impose spending costs on state, local, or tribal governments in the aggregate, or by the private sector.

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

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

On October 1, 2015, CMS published a proposed rule with a request for comments. 80 Fed. Reg. 59,404. CMS received approximately 1,300 public comments from individuals, health care providers, corporations, government agencies, trade associations, and major laboratory organizations. CMS summarized the public comments related to each proposal, and responded to the comments in the final rule.

CMS states that it ordinarily publishes a notice of proposed rulemaking in the *Federal Register* to provide for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. However, this procedure can be waived for good cause, if it is determined that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest, and a statement incorporating the finding and the reasons in the rule.

CMS stated that it is finalizing the Civil Monetary Penalty (CMP) amounts adjusted in accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (sec. 701 of the Bipartisan Budget Act of 2015, Pub. L. No. 114-74) (the 2015 Act) without public notice and comment. CMS states that the 2015 Act is very prescriptive in the formula that the agency must apply in adjusting the civil monetary penalties, leaving no flexibility to exercise discretion in calculating the inflation adjustments to the CMP amounts. Therefore, CMS found good cause to waive notice and comment procedures as unnecessary.

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

CMS states that as stated in section 1834A(h)(2) of the Social Security Act (the Act), Chapter 35 of title 44, United States Code, PRA shall not apply to the information collection requirements contained in section 1834A of the Act. Consequently, the information collection requirements contained in the final rule need not be reviewed by the Office of Management and Budget.

Statutory authorization for the rule

The final rule was promulgated under the authority of sections 1833(h) of the Act. (42 U.S.C. § 1395l(h)), and section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. No. 113-93, enacted on April 1, 2014) which added section 1834A to the Act. (42 U.S.C. § 1395m-1).

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

CMS determined that the final rule is an economically significant rule because it believes that the changes to how CLFS payment rates will be developed will overall decrease payments to entities paid under the CLFS. CMS estimates that this final rule is economically significant as measured by the \$100 million threshold. The final rule was reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

CMS has examined the CLFS provisions included in the final rule in accordance with the executive order on federalism, and determined that they will not have a substantial direct effect on state, local, or tribal governments, preempt state law, or otherwise have a federalism implication. While CMS has limited information about entities billing CLFS with government ownership, the limited amount of information it currently has indicates that the number of those entities, as well as CLFS payment amounts associated with them, are minimal. Based on 2013 claims data, CMS received only 21,627 claims for CLFS services from a total of 50 state or local public health clinics (0.1 percent of total laboratories that billed under CLFS). However, CMS noted that the final rule will potentially affect payments to a substantial number of laboratory test suppliers, and some effects may be significant.