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March 21, 2005

The Honorable Charles E. Grassley
Chairman
The Honorable Max Baucus
Ranking Minority Member
Committee on Finance
United States Senate

The Honorable Joe Barton
Chairman
The Honorable John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

The Honorable William M. Thomas
Chairman
The Honorable Charles B. Rangel
Ranking Minority Member
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare and Medicaid Services: Medicare Program: Changes to the Medicare Claims Appeal Procedures*

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 and Medicaid Services (CMS), entitled "Medicare Program: Changes to the Medicare Claims Appeal Procedures" (RIN: 0938-AM73). We received the rule on March 3, 2005. It was published in the Federal Register as an "interim final rule with comment period" on March 8, 2005. 70 Fed. Reg. 11420.

The interim final rule implements the changes to the Medicare claims appeal procedures by section 521 of the Medicare, Medicaid, and SCHIP Benefits Act of 2000 (BIPA). The rule also provides for implementing the new statutory

requirements enacted in Title IX of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

The interim final rule has an announced effective date of May 1, 2005. The Congressional Review Act 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). The rule was received by Congress on March 3, 2005, and was published in the Federal Register on March 8, 2005. Therefore, the final rule does not have the required 60-day delay in its effective date.

Enclosed is our assessment of the 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 indicates that, with the exception of the 60-day delay in the effective date, CMS complied with the applicable requirements.

If you have any questions about this report, please contact James W. Vickers, Assistant General Counsel, at (202) 512-8210. The official responsible for GAO evaluation work relating to the subject matter of the rule is Marjorie Kanof, Managing Director, Health Care. Ms. Kanof can be reached at (202) 512-7101.

signed

Kathleen E. Wannisky
Managing Associate General Counsel

Enclosure

cc: Ann Stallion
Regulations Coordinator
Department of Health and
Human Services

ENCLOSURE

ANALYSIS UNDER 5 U.S.C. § 801(a)(1)(B)(i)-(iv) OF A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
CENTERS FOR MEDICARE AND MEDICAID SERVICES
ENTITLED
"MEDICARE PROGRAM: CHANGES TO THE MEDICARE
CLAIMS APPEAL PROCEDURES"
(RIN: 0938-AM73)

(i) Cost-benefit analysis

CMS prepared a Regulatory Impact Analysis in connection with the interim final rule. While CMS does not expect the rule to have a substantial financial impact on beneficiaries, providers, or suppliers, the federal costs to implement the rule could exceed $100 million.

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

The Administrator of CMS has certified that the interim final rule will not have a significant economic 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

The interim final rule does not contain either an intergovernmental or private sector mandate, as defined in title II, of more that $100 million 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.

The portion of the interim final rule that deals with the appeals provisions required by BIPA was promulgated using the notice and comment procedures found at 5 U.S.C. 553. On November 15, 2002, a Notice of Proposed Rulemaking was published in the Federal Register. In response, CMS received 37 comments, which are discussed in the preamble to the interim final rule.

CMS has found "good cause" under 5 U.S.C. 553 to forgo notice and comment procedures regarding the portion of the interim final rule implementing the provisions of the MMA since the provisions are essentially nondiscretionary. However, CMS is requesting comments on those provisions for consideration before the rule is finalized.

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

The interim final rule contains an information collection that is subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. CMS estimates that the appointment of a representative, which must be in writing, will be used by 27,277 individuals and entities each year. The burden is estimated at 15 minutes to supply the information or 6,819 hours on an annual basis.

Statutory authorization for the rule

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

Executive Order No. 12866

The interim final rule was reviewed by OMB and found to be an "economically significant" regulatory action under the order.

Executive Order No. 13132 (Federalism)

CMS states that the interim final rule will not have a substantial effect on state or local governments.