Because the delay in the effective date was caused by EPA’s inadvertent failure to submit the rule under the CRA, EPA does not believe that affected entities that acted in good faith relying upon the effective date stated in the July 2, 1997 Federal Register should be penalized if they were complying with the rule as promulgated.

B. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a “significant regulatory action” and is therefore not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or involve special considerations of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). Because this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). EPA’s compliance with these statutes and Executive Orders for the underlying rule is discussed in the July 2, 1997 Federal Register document.

Pursuant to 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office; however, in accordance with 5 U.S.C. 808(2), this rule became effective on December 30, 1997. This rule is not a “major rule” as defined in 5 U.S.C. 804(2).

This final rule only amends the effective date of the underlying rule; it does not amend any substantive requirements contained in the rule. Accordingly, to the extent it is available, judicial review is limited to the amended effective date. Pursuant to section 19 of TSCA, challenges to this amendment must be brought within 60 days of today’s publication of this rule.


Carol M. Browner,
Administrator.

[FR Doc. 98–264 Filed 1–2–98; 1:34 pm]

B. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a “significant regulatory action” and is therefore not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation with State officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or involve special considerations of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). Because this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). EPA’s compliance with these statutes and Executive Orders for the underlying rule is discussed in the July 2, 1997 Federal Register document.

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This final rule only amends the effective date of the underlying rule; it does not amend any substantive requirements contained in the rule. Accordingly, to the extent it is available, judicial review is limited to the amended effective date. Pursuant to section 19 of TSCA, challenges to this amendment must be brought within 60 days of today’s publication of this rule.


Carol M. Browner,
Administrator.

[FR Doc. 98–264 Filed 1–2–98; 1:34 pm]
This interim final rule implements section 4316 of the Balanced Budget Act of 1997. It revises the process for establishing a realistic and equitable payment amount for all Medicare Part B services (other than physician services) when the existing payment amounts are inherently unreasonable because they are either grossly excessive or deficient. This rule describes the factors HCFA (or its carrier) will consider and the procedures it will follow in establishing realistic and equitable payment amounts.

**Effective Date:** These regulations are effective on March 9, 1998. Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on March 9, 1998.

**Addresses:** Mail an original and 3 copies of written comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-1908-IFC, P.O. Box ____ , Baltimore, MD 21207–5187.

If you prefer, you may deliver an original and 3 copies of your written comments to one of the following addresses:


Comments may also be submitted electronically to the following e-mail address: hcfa1908@hcfa.gov. E-mail comments must include the full name, address, and affiliation (if applicable) of the sender, and must be submitted to the referenced address in order to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments. Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1908–IFC.

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, D.C., on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

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**For further information:** Contact William J. Long, (410) 785–5670.

**Supplementary Information:**

1. **Background**

Title XVIII of the Social Security Act (the Act) contains various methodologies for making payment under Part B of the Medicare program. These payment methodologies vary among the different categories of items and services covered under Part B. Section 4316 of the Balanced Budget Act of 1997 (BBA), however, permits the Secretary to diverge from title XVIII's statutory-prescribed payment methodologies if their application results in the determination of an amount that, because it is grossly excessive or deficient, is not inherently reasonable. Section 4316 of the BBA also requires the Secretary to describe the factors to be considered in determining an amount that is realistic and equitable.

The inherent reasonableness concept is not new to the statute. The Secretary has taken the position that the authority to regulate unreasonable payment amounts was inherent in section 1842 of the Act. Moreover, effective September 10, 1986, section 9304(a) of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 added section 1842(b)(8) and (b)(9) of the Act. These provisions permit the Secretary to diverge from the statutory-prescribed payment methodologies if their application results in the determination that the payment amount for a particular service or group of services, because of its being grossly excessive or deficient, is not inherently reasonable. The statute requires the Secretary to describe in regulations the factors to be considered in determining an amount that is realistic and equitable.

Regulations implementing this provision are contained in 42 CFR 405.502(g) and (h), which were first published in the Federal Register on