

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 consideration 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.

Dated: December 30, 1997.

**Carol M. Browner,**  
Administrator.

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

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 721

[FRL-5943-9]

#### Technical Amendments to Aliphatic Ester; Revocation of Significant New Use Rule: Correction of Effective Date Under Congressional Review Act (CRA)

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule; correction of effective date under CRA.

**SUMMARY:** On July 2, 1997 (62 FR 35691), the Environmental Protection Agency published in the **Federal Register** a final rule that revoked a significant new use rule under the Toxic Substances Control Act (TSCA) for aliphatic ester based on a new evaluation of toxicity data. The rule established an effective date of August 1, 1997. This document corrects the effective date of the rule to December 30, 1997 to be consistent with sections 801 and 808 of the Congressional Review Act (CRA), enacted as part of the Small Business Regulatory Enforcement Fairness Act.

**EFFECTIVE DATE:** December 30, 1997.

**FOR FURTHER INFORMATION CONTACT:** Angela Hofmann, Director, Regulatory Coordination Staff, Office of Prevention, Pesticides, and Toxics, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Telephone: (202) 260-2922.

#### SUPPLEMENTARY INFORMATION:

##### A. Background

Section 801 of the CRA precludes a rule from taking effect until the agency promulgating the rule submits a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the General Accounting Office (GAO). EPA recently discovered that it had inadvertently failed to submit the above rule as required; thus, although the rule was promulgated July 2, 1997, by operation of law, the rule did not take effect on August 1, 1997 as stated. After EPA discovered its error, the rule was submitted to both Houses of Congress and the GAO on December 11, 1997. This document amends the effective date of the rule consistent with the provisions of the CRA.

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary or

contrary to the public interest, an agency may issue a rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making today's rule final without prior proposal and opportunity for comment because EPA merely is correcting the effective date of the promulgated rule to be consistent with the congressional review requirements of the Congressional Review Act as a matter of law and has no discretion in this matter. Thus, notice and public procedure are unnecessary. The Agency finds that this constitutes good cause under 5 U.S.C. 553(b). Moreover, since today's action does not create any new regulatory requirements and affected parties have known of the underlying rule since July 2, 1997, EPA finds that good cause exists to provide for an immediate effective date pursuant to 5 U.S.C. 553(d)(3) and 808(2).

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 consideration 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.

Dated: December 30, 1997.

**Carol M. Browner,**

*Administrator.*

[FR Doc. 98-263 Filed 1-2-98; 1:29 pm]

BILLING CODE 6560-50-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

#### 42 CFR Part 405

[HCFA-1908-IFC]

RIN 0938-A137

#### Medicare Program; Application of Inherent Reasonableness to All Medicare Part B Services (Other than Physician Services)

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Interim final rule with comment period.

**SUMMARY:** 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:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, D.C. 20201, or Room C5-09-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Comments may also be submitted electronically to the following e-mail address: hcfa1908ifc@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).

**Copies:** To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512-1800 or by faxing to (202) 512-2250. The cost for each copy is \$8. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through GPO Access, a service of the U.S. Government Printing Office. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the database by using the World Wide Web; the Superintendent of Documents home page address is [http://www.access.gpo.gov/su\\_docs/](http://www.access.gpo.gov/su_docs/), by using local WAIS client software, or by telnet to swais.access.gpo.gov, then login as guest (no password required). Dial-in users should use communications software and modem to call (202) 512-1661; type swais, then login as guest (no password required). For general information about GPO Access, contact the GPO Access User Support Team by sending Internet e-mail to [help@eids05.eids.gpo.gov](mailto:help@eids05.eids.gpo.gov); by faxing to (202) 512-1262; or by calling (202) 512-1530 between 7 a.m. and 5 p.m. Eastern time, Monday through Friday, except for Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** William J. Long, (410) 786-5655.

#### SUPPLEMENTARY INFORMATION:

##### I. 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 statutorily-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 statutorily-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