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–AI37

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/, 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; 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

August 11, 1986 (51 FR 28710). These regulations describe the factors to be used in determining if the application of the reasonable charge methodology results in a charge that is grossly excessive or grossly deficient. They also describe the factors to be considered in establishing a reasonable charge that is realistic and equitable.

As implemented by the current regulations, section 1842(b)(8) of the Act applies not only to our authority to establish national reasonable charge limits, but also to our carriers' authority to establish carrier-level reasonable charge limits on grossly excessive or deficient charges.

Section 4316 of the BBA amends section 1842(b)(8) of the Act and includes the following key differences:

- It excludes physician services from application of inherent reasonableness.
- It extends the authority to establish special payment limits to Medicare carriers regardless of the methodology used for determining payment and simplifies the inherent reasonableness process for adjustments to payment amounts that are 15 percent or less.
- It allows the Secretary to streamline the factors to be considered in making an inherent reasonableness determination.

II. Provisions of this Interim Final Rule

This interim final rule revises 42 CFR 405.502 (g) and (h) by excluding references to physician services. It also deletes specific references to the reasonable charge payment methodology. We have deleted these references because the inherent reasonableness provisions apply to all Part B services, except physician services, irrespective of the payment methodology. We have also simplified the process for making adjustments to payment amounts for a category of items or services when the increase or decrease in the payment amount is no more than 15 percent. (For purposes of § 405.502 (g) and (h), a ''category of items or services'' may consist of a single item or service or any number of items or services.)

Section 4316(a) of the BBA amends section 1842(b)(8)(C) of the Act to require the Secretary to consider the following factors in making inherent reasonableness determinations concerning payment for Part B services (other than physician services):

- Medicare and Medicaid are the sole or primary sources of payment for a category of items or services.
- The payment amounts for a category of items or services do not reflect changing technology, increased facility with that technology, or changes in acquisition, production, or supplier costs.
- The payment amounts for a category of items or services are grossly higher or lower than the payments made for the same category of items or services by other purchasers in the same locality.

Amended section 1842(b)(8)(C) of the Act also permits the Secretary to consider any additional factors determined to be appropriate. Therefore, we have retained four of the five factors that appear in § 405.502(g)(1), because they remain as appropriate examples of factors that may result in deficient or excessive payment amounts. We removed the factor related to the use of new technology for which an extensive charge history does not exist, because we would not use the inherent reasonableness criteria to establish payment amounts for a category of items or services brought about by new technology. There is already in place a process for establishing payment amounts for new items or services for which an extensive charge history does not exist. The additional factors we may consider include, but are not limited to, the following:

- The market place is not competitive.
- The payment amounts in a particular locality grossly exceed amounts paid in other localities for the category of items or services.
- The payment amounts grossly exceed acquisition or production costs for the category of items or services.
- There have been increases in payment amounts that cannot be explained by inflation or technology.

When we implemented section 9304(a) of COBRA of 1985, we interpreted the law as codifying both our authority and a carrier's authority to establish realistic and equitable payment amounts. We are interpreting the provisions of section 4316 of the BBA in the same way. Thus, these final regulations describe the circumstances and factors we and our carriers will use in setting realistic and equitable payment amounts if the existing payment amounts are grossly excessive or deficient.

Section 4316 of the BBA amends section 1842(b)(8) of the Act by adding provisions that apply if a reduction or increase would vary the payment amount by less than 15 percent ''during any year.'' (Other provisions apply to larger increases and decreases.) By its own terms, the 15-percent variance applies to the amount of an inherent reasonableness adjustment for any given year. Under this authority, we (or a carrier) may determine that more than a 15-percent adjustment is warranted, but we may choose to apply only a 15-percent adjustment in any given year and use the ''15 percent'' methodology. For example, we (or a carrier) may determine that a 25-percent reduction is warranted. However, the adjustment could be accomplished over 2 years—15 percent applied the first year, and 10 percent applied the following year.

Other than these changes and some minor modifications, the revised regulations are the same as the final regulations that were published in the **Federal Register** (53 FR 26067) on July 11, 1988.

III. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments that we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We believe that it is unnecessary to publish this regulation as a proposed rule since it is not significantly changing the existing methodology for application of the inherent reasonableness process. This process has been specified in regulations since 1986. We also believe that it would be contrary to the public interest to delay implementation of these regulations by publishing a proposed rule. Finalizing this rule is clearly in the interest of the public because affording notice and opportunity for comment would postpone the time that limits may be established on grossly excessive charges and would unnecessarily impede further savings to the Medicare trust fund and beneficiaries. We believe that it is contrary to the public interest to

provide a notice of proposed rulemaking since it would delay the implementation of these provisions.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day comment period for public comment.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

VI. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, non-profit organizations and government agencies. Most hospitals and most other providers and suppliers are small entities, either by non-profit status or by having revenues of $5 million or less annually. For purposes of the RFA, all suppliers of Medicare Part B services are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

We expect suppliers of Part B services, other than physician services, to be affected by this rule. We do not have sufficient data to predict exactly the nature of the impact of this rule or the magnitude of such impact. Below, we discuss likely outcomes.

Should the provisions of these regulations be applied, the resultant payment amounts will no longer be grossly excessive or deficient. If a payment amount is adjusted upward because it is deficient, it will benefit suppliers and beneficiaries. A more generous payment amount may result in greater availability of items and services to Medicare beneficiaries. The converse may not be true if the payment amount is adjusted downward. A lower payment amount should not necessarily result in a lack of availability of items and services since the revised payment amount would be realistic and equitable. We believe that a realistic and equitable payment amount would ensure continued availability of items and services. Thus, we believe that the application of an adjustment will merely serve as a vehicle for eliminating windfall profits. This adjustment will benefit the Medicare program by reducing costs and benefit beneficiaries by reducing coinsurance payments.

For these reasons, we are not preparing an analysis for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

For the reasons set forth in the preamble, 42 CFR chapter IV is amended as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Part 405 is amended as set forth below:

1. The authority citation for part 405, subpart E, continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 405.502, paragraphs (g) and (h) are revised to read as follows:

§ 405.502 Criteria for determining reasonable charges.

* * * * *

(g) *Determination of payment amounts in special circumstances*—(1) *General.* (i) For purposes of this paragraph, a ''category of items or services'' may consist of a single item or service or any number of items or services.

(ii) HCFA or a carrier may determine that the standard rules for calculating Part B payment amounts for a category of items or services identified in section 1861(s) of the Act (other than physician services paid under section 1848 of the Act) will result in grossly deficient or excessive amounts.

(iii) If HCFA or the carrier determines that the standard rules for calculating payment amounts for a category of items or services set forth in this subpart will result in grossly deficient or excessive amounts, HCFA or the carrier may establish special payment limits that are realistic and equitable for a category of items or services.

(iv) The limit on the payment amount is either an upper limit to correct a grossly excessive payment amount or a lower limit to correct a grossly deficient payment amount.

(v) The limit is either a specific dollar amount or is based on a special method to be used in determining the payment amount.

(vi) Except as provided in paragraph (h) of this section, a payment limit for a given year may not vary by more than 15 percent from the payment amount established for the preceding year.

(vii) *Examples of excessive or deficient payment amounts.* Examples of the factors that may result in grossly deficient or excessive payment amounts include, but are not limited to, the following:

(A) The marketplace is not competitive. This includes circumstances in which the marketplace for a category of items or services is not truly competitive because a limited number of suppliers furnish the item or service.

(B) Medicare and Medicaid are the sole or primary sources of payment for a category of items or services.

(C) The payment amounts for a category of items or services do not reflect changing technology, increased facility with that technology, or changes in acquisition, production, or supplier costs.

(D) The payment amounts for a category of items or services in a particular locality are grossly higher or lower than payment amounts in other comparable localities for the category of items or services, taking into account the relative costs of furnishing the category of items or services in the different localities.

(E) Payment amounts for a category of items or services are grossly higher or lower than acquisition or production

costs for the category of items or services.

(F) There have been increases in payment amounts for a category of items or services that cannot be explained by inflation or technology.

(G) The payment amounts for a category of items or services are grossly higher or lower than the payments made for the same category of items or services by other purchasers in the same locality.

(2) *Establishing a limit.* In establishing a payment limit for a category of items or services, HCFA or a carrier considers the available information that is relevant to the category of items or services and establishes a payment amount that is realistic and equitable. The factors HCFA or a carrier consider in establishing a specific dollar amount or special payment method for a category of items or services may include, but are not limited to, the following:

(i) *Price markup.* This is the relationship between the retail and wholesale prices or manufacturer's costs of a category of items or services. If information on a particular category of items or services is not available, HCFA or a carrier may consider the markup on a similar category of items or services and information on general industry pricing trends.

(ii) *Differences in charges.* HCFA or a carrier may consider the differences in charges for a category of items or services made to non-Medicare and Medicare patients or to institutions and other large volume purchasers.

(iii) *Costs.* HCFA or a carrier may consider resources (for example, overhead, time, acquisition costs, production costs, and complexity) required to produce a category of items or services.

(iv) *Utilization.* HCFA or a carrier may impute a reasonable rate of use for a category of items or services and consider unit costs based on efficient utilization.

(v) *Payment amounts in other localities.* HCFA or a carrier may consider payment amounts for a category of items or services furnished in another locality.

(3) *Notification of limits*—(i) *National limits.* HCFA publishes in the **Federal Register** proposed and final notices announcing a special payment limit described in this paragraph (g) before it adopts the limit. The notices set forth the criteria and circumstances, if any, under which a carrier may grant an exception to a payment limit for a category of items or services.

(ii) *Carrier-level limits.* A carrier proposing to establish a special payment limit for a category of items or services must inform the affected suppliers and State Medicaid agencies of the factors it considered in determining and in establishing the limit, as described in paragraphs (g)(1) through (g)(3) of this section, and solicit comments. The carrier must evaluate the comments it receives and inform the affected suppliers, State Medicaid agencies, and HCFA of any final limits it establishes. HCFA acknowledges in writing to the carrier that it received the carrier's notification. After the carrier has received HCFA's acknowledgement, the limit may be effective for services furnished at least 30 days after the date of the carrier's notification.

(h) *Special payment limit adjustments greater than 15 percent of the payment amount.* In addition to applying the general rules under paragraphs (g)(1) through (g)(3) of this section, HCFA applies the following rules in determining and establishing a payment adjustment greater than 15 percent of the payment amount for a category of items or services within a year:

(1) *Potential impact of special limit.* HCFA considers the potential impact on quality, access, beneficiary liability, assignment rates, and participation of suppliers.

(2) *Supplier consultation.* Before making a determination that a payment amount for a category of items or services is not inherently reasonable by reason of its grossly excessive or deficient amount, HCFA consults with representatives of the suppliers likely to be affected by the change in the payment amount.

(3) *Publication of national limits.* If HCFA determines under this paragraph (h) to establish a special payment limit for a category of items or services, it publishes in the **Federal Register** proposed and final notices of a special payment limit before it adopts the limit. The notice sets forth the criteria and circumstances, if any, under which a carrier may grant an exception to the limit for the category of items or services.

(i) *Proposed notice.* The proposed notice——

(A) Explains the factors and data that HCFA considered in determining that the payment amount for a category of items or services is grossly excessive or deficient;

(B) Specifies the proposed payment amount or methodology to be established with respect to a category of items or services;

(C) Explains the factors and data that HCFA considered in determining the payment amount or methodology, including the economic justification for a uniform fee or payment limit if it is proposed;

(D) Explains the potential impacts of a limit on a category of items or services as described in paragraph (h)(1) of this section; and

(E) Allows no less than 60 days for public comment on the proposed payment limit for the category of items or services.

(ii) *Final notice.* The final notice——

(A) Explains the factors and data that HCFA considered, including the economic justification for any uniform fee or payment limit established; and

(B) Responds to the public comments.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance)

Dated: December 12, 1997.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Approved: December 30, 1997.

Donna E. Shalala,

Secretary.

[FR Doc. 98–269 Filed 1–6–98; 8:45 am]

BILLING CODE 4120–01–P

ENVIRONMENTAL PROTECTION AGENCY

48 CFR Parts 1505, 1514, 1537, 1548, and 1552

[FRL–5945–5]

Technical Amendments to Acquisition Regulation; Removal of Outdated or Unnecessary Coverage: 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 October 24, 1996 (61 FR 55118), the Environmental Protection Agency published in the **Federal Register** a final rule concerning the removal from EPA Acquisition Regulations of outdated or unnecessary coverage on Exchange of Acquisiton Information, Past Performance, Advisory and Assistance Services, and Policies and Procedures on Value Engineering. This rule established an effective date of October 24, 1996. 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.