*J. Congressional Review Act*

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. 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 United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective on January 12, 2006.

**List of Subjects in 40 CFR Part 420**

Environmental protection, Iron, Steel, Waste treatment and disposal, Water pollution control.

Dated: December 7, 2005.

**Stephen L. Johnson,**

*Administrator.*

■ For reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

## PART 420—IRON AND STEEL MANUFACTURING POINT SOURCE CATEGORY

■ 1. The authority citation for part 420 is revised to read as follows:

**Authority:** 33 U.S.C. 1311, 1314, 1316, 1317, 1318, 1342, and 1361.

■ 2. Section 420.03 is amended by removing and reserving paragraph (c), by removing the ''; and'' at the end of paragraph (f)(1) and adding a period in its place, and by adding paragraph (f)(3) to read as follows:

**§ 420.03 Alternative effluent limitations representing the degree of effluent reduction attainable by the application of best practicable control technology currently available, best available technology economically achievable, best available demonstrated control technology, and best conventional pollutant control technology (the ''water bubble'').**

* * * * *

(f) * * *

(3) There shall be no alternate effluent limitations for O&G in sintering process wastewater unless the alternative limitations are more stringent than the otherwise applicable limitations in subpart B of this part.

**§ 420.14 [Amended]**

■ 3. Section 420.14 is amended in paragraph (a)(1) by removing the date ''November 19, 2012'' and replacing it with the date ''November 18, 1992.''

**§ 420.16 [Amended]**

■ 4. Section 420.16 is amended in paragraph (a)(1) by removing the date ''November 19, 2012'' and replacing it with the date ''November 18, 1992.''

**§ 420.24 [Amended]**

■ 5. Section 420.24 is amended in paragraph (a) by removing the date ''November 19, 2012'' and replacing it with the date ''November 18, 1992.''

**§ 420.26 [Amended]**

■ 6. Section 420.26 is amended in paragraph (a)(1) by removing the date ''November 19, 2012'' and replacing it with the date ''November 18, 1992.''

[FR Doc. 05–23973 Filed 12–12–05; 8:45 am]

**BILLING CODE 6560–50–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

### 42 CFR Part 405

**[CMS–1908–F]**

**RIN 0938–AN81**

## Medicare Program; Application of Inherent Reasonableness Payment Policy to Medicare Part B Services (Other Than Physician Services)

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule finalizes the process that was set forth in an interim final rule published on December 13, 2002, for establishing a realistic and equitable payment amount for Medicare Part B services (other than physicians' services) when the existing payment amounts are inherently unreasonable because they are either grossly excessive or grossly deficient. This process does not apply to services paid under a prospective payment system, such as outpatient hospital services or home health services. The December 2002 interim final rule also described the factors we (or our carriers) will consider and the procedures we will follow in establishing realistic and equitable payment amounts for Medicare Part B services.

In addition, this final rule responds to public comments we received on two provisions in the December 13, 2002 interim final rule relating to how we define grossly excessive or deficient payment amounts and to the criteria for using valid and reliable data in applying the inherent reasonableness authority.

**EFFECTIVE DATE:** This final rule is effective on February 13, 2006.

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

**SUPPLEMENTARY INFORMATION:**

**Electronic Access**

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**I. Background: Legislative and Regulatory Authority**

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 Medicare Part B.

*A. The Consolidated Omnibus Budget Reconciliation Act of 1985*

Section 9304(a) of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA of 1985), Public Law 99–272, effective September 10, 1986, added section 1842(b)(8) to the Act, which expressly authorizes the Secretary to deviate from the payment methodologies prescribed in the Act if their application results in a payment amount for a particular service or group of services that is determined to be grossly excessive or deficient and, therefore, is not inherently reasonable. The statute also requires the Secretary to describe in regulations the factors to be considered in determining an amount that is realistic and equitable. The Secretary has always taken the position that the authority to regulate unreasonable payment amounts is inherent in his or her authority to determine reasonable charges according

to section 1842 of the Act, and, since January 1, 1991, has taken the position that this authority applies to other Part B payment methodologies, not just those payment methodologies under section 1842 of the Act.

On August 11, 1986, we published a final rule with comment period in the **Federal Register** (51 FR 28710) to implement the provisions of section 1842(b)(8) of the Act, as added by section 9304(a) of the COBRA of 1985, under regulations at 42 CFR 405.502(g) and (h). These regulations described 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. The regulations also described the factors to be considered in establishing a reasonable charge that is realistic and equitable. When we implemented section 1842(b)(8) of the Act, as added by section 9304(a) of the COBRA of 1985, we interpreted the statute as applying not only to the Secretary's authority to establish national reasonable charge limits, but also to the Medicare carriers' authority to establish carrier-level reasonable charge limits on grossly excessive or deficient charges.

*B. The Omnibus Budget Reconciliation Act of 1986*

Section 9333 of the Omnibus Budget Reconciliation Act of 1986 (OBRA)(Pub. L. 99–509) amended section 1842(b)(8) of the Act and added new paragraphs (b)(9) and (b)(10). These amendments specified the distinct procedures under which the Secretary may establish special reasonable charge limits for physicians' services and provided for a limitation on the amount that nonparticipating physicians may charge for a service if a special reasonable charge limit is established for that physician service.

On July 11, 1988, we issued a final rule in the **Federal Register** (53 FR 26067) that conformed the regulations to the provisions of section 1842(b)(8) of the Act, as amended by the OBRA, and sections 1842(b)(9) and (b)(10) of the Act, as added by the OBRA. That final rule also responded to comments received on the August 11, 1986 final rule with comment period that implemented section 9304(a) of the COBRA of 1985.

*C. The Balanced Budget Act of 1997*

Section 4316 of the Balanced Budget Act of 1997 (BBA), Public Law 105–33, enacted on August 5, 1997, amended sections 1842(b)(8) and (b)(9) of the Act, which permit the Secretary to deviate from the payment methodologies prescribed in title XVIII of the Act if their application results in a payment amount that, because it is determined to be grossly excessive or deficient, is not inherently reasonable. Sections 1842(b)(8) and (b)(9) of the Act, as amended, also require the Secretary to describe the factors to be considered in determining an amount that is realistic and equitable. Specifically, section 4316 of the BBA amended section 1842(b)(8) of the Act to—

- Exclude physicians' services from application of the inherent reasonableness payment policy;
- Extend the authority to establish special payment limits to Medicare carriers, regardless of the methodology for determining payment;
- Simplify the inherent reasonableness process for adjustments to payment amounts that are 15 percent or less. Specifically, section 4316 of the BBA amended section 1842(b)(8) by adding provisions that apply if a reduction or increase would vary the payment amount by 15 percent or less ''during any year.'' (Other provisions apply to larger increases and decreases.) 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.
- Require the Secretary to consider the following factors in making inherent reasonableness determinations concerning payment for Part B services (other than physicians' services) and permit the Secretary to consider any additional factors determined to be appropriate:

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

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

(3) 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.

Section 4316 of the BBA also made minor changes to section 1842(b)(9) of the Act relating to the process for formally notifying the public of, and obtaining public comment on, a proposed inherent reasonableness determination and a proposed payment adjustment and for announcing the final payment adjustment determination.

On January 7, 1998, we published in the **Federal Register** (63 FR 687) an interim final rule that implemented sections 1842(b)(8) and (b)(9) of the Act, as amended by section 4316 of the BBA. In the January 7, 1998 interim final rule, we revised § 405.502(g) and (h) to exclude references to physicians' services from the application of the inherent reasonableness policy. We also deleted specific references to the reasonable charge payment methodology because the inherent reasonableness provisions apply to all Part B services, except physicians' services, irrespective of the payment methodology. However, we specified that the rule did not apply to services paid under a prospective payment system, such as outpatient hospital services or home health services. We also reflected the change in the statute that permitted us to simplify 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 per year. (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.)

Although the BBA gave the Secretary discretion to reduce the number of factors that are used to make inherent reasonableness determinations, in the January 1998 interim final rule, we retained four of the five factors that appeared in § 405.502(g)(1) because they remain as appropriate factors for determining 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 there was already in place an alternative process for establishing payment amounts for new items or services for which an extensive charge history does not exist. (We note that we reinserted this example of a factor in the December 13, 2002 interim final rule discussed in section I.D. of this final rule because we had received requests that this example factor not be deleted.) We included the following additional factors we may (but we are not limited to) consider:

- 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.

We interpreted the provisions of section 4316 of the BBA relating to the Secretary's authority and a Medicare carrier's authority in the same manner that we had done for the COBRA of 1985. That is, we interpreted the statute as codifying both our authority and a carrier's authority to establish realistic and equitable payment amounts. Thus, in the January 7, 1998 interim final rule, we described the circumstances and factors our carriers and we would use in setting realistic and equitable payment amounts if the existing payment amounts are grossly excessive or deficient.

*D. The Balanced Budget Refinement Act of 1999*

Section 223 of the Balanced Budget Refinement Act (BBRA) of 1999, Public Law 106–113, enacted on November 29, 1999, prohibited the use of the inherent reasonableness authority under section 1842(b) of the Act until the following events had occurred:

*Event 1:* The Comptroller General had released a report regarding the impact of the Secretary's fiscal intermediaries' and carriers' use of the authority. (This report, entitled ''Medicare Payments-Use of Revised 'Inherent Reasonableness' Generally Appropriate (GAO/HEHS–OO–79),'' was released by the General Accounting Office (GAO) (now the Government Accountability Office) in July 2000.)

*Event 2:* The Secretary had published a notice of final rulemaking in the **Federal Register** that related to the authority and that responded to the GAO report and to comments received in response to the Secretary's interim final regulation relating to the authority that was published on January 7, 1998. (The notice of final rulemaking was published in the **Federal Register** on December 13, 2002 (67 FR 76684), and is discussed below in this section I.D. of this final rule. That notice also responded to the GAO report.)

*Event 3:* In publishing the final regulation, the Secretary had reevaluated the appropriateness of the criteria included in the interim final regulation for identifying payments that are excessive or deficient. (The December 13, 2002 interim final rule, discussed below in this section I.D. of this final rule, provided greater specificity of the criteria for identifying grossly excessive or deficient payments and provided opportunity for further public comment because of that specificity. We are responding to the public comments received on these more specific criteria under section II. of this final rule.)

*Event 4:* The Secretary had taken appropriate steps to ensure the use of valid and reliable data when exercising the authority. (The December 13, 2002 interim final rule, discussed below in this section I.D. of this final rule, addressed the use of valid and reliable data and provided opportunity for further public comment on this area. We are responding to the public comments received on the use of data under section II. of this final rule.)

As we indicated earlier, section 223 of the BBRA directed us to respond to the July 2000 GAO report. In its report, the GAO found that CMS' use of the revised inherent reasonableness process was generally appropriate and made four specific recommendations.

*Recommendation:* In publishing the final rule on the inherent reasonableness process, CMS should define with sufficient clarity the terms ''grossly excessive'' and ''grossly deficient.''

*Recommendation:* For future inherent reasonableness reviews based on survey data, CMS or the carriers should develop and implement a more structured survey design, including sample selection, survey instrumentation, and data collection methods, and ensure that the design is consistently used by all entities conducting the survey.

*Recommendation:* CMS and the carriers should collect and analyze additional information to more precisely estimate any payment reductions for glucose test strips, albuterol sulfate, and enteral formulas, as well as for additional payment reductions in subsequent years for lancets, eyeglass frames, latex Foley catheters, and catheter insertion trays without drainage bags.

*Recommendation:* CMS should monitor indicators that could signal potential problems with patient access to the product groups for which it is reducing maximum payments and act quickly to rectify any problems that arise.

On December 13, 2002, we published in the **Federal Register** (67 FR 76684) an interim final rule that constituted a notice of final rulemaking relating to the inherent reasonableness authority provisions as required by section 223 of the BBRA. In the December 13, 2002 interim final rule, we responded to the recommendations of the GAO report and responded to the public comments received on the January 7, 1998 interim final rule that implemented section 4316 of the BBA.

We note that we issued the December 13, 2002 document as an interim final rule so that the public would have an additional opportunity to comment particularly on two provisions that contained further specificity than that found in the January 7, 1998 interim final rule. These provisions, discussed below, related to (1) defining grossly excessive and deficient payment amounts (§ 405.502(g)(1)(ii) of the regulations); and (2) taking appropriate steps to ensure the use of valid and reliable data when exercising the inherent reasonableness authority (§ 405.502(g)(4) of the regulations). We are responding to the public comments received on these two provisions in section II. of this final rule. We had already received public comments on the other BBRA provisions that were implemented when we published the January 7, 1998 interim final rule; these comments were addressed in section V. of the December 13, 2002 interim final rule. We also refer the readers to section IV. of the December 13, 2002 interim final rule (67 FR 76686) for a full discussion of CMS' responses to the GAO report recommendations.

We note that the statute applies inherent reasonableness to Part B items and services, except for physicians' services as defined and paid for under section 1848 of the Act. Hospital outpatient services are not excluded from the inherent reasonableness provisions of the law. In addition, the inherent reasonableness authority can be used in cases for which the standard rules for determining payment amounts for drugs paid under section 1842(o) of the Act or laboratory services paid under section 1842 of the Act result in grossly deficient or excessive payment amounts. However, we decided that we would not apply the inherent reasonableness provisions to services paid under a prospective payment system such as outpatient hospital services or home health services. In 2002, we excluded those payment methodologies from the application of inherent reasonableness because we believe they have other mechanisms to address the concerns otherwise appropriately addressed through an inherent reasonableness mechanism. In addition, as discussed under section II. of this preamble, because of the new pricing methodology for Part B drugs established by section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), we do not anticipate the need to apply the inherent reasonableness provisions to these drugs at this time; however, we

are retaining our authority to apply inherent reasonableness to these drugs if the need arises.

**II. Provisions of This Final Rule**

As discussed in section I.D. of this preamble, in the interim final rule published in the **Federal Register** on December 13, 2002, we provided an additional opportunity for public comment on two provisions of that interim final rule because the two provisions contained further specificity than that found in the January 7, 1998 interim final rule: (1) the definition of grossly excessive and deficient payment amounts; and (2) criteria for the use of valid and reliable data when exercising the inherent reasonableness authority.

We received 189 timely pieces of correspondence in response to the December 13, 2002 interim final rule. A large number of these comments concerned issues (other than the two provisions on which we particularly invited additional public comments) that we had received public comments on and responded to in the December 13, 2002 interim final rule (67 FR 76684). The comments and our responses follow, along with a cross reference to the page in which they appeared in the December 13, 2002 **Federal Register**. These included comments on the use of an inherent reasonableness appeals process (page 76688); carriers' use of the inherent reasonableness authority (page 76691); the application of inherent reasonableness authority to laboratory services (page 76690); delaying application of the inherent reasonableness authority to laboratory services pending CMS' response to the Institute of Medicine's study on Medicare Part B laboratory services (page 76688); the definition and clarification of factors used to determine grossly excessive or deficient payment amounts (the factors are the examples mentioned in § 405.502(g)(1)(vii) and do not relate to the definition of grossly excessive and deficient payment amounts) (page 76689); the use of cost and charges as factors for determining grossly excessive or deficient payment amounts (page 76690); the use of an all-inclusive rather than a nonexclusive list of inherent reasonableness factors (page 76689); the use of the terms ''floor'' and ''ceiling'' rather than ''payment limit'' when referring to inherent reasonableness adjustments (page 76690); establishing a fair and open inherent reasonableness process (page 76688); delaying implementation of the inherent reasonableness authority rule (page 76687); establishing a petition process for inherent reasonableness determinations (page 76692); detection of grossly deficient payment amounts (page 76688); and the reaction of other payors to Medicare payment limits established using inherent reasonableness authority (page 76688). Because we addressed these issues in promulgating the December 13, 2002 interim final rule, we refer the readers to that document; we will not repeat our responses in this final rule except for the effect on beneficiary access. As stated in our December 13, 2002 interim final rule, we will monitor patient access to items for which payment amounts are adjusted using the inherent reasonableness process by periodically checking the rate at which suppliers are accepting assignment for these items and by monitoring any beneficiary complaints regarding access (page 76687).

A discussion of the two provisions on which we solicited additional public comments, summaries of the public comments that we received in response to them, and the Departmental responses follow.

*A. Definition of Grossly Excessive and Deficient Payment Amounts*

In the December 13, 2002 interim final rule, in response to the GAO recommendation and in response to public comments received on the January 1998 interim final rule, we clarified when a payment amount is considered grossly excessive or deficient for purposes of applying the inherent reasonableness authority. We specified in § 405.502(g)(1)(ii) that a payment amount will not be considered grossly excessive or grossly deficient if the overall payment adjustment is less than 15 percent. This definition does not preclude adjustments of less than 15 percent in a given year once it is determined that an overall adjustment of 15 percent or more is justified.

The statute provides two different processes once a determination is made that a payment amount is grossly excessive or deficient. That is, the statute specifies a process for adjustments of 15 percent or more in a given year and a simplified process for adjustments of less than 15 percent in a given year. However, the statute did not define what constitutes a grossly excessive or deficient payment amount. Nevertheless, the statute placed significant importance on a 15-percent criterion. For this reason, we have decided that differences between current and proposed payment amounts of less than 15 percent will not be considered grossly excessive or grossly deficient and, therefore, will not provide a sufficient basis for using inherent reasonableness authority. This definition does not preclude adjustments of less than 15 percent in a given year once it is determined that an overall adjustment of 15 percent or more is justified.

As directed by the statute, in the December 13, 2002 interim final rule, we reviewed the criteria for identifying payments that are excessive or deficient set forth in the January 7, 1998 interim final rule and codified in § 405.502(g)(1)(vii) of the regulations. While amended section 1842(b)(8)(C) of the Act does not specifically require that we include all the factors for making inherent reasonableness determinations for a category of items or services in regulations, it permits the Secretary to consider any additional factors determined to be appropriate. The examples listed in § 405.502(g)(1)(vii) are merely examples, and the regulation explicitly states that the list of examples is not all-inclusive. When making an inherent reasonableness determination, we can use one or more of the examples listed in the regulation or an example that is not listed in the regulation. This approach allows us to adapt the methodology we use to address the various specific issues that may pertain to any particular case regarding the use and availability of data as well as other factors relevant to making an inherent reasonableness determination in that case.

In the December 13, 2002 interim final rule, we pointed out that the criteria in § 405.502(g)(1)(vii) were never intended to include every set of circumstances where inherent reasonableness would be considered appropriate. These same criteria had also been included in the August 11, 1986 final regulation and, therefore, were not new; they had been in effect for over 10 years. These criteria were originally established by the Congress and were contained in section 1842(b)(8) of the Act until it was revised by section 4316 of the BBA. We also indicated that the criteria remain as appropriate at the time of issuance of the interim final rule as they were when the Congress established them. Further, we indicated that we would need compelling reasons for determining that any of the criteria were inappropriate. These criteria are furnished as examples of situations of possible grossly excessive or deficient payment amounts, and we believe they are realistic and continue to be relevant.

*Comment:* Five commenters agreed with CMS' definition of grossly excessive and grossly deficient. Seven commenters stated that the regulations failed to provide a complete or adequate

definition of the terms. The commenters were concerned that the definition set forth in the regulations did not comply with the statutory requirement to fully describe all the factors that CMS or its carriers will use to determine whether a payment is grossly excessive or deficient. While some of the commenters indicated their support for using a quantitative value of 15 percent to define a grossly excessive payment amount, they argued that the definition should also incorporate the use of objective criteria for consistency in determining grossly excessive payment amounts. The commenters indicated that, in the absence of a clear and precise definition, CMS or its carriers could arbitrarily establish new factors or criteria for determining grossly excessive payment amounts.

One commenter stated that CMS has rebuffed industry assistance in developing a definition that incorporates objective benchmarks. This commenter indicated that without a more precise definition, providers, suppliers, and beneficiaries would not receive adequate notice of program policies.

*Response:* We appreciate the commenters' support for CMS' definition of grossly excessive and grossly deficient. The statute does not specifically require us to fully describe or include all the factors that may be used in making inherent reasonableness determinations. Section 1842(b)(8)(C) of the Act provides examples of factors that can result in payment amounts that are grossly excessive or grossly deficient. The Act also provides methods that can be used to establish reasonable payment amounts. We do not believe it is practical or necessary to further describe these lists of examples or to make them the only methods we can use. Rather, we believe it is more appropriate to establish general factors that allow us flexibility in adapting inherent reasonableness applications to a wide array of items of services encompassed under Medicare Part B, under different marketing conditions, and considering the availability of data. In addition, we believe that the proposed use of the 15-percent threshold to define a grossly excessive or deficient payment amount is appropriate and is an objective criterion.

We note that no item or service is subject to a change in payment under the inherent reasonableness authority until the proposed change is published by either CMS in the **Federal Register** or its carriers in their own publication and after public comments received in response to the proposed notice are considered.

*Comment:* One commenter stated that CMS' decision to set the percentage threshold definition for a grossly excessive or deficient payment amount at 15 percent did not appear to be consistent with section 1842(b)(8) of the Act and the GAO report. The commenter stated that section 1842(b)(8) of the Act appeared to anticipate the need for grossly excessive or deficient payment adjustments at percentages less than 15 percent. The commenter argued that the GAO report clearly stated that an adjustment of less than 15 percent could qualify as a grossly excessive or deficient payment amount. For these reasons, the commenter urged CMS to lower the 15-percent threshold to be consistent with section 1842(b)(8) of the Act and the GAO report and suggested setting the threshold at 7.5 percent.

*Response:* While the commenter is correct regarding the statement included in the GAO report concerning the use of a 15-percent threshold, we explained in section IV. of the December 13, 2002 interim final rule in response to a GAO recommendation our reason for not setting the threshold at less than 15 percent. As stated in that rule, the statute does not define what constitutes a grossly excessive or deficient payment amount. Rather, the statute provides two different processes once a determination is made that a payment amount is grossly excessive or deficient. That is, the statute specifies a process for adjustments of 15 percent or more in a given year and a simplified process for adjustments of less than 15 percent in a given year. In so doing, the statute places significant importance on a 15-percent criterion. For these reasons, we determined that differences between current and proposed payment amounts of less than 15 percent will not be considered grossly excessive or grossly deficient and, therefore, do not provide a basis for using the inherent reasonableness authority. Our definition of grossly excessive or deficient does not preclude adjustments of less than 15 percent in a given year once it is determined that an overall adjustment of 15 percent or more is justified.

*Comment:* Four commenters believed that CMS' interpretation and definition of grossly excessive in relation to overpayment for Medicare Part B drugs is incorrect and without a factual basis. The commenters indicated that the statute does not define what constitutes a grossly excessive payment amount. Some of the commenters urged CMS to adopt a more realistic understanding of the implications of its stated policy on the delivery of health care to patients with cancer in this country.

*Response:* The commenters are correct in stating that the statute does not define what constitutes a grossly excessive payment amount. The statute applies inherent reasonableness to Part B items and services other than physicians' services as defined and paid for under section 1848 of the Act. Drugs are paid under section 1842(o) of the Act and not section 1848 of the Act. The inherent reasonableness authority can and should be used in cases for which the standard rules for determining payment amounts for drugs result in grossly deficient or excessive payment amounts. Effective January 1, 2004, section 303 of Public Law 108–173, enacted on December 8, 2003, established a new pricing methodology for Part B drugs, including those furnished by oncologists to their cancer patients, that are not paid on a cost or prospective payment basis. Because of this new pricing methodology, we do not anticipate the need to apply the inherent reasonableness authority to Part B drugs at this time, although we retain our authority to do so. Public Law 108–173 did not amend section 1848 of the Act to explicitly exclude Part B drugs from the inherent reasonableness authority. Therefore, although we believe we have the authority to do so, we will not exclude Part B drugs from the group of services for which we would consider using the inherent reasonableness authority.

*Comment:* One commenter stated that CMS and the carriers must consider the service components (for example, transportation, set-up, patient education, and servicing) of all Part B therapies and items when defining the grossly excessive payment amounts.

*Response:* We agree with the commenter. The regulations require that when using wholesale costs, the cost of services necessary to furnish a product will be taken into account in making an inherent reasonableness determination. However, we believe that for other types of comparison, for example, using a retail price, that price generally includes the service component. Should the retail price not include recognition of a service component, the service component will, of course, be considered in making an inherent reasonableness determination.

*Comment:* Three commenters urged CMS to revise its definition of grossly excessive or grossly deficient to provide sufficient notice about the specific payment allowances that would be subject to the inherent reasonableness authority. The commenters believed that

the 15-percent threshold should be based on objective criteria that would measure market reality rather than basing it on a nonexclusive list of factors. The commenters recommended that CMS revise the definition of grossly excessive or grossly deficient to state that a Medicare payment amount for a category of items or services will be considered grossly excessive or deficient ''only if the average amount paid by all non-Medicare payers for the same category of items or services is at least 15 percent greater or less than such Medicare amount.''

*Response:* We do not believe it is necessary to revise our definition of grossly excessive or grossly deficient to provide notice about the specific payment allowances. The statute applies inherent reasonableness to Part B items and services other than physicians' services as defined and paid for under section 1848 of the Act. However, we decided not to apply this rule to services paid under a prospective payment system such as hospital outpatient services or home health services. As previously stated, no item or service is subject to a change in payment under the inherent reasonableness authority until the proposed change is published by either CMS in the **Federal Register** or its carriers in their own publications after public comments are received in response to the proposed notice and are considered. In addition, we believe that our definition is appropriate and does include an objective criterion, that is, 15 percent.

*Comment:* Three commenters suggested that the definition of grossly excessive or grossly deficient clearly indicate that all available data sources will be evaluated before we make an inherent reasonableness determination and that a single non-Medicare payor's payment amounts for an item would not be used to establish a Medicare payment amount using inherent reasonableness authority. The commenters indicated that the wide variation among the various sources available for price data warrants the evaluation of all sources before making any inherent reasonableness determination.

*Response:* We do not believe that it is necessary to modify our definition of grossly excessive and grossly deficient as the commenters suggested. Section 1842(b)(8) of the Act provides that comparing Medicare payments made by other purchasers is an appropriate way to determine whether or not Medicare payment amounts are reasonable. Section 405.502(g)(4) of the regulations was added in response to a GAO recommendation to ensure the use of valid and reliable data in making an inherent reasonableness determination. Under this regulation, CMS and its carriers must meet 11 criteria, to the extent they are applicable, in determining whether a payment amount is grossly excessive or deficient. For these reasons, the use of prices from a single payor would not be used to determine Medicare's payment amounts.

*Comment:* Three commenters stated that the definition of grossly excessive or grossly deficient must ensure that Medicare's policy of affording beneficiaries choices among a wide selection of services, products, and brands is retained.

*Response:* We do not believe that using the inherent reasonableness authority will limit beneficiaries' choices of Medicare items and services because the purpose of the authority is to ensure that Medicare makes payments that are realistic and equitable, and better reflect market prices. 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. If the payment amount is adjusted downward, the lower payment amount should not necessarily result in a lack of availability of items and services because 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 excessive profits. An adjustment would benefit the Medicare program by reducing costs and benefit beneficiaries by reducing coinsurance payments. Moreover, we will monitor all complaints from beneficiaries, suppliers, providers, and others regarding patient access to items and services for which payment amounts may be adjusted using the inherent reasonableness process.

*Comment:* One commenter believed it was inappropriate to set the threshold at 15 percent to define a grossly excessive or deficient payment amount for certain orthotics and prosthetics. The commenter stated that these items are highly customized, vary in complexity based on the patient, are priced differently by manufacturers based on various factors, and require extensive labor and skill to manufacturer them. The commenter suggested that CMS increase the threshold from 15 percent to 20 percent for orthotics and prosthetics.

*Response:* While the statute does not define what constitutes a grossly excessive or deficient payment amount, it nevertheless places significant importance on a 15-percent criterion. For this reason, we believe that it is appropriate to adopt and apply a 15-percent criterion consistently to all Medicare Part B items and services, including orthotics and prosthetics.

*Comment:* Fifteen commenters were concerned that applying the definition of grossly excessive to payment amounts for Medicare Part B chemotherapy drugs administered in physicians' offices will greatly impede beneficiaries' access to care, force physicians to abandon their oncology practices, and completely undermine the efficacy of cancer care in this country.

*Response:* We are aware that oncologists and cancer patients continue to raise concerns about access to chemotherapy. Effective January 1, 2004, section 303 of Public Law 108–173 established a new pricing methodology for drugs and biologicals that are not paid on a cost or prospective payment system basis. It also increased the physician fee schedule amounts for chemotherapy drug administration services. In addition, for 2005 CMS initiated a demonstration in which providers were reimbursed for measuring and providing data on patient outcomes in three areas of concern often cited by patients undergoing chemotherapy: Controlling pain, minimizing nausea and vomiting, and reducing fatigue. Following extensive discussions with various groups representing the interests of oncologists and advocates for patient care, we decided to retain the demonstration project for 2006, but we will revise the codes for reporting in order to take a further step toward encouraging quality care and promoting best clinical practices that should lead to improved patient outcomes. We will eliminate the CY 2005 codes specific to the assessment of patient symptoms, while maintaining our focus on quality cancer care, including the management of debilitating symptoms, to assure the best possible quality of life for cancer patients. At this time, we do not have evidence to suggest that access problems have occurred as a result of the payment policy changes enacted by Public Law 108–173. Office-based chemotherapy care appears to be continuing at historical levels. We will continue to monitor patient access closely.

As we stated previously, we have decided not to subject Part B drugs paid under a prospective payment system such as the hospital outpatient prospective payment system to the inherent reasonableness provisions. In addition, because of the recent legislative changes in payment for Part B covered drugs, including chemotherapy drugs, we do not anticipate an immediate need to apply the inherent reasonableness authority to Part B drugs, but we are retaining our authority for these drugs in the future should the need arise.

*B. Use of Valid and Reliable Data*

In the December 2002 interim final rule, we revised the regulation to include a new section that provided a methodology taken from the GAO report to ensure the use of valid and reliable data in making an inherent reasonableness determination (§ 405.502(g)(4)). Because the GAO found that the carriers did not use consistent methods to collect and analyze pricing data and did not develop written guidelines for data collection and analysis, in the December 13, 2002 interim final rule, we included in the regulations at § 405.502(g)(4) the following 11 steps to be completed:

- Developing written guidelines for data collection and analysis.
- Ensuring consistency in any survey to collect and analyze pricing data.
- Developing a consistent set of survey questions to use when requesting retail prices.
- Ensuring that sampled prices fully represent the range of prices nationally.
- Considering the geographic distribution of Medicare beneficiaries.
- Considering relative prices in the various localities to ensure that an appropriate mix of areas with high, medium, and low consumer prices was included.
- Considering criteria to define populous State, less populous State, urban area, and rural area.
- Considering a consistent approach in selecting retail outlets within selected cities.
- Considering whether the distribution of sampled prices from localities surveyed is fully representative of the distribution of the U.S. population.
- Considering the products generally used by beneficiaries and collecting prices of these products.
- When using wholesale costs, considering the cost of the services necessary to furnish a product to beneficiaries.

In addition, based on the GAO concerns about the carriers' price survey, the durable medical equipment regional carriers (DMERCs) did not finalize their September 1998 proposed adjustments because the methodology used by the carriers' for making the proposed adjustments did not reflect our revised regulatory criteria, based on recommendations by GAO, for making inherent reasonableness determinations. Likewise, we did not finalize the CMS inherent reasonableness proposals that were published in August 1999 because the methodology used for making the proposed adjustments also did not reflect the revised criteria recommended by GAO and adopted in the December 13, 2002 interim final rule.

We indicated that, in some instances, it may be appropriate to use cost rather than retail or wholesale prices in determining whether a payment amount is grossly excessive or deficient. In those instances in which we use cost data, we consider all costs of the supplier, that is, both direct and indirect costs, as well as any service component costs.

As mentioned previously, section 223(b) of the BBRA required that, in publishing a final regulation on inherent reasonableness, the Secretary take appropriate steps to ensure the use of valid and reliable data when exercising inherent reasonableness authority. The 11 criteria specified above in the December 13, 2002 interim final rule define the steps we will take to ensure the use of valid and reliable data. We specifically solicited public comments on these criteria. The comments we received and our responses appear below.

*Comment:* One commenter, representing family physicians, family practice residents, and medical students, supported CMS' data collection methods for obtaining valid and reliable data for making inherent reasonableness determinations. However, another commenter believed that implementation of the inherent reasonableness regulation should be delayed until further research data are produced that depict the full range of socioeconomic and medical effects of payment adjustments. The commenter believed that a full research study that includes the results of these effects would have a better outcome on CMS' implemented decisions for reimbursement of oncology services.

*Response:* We appreciate the commenter's support. In response to the suggestion that we delay implementation of the inherent reasonableness authority until research study results are available that assess the impact of payment adjustments made using the inherent reasonableness process on payment for oncology services, we do not believe that such a delay is warranted and would be beneficial. As previously mentioned, because of the recent legislative changes under Public Law 108–173 in payment for Part B drugs not subject to a prospective payment system, we do not now anticipate needing to apply the inherent reasonableness authority to these drugs, although we are retaining this authority should the need arise. Public Law 108–173 also increased the physician fee schedule amounts for chemotherapy drug administration services.

*Comment:* Some commenters commended CMS for implementing the GAO recommendations. Other commenters suggested that CMS withdraw the inherent reasonableness rule until CMS sets forth valid and reliable data to assess reasonableness in the establishment of Medicare payment amounts. One commenter believed that the provision of § 405.502(g)(2)(i) that grants CMS or its carriers the authority to identify a ''price markup'' in the absence of verifiable data does not coincide with the GAO intent and contradicts the GAO recommendation that CMS'' decisions should be based on valid and reliable data.

*Response:* The regulations themselves do not make an inherent reasonableness determination, nor do they contain data upon which such a determination would be based. Rather, the regulations provide a methodology to ensure the use of valid and reliable data in making an inherent reasonableness determination. With regard to the use of the valid and reliable data criteria, these criteria were adopted in their entirety from the GAO report and, thus, properly reflect the GAO's intent and recommendations.

*Comment:* Several commenters stated that the regulation text containing the guidelines for data collection concerning retail and wholesale pricing surveys is vague; the text lacks specific criteria (for example, parameters for data collection and analysis) that link the data collection to the determination of the payment adjustments. The commenters believed that the criterion set forth for the data sample will not appropriately depict a ''valid and reliable'' data set. Two commenters pointed out that, although the inherent reasonableness rule clearly identifies geographic distribution in its data analysis, CMS failed to identify and define the measurable criteria for consideration of the involved geographic areas. The commenters suggested that CMS consider another survey methodology that includes

clearer and statistically sound techniques for collecting the data.

*Response:* We believe that § 405.502(g)(4) of the regulations appropriately sets forth the steps that we will take to ensure the use of valid and reliable data when exercising inherent reasonableness authority. We believe that it is impractical to adopt in regulations the level of specificity for data suggested by the commenters because the inherent reasonableness authority is applied to a wide array of Medicare Part B items and services and under an array of different marketing conditions.

*Comment:* Several commenters stated that drug ''acquisition cost'' is not the true estimated measurement for the inflation of chemotherapy drug cost. The commenters believed that there are additional factors that CMS should take into account, such as facility overhead, procurement, and production cost. One commenter recommended that CMS use data that reflect technological advances. The commenter pointed out that as its company discovers new technological advances for cancer treatment, it alters the total cost of a drug therapy and that under the current policy CMS would not be able to capture these most current data set that would correlate with drug therapy technological advances and the most current drug therapy costs.

*Response:* As previously stated in section II.A. of this final rule, we have decided not to subject Part B drugs paid under a prospective payment system such as the hospital outpatient prospective payment system to the inherent reasonableness provisions. In addition, because of the recent legislative changes under Public Law 108–173 in payment for Part B drugs not subject to a prospective payment system, we do not now anticipate needing to apply the inherent reasonableness authority to these drugs, although we are retaining our authority should the need arise.

We recognize that there are costs associated with procuring drugs beyond the actual ingredient cost such as shipping. In the event that the inherent reasonableness authority were applied to Part B drugs, we would consider these costs to the extent that they are not already reimbursed through our drug administration payments.

*Comment:* Several commenters stated that major differences exist between the various health care payment programs and the Medicare program and suggested that CMS assure that the proposed use of payment data from the Veterans Administration (VA), the Medicaid program, and volume discounted programs in making inherent reasonableness determinations does not result in unreliable, flawed data.

The commenters believed that the VA payment data are not valid or reliable for inherent reasonableness determinations under Medicare because the VA payment system requires VA to act as a provider and a distributor, while the Medicare payment system provides payments to individual providers and suppliers for the provision of services. Therefore, the commenter believed that the VA pricing is not an appropriate comparison for data analysis to determine payment for drug rates. One commenter stated that the Medicaid payment system has fixed rates and percentages for certain States and that these prearranged payment amounts would cause the data set to be skewed for purposes of inherent reasonableness determinations. The commenters disagreed with CMS' decision to include small businesses with small purchases in the data set for volume discounts with large businesses with large purchase volumes without CMS considering the difference in volume purchase commitments. The commenters believed that this is just one of the many fundamental differences between the VA and Medicare that would result in drastic differences in the cost of items and services. One commenter submitted data that compared the prices of motorized wheelchairs for Medicare Part B claims to the same products purchased by the VA and the results of its research study which, the commenter believed, prove that the CMS methodology is unreliable.

Several commenters suggested that, because the purchasers' administrative costs are atypical of Medicare claims, CMS should either use the volume discounted data for specific categories or use the pricing data for analyses after carefully examining the data for validity and eliminating invalid data.

*Response:* While the statute generally does not give CMS the authority to negotiate volume discounts with suppliers, it also does not permit CMS to subsidize the discounts that suppliers grant to other purchasers. CMS' charge is to calculate a fair and equitable payment amount, not to underwrite suppliers' profitability. Medicare is the largest volume purchaser for many medical items and services. As a payer, Medicare expenditures represent 17.6 percent of total national health expenditures by all payers. Expenditures for Part B, excluding physicians' services, are approximately $60 billion per year. Although Medicare does not give specific volume guarantees to suppliers and does not ask for volume discounts, there is a predictable volume of Medicare business, and suppliers have the opportunity to profit from this. To suggest that Medicare's payment be higher than other purchasers' payment in light of the large Medicare volume is unwarranted. Logically, it does not follow that a large purchaser such as Medicare should be expected to pay more than other smaller purchasers.

*Comment:* Several commenters who supported the 11 criteria that CMS or its contractors will use to make grossly excessive and grossly deficient inherent reasonableness determinations suggested that ''median retail pricing data'' should also be a part of the evaluating criteria; and that CMS define ''retail'' as the term relates to the 11 criteria. The commenters recommended that CMS consider the frequency by which patients utilize various products. The commenters pointed out that products used more frequently are generally lower in price than products that are not used frequently and further added that the use of the reduced retail prices of products used by most beneficiaries would not conform to the valid and reliable data criterion. The commenters also suggested that CMS expand the survey to include products used by non-Medicare patients in an effort to eliminate a biased data set.

*Response:* We do not believe that median pricing data must be used to ensure that data are valid and reliable. The selection of a median may be used as a measure of the reasonableness of a price and, if it were used, would be discussed in further detail in the public notice when CMS or its carriers elect to make an inherent reasonableness determination. ''Retail'' has the standard dictionary meaning, and we see no reason to further define it in regulation. With regard to the rates at which products are consumed, regulations already provide that we consider the rate at which the product is generally used by beneficiaries.

Further, products used less frequently are also considered in the regulations, which provide that prices must represent the range of prices nationally and that prices must consider an appropriate mix of prices. In order to make like comparisons, we do not believe we should compare products used by Medicare beneficiaries to the types of products used by non-Medicare patients.

*Comment:* One commenter opposed CMS' and its contractors' use of research data from outside of the United States

because of the difference in pricing systems.

*Response:* At the present time, we do not anticipate using data from outside the United States but, if we do, we would take into account legitimate pricing differences.

*Comment:* One commenter recommended that CMS provide and make available, possibly on the Internet, the full research study that entails the criteria, surveys, and resulting data utilized by CMS and its contractors in making inherent reasonableness determinations.

*Response:* The regulations provide great specificity regarding the criteria and data that are to be used in making inherent reasonableness determinations and great specificity regarding public notice of such determinations. It is our intention to publish all data used in making determinations in any proposed notice. In the future, we also anticipate publishing data on the Internet.

*C. Other Provisions Addressed in the December 13, 2002 Interim Final Rule*

In the December 13, 2002 interim final rule, we addressed the public comments that we had received on the January 7, 1998 interim final rule. In response to comments on the January 7, 1998 interim final rule, we made the following other changes in the December 13, 2002 interim final rule:

- We clarified the difference between a national determination and a carrier determination (§ 405.502(g)(1)(iii)). We also revised § 405.502(g)(3) to provide further clarification on the terms we use to distinguish between inherent reasonableness activities conducted by CMS and inherent reasonableness activities conducted by the carriers.
- We included an example of new technology that exists and is not reflected in the existing payment allowance (§ 405.502(g)(2)(vii)(H)).
- We clarified language to provide suppliers the opportunity to comment on a carrier's proposed inherent reasonableness payment allowances as well as the factors a carrier considered; and added a requirement that a carrier notify us in writing of any final limits it proposes to establish (§ 405.502(g)(3)(ii)).
- We added language to provide that, when payment adjustments of more than 15 percent are spread out over multiple years, subsequent adjustments will be reviewed for their appropriateness (§ 405.502(g)(5)). As recommended in the GAO report, when adjustments of more than 15 percent are spread out over multiple years, we will review market prices in the years subsequent to the year that the initial 15-percent reduction is effective. The purpose of this review is to ensure that further reductions continue to be appropriate.
- We revised § 405.502(g)(3)(ii) to clarify the procedures and the sequence of steps a carrier will follow in making an inherent reasonableness determination.

In this **Federal Register** document, we are finalizing, with minor editorial changes, the above revisions that were included in the December 13, 2002 interim final rule.

*D. Other Issues Addressed in the Public Comments Received*

Some of the timely correspondence received in response to the December 13, 2002 interim final rule included public comments on issues other than the two provisions on which we particularly invited additional public comments. These included comments on application of inherent reasonableness authority to ambulance services paid on a fee schedule basis; application of inherent reasonableness authority to oncology drugs administered in physicians' offices; use of current profit margins from oncology drugs administered in physicians' offices to subsidize certain oncology services; impact of inherent reasonableness policy on community oncologists; impact of inherent reasonableness policy on cancer patients' access to care; use of acquisition cost as a factor in determining inherently unreasonable oncology drug costs; application of inherent reasonableness policy to nonpass-through drugs and biologicals paid under the hospital outpatient prospective payment system; use of a comprehensive rather than isolated approach to implementing inherent reasonableness policy changes for oncology drugs administered in physicians' offices; consideration of a Congressionally-driven balanced solution for implementing inherent reasonableness policy changes; seeking the advice of key industry associations prior to implementing inherent reasonableness policy changes for oncology drugs administered in physicians' offices; and reaction to the quality of analysis included in the GAO report. Because these comments pertain to issues on which we had previously received and considered public comment, we consider them outside the scope of the solicitation of public comments on the interim final rule. Therefore, we are not addressing them in this final rule. We will consider them in development of future policy changes. We also refer the readers to the related public comments we addressed in the December 13, 2002 interim final rule.

*E. Adoption of December 13, 2002 Interim Final Rule as Final*

After analysis of the public comments received, we have determined that no further changes, other than minor editorial and drafting changes, are necessary to the regulations under § 405.502(g) and (h) relating to inherent reasonableness determinations. These changes are editorial in nature or involve coding and language changes to conform to established CFR drafting rules. The provisions of the December 13, 2002 interim final rule are finalized, effective 60 days after the publication date of this document in the **Federal Register**.

## III. Collection of Information Requirements

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

## IV. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

*A. Executive Order 12866*

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) 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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This regulation has no immediate economic effect on current Medicare payments. However, it establishes a process that could be used in the future to set reasonable and equitable payment amounts. Because this rule does not include any actual inherent reasonableness determinations, it has no immediate impact on Medicare payment amounts. However, we believe that the

future application of the inherent reasonableness authority has the potential to have significant impact on Medicare payment amounts. Therefore, this final rule is considered to be economically significant and is a major rule. We base our belief on the June 2002 OIG report that indicated that Medicare may be overpaying between $130 million and $958 million per year for 16 items of medical equipment. In addition, the GAO indicated that Medicare may be overpaying for medical equipment by more than 20 percent. However, these reports were not done to the specifications we are finalizing in this rule and, therefore, they may not be an accurate estimate of the specific dollar impact that could result from the future application of inherent reasonableness under these requirements. Because we recognize the potential for future payment adjustments, either upward or downward, when CMS makes adjustments we will publish in the **Federal Register** regulatory impact statements that will comply with Executive Order 12866 and the Regulatory Flexibility Act whenever the dollar impact of inherent reasonableness determinations exceed $100 million in any 1 year.

At this time, we lack sufficient data to conduct a quantitative analysis of the impact of this rule. We lack such data because, until we are able to conduct an inherent reasonableness study using the published criteria, we are unable to determine whether Medicare is overpaying or underpaying for items or services and to what degree. We do not know if, or when, or for which services, we would make payment adjustments, or the percentage adjustment we would make, or even the particular industry that would be affected. In addition, we do not know if these adjustments would increase or decrease Medicare payment amounts. As a result, we cannot anticipate the specific dollar effect or impact on suppliers and beneficiaries.

*B. Regulatory Flexibility Analysis*

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities either by nonprofit status or by having revenues of $6 million to $29 million or less in any 1 year (see 65 FR 69432 for details). 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. Because this final rule does not include any actual inherent reasonableness determinations, it will not have an impact on small businesses. However, it finalizes the establishment of a process that could be used in the future to establish reasonable and equitable payment amounts.

We do not expect suppliers of Part B services to be immediately affected by this rule because the rule will have no immediate impact on Medicare payment amounts. However, we do believe that use of inherent reasonableness has the potential to significantly impact small businesses in the future. This belief is based on a June 2002 OIG report cited earlier which indicated that Medicare may be overpaying between $130 million and $958 million per year for 16 items of medical equipment. In addition, the GAO indicated that Medicare may be overpaying for medical equipment by more than 20 percent. However, we are still unable to predict the specific dollar impact on the future application of inherent reasonableness. Because we recognize the potential for future payment adjustments, either upward or downward, when CMS makes adjustments, we will publish in the **Federal Register** impact statements that will comply with Executive Order 12866 and the Regulatory Flexibility Act whenever the dollar impact of inherent reasonableness determinations exceed $100 million in any 1 year, or when the adjustments will have a significant impact on a substantial number of small entities.

We do not have sufficient data to predict exactly the nature of the future impact of this rule or the magnitude of the 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. If the payment amount is adjusted downward, a lower payment amount should not necessarily result in a lack of availability of items and services because the revised payment amount would be realistic and equitable and would better reflect market prices for the given item or service. We believe that a realistic and equitable payment amount would ensure continued availability of items and services. This adjustment would benefit the Medicare program by reducing costs, thereby protecting the Medicare Trust Fund, and benefit beneficiaries by reducing coinsurance payments. In addition, this regulation only specifies the criteria and methodology for determining when payment for a service or item is inherently unreasonable and does not result in any adjustments.

If CMS initiates an inherent reasonableness determination that results in payment adjustments in excess of $100 million in any 1 year, we will publish in the **Federal Register** an analysis in compliance with Executive Order 12866. If the CMS adjustment will have a significant impact on a substantial number of small entities, we will also conduct an analysis in accordance with the Regulatory Flexibility Act. In cases where one or more of our carriers undertake an adjustment using this inherent reasonableness authority that either has an impact of $100 million or more in any 1 year or has a significant effect on a substantial number of small entities, the carrier(s) will notify providers of the planned adjustment and the analysis on which it is based. In this way, affected parties would be able to comment on the planned adjustment.

*C. Impact on Rural Areas*

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 603 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 100 beds. We are not preparing a rural impact analysis because we have determined that this final rule will not have a significant economic impact on the operation of a substantial number of small rural hospitals.

*D. Unfunded Mandates*

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal government, in the aggregate, or by the private sector of $110 million. This final rule does not mandate expenditures by State, local, or tribal governments, or by the private sector. Therefore, the requirements of section 202 do not apply.

*E. Executive Order 13132*

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed

rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Because this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

*F. Executive Order 12866*

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

**List of Subjects in 42 CFR 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, part 405 is amended as follows:

## PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

### Subpart E—Criteria for Determining Reasonable Charges

■ 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. Section 405.502 is amended by revising paragraphs (g) and (h) 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 (g), a ''category of items or services'' may consist of a single item or service or any number of items or services.

(ii) CMS or a carrier may determine that the standard rules for calculating payment amounts set forth in this subpart for a category of items or services identified in section 1861(s) of the Act (other than physicians' services paid under section 1848 of the Act and those items and services for which payment is made under a prospective payment system, such as outpatient hospital services or home health services) will result in grossly deficient or excessive amounts. A payment amount will not be considered grossly excessive or deficient if it is determined that an overall payment adjustment of less than 15 percent is necessary to produce a realistic and equitable payment amount. For CMS-initiated adjustments, CMS will publish in the **Federal Register** an analysis of payment adjustments that exceed $100 million per year in compliance with Executive Order 12866. If CMS makes adjustments that have a significant effect on a substantial number of small entities, it will publish an analysis in compliance with the Regulatory Flexibility Act.

(iii) If CMS or the carrier determines that the standard rules for calculating payment amounts for a category of items or services will result in grossly deficient or excessive amounts, CMS, or the carrier, may establish special payment limits that are realistic and equitable for a category of items or services. If CMS makes a determination, it is considered a national determination. A carrier determination is one made by a carrier or intermediary or groups of carriers or intermediaries even if the determination applies to payment in all States.

(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.

(H) A new technology exists which is not reflected in the existing payment allowances.

(2) *Establishing a limit.* In establishing a payment limit for a category of items or services, CMS 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 CMS or a carrier considers 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.* Price markup 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, CMS or a carrier may consider the price markup on a similar category of items or services and information on general industry pricing trends.

(ii) *Differences in charges.* CMS 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.* CMS 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) *Use.* CMS or a carrier may impute a reasonable rate of use for a category of items or services and consider unit costs based on efficient use.

(v) *Payment amounts in other localities.* CMS 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.* CMS publishes in the **Federal Register** proposed and final notices announcing a special payment limit described in paragraph (g) of this section 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) A carrier proposing to establish a special payment limit for a category of items or services must inform the affected suppliers and Medicaid agencies of the proposed payment amounts and the factors it considered in proposing the particular limit, as described in paragraphs (g)(1) through (g)(4) of this section and must solicit comments. The notice must also consider the following:

(*1*) The effects on the Medicare program, including costs, savings, assignment rates, beneficiary liability, and quality of care.

(*2*) What entities would be affected, such as classes of providers or suppliers and beneficiaries.

(*3*) How significantly would these entities be affected.

(*4*) How would the adjustment affect beneficiary access to items or services.

(B) Before publication of a final notice, the carrier must—

(*1*) Evaluate the comments it receives on the proposed notice.

(*2*) Notify CMS in writing of any final limits it plans to establish. CMS will acknowledge in writing to the carrier that it received the carrier's notification.

(*3*) After receipt of CMS' acknowledgement, inform the affected suppliers and State Medicaid agencies of any final limits it establishes.

(C) The effective date for a final payment limit may apply to services furnished at least 60 days after the date that the carrier notifies affected suppliers and State Medicaid agencies of the final limit.

(4) *Use of valid and reliable data.* In determining whether a payment amount is grossly excessive or deficient and in establishing an appropriate payment amount, valid and reliable data are used. To ensure the use of valid and reliable data, CMS or the carrier must meet the following criteria to the extent applicable:

(i) Develop written guidelines for data collection and analysis.

(ii) Ensure consistency in any survey to collect and analyze pricing data.

(iii) Develop a consistent set of survey questions to use when requesting retail prices.

(iv) Ensure that sampled prices fully represent the range of prices nationally.

(v) Consider the geographic distribution of Medicare beneficiaries.

(vi) Consider relative prices in the various localities to ensure that an appropriate mix of areas with high, medium, and low consumer prices was included.

(vii) Consider criteria to define populous State, less populous State, urban area, and rural area.

(viii) Consider a consistent approach in selecting retail outlets within selected cities.

(ix) Consider whether the distribution of sampled prices from localities surveyed is fully representative of the distribution of the U.S. population.

(x) Consider the products generally used by beneficiaries and collect prices of these products.

(xi) When using wholesale costs, consider the cost of the services necessary to furnish a product to beneficiaries.

(5) *Review of market prices.* If CMS or a carrier makes a payment adjustment of more than 15 percent under this paragraph (g), CMS or the carrier will review market prices in the years subsequent to the year that the initial reduction is effective in order to ensure that further reductions continue to be appropriate.

(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)(5) of this section, CMS applies the following rules in 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.* CMS 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, CMS consults with representatives of the supplier industry likely to be affected by the change in the payment amount.

(3) *Publication of national limits.* If CMS determines under this paragraph (h) to establish a special payment limit for a category of items or services, it publishes in the **Federal Register** the proposed and final notices of a special payment limit before it adopts the limit. The notices set 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 CMS 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 for a category of items or services;

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

(B) Responds to the public comments.

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

Dated: June 13, 2005.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: December 1, 2005.

**Michael O. Leavitt,**

*Secretary.*

[FR Doc. 05–24020 Filed 12–12–05; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

## Federal Emergency Management Agency

## 44 CFR Part 65

**[Docket No. FEMA–B–7455]**

## Changes in Flood Elevation Determinations

**AGENCY:** Federal Emergency Management Agency (FEMA), Department of Homeland Security.

**ACTION:** Interim rule.

**SUMMARY:** This interim rule lists communities where modification of the Base (1% annual-chance) Flood Elevations (BFEs) is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified BFEs for new buildings and their contents.

**DATES:** These modified BFEs are currently in effect on the dates listed in the table below and revise the Flood Insurance Rate Maps in effect prior to