FOR FURTHER INFORMATION CONTACT: Mr. Jack Potosnak, PE, Remedial Project Manager, U.S. EPA Region III (3HS13), 1650 Arch Street, Philadelphia, PA 19103–2029, (215) 814–3362.

SUPPLEMENTARY INFORMATION: The portions of the site to be deleted from the NPL are the OU–11 Sellite Plant, the OU–12 North and South Powerhouses and Vicinity, the ENV–6 Wetlands Mitigation area, ESI–3 Tract 21, the ESI–5 Refueling Depot, and the ESI–9 Main and Outgoing Classification Yards.

A Notice of Intent to Delete for this site was published October 22, 2002 (67 FR 64846). The closing date for comments on the Notice of Intent to Delete was November 21, 2002. EPA received no comments.

EPA identifies releases which appear to present a significant risk to public health, welfare, or the environment, and it maintains the NPL as the list of those releases. Releases on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund. Any release deleted from the NPL remains eligible for Fund-financed remedial actions in the unlikely event that conditions at the site warrant such action. Section 300.425(e)(3) of the NCP states that Fund-financed actions may be taken at sites deleted from the NPL. Deletion of a site from the NPL does not affect responsible party liability or impede agency efforts to recover costs associated with response efforts.

List of Subjects in 40 CFR Part 300

Environmental protection, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Reporting and recordkeeping requirements, Superfund.

Dated: December 2, 2002.

Donald S. Welsh,

Regional Administrator, U.S. Environmental Protection Agency, Region III.

40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

2. Table 2 of appendix B to part 300 is amended by revising the entry for WV, Ordnance Works (USARMY), Point Pleasant to read as follows:

Appendix B to Part 300—National Priorities List

St	Site name	City/County	Notes [a]
*	*	*	*
WV	West Virginia Ordnance (USARMY)	Point Pleasant	P

[a] P=Sites with partial deletion(s).

[FR Doc. 02–31240 Filed 12–12–02; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Center for Medicare & Medicaid Services

42 CFR Part 405

[CMS–1908–IFC]

RIN 0938–AJ97

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

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

ACTION: Interim final rule.

SUMMARY: This interim final rule sets forth 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. We also do not intend to apply this rule to services paid under a prospective payment system, such as outpatient hospital or home health. This rule describes the factors we (or our carrier) will consider and the procedures we will follow in establishing realistic and equitable payment amounts. This rule also responds to the public comments we received on the interim final rule with comment period that described the factors we will follow in establishing realistic and equitable payment amounts. In addition, the rule responds to a General Accounting Office report (as required by section 223 of the Balanced Budget Refinement Act of 1999), and it implements sections 1842(b)(8) and (b)(9) of the Social Security Act as revised by section 4316 of the Balanced Budget Act of 1997.

DATES: *Effective date:* These regulations are effective on February 11, 2003.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on February 11, 2003.

ADDRESSES: In commenting, please refer to file code CMS–1908–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission or e-mail. Mail written comments (one original and three copies) to the following address only:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1908–IFC, P.O. Box 8017, Baltimore, MD 21244–8017.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses:

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for commenters wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

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

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* Comments received timely will be available for public inspection as they are received,

generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call telephone number: (410) 786–7195.

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), Pub. L. 105–33, enacted on August 5, 1997, however, permits 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. 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 always taken the position that the authority to regulate unreasonable payment amounts is inherent in his authority to determine reasonable charges according to section 1842 of the Act. Moreover, effective September 10, 1986, section 9304(a) of the Consolidated Omnibus Budget Reconciliation Act (COBRA) (Pub. L. 99–272) of 1985 added section 1842(b)(8) and (b)(9) of the Act. These provisions expressly authorize 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 is therefore, 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) and were published on August 11, 1986 in the **Federal Register** (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. The regulations 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.

On January 7, 1998 we published in the **Federal Register** (63 FR 687) an interim final rule implementing section 4316 of the BBA.

II. Provisions of the 1998 Interim Final Rule

In the January 7, 1998 interim final rule, we revised § 405.502(g) and (h) by excluding references to physician services. We also deleted specific references to the reasonable charge payment methodology. We deleted these references because the inherent reasonableness provisions apply to all Part B services, except physician services, irrespective of the payment methodology. However, we do not intend to apply this rule to services paid under a prospective payment system, such as outpatient hospital 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 gives the Secretary discretion to reduce the number of factors that are used to make inherent reasonableness determinations, we retained all but one of the 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 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 reinserted this example in the final regulation; however, due to comments we received requesting that this example not be deleted.)

When we implemented section 9304(a) of COBRA of 1985, we interpreted the statute as codifying both our authority and a carrier's authority to establish realistic and equitable payment amounts. We interpreted the provisions of section 4316 of the BBA in the same way. Thus, the final regulations describe 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.

Section 4316 of the BBA amends section 1842(b)(8), 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.

Other than these BBA changes and some minor modifications, the revised 1998 interim final regulations were the same as the final regulations that were published in the **Federal Register** (53 FR 26067) on July 11, 1988.

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 currently contained in § 405.502(g), it permits the Secretary to consider any additional factors determined to be appropriate. The additional pre-BBA factors we may consider, in accordance with current § 405.502(g)(1), include 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.

III. Balanced Budget Refinement Act of 1999

Section 223 of the Balanced Budget Refinement Act (BBRA) of 1999, Pub. L. 106–113, enacted on November 29, 1999, prohibits the use of the inherent reasonableness authority until the following events have occurred:

Step 1: The Comptroller General releases 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) in July 2000. A discussion of this report and our response to its recommendations is contained in section IV of this regulation.

Step 2: The Secretary has published a notice of final rulemaking in the **Federal Register** that relates to the authority and that responds to the 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.

This regulation constitutes a notice of final rulemaking relating to inherent reasonableness authority. In addition to responding to the GAO Report, this regulation also responds to the comments received regarding the interim final regulation that was published January 7, 1998. Section V of this regulation includes our responses to these comments. However, we are issuing this regulation as an interim final rule so that the public will have an additional opportunity to comment. We are particularly interested in receiving comments on two provisions that contain further specificity than found in the 1998 interim final rule. These two provisions are the definitions of ''grossly excessive'' and ''grossly deficient'' in § 405.502(g)(1)(ii) and the criteria for using valid and reliable data in § 405.502(g)(4). Comments on the 1998 interim final rule are addressed in section V of this interim final rule.

Step 3: In publishing the final regulation, the Secretary will reevaluate the appropriateness of the criteria included in the interim final regulation for identifying payments that are excessive or deficient.

The criteria set forth in the interim final rule were never intended to include every set of circumstances where inherent reasonableness would be considered appropriate. We have reviewed the criteria that were included in the interim final rule. These same criteria were also included in the 1986 final regulation and are, therefore, not new but have been in effect for over 10 years. These criteria were originally established by the Congress. We believe the criteria remain as appropriate today as they were when the Congress established them, and we would need compelling reasons for determining that any of the criteria are inappropriate. A more detailed discussion of the criteria is contained in section V of this preamble. Once again, we would point out that 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. In addition, the criteria were never intended to include every set of circumstances for which inherent reasonableness would be considered appropriate.

Step 4: Take appropriate steps to ensure the use of valid and reliable data when exercising the authority.

The regulation has been revised to include a new section that provides a methodology taken from the GAO report to ensure the use of valid and reliable data (§ 405.502(g)(4)). The criteria include doing the following:

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

IV. Response to GAO Report

In July 2000, the GAO released a report entitled ''Medicare Payments—Use of Revised 'Inherent Reasonableness' Generally Appropriate (GAO/HEHS–00–79).'' This interim final regulation responds to the GAO report and, in section V, responds to the comments received regarding the January 7, 1998 interim final regulation. In its report, the GAO found that CMS's use of the revised inherent reasonableness process was generally appropriate. Also, the GAO made four specific recommendations that are discussed below.

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

Response: We concur with this recommendation. The GAO indicated that the definition of these terms is needed so that it is clear to the medical equipment industry precisely what constitutes grossly excessive or grossly deficient. In its report, the GAO states that ''clearly an adjustment of under 15 percent could qualify [as grossly excessive or grossly deficient], because the inherent reasonableness authority extends to situations in which the difference between a current and proposed payment amount is under 15 percent.''

In addition, 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 does not define what constitutes a grossly excessive or deficient payment amount. Nevertheless, the statute places significant importance on a 15 percent criterion. For this reason, we believe that differences between current and proposed payment amounts of less than 15 percent should not be considered grossly excessive or grossly deficient and therefore do 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.

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.

Response: In September of 1998, the carriers proposed reducing payment

amounts for blood glucose test strips, lancets, intermittent urinary catheters, basic enteral formula, albuterol sulfate (an inhalation solution), and eyeglass frames. The basis for these payment reductions was their determination that the current fees were grossly excessive. The carriers based this determination on a comparison of the current fees with the retail prices charged by suppliers. The retail data were gathered from telephone inquiries and on-site visits to retailers. Each DMERC obtained retail prices from four States in their region (three populous States and one less populous State). Thus, the carriers obtained prices from a total of 16 States across the country (12 populous States and 4 less populous States). Within each State, the carriers obtained prices from three urban areas and two rural areas. Within each urban area, the carriers obtained prices from four large stores and one small store. Within each rural area, the carriers selected one store. At least 200 observations were made for each of the six items with over 1,000 observations being made for blood glucose test strips.

The following are the GAO's main criticisms of this retail price survey as stated in the report and our responses:

- The carriers' sampling plan was developed without fully considering the geographic distribution of Medicare beneficiaries.

Based on this criticism from the GAO, in the future we will ensure that greater consideration is given to survey design including the geographic distribution of Medicare beneficiaries for the purpose of conducting retail price surveys.

- The carriers did not consider relative prices in the localities from which they sampled, which would have helped ensure that an appropriate mix of areas with high, medium, and low consumer prices was included.

The carriers surveyed both large and small States, urban and rural areas, and independent and chain stores for this purpose. In the future, we will take steps to ensure that consideration is given to including areas with high, medium, and low consumer prices.

- The carriers did not establish criteria to define populous State, less populous State, urban area, rural area, and, consequently, each carrier used different criteria in selecting locations.
- We will adopt more standard definitions of what constitutes populous States, less populous States, urban areas, and rural areas and will ensure that the carriers use these definitions.
- The carriers were not consistent in how they chose retail outlets within selected cities.

While the carriers surveyed both independent and chain stores, we will instruct the carriers to be more consistent in the methodology they use to make these selections.

- The carriers did not use consistent methods to collect and analyze the pricing data and did not develop written guidelines for data collection and analysis.

The carriers did use written spreadsheets to contain the basic information that they were looking for when they contacted each retail store. The method that was used was a simple example of price shopping, namely, pricing data were collected by contacting retail stores to find out how much they charge for a certain list of items. The carriers followed general guidelines that were provided by CMS. We will issue more detailed guidelines to the carriers to ensure that a more standardized method is used when obtaining pricing information in the future.

Also, based on these GAO criticisms of the carriers price survey, the carriers will not finalize their September 1998 proposed adjustments since the methodology used by the carriers' for making the proposed adjustments does not reflect the revised regulatory criteria recommended by GAO for making inherent reasonableness determinations. Likewise, the CMS inherent reasonableness proposals that were published in August 1999 will not be finalized since the methodology used for making the proposed adjustments also do not reflect the revised criteria recommended by GAO and adapted in this final regulation.

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.

Response: See response to previous recommendation.

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.

Response: As stated in our comments on the draft report, 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.

V. Comments and Responses

A. General

The January 7, 1998 interim final rule invited comments. The specific comments and our responses to these comments follow:

Comment: Only the Congress should be permitted to revise payment rates.

Response: The inherent reasonableness authority was first expressly granted to the Secretary by the Congress in section 9304 of COBRA of 1985. The inherent reasonableness process was specifically established by the Congress for the Secretary to use in adjusting unreasonable payment amounts. In section 4316 of the BBA, the Congress further modified the inherent reasonableness authority which allows the Secretary to revise payment rates. Therefore, the Congress clearly granted the Secretary the authority to revise payment rates using the inherent reasonableness process.

Comment: The statute limits inherent reasonableness adjustments to particular items, not categories of items.

Response: The regulations have always referred to inherent reasonableness as applying to categories of services. While the statute makes reference to particular items or services, we do not believe that this precludes our applying inherent reasonableness to categories of particular items or services that are similar in function and technology, for example, durable medical equipment grouped together under the same code in the Health Care Common Procedure Coding System (HCPCS). It would be impractical to make separate inherent reasonableness adjustments for each unique item or service. For example, it would not be practical to make inherent reasonableness determinations for every different manufacturer, brand name, or model of a specific type of wheelchair described by a particular HCPCS code. Moreover, if a category of items is so similar that payment is made based on the same code and same payment determination, it seems to us completely logical to apply the same limitation to the whole category.

Comment: The inherent reasonableness provision should not be applied to hospital outpatient services.

Response: The statute applies inherent reasonableness to all Part B items and services other than physicians' services as defined and paid for under section 1848 of the Act. By statute, hospital outpatient services,

therefore, are not excluded from the inherent reasonableness process. However, we do not intend to apply this rule to services paid under a prospective payment system, such as outpatient hospital or home health services.

Comment: The inherent reasonableness provision should not be applied to drugs administered in physicians' offices.

Response: The statute applies inherent reasonableness to all 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. However, we do not intend to apply this rule to services paid under a prospective payment system, such as outpatient hospital or home health services. Further, no item or service will be subjected to a change in payment under the inherent reasonable authority until it is published by either CMS in the **Federal Register** or its carriers in their own publication and consideration of comments received in response to the proposed notice. (CMS notices are published in the **Federal Register**.)

Comment: It would be inappropriate for CMS to change laboratory payments while the Institute of Medicine is conducting a study on Part B payments.

Response: Before applying inherent reasonableness to laboratory services, we will consider the results of the study conducted by the Institute of Medicine. As we noted above, the inherent reasonableness authority can and should be used in cases where the standard rules for determining payment amounts for laboratory services result in grossly deficient or excessive payment amounts. Moreover, no item or service will be subjected to a change in payment under the inherent reasonableness authority until it is published by either CMS in the **Federal Register** or its carriers in their own publication and consideration of comments received in response to the proposed notice.

Comment: CMS should not ignore grossly deficient situations. CMS should include the mechanisms for increasing deficient payments.

Response: 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. If we determine that a payment amount is grossly deficient, then we will propose that the payment amount be adjusted using the inherent reasonableness process.

Comment: CMS should increase payment allowances for items used by ostomy patients.

Response: The inherent reasonableness authority was suspended by the BBRA (see section III of this final rule for a discussion of the BBRA). Before that statute, we were reviewing the payment amounts for several ostomy items to determine if inherent reasonableness adjustments were necessary. We intend to continue reviewing payment for these items once the inherent reasonableness authority is restored.

Comment: If CMS or a carrier decides to reduce excessive payment allowances by more than 15 percent spread out over 2 or more years, it should repeat the review process each year; otherwise, this provision contravenes congressional intent.

Response: 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. However, the GAO does not recommend that a new proposed notice be published for each year in which reductions are implemented in addition to the initial 15 percent reduction, and we agree that it is not necessary to publish another notice.

Comment: Arbitrary adjustments to payment rates will affect patient access, assignment rates, beneficiary liability, and quality of care.

Response: The purpose of the inherent reasonableness process is to establish realistic and equitable payment amounts when it is determined that the current payment methods result in amounts that are grossly excessive or grossly deficient. If payment amounts are proposed using the inherent reasonableness process that are not realistic and equitable, then the public has an opportunity to address this during the comment period. Information we or our carriers receive during the comment period or at any other time that demonstrates that inherent reasonableness adjustments will affect patient access, assignment rates, beneficiary liability, or quality of care would result in our appropriately adjusting the payment amount.

Whether attempting to adjust payments centrally through a **Federal Register** notice or through the Medicare carriers, we believe that payment adjustments can only be effective if they follow a defensible process for doing so and are based on accurate information. As described in § 405.502(g)(1) through (g)(4) of this regulation, 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 considered in proposing the particular limit. As part of its analysis, all carriers must also consider the following elements:

- The effects on the Medicare program, including costs, savings, assignment rates, beneficiary liability, and quality of care.
- What entities would be affected such as classes of providers or suppliers and beneficiaries.
- How significantly would these entities be affected.
- How would the adjustment affect beneficiary access to items or services.

The intent of these requirements is to assure that carriers collect sufficient information on market prices and potential effects on suppliers and beneficiaries before taking action.

Comment: Inherent reasonableness adjustments could cause other payers to subsidize the Medicare program.

Response: The goal of the inherent reasonableness process is to establish payment amounts that are realistic and equitable. When Medicare has realistic and equitable payment amounts, this should not result in other payers subsidizing the Medicare program, or conversely, Medicare subsidizing other payers.

Comment: CMS needs to establish an inherent reasonableness appeals procedure.

Response: The statute does not provide for an appeals process in the case of inherent reasonableness adjustments to payment amounts. Thus, the Congress obviously did not intend for a special appeal process to be available. However, issues or concerns identified during the public comment period on proposed inherent reasonableness adjustments are given full consideration and a final determination is published before the actual adjustments in payment are made. The comment period, therefore, provides a mechanism for commenters to raise issues and concerns regarding inherent reasonableness adjustments before they are put in place. In addition, after an adjustment is made, we will continue to monitor issues relating to patient access and take corrective action if necessary.

B. Factors Used in Making an Inherent Reasonableness Determination

Comment: CMS should consider all the factors that may result in grossly deficient or excessive payment and not limit consideration to just one or two of the factors.

Response: The examples listed in § 405.502(g)(1)(vii) are just 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.

Comment: The regulation should include greater specificity and guidance on the criteria and data that will be used to make payment adjustments. It should define grossly deficient or excessive. It should also define ''windfall profit.''

Response: Both § 405.502(g)(1)(vii) and section 1842(b)(8)(C) of the statute give examples of factors that can result in payment amounts that are grossly excessive or grossly deficient. The Act and regulation also give examples of methods that can be used in order to establish reasonable payment amounts. It is not necessary or practical to make these lists of examples all-inclusive. Moreover, having general criteria allows us flexibility in adapting inherent reasonableness applications to the wide array of items and services encompassed within Medicare Part B, different marketing conditions, and the availability of data. We define the terms ''grossly excessive'' and ''grossly deficient'' in this rule in section IV dealing with the GAO report and its recommendations. In this rule, we removed the term ''windfall'' and we replaced it with the term ''excessive'' because for purposes of this regulation they both have the same meaning. We define the term excessive in § 405.502(g)(1)(ii).

Comment: The factors to be considered should be rephrased to ensure that they apply to deficient payment allowances as well as excessive payment allowances.

Response: The factors in § 405.502(g)(1)(vii) apply to both excessive and deficient payment amounts.

Comment: CMS should specify that national inherent reasonableness determinations are made by CMS, and carrier determinations are made by carriers/intermediaries or groups of carriers/intermediaries without regard to whether the determination applies in every carrier area or to a particular geographic area.

Response: We agree with this comment, and we are revising § 405.502(g)(3) of the regulation to provide further clarification on the terms we use to distinguish between inherent reasonableness conducted by CMS and inherent reasonableness conducted by the carriers.

Comment: CMS should use caution when comparing Medicare payment amounts to other purchasers' payment amounts. Some suppliers may take a loss on a small portion of business.

Response: We recognize that some suppliers' charges may reflect marketing strategies and business practices independent of Medicare. For example, some businesses may sell an item for less than cost in order to increase customer traffic. Also, some suppliers may charge excessive amounts for products in order to subsidize other products. However, the purpose of inherent reasonableness is not to accommodate marketing strategies, but to ensure that the Medicare payment amounts for items or categories of items are realistic and equitable. In addition, in identifying prices, we check a variety of suppliers and types of suppliers. This levels out the effect of these marketing strategies.

Comment: In comparing Medicare's allowances with other purchasers' allowances, CMS should take into account volume commitments to suppliers by other purchasers. It would be inappropriate to compare laboratory prices charged to physicians and other large purchasers to prices charged to Medicare because physicians and other purchasers can guarantee the laboratory a certain volume of patients and need only bill once per month. Billing Medicare for each patient is more expensive.

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's charge is to calculate a fair and equitable payment amount, not to underwrite suppliers' profitability. Medicare is the largest volume purchaser for many 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 physician 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 payments be higher than other purchasers' payments 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: CMS should not use the Veterans Administration's (VA) prices for comparison as the VA program is vastly different than Medicare.

Response: Section 1842(b)(8) of the Act provides that comparing Medicare payments with payments made by other purchasers is an appropriate way to determine whether or not Medicare payment amounts are reasonable. The VA is a major purchaser of medical supplies and devices. The VA payment amounts in some cases, such as for oxygen equipment, are retail prices and can be compared with Medicare's payment amount without adding a mark-up factor. In other cases, the VA purchases items directly from manufacturers and supplies them to the VA patients. In addition, the VA may directly provide certain services that would otherwise be provided by suppliers under the Medicare program. Therefore, in many cases, the VA payments represent wholesale prices, and, thus, we have imputed a markup before comparing these amounts to Medicare payment amounts. Using wholesale prices with a markup has long been recognized in regulations at § 405.502(g)(2) as an appropriate method for determining reasonable payment amounts under the inherent reasonableness authority. When we publish a proposed inherent reasonableness notice, we will explain the criteria we used to establish an appropriate markup.

Comment: In determining if the marketplace is not competitive, CMS should consider if the lack of competition is a result of Medicare's deficient payment allowances.

Response: The examples in § 405.502(g)(1)(vii) are situations for which adjustments in payment may be required, such as the one referred to in this comment, may or may not result in excessive or deficient payment amounts. That is, the number of suppliers for a particular item does not in itself indicate whether or not our payment amount is excessive or deficient. While the number of suppliers may in certain cases be relevant and be considered, it would have to be considered along with

other factors to determine if an inherent reasonableness adjustment is warranted. We believe the language used in the regulation is consistent with this interpretation.

Comment: In determining if the payment allowance in a locality is different than the amount paid in other localities, CMS should consider differences in costs in the other localities.

Response: For purposes of inherent reasonableness, it is not always necessary to consider local variations in payment amounts which is consistent with the Congress limiting the degree of local variation by eliminating the reasonable charge payment methodology for most items and services. In the past, the reasonable charge methodology in some instances resulted in variations among areas as high as 300 percent. In place of the reasonable charge payment methodology, the Congress has established fee schedule payment methodologies with national payment limits or caps for most items and services previously paid on a reasonable charge basis. In the case of durable medical equipment (DME) and prosthetics and orthotics, the Congress established a fee schedule methodology with national floors and ceilings that allow maximum variations only up to 15 percent for DME and 30 percent for prosthetics and orthotics. (According to regulations at §§ 442.220 and 442.228, for DME, the ceiling is equal to the weighted average of local payment amounts; the floor is equal to 85 percent of the weighted average. For prosthetics and orthotics, the ceiling is equal to 120 percent of the national average purchase price; the floor is equal to 90 percent of the national average.) Also, we note that for some items covered by Medicare, items are available for an established price on a national basis through catalogues or the internet. For this reason, the regulatory provision pertaining to local variations in costs will probably have limited applicability. However, when it is used, we will take into account the relative costs of furnishing a category of items or services in different locations as described in the regulation.

Comment: In determining whether the payment allowances are grossly in excess of acquisition or production costs, CMS should consider other types of relevant costs, for example, rent. CMS should consider all direct and indirect costs, including any service component, in making an inherent reasonableness determination.

Response: 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 will consider both direct and indirect costs of the supplier as well as any service component.

Comment: In determining if increases in payment amounts cannot be explained by inflation or technology, CMS should also examine other factors such as malpractice or product liability risks.

Response: If we determine that increases in payment amounts cannot be explained by inflation or technology but can be explained by other factors, we will consider these other factors when making an inherent reasonableness determination.

Comment: By removing the example relating to increases in payment amounts that cannot be explained by inflation or technology, in the interim final rule with comment, CMS would never again consider making an inherent reasonableness adjustment based on new technology.

Response: As indicated previously, the factors listed in § 405.502(g)(1)(vii) are merely examples. There is no requirement that any specific example must be used or that only the specific examples listed in the regulation can be used. However, because this is a good example, we are putting it back into the regulation.

Comment: CMS should consider improvements in technology in making an inherent reasonableness determination.

Response: As indicated in § 405.502(g)(1)(vii)(C) of this final rule, improvements in technology are listed as a factor that we may consider when making inherent reasonableness determinations.

Comment: CMS's gap-filling methodology does not result in adequate payment levels for medical equipment and supplies, especially for new technology.

Response: Section 1834 of the Act stipulates that the fee schedule payment amounts for DME and prosthetics and orthotics be calculated based on the average reasonable charge for the item from a base period, for example, 1986 and 1987. These base fee schedule amounts are updated on an annual basis by a factor legislated by the Congress. When the reasonable charge data from the base period do not exist, for example, when an item was not on the market at that time, the Medicare carriers establish the base fee schedule amounts using a ''gap-filling'' methodology. This methodology is used to approximate historic reasonable charges, from the base period. For example, Medicare carriers may use fee schedule amounts for comparable items or supplier price lists with prices for comparable items.

When base year data are not available and more current prices are used, the carriers decrease the more current prices by a ''deflation'' factor in order to approximate the base year price for gap-filling purposes. The deflation factors are based on the percentage change in the consumer price index for all urban consumers (CPI–U) from the mid-point of the fee schedule base period to the mid-point of the year that the price is in effect. The gap-filling process is only used when the base year data required by the statute for use in calculating the fee schedules do not exist. We believe that this methodology does result in adequate payment amounts by taking into account comparable prices, retail prices, and inflationary factors. However, we can adjust gap-filled fee schedule amounts that we determine are grossly excessive or grossly deficient using the inherent reasonableness process.

Comment: For laboratory services, competitive pricing or changing technology are not relevant to pricing under inherent reasonableness since laboratory services are paid on a fee schedule basis.

Response: Fee schedules as payment methodologies do not preclude the use of inherent reasonableness. The inherent reasonableness process is the process that the Congress has established to address fee schedule amounts or other payment amounts that are not reasonable for various reasons. As indicated by previous GAO and the Office of Inspector General (OIG) reports, fee schedule payment amounts may not always be realistic and equitable. Inherent reasonableness, as authorized by the statute, allows us to look at other factors such as competitive pricing and changes in technology in order to determine whether the fee schedule amounts are excessive or deficient.

Comment: The methodology for making inherent reasonableness determinations should include valid statistical techniques.

Response: As mentioned previously, section 223(b) of the BBRA requires that, in publishing this regulation, the Secretary will take appropriate steps to ensure the use of valid and reliable data when exercising inherent reasonableness authority. We have added a provision in § 405.502(g)(4) of the final regulation that defines the steps we will take to ensure the use of valid and reliable data. See our response

regarding this topic in section III of this regulation.

Comment: CMS does not have the authority under inherent reasonableness to require that it receive the ''best price.''

Response: The commenter is referring to a methodology that we may use in determining whether payment amounts are grossly excessive or grossly deficient. As described in § 405.502(g)(1)(vii)(D), one methodology that may be used to make an inherent reasonableness determination is whether the payment amount for an item or service is substantially higher or lower than the payments made for the item or service by other purchasers in the same locality. If we identify a price and there are indications that the item or service is readily available at that price, then, we believe, this price would be a realistic and equitable payment amount. As the GAO observed in its report on inherent reasonableness, ''retail prices represent the prices generally available to individual beneficiaries, include a share of the costs of maintaining retail space as well as other services, and are generally higher than what a prudent large-volume purchaser would pay.'' Therefore, using the best retail price available on the open market for an item or service would be appropriate as long as beneficiary access to the item or service is not significantly affected.

Comment: CMS needs to find a ''pattern'' of excessive charges before it can use its inherent reasonableness authority.

Response: We disagree with this comment. We do not believe that identifying patterns of excessive charges is necessary to determine that Medicare is paying a grossly excessive or deficient payment amount. For example, even though multiple payers may be paying an excessive amount for an item or service, a single payer may be paying significantly less than the other payers. This may be the result of the single payer using a more innovative payment methodology, such as competitive bidding or negotiated rate setting. We do not believe we should be precluded from comparing, in this case, Medicare's excessive payment amount with another entity's significantly lower amount that was a result of a more innovative payment methodology.

C. Factors Used in Establishing a Special Payment Amount

Comment: A payment amount should not be established based on bulk purchasing.

Response: In an open market system, bulk purchasing ordinarily results in a discounted price. Medicare pays for items on an individual claim-by-claim basis and does not enter into contracts to purchase a predetermined number of items. Nevertheless, a large volume of claims is paid by Medicare and the total Medicare dollars that are paid out for Part B items and services (other than physician services) (approximately $60 billion dollars in fiscal year 2001) are significant. Because Medicare may account for a significant part of the market, we believe that Medicare should not be precluded from taking into consideration discounts available to other payers when determining what constitutes a reasonable payment amount for an item or service.

Comment: A payment amount should permit the small supplier to continue to have reasonable revenues and profit margins. For example, mail order catalogs should not be used for establishing a payment amount because small dealers are unable to take advantage of discounted pricing.

Response: The purpose of inherent reasonableness is to replace grossly excessive and grossly deficient payment amounts with realistic and equitable payment amounts. We recognize that small suppliers may be necessary to provide service to beneficiaries and to ensure appropriate access to items and services. However, there are instances in which catalog prices are useful in determining whether adjustments in payments are warranted. For example, in 1995, catalog prices were used to reduce the Medicare payment amounts for home blood glucose monitors and, since then, we have not received any complaints that beneficiaries are having trouble obtaining home blood glucose monitors. Other items, such as blood glucose test strips, are ordinarily purchased by Medicare beneficiaries through catalogs.

Comment: A payment amount should reflect the ''added'' costs of doing business with Medicare.

Response: In considering retail prices, we recognize that businesses, in setting these prices, take into account the costs of providing their customers with appropriate services. For example, retail stores take into account the costs of processing VISA and MasterCard claims, including the user fees that suppliers must pay to accept credit cards and the costs of submitting bills to credit card companies. Businesses generally do not charge VISA and MasterCard customers more than other customers. Also, it should be noted that there are distinct costs to service cash customers, such as necessary security systems and the deposit of funds in banks. Ordinarily, purchasers, whether they use coupons, obtain an American Association of Retired Persons (AARP) discount, use a credit card, write a check, or use private or public insurance, do not expect to pay more than the retail price; nor does a customer needing help in selecting a particular item expect to pay more than the retail price. Thus, retail prices take into account these costs of doing business. However, if we do not consider retail prices, but instead use wholesale prices as a basis for calculating inherent reasonableness, we will include a markup to make these prices comparable to retail prices.

Comment: CMS should establish single national payment amounts and should not recognize any geographic variation.

Response: There are instances in which it is appropriate to establish a single national payment amount (for example, home blood glucose monitors). There may be other items that are available at the same price on a national basis. However, in other instances, when there is a significant labor or service component, it may not be appropriate to establish a single national payment amount for an item or service. The Congress seemed to recognize, to a limited extent, the need for variation in payment amounts for some items and services. For example, the Congress mandated both upper and lower limits for the fee schedule amounts for DME, with a range in payment of 15 percent.

Comment: Reductions should not exceed 7 percent in 1 year and should be limited to a total of 20 percent over 3 years.

Response: The statute provides us the authority to adjust payments by as much as necessary in order to correct a grossly excessive or grossly deficient payment amount. It would be inappropriate for Medicare to spend excessive amounts for items and services, once it had determined that the payment amount was grossly excessive or deficient.

D. Carrier Procedures

Comment: Inherent reasonableness decisions should not be made by carriers but should be made through the formal rulemaking process or at least published in the **Federal Register**. Carriers should not be permitted to reprice items without national policy or greater CMS scrutiny. The carriers are making de facto national policy under this rule.

Response: Before the BBA, CMS requested an amendment to the inherent reasonableness statutory requirements to allow carriers to make inherent reasonableness adjustments so that we could respond timely to frequent price

changes in the marketplace. We had specifically asked the Congress to drop the requirement that all inherent reasonableness determinations had to be made through publishing in the **Federal Register** so that carriers could make their own inherent reasonableness determinations without pursuing the cumbersome and lengthy **Federal Register** process. The BBA gives us that latitude.

As authorized by section 1842(a) of the Act, carriers, under our direction, have historically been used to make determinations regarding payment amounts, coverage determinations, in the absence of a national coverage determination, and utilization safeguards. Also, section 1842(b) of the Act specifies that inherent reasonableness adjustments of more than 15 percent a year must be published in the **Federal Register**. This clearly demonstrates that it was the intent of the Congress that adjustments of 15 percent or less in a given year can be made without publishing in the **Federal Register**. The regulations specifically provide for inherent reasonableness adjustments to be made by the Secretary or our carriers and includes specific instructions for carrier use of inherent reasonableness. Specifically, carriers are able to make inherent reasonableness determinations efficiently and respond quickly to price changes in the market place. Before the BBA, we completed only one inherent reasonableness adjustment because of the cumbersome statutory requirements. Because of the cumbersome inherent reasonableness process, we were not able to use inherent reasonableness to address the numerous OIG, GAO, and newspaper reports that Medicare's payments were excessive. The effect of the BBA was to facilitate the implementation of inherent reasonableness determinations by allowing carriers to make payment adjustments. The GAO concurs that the use of carriers to make inherent reasonableness adjustments is appropriate. The GAO states in its report on inherent reasonableness that:

> CMS acted within its authority in delegating the revised inherent reasonableness process to the carriers. The BBA was important in removing the barriers that prevented the carriers from conducting inherent reasonableness reviews. * * * Moreover, delegation is proper because pricing Medicare goods and services is already a responsibility of the carriers and the statute does not specifically preclude delegation of this authority to the carriers.

Comment: CMS needs to ensure against arbitrary and capricious decisions and carrier abuse of inherent reasonableness authority. Carriers should seek CMS's review and approval of all inherent reasonableness adjustments.

Response: The regulation requires that no payment adjustments may take place without informing suppliers of the proposed payment amounts, the factors considered in proposing the limit, and soliciting comments from suppliers. After considering the comments received, the regulation also requires the carriers to inform CMS of any inherent reasonableness limitations it plans to establish. No limitations can take affect until we have informed the carriers that we have received the carrier's notification. This allows us the opportunity to review the carrier's determination and ensure that arbitrary and capricious limitations are not implemented. 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 one year, or has a significant effect on a substantial number of small entities, the carrier or carriers 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.

Comment: Carriers may abuse their inherent reasonableness authority by reducing payment allowances by more than 15 percent over more than a 1-year period without the procedural protection of rulemaking, that is, compliance with the Administrative Procedure Act (APA).

Response: The statute allows the carriers to make inherent reasonableness adjustments of more than 15 percent over 2 or more years as long as the adjustments do not exceed 15 percent in a single year. This was confirmed in the GAO report on inherent reasonableness. In addition, before implementing inherent reasonableness limits, the carriers are required by the regulation to inform affected suppliers of the factors it used in establishing the limit and to provide the opportunity for suppliers to comment.

Comment: Allowing carriers to make independent payment decisions will result in payment disparities between carriers.

Response: Inherent reasonableness is the authority for establishing realistic and equitable payment amounts. In some cases, applying inherent reasonableness may result in payment amounts that vary by geographic area. In other cases, it may be justifiable to eliminate payment disparities by establishing a single national payment amount. In certain situations, the Congress has recognized the need for variation in payment amounts.

Comment: Carriers should only be permitted to make inherent reasonableness adjustments once every 5 years or be limited in the number of items subject to inherent reasonableness.

Response: The statute does not limit the number of times that this authority may be used, nor does it limit the number of items that can be reviewed using this authority. In some cases, it may be necessary to make more frequent adjustments than every 5 years to take into account changes in technology or economics.

Comment: Section 4554 of the BBA requires that any advisory committee established by a carrier for coverage and administrative policies under Part B will include an individual to represent the independent clinical laboratories.

Response: Section 4554 of the BBA, by its own terms, provides only for laboratory representatives to be on carrier advisory committees for coverage and administrative policies. This section does not implicate Medicare payment policies, nor is there any implication that an advisory committee would be part of an inherent reasonableness review of payment levels by the carrier.

Comment: This rule should apply to intermediaries as well as carriers.

Response: The inherent reasonableness authority applies to all Part B items and services except physician services. Therefore, this rule applies to both carriers and intermediaries who process Medicare Part B claims. However, we do not intend to apply this rule to services paid under a prospective payment system, such as outpatient hospital or home health services.

Comment: A process should be put into place to allow suppliers to formally petition carriers for inherent reasonableness reviews. The petitions would be required to meet specific standards to be considered for inherent reasonableness.

Response: Anyone has the opportunity to submit a request to CMS or a Medicare carrier for an inherent reasonableness adjustment. The regulations provide guidance on the criteria that will be used in determining whether an adjustment in the Medicare payment amount(s) is warranted. We do not believe that there would be an added benefit to creating a formal process; we believe that it is best to keep the process flexible so that we and the carriers can respond to the various situations that could arise. For example,

the type and quantity of data needed in order to conduct an inherent reasonableness review cannot be determined ahead of time and may vary significantly depending on the item or service at issue.

Comment: Will carriers take into account suppliers' administrative and service costs in making inherent reasonableness determinations?

Response: In those cases for which actual cost data are used as a basis for an inherent reasonableness determination, administrative and service costs would be taken into account. Conversely, when we or a carrier use retail prices or data on payments made by other payers as a basis for an inherent reasonableness determination, administrative and service costs are typically included as part of the retail prices or third party payer amounts.

Comment: Who at the DMERC has inherent reasonableness authority?

Response: Each carrier determines which of its staff or components are best qualified to conduct inherent reasonableness reviews, as they do in the case of other pricing issues.

Comment: Carriers should be required to provide affected parties with the data and all relevant information they use to make inherent reasonableness determinations.

Response: The carriers will publish the data and all relevant information they use to make inherent reasonableness determinations in the proposed notice to suppliers. Any additional background data used by the carriers in making inherent reasonableness determinations that are not published in the proposed notice will be made available.

Comment: Carriers need more guidance to ensure that they contact all relevant parties when publishing an inherent reasonableness adjustment.

Response: Carriers will be required to notify all suppliers and/or organizations representing suppliers of any proposed inherent reasonableness adjustments. Therefore, those parties that are directly affected by the changes in payment will be notified of the proposed adjustments and may respond to these proposed changes before they take effect (*see* § 405.502(g)(3)(ii)).

Comment: Carriers should provide a written response to comments on inherent reasonableness adjustments.

Response: In the final notice of inherent reasonableness that is sent to suppliers and/or organizations representing suppliers, the carriers will be required to provide written responses to the comments they received on the proposed notice of inherent reasonableness.

Comment: The sequence of steps a carrier will follow in making an inherent reasonableness determination should be made clearer.

Response: We concur with this comment. We have revised § 405.502(g)(3)(ii) to clarify the procedures a carrier must follow.

Comment: Interested parties should have the ability to comment on decisions when the adjustment is less than 15 percent.

Response: All proposed inherent reasonableness adjustments will be published and a comment period will be provided for all adjustments regardless of the percentage change in payment; some will be published on a carrier-wide basis, while those made by CMS will be published in the **Federal Register**.

E. Impact

Comment: In compliance with the APA, the inherent reasonableness rule should be withdrawn and published as a notice of proposed rulemaking with a public comment period. This would give the industry the opportunity to comment before implementation. Suppliers no longer have the procedural safeguards that have been in place since 1986. ''Good cause'' does not exist to waive the proposed rulemaking process.

Response: Section 223 of the BBRA prohibits us from using the inherent reasonableness authority until we respond to the GAO report and publish a notice of final rulemaking that responds to comments received on the January 7, 1998, interim final regulation on inherent reasonableness. We are meeting the mandate of section 223 of the BBRA by publishing this interim final rule and are therefore in compliance with the statute. Moreover, consistent with both section 223 of the BBRA and the APA, the 1998 interim final rule served the same purpose as a notice of proposed rulemaking since this regulation invited public comment. This interim final rule responds to the comments we received on the 1998 interim final regulation.

Also, we note that the GAO report addressed this issue and concluded that a notice of proposed rulemaking was not necessary. Specifically, the GAO report states that ''going through the notice of proposed rulemaking to issue inherent reasonableness regulations would have serious financial implications for Medicare and its beneficiaries.'' In addition, the GAO states that ''CMS's reliance on the good cause exception to bypass formal notice and comment rulemaking procedures seems reasonable.''

Comment: The rule does not comply with the Regulatory Flexibility Act and will have a significant economic impact on a substantial number of small entities. In addition, CMS indicates in the regulatory impact statement that it has insufficient data to predict exactly the nature of the impact of this rule; yet CMS certifies that the rule will not have a significant impact on a substantial number of small entities.

Response: Because this rule does not include any actual proposed or final inherent reasonableness determinations, it will have no impact on Medicare's payment amounts. However, we believe that the rule, by allowing us to conduct inherent reasonableness in the future, has the potential to significantly impact small businesses. This belief is based on a June 2002 OIG report indicating that Medicare may be overpaying between $130 million and $958 million per year for 16 items of medical equipment. In addition, in 2002, the GAO indicated that Medicare may be overpaying for medical equipment by more than 20 percent. However, we are unable to predict the specific dollar impact based on the future application of inherent reasonableness. Since we recognize the potential for future payment adjustments, either upward or downward, we will publish in the **Federal Register** impact statements that will comply with Executive Order 12866 whenever CMS proposed national limits and the dollar impact of inherent reasonableness determinations exceeds $100 million in any one year, and will address impact on small entities in accordance with the Regulatory Flexibility Act. However, we believe that, if inherent reasonableness adjustments are applied, then they will eliminate grossly excessive or deficient payment amounts. 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 excessive profits. This adjustment will benefit the Medicare program by

reducing costs and benefit beneficiaries by reducing coinsurance payments.

Comment: The rule does not comply with the Contract With America Advancement Act of 1996, which requires that a major rule must be submitted to the Congress before that rule can become effective.

Response: Since this rule has been determined to be a major rule, it is being submitted to the Congress consistent with the Contract With American Advancement Act.

Comment: In making inherent reasonableness determinations, CMS should have to consider the impact on quality of care, access issues, and the financial viability of suppliers in the marketplace.

Response: We will consider the impact of future inherent reasonableness adjustments, and as stated above, whenever CMS proposed national limits and the dollar impact of inherent reasonableness determinations exceed $100 million in any one year, we will analyze the impact on quality of care, access issues, and the financial viability of suppliers in the marketplace. However, we do not believe that using the inherent reasonableness authority will have a negative impact because the purpose of the authority is to ensure that Medicare makes payments that are realistic and equitable, and better reflect market prices.

F. Effective Date

Comment: The effective date should be 6 months following publication of payment reductions.

Response: The effective date for payment adjustments will be determined on a case-by-case basis, but in no case will the effective date be sooner than 60 days after publication of the final notice of inherent reasonableness. We believe that in most cases it would not be in the best interest of the Medicare program to delay implementation of inherent reasonableness adjustments more than 60 days as this would result in the continuation of payment amounts that are either grossly excessive or deficient.

Comment: All inherent reasonableness decisions should be made at the same time so that suppliers can offset payment reductions with payment increases.

Response: The purpose of inherent reasonableness is not to be budget neutral or to make an equal number of increases and decreases in payment. The purpose is to address situations in which the standard payment rules result in grossly excessive or deficient amounts. It would be unreasonable for us to delay making an increase in payment because we have not yet identified an item or service that warranted a decrease in payment. The converse is also true. We note that historically the GAO and OIG have conducted studies that indicate that Medicare's payment amounts are generally excessive.

Comment: Carriers should have to provide for a 60-day comment period and a 60-day notification period before the effective date of an inherent reasonableness determination.

Response: We concur with the commenter. We will inform carriers to provide for a 60-day comment period and that any final carrier inherent reasonableness determination may not be effective until 60 days following public notice.

VI. Provisions of This Interim Final Regulation

In response to comments on the January 7, 1998 interim final rule, we made the following changes in this interim final rule:

- Clarified § 405.502(g)(1)(ii) by stating that a payment amount will not be considered grossly excessive or grossly deficient if the overall payment adjustment is less than 15 percent.
- Amended § 405.502(g)(1)(iii) by clarifying the difference between a national determination and a carrier determination.
- Added § 405.502(g)(2)(vii)(H) to include an example of new technology that exists and is not reflected in the existing payment allowance.
- Amended § 405.502(g)(3)(ii) by adding ''proposed payment amounts and the'' to the first sentence to provide suppliers the opportunity to comment on the carrier's proposed payment allowances as well as the factors the carrier considered; and adding a requirement that a carrier notify us in writing of any final limits it plans to establish.
- Added § 405.502(g)(4) to include the criteria for using valid and reliable data.
- Added § 405.502(g)(5) 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.

However, because we are interested in receiving comments on this rule, particularly the two provisions that contain further specificity than found in the 1998 interim final rule, we are publishing this rule as an interim final rule and are soliciting comments. These two provisions are the definitions of ''grossly excessive'' and ''grossly deficient'' in § 405.502(g)(1)(ii) and the criteria for using valid and reliable data in § 405.502(g)(4). We already received comments on the other provisions when we published the interim final rule in January 1998. These comments are addressed in section V of this interim final rule.

VII. 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.

VIII. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 16, 1980 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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). This regulation has no immediate economic effect on current Medicare payments. However, it establishes a process that could be used in the future to establish reasonable and equitable payment amounts. Because this rule does not include any actual inherent reasonableness determinations, it has no immediate impact on Medicare's payment amounts. However, we do believe that the future use of inherent reasonableness has the potential to have significant impact; therefore it is a major rule. This belief is based on a June 2002 OIG report indicating that Medicare may be overpaying between $130 million and $958 million per year for 16 items of medical equipment. In addition, the GAO recently 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 establishing 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. Since 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 one 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 publish this rule, and we are able to conduct an inherent reasonableness study using the criteria described in this rule, 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. Also, 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.

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 $26 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. Since this rule does not include any actual inherent reasonableness determinations, it will not have an impact on small businesses. However, it establishes a process that could be used in the future to establish reasonable and equitable payment amounts.

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 100 beds.

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 governments, in the aggregate, or by the private sector, of $110 million. This regulation does not mandate expenditures by State, local, or tribal governments, or by the private sector. Therefore, the requirements of section 202 do not apply.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates 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. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

We do not expect suppliers of Part B services to be immediately affected by this rule since the rule will have no immediate impact on Medicare's 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 indicating that Medicare may be overpaying between $130 million and $958 million per year for 16 items of medical equipment. In addition, the GAO recently 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. Since 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 one 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. 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, 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 will 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 a service or item is inherently unreasonable and does not result in any adjustments.

After publication of this regulation, if CMS initiates an inherent reasonableness determination that results in payment adjustments in excess of $100 million in any one year, CMS 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 one year, or has a significant effect on a substantial number of small entities, the carrier or carriers 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.

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, part 405 is amended as set forth below:

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. 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) 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 physician 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 or home health) 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/intermediary or groups of carriers/intermediaries even if the determination applies to all State fees.

(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 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, CMS 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.* 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)(A) *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 Medicaid agencies of the proposed payment amounts, the factors it considered in proposing the particular limit, as described in paragraphs (g)(1) through (g)(4) of this section, and 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) The carrier must evaluate the comments it receives. The carrier must 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. After the carrier has received CMS's acknowledgement, the carrier must inform the affected suppliers and State Medicaid agencies of any final limits it

establishes. 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 excessive or deficient and in establishing an appropriate payment amount, valid and reliable data will be 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) If CMS or a carrier makes a payment adjustment of more than 15 percent spread over multiple years, 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)(4) 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 paragraph (h) of this section 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.

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

Dated: February 2, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: July 22, 2002.

Tommy G. Thompson,

Secretary.

[FR Doc. 02–31126 Filed 12–12–02; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 90

[WT Docket No. 96–86; FCC 02–216]

The Development of Operational, Technical and Spectrum Requirements for Meeting Federal, State and Local Public Safety Agency Communication Requirements Through the Year 2010

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In view of the Federal Communications Commission's commitment to ultimately require equipment operating in the 764–776 MHz and 794–806 MHz band (''700 MHz public safety band'') General Use and State License channels to meet a spectrum efficiency requirement of one voice channel per 6.25 kHz, the Commission in this item adopted a phased-in implementation of (*i.e.*, a ''single migration path'' to) this spectrum efficiency requirement. The rules adopted are based on the record developed in response to the *Fifth Notice of Proposed Rule Making* in the above-captioned proceeding. These rules are intended to promote the efficient, effective, and maximum use of 700 MHz public safety band General Use and State License channels without hindering development and deployment of public safety equipment. In addition, in order to comport with current international agreements, a Commission rule was revised, which had incorrectly implied that Canadian television signals are entitled to interference protection within the United States.

DATES: Effective January 13, 2003.

FOR FURTHER INFORMATION CONTACT: Roberto Mussenden, Esq., 202/418–0680, *rmussend@fcc.gov,* Wireless Telecommunications Bureau.

SUPPLEMENTARY INFORMATION: This is a summary of the Federal Communications Commission's Report and Order, FCC 02–216, adopted on July 16, 2002, and released on August 2, 2002. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center, 445 12th Street, SW., Washington, DC 20554. The complete text may be purchased from the Commission's copy contractor, Qualex International, 445 12th Street, SW., Room CY–B402, Washington, DC 20554. The full text may also be downloaded at: *http://www.fcc.gov.* Alternative formats are available to persons with disabilities by contacting