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Report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives

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MEDICARE PAYMENTS

Use of Revised "Inherent Reasonableness" Process Generally Appropriate

GAO/HEHS-00-79

Contents

Abbreviations

APA	Administrative Procedure Act
BBA	Balanced Budget Act of 1997
DMERC	Durable Medical Equipment Regional Carrier
HCFA	Health Care Financing Administration
HCPCS	HCFA Common Procedure Coding System
HHS	Department of Health and Human Services
MSA	metropolitan statistical area
OMB	Office of Management and Budget
VA	Department of Veterans Affairs

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Health, Education, and
Human Services Division

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July 5, 2000

The Honorable William M. Thomas
Chairman, Subcommittee on Health
Committee on Ways and Means
House of Representatives

Dear Mr. Chairman:

In 1998, Medicare paid at least $5.9 billion for medical equipment and supplies on behalf of beneficiaries who live at home or in long-term-care facilities such as nursing homes.[1] Generally, Medicare uses a fee schedule to determine the amount it will pay for most medical equipment and supplies. Even when Medicare paid more than market prices for certain medical equipment and supplies, the Health Care Financing Administration (HCFA)—the agency that administers the Medicare program—had almost never adjusted payment amounts. This was because the process imposed by statute for changing unreasonably high or low Medicare payments, called the "inherent reasonableness" process, was slow and cumbersome and not even available for some items, such as surgical supplies.[2]

In response to the problems with excessive payments for some items that we and others identified, the Congress authorized HCFA in section 4316 of the Balanced Budget Act of 1997 (BBA) to use a revised inherent reasonableness process to adjust Medicare payments by up to 15 percent a

[1]This amount represents payments made by the Medicare program and its beneficiaries, who pay a copayment of 20 percent for durable medical equipment and other types of medical products, such as medical supplies, prosthetic and orthotic devices, enteral nutrition products, and certain outpatient drugs (hereafter collectively referred to as "medical equipment and supplies").

[2]See *Medicare: Excessive Payments for Medical Supplies Continue Despite Improvements* (GAO/HEHS-95-171, Aug. 8, 1995); *Medicare: Need to Overhaul Costly Payment System for Medical Equipment and Supplies* (GAO/HEHS-98-102, May 12, 1998); Department of Health and Human Services (HHS) Office of Inspector General, *Are Medicare Allowances for Albuterol Sulfate Reasonable?* OEI-03-97-00292 (Washington, D.C.: HHS, Aug. 1998); HHS Office of Inspector General, *Payments for Enteral Nutrition: Medicare and Other Payers*, OEI-03-94-00021 (Washington, D.C.: HHS, May 1996).

year for items such as medical equipment and supplies.[3] This revised process was expected to streamline the implementation of payment adjustments. HCFA published an interim final rule with comment period on January 7, 1998, to implement the process.[4] Most regulations are published first in a proposed form and become effective only when published as a final rule, which gives an agency time to respond to public comments solicited through the notice of proposed rulemaking. In this case, the interim final rule became effective 60 days after it was first published. Because the interim final rule was not preceded by a notice of proposed rulemaking, HCFA solicited comments through the interim final rule but did not respond to them before the regulation became effective.

Under the interim final rule, the four contractors that process Medicare claims for medical equipment and supplies—the Durable Medical Equipment Regional Carriers (DMERC)—may adjust payment rates determined to be excessive or deficient by up to 15 percent after reporting their plans to HCFA. In 1998, the DMERCs surveyed retail prices for groups of products that they suspected had excessive Medicare payment rates. In September 1998, the DMERCs notified suppliers that they proposed to adjust Medicare payments for eight groups of products, including glucose testing supplies, a type of urinary catheter, and standard dietary formulas for tube feeding (enteral formulas). The DMERCs solicited comments on this proposal. Following an outpouring of concern from industry groups representing different manufacturers and providers of medical equipment and supplies and your request that we review these actions, HCFA suspended the proposed payment reductions. In November 1999, the Congress passed legislation prohibiting HCFA from using its inherent reasonableness authority until this report is issued and a final rule has been published that responds to this report and to public comments.

You requested that we examine HCFA's and the DMERCs' actions to implement this authority and answer the following questions: (1) Was it proper for HCFA to issue its inherent reasonableness regulations as an interim final rule, and is HCFA authorized to delegate responsibility for making payment adjustments to the DMERCs? (2) Were the DMERCs'

[3]P.L. 105-33, 4316, 111 Stat. 251, 390-392.

[4]63 *Fed. Reg.* 687 (hereafter referred to as the "interim final rule"). HCFA officials indicated to us that they were unable to issue these regulations as soon as they would have liked because the BBA included many other Medicare changes requiring regulatory action that had to be given priority over the inherent reasonableness regulations.

survey methods adequate to support the proposed payment reductions? (3) Will the proposed payment reductions reduce patient access to the affected medical products?

To address these questions, we reviewed relevant laws and regulations and interviewed HCFA officials and staff from the DMERCs. We also met with various representatives from the industry groups involved. We analyzed the DMERCs' survey methodology, procedures, and data and obtained limited data on prices for some medical equipment and supplies. We performed our work from April 1999 to May 2000 in accordance with generally accepted government auditing standards. Appendix I provides a more detailed discussion of our scope and methodology.

Results in Brief

HCFA acted properly in issuing an interim final rule to implement the inherent reasonableness provision of the BBA because these regulations did not substantially change the factors to be considered in making inherent reasonableness determinations, and thus the criteria were met for bypassing the general requirement for issuing a notice of proposed rulemaking. Specifically, under the revised regulations, HCFA and the DMERCs would conduct payment reviews under the same circumstances and consider essentially the same information as in the past. As provided by the BBA, they would be able to adjust payment amounts by up to 15 percent a year without using lengthier public notice and comment procedures. Furthermore, in our opinion, it is clearly within HCFA's authority to delegate partial responsibility for adjusting payment rates to the DMERCs. HCFA has long delegated similar types of responsibilities to the DMERCs and other claims processing contractors, and the BBA, which amended Medicare law to enable use of the revised process, did not preclude such delegation.

Using retail surveys as a basis for adjusting Medicare payments represents a sound concept for pricing products that can be purchased in retail outlets. The survey data clearly showed that Medicare payments are much higher than the median surveyed retail prices for five of the products the DMERCs reviewed: lancets, eyeglass frames, urinary catheters, and two types of catheter insertion trays. As a result, sufficient information supports proposed payment reductions of up to 15 percent for these items. However, the DMERCs did not follow a rigorous survey process, and this led us to question the proposed smaller payment reductions for glucose test strips and albuterol sulfate. For the eighth surveyed product—enteral formulas—more pricing information is needed before the payment amount

can be adjusted because the DMERCs did not price products specifically packaged and used for tube feeding and instead priced products that are generally used as oral supplements. Retail surveys may not be the best strategy for setting payment amounts for items not generally sold at retail prices, such as enteral formulas. For such products, using wholesale prices plus a reasonable markup may represent a better payment-setting mechanism.

It is difficult to predict whether the proposed payment reductions will limit patient access because Medicare has implemented few comparable reductions in recent years. Fewer suppliers may be willing to provide these items to beneficiaries at the reduced payment rates, thus limiting beneficiary access to these items. Because retail prices—which include retailers' costs for both acquisition and service—were used to establish the proposed reductions, we believe that access to these products is not likely to be significantly affected. However, HCFA should monitor indicators of potential access problems when payments are reduced so that action can be taken before beneficiaries experience difficulties obtaining medically necessary items or have to pay significantly higher out-of-pocket expenses.

We are making several recommendations to the HCFA Administrator to improve HCFA's final rule on and use of its inherent reasonableness authority. In commenting on our report, HCFA agreed with the recommendations and said it will implement them.

Background

Medicare is a health insurance program that covers almost all people aged 65 and older and certain disabled people. Through its supplemental medical insurance program (part B), Medicare covers medically necessary durable medical equipment such as hospital beds and walkers. Medicare also covers other types of medical items, including certain prescription drugs used with durable medical equipment for elderly and disabled people who live at home or in long-term-care facilities. Medicare pays 80 percent of the amount on its fee schedule or the allowed amount for medical equipment and supplies, or 80 percent of the amount claimed, whichever is lower. Beneficiaries are responsible for the remaining 20 percent. Claims for Medicare-covered services and supplies are processed and paid by insurance companies that contract with HCFA. Four specialized contractors—the DMERCs—administer claims for medical equipment and supplies.

Medicare Payment Allowances for Medical Equipment and Supplies Established for Product Groups

Medicare groups medical products into categories and pays a specified amount for each category. Each category is identified by a unique code under the HCFA Common Procedure Coding System (HCPCS).[5] There are about 1,900 product groups in total. All of the items categorized under a particular product group have the same payment allowance and are considered to be similar items. When suppliers or beneficiaries submit a claim to Medicare, they use the product group they believe best describes the specific item that was provided.

Medicare part B has different methodologies, specified in law, for determining payment amounts for different categories of medical equipment and supplies. For most of the products the DMERCs surveyed—such as diabetic supplies, catheters, and catheter insertion trays—a fee schedule is used to determine the amount Medicare pays. Medicare has a separate fee schedule for each state for most categories of items. These fee schedules are based on average supplier charges on Medicare claims allowed in each state in 1986 and 1987. In 1990, the Congress amended the fee schedule provisions to impose upper and lower limits on fees paid in different states to reduce variation in what Medicare paid for similar items in different parts of the country.[6] The upper limit is the median of all state fees, and the lower limit is 85 percent of the median of all state fees. Before the BBA was enacted, the state fees were adjusted for inflation each year using a formula usually based on the consumer price index. Section 4551(a)(1) of the BBA amended Medicare law by freezing the fee schedules for these categories of medical equipment and supplies for 5 years, beginning in 1998.

For orthotic and prosthetic devices, including off-the-shelf items such as eyeglass frames, Medicare uses 10 regional fee schedules, which are also based on historical supplier charges and are subject to upper and lower limits. The upper limit is 120 percent of the average of all regional fees, and the lower limit is 90 percent of the average of all regional fees. Section 4551(a)(2) of the BBA limited the increase in these regional fee schedules to 1 percent per year for 5 years, beginning in 1998.

[5]Hereafter, the HCPCS codes are referred to as “product groups.”

[6]Omnibus Budget Reconciliation Act of 1990, P.L. 101-508, 5152(b), 104 Stat. 1388, 1388—74 and 1388-75 (Supp. II 1990).

Medicare uses other methodologies to determine the payment amounts for enteral formulas and prescription drugs. Medicare covers enteral nutrition formulas for beneficiaries who are unable to take sufficient food by mouth and must be fed through a tube. Medicare payment for enteral formulas is based on supplier charges, using a reasonable charge methodology. A maximum payment limit has been established for these items, but individual suppliers may receive less than the maximum payment if their actual or customary charge, or the prevailing charge in the locality, is lower than the maximum payment. Section 4315 of the BBA permitted HCFA to replace the reasonable charge methodology for enteral formulas (and other items) with a fee schedule, while section 4551(b) limited payments for these items to their 1995 levels for 5 years, beginning in 1998.

For prescription outpatient drugs that generally are covered if they must be used in conjunction with durable medical equipment, such as albuterol sulfate, Medicare payments are based on 95 percent of the average wholesale price of the drug.[7] If a drug has multiple brand name and generic sources, the DMERCs calculate 95 percent of the median of the average wholesale prices for generic and comparable brand name products.

Medicare Payment Amounts Adjusted Through Inherent Reasonableness Process

Because most Medicare payments for medical equipment and supplies are based on historical charges, they may become out of line with market prices over time. The Social Security Act and the corresponding Medicare regulations have long allowed HCFA to determine whether the standard methods of determining payments result in amounts that are unreasonably high or low.[8] In these cases, HCFA may use other pricing methods to align payment amounts with current market prices. HCFA does this by using the inherent reasonableness process.

[7]42 U.S.C. 1395u(o)(1) (Supp. III 1997). Under certain circumstances, Medicare covers medically necessary outpatient drugs that must be administered in a physician's office or used with durable medical equipment, such as albuterol sulfate, which is used with a nebulizer. Certain other specific types of drugs are also covered, including antirejection drugs used after organ transplants and oral cancer drugs.

[8]In 1975, language was added to the regulations governing the determination by carriers of reasonable charges, specifically providing for the use of "[o]ther factors that may be found necessary and appropriate with respect to a specific item or service to use in judging whether the charge is inherently reasonable." 20 C.F.R. 405.502(a)(4) (1976). This provision, as amended, is now at 42 C.F.R. 405.502(a)(7) (1999).

Prior to 1987, when Medicare payments for medical equipment and supplies were based on supplier charges, Medicare contractors independently conducted inherent reasonableness reviews to adjust Medicare payment levels. They gathered relevant data and set new payments on the basis of their analysis after notifying suppliers. While HCFA generally evaluated the procedure followed and functions performed by the contractor, contractor determinations of payment levels were not reviewed on a case-by-case basis. In 1986, HCFA was required by law to establish regulations describing the factors to be used in an inherent reasonableness review.[9] In 1987, a new Medicare payment methodology for medical equipment and supplies, primarily based on fee schedules, was enacted.[10] That law was amended in 1988 to require that the inherent reasonableness process for medical equipment and supplies include detailed notice and comment rulemaking procedures that could be accomplished only by HCFA—not by the DMERCs.[11] As stated previously, this requirement made the inherent reasonableness process long and cumbersome. Changing an unreasonable payment amount for any product group required, among other things, a formal rulemaking process that involved the Administrator of HCFA, the Secretary of Health and Human Services, and the Director of the Office of Management and Budget (OMB). HCFA has successfully used the inherent reasonableness process in only one instance: it took almost 3 years to adjust the Medicare fee schedule for blood glucose monitors.

[9]The Consolidated Omnibus Budget Reconciliation Act of 1985, P.L. 99-272, 9304(a), 100 Stat. 82, 190 (1986), required regulations describing the factors to be used in determining cases in which charges are unreasonable and the factors to be considered in establishing charges that are realistic and equitable. HCFA promptly promulgated these regulations. 51 *Fed. Reg.* 28,710 (Aug. 11, 1986). The Omnibus Budget Reconciliation Act of 1986, P.L. 99-509, 9333, 100 Stat. 1874, 2025, added detailed procedures to be followed for any inherent reasonableness review with respect to physician services, including publication of the proposed adjustment in the *Federal Register*. 42 U.S.C. 1395u(b)(8)(B) – (C) and (9) (Supp. IV 1986).

[10]In addition, the legislation, which was effective Jan. 1, 1989, imposed a moratorium on inherent reasonableness review for medical equipment and supplies until Jan. 1, 1991. Omnibus Budget Reconciliation Act of 1987, P.L. 100-203, 4062(b) and (e), 101 Stat. 1330, 1330-100—1330-107 and 1330-109. 42 U.S.C. 1395m (Supp. V 1987).

[11]Medicare Catastrophic Coverage Act of 1988, P.L. 100-360, 411(g)(1)(B)(xiii), 102 Stat. 683, 782. These procedures were previously applicable only to any inherent reasonableness review with respect to physician services. 42 U.S.C. 1395m(a)(10)(B) (1988).

Following several reports that Medicare was overpaying for medical equipment and supplies and needed more flexibility to adjust payment amounts, the Congress, in the Balanced Budget Act of 1997, expanded HCFA's options for making inherent reasonableness adjustments. The law no longer requires HCFA to use the formal rulemaking process to make inherent reasonableness adjustments as long as the annual adjustments are 15 percent or less. The only requirement remaining is that HCFA describe in regulation the factors to be used in determining when payment amounts are not inherently reasonable as well as those to be considered in establishing reasonable payment amounts.[12] These are factors to be considered in any future inherent reasonableness review and are not specific to any particular product or service.

In revising the existing inherent reasonableness regulations, HCFA set up three different procedures for conducting the inherent reasonableness process and adjusting payment amounts:

- HCFA adjusts payment amounts by more than 15 percent in a year,
- HCFA adjusts payment amounts by up to 15 percent in a year, and
- the DMERCs adjust payment amounts by up to 15 percent in a year. (See app. II for an illustration of the three inherent reasonableness procedures.)

The original inherent reasonableness process—which required the notice of proposed rulemaking—now applies only to payment adjustments of more than 15 percent in a year. However, the regulations do not articulate under what circumstances HCFA and the DMERCs will use the three inherent reasonableness procedures.

HCFA and the DMERCs follow different procedures to adjust Medicare payments by up to 15 percent a year. In adjusting payments for medical equipment and supplies, HCFA employs public notice and comment procedures.[13] The DMERCs, on the other hand, can bypass the requirement for public notice and comment. Instead, through local bulletins, the DMERCs inform the affected suppliers of the factors considered in

[12]42 U.S.C. 1395u(b)(8)(A)(i) (Supp. III 1997). This is essentially the same requirement in effect since 1986.

[13]However, if HCFA uses the inherent reasonableness process for adjustments of 15 percent a year or less, it can bypass some statutorily imposed procedural requirements, including the specific requirement for consultation with suppliers and supplier representatives.

adjusting a payment amount and provide direct notice of the proposed inherent reasonableness adjustments. They also solicit supplier comments. The DMERCs must evaluate the comments and notify HCFA regarding the proposed payment amounts. Once HCFA acknowledges in writing that it has received this notification, the DMERCs' proposed payment amount may be applied 30 days after their notification to HCFA. The DMERC procedure is expected to reduce the time needed to implement the inherent reasonableness process and hereafter is called "streamlined" inherent reasonableness authority.

HCFA Acted Properly and Within Its Authority in Establishing the Revised Inherent Reasonableness Process

Industry groups expressed concern that HCFA did not publish a notice of proposed rulemaking before issuing its regulations on the use of the revised inherent reasonableness process. However, we believe that HCFA acted properly in issuing the regulations in this fashion because the criteria were met for bypassing the general requirement for issuing a notice of proposed rulemaking. HCFA also acted within its authority in delegating the revised inherent reasonableness process to the DMERCs. The BBA was important in removing the barriers that prevented the DMERCs from conducting inherent reasonableness reviews; however, HCFA did not materially change the factors to be considered under the inherent reasonableness process in the revised regulations. HCFA and the DMERCs will conduct inherent reasonableness reviews under the same circumstances and may consider almost all of the same factors they did when conducting inherent reasonableness reviews in the past. Moreover, delegation is proper because pricing Medicare goods and services is already a responsibility of the DMERCs and the statute does not specifically preclude delegation of this authority to the DMERCs.

HCFA Acted Properly in Publishing the Revised Inherent Reasonableness Regulations as an Interim Final Rule

Section 4316 of the BBA enabled HCFA to use a more flexible, simplified process to adjust unreasonably high or low Medicare payment amounts by up to 15 percent per year. On January 7, 1998, HCFA revised its inherent reasonableness regulations in the form of an interim final rule with comment period, which became effective on March 9, 1998.[14] The DMERCs were delegated authority under the rule to make inherent reasonableness adjustments of up to 15 percent a year. By issuing the rule in this fashion,

[14]63 *Fed. Reg.* 687. In general, an agency will publish a final rule on an "interim" basis to give it the force of law either immediately or soon after publication.

HCFA was able to finalize the regulation on an expedited basis, allowing the DMERCs to quickly begin their inherent reasonableness reviews.

Various industry groups likely to be affected by future inherent reasonableness adjustments believed that HCFA deprived them of the opportunity to comment on the revised inherent reasonableness regulations because HCFA did not issue a notice of proposed rulemaking. The Small Business Administration also contended that by not publishing a proposed rule HCFA was able to avoid analyzing the potential effect that the regulation would have on small businesses. Proposed rules are not legally binding until after a public comment period and the issuance of a final rule, a process that can sometimes take years to complete.

When federal agencies take official action, they are generally required to publish a proposed rule in the *Federal Register* and provide interested parties the opportunity to participate by submitting written comments and other material for the agency to consider before such rules become effective. Whenever a proposed rule is published, an agency also must publish an initial regulatory flexibility analysis describing the effect on small businesses.[15] Unless otherwise required by statute, however, an agency may bypass proposed rulemaking when it determines for good cause that it is impracticable, unnecessary, or contrary to the public

[15]5 U.S.C. 603(a).

interest.[16] This also permits an agency to bypass the requirement to publish an initial regulatory impact statement.

HCFA concluded that publishing a proposed rule in this case was both unnecessary and contrary to the public interest. HCFA asserted that it was unnecessary because the revised inherent reasonableness regulations did not significantly change the underlying inherent reasonableness methodology. The inherent reasonableness methodology already in place when the interim final rule was issued called for replacement of the standard payment amount when application of the statutory payment methodology resulted in a Medicare payment amount that was "grossly excessive" or "grossly deficient" and thus not inherently reasonable. These existing inherent reasonableness regulations described the factors to be used in determining when a Medicare payment amount is grossly excessive or deficient and in establishing a realistic and equitable payment amount. The revised regulations did not materially change these existing regulations.

[16]This is the "good cause" exception to the Administrative Procedure Act (APA) requirement for a notice of proposed rulemaking. 5 U.S.C. 553(b)(B). The APA was enacted, in part, so that federally regulated parties would receive the due process protections guaranteed by the Constitution. The Constitution guarantees due process whenever the government seeks to deprive a person of life, liberty, or property. The process that is due depends in large measure on the life, liberty, or property interest at stake, but the most basic element of due process is notice and an opportunity to be heard. When establishing or changing substantive legal standards, HCFA generally must follow APA rulemaking procedures. 42 U.S.C. 1395hh(a)(2) and (b) (1994). However, establishing Medicare payment rates generally does not raise due process issues because no protected life, liberty, or property interests are at stake. Participation in Medicare does not give rise to a constitutional right to a certain level of payment. Provider participation in Medicare was discussed by the 6th Circuit Court of Appeals in a case involving the application of the inherent reasonableness process to a durable medical equipment provider prior to the 1987 amendments:

"Before analyzing the determination of the 1987 I[nherently] R[easonable] A[llowance] amount, we pause to note that participation in the Medicare program is voluntary. If a supplier is not satisfied with the IRA a carrier has chosen to apply, that supplier may choose not to act as a Medicare supplier. ... [T]his court has held ... '[that p]roviders of health care who choose to participate in the federally sponsored program for the aged and disabled do so with no guarantee of solvency. Just as those who choose to serve individuals not covered by Medicare assume the risks of the private market, those who opt to participate in Medicare are not assured of revenues.'"

Queen City Home Health Care Co. v. Sullivan, 978 F.2d 236, 247 (6th Cir. 1992), quoting *Livingston Care Center, Inc. v. U.S.*, 934 F.2d 719, 720-21 (6th Cir. 1991), *cert. denied*, 502 U.S. 1003 (1991).

Additionally, HCFA allowed for a 60-day comment period before the interim final rule became effective and has indicated that before finalizing its regulations on the inherent reasonableness process it will consider any comments received. HCFA also stated that it is contrary to the public interest to delay savings to the Medicare program and to beneficiaries—in the form of lower copayments—that could be achieved through the revised inherent reasonableness process.

HCFA's reliance on the good cause exception to bypass formal notice and comment rulemaking procedures seems reasonable. The revised inherent reasonableness regulations change neither the factors that may be considered in determining whether a payment amount is grossly excessive or deficient nor the sources of information that can be used to establish realistic and equitable payment amounts. For example, Medicare payment amounts can be determined to be excessive if they are much higher than production and supplier acquisition costs for products covered under the reviewed product group.[17] These costs also can be considered in establishing a realistic and equitable payment amount.[18] This methodology for applying the inherent reasonableness process has existed in regulation since 1986 and has already been through a formal notice and comment rulemaking process.[19] We believe it is a reasonable interpretation of the statute. HCFA should respond to industry concerns regarding this methodology in the final rule on the inherent reasonableness process.

[17]42 C.F.R. 405.502(g)(1)(vii)(E) (1999). Compare with 42 C.F.R. sec. 405.502(g)(1)(vi) (1997).

[18]42 C.F.R. 405.502(g)(2)(iii) (1999). Compare with 42 C.F.R. sec. 405.502(g)(2)(iii) (1997).

[19]HCFA solicited and obtained public comments on the inherent reasonableness methodology when the agency published a notice of proposed rulemaking, that is, a proposed rule, on Feb. 18, 1986, 51 *Fed. Reg.* 5,726, and again when a final rule with comment period was published on Aug. 11, 1986, 51 *Fed. Reg.* 28,710. Public comments on the proposed rule were discussed in the Aug. 1986 rulemaking. Further comments were discussed when the rules were finalized on July 11, 1988, 53 *Fed. Reg.* 26,067.

The legislative history of the good cause exception provides that notice and comment are unnecessary in cases in which "minor or merely technical" amendments to regulations are issued.[20] The leading precedent for this line of argument is *National Helium Corp. v. FEA*, in which the court considered notice and comment unnecessary because a change in a pricing regulation was largely technical and did not substantively alter the existing regulatory framework or application of the rules to the parties involved in the case.[21] Similarly, the only significant change to the inherent reasonableness regulations is permitting the use of a less cumbersome process when adjusting Medicare payments by up to 15 percent per year and allowing once again the DMERCs to make inherent reasonableness adjustments. The inherent reasonableness framework and its application to suppliers remain essentially intact.

Likewise, we accept HCFA's finding that good cause exists to bypass the formal notice and comment procedures because it would be contrary to the public interest to delay the savings to the Medicare program and its beneficiaries. Numerous GAO and HHS Office of Inspector General reports have documented that Medicare overpays for certain medical equipment and supplies.[22] HCFA has a fiduciary responsibility to safeguard Medicare funds. The BBA gave HCFA the flexibility to act expeditiously in adjusting unreasonable Medicare payments for medical products. The imposition of the notice and comment procedures associated with proposed rulemaking would hinder HCFA's ability to bring Medicare payments in line with market prices in a timely manner. In short, we find that going through the notice of proposed rulemaking to issue the inherent reasonableness regulations would have serious financial implications for Medicare and its beneficiaries.

[20]S. Doc. No. 248, 79th Cong., 2d Sess. at 200, 258 (1946). See also Ellen R. Jordan, *The Administrative Procedure Act's "Good Cause" Exemption*, 36 Admin. L. Rev. 113, 129 (1984) and Juan J. Lavilla, *The Good Cause Exemption to Notice and Comment Rulemaking Requirements Under the Administrative Procedure Act*, 3 Admin. L. J. 317, 334 (1989).

[21]569 F.2d 1137, 1146 (Temp.Emer.Ct.App. 1977).

[22]See GAO/HEHS-98-102, May 12, 1998; and HHS Office of Inspector General, *Are Medicare Allowances for Albuterol Sulfate Reasonable?* and *Payments for Enteral Nutrition: Medicare and Other Payers.*

HCFA Has Authority to Delegate Responsibility to the DMERCs

HCFA acted within its authority when it delegated certain responsibilities under the revised inherent reasonableness process to the DMERCs. The DMERCs have the authority under the regulations to make inherent reasonableness adjustments of up to 15 percent a year. Some supplier groups commented that it was improper for HCFA to bypass its complex set of regulatory procedures for adjusting Medicare payments and allow the DMERCs to conduct inherent reasonableness reviews. These groups said that if the DMERCs jointly act to adjust Medicare payment rates, this action would set payment rates at the national level, and the inherent reasonableness process applicable to HCFA should be followed.

Neither section 4316 of the BBA, which amended the inherent reasonableness provision of the Social Security Act, nor the Social Security Act itself specifically precludes HCFA from delegating responsibility under the revised inherent reasonableness process to the DMERCs. Moreover, section 4316 of the BBA removed the legal barriers that had prevented the DMERCs from making use of the inherent reasonableness process over durable medical equipment, prosthetics, orthotics, and supplies. This provision is included in Medicare law under the section regarding the use of Medicare contractors in administering benefits. Although the BBA is silent on the issue of DMERC delegation, we believe that HCFA made a reasonable interpretation of the statute to permit delegation of the "streamlined" inherent reasonableness authority to its contractors.

HCFA has long relied on its Medicare contractors and their expertise to handle pricing and payment issues. The DMERCs have staff who conduct payment reviews by collecting historical and current catalog prices. These pricing staff review information to establish initial payment amounts for products covered under newly created product groups. An individual DMERC can also adjust states' base fees when information indicates that they are inappropriate. For example, a DMERC may determine that problems with supplier charge data have led to inaccurate and unreasonable state base fees. Because these adjustments can affect suppliers, the regulations require the DMERCs to inform the affected suppliers and give them 30 days to comment. These DMERC pricing activities preceded the revised inherent reasonableness process under the BBA. Given that inherent reasonableness determinations are well within the expertise of DMERC staff and that HCFA has a responsibility to adjust unreasonable Medicare payments in a timely manner, HCFA's delegation of inherent reasonableness authority to the DMERCs is reasonable.

DMERCs' Reviews Adequate for Reducing Medicare Payments for Five of Eight Product Groups

The DMERCs exercised their streamlined inherent reasonableness authority by surveying retail prices for certain commonly used medical products. They found that Medicare pays more than the median surveyed retail prices for these product groups. While the DMERCs collected a large number of retail prices from different locations, they did not conduct the retail surveys as rigorously as they could have. Despite problems in the survey process, we believe the results can be used as a basis for adjustments of up to 15 percent for the product groups for which Medicare payments clearly exceed median retail prices by more than 15 percent—lancets, eyeglass frames, a type of urinary catheter, and two types of catheter insertion trays (because their price adjustments were based on the adjustment for catheters). However, the surveys are not sufficient, without additional information and analysis, to serve as a basis to adjust payments for glucose test strips, albuterol sulfate, and enteral formulas because the DMERCs did not follow a rigorous methodology to ensure that the payment amounts set for these items were appropriate.

Retail Prices Used to Propose Payment Reductions for High-Volume Products

The DMERCs began their use of the streamlined inherent reasonableness authority by reviewing prices for products that were frequently used by Medicare beneficiaries, that could be purchased in retail stores, and for which Medicare appeared to overpay. They chose items that were also purchased by retail customers who were not Medicare beneficiaries so that the current Medicare payment amount would have less influence on the price set in the retail market. The DMERCs surveyed prices for six of the eight reviewed product groups: glucose test strips, lancets, standard eyeglass frames, latex Foley catheters, category 1 enteral tube-feeding formulas, and albuterol sulfate (an inhalation drug used with a nebulizer). For the other two product groups, they planned to use prices collected on catheters to propose payment adjustments for two types of catheter insertion trays, because catheters are the main component in the trays. Several of the product groups—albuterol sulfate, enteral formulas, and catheters—were ones that the HHS Office of Inspector General and we had identified as being overpriced.

The four DMERCs surveyed retail stores in at least 16 states and used the median retail price for each item as the benchmark for a reasonable maximum payment amount. Using the median price is similar to the statutory method for establishing Medicare payment limits for most

medical products based on the median of state fees.[23] The DMERCs also used the median or average catalog price, whichever is lower, as the basis for the maximum payment amounts for new product groups.

Through the retail survey, the DMERCs found that the median retail prices were less than Medicare's maximum payment amounts for the six product groups surveyed. As a result, the DMERCs proposed new maximum payment allowances based on the median retail prices for these product groups (see table 1). For the other two product groups reviewed—two types of catheter insertion trays—the DMERCs proposed to reduce state fees, but they did not collect retail prices for these items because the trays are not generally purchased in retail settings. Instead, for these two product groups the DMERCs proposed adjusting state fees on the basis of the payment reductions for latex Foley catheters, which, according to HCFA officials, are the most expensive items included in the insertion trays. For these two product groups, the highest payment reductions the DMERCs proposed were about 23 percent for catheter insertion trays without drainage bags (with 15 percent applied in the first year) and 14 percent for trays with drainage bags.

Table 1: 1998 Medicare Maximum Payment Allowance, Median Retail Price, and Percentage Reduction for Six Product Groups Under Inherent Reasonableness Review

Product group	1998 Medicare maximum payment allowance[a]	Median retail price[b]	Percentage reduction
Glucose test strips (50 per box)	$36.73	$35.49	3.4
Lancets (100 per box)	12.15	7.81	35.7
Eyeglass frames	62.06	49.00	21.0
Coated latex Foley catheters	11.70	8.89	24.0
Category 1 enteral formulas (per 100 calories)	0.61	0.51	16.4
Albuterol sulfate (.83 percent per 3 ml. vial)	0.47	0.42	10.6

[23]See, for example, 42 U.S.C. 1395m(a)(2) (1994).

[a]These allowances represent the upper payment limit of the fee schedule for glucose test strips, lancets, eyeglass frames, and catheters. For these product groups, the maximum payment allowances are also the median of state fees. These allowances also represent the maximum reasonable charge for category 1 enteral formula and the payment amount for albuterol sulfate. Medicare pays 80 percent of these allowances, and the beneficiary pays the remaining 20 percent.

[b]The median retail price would replace the maximum payment allowance for these product groups.

Source: HCFA.

As table 1 shows, four product groups that the DMERCs surveyed had differences between the Medicare maximum payment allowance and the median retail price of more than 15 percent. Because the DMERC inherent reasonableness process can be used only to adjust prices by up to 15 percent a year, for these product groups the DMERCs proposed a 15-percent reduction for the first year and additional adjustments in future years until the difference is eliminated. For example, imposing the 35.7-percent payment reduction for lancets would involve adjustments of 15 percent for 2 years, and a partial adjustment of 5.7 percent in the third year.

For products paid under the fee schedule, the proposed payment reductions would vary by state. In some states, there would be little or no reduction in fees paid for certain product groups. For example, 8 states that previously had the lowest fees for eyeglass frames and 21 states with the lowest fees for glucose test strips would experience no payment change because the fees paid in those states were below the new proposed fees.[24] Other states would experience less than the maximum change. (See app. III for state fees and proposed payment reductions by reviewed product group.)

Industry groups raised two major concerns about the DMERCs' proposals to reduce Medicare payments for the eight reviewed product groups. They believed that using the revised inherent reasonableness process when the total percentage reductions in Medicare payments exceeded 15 percent would violate congressional intent. They also stated that the proposed 3.4-percent reduction in the upper payment limit for glucose test strips does not indicate that Medicare's fee schedule is grossly excessive. Therefore, they did not believe a payment reduction is warranted.

[24]The industry contended that these state fees that fell below the median surveyed retail price should be increased. According to HCFA, none of the state fees were adjusted upward, including those that were lower than the proposed amounts, because there are no apparent access problems under the current payment levels, which agency officials said is the criterion that is generally used in determining whether payment amounts should be raised.

According to the statute, if the revised process is used, inherent reasonableness payment adjustments cannot exceed 15 percent in a single year.[25] HCFA has asserted that if it or the DMERCs determine that Medicare payments should be reduced by more than 15 percent in total, they may use the revised process to implement these reductions incrementally over several years until the full reduction is achieved. In our opinion, the law does not preclude HCFA or the DMERCs from using the revised inherent reasonableness process as long as the adjustments do not exceed 15 percent in a single year.[26] However, HCFA and the DMERCs should have firm evidence to justify subsequent payment reductions. To develop that evidence, HCFA or the DMERCs should confirm market prices in the subsequent years to ensure that the proposed reductions continue to be appropriate.

In addition, the inherent reasonableness process can be used only when Medicare payments are "grossly excessive or deficient." The law does not define when a payment amount is "grossly excessive," although clearly an adjustment of under 15 percent could qualify, because the inherent reasonableness authority extends to situations in which the difference between a current and proposed payment amount is under 15 percent. The revised inherent reasonableness regulations also do not define when a payment amount is "grossly excessive." HCFA pointed out that because of the very high number of some items paid for by Medicare, even a relatively small excess payment per product group can lead to high overpayments. As a result, HCFA believes that overpaying for a single product group by even a small amount can be characterized under the statute as grossly excessive.

[25]42 U.S.C. 1395u(b)(8)(A)(ii) (Supp. III 1997). HCFA may make a determination that "would result" in an increase or decrease of more than 15 percent over the previous year's payment amount only if the agency follows certain additional procedures, which include supplier consultation and a beneficiary liability impact analysis. 42 U.S.C. 1395u(b)(8)(B) – (D) and 1395u(b)(9). Because Medicare contractors cannot carry out all of these procedures, their authority to impose inherent reasonableness payment adjustments of more than 15 percent per year is thereby precluded.

[26]As of November 1999, there have been two notices of proposed inherent reasonableness adjustments under the revised process. The September 1998 notice by the DMERCs is the subject of this report. See, for example, *http://www.medicare-link.com/DMERC/news/dme40.pdf*, p. 6, as of Feb. 11, 2000. HCFA also issued a proposed notice in 64 *Fed. Reg.* 44,227 (Aug. 13, 1999). HCFA must still abide by the clearance process for its proposed inherent reasonableness reductions, but since it invoked its option to incrementally reduce the payment amounts by no more than 15 percent a year, it did not have to comply with certain provisions of the statute, such as supplier consultation and a beneficiary liability impact analysis.

Issuing a final rule will give HCFA an opportunity to better explain the terms "grossly excessive or deficient" payment—and not just give examples of factors that may result in grossly excessive or deficient payments—so that suppliers are aware of the different criteria for conducting inherent reasonableness reviews.

DMERC Survey Process Has Shortcomings, Suggesting Certain Results Should Be Used With Caution

The DMERCs' surveys of retail prices had deficiencies, which limits our confidence in the use of the results to estimate reasonable payment reductions for three of the eight product groups. In general, we believe the survey results clearly indicated that Medicare overpaid for five of the eight product groups. The DMERCs sampled prices in different states and collected a large number of retail prices to develop their payment proposals. However, they did not choose their sample in a consistent way, nor did they set sufficient criteria so that we could be assured that the locations sampled represented retail prices nationally. The DMERCs also did not follow a consistent methodology, leading to differences in how they collected and analyzed retail prices, such as not properly calculating state sales taxes for all items. In addition, the DMERCs did not survey the types of enteral formulas and the packaging systems considered most appropriate and generally used for tube feeding. Instead, they obtained prices for cans of oral nutritional supplements.

Despite these deficiencies, we believe that the surveys provide a sufficient basis to adjust payments by up to 15 percent for the product groups for which Medicare pays substantially more than 15 percent above the median retail price. However, for glucose test strips and albuterol sulfate, the difference between the current maximum Medicare payment amount and the DMERCs' median surveyed price was less than 15 percent, and thus the precision of the survey results becomes more critical to setting the new payment amounts. Similarly, the survey results are questionable for enteral formulas, because the DMERCs did not survey the types of enteral formulas and the packaging systems considered most appropriate and generally used for tube feeding. As a result, we do not believe the surveys of glucose test strips, albuterol sulfate, and enteral formulas provide a sufficient basis, without gathering more information, to adjust the payment amounts.

DMERC Sample of Prices Was Large but Might Not Fully Represent the Range of Retail Prices

The DMERCs collected about 2,800 prices for the six product groups. They used a judgmental sample, meaning that they chose certain locations to obtain retail prices that they believed represented a good mix of localities across the country. However, they did not choose a sample of states and

localities for their surveys of retail stores or samples of stores in those locations in a consistent way. Setting criteria would have ensured that the prices sampled fully represented the range of retail prices nationally.

To establish a median retail price, the DMERCs decided that each would select three populous states and one less populous state, and within each state, sample three urban areas and two rural areas. Then, within each urban area the DMERCs agreed to select four large stores and one small store, while within each rural area they were to select one store.

A weakness in the DMERCs' sampling plan is that it was developed without fully considering the geographic distribution of Medicare beneficiaries. Also, the DMERCs 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. Furthermore, the DMERCs did not establish criteria to define populous state, less populous state, urban area, and rural area, and consequently each DMERC used different criteria in selecting locations. The DMERCs were also not consistent in how they chose retail outlets within the selected cities.

Because of the sampling methodology used, we cannot be certain that the full range of retail prices that Medicare beneficiaries might pay was reflected in the DMERCs' sample. As a result, it is not clear how close the median of sampled prices may be to the median of national prices for each product group. In our opinion, this weakness is less important when the current Medicare payments are significantly higher than the proposed payment amounts. This is because the precision of the median price does not matter as much when a payment adjustment of up to 15 percent in the first year would still leave the Medicare payment higher than the median. However, the quality of the sample becomes a more significant issue when the difference between the current maximum payment and the median is small—such as the estimated 3.4-percent proposed reduction for glucose test strips.

Industry groups contended that large urban areas were underrepresented in the DMERCs' surveys of retail prices. These groups claimed that median retail prices in large urban areas are higher than in other population areas and therefore underrepresenting these areas resulted in a downward bias in the surveyed median price. We found that the distribution of sampled prices from localities surveyed was not fully representative of the distribution of the U.S. population (see table 9 in app. IV). However, this did

not appear to give a downward bias to the survey results, because the DMERCs sampled retail prices in many large urban areas, and the larger urban areas in the survey did not always have the higher median retail prices (see table 10 in app. IV).

Survey Methods Were Not Consistent Among the DMERCs

The DMERCs did not use consistent methods to collect and analyze the pricing data. HCFA provided guidance on survey methodologies because the DMERCs were conducting a retail survey for the first time under the revised inherent reasonableness process. The DMERCs also discussed with HCFA the methods to be used in their surveys. But the DMERCs did not develop written guidelines for data collection and analysis. As a result, we found differences among the DMERCs' practices in requesting pricing data and in calculating the proposed reductions. The DMERCs did not develop a consistent set of survey questions to use when they requested prices from retail stores. This made their survey less rigorous, and it was impossible to determine, after the fact, whether they collected price information in a consistent way.

Various industry groups were concerned that the DMERCs consistently sampled less expensive products that beneficiaries rarely use and that the survey results included prices for products that were temporarily "on sale." They were also concerned that the DMERCs conducted primarily telephone surveys, which, compared with site visits, may have missed pricing information on higher priced items available in a store. However, these are not valid criticisms of the survey because, as a general principle, the Medicare program covers products to the extent that they are medically necessary but does not cover deluxe products, such as designer eyeglass frames, or products with features that are designed only for personal convenience and comfort. HCFA's guidance to the DMERCs was based on this principle. Generally, the DMERCs were to survey retail stores for the most reasonably priced item that a consumer could buy within the surveyed product groups. The exceptions were glucose test strips and lancets. Since specific brands of diabetic supplies must be used in conjunction with specific blood glucose monitors, the DMERCs were asked to survey different brands of test strips and lancets so that prices reflected testing supplies used with different blood glucose monitor models currently on the market.

We found that for glucose test strips and lancets, the DMERCs collected prices for a range of brands to ensure that they had information on a variety of testing supplies used with different monitor models. For other product groups, the DMERCs did not collect as many prices. When they obtained

prices for different-sized packages for the same brand of testing supplies or for various items within a product group from the same store on the same day, they generally used the packaging size with the lowest unit price or the lowest-priced sample to calculate the median price.

In addition to inconsistencies in collecting data, the DMERCs were not always consistent in calculating the state sales tax to be added to the purchase price for some of the items.[27] The tax treatment of medical equipment and supplies varies among states. For example, many states exempt eyeglasses from state sales tax, whereas other states do not. Our preliminary analysis showed that the DMERCs correctly calculated the sales tax in many of the surveyed states, but for other states, they either overstated or understated the sales tax. Because the DMERCs erred in both directions, the net effect is considerably lessened.

While these errors in calculating sales tax had a negligible effect on the proposed payment amounts for most items, they did affect the proposed payment limit for glucose test strips and albuterol sulfate because the proposed reductions are small. For example, our preliminary analysis indicated that the DMERCs incorrectly applied sales taxes to prices of glucose test strips sampled in seven states. Once we applied what we believe are the appropriate sales taxes, the median retail price rose to $35.99—a 2.0-percent, rather than a 3.4-percent, reduction from the current payment limit for this item. In the case of albuterol sulfate, we found that prescription drugs are exempt from sales tax in the states where prices were sampled. One DMERC added sales taxes even though taxes may not have been applicable in those states. Correcting this appeared to reduce the median surveyed price to $.41—which represents a 12.7-percent, rather than a 10.6-percent, reduction in the payment amount.

We believe that the DMERCs could have avoided some of their inconsistent survey practices and been less open to criticism if they had used a written survey guide to help collect and prepare the pricing data. It is standard practice when collecting survey data to use a written survey instrument to help ensure that all respondents are asked the same questions in the same manner so that the data collected are consistent and comparable.

[27]We did not review the state sales taxes applicable to enteral formulas because we had other concerns about the survey of that product group.

DMERCs Did Not Survey Enteral Products Used in Tube Feeding

In our 1998 report on Medicare payments for medical equipment and supplies, we found that different types of items can be billed under the same product group and that HCFA does not know the specific items supplied to a beneficiary under its billed product groups.[28] To set a maximum payment amount for enteral formulas, the DMERCs surveyed prices on some types of items covered under the product group for tube-feeding formulas. However, our review of the survey results indicated that the DMERCs did not sample the most appropriate enteral formulas for tube feeding. They also did not collect pricing data on sterile prefilled formula bags, which are commonly used for enteral feeding in nursing homes to reduce the risk of patient infection. As a result, we do not believe that the survey results support the proposed payment reduction without additional information and analysis.

To price enteral formulas, the DMERCs primarily sampled over-the-counter items sold in retail stores as oral nutritional supplements. Medicare covers enteral formulas intended for beneficiaries who must be fed through a tube but not when the formulas are used as oral supplements. HCFA's rationale for pricing oral supplements was that they could be used in feeding tubes. However, several pharmacists and enteral nutritionists told us that while over-the-counter formulas can be used for a small subset of tube-fed patients, such formulas are generally not the most appropriate products for tube feeding. They also said that although over-the-counter formulas were used for this purpose in the past, new formulas have been developed specifically for tube-fed patients that are better tolerated and are more widely provided to Medicare beneficiaries.

Moreover, when we reviewed enteral products approved by several hospitals, medical centers, and VA hospitals for standard tube feeding, we found that these facilities did not generally include as approved formulas the over-the-counter formulas that the DMERCs surveyed. In addition, we reviewed billing data from two large Medicare medical suppliers and found that specialized tube-feeding formulas—not the products the DMERCs surveyed—were the most common items provided to beneficiaries under the enteral formula product group. By not surveying the prefilled bags, the DMERCs did not develop any price information on this type of packaging, even though this type of packaging represented about half of the products these two suppliers billed to Medicare under the product group.

[28]See GAO/HEHS-98-102, May 12,1998.

As the industry contended, the specialized formulas for tube-fed patients packaged in cans or prefilled formula bags were generally not available over-the-counter. As a result, a retail survey was not the best way to establish the payment amount for category 1 enteral formulas. Because we do not know whether prices for oral supplements are similar to the tube-feeding formulas generally used, in cans or prefilled bags, we do not know whether the proposed reduction in Medicare's payment amount for this product group is reasonable. To set an appropriate payment amount, the DMERCs or HCFA needs to determine the products generally used by beneficiaries, and the distribution channels for those products, and then collect additional price information on those products.

Other Data Suggest Medicare Payments for Enteral Formulas and Other Product Groups May Be Too High

Despite our concerns about the methods used to conduct the survey of retail prices and the results for glucose test strips, albuterol sulfate, and enteral formulas, Medicare fees may be excessive for these product groups. Surveying retail prices is not the only method of reasonably establishing what Medicare should pay. In fact, using retail prices may lead Medicare to continue to overpay suppliers for some product groups that are not typically or often purchased by beneficiaries in a retail setting.

Retail surveys may be appropriate for determining a reasonable reimbursement rate for beneficiaries who typically purchase items off the shelf. Retail prices reflect the costs of getting the items to the consumer—both the costs for the store to acquire the items and the costs to deliver them in a retail setting—plus a profit margin. According to HCFA, retail prices can also include some service costs, such as credit card billing and pharmacy services.[29] Certain product groups, such as eyeglass frames, are usually consumer goods for which retail prices represent the prices generally charged to the public for these goods. Some product groups, such as glucose test strips and lancets, have both a consumer and an institutional market. For these product groups, beneficiaries and suppliers purchase the same items and bill Medicare for reimbursement. Other product groups frequently billed to Medicare, such as catheters and related products, are generally purchased only by suppliers such as nursing home suppliers and home medical equipment and supply companies. These

[29]Industry groups commented that retail prices do not take into account the suppliers' administrative costs of submitting Medicare claims for medical equipment and supplies. HCFA asserts that retail prices more than adequately reimburse suppliers for their administrative costs of doing business with Medicare.

entities provide medical equipment and supplies to nursing home and home-bound beneficiaries and bill Medicare on their behalf.

Suppliers generally pay wholesale prices that reflect volume discounts for purchasing items in bulk and have different costs to deliver items to beneficiaries than do retail outlets. Yet Medicare pays the same amount for an item that beneficiaries purchase at retail and suppliers purchase at volume discount.

A strategy other than using retail prices may be more appropriate for estimating reasonable Medicare payments for products generally provided by suppliers, such as enteral formulas. A better estimate may be based on wholesale prices or suppliers' acquisition costs with a reasonable markup for service costs. HCFA and the DMERCs may be able to get information on suppliers' costs to acquire the item, such as a wholesale price. Medicare payments should also cover any services necessary to furnish a product to beneficiaries. These services can include beneficiary education and training, delivery, and the cost of billing Medicare for the product. It may be more difficult to determine a reasonable markup for the costs of providing services associated with the product to the beneficiary. Nonetheless, identifying these services, estimating their costs, and adding this markup to the wholesale price may be one way to set new and reasonable maximum payment amounts.

The prices that the Department of Veterans Affairs (VA) pays for medical equipment and supplies provide a rough estimate of the wholesale prices that large suppliers pay because VA is a large purchaser. As table 2 shows, median VA prices for five of the six surveyed product groups were considerably lower than current Medicare payment amounts. However, VA prices do not include all the service costs associated with getting the product to the beneficiary. How much markup would be necessary to account for these costs is not certain. However, as table 2 also shows, sizable markups could be added to VA prices and the results would still be less than Medicare's maximum payment allowances. For example, adding a 100-percent markup to the VA price for category 1 enteral formulas would result in Medicare paying $.34 instead of $.61 per 100 calories.

Table 2: 1998 Medicare Expenditures, Medicare Maximum Payment Allowance, VA Median Price, and Percentage Markup, by Product Group

Product group	1998 Medicare expenditures	1998 Medicare maximum payment allowance[a]	1998 VA median price	Percentage markup added to VA price
Glucose test strips (50 per box)	$291,906,224	$36.73	$21.29	72.5
Albuterol sulfate (.83 percent per 3 ml. vial)	207,317,969	0.47	0.11	327.3
Category 1 enteral formulas (per 100 calories)	189,683,827	0.61	0.17[b]	258.8
Lancets (100 per box)	32,989,146	12.15	4.03	201.5
Eyeglass frames	22,599,790	62.69	32.95	90.3
Coated latex Foley catheters	1,580,344	11.70	[c]	[c]

[a]These allowances represent the upper payment limit of the fee schedule for glucose test strips, lancets, eyeglass frames, and catheters. For these product groups, the maximum payment allowances are also the median of state fees. These allowances also represent the maximum reasonable charge for category 1 enteral formulas and the payment amount for albuterol sulfate. Medicare pays 80 percent of these allowances, and the beneficiary pays the remaining 20 percent.

[b]The median VA price represents the standard tube-feeding formula, which is purchased in cans. VA uses other tube-feeding formulas in cans for a subset of patients who have special dietary needs. VA prices for these products range from $.12 to $.19 per 100 calories. VA does not have a contract for prepackaged delivery systems.

[c]Not applicable.

Sources: 1998 Medicare expenditures are from the Statistical Analysis Durable Medical Equipment Regional Carrier; 1998 Medicare maximum payment allowances and the 1998 VA median prices are from HCFA; and the percentage markup is a GAO calculation.

For items that are not generally purchased in a retail setting, such as enteral formulas for tube feeding, setting new payment amounts by using the median VA price plus an appropriate markup may represent a better way to set the amount. HCFA is currently using VA prices with a markup for service delivery in its inherent reasonableness review of six other items.[30] On August 13, 1999, HCFA issued a proposed notice to reduce Medicare payments for five items of durable medical equipment and one prosthetic device using VA contract prices as a base and adjusting those prices upward by 67 percent to account for supplier costs. HCFA developed its 67-percent markup using the median of the differences between wholesale and suggested retail prices for over 200 types of medical equipment and devices submitted to HCFA for product category coding by manufacturers between 1989 and 1998. These coding requests generally involved new products and technology, and HCFA reasonably assumed the markup would be higher on such items than on items that had been on the market a number of years. This inherent reasonableness adjustment is on hold pending issuance of this report and the final rule.

Access Problems Unlikely to Occur, but Monitoring Needed

While it is impossible to forecast with certainty whether any access problems may result from the proposed payment reductions, we believe that it is likely that sufficient numbers of suppliers will still be willing to provide these product groups to beneficiaries after payment reductions of up to 15 percent for eyeglass frames, lancets, catheters, and catheter insertion trays. As a result, beneficiaries are unlikely to experience access problems. After such reductions, Medicare payments will still be higher than the median retail prices for these items, and because the payment reductions are based on retail prices, suppliers will likely continue to have the financial incentive to provide these products to beneficiaries. However, HCFA should monitor the situation to determine whether significant problems with access to medical equipment and supplies arise because payments have become too low. If so, HCFA could then use its inherent reasonableness authority to adjust payments so that Medicare continues to pay prudently while beneficiaries continue to have adequate access to needed medical equipment and supplies.

[30]See 64 *Fed. Reg.* 44,227. These six items are folding pickup walker, folding wheeled walker without seat, stationary fixed-arm commode chair, two types of transcutaneous electrical nerve stimulators, and vacuum erection system.

Proposed Payment Reductions Are Unlikely to Affect Patient Access

The effect of the proposed payment reductions on beneficiary access depends on whether Medicare payment amounts fall below the point at which sufficient numbers of suppliers are willing to provide the items. If the payment amount drops so far that it no longer covers suppliers' legitimate costs—including the cost of doing business with Medicare—then suppliers may be unwilling to provide the item for the Medicare payment amount and beneficiaries may experience access problems.

We believe it is unlikely that reducing Medicare payments by up to 15 percent for lancets, eyeglass frames, catheters, and catheter insertion trays will affect patient access because the current Medicare payment exceeds the median retail price by more than 15 percent. The DMERCs' intention in using retail prices was to eliminate excessive payments while ensuring that beneficiaries could continue to obtain these products over-the-counter. As we observed earlier in this report, retail prices (1) represent the prices generally available to individual beneficiaries, (2) include a share of the costs of maintaining retail space as well as other services, and (3) are generally higher than what a prudent large-volume purchaser would pay. Under these circumstances, basing inherent reasonableness reductions on retail prices is conservative and not likely to affect the availability of these items.

To determine whether access is affected by payment reductions, HCFA could monitor various indicators of potential access problems. These indicators could include the percentage of suppliers willing to accept the Medicare-allowed payment amounts for the surveyed items and the number of beneficiary complaints. Monitoring access is particularly important in higher cost geographic areas. Similarly, monitoring access may be more critical for product groups for which the national median retail prices are closer to the current Medicare maximum payment amounts. Should access problems occur, HCFA could adjust payment amounts as necessary.

HCFA has reduced prices in the past for items it believed were overpriced with no significant effect on patient access to the item in question. For example, section 4552 of the BBA reduced Medicare's fees for home oxygen by 30 percent after we reported that Medicare's fees were excessive compared with those paid by VA. Subsequently, we reported that, according to preliminary indications, access to home oxygen equipment remained

substantially unchanged.[31] We found that despite the reduction, the number of Medicare beneficiaries using home oxygen equipment continued to increase, as did the percentage of home oxygen suppliers willing to accept the Medicare fee as full payment. In Polk County, Florida, a competitive bidding demonstration allowed HCFA to achieve an additional 16-percent reduction in price (beyond the 30-percent BBA reduction) for home oxygen. This competitive bidding experiment is being closely monitored through an independent evaluation, and a number of beneficiary protections are in place, including a full-time ombudsman and the right for beneficiaries to continue using their home oxygen provider as long as that provider accepts the new payment amount.

Conclusions

HCFA acted properly when it issued the revised inherent reasonableness regulations as an interim final rule and has the authority to delegate responsibility to the DMERCs to make inherent reasonableness payment adjustments in certain circumstances. As required by the Congress, HCFA must finalize the inherent reasonableness regulations and respond to industry concerns, particularly regarding the agency's policies and procedures in applying the revised inherent reasonableness process. This will give HCFA the opportunity to better explain its understanding of the term "grossly excessive or deficient" so that the criteria for conducting inherent reasonableness reviews are clear to all parties.

The DMERCs' use of retail surveys to determine an appropriate price for items that have a wide retail market is sound. In general, there is sufficient evidence to indicate that Medicare overpays for most of the reviewed product groups. Consequently, we believe that the median prices from the DMERCs' retail surveys can serve as an adequate basis for making up to 15-percent payment reductions for eyeglass frames, lancets, catheters, and catheter insertion trays—items with a considerable difference between the median retail price and Medicare's maximum payment allowance. However, problems with the survey lead us to question whether further payment reductions for these products should be made in subsequent years without some additional data-gathering and analysis. In addition, while relying on retail surveys when pricing products generally purchased by beneficiaries in retail settings is sound, using this method for other product

[31] *Medicare: Access to Home Oxygen Largely Unchanged; Closer HCFA Monitoring Needed* (GAO/HEHS-99-56, Apr. 5, 1999).

groups may complicate pricing efforts and lead to higher Medicare payment amounts than are warranted.

Because the DMERCs did not follow a rigorous survey process, their estimates of retail prices are less precise than they could be. This matters more when the difference between the current Medicare payment amount and the estimated median retail price is smaller. As a result, the DMERCs should supplement their data with additional information and analysis before reducing Medicare payments for glucose test strips and albuterol sulfate. In addition, because the DMERCs did not collect information on specific enteral formulas that are considered most appropriate by clinical experts and are most commonly used for tube feeding, the DMERCs should also gather more data to assess whether the proposed payment reduction for this product group may be too high or too low.

The results of the DMERCs' inherent reasonableness surveys for eyeglass frames, lancets, catheters, and catheter insertion trays will not result in payment allowances that are set artificially low. Therefore, we believe that beneficiary access to these items is likely to be unaffected by the payment reductions. The payment reductions should have the positive effect of preventing overpayment by Medicare and saving taxpayers money without harming beneficiaries. However, we believe it is important for HCFA to monitor indications of problems with beneficiary access to medical equipment and supplies, particularly in high-cost geographic areas or after multiple payment reductions have been made, and be ready to respond if access appears to become limited.

Recommendations

We recommend that

- in promulgating the final rule on the inherent reasonableness process, HCFA define with sufficient clarity the terms "grossly excessive" and "grossly deficient;"
- HCFA and the DMERCs 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;
- for future inherent reasonableness reviews based on survey data, HCFA or the DMERCs 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; and
- HCFA 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.

Agency Comments and Our Evaluation

HCFA commented on a draft of this report and generally agreed with its findings and conclusions. (HCFA's letter is printed in app. V.) HCFA also stated that it intended to incorporate all of our recommendations as it moved forward with its promulgation of the final rule and use of the inherent reasonableness process.

In its comments, HCFA emphasized the efforts it has made to be a more prudent purchaser of health care services and items by using new authority granted by the BBA to conduct competitive bidding demonstrations and to exercise streamlined authority in using inherent reasonableness principles. Following the issuance of this report, HCFA plans to publish as quickly as possible a final regulation that incorporates our recommendations and to proceed with the price adjustments we found appropriate—which will save an estimated $8 million annually in grossly excessive payments.

HCFA expressed concerns that our report could have the unintended effect of hindering HCFA's ability to effect needed adjustments using its inherent reasonableness authority. It stated that the DMERCs' efforts to gather data to support planned price reductions were far more extensive than any data collection that had been done in the past, and met or surpassed earlier recommendations that urged HCFA to use a streamlined inherent reasonableness process. Nothing in this report is intended to hinder HCFA's efforts to use the inherent reasonableness process to achieve appropriate payment amounts.

We will send copies of this report to the Honorable Donna E. Shalala, Secretary of Health and Human Services; the Honorable Nancy-Ann Min DeParle, Administrator of HCFA; appropriate congressional committees; and others who are interested.

If you or your staff have any questions, please call me at (312) 220-7600 or Sheila Avruch at (202) 512-7277. Other major contributors to this report include Teruni Rosengren, Victoria Smith, Michelle St. Pierre, and Craig Winslow.

Sincerely yours,

Leslie G. Aronovitz
Associate Director, Health Financing and
Public Health Issues

Scope and Methodology

We conducted our study between April 1999 and May 2000 in accordance with generally accepted government auditing standards. To determine whether HCFA (1) acted properly in issuing its inherent reasonableness regulations as an interim final rule and (2) has the authority to delegate the inherent reasonableness process to the DMERCs, we reviewed the laws and regulations, relevant case law, and legislative history of the inherent reasonableness process under the Medicare Act. We also reviewed the notice and comment requirements of the Administrative Procedure Act and relevant case law. Additionally, we reviewed industry comments and HCFA's pre-BBA legislative initiative to improve the inherent reasonableness process.

We evaluated the DMERCs' surveys of retail prices used to develop the payment proposals for the following eight product groups:

- blood glucose test or reagent strips for home blood glucose monitor, per 50 strips (A4253);
- lancets, per box of 100 (A4259);
- insertion tray without drainage bag with indwelling catheter, Foley type, two-way latex with coating (A4311);
- insertion tray with drainage bag with indwelling catheter, Foley type, two-way latex with coating (A4314);
- indwelling catheter, Foley type, two-way latex with coating—Teflon, silicone, silicone elastomer, or hydrophilic (A4338);
- enteral formulas—category 1, semisynthetic intact protein/protein isolates, 100 calories = 1 unit (B4150);
- albuterol, inhalation solution administered through durable medical equipment, unit dose form, per mg (K0505); and
- frames, purchase (standard) (V2020).

We met with industry groups representing manufacturers, distributors, medical equipment and supply companies, enteral formula providers, and long-term care providers to discuss their concerns regarding the survey and how HCFA implemented the inherent reasonableness process. We reviewed their written comments on HCFA's interim final rule and the DMERCs' inherent reasonableness notices and industry-sponsored studies. We also met with an organization that lobbies for people who have had ostomy surgery. In addition, we reviewed GAO and HHS Office of Inspector General reports on the adequacy of Medicare payments for medical equipment and supplies.

We met with HCFA officials and contacted the pricing staff from the four DMERCs to discuss the revised inherent reasonableness process and methods for implementing it. The individual DMERCs provided us with data on the retail surveys. They also gave us information on the survey process including the survey questions they asked and the state sales tax they applied to the purchase price of the items surveyed. The primary states from which survey data were obtained were California, Florida, Idaho, Indiana, Maine, Massachusetts, Michigan, Minnesota, Missouri, New York, North Dakota, Pennsylvania, South Carolina, Tennessee, Texas, and West Virginia. (The DMERCs surveyed other states to collect supplemental data.) We also discussed Medicare payment policies for the surveyed items with HCFA officials and obtained the final inherent reasonableness survey results from them.

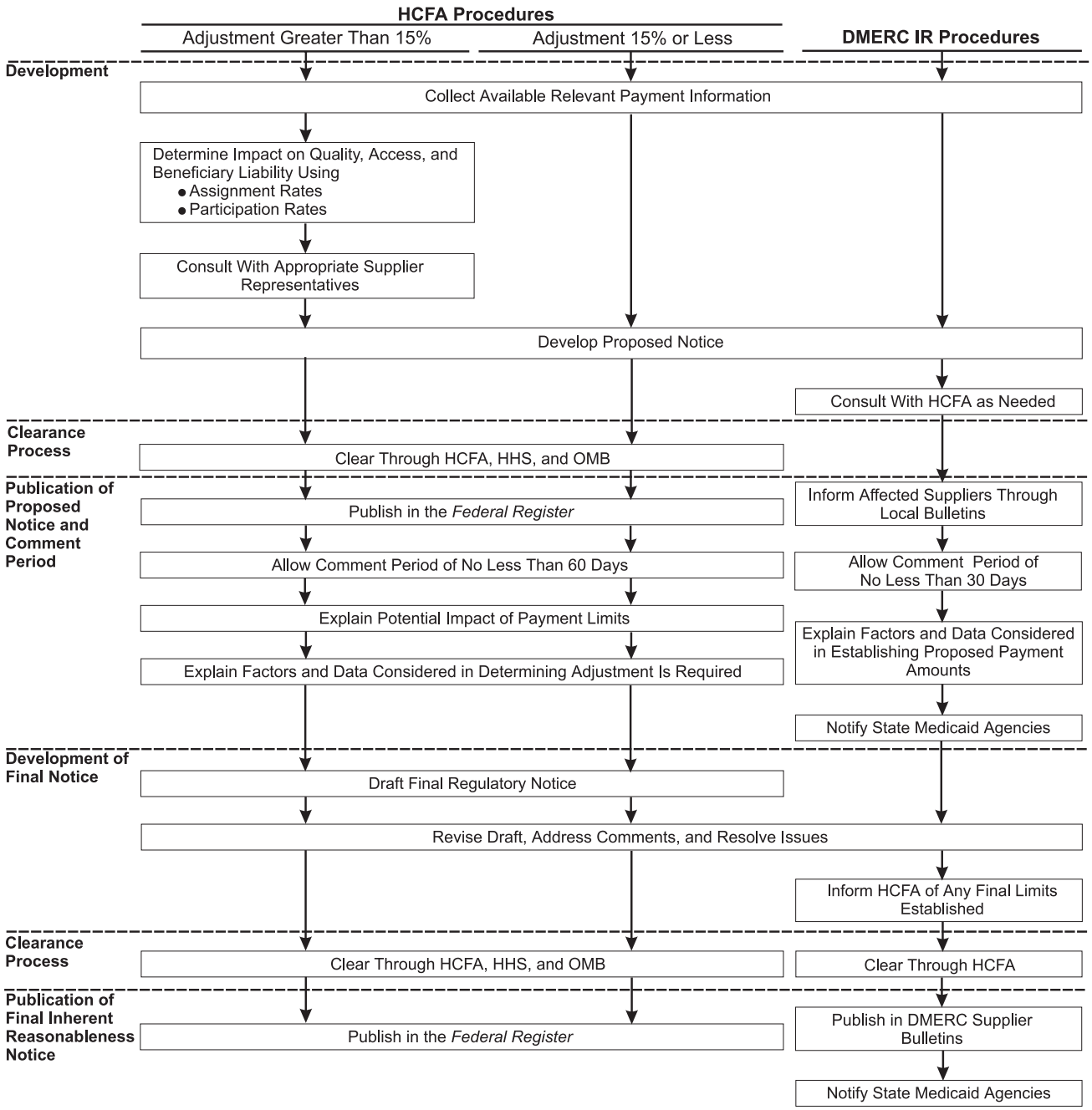
Because the DMERCs provided us with more detailed survey data, we validated those data against the final inherent reasonableness survey results. We compared each price as reported by the individual DMERCs with the prices included by HCFA in the final results and reconciled any discrepancies identified. In addition, we verified whether state sales tax was appropriately applied for each surveyed item for each surveyed state. We reviewed state sales tax statutes, regulations, administrative opinions, and publicly available guidance. We also discussed these matters with state Department of Revenue officials. In cases in which state sales tax appeared to be inappropriately applied, we recalculated the median retail price using our best estimate of the applicable state sales tax at the time the prices were surveyed.

To assess the DMERC survey process and results, we reviewed the survey design and methodology with our senior methodologists and statisticians. We also conducted several analyses to determine whether any systematic biases existed in the data collection. For example, for each surveyed item, we estimated the percentage of the sample prices that were obtained from phone calls versus site visits. To assess the representativeness of survey results, we used 1996 census estimates and the metropolitan statistical area (MSA) population classification of the locations of stores from which prices were gathered to compare the distribution of surveyed prices with the general distribution of the U.S. population. We conducted a similar analysis to determine whether the sample prices were obtained from stores with an urban/rural distribution similar to that of the U.S. population. For this comparison, we excluded the populations of Alaska, Hawaii, and the U.S. territories since the inherent reasonableness limits were not applied to these locations. For each surveyed item, we also calculated median survey

prices for each MSA population classification to determine whether a systematic downward bias existed in the overall median prices estimated by the survey.

To determine whether the DMERCs surveyed appropriate products, we obtained product utilization data on enteral formulas from two large Medicare suppliers. We also discussed the types of enteral formulas used for tube feeding and oral supplementation with clinicians and pharmacists at VA hospitals and other hospitals, enteral formula providers, and manufacturers. To identify VA prices for tube-feeding formulas, VA provided us with its 1998 national contract for enteral products. HCFA also provided us with its survey results on prices that VA medical centers paid for certain items of medical equipment and supplies.

Comparison of the Inherent Reasonableness Procedures for HCFA and the DMERCs



1998 Fee Payments and the Total Proposed Payment Reductions for the Surveyed Product Groups, by State

Table 3: 1998 State Fees and the Total Proposed Percentage Reductions for Glucose Testing Strips

State	1998 state fee[a]	Total percentage payment reduction
AL	$36.73	3.4
AR	36.73	3.4
CA	36.73	3.4
CT	36.73	3.4
DC	36.73	3.4
FL	36.73	3.4
IA	36.73	3.4
IL	36.73	3.4
LA	36.73	3.4
MA	36.73	3.4
MD	36.73	3.4
ME	36.73	3.4
MI	36.73	3.4
MS	36.73	3.4
NH	36.73	3.4
NJ	36.73	3.4
NY	36.73	3.4
OR	36.73	3.4
PA	36.73	3.4
SC	36.73	3.4
TN	36.73	3.4
UT	36.73	3.4
VA	36.73	3.4
VT	36.73	3.4
WV	36.73	3.4
OH	36.54	2.9
WY	35.71	0.6
KY	35.65	0.5
AZ	34.50	0.0
MN	34.35	0.0
MT	34.21	0.0
RI	34.21	0.0
DE	34.20	0.0
WI	33.92	0.0

(Continued From Previous Page)

State	1998 state fee[a]	Total percentage payment reduction
GA	33.86	0.0
SD	33.76	0.0
WA	33.19	0.0
ID	33.10	0.0
ND	33.09	0.0
TX	32.95	0.0
IN	32.48	0.0
NV	32.20	0.0
NC	31.69	0.0
NM	31.61	0.0
NE	31.53	0.0
KS	31.37	0.0
CO	31.22	0.0
MO	31.22	0.0
OK	31.22	0.0

Note: The table does not include Alaska and Hawaii because they are exempt from the national fee schedule and therefore are not subject to the proposed payment reductions.

[a]The 1998 state fee represented the amount Medicare allowed in each state at the time of the DMERCs' inherent reasonableness survey. Medicare pays 80 percent of the allowed state fee and the beneficiary pays the remaining 20 percent.

Table 4: 1998 State Fees and Total Proposed Percentage Reductions for Lancets

State	1998 state fee[a]	Total percentage payment reduction
AR	$12.15	35.7
AZ	12.15	35.7
CO	12.15	35.7
CT	12.15	35.7
FL	12.15	35.7
GA	12.15	35.7
IA	12.15	35.7
IL	12.15	35.7
KY	12.15	35.7
LA	12.15	35.7
MI	12.15	35.7
MN	12.15	35.7
MO	12.15	35.7
MO	12.15	35.7
MT	12.15	35.7
NC	12.15	35.7
ND	12.15	35.7
NJ	12.15	35.7
NM	12.15	35.7
NV	12.15	35.7
NY	12.15	35.7
OR	12.15	35.7
TX	12.15	35.7
UT	12.15	35.7
WA	12.15	35.7
WY	12.15	35.7
CA	11.81	33.9
NE	11.70	33.3
SC	11.62	32.8
VA	11.54	32.3
KS	11.42	31.6
TN	11.16	30.0
SD	11.01	29.0
WV	10.95	28.7

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State	1998 state fee[a]	Total percentage payment reduction
IN	10.54	25.9
OK	10.44	25.2
WI	10.44	25.2
ID	10.38	24.8
AL	10.33	24.4
DC	10.33	24.4
DE	10.33	24.4
MA	10.33	24.4
MD	10.33	24.4
ME	10.33	24.4
MS	10.33	24.4
NH	10.33	24.4
OH	10.33	24.4
PA	10.33	24.4
RI	10.33	24.4
VT	10.33	24.4

Note: Table does not include Alaska and Hawaii because they are exempt from the national fee schedule and therefore are not subject to the proposed payment reductions.

[a]The 1998 state fee represented the amount Medicare allowed in each state at the time of the DMERCs' inherent reasonableness survey. Medicare pays 80 percent of the allowed state fee and the beneficiary pays the remaining 20 percent.

Table 5: 1998 State Fees and Total Proposed Percentage Reductions for Latex Foley Catheters

State	1998 state fee[a]	Total percentage payment reduction
AL	$11.70	24.02
AR	11.70	24.02
AZ	11.70	24.02
CA	11.70	24.02
CO	11.70	24.02
DC	11.70	24.02
FL	11.70	24.02
IA	11.70	24.02
ID	11.70	24.02
IL	11.70	24.02
IN	11.70	24.02
KS	11.70	24.02
KY	11.70	24.02
LA	11.70	24.02
MA	11.70	24.02
ME	11.70	24.02
MI	11.70	24.02
MN	11.70	24.02
MO	11.70	24.02
MS	11.70	24.02
MT	11.70	24.02
ND	11.70	24.02
NE	11.70	24.02
NH	11.70	24.02
NV	11.70	24.02
OH	11.70	24.02
OR	11.70	24.02
SC	11.70	24.02
SD	11.70	24.02
TX	11.70	24.02
UT	11.70	24.02
VA	11.70	24.02
VT	11.70	24.02
WA	11.70	24.02

(Continued From Previous Page)

State	1998 state fee[a]	Total percentage payment reduction
WI	11.70	24.02
WV	11.70	24.02
WY	11.70	24.02
CT	11.26	21.05
RI	11.10	19.91
NC	10.37	14.27
TN	10.31	13.77
DE	10.08	11.81
MD	10.08	11.81
NJ	10.08	11.81
PA	10.08	11.81
GA	9.95	10.65
NM	9.95	10.65
NY	9.95	10.65
OK	9.95	10.65

Note: Table does not include Alaska and Hawaii because they are exempt from the national fee schedule and therefore are not subject to the proposed payment reductions.

[a]The 1998 state fee represented the amount Medicare allowed in each state at the time of the DMERCs' inherent reasonableness survey. Medicare pays 80 percent of the allowed state fee and the beneficiary pays the remaining 20 percent.

Table 6: 1998 State Fees and Total Proposed Percentage Reductions for Catheter Insertion Trays Without Drainage Bags

State	1998 state fee[a]	Total percentage payment reduction
DC	$12.04	23.34
IA	12.04	23.34
ID	12.04	23.34
KS	12.04	23.34
MO	12.04	23.34
OR	12.04	23.34
VA	12.04	23.34
NE	12.26	22.92
NH	12.69	22.14
VT	13.18	21.32
MA	13.33	21.08
ME	13.33	21.08
AZ	14.00	20.07
CA	14.16	19.84
IL	14.16	19.84
IN	14.16	19.84
MI	14.16	19.84
MN	14.16	19.84
MT	14.16	19.84
ND	14.16	19.84
NV	14.16	19.84
OH	14.16	19.84
SD	14.16	19.84
UT	14.16	19.84
WA	14.16	19.84
WI	14.16	19.84
WV	14.16	19.84
WY	14.16	19.84
RI	12.04	18.36
CT	13.26	17.87
FL	12.04	14.58
TX	12.29	14.28
CO	12.52	14.02
AL	14.16	12.39

(Continued From Previous Page)

State	1998 state fee[a]	Total percentage payment reduction
AR	14.16	12.39
KY	14.16	12.39
LA	14.16	12.39
MS	14.16	12.39
SC	14.16	12.39
NC	14.16	10.45
TN	13.61	10.43
DE	12.04	9.88
MD	12.04	9.88
NJ	12.04	9.88
PA	12.04	9.88
NY	12.90	8.22
GA	14.16	7.49
NM	14.16	7.49
OK	14.16	7.49

Note: Table does not include Alaska and Hawaii because they are exempt from the national fee schedule and therefore are not subject to the proposed payment reductions.

[a]The 1998 state fee represented the amount Medicare allowed in each state at the time of the DMERCs' inherent reasonableness survey. Medicare pays 80 percent of the allowed state fee and the beneficiary pays the remaining 20 percent.

Table 7: 1998 State Fees and Total Percentage Payment Reductions for Catheter Insertion Trays With Drainage Bags

State	1998 state fee[a]	Total percentage payment reduction
AZ	$20.50	13.71
ID	20.50	13.71
MA	20.50	13.71
ME	20.50	13.71
NH	20.50	13.71
NV	20.50	13.71
OR	20.50	13.71
VA	20.50	13.71
VT	20.50	13.71
MT	21.96	12.80
DC	22.90	12.27
CA	24.12	11.65
IA	24.12	11.65
IL	24.12	11.65
IN	24.12	11.65
KS	24.12	11.65
MI	24.12	11.65
MN	24.12	11.65
MO	24.12	11.65
ND	24.12	11.65
NE	24.12	11.65
OH	24.12	11.65
SD	24.12	11.65
UT	24.12	11.65
WA	24.12	11.65
WI	24.12	11.65
WV	24.12	11.65
WY	24.12	11.65
RI	20.50	10.78
CT	24.12	9.83
FL	20.50	8.56
MS	20.50	8.56
AL	20.78	8.45
AR	24.12	7.28

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State	1998 state fee[a]	Total percentage payment reduction
CO	24.12	7.28
KY	24.12	7.28
LA	24.12	7.28
SC	24.12	7.28
TX	24.12	7.28
NC	24.12	6.14
TN	23.18	6.13
MD	20.50	5.80
DE	22.90	5.20
NJ	22.90	5.20
PA	22.90	5.20
GA	22.26	4.76
NM	22.42	4.73
NY	23.27	4.56
OK	23.37	4.54

Note: Table does not include Alaska and Hawaii because they are exempt from the national fee schedule and therefore are not subject to the proposed payment reductions.

[a]The 1998 state fee represented the amount Medicare allowed in each state at the time of the DMERCs' inherent reasonableness survey. Medicare pays 80 percent of the allowed state fee and the beneficiary pays the remaining 20 percent.

Table 8: 1998 Fees and Total Proposed Percentage Reductions for Eyeglass Frames, by State

State	1998 fee[a]	Total percentage payment reduction
AZ	$62.06	21.04
CA	62.06	21.04
NV	62.06	21.04
AL	59.85	18.13
FL	59.85	18.13
GA	59.85	18.13
KY	59.85	18.13
MS	59.85	18.13
NC	59.85	18.13
SC	59.85	18.13
TN	59.85	18.13
IL	55.85	12.27
IN	55.85	12.27
MI	55.85	12.27
MN	55.85	12.27
OH	55.85	12.27
WI	55.85	12.27
CO	54.54	10.16
MT	54.54	10.16
ND	54.54	10.16
SD	54.54	10.16
UT	54.54	10.16
WY	54.54	10.16
ID	52.63	6.90
OR	52.63	6.90
WA	52.63	6.90
CT	52.61	6.86
MA	52.61	6.86
ME	52.61	6.86
NH	52.61	6.86
RI	52.61	6.86
VT	52.61	6.86
AR	49.98	1.96
LA	49.98	1.96

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State	1998 fee[a]	Total percentage payment reduction
NM	49.98	1.96
OK	49.98	1.96
TX	49.98	1.96
IA	49.03	0.06
KS	49.03	0.06
MO	49.03	0.06
NE	49.03	0.06
DC	46.55	0.0
DE	46.55	0.0
MD	46.55	0.0
NJ	46.55	0.0
NY	46.55	0.0
PA	46.55	0.0
VA	46.55	0.0
WV	46.55	0.0

Note: Table does not include Alaska and Hawaii because they are exempt from the national fee schedule and therefore are not subject to the proposed payment reductions.

[a]The 1998 fee represented the amount Medicare allowed at the time of the DMERCs' inherent reasonableness survey. Medicare pays 80 percent of the allowed fee and the beneficiary pays the remaining 20 percent.

GAO Analysis of DMERC Sampling Methods

We compared the distribution of population areas where the DMERCs conducted their retail price surveys with the distribution of population areas for the United States to assess whether the median surveyed price represented a national median price. For each product group surveyed, we categorized each price sample according to the population level of the area from which the price was surveyed. The population areas ranged from metropolitan statistical areas (MSA) with 1 million or more people to non-MSAs.[1] Table 9 shows the percentage of prices the DMERCs collected by population compared with the distribution of population areas for the United States. The DMERCs collected more prices in MSAs with 1 million or more people than they collected in MSAs of fewer than 100,000 people; however, the survey results were not fully representative of the general distribution of the U.S. population.

Table 9: Percentage of Surveyed Prices, by Population Level, Compared With U.S. Population

Population level	Glucose test strips	Lancets	Catheters	Enteral formulas	Albuterol sulfate	Eyeglass frames	U.S. population[a]
MSA of 1 million or more	**49.5**	45.9	**46.8**	34.8	41.0	47.4	52.2
MSA of 250,000-999,999	22.2	24.5	18.4	32.1	**29.8**	24.3	19.5
MSA of 100,000-249,999	13.5	14.1	9.0	15.8	13.1	14.2	7.6
MSA of fewer than100,000	5.2	**4.0**	5.5	**3.9**	3.9	**2.3**	0.6
Non-MSA	9.6	11.5	20.4	13.5	12.1	11.9	20.1
Total	**100**	**100**	**100**	**100**	**100**	**100**	**100**

Note: Numbers in bold indicate areas with highest median surveyed price for that product group.

[a]Based on 1996 Bureau of the Census estimates. Excludes Alaska and Hawaii.

Our review of the survey results showed that areas with the largest populations did not necessarily have higher prices. For each product group surveyed, we analyzed the median surveyed price for each population level and found no consistent relationship between median price and area population level. As shown in table 10, the highest median surveyed price

[1]According to the Bureau of the Census, the general concept of an MSA is that of a core area containing a large population nucleus, together with adjacent communities having a high degree of economic and social integration with that core.

that the DMERCs surveyed for each product group is associated with different population levels. For four of the six product groups surveyed, the highest median price the DMERCs surveyed was associated with population levels that were overrepresented, compared with the U.S. population. For example, the highest median price for lancets was found in MSAs with fewer than 100,000 people. As shown in table 9, less than 1 percent of the U.S. population lives in MSAs of this size, while 4 percent of the DMERCs' surveyed prices for lancets came from MSAs of this size. This means that there are more samples of this highest price than one would expect in the overall population. These results do not provide evidence that the samples chosen by the DMERCs resulted in a systematic downward bias in the median price. The data, in fact, suggest more of an upward bias than a downward bias.

Table 10: Median Surveyed Price by Product Group and Population Level

Population level	Glucose test strips	Lancets	Catheters	Category 1 enteral formulas	Albuterol sulfate	Eyeglass frames
MSA of 1 million or more	**$35.99**	$7.87	**$10.00**	$.51	$.41	$40.65
MSA of 250,000-999,999	34.87	7.23	7.25	.51	**.45**	51.70
MSA of 100,000-249,999	35.39	8.22	8.66	.52	.36	51.07
MSA of less than100,000	35.98	**8.56**	3.45	**.56**	.36	**54.48**
Non-MSA	34.99	7.42	7.98	.50	.39	52.00

Note: Numbers in bold indicate areas with highest median price for the product group.

Comments From the Health Care Financing Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

DATE: MAY 30 2000

TO: Leslie G. Aronovitz
Associate Director
Health Financing and Public Health Issues
General Accounting Office (GAO)

FROM: Nancy-Ann Min DeParle
Administrator

SUBJECT: GAO Draft Report: "Medicare Payments: Use of Revised Inherent Reasonableness Process Generally Appropriate." (GAO/HEHS-00-79)

Thank you for the opportunity to comment on this draft report, Medicare Payments: Use of Revised "Inherent Reasonableness" Process Generally Appropriate (GAO/HEHS-00-79).

We appreciate the GAO's overall support for our efforts to ensure that beneficiaries and taxpayers pay appropriately for durable medical equipment and other supplies. As the report makes clear, we have moved aggressively to take advantage of the new authority Congress granted in the Balanced Budget Act of 1997 (BBA) to allow Medicare to pay more reasonable prices for many items and services. As part of the President's plan to modernize and strengthen the Medicare program, we have asked Congress for additional authority to use competition and private-sector techniques to make Medicare a more prudent purchaser of health care services.

For years, Medicare payment for durable medical equipment and other supplies has been based on outdated fee schedules required by law. Before the BBA, the Health Care Financing Administration (HCFA) had very limited authority to reduce Medicare payments for some items even when the General Accounting Office and the HHS Inspector General found the fee schedule established prices that far exceeded what other insurers paid. The BBA gave us two new tools to help ensure that Medicare pays appropriately for these items – the ability to conduct competitive bidding demonstrations and a streamlined authority to use inherent reasonableness principles to adjust the fee schedule where Medicare reimbursements were "grossly excessive" or "grossly deficient."

We moved to develop a competitive bidding demonstration, which uses private-sector techniques to ensure Medicare pays reasonable prices while protecting quality and access for beneficiaries. The first demonstration – in Polk County, Florida – is saving beneficiaries and the Medicare program an average of 17 percent on items included in the bidding process. We are now soliciting bids from suppliers in the San Antonio, Texas region for a second demonstration.

Page 2- Leslie G. Aronovitz

We and the four Durable Medical Equipment Regional Carriers (DMERCs), which process and pay Medicare claims for medical supplies, also took significant steps to use the expanded inherent reasonableness authority in the BBA. HCFA published an interim final rule to implement the process in January 1998. Later in 1998, the DMERCs conducted retail surveys and proposed price reductions on eight categories of products. In August 1999, HCFA issued a proposed notice to reduce Medicare payments for six other items. Industry groups and some members of Congress expressed concerns about both initiatives, and Congress in November 1999 passed new legislation that prohibits HCFA from using its inherent reasonableness authority until the GAO issues this report and HCFA issues a final rule.

We are pleased that the GAO overall found that HCFA and the DMERCs acted appropriately, and within our legal authority, in implementing their inherent reasonableness authority and in developing and proposing price reductions. We intend to move forward as quickly as possible to publish a final rule. Due to the rule-making process, HCFA cannot discuss in detail what exact steps we will take. However, in this rule, HCFA would issue final decisions regarding the proposed price reductions that the GAO found appropriate – for lancets, eyeglass frames, and indwelling catheters. If implemented, these reductions alone would save an estimated $8 million annually in payments. In addition, we intend to issue a final notice regarding the six items addressed in our August 1999 proposed notice. If implemented, the adjustments for these six items would result in estimated savings of $120 million over five years. In issuing the final rules, HCFA will carefully consider all comments received, including your report.

We do have some concerns that this report could have the unintended effect of hindering HCFA's ability to conduct timely and needed adjustments to Medicare's payment amounts using inherent reasonableness principles. In the BBA, Congress provided the authority for a more streamlined, less cumbersome inherent reasonableness process. The efforts of the DMERCs in gathering accurate pricing data in support of their proposed reductions were very extensive. We believe these efforts met or surpassed earlier recommendations that urged HCFA to use a streamlined inherent reasonableness process.

In an effort to better protect beneficiaries and taxpayers from excessive prices, we intend to incorporate all the GAO's recommendations as we move forward. We appreciate the effort that went into this report and the opportunity to review and comment on the issues raised. We look forward to working with GAO on this and other issues.

Attachment

Comments of the Health Care Financing Administration (HCFA)
on the General Accounting Office (GAO) Draft Report
"Medicare Payments: Use of Revised Inherent Reasonableness Process Generally Appropriate"

GAO Recommendation

In promulgating the final rule on the inherent reasonableness process, HCFA define with sufficient clarity the terms "grossly excessive" and "grossly deficient."

HCFA Comment

We concur. We intend to address the issue of defining the terms "grossly excessive" and "grossly deficient" in the final rule on the inherent reasonableness process.

GAO Recommendation

HCFA and the DMERCs undertake additional information collection and analysis to more precisely estimate any payment reductions for glucose test strips, and albuterol sulfate and enteral formulas as well as for additional payment reductions in subsequent years for lancets, eyeglass frames, coated latex Foley catheters, and catheter insertion trays.

HCFA Comment

We concur. We will gather more information regarding those items you identified as requiring additional data collection, namely test strips, albuterol sulfate, and category 1 enteral formula. By law, HCFA can only increase or decrease the payments by 15% a year. As you recommend, HCFA will gather additional data before making any reductions in future years.

GAO Recommendation

For future inherent reasonableness reviews based on survey data, HCFA or the DMERCs 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.

HCFA Comment

We concur. In the event that data obtained through a survey process is used for inherent reasonableness purposes in the future, we will develop a more structured survey design that would be consistently used in the survey process. We would consult with the GAO and OIG when we develop such a survey design to gather additional insight on how to conduct the survey.

1

GAO Recommendation

HCFA 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 and problems that arise.

HCFA Comment

We concur. In cases where HCFA uses its authority, HCFA will monitor patient access to items for which payment amounts are adjusted using the inherent reasonableness process. This would be accomplished by periodically checking the rate at which suppliers are accepting assignment for these items and by monitoring any beneficiary complaints regarding access.

2

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Postage & Fees Paid
GAO
Permit No. GI00