October 12, 1999

Ms. Nancy-Ann DeParle
Administrator, Health Care Financing Administration
Department of Health and Human Services
Attention: HCFA-1050-PN
Room 443-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Proposed Inherent Reasonableness Notice; Special Payment Limits for Certain Durable Medical Equipment and Prosthetic Devices—HCFA-1050-PN

Dear Ms. DeParle:

The Health Industry Manufacturers Association (HIMA) offers the following comments on the Proposed Notice of Inherent Reasonableness published by the Health Care Financing Administration (HCFA) on August 13, 1999 (64 *Federal Register*, No. 156, pages 44227-44231). The Notice recommends reductions in Medicare payment levels for certain durable medical equipment and prosthetic devices, specifically two types of folding walkers (HCPCS codes E0135 and E0143), commode chairs (HCPCS code E0163), two types of transcutaneous electrical nerve stimulators (HCPCS codes E0720 and E0730), and vacuum erection systems (HCPCS code L7900) (hereinafter collectively referred to as "items" or "six items").

HIMA is the largest association of medical technology innovators in the world, representing more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. HIMA's members account for nearly 90 percent of the $62 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $147 billion purchased annually around the world. These products play instrumental roles in saving and improving the lives of millions of patients worldwide on a daily basis. As such, we have a direct and continuing interest in public policies that affect the availability and development of such innovations.

HIMA supports the goal of seeking greater economy and efficiency in Medicare payment programs. We believe this is in the best interest of patients, the medical device industry, and the U.S. economy as a whole. At the same time, we are troubled when implementation of such

mechanisms is inconsistent with the letter and intent of the law and when implementation threatens both patient access to, and continued innovation and research in, medical technology. Patient access—whether defined as access of today's patients to current products, or access of future Medicare patients to innovations still in the R&D pipeline—must always be the primary concern of all Medicare payment programs. It must also be the measure against which virtually every policy change is judged.

For all of these reasons, we oppose the proposed reductions and urge HCFA to withdraw the proposal. We base this recommendation upon a careful analysis of the August 13, 1999, HCFA proposal and the following conclusions we have drawn from that analysis:

- The current Medicare payment rates for these home health supplies are not "grossly excessive," as that term is used by Congress and HCFA.

- The analysis supporting the proposed new payment limits is so flawed as to be arbitrary and capricious under the Administrative Procedures Act (APA).

- The HCFA Notice violates the notice and comment procedures set forth in the inherent reasonableness statute and regulations.

We are doubly concerned because we believe that these proposals represent only a beginning for HCFA. The agency indicates it is working from a list of 100 technologies ranked by medical expenditures. If it proceeds to make use of this cost-cutting tool without following the procedures set forth by Congress and without grounding this cost-cutting tool on a firm methodological foundation, the impact could be devastating for patient access, as well as for continued device innovation. As a fundamental step, the agency must act soon to share with the public its methodology, data, and rationale if voices other than that of the agency itself are to be heard meaningfully on this issue.

The following presents our detailed views and conclusions on the August 13, 1999, proposal.

I. HCFA's NOTICE VIOLATES THE PROCEDURAL REQUIREMENTS FOR INHERENT REASONABLENESS ADJUSTMENTS

The inherent reasonableness statute and regulations require HCFA to publish notice of its intent to exercise its inherent reasonableness authority and give the public the opportunity to comment. 42 USC § 1395u(b)(8) and (9); 42 CFR 405.502(g) and (h). Among other things, the notice and comment procedures help to ensure that the agency's decisions are informed. Because, however, HCFA failed to use the proper notice and comment procedure and because the Notice was inadequate regardless of which process applied, the Notice violated the inherent reasonableness statutory provisions and regulations.

A. HCFA used the wrong notice and comment process.

As you are aware, the inherent reasonableness rule contains two separate notice and comment procedures for national-level payment adjustments proposed by HCFA. The two procedures vary depending on whether an inherent reasonableness payment adjustment will be greater than 15%. Under the regulations set forth in 42 CFR 405.502, the two options can be summarized as follows:

- National payment limit adjustment not exceeding 15%. If a national-level payment change will not exceed 15%, then HCFA may establish the new limit by publishing in the *Federal Register* proposed and final notices announcing the special payment limit. 42 CFR 405.502(g)(3)(i). HCFA's notice must set forth the criteria and circumstances, if any, under which a carrier may grant an exception to a payment limit for a category of items or services.

- Payment adjustment exceeding 15%. The notice and comment procedure for payment adjustments greater than 15% is as follows (42 CFR 405.502(h)):

    - HCFA will consider the potential impact of the payment adjustment on quality, access, beneficiary liability, assignment rates, and participation of suppliers.

    - HCFA will consult with representatives of the suppliers likely to be affected by the change in the payment amount.

    - HCFA will publish in the *Federal Register* proposed and final notices of the special payment limit. The notices will set forth the criteria and circumstance, if any, under which a carrier may grant an exception to the limit for the category of items or services.

        - The proposed notice will: (i) explain the factors and data that HCFA considered in determining that the proposed payment amount for a category of items or services is grossly excessive or deficient; (ii) specify the proposed payment amount or methodology to be established with respect to a category of items or services; (iii) explain the factors and data that HCFA considered in determining the payment amount or methodology, including the economic justification for a uniform fee or payment limit if it is proposed; and (iv) explain the potential impact of a limit on quality, access, beneficiary liability, assignment rates, and participation of suppliers.

        - The final notice will explain the factors and data that HCFA took into account, and respond to comments received.

B. HCFA should have used the process for payment adjustments exceeding 15%.

The new special payment limits proposed in the Notice reduce Medicare fee schedule amounts

for the six items by more than 15%. Therefore, HCFA should have gone about soliciting public input using the more rigorous notice and comment process to initiate such a reduction. 42 USC § 1395u(b)(9); 42 CFR 405.502(h). In enacting this requirement, Congress determined that changes of more than 15% raised significant issues that need to be considered, and more interested parties need to be consulted.

The statute further states that such changes are measured over the course of a year to prevent HCFA from making multiple adjustments in a given year that add up to more than 15 percent without following the more demanding process. In particular, section 4316(a) states:

> the Secretary may not apply factors that would increase or decrease the payment under this part during any year for any particular item or service by more than 15 percent from such payment during the preceding year except as provided in subparagraph (B).

The statute quite simply prohibits HCFA from changing the payment for an item under the inherent reasonableness authority during any year by more than 15% from the prior year without following the expanded process.

In an attempt to circumvent the more rigorous process, HCFA has turned the one-year period on its head and proposed to phase-in the special payment amounts over several years. In the Notice, HCFA proposed that the fee schedule amounts for the six items be reduced incrementally by a factor of 15% or less per year until they are equal to the special payment limits applicable to each item.

The 15% per year limitation was intended to prevent HCFA from initiating more than one inherent reasonableness action in the same year that would cumulatively change the payment levels by more than 15% for a particular service without going through the more exhaustive notice and comment process. HCFA's idea of using a single inherent reasonableness action to determine reductions in more than one year that add up to more than 15% flatly violates the statutory language. By its own account, HCFA is proposing to decrease the payment by more than 15 percent for the six items without following the appropriate process. The statute says nothing about looking only at the portion of the changes that would be <u>felt</u> this year. It is the <u>action (or cumulative actions)</u> of deciding to decrease the payment by more than 15 percent which cannot take place in a single year, not the <u>effect</u> of that action(s). If HCFA proposes changes during a given year that would exceed 15%, it must follow the expanded process, whether or not the agency proposes to spread the changes out over succeeding years.

Not only does the HCFA interpretation violate the express language of the statute, it makes no sense from a policy perspective. The potential negative consequences of changes greater than 15% are not lessened materially if the changes are simply spread over time. HCFA addresses this point in the Notice by stating that the purpose of phasing in the changes is to give suppliers an extended period in which to adjust to the reductions in payment. HCFA offers no evidence or explanation for why bleeding to death slowly is preferable.

Moreover, such an interpretation presumes that Congress meant for the agency to set prices years in advance through the inherent reasonableness provision. HCFA can not possibly know what reasonable prices will be down the road, nor could that be what Congress intended.

HCFA may not ignore the statutory provision by adopting a reduction in payment levels of well over 15% for services in a single inherent reasonableness action even if the agency is willing to spread the changes over more than one year. HCFA's actions violate the express language of the statute, and its interpretation simply makes no sense.

C. The Notice does not provide suppliers with adequate information about HCFA's grossly excessive determination or its determinations of the reasonable limit.

There is much law on what notice is adequate in a notice and comment setting. According to the court in *Solite Corporation v. U.S. Environmental Protection Agency*, 952 F.2d 473 (D.C. Cir. 1991):

> The APA requires that a notice of proposed rulemaking include "either the terms or substance of the proposed rule or a description of the subjects and issues involved," 5 U.S.C. § 553(b), and that the agency "give interested persons an opportunity to participate in the rulemaking through submission of written data, views, or arguments." 5 U.S.C. § 553(c); *see Air Transport Ass'n v. CAB*, 732 F.2d 219, 224 (D.C. Cir. 1984). Integral to the notice requirement is the agency's duty "to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules. . . . An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary." *Connecticut Light and Power Co. v. NRC*, 673 F.2d 525, 530-31 (D.C. Cir.), *cert. denied* 103 S. Ct. 79 (1982).

As explained below, HCFA does not give enough pertinent information in the Notice regarding why it concluded that the payment levels for six items were "grossly excessive." In addition, the Notice does not provide sufficient information regarding the methodology HCFA used to conduct the evaluation that formed the basis for setting the proposed limits for the durable medical equipment and prosthetic devices.

- *The Notice does not identify the basis for HCFA's "grossly excessive" determinations*.

  HCFA's regulations include numerous examples of factors that could result in "grossly excessive" or "grossly deficient" payment amounts for a particular category of items or services. 42 CFR 405.502. The examples of factors listed in the regulations include the following (42 CFR 405.502(g)(vii)):

- The marketplace is not competitive;

- Medicare and Medicaid are the sole or primary sources of payment for a category of items;

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

- The payment amounts for a category of items or services in a particular locality are grossly higher or lower than payment amounts in other comparable localities;

- Payment amounts for a category of items or services are grossly higher or lower than acquisition or production costs for the category of items or services;

- There have been increases in payment amounts for a category of items or services that cannot be explained by inflation or technology; and

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

When HCFA provides notice of a "grossly excessive" determination, it is supposed to identify the facts that support its determination as measured by the criteria that HCFA has set forth. The Notice contains no information on any of the criteria, or even an explanation regarding why some other criteria not listed in the regulations are appropriate (if that is HCFA's position). As a consequence, HIMA cannot analyze the appropriateness of the determination if we are not given any explanation of how the agency applied the criteria listed in the regulation.

Although HCFA did not provide any explanation of how the pricing for the six items was "grossly excessive" under the criteria of the rule, HCFA made the following observations in its Notice:

> We have determined that the Medicare fee schedule amounts for five durable medical equipment items and one prosthetic device are not inherently reasonable because they are grossly excessive relative to the amounts paid for these items by the Department of Veterans Affairs . . . The special payment limits would be based on the median wholesale prices paid by the Department of Veterans Affairs for these items plus an appropriate mark up.

As already noted, that explanation does not tie back to any of the criteria that HCFA has listed for making the threshold determination of whether a "grossly excessive" payment level

exists. Further, valid questions exist regarding whether Department of Veterans Affairs (VA) data is a good standard of comparison. While the list of factors to be considered in the regulation is not presented as an exhaustive list, we must conclude that any other factors would be of the same type and character. Yet the proffered explanation for the reduction, i.e., the current prices are out of step with VA prices, is not of the same caliber or significance.

- *The notice does not provide adequate information for the public to evaluate the basis for HCFA's determination of the "realistic and equitable" limit.*

  The Notice does not provide adequate information concerning the basis for the proposed payment limit for the identified items. The Notice explained that HCFA conducted an evaluation of the current reimbursement rates for the six items and found them to be out of step with the rates the VA pays. Moreover, the Notice describes the agency's evaluation process as including at least four separate data gathering steps. The Notice, however, does not provide any information regarding the methodology used in collecting the data at each of the four steps.

  HIMA needs to know at least the following basic information before it can comment meaningfully:

  - Payment and pricing data collected for the decubitus care equipment, TENS devices, and the other Medicare items contained in HCFA's list of 100 items targeted for possible rate adjustments, plus the:

    - Criteria HCFA used to select these items to be reviewed.

    - Criteria HCFA used to identify 20 items from the list of 100 items that warranted further review.

  - Information on the VA data, including:

    - HCFA's rationale for selecting VA pricing information as its standard of comparison.

    - Any evaluation of the specific products in each of the 20 items that were actually obtained by the VA as compared to the set of products that are encompassed in each of the 20 items and that are purchased through other entities. For example, if there are circumstances in which one of the 20 items includes a number of products that are sold through various entities and the VA purchases only one of the products, HCFA should indicate all such instances and provide the rationale for why the VA prices were assumed to be representative of the broader range of products.

- HCFA's rationale for using wholesale prices plus markup rather than using retail prices, including any data or information reviewed with respect to sales of each of the items.

- HCFA's rationale for selecting specific VA prices for each of the items. In particular, the rationale for use (or non-use) of VA prices that involve exclusive contracts with a provider, as opposed to VA prices for the same product that do not involve exclusive contracts.

- Data collected on the 1998 fee schedule amounts for the six items for areas within and areas outside the continental United States.

- Data collected on the coding recommendations for over 200 HCPCS codes and information identifying the HCPCS codes reviewed.

By asking for the methodology used in collecting the data in each of the four steps, we are trying to learn, in any instance in which the sample was taken, and what measures were used to ensure that the sample was random, representative, sufficient in size, and unbiased.

We have contacted, by telephone, Mr. Joel Kaiser at HCFA to obtain this information. Mr. Kaiser provided us with a copy of VA data. On September 22, 1999, we sent HCFA a written request for the additional information noted above. We have received no information on the methodology of the evaluation or data collected despite the fact that we specifically alerted the agency to the impending deadline. A copy of the letter is enclosed for your review.

II. HCFA HAS NOT JUSTIFIED ITS DETERMINATION THAT CURRENT PRICES ARE "GROSSLY EXCESSIVE" OR THAT ITS REVISED PRICES ARE "REALISTIC AND EQUITABLE"

There is no sound basis provided in the Notice demonstrating that the current rates for the six items are grossly excessive, nor that the proposed methodology based on VA rates and mark-ups will yield realistic and equitable payment levels. In fact, the use of the VA data—which we will show later to be artificially narrow and unrepresentative of the true marketplace—tends to bias the estimated prices inappropriately downward. This bias results in overstating significantly the need for any downward adjustment in Medicare rates for the six items.

A. There are no market distortions and no "grossly excessive" prices.

All of the factors HCFA cites in its proposed rule as possibly indicating that a payment level is "grossly excessive" suggest that HCFA must identify a distortion that is keeping the marketplace from arriving at a reasonable price. The factor offered by HCFA as evidence that a reduction in payment levels is justified (i.e., a difference between VA and Medicare rates) simply does not relate to the kinds of factors that HCFA has defined, in its regulation described above, as the

appropriate criteria for judging "gross excess." HCFA has not identified anything in the market for the items that is preventing the market from producing reasonable prices.

B. HCFA's methodology and use of the data are flawed and do not produce "realistic and equitable" prices.

HCFA's evaluation does not provide a sound and unbiased basis on which to make findings about adjustments in prices. The agency did not conduct a survey of representative prices and did not make use of available marketplace information. Stated more colloquially, HCFA did not look at real-world, marketplace prices in any way or in any form in arriving at its conclusions. Rather than performing an appropriately-designed market survey that could yield a representative sample, HCFA instead elected only to compare Medicare rates with VA rates.

We have real concerns with this course of action:

- First, the HCFA Notice offers no rational explanation of why HCFA chose VA rates as the relevant benchmark for any specific item's prices.

- Second, the Notice does not provide any information supporting HCFA's premise that current prices paid by the VA for any or all of the items under review are representative of wholesale prices in the marketplace.

- Third, the Notice provides no information indicating that HCFA took into account product mix and actual sales to the general population, the VA, or the Medicare population.

- Finally, it does not appear that HCFA considered any differences in costs of contracting (e.g., billing) with the VA and with actual wholesalers.

At the outset, it is important to recognize that current prices paid by the VA are not likely to be representative of wholesale prices in the marketplace. VA regulations demand that the agency receive "most favored customer pricing" from its vendors. To do business with VA, manufacturers are *required* to discount their wholesale prices (if they provide wholesale pricing) or substantially discount their list price. These factors indicate that VA prices are generally the best prices available to any purchaser—which indicates that they are likely to be lower than prices to other entities. At a minimum, these factors indicate that HCFA should expressly have provided a rationale and explanation for choosing the VA prices as representative of marketplace wholesale prices.

Furthermore, the use of a single VA rate for an item assumes that there is a similar product mix in purchases by the VA and by the general public or the Medicare population. There is no factual basis or analysis of this issue in the HCFA Notice. To the extent that an item purchased by the VA is a low-end (lower priced) item or predominately a low-end item, while purchases in the marketplace reflect a different product mix, the VA rate will not be representative of marketplace purchases or wholesale prices. For example, one manufacturer of vacuum erection

devices (HCPCS code L7900) reports that for 1998, approximately 90% of all sales to VA hospitals were for the company's low-end model. The profile of this company's non-VA sales, however, is very different from that of its VA sales. In 1998, about 80% of non-VA sales by this manufacturer were for the two higher-end models. Because the methodology used by HCFA almost exclusively incorporates sales of the low-end model, it underestimates the appropriate Medicare reimbursement rate.

There is another potential source of bias in the choice of the VA rate as the relevant wholesale price. The VA price will be a particularly poor proxy for the true wholesale price to the extent it is based on exclusive Veterans Integrated Services Network (VISN) contracts. In general, marketplace prices will tend to be lower for those customers that can guarantee high volumes or provide opportunities for lower costs of administering contracts. The prices under exclusive contracts—those in which a particular manufacturer is selected as the sole supplier—will be the best price offered in exchange for a commitment of all of the VA's business. These prices will tend to be set at low rates and, more importantly, are not even representative of rates paid by the VA to manufacturers under non-exclusive contracts.

There are ancillary risks associated with the assumption in the HCFA Notice that the VA rate is representative of wholesale rates and is an appropriate basis for establishing payment levels. The fact that a manufacturer may offer the VA a particular rate on the Federal Supply Schedule does not necessarily mean that this rate could economically be offered to all purchasers in the marketplace. In particular, other purchasers may not be able to meet some of the criteria met by the VA including: large volumes of purchases; willingness to commit to volume purchasing; predictable volumes of purchases; and one-step billing procedures.

The choice of VA pricing as a proxy for wholesale prices in the marketplace, based on all of these factors, raises fundamental concerns about its validity—none of which are addressed in the HCFA Notice. These concerns are compounded by HCFA's decision to establish retail prices simply by applying a 67% markup to the VA wholesale rates. The HCFA Notice does not provide any data or information supporting the selection of the specific 67% markup. There is no information provided to demonstrate that the products on which this mark-up is based are in any way similar to or representative of the six items. Further, the proposed 67% mark-up does not appear to take into account any added cost of doing business with Medicare. Significant costs incurred by suppliers in the Medicare claims billing process would not be reflected in the VA prices because the supplier has no individual claims billing burden under the VA system.

Finally, there is no discussion in the Notice of an alternative to which HCFA has turned in other circumstances in reviewing payment levels—consideration of marketplace data, prices, and sales. There is no basis provided in the Notice for rejecting the practical alternative of conducting a marketplace survey of items to determine the appropriateness of current payment levels. With appropriate methodology and design, a marketplace survey can provide a practical and efficient way to assess the marketplace. Instead, HCFA appears to have used the flawed VA rate plus a 67% mark-up for identifying (incorrectly) possible excessive charges, and then compounds the error by establishing proposed payment levels based on its flawed methodology.

C. HCFA's reliance on a flawed evaluation is arbitrary and capricious under the Administrative Procedures Act.

In failing to conduct a survey or detailed and principled analyses of representative, marketplace prices for the six items and, instead, relying upon the narrow subset of prices paid by the VA, HCFA did not follow basic principles of survey design and methodology. As a result, HCFA has erred by relying on such a flawed evaluation to establish prices for the six items, and, therefore, the decision to reduce Medicare payments is arbitrary and capricious.

In taking action, an agency must consider the relevant factors and articulate a rational connection between the facts found and the choice made. *Baltimore Gas and Electric Co. v. Natural Resources Defense Council, Inc.*, 103 S. Ct. 2246 (1983). An action is arbitrary and capricious if the agency relied on factors other than those intended by Congress, did not consider an important aspect of the issue confronting the agency, or offered an explanation for its decision which runs counter to the evidence before the agency or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Company*, 103 S. Ct. 2856 (1983).

In *St. James Hospital v. Heckler*, the United States Court of Appeals held that the Secretary's Malpractice Rule was arbitrary and capricious because the study relied upon in developing the Malpractice Rule was statistically unreliable. *St. James Hospital v. Heckler*, 760 F.2d 1460 (7th Cir. 1985). The Malpractice Rule contained a new formula for reimbursing Medicare health care providers for malpractice insurance premiums associated with the care of Medicare patients. *Id*. At 1462. In developing the Malpractice Rule, the Secretary relied upon the statistical information contained in a study known as the Westat study. The general purpose of the Westat study was to analyze the frequency and type of malpractice claims and awards between July 1, 1976 and October 31, 1976. *Id*. At 1466. Problems with the Westat study included, but were not limited to, the statistical error of not acquiring data from self-insuring providers (usually hospitals) and surveying only those malpractice claims that closed during a single four-month period. *Id*. The Court recognized the statistical limitations of the Westat study and determined the Secretary committed a clear error of judgment in relying on the study as the sole empirical basis for the Malpractice Rule. *Id*. At 1468.

Similarly, in *Almay v. Califano*, cosmetic manufacturers challenged the FDA's proposed regulation governing hypoallergenic cosmetics. *Almay, Inc. v. Califano*, 569 F.2d 674 (D.C. Cir. 1977). Essentially, the dispute between the cosmetic manufacturers and the FDA centered around the FDA's definition of "hypoallergenic." In defining the term hypoallergenic, the FDA relied upon the Bureau of Consumer Protection of the Federal Trade Commission (FTC) consumer survey on hypoallergenic cosmetics. The FTC consumer survey was: (1) limited in population sample and number of questions; (2) silent in important respects; (3) lacked a breakdown between users and non-users; (4) lacked a tabulation; (5) established that consumers lacked medical knowledge sufficient to distinguish skin reactions; (6) produced results which should be used with caution; and (7) probably produced fewer "correct" definitions because it

was not limited to consumers interested in the subject, *i.e.*, hypoallergenic cosmetic users. *Id*. At 682. The Court held that the FDA's action in reliance on such a flawed survey was arbitrary and capricious. The Court further emphasized the need for rationality, in the interest of justice and in the interest and continued viability and public acceptance of the federal regulatory scheme. *Id*. At 682.

As these cases demonstrate, courts routinely set aside agency decisions that are grounded in inadequate surveys. Indeed, this seems a clearer case of an arbitrary and capricious agency action because HCFA failed to follow even the basic elements of survey technique. As a result, we believe a court would invalidate the HCFA's decision.

III. HCFA PROPOSES TO LAUNCH ANOTHER ROUND OF PROPOSED CUTS, DESPITE THE FACT THAT KEY ISSUES RAISED BY ITS EARLIER ACTIONS REMAIN UNRESOLVED

HIMA's final concern is simply that HCFA is launching another round of inherent reasonableness payment reductions despite the fact that serious public concerns, including concerns expressed in Congress, abound over the agency's previous actions regarding implementation of this authority. Most troubling, virtually none of these issues has been resolved.

Last year, HIMA sent comments to HCFA on its January, 1998, interim final rule implementing the agency's inherent reasonableness authority, and HIMA also sent HCFA comments on the Fall, 1998, initial notices of inherent reasonableness proposed by the agency's Durable Medical Equipment Regional Carriers regarding blood glucose test strips and lancets. In our letters, as well as in the detailed economic and procedural analyses we included, we pointed out many defects in the inherent reasonableness process. To this day, HCFA has not resolved these issues.

The concerns we are today raising in this letter include many of the same issues we have previously raised. We believe that HCFA continues to act arbitrarily without regard to matters we have addressed before: the impact of severe Medicare payment reductions on beneficiary access, on medical technology innovation, and on Due Process HCFA offers the public.

A. The General Accounting Office is currently investigating HCFA's last proposed payment cuts

Because of the problems with HCFA's 1998 inherent reasonableness adjustments to test strips and lancets, Rep. Bill Thomas (R-Calif.), Chairman of the House subcommittee that oversees Medicare, has asked the General Accounting Office (GAO) to investigate whether HCFA has overstepped the bounds of its inherent reasonableness authority. Rep. Thomas requested that the GAO determine what impact on patients the GAO may anticipate as a result of the proposed inherent reasonableness adjustments. Rep. Thomas also noted his concern about the impact on small business.

Rep. Thomas requested the GAO to evaluate several issues including, but not necessarily limited to, HCFA's use of retail prices in conducting a survey and the role of DMERCs in the process. The GAO has not completed its review of the 1998 inherent reasonableness reductions or its review of the inherent reasonableness process itself. The outcome of the GAO report could have substantial impact on how HCFA conducts inherent reasonableness evaluations. It makes no sense that HCFA would initiate another inherent reasonableness reduction without the benefit of the GAO report. It makes even less sense that HCFA would repeat many of the same mistakes it made in 1998.

B. HCFA has not responded to the comments on its interim final rule published in January, 1998

In his request to the GAO, Rep. Thomas also expressed concern regarding HCFA's promulgation of its inherent reasonableness authority via an interim final rule rather than a proposed rule with a notice and comment period. Rep. Thomas stated that "the use of an interim final rule can undermine the fundamental belief that HCFA should comply with due process procedures in exercising its authority." In addition to raising substantive concerns about the content of the rule, many of the public comments filed after the rule became effective disagreed with HCFA's decision not to seek prior comment for such an important subject. Because the comments raised very important issues that were not considered in formulating the existing rule, HCFA should respond to the comments before the agency further pursues any inherent reasonableness actions.

IV. CONCLUSION

As this letter explains, the action proposed by HCFA violates the law.

- First, HCFA failed to provide adequate notice of its intended action and failed to comply with national-level notice process for payment adjustments exceeding 15%.

- Second, the proposed changes are arbitrary and capricious because they are based on a flawed evaluation and inadequate data.

Beyond this violation of the law, the HCFA proposal is ill-conceived in offering these reductions, when the appropriateness—perhaps even the legality of another HCFA proposal to make similar reductions more than a year ago—are yet unresolved and under study by the GAO.

It might be somewhat easier to overlook such flaws were it not for the clear impact on patient health they portend. But these are deep cuts. They cannot help but affect access to therapies patients need. Especially troubling is their potentially chilling effect on the willingness of innovators to take the financial and professional risks of continuing in such product categories targeted for reductions. And equally of concern must be the subtle, though clear, message they hold for innovators in other fields of medical technology that may well be addressed in similar Notices in the future.

Therefore, we respectfully request that HCFA withdraw the proposal of August 13, 1999, to make such dramatic reductions in payment levels for these technologies.

Respectfully Submitted,

Pamela G. Bailey

Enclosure--HIMA FOIA Request for Information on the Methodology of HCFA's Inherent Reasonableness Evaluation (September 22, 1999)