MEDICARE CARRIER ASSESSMENT OF NEW TECHNOLOGIES

OFFICE OF INSPECTOR GENERAL

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EXECUTIVE SUMMARY

PURPOSE AND OBJECTIVES

This inspection report reviews technology assessment activities by the Medicare carriers. We examined how the carriers identify new technologies, and how they make decisions about coverage and pricing for new devices, diagnostic tests, procedures, and treatment modalities. Also, we addressed how the carriers perceive their overall performance in carrying out technology assessment activities.

BACKGROUND

Total Medicare expenditures increased at an average annual rate of 12 percent over the years 1976 to 1988, but Medicare Part B expenditures increased at an annual rate of 18 percent over the same years. In dollar terms, the Part B payments made by Medicare carriers increased an average of $1.8 billion a year, to $26.1 billion in 1988. Studies conducted by the Health Care Financing Administration (HCFA) and the Office of Technology Assessment indicate that new health care technologies account for a substantial portion of the annual increase.

In their role as processors of approximately 400 million claims annually for health care items and services, the Medicare carriers are usually the program's first point of contact with technologies new to the medical marketplace.

The carriers are called upon to identify and to make coverage and pricing decisions about almost all new health care technologies. Ordinarily the carriers decisions are final; HCFA carries out national assessments on only 20 or 30 new technologies a year.

METHODOLOGY

We based this inspection on:

- structured interviews with representatives of all the Medicare carriers that were responsible for processing Part B claims during the summer of 1988;
- written information provided by the carriers concerning their experiences in assessing five particular new technologies;
- discussions with outside observers, including representatives of manufacturers, insurance organizations, and national organizations active in assessing health care technology; and
- the HCFA's Medicare Part B payment data records, from which we derived payment amounts for particular codes provided by the carriers.

MAJOR FINDINGS

Our findings on carrier assessment of new technologies reflect three major themes: (1) limited information about emerging technologies, (2) inconsistent coverage and pricing decisions, and (3) economies not realized. We reflect these themes in our findings:

> *The HCFA has moved to improve carrier coverage and pricing. However, carriers desire additional and more timely information on coverage and pricing matters.*
>
> *Carriers are inconsistent in coverage and pricing decisions involving new technologies. Some of the variations are unwarranted (particularly in pricing).*
>
> *Carriers have no system for ensuring that payments for new technologies decrease in response to decreasing costs for delivering an item or service.*

We organized our individual findings according to the Medicare carriers' process for assessment of new technologies: (1) identifying the new technology as such, (2) deciding whether or not to include it as a Medicare covered item or service, and (3) deciding on the reimbursement amount, or price, to allow for it.

Overall Performance

- The carriers' self-rankings indicate substantial room for improvement in the way they assess new technologies. In only one of four categories do a majority rate the carrier performance as good.

Identification

- More than one-third of all carriers have experienced major problems with the identification of new technologies. Included among them are 6 of the 11 largest carriers.

Coverage

- Most carriers use professional acceptance as a major criterion when making coverage decisions about new technologies. Less than 10 percent of the carriers cite cost effectiveness as a major criterion.

- Respondents at one-third of the carriers say that the carriers, as a group, are at most minimally consistent in making coverage decisions about new technologies.

- When they make coverage decisions about new technologies, most carriers get input from such operationally related sources as HCFA, other carriers, or their own private business segments.

- However, the carriers strongly support the concept of a national clearinghouse that would share information about coverage issues among carriers.

Pricing

- Most carriers use more than one method to set reimbursement amounts for new technologies. The method used by the most carriers is that of comparison to similar codes.

- Reimbursement amounts allowed for new technologies vary significantly from one carrier to another. The variation is much greater than that accounted for by differences in per capita personal income across the country.

- Although about half the respondents think that the cost of providing a new technology tends to decrease during the 2 or 3 years following its introduction, none identify any special initiatives to avoid overpayments by Medicare in such instances.

RECOMMENDATIONS

The HCFA should continue to improve its own capability and that of the carriers to identify emerging technologies and to make more informed, explicit, and consistent coverage and pricing decisions concerning new technologies.

Toward this end HCFA should:

(1) continue to improve communication among the carriers through increased use of national and regional technical advisory groups,

(2) continue to improve carrier access to comparative Medicare payment information about new technologies,

(3) review the performance of carriers in identifying, covering, and pricing specific new technologies, and

(4) cooperate with the Public Health Service in proactively and routinely compiling and rapidly disseminating information on new health care technologies through clearinghouses or other appropriate means.

The HCFA should seek legislative authority to broaden the bases upon which it can establish reimbursement amounts for new and emerging technologies other than physician services. This authority should be available to HCFA both at the time of the initial coverage decision and as the technology matures.

The legislation should supplement current authorities by allowing HCFA to:

(1) limit initial payments based on a consideration of the cost of developing and delivering the technology,

(2) subsequently reduce the allowable charges for new technologies as they mature in order to take advantage of reduced costs, and

(3) establish regional or national reimbursement limits based on simple and easily verifiable criteria such as the mere existence of substantial variation in reimbursement rates.

COMMENTS AND OIG RESPONSE

In its written comments and at subsequent meetings, the HCFA recognized that problems exist with the carrier assessment of new technologies and noted that it has taken numerous recent initiatives to improve technology assessment. Some of the actions we recommended are included among the HCFA initiatives. The HCFA was concerned that our findings, at least in part, may no longer be valid because of its recent efforts. It asked the OIG to conduct an additional study aimed at assessing the effectiveness of its recent initiatives.

We agree that HCFA has moved to resolve the problems addressed in this study. For this reason we have removed from this report a statement, contained in the draft report, that the current procedures for carrier coverage and pricing of new technologies constitute a material internal control weakness within the meaning of the Federal Manager's Financial Integrity Act. We have agreed to work with HCFA in evaluating the effectiveness of its efforts to improve carrier assessment of new technology.

The HCFA agreed that additional legislative authority would help it improve coverage and pricing decisions for nonphysician services. The HCFA believes that physician payment reforms recently enacted in the Omnibus Budget Reconciliation Act of 1989 (OBRA-89) will provide an appropriate framework and sufficient authority to improve coverage and pricing decisions relating to physician payments.

We agree and we have modified our legislative recommendations to focus exclusively on nonphysician services. But we are concerned about the practical aspects of the new physician payment reform provisions. In order to develop fee schedules for new and emerging treatment modalities, HCFA must identify them. We believe that the ability to identify emerging new technologies is the area of greatest weakness in the current system. We are hopeful that HCFA's recent initiatives will be effective in addressing this weakness. We will know more when our future evaluations, mentioned above, are completed.

We also remain concerned that the many Part B payments for nonphysician services, such as durable medical equipment, prosthetics, and physiological testing, are not covered by the payment reforms of OBRA-89 . We believe our legislative proposals are particularly important for these nonphysician services.

The HCFA disagreed with our recommendation for disseminating coverage and pricing information among carriers through a clearinghouse because it would not be cost effective, and because carriers do not use current clearinghouses. We continue to support this recommendation. In our survey, the carriers themselves asked for this kind of assistance. We believe the current clearinghouses are too passive and often impracticably slow because they rely upon specific requests from the carriers. What we have in mind is a more proactive and orderly dissemination of information. We think that a more proactive clearinghouse would be an effective way to do this, but we would support any other technique provided it is aggressive and systematic. We have modified the wording of the recommendation to make our intent more clear.

The Public Health Service and the Office of the Assistant Secretary for Planning and Evaluation both recognized the need to improve carrier coverage and pricing decisions. They both supported the idea of a clearinghouse to share coverage and pricing information.

The Health Insurance Association of America and the Health Industry Manufacturers Association also commented on our draft report. They agreed with most of our findings and recommendations.

The text of all comments and our detailed responses to them are in appendix D.

TABLE OF CONTENTS

EXECUTIVE SUMMARY

INTRODUCTION 1

FINDINGS 6

Carrier Identification Of New Technologies 6

Carrier Coverage Of New Technologies. 8

Carrier Pricing Of New Technologies. 16

Overall Carrier Performance In Assessment Of New Technologies 22

RECOMMENDATIONS 24

Comments And OIG Response 26

APPENDIX A

Methodological Notes A-1

APPENDIX B

Case Studies B-1

APPENDIX C

Glossary C-1

APPENDIX D

Comments On The Draft Report And OIG Responses D-1

APPENDIX E

Endnotes E-1

INTRODUCTION

BACKGROUND

Basis in the Law

Medicare is a health insurance program for the aged and disabled. Since enactment in 1965 it has provided coverage for broad categories of benefits.[1] Among these benefits are (1) services by physicians, and (2) supplies such as equipment and diagnostic tests ordered by physicians. All of these are covered under supplementary medical insurance (Part B of Medicare). Hospital insurance (Part A) covers services provided by hospitals, skilled nursing facilities, and home health agencies.

Generally, Part B of Medicare covers all services ordinarily furnished by physicians licensed to practice medicine and those items or services furnished by nonphysician suppliers under a physician's supervision or in response to a physician's request. But coverage is not unlimited. The law provides a general exclusion that applies to every claim for benefits:

> *"...no payment may be made for any expenses which... are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the function of a malformed body member...."*[2]

Administration by Carriers

The law assigns to the Secretary of Health and Human Services (HHS) overall responsibility for administering Medicare. Within HHS, the Health Care Financing Administration (HCFA) has primary responsibility for Medicare operations. The law authorizes the Secretary to enter into contracts with carriers for performance of payment and other program functions.[3] Under Part B, these carriers are private insurance organizations that contract with the Secretary to make coverage determinations, set reimbursement amounts, and disburse payments in a local service area, most often a State.

One of the essential functions that carriers perform is the making of coverage decisions in response to claims for benefits. Carriers do not rely on an all-inclusive list of Medicare covered items and services. In principle, each of the estimated 500 million Medicare Part B claims filed annually is the subject of a coverage determination by a carrier. In practice, few individual claims present serious coverage issues. Small numbers each year include new or unusual devices, tests, procedures, or treatment modalities which the carriers must assess, and for which they must make coverage and pricing decisions.

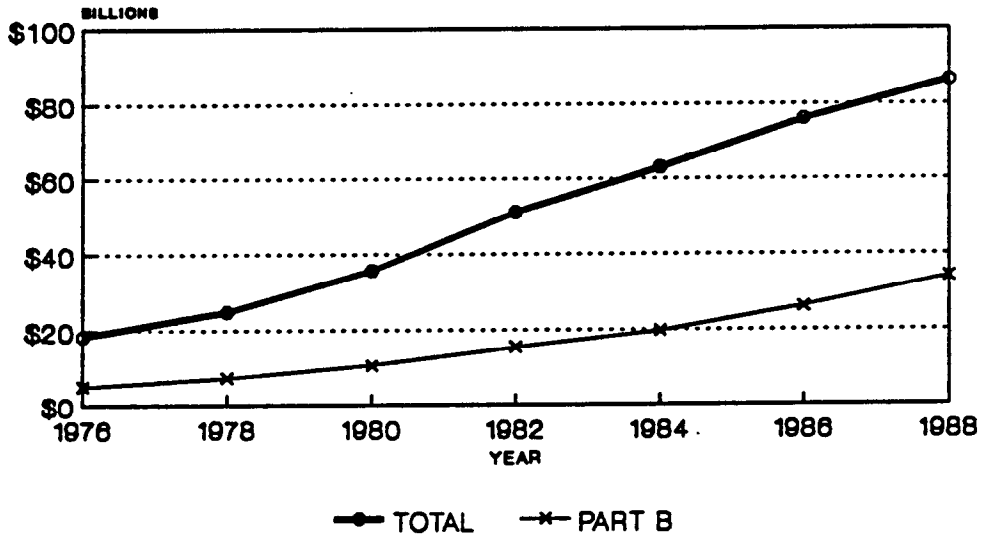
Carriers are bound by policy guidance that HCFA has issued on a specific new technology. When such guidance is not offered, each carrier is authorized to make decisions about what is reasonable and necessary and to apply these decisions in making coverage determinations for individual claims.[4]

Because they receive and adjudicate claims, carriers perform the bulk of assessment on new technologies. A small number of items and services (usually 20 to 30 a year) become the subjects of a nationally centralized technology assessment process, either because they present broad national policy issues or because it has become apparent that different carriers have made inconsistent coverage decisions. Carriers refer these issues to HCFA, which coordinates the centralized assessment and advises the carriers of the result.

Trends in Medicare

Total Medicare expenditures increased at an average annual rate of 12 percent over the years 1976 to 1988, but Medicare Part B expenditures increased at an annual rate of 18 percent over the same years (figure 1). In dollar terms, the Part B payments made by Medicare carriers increased an average of $1.8 billion a year, to $26.1 billion in 1988. Studies conducted by HCFA and the Office of Technology Assessment indicate that new health care technologies account for a substantial portion of the annual increase.

FIGURE 1
MEDICARE PAYMENTS, TOTAL AND PART B
1976 - 1988



SOURCE: HEALTH CARE FINANCING ADMINISTRATION, OFFICE OF THE ACTUARY

The increasing number of enrollees contributes about 13 percent of the increase for Part B expenditures.[5 6] Inflation, the largest factor, contributes about 50 percent of the increase, and increasing use of services contributes the remaining 37 percent. The latter two factors reflect

the effects of technological innovation. Both include the costs of developing and introducing new items and services and demand for new services.[7]

PURPOSE AND OBJECTIVES

This study reviews technology assessment activities by the Medicare carriers. It examines how the carriers identify new technologies and how they make decisions about coverage and pricing for new devices, diagnostic tests, procedures, and treatment modalities. It also addresses how the carriers perceive their overall performance in carrying out these functions.

METHODOLOGY

We interviewed each of the 45 carriers about the process they use to assess new technologies and their evaluation of the assessment activity. We spoke with medical directors of all 29 carriers who had them. In the case of 16 carriers that did not have medical directors, we interviewed responsible staff persons who were knowledgeable about Medicare operations. Our detailed, structured interviews followed introductory letters and preliminary conversations to identify the respondents at each carrier. We interviewed chief medical officers and those who oversee decisions about new technologies; as such these persons are likely to be highly knowledgeable about carrier assessment activity.

Since all carriers participate in technology assessment, we chose to interview all of them. In analyzing their responses, we grouped the carriers by size, census region, type (Blue Shield plan or commercial carrier), and presence of a medical director.

In addition, we interviewed 12 observers outside the carriers for independent perspectives on how well the carriers are doing in assessing new technologies and for recommendations on any improvements that might be made (appendix A).

For a snapshot view of actual experiences, we asked the carriers about decisions they have made concerning a selection of new technologies. Through the introductory letters we asked what procedure codes they used for 12 technologies during the years 1985 through 1987. For 5 of these technologies we also asked for the carriers' experience with the key elements in the assessment: identification, coverage, and pricing (appendix B).

We reviewed HCFA's Part B payment records for these same five technologies in order to determine the number of services reported by each carrier in the years 1985-1987 and the actual expenditures reported. Brief descriptions of the technologies can be found in appendix C.

OTHER STUDIES AND ACTIONS

In 1984 the Office of Technology Assessment explored the dual relationship between Medicare and technology and identified policy options.[8] In 1985 the consulting firm of Lewin and Associates, under a contract with the Assistant Secretary for Planning and

Evaluation, examined the Medicare coverage process for new technologies and recommended changes in five specific areas of policy-making.[9] And HCFA itself studies technology assessment in its role as the source of policy guidance for the carriers.[4 10]

During 1987, in compliance with the terms of an agreement to settle a beneficiary's lawsuit, HCFA published in the Federal Register a notice and request for comments about procedures for medical services coverage decisions.[11] Many of these comments reflected opinions that Medicare is not consistent, particularly in coverage decisions.

In January of 1989, following analysis of the comments, HCFA published a proposed rule on criteria and procedures for making medical services coverage decisions that relate to health care technology.[12] The proposed rule addresses criteria and procedures for HCFA decisions as to whether and under what circumstances specific health care technologies could be considered reasonable and necessary and therefore covered under Medicare. The rule would provide for more openness and streamlining of the decision making process through increased public participation and expedited review of new breakthrough technologies.

A second lawsuit,[13] recently certified as a class action in U.S. District Court in Massachusetts, seeks in effect an individual technology assessment by the carriers for each claim. If successful, no claim could be denied on the basis of a centralized decision that an item or service is not reasonable or necessary within the meaning of Medicare law.

Along with the regulatory process, HCFA has moved with a number of administrative actions aimed at improving the assessment of new technologies, including that done by the carriers. Among these actions are the following:

- All carriers are required to submit a copy of all medical coverage policy. This policy will be reviewed to identify carriers with widely variant policy.

- All carriers are required to have licensed physicians as medical directors.

- Medical directors conferences are to be held at least annually (in fact have been semiannual) and are to devote attention to technology assessment.

- The Coverage and Payment Technical Advisory Group and the HCFA Physicians' Panel both discuss emerging technology and coverage issues.

- The HCFA is evaluating the reasonableness of price levels for real time cardiac monitoring.

In May 1988, the National Advisory Council on Health Care Technology Assessment issued a report on the Medicare coverage process.[14] The report is organized in chronological order of the steps in the coverage and assessment process that applies to those technologies chosen for

national assessment. It is exemplified by the progress of nine selected technologies. The Council made 23 recommendations for improving the timeliness, openness, and quality of this assessment process. National technology assessments are, of course, binding on carriers when incorporated into HCFA instructions. Moreover, the national process provides a model for portions of the carriers' own assessment activities.

FINDINGS

Our findings on carrier assessment of new technologies reflect three major themes: (1) limited information about emerging technologies, (2) inconsistent coverage and pricing decisions, and (3) economies not realized. We reflect these themes in our findings:

> *The HCFA has moved to improve carrier coverage and pricing. However, carriers desire additional and more timely information on coverage and pricing matters.*
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> *Carriers are inconsistent in coverage and pricing decisions involving new technologies. Some of the variations are unwarranted (particularly in pricing).*
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> *Carriers have no system for ensuring that payments for new technologies decrease in response to decreasing costs for delivering an item or service.*

We organized our individual findings according to the Medicare carriers' process for assessment of new technologies: (1) identifying the new technology as such, (2) deciding whether or not to include it as a Medicare covered item or service, and (3) deciding on the reimbursement amount, or price, to allow for it.

CARRIER IDENTIFICATION OF NEW TECHNOLOGIES

Carriers rely primarily upon claims submissions and physician inquiries to identify new technologies.

For the identification of new technologies, carriers for the most part react to inputs from agents outside of Medicare. Few carriers actively seek to identify new technologies, and they usually react to external sources.

According to 80 percent of the carriers, the claims processing department is the primary site for identification of a new technology. Significant characteristics that trigger identification and review include claims submitted without a procedure code, or claims for items or services the carrier has not seen before or that have no established pricing. One carrier representative stated: "The claim cannot be categorized or explained and we don't know how to process it." Thus, identification takes place by exception—if the claim cannot be paid, it is passed on for further review.

Fewer than 20 percent of the carriers have written guidelines to address identification of new technologies. Those who do include the guidelines in their claims processing manuals. Ordinarily, a new technology is identified not by its meeting a defined criterion, but by its failing to fit payment instructions.

At the larger carriers particularly, departments other than claims processing, often professional relations or utilization review, identify new technologies. These departments are contacted by external sources such as physicians, manufacturers, national associations, and beneficiaries. Physicians account for the substantial majority of these contacts. They approach the carriers by telephone or letter or talk with carrier medical staff and advisers at professional meetings. Some physicians call a carrier before submitting a claim to learn if Medicare will cover an item or service. Others question the reimbursement amount received on a new technology about which the carrier was unaware.

Besides input from physicians, about one-third of the carriers identify manufacturers as a source for identification of new technologies. Larger carriers tend to rely on larger numbers of sources to identify new technologies. Of the 11 largest carriers, 10 draw on 3 or more sources, but only 13 of the 34 smaller carriers rely on as many.

More than one-third of all carriers have experienced major problems with the identification of new technologies. Included among them are 6 of the 11 largest carriers.

Providers sometimes cause significant problems for carriers by giving inadequate descriptions of new technologies on claims submitted for payment. If a claim carries a procedure code that does not accurately describe a new technology, this delays or defeats carrier identification. Intentionally or not, providers can thus exploit a vulnerability in the carrier identification process. Ten carriers report that a new technology billed under an established procedure code would not be recognized as new but would be paid as submitted. A carrier's failure to recognize a new technology can lead to several problems for beneficiaries, physicians, the health care industry, and program administrators. Any Medicare overpayments are subject to recovery. These overpayments, if not corrected promptly, create an erroneous impression throughout the community that Medicare now pays for the new technology. This opens the way to still more incorrect bills and additional improper payments. A carrier that does not recognize a new technology is prevented from informing providers at an early stage about Medicare's assessment of the technology. The carrier's claims processing department receives little or no guidance about the new technology, and the errors compound with each new claim submitted.

Sometimes, manufacturers also create problems for the carriers by providing data that are not relevant, objective, or complete. Many medical directors feel that promotional material is of questionable value to their assessment task simply because it is used as a marketing tool. One representative of a large carrier went on to say: "Technologies are presented initially by manufacturers who send their own literature and reference material. We have to follow up with our own literature search and often refute what is claimed by the manufacturer." Some carriers have developed referral procedures that attempt to place constraints on submission of promotional material in connection with assessment of new technologies.[15]

Sixty percent of carriers report that HCFA provides them with information on the identification of new technologies no more than occasionally.

The HCFA provides policy guidance to the carriers on allaspects of assessment for new technologies. All carriers receive the Coverage Issues Manual with information about national coverage decisions. However, a majority of the carriers say that they receive information about other new technologies, that have not been subjects of a national decision, no more than occasionally. Only one-third of the carriers report receiving information often or very often, and one-fourth say they receive it rarely or never.

Most carriers describe the information that HCFA supplies as guidelines (including manuals) and alerts to new technologies that have been identified elsewhere. The HCFA usually transfers information to the carriers formally, in manual instructions or written guidelines. These are the items carriers find most useful. Some carriers, however, say that they would like HCFA to provide more timely and specific information on the experience of other carriers with new technologies, and on when such technologies cease to be investigational or become obsolete.

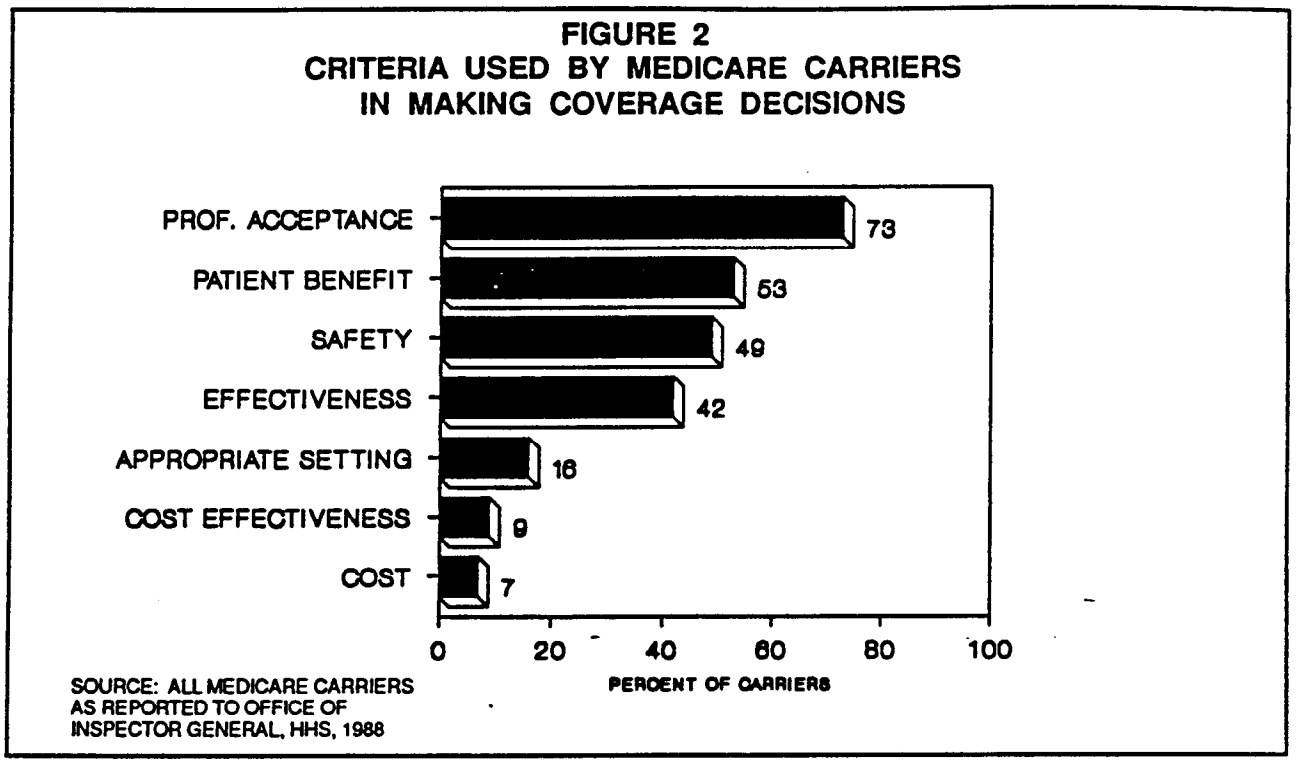
CARRIER COVERAGE OF NEW TECHNOLOGIES

Most carriers use professional acceptance as a major criterion when making coverage decisions about new technologies. Less than 10 percent of the carriers cite cost effectiveness as a major criterion.

In making coverage decisions, carriers use a small and consistent set of criteria, which include professional acceptance, patient benefit, safety and effectiveness (figure 2). These same criteria were identified in other studies of coverage decision making.[6 9] Guidelines issued by the Blue Cross and Blue Shield Association,[16] comments submitted in response to HCFA's notice,[4] and responses of the outside observers we interviewed taken together reflect a consensus about criteria for coverage.

Acceptance by the profession, which is identified by most medical directors as a major criterion, commonly has four characteristics. A new technology is generally accepted if:

- research and investigation are complete,
- value for diagnosis or treatment is demonstrated,
- it is in general use for patient care, and
- it does not involve drugs or devices not cleared by government regulators.



Since each of the carriers interprets the meaning of demonstrated value and general use within its service area, coverage decisions can and do vary, reflecting differences in local practice patterns. These variations are of concern to some carrier representatives who feel that health care has become "a much more uniform process nationally than it was in 1965 when Medicare was enacted." One of the medical directors observes, "the idea of local practice patterns that was accurate 20 or 30 years ago no longer applies today." The carriers are looking for more coordination—some even say uniformity—in coverage decisions.

The economic criteria, cost and cost effectiveness, are at the low end of the response scale in figure 2. Most carrier representatives view them as criteria for pricing only. They take the cost or cost effectiveness of a new technology into account only to limit payment to that for an older item or service that provides the same patient outcome. Among the remaining carriers that do not use the economic criteria, several dismiss them as irrelevant to health care decisions.

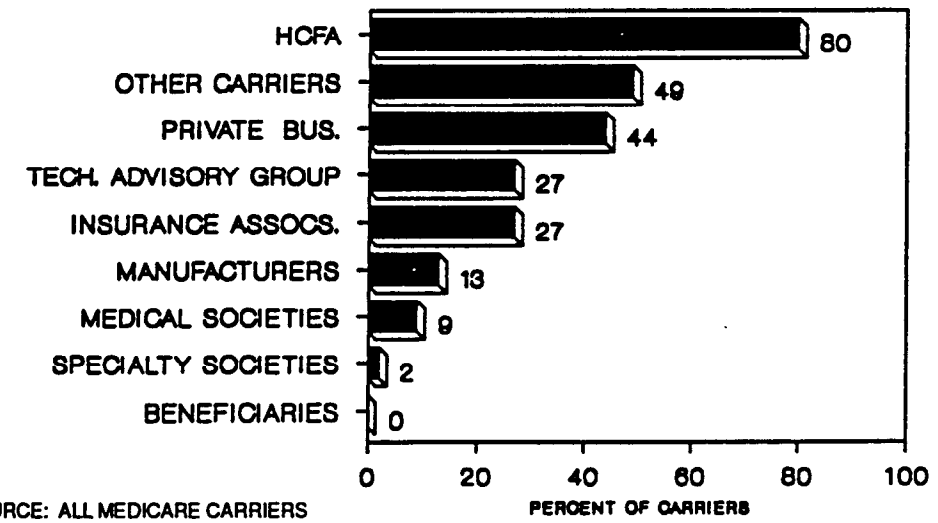
Five of the 12 outside observers we interviewed, including 3 of 4 manufacturer representatives giving their own opinions, feel that cost effectiveness should be considered as a major criterion in making Medicare coverage decisions.[17] One representative feels that carriers do use cost effectiveness but do not admit to doing so. This observer feels that the practice impairs the credibility of Medicare and suggests that HCFA publish a listing of coverage criteria that mandates consideration of cost effectiveness. On the other hand, six national organizations, including the Health Industry Manufacturers Association, express concern with use of cost effectiveness as a coverage criterion for Medicare.[18]

One manufacturer proposes that the burden of demonstrating relative efficacy should be assumed by the proponent of a new technology as an integral and routine part of research and development. According to this observer, a new technology should be shown to be economically responsible in order to earn Medicare coverage. All four of the manufacturer representatives whom we interviewed accept that burden of proof as part of their development costs.

When they make coverage decisions about new technologies, most carriers get input from such operationally related sources as HCFA, other carriers, or their own private business segments.

Carriers seek background and evaluation information from external sources to add to the knowledge of medical practice and scientific literature that their medical advisers bring to the assessment task. For this they turn to familiar organizations, primarily HCFA (figure 3). For instance, in our case study of tissue plasminogen activator, we found that 18 carriers (out of 27 that reported decisions) drew input from HCFA, and 16 from other carriers (see appendix B). Likewise, in the study by the Office of Technology Assessment, HCFA and other insurance companies are the two sources named most frequently by medical consultants.[19]

FIGURE 3
EXTERNAL SOURCES USED BY CARRIERS IN MAKING COVERAGE DECISIONS



SOURCE: ALL MEDICARE CARRIERS AS REPORTED TO OFFICE OF INSPECTOR GENERAL, HHS, 1988

The HCFA supports a number of Technical Advisory Groups (TAGs) consisting of contractor (carrier or intermediary) representatives and HCFA staff who meet to discuss and share information on common concerns. Although one carrier TAG centers its attention on coverage and payment issues, little more than one-fourth of the carriers identify it as an external source for information. Those who do so tend to be among the 10 or 12 carriers with

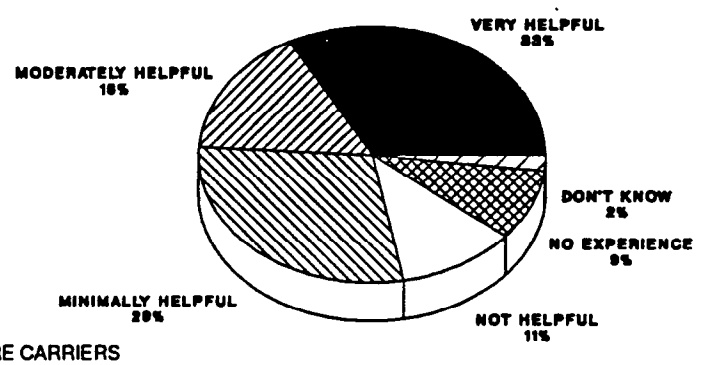
active representation in the group. All the carriers are aware of the existence of this TAG and receive minutes or reports of meetings. However, the extent to which each carrier uses the TAG discussions seems to vary directly with the extent of participation by its staff.

We learned of the Medical Issues Technical Advisory Group (MITAG) that includes the medical directors of all five carriers in HCFA's New York region. The MITAG meets twice a year, with the HCFA regional office providing administrative and organizational support. Carrier medical directors and their staffs set the agenda, make presentations, and lead the discussions. All the carriers in the region agree with HCFA that the MITAG facilitates exchange of important information, provides a forum for useful discussion of new technologies, and promotes consistency in carrier decisions. All consider active involvement by the medical directors critical to the group's effectiveness.

Carriers get less input from sources less closely associated with their own organizations and those less closely associated with Medicare administration. Notable for their absence as sources of input for coverage decision making are the Professional Review Organizations, State and Federal Government agencies, and suppliers of health care equipment. Fewer than 10 percent of the carriers draw upon local or State medical associations. None report any input from beneficiaries or beneficiary interest groups.

About half the carriers find the support they get from HCFA at least moderately helpful in making coverage decisions about new technologies. An additional 40 percent view HCFA support as minimally or not helpful.

FIGURE 4
HOW CARRIERS RECIEVE HCFA SUPPORT FOR MAKING COVERAGE DECISIONS



SOURCE: ALL MEDICARE CARRIERS AS REPORTED TO OFFICE OF INSPECTOR GENERAL, HHS, 1988

About half the carriers react positively to the help they get from HCFA in making coverage decisions, and many of these find the support very helpful (figure 4). Carriers find HCFA support helpful when it provides definite answers to specific questions. Included among the HCFA support that carriers find helpful are policy guidelines in the Medicare Carriers Manual and the Coverage Issues Manual. Several carriers single out the transmittal on magnetic resonance imaging as an illustration of how it should be done.[20] This transmittal, they say, includes definitive criteria and guidelines that are well researched, well documented, and well presented. Carriers also find helpful HCFA's sharing of experiences that other carriers have had with specific technologies. They appreciate the opportunity to share responses by HCFA central and regional offices to specific requests.

Among those carriers who say that HCFA is not helpful, the theme of timeliness dominates; information comes to them slowly. Some carriers mentioned, too, that information from HCFA is overly open to interpretation. The guidelines are not as specific as they could be. Each carrier is left to make its own coverage decisions, opening up the potential for inconsistency. The carriers want HCFA to provide more background, a better rationale for decisions, and prompter exchange of information among carriers.

A number of carriers ask that HCFA provide them with a sense of reasonable pricing ranges for new technologies, possibly by passing along reimbursement rates set by other carriers. They bring up this point while addressing coverage questions. Many carriers see pricing, or at least the setting of relative values, as an integral part of the coverage decision process. Their perception is not unique to their role as carriers. A number of medical directors routinely include pricing recommendations along with their coverage decisions for Medicare and for private business segments.

At most carriers, physicians have the key role in making coverage decisions about new technologies. About one-fourth of the carriers, however, involve nonphysicians extensively in this process.

Although each carrier approaches the assessment of new technologies in its own way, the nature of the task leads to some common features among the different approaches. At each carrier one person has the key role in technology assessment. That person assembles and evaluates data and opinions and prepares the carrier decision (which may still need to be ratified by responsible authority in the carrier organization). The medical director has this key role at the 29 carriers that employ such a person. Other carriers involve nonphysicians extensively in the assessment process. Nurses were the coverage decision makers, for example, at 6 carriers out of 32 that covered the infusade pump, one of our case studies described in appendix B.

All 11 of the larger carriers have medical directors. All of them take the key role in technology assessment at their carriers, and nine of them work with medical advisory committees on such matters. These committees can be structured or informal, continuing or task oriented, internal or inclusive of physicians from outside the carrier. Many of the carriers that use committees think that the most objective committees involve more than one type of

medical specialist on every issue. They see consultant bias as an important vulnerability in technology assessment and seek input from other specialists as a check. Some carriers extend the concepts of openness and balance further by including the participation of other health care professionals. A few carriers allow for public input to the advisory committees.

At 12 carriers, the medical directors report that in assessing new technologies they work essentially alone. They frequently seek information from colleagues, research centers, specialty groups, and other medical directors, but the core evaluation is theirs alone. In supporting this approach, some note that an individual is better able to make a prompt decision than is a committee.

Only 8 of the 17 smallest carriers have medical directors. Most carriers without medical directors draw upon consultant physicians and precedents, but they have no internal process for assessment at the physician level. Smaller carriers often look to larger neighbors for advice in the form of precedents. A carrier with one or more centers of medical research in its service area is likely to receive some of the first claims for new technologies. But knowledge now spreads so quickly that small carriers see claims for some new technologies at almost the same time as their larger counterparts.

Nonphysicians who are involved extensively in the process for coverage decision making:

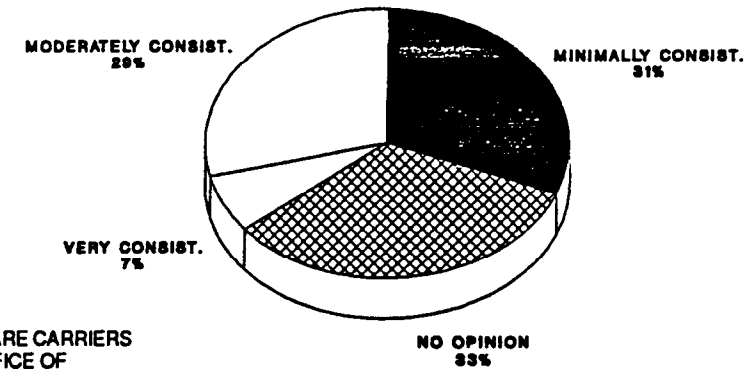
- rarely have operating guides,
- have few explicit limits to discretion, and
- usually are subject to internal quality review of their work in assessing new technologies.

Beginning in 1989 all carriers are required to have medical directors. Still, there may be a continuing role for experienced nonphysicians in support of the medical directors, and that role could be extensive in some situations.

Respondents at one-third of the carriers say that the carriers, as a group, are at most minimally consistent in making coverage decisions about new technologies.

The carriers split into three nearly equal groups in their opinions about consistency (figure 5). Many of the carrier representatives who say that coverage decisions are not consistent attribute this situation to a widespread lack of communication among the carriers. Representatives at other carriers say that more prompt, more effective, and more frequent communication between HCFA and the carriers would operate to increase consistency. Many of the respondents feel that regional medical meetings and a central coverage clearinghouse could open new possibilities for communication.

FIGURE 5
HOW CARRIERS VIEW THE CONSISTENCY OF THEIR GROUP IN MAKINNG COVERAGE DECISIONS



SOURCE: ALL MEDICARE CARRIERS AS REPORTED TO OFFICE OF INSPECTOR GENERAL, HHS, 1988

Almost all of the respondents who express an opinion regard consistency of carrier actions as a desirable attribute. Although some of them attribute inconsistency to differences in local patterns of medical practice, most say that new medical knowledge diffuses quickly through the health care delivery system today, much more quickly than was true at the birth of Medicare a quarter century ago. Few agree with the medical director who sees virtue in inconsistency, saying: "Lack of variability may not be an asset. What is to prevent all of us from going off in the wrong direction together?"

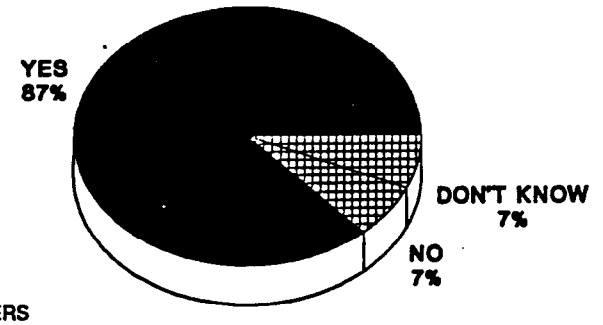
Those who say that the carriers are at least moderately consistent feel that by "asking around" they can get "a fair exchange of information." In their view any reported examples of inconsistency represent exceptions that have slipped through the system. These carriers cite their experiences with physicians who have moved from one carrier's service area to another. Such physicians sometimes have reported to the new carrier broader coverage and higher payments by the previous carrier. When the new carrier called to check the report, it was not confirmed.

Some medical directors believe that inconsistency gives the entire Medicare program a bad name, "especially when durable medical equipment is covered by one carrier and not another. It is difficult to make providers and beneficiaries see how Medicare can be a national program but not be consistent on what is covered." Experience with transtracheal oxygen in one of our case studies illustrates the point. During 1985, 18 carriers used 8 procedure codes in processing claims for tube insertion and gas supplies; in 1987, 25 carriers paid for the procedure and supplies under 10 codes (see appendix B).

The carriers strongly support the concept of a national clearinghouse that would share information about coverage issues among carriers.

The coverage clearinghouse may be an idea whose time has come.[21] All but six of the carriers (87 percent) regard it as a good idea (figure 6). Many carriers are extremely positive about the notion, calling it "an absolute necessity," or "a long overdue development." Those few carriers who do not consider the clearinghouse to be a good idea are troubled by its possible costs. It would entail creation of a new bureaucracy, they say, which would only add to the demands on their time and resources.

FIGURE 6
DO CARRIERS CONSIDER THE COVERAGE CLEARINGHOUSE A GOOD IDEA



.SOURCE: ALL MEDICARE CARRIERS AS REPORTED TO OFFICE OF INSPECTOR GENERAL, HHS, 1988

Those carriers who favor a clearinghouse cite the benefits of drawing on research already completed, thus eliminating needless duplication. They also believe that a clearinghouse would speed up the flow of information, a significant point in light of the carriers' desire for a faster flow of information from HCFA. An effective clearinghouse provides information promptly. Smaller carriers, with fewer resources for doing research, anticipate that a clearinghouse would furnish more complete information than they could obtain on their own. And finally, because participation by noncarriers could open access to a larger base of information, two-thirds of the carriers would welcome outsiders as contributors and as users.

Some important efforts now taking place are aimed at providing centralized information resources for health care technology assessment. Included among them are:

- American Medical Association, Diagnostic and Therapeutic Technology Assessment Project (DATTA). Uses consultants selected from a panel of more than 1000 physicians and publishes assessments in the association's Journal.

- Blue Cross and Blue Shield Association, Technology Evaluation and Coverage Project (TEC). Provides technical assistance to member plans for their consideration along with other factors in making coverage decisions.

- Health Insurance Association of America, Medical Practice Assessment Center (PAC). Began in 1987 with a report on underevaluated health care technologies. Included information on obsolete technologies, and commissioned a study on quality assessment.

- National Academy of Science, Institute of Medicine (IOM), Council on Health Care Technology. Developing an information clearinghouse on technology and technology assessment as mandated by Congress in 1984. Published an initial directory in 1988.

- National Center for Health Services Research and Health Care Technology Assessment through its Office of Health Technology Assessment (OHTA). Evaluates the safety and effectiveness of new technologies and synthesizes the results in an *Assessment Report* that is disseminated widely. This Office was reorganized under the recently enacted Omnibus Budget Reconciliation Act of 1989 (OBRA-89).

Few carriers draw on these resources now. One-fourth of the 27 Blue Shield plan carriers include TEC as an external source from which they get information for making coverage decisions. Just three carrier representatives, all of them medical directors, name DATTA as a source, and only one mentions IOM.

CARRIER PRICING OF NEW TECHNOLOGIES

Most carriers use more than one method to set reimbursement amounts for new technologies. The method used by the most carriers is that of comparison to similar codes..

Carriers set the reimbursement amounts for items and services covered under Part B of Medicare, including new technologies, by using a methodology called reasonable charge determination.[22] Ordinarily this methodology means that carriers collect histories of billed charges for each item or service. They allow as a reasonable reimbursement amount the lowest of (a) the billing provider's customary charge, (b) the prevailing charge for similar items or services in the locality, or (c) the actual charge. Sometimes it has proved difficult to collect charge histories for truly innovative technologies.

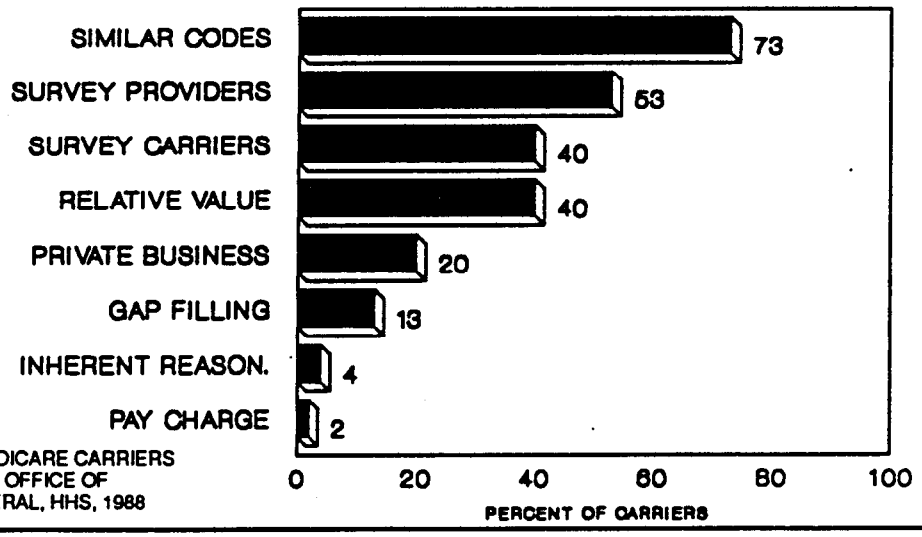
Moreover, the law places restrictions on the reimbursement amount allowed, additional to those derived for billed charge histories. Among these limitations have been freezes in physician fees, adjustments for inherent reasonableness, restrictions on overpriced procedures, special limits for cataract glasses and lenses, and controls on services by physician assistants and nurse anesthetists.

More recently, as part of OBRA-89, Congress amended the law to provide for payment of physician services according to a resource based relative value scale (RBRVS). The new

provisions address physician services only. They do not provide relative values for nonphysician services, nor do they extend to health care items covered by Medicare. And OBRA-89 does not address the potential for expansion of HCFA or carrier authority to broaden the bases upon which they can make reasonable charge determinations for the new and emerging technologies not covered by RBRVS.

The Medicare Carriers Manual gives policy guidance about the methods carriers should use to set the reimbursement amounts for a new technology that does not have a billing history.[23] The carriers consider an average of three methods when they are pricing a new technology. The most common methods seek to establish some relationship with prior experience (figure 7). Almost three-fourths of the carriers compare a new technology with similar codes. Often this comparison can be made by the carrier's own staff of reasonable charge specialists, using internal data. About one-half of the carriers seek precedents from providers or other carriers, and one-fifth from their own private business segments. All three of these common pricing methods involve contacts outside the Medicare carrier.

FIGURE 7
METHODS USED BY MEDICARE CARRIERS FOR PRICING NEW TECHNOLOGIES



SOURCE: ALL MEDICARE CARRIERS AS REPORTED TO OFFICE OF INSPECTOR GENERAL, HHS, 1988

About 40 percent of the carriers use another approach to pricing, relative value, which offers an estimate of the physician effort needed to deliver a service or procedure. Carriers especially prefer this method for surgical services. Their consultants and medical advisers often include relative value recommendations as an integral part of opinions about coverage. Or a carrier may draw on professional associations and published analyses for relative values. Some respondents, however, feel that reliance on specialist opinion makes the carrier vulnerable to

consultant bias. They would welcome a national fee schedule or a set of relative values provided by HCFA.

Although only 1 carrier reported a policy of simply paying submitted charges for a new technology, 13 set the reimbursement amount for plethysmography in this way (see appendix B). Some of these 13 pay submitted charges until they have accumulated sufficient charge data (through as few as four claims) to perform a reasonable charge analysis.

Few carriers report that they use inherent reasonableness to set prices for new technologies. Only two respondents in our carrier interviews include it as one of their pricing methods. In our case studies an average of four carriers report that they used inherent reasonableness in setting the price for each of the five new technologies. The maximum is eight carriers for the infusade pump.

Almost half of the carriers spoke of opportunities for making more clear the Medicare Carriers Manual instructions on calculation of reasonable charges. The instructions for new technologies, in particular those which have no prior charge history, could be made simpler. One respondent found that the instructions "have become so complicated as to be almost unbelievable." Another offered the opinion that "A Philadelphia lawyer could not figure it out." And a third respondent suggested that the whole process "reduces to a nonscientific wild guess. Usually, the price is on the high side. Almost always, it goes up."

These respondents and their counterparts at other carriers repeatedly ask for a framework that would allow them to know that their pricing decisions are not inconsistent with those of other carriers or the national Medicare program. They are looking for a better way to make comparisons with other carriers, non-Medicare payers, providers and suppliers, and most importantly HCFA's own pricing information.

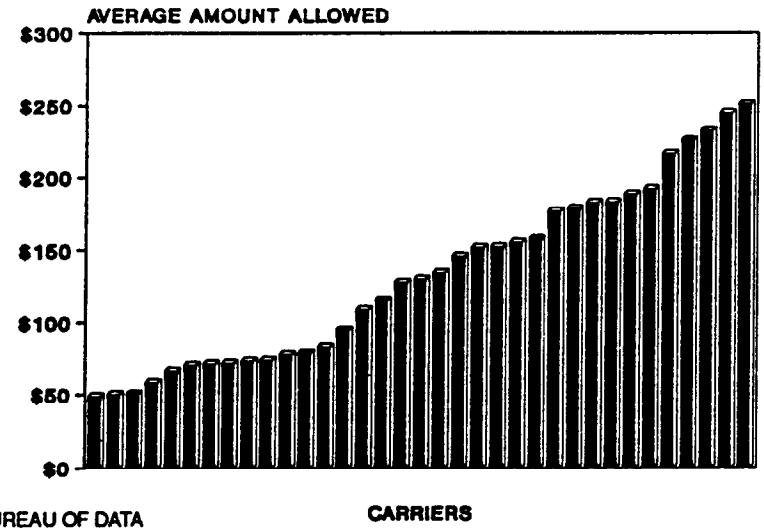
Reimbursement amounts allowed for new technologies vary significantly from one carrier to another. The variation is much greater than that accounted for by differences in per capita personal income across the country.

Not surprisingly, in view of the variety of methods that carriers are allowed to use to set reimbursement amounts, the average amount allowed for the same new technology can differ by several hundred dollars from one carrier to another. The 1987 data for one of our case study technologies, real time cardiac monitoring, illustrates this discrepancy (figure 8). It shows that the average amount allowed for this service varies widely, from a low of $49.17 at one carrier to a high of $251.10 at another.

The two carriers which allowed (and presumably paid) the highest total amounts for real time cardiac monitoring during 1987 together accounted for 81 percent of the national total allowed and 65 percent of the national total number of services. The average amount allowed per service by these 2 carriers, $233.62, was 75 percent higher than the national average of $132.26. Yet the carrier which allowed the third highest total amount on average allowed

$82.67 per service, 62 percent of the national average. Higher volumes by themselves do not account for the variations in average amounts allowed by the carriers.

FIGURE 8
AVERAGE AMOUNTS ALLOWED BY CARRIERS
FOR REAL TIME CARDIAC MONITORING, 1987



SOURCE: HCFA, BUREAU OF DATA MANAGEMENT AND STATISTICS, PART B MEDICARE ANNUAL DATA SYSTEM

Neither is there a ready connection between average amounts allowed and economic circumstances in different parts of the country. The second and fourth lowest average amounts allowed for real time cardiac monitoring services during 1987 occurred in large industrial States of the Northeast. These States are above the national average in per capita personal income.[24] The fourth highest average amount allowed occurred in a rural southern State ranked 42 for personal income. It might seem that higher incomes would support, or even call for, higher average amounts allowed. This is not the case.

Significant variation in reimbursement amounts for new technologies seems to be the rule more than the exception. The same pattern appeared for real time cardiac monitoring services in 1985 and 1986. A similar pattern occurred each year for the other new technologies included in our case studies (table B-3 in appendix B).

We want to emphasize again that the data which show the price variations are the product of reporting by the carriers. The procedure codes for which we accumulated amounts allowed from HCFA's Part B Medicare Annual Data System (BMAD) are those codes reported to us directly by the carriers, as described in the methodological notes of appendix A. We can make no judgement about the possibility for additional payments made under different codes.

We also emphasize that BMAD is a relatively new data base and some data may not have been reported accurately. For example, two of the largest carriers, together accounting for more

than half of the national total amount allowed for real time cardiac monitoring during 1985 and 1986, show no amounts allowed during 1987. Another carrier, third highest in total amount allowed and highest in average amount allowed for real time cardiac monitoring during 1985, shows no such data for 1986.

Despite possible limitations on completeness of the data, the variation illustrated in figure 8 is real. Variation occurs for each case study and each year. And the variation reflects something more than differing economic circumstances across the country. In fact, for our case studies, the average amounts allowed typically vary by a factor of five. This well exceeds the factors of 1 or 2 found in ranges of compiled data on per capita personal income [24] or cost of living indexes [25] in different locations. Even the ranges for reported physicians' fees vary by less than a factor of 2 between census regions.[26]

The carrier representatives with whom we spoke (for the most part medical directors) note that new technologies often come into use through the efforts of one or two innovative manufacturers operating nationwide. These observers note that this can be true even if the actual delivery of the technology to a patient is completed by one of a large number of physicians operating in accord with local practice. They see much less reason for such a nationally standard technology to vary in price than there is for an item produced locally, or for a traditional medical service such as a physician office visit.

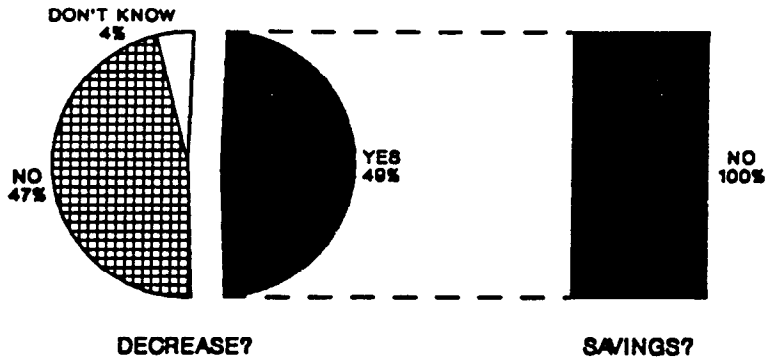
These carrier representatives, as well as the representatives of four manufacturers whom we interviewed, see medical practice becoming more uniform nationally. They offer little basis for variation in the cost of delivering a new technology beyond what is needed to account for local costs of labor, rent and goods, as reflected in overall cost of living indexes.

Although about half the respondents think that the cost of providing a new technology tends to decrease during the 2 or 3 years following its introduction, none identify any special initiatives to avoid overpayments by Medicare in such instances.

Those carrier respondents who feel that the cost of providing a new technology decreases with increasing utilization (figure 9) attribute this to differing factors associated with the particular technology. For newly developed surgical procedures the respondents say that demands on time and skill tend to decrease with experience gained in practice. They see this as the chief reason that the cost of providing a new surgical procedure decreases. Moreover, they note that the surgical support team and any hospital or other facility support resources tend to become more efficient over time. This also contributes to decreasing the cost of providing the service.

For manufactured items such as medical devices, the respondents see economies of repeated production as the chief contributor to decreases in the cost of providing a new technology. Likewise, they see the promotion and distribution organizations for the item as operating more efficiently after a few years of experience have been gained and the high cost of product introduction has been absorbed.

FIGURE 9
DO NEW TECHNOLOGY COSTS TEND TO DECREASE WITH USE AND ARE THERE MEDICARE SAVINGS?



SOURCE: ALL MEDICARE CARRIERS AS REPORTED TO OFFICE OF INSPECTOR GENERAL, HHS, 1988

If the cost of delivering a new product decreases, and respondents at half the carriers think it does, it might appear reasonable for carriers to reflect this lower cost in lower Medicare reimbursement amounts. Yet, none of the respondents identifies any special initiatives by the carriers to capture savings for Medicare when the cost of providing a new technology decreases. The carriers are aware of only two major instances where Medicare allowances decreased to recognize economies of scale associated with new technology: cataract extraction and coronary artery bypass grafts.[27]

Carriers go along with the marketplace because of the Medicare law's definition of reasonable charges.[28] The carriers see this marketplace as one in which fancy new procedures tend to command the highest prices, pulling up all payment levels along with them. They see Medicare's reasonable charge structure, based on billed charge histories, furnishing an incentive for continuing inflation. Few carriers, as already noted, report using inherent reasonableness as a basis for pricing decisions. The data needed to relate Medicare prices to the cost of providing an item or service are trade protected and not often made available to the carriers. Some carriers maintain simply that charges are their only concern, and that the cost of providing a new technology has no role to play in Medicare pricing.

"The medical marketplace can be perverse," notes the medical director at a large carrier. "If a new technology is successful, many providers acquire the capability to use it. Because the fixed demand is spread over a larger number of providers, the number of services available to each decreases. One consequence is an increase in prices in the attempt to maintain revenues in the face of decreasing volume. This is not how the marketplace ought to work."

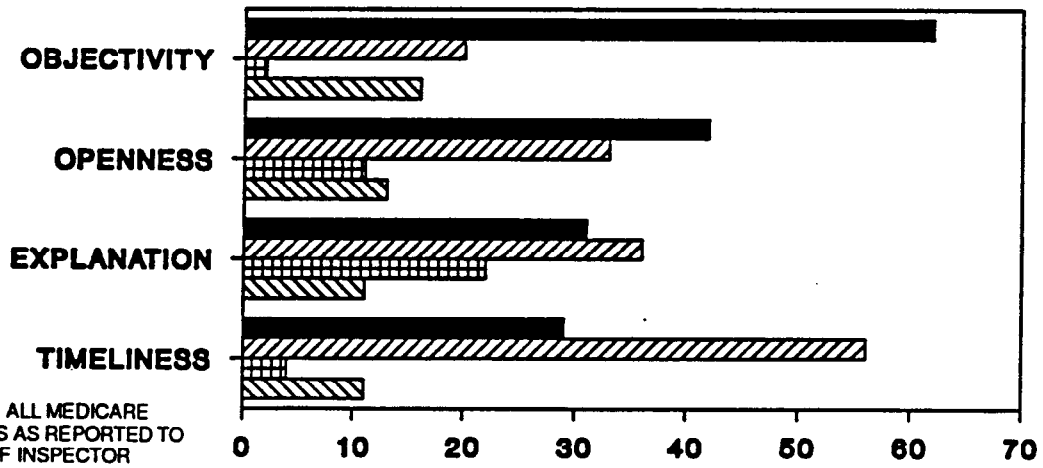
Many carriers are looking to HCFA for guidance on the reasonable range within which their price for a new technology should fall. They want to know that their prices are not out of line with other regions of the country.

OVERALL CARRIER PERFORMANCE IN ASSESSMENT OF NEW TECHNOLOGIES

The carriers' self-rankings indicate that there is substantial room for improvement in the way they assess new technologies. In only 1 of 4 categories do a majority rate the carrier performance as good.

In appraising their own performance in handling new technologies, the carriers indicate that there is much room for improvement. This, they suggest, is particularly true with respect to their *objectivity* in making decisions; *openness* to public input; *explanation* to beneficiaries and providers about coverage and pricing decisions; and *timeliness* in making such decisions (figure 10). The carriers' perceptions of their limitations in these areas are in accord with concerns raised in prior studies of technology assessment [6 9] and in public comments that HCFA received in response to its April 29, 1987 notice on Medicare coverage criteria.[4]

FIGURE 10
CARRIER SELF RANKINGS OF PERFORMANCE IN ASSESSING NEW TECHNOLOGIES



SOURCE: ALL MEDICARE CARRIERS AS REPORTED TO OFFICE OF INSPECTOR GENERAL, HHS, 1988

Among the four aspects of performance that we identified, it is only with respect to the carriers' use of objective criteria in making coverage and pricing decisions that a majority rate the carrier performance as good (figure 10). But even here, it is apparent that there is considerable room for improvement. About one-fifth of the carriers rate their performance in terms of objectivity as no better than fair.

Similarly, in appraising the effect of their technology assessment activity on innovation by providers and on beneficiary access to new technologies, the carriers indicate that there is room for improvement. About 40 percent of the carriers rated their effect on innovation as good. Only 25 percent rated their effect on beneficiary access as good. In this context it is pertinent to note that HCFA's annual carrier performance evaluation program (CPEP) reviews do not include a set of elements specifically addressing technology assessment activity. About one-half of the carriers report that HCFA evaluates this activity either implicitly in other CPEP elements or separately through ongoing monitoring. About one-fourth of the carriers indicate that there is no HCFA evaluation of their technology assessment activity, and about one-fourth say they do not know if such evaluation takes place.

RECOMMENDATIONS

Based upon the findings above, the time has come for new national initiatives that foster consistency in the administration of the Medicare program and in the identification, coverage, and pricing of new technologies. In this context we make the following recommendations:

> ***The HCFA should continue to improve its own capability and that of the carriers to identify emerging technologies and to make more informed, explicit, and consistent coverage and pricing decisions concerning new technologies.***

Toward this end HCFA should:

1. Continue to improve communication among the carriers through increased use of national and regional technical advisory groups.

At national and regional levels, HCFA should facilitate more frequent meetings at which carrier officials and HCFA officials discuss new technologies and how to respond to them. Because of the information shared in such meetings, they can be quite effective in promoting greater consistency in coverage and pricing decisions. The Medical Issues Technical Advisory Group in Region II, which for some time has served as a forum for discussion among HCFA officials and carrier medical directors, appears to be a good example of the kind of collaborative effort that should be replicated.

2. Continue to improve carrier access to comparative Medicare payment information about new technologies.

Recently, HCFA has given carriers access to the carrier payment amounts that are stored in its files, such as in the Medicare Part B Annual Data Set (BMAD). The HCFA should explore the best ways of making such data available. Given the vast amount of data involved, it would probably be preferable to disseminate the information selectively, perhaps through a query facility or as summaries, rather than through mass distribution to all carriers. Selective distribution would allow each carrier to give a more intensive review to the pricing decisions most relevant to its own experience.

When carriers have the capacity to compare their payment amounts for particular new technologies with one another, those with unusually high or low amounts would quite likely reexamine the bases for their payment determinations. Over time, the likely effect would be greater consistency in payment levels.

3. Review the performance of carriers in identifying, covering, and pricing specific new technologies.

The HCFA should carry out such a review through regional office monitoring visits and through the annual Contractor Performance Evaluation Program. The HCFA should make

clear to the carriers that identification, coverage, and pricing of new technologies are essential parts of their role and that each will be considered in evaluating their overall performance.

4. Cooperate with the Public Health Service in proactively and routinely compiling and rapidly disseminating information on new health care technologies through clearinghouses or other appropriate means.

Any such clearinghouse should be established with input from the carriers and in a way that maximizes carrier access to information bearing on their identification, coverage, and pricing of new technologies. It should have clear operating parameters that assure accurate acquisition and rapid dissemination of data.

To broaden the information base and reduce unnecessary duplication, HCFA and PHS should also pursue thepossibility of sharing the benefits and costs of the clearinghouse with other interested parties, such as the American Medical Association, Blue Cross and Blue Shield Association, Health Insurance Association of America, or the Institute of Medicine.

The HCFA should seek legislative authority to broaden the bases upon which it can establish reimbursement amounts for new and emerging technologies other than physician services. This authority should be available to HCFA both at the time of the initial coverage decision and as the technology matures.

The legislation should supplement current authorities by allowing HCFA to:

(1) limit initial payments based on a consideration of the cost of developing and delivering the technology,

(2) subsequently reduce the allowable charges for new technologies as they mature in order to take advantage of reduced costs, and

(3) establish regional or national reimbursement limits based on simple and easily verifiable criteria such as the mere existence of substantial variation in reimbursement rates.

COMMENTS AND OIG RESPONSE

In its written comments and at subsequent meetings, the HCFA recognized that problems exist with the carrier assessment of new technologies and noted that it has taken numerous recent initiatives to improve technology assessment. Some of the actions we recommended are included among the HCFA initiatives. The HCFA was concerned that our findings, at least in part, may no longer be valid because of its recent efforts. It asked the OIG to conduct an additional study aimed at assessing the effectiveness of its recent initiatives.

We agree that HCFA has moved to resolve the problems addressed in this study. For this reason we have removed from this report a statement, contained in the draft report, that the current procedures for carrier coverage and pricing of new technologies constitute a material internal control weakness within the meaning of the Federal Manager's Financial Integrity Act. We have agreed to work with HCFA in evaluating the effectiveness of its efforts to improve carrier assessment of new technology.

The HCFA agreed that additional legislative authority would help it improve coverage and pricing decisions for nonphysician services. The HCFA believes that physician payment reforms recently enacted in the Omnibus Budget Reconciliation Act of 1989 (OBRA-89) will provide an appropriate framework and sufficient authority to improve coverage and pricing decisions relating to physician payments.

We agree and we have modified our legislative recommendations to focus exclusively on nonphysician services. But we are concerned about the practical aspects of the new physician payment reform provisions. In order to develop fee schedules for new and emerging treatment modalities, HCFA must identify them. We believe that the ability to identify emerging new technologies is the area of greatest weakness in the current system. We are hopeful that HCFA's recent initiatives will be effective in addressing this weakness. We will know more when our future evaluations, mentioned above, are completed.

We also remain concerned that the many Part B payments for nonphysician services, such as durable medical equipment, prosthetics, and physiological testing, are not covered by the payment reforms of OBRA-89 . We believe our legislative proposals are particularly important for these nonphysician services.

The HCFA disagreed with our recommendation for disseminating coverage and pricing information among carriers through a clearinghouse because it would not be cost effective, and because carriers do not use current clearinghouses. We continue to support this recommendation. In our survey, the carriers themselves asked for this kind of assistance. We believe the current clearinghouses are too passive and often impracticably slow because they rely upon specific requests from the carriers. What we have in mind is a more proactive and orderly dissemination of information. We think that a more proactive clearinghouse would be an effective way to do this, but we would support any other technique provided it is

aggressive and systematic. We have modified the wording of the recommendation to make our intent more clear.

The Public Health Service and the Office of the Assistant Secretary for Planning and Evaluation both recognized the need to improve carrier coverage and pricing decisions. They both supported the idea of a clearinghouse to share coverage and pricing information.

The Health Insurance Association of America and the Health Industry Manufacturers Association also commented on our draft report. They agreed with most of our findings and recommendations.

The text of all comments and our detailed responses to them are in appendix D.

APPENDIX A

METHODOLOGICAL NOTES

CARRIERS

We held discussions with representatives of the 45 geographic carriers that processed Medicare Part B claims during the summer of 1988, when our data gathering was completed. In those instances when a single Blue Shield plan held contracts for more than one area (as Arkansas Blue Shield served Arkansas and Louisiana), we aggregated their activities in all the areas and regarded them as one carrier with one medical director. For the commercial insurance organizations that held more than one contract, we regarded each field office (which may serve more than one State) as a separate carrier. We did not interview the Railroad Retirement Board, whose function is primarily oversight, although it is often termed a carrier.

We treated the carrier responses to our questions as dependent variables and analyzed them against four independent variables: size, region, carrier type, and presence of a medical director. We used the commercial software programs dBASE III Plus and Lotus 1-2-3 to accumulate and sort responses. For analyses we used the Stat-Packets software package of statistical analysis programs on a microcomputer. Using this software, we developed correlations and broke response data down into separate categories for each independent variable.

Size

We ranked the carriers according to the aggregated total of Part B disbursements each made in 1986 as given in HCFA records. Using variance techniques, we identified four clusters of carriers differentiated on the basis of payments:

Cluster	Number of Carriers	Total Disbursements*
1 (Smallest)	17	$1.75 billion
2	17	$5.29 billion
3	8	$7.11 billion
4 (Largest)	3	$4.49 billion

*This total of disbursements differs from the Part B payments in figure 1 because they draw on two different data sources. This total may not be complete; figure 1 is accurate for the amounts paid out. The ranking of the carriers by size should not be affected by the difference.

Region

We used the categorization developed by the U.S. Department of Commerce, Bureau of the Census. The four geographic regions of the country were the Northeast, Midwest, South, and West.

Type of Carrier

Of the 45 total carriers as defined above, 27 were Blue Shield plans and 18 were commercial insurance organizations.

Medical Director

In preliminary discussions, we identified the medical directors at 29 carriers. The remaining carriers either had no medical director or had none with responsibility for the Medicare segment of their business. During the course of this study we learned that HCFA has advised the carriers that each would be required to have a medical director for Medicare beginning in 1989.

OUTSIDE OBSERVERS

We held discussions with representatives of organizations external to the carriers, each of them related to and concerned with carrier technology assessment activities. These included:

- four manufacturers of new technologies that were included in our case studies (see appendix B),
- five insurance organizations (including four medical directors not now active in Medicare work), and
- three national organizations active in health care technology assessment.

APPENDIX B

CASE STUDIES

Following telephone discussions with medical directors at 21 carriers (separate from the study interviews described in appendix A), and with physician consultants at Part A intermediaries, Professional Review Organizations, or in private practice, we developed a list of 50 technologies that were characterized as recent subjects of technology assessment. We reduced the list to 12 that included a balance among new devices, diagnostic tests, and surgical procedures. In making this reduction we included some highly innovative technologies along with some incremental improvements.

In an introductory letter, we asked the carriers to give us the procedure codes they had used for each of the 12 technologies during 1985-87. (Our request asked for 13 technologies, but the wording for one of these was ambiguous. We have excluded it from the analysis.) All carriers should use the same HCFA Common Procedure Coding System (HCPCS). Table B-1a summarizes the responses. Some, but not all and in no instance all 45, of the carriers reported definite codes they used in processing claims for the 12 technologies. Absence of a code could mean that the carrier had (a) not yet received a claim for the given technology, or (b) not yet assigned it a distinct code, or (c) had made an affirmative decision against coverage for the technology.

Tables B-1b and B-1c in this appendix summarize the carrier responses on numbers of codes used. The number of codes for each technology indicates how closely the carriers adhere to HCPCS. Subject to HCFA concurrence, carriers have within HCPCS the option to assign a local code to an item or service in order to facilitate payment and utilization reviews. Carriers may want to use local codes for new technologies until billing and use patterns have been established.

Following a review of the procedure codes reported by the carriers, we obtained from HCFA the amounts paid during 1986 for the most common codes. We selected for detailed case studies five of the technologies that showed substantial volume of Medicare claims activity. To the extent possible with such a small group we balanced our selection to include devices, tests, and techniques. We asked the carriers to identify:

- the source that brought the new technology to the carrier's attention,
- the department that identified the new technology,
- who made the coverage decision,
- the criteria used in making the coverage decision,

- the external sources drawn upon in making the coverage decision,
- the methods used for setting a reasonable charge,
- whether the reasonable charge had been changed, and
- the methods used in setting the new reasonable charge.

Tables B-2a through B-2e in this appendix summarize the carrier responses to questions about the coverage decision making process. The responses in most categories total less than 45 because we directed questions on any given technology only to those carriers who had identified a procedure code in response to our introductory letter (except tissue plasminogen activator, the subject of a national coverage decision in early 1988). Not all carriers answered all questions that were directed to them, and some gave multiple answers, so the response totals are not necessarily the same for different questions about any one technology.

Table B-3 in this appendix lists averages, ranges, and standard deviations of the amounts allowed by the carriers for each of three new technologies included in our case studies. We excluded tissue plasminogen activator from this listing because so few carriers reported payments during the years 1985-1987. We excluded infusade pumps because some of the available pricing data referred to surgical implantation of the device and some referred to supplies used with the pump.

TABLE B-1a

NUMBER OF CARRIERS REPORTING CODES FOR EACH TECHNOLOGY 1985-1987

TECHNOLOGY	1985	1986	1987
Magnetic Resonance Imaging for Diagnosis of Stroke	27	38	41
Extracorporeal Shock Wave Lithotripsy	7	41	44
Cochlear Device Implantation	6	38	41
Intracardiac Electrophysiological Testing: Induction of Arrythmia by Electrical Pacing	36	38	40
Real Time Cardiac Monitoring	23	29	43
Punctum Plug Procedure: Laser Canaliculoplasty	27	31	35
Plethysmography: Noninvasive Vascular Diagnostic Testing of the Lower Extremity	41	43	44
Infusade Pumps: Implantation and Supplies	36	38	43
Transtracheal Oxygen: Tube Insertion and Gas Supply	18	19	25
Laser Surgery: Trabeculoplasty	40	42	44
Decompression of Median Nerve at Carpal Tunnel: Arthroscopic or Laser Procedure	29	30	33
Tissue Plasminogen Activator	14	17	19

SOURCE: *Medicare Carriers as Reported to Office of Inspector General*, HHS, 1988

TABLE B-1b

NUMBER OF HCPCS PROCEDURE CODES USED FOR EACH TECHNOLOGY 1985-1987

TECHNOLOGY	1985	1986	1987
Magnetic Resonance Imaging for Diagnosis of Stroke	2	2	2
Extracorporeal Shock Wave Lithotripsy	12	4	4
Cochlear Device Implantation	3	1	2
Intracardiac Electrophysiological Testing: Induction of Arrythmia by Electrical Pacing	8	8	10
Real Time Cardiac Monitoring	16	14	18
Punctum Plug Procedure: Laser Canaliculoplasty	5	6	9
Plethysmography: Noninvasive Vascular Diagnostic Testing of the Lower Extremity	4	3	3
Infusade Pumps: Implantation and Supplies	25	25	27
Transtracheal Oxygen: Tube Insertion and Gas Supply	8	8	10
Laser Surgery: Trabeculoplasty	4	3	3
Decompression of Median Nerve at Carpal Tunnel: Arthroscopic or Laser Procedure	3	3	4
Tissue Plasminogen Activator	8	9	12

SOURCE: *Medicare Carriers as Reported to Office Of Inspector General*, HHS, 1988

TABLE B-1c

NUMBER OF LOCAL PROCEDURE CODES USED FOR EACH TECHNOLOGY 1985-1987

TECHNOLOGY	1985	1986	1987
Magnetic Resonance Imaging for Diagnosis of Stroke	0	0	0
Extracorporeal Shock Wave Lithotripsy	9	4	3
Cochlear Device Implantation	0	0	1
Intracardiac Electrophysiological Testing: Induction of Arrythmia by Electrical Pacing	3	5	4
Real Time Cardiac Monitoring	2	1	0
Punctum Plug Procedure: Laser Canaliculoplasty	1	2	3
Plethysmography: Noninvasive Vascular Diagnostic Testing of the Lower Extremity	0	0	0
Infusade Pumps: Implantation and Supplies	6	7	8
Transtracheal Oxygen: Tube Insertion and Gas Supply	1	1	3
Laser Surgery: Trabeculoplasty	3	2	2
Decompression of Median Nerve at Carpal Tunnel: Arthroscopic or Laser Procedure	1	1	1
Tissue Plasminogen Activator	0	0	0

SOURCE: *Medicare Carriers as Reported To Office of Inspector General*, HHS, 1988

TABLE B-2a

CASE STUDY - REAL TIME MONITORING

IDENTIFICATION

SOURCE OF INITIAL IDENTIFICATION	NUMBER OF CARRIERS
Claims	23
Physicians	13
Beneficiaries	0
Manufacturers	18
Others	21

CARRIER DEPARTMENT	NUMBER OF CARRIERS
Claims	23
Utilization Review	12
Prof. Relations	5
Other	20

COVERAGE

DECISION MAKER	NUMBER OF CARRIERS
Clerical	2
Nurse	9
Physician	16
Manager	6
Other	17

CRITERIA USED	NUMBER OF CARRIERS
Safety	10
Effectiveness	28
Cost	10
Prof. Acceptance	26
Patient Benefit	17
Appropriate Setting	8
Other	11

EXTERNAL SOURCE OF ADVICE	NUMBER OF CARRIERS
HCFA	28
PRO	0
Medical Society	6
State	0
Other Payers	4
Manufacturers	18
Suppliers	10
Other	16

PRICING

INITIAL METHOD	NUMBER OF CARRIERS
Gap Filling	6
Comparable Procedure	18
Relative Value	13
Survey	3
Billed Charges	5
Inherent Reasonableness	4
Other	3

CHANGE MADE IN PRICE	NUMBER OF CARRIERS
Increase	10
Decrease	6
No Change	18

METHOD FOR NEW PRICE	NUMBER OF CARRIERS
Charge History	9
Gap Filling	2
Survey	0
Precedents	0
Billed Charges	0
Inherent Reasonableness	2
Other	5

SOURCE: *Medicare Carriers, as Reported to Office of Inspector General*, HHS, 1988

TABLE B-2b

CASE STUDY - PUNCTUM PLUG PROCEDURE

IDENTIFICATION

SOURCE OF INITIAL IDENTIFICATION	NUMBER OF CARRIERS
Claims	26
Physicians	13
Beneficiaries	0
Manufacturers	3
Others	3

CARRIER DEPARTMENT	NUMBER OF CARRIERS
Claims	14
Utilization Review	9
Prof. Relations	4
Other	13

COVERAGE

DECISION MAKER	NUMBER OF CARRIERS
Clerical	1
Nurse	7
Physician	20
Manager	1
Other	10

CRITERIA USED	NUMBER OF CARRIERS
Safety	20
Effectiveness	27
Cost	13
Prof. Acceptance	26
Patient Benefit	20
Appropriate Setting	8
Other	8

EXTERNAL SOURCE OF ADVICE	NUMBER OF CARRIERS
HCFA	7
PRO	0
Medical Society	11
State	2
Other Payers	5
Manufacturers	6
Suppliers	4
Other	18

PRICING

INITIAL METHOD	NUMBER OF CARRIERS
Gap Filling	2
Comparable Procedure	9
Relative Value	7
Survey	3
Billed Charges	10
Inherent Reasonableness	2
Other	5

CHANGE MADE IN PRICE	NUMBER OF CARRIERS
Increase	6
Decrease	0
No Change	24

METHOD FOR NEW PRICE	NUMBER OF CARRIERS
Charge History	4
Gap Filling	0
Survey	0
Precedents	0
Billed Charges	1
Inherent Reasonableness	0
Other	1

SOURCE: *Medicare Carriers, as Reported to Office of Inspector General*, HHS, 1988

TABLE B-2c

CASE STUDY - PLETHYSMOGRAPHY, VASCULAR

IDENTIFICATION

SOURCE OF INITIAL IDENTIFICATION	NUMBER OF CARRIERS
Claims	28
Physicians	21
Beneficiaries	0
Manufacturers	1
Others	9

CARRIER DEPARTMENT	NUMBER OF CARRIERS
Claims	16
Utilization Review	11
Prof. Relations	3
Other	16

COVERAGE

DECISION MAKER	NUMBER OF CARRIERS
Clerical	1
Nurse	9
Physician	23
Manager	5
Other	14

CRITERIA USED	NUMBER OF CARRIERS
Safety	16
Effectiveness	29
Cost	9
Prof. Acceptance	26
Patient Benefit	19
Appropriate Setting	12
Other	12

EXTERNAL SOURCE OF ADVICE	NUMBER OF CARRIERS
HCFA	34
PRO	0
Medical Society	13
State	2
Other Payers	7
Manufacturers	2
Suppliers	2
Other	16

PRICING

INITIAL METHOD	NUMBER OF CARRIERS
Gap Filling	2
Comparable Procedure	5
Relative Value	11
Survey	3
Billed Charges	13
Inherent Reasonableness	5
Other	5

CHANGE MADE IN PRICE	NUMBER OF CARRIERS
Increase	21
Decrease	2
No Change	16

METHOD FOR NEW PRICE	NUMBER OF CARRIERS
Charge History	18
Gap Filling	1
Survey	1
Precedents	0
Billed Charges	7
Inherent Reasonableness	0
Other	1

SOURCE: *Medicare Carriers, as Reported to Office of Inspector General*, HHS, 1988

TABLE B-2d

CASE STUDY - INFUSADE PUMP

IDENTIFICATION

SOURCE OF INITIAL IDENTIFICATION	NUMBER OF CARRIERS
Claims	22
Physicians	14
Beneficiaries	0
Manufacturers	15
Others	15

CARRIER DEPARTMENT	NUMBER OF CARRIERS
Claims	12
Utilization Review	11
Prof. Relations	6
Other	16

COVERAGE

DECISION MAKER	NUMBER OF CARRIERS
Clerical	1
Nurse	12
Physician	22
Manager	3
Other	15

CRITERIA USED	NUMBER OF CARRIERS
Safety	21
Effectiveness	31
Cost	17
Prof. Acceptance	23
Patient Benefit	22
Appropriate Setting	12
Other	8

EXTERNAL SOURCE OF ADVICE	NUMBER OF CARRIERS
HCFA	34
PRO	0
Medical Society	10
State	1
Other Payers	7
Manufacturers	15
Suppliers	11
Other	12

PRICING

INITIAL METHOD	NUMBER OF CARRIERS
Gap Filling	3
Comparable Procedure	5
Relative Value	3
Survey	9
Billed Charges	6
Inherent Reasonableness	8
Other	8

CHANGE MADE IN PRICE	NUMBER OF CARRIERS
Increase	14
Decrease	0
No Change	22

METHOD FOR NEW PRICE	NUMBEROF CARRIERS
Charge History	6
Gap Filling	1
Survey	3
Precedents	0
Billed Charges	3
Inherent Reasonableness	1
Other	0

SOURCE: *Medicare Carriers, as Reported to Office of Inspector General*, HHS, 1988

TABLE B-2e

CASE STUDY - TISSUE PLASMINOGEN ACTIVATOR

IDENTIFICATION

SOURCE OF INITIAL IDENTIFICATION	NUMBER OF CARRIERS
Claims	9
Physicians	11
Beneficiaries	0
Manufacturers	10
Others	18

CARRIER DEPARTMENT	NUMBER OF CARRIERS
Claims	6
Utilization Review	10
Prof. Relations	6
Other	13

COVERAGE

DECISION MAKER	NUMBER OF CARRIERS
Clerical	0
Nurse	7
Physician	14
Manager	2
Other	11

CRITERIA USED	NUMBER OF CARRIERS
Safety	11
Effectiveness	16
Cost	8
Prof. Acceptance	14
Patient Benefit	10
Appropriate Setting	13
Other	12

EXTERNAL SOURCE OF ADVICE	NUMBER OF CARRIERS
HCFA	18
PRO	0
Medical Society	5
State	0
Other Payers	5
Manufacturers	6
Suppliers	1
Other	16

PRICING

INITIAL METHOD	NUMBER OF CARRIERS
Gap Filling	0
Comparable Procedure	4
Relative Value	3
Survey	4
Billed Charges	6
Inherent Reasonableness	2
Other	0

CHANGE MADE IN PRICE	NUMBER OF CARRIERS
Increase	2
Decrease	0
No Change	19

METHOD FOR NEW PRICE	NUMBER OF CARRIERS
Charge History	1
Gap Filling	1
Survey	0
Precedents	0
Billed Charges	0
Inherent Reasonableness	0
Other	1

SOURCE: *Medicare Carriers, as Reported to Office of Inspector General*, HHS, 1988.

TABLE B-3

AVERAGE AMOUNTS ALLOWED FOR NEW TECHNOLOGIES
NATIONAL AVERAGES AND RANGES, 1985-1987

TECHNOLOGY	AVERAGE AMOUNT ALLOWED		
YEARS	*NATIONAL AVERAGE*	*RANGE LOW - HIGH*	*STANDARD DEVIATION*
REAL TIME CARDIAC MONITORING:			
1985	$ 94.40	$21.20-$ 178.71	$42.45
1986	$105.20	$23.82-$ 239.50	$52.51
1987	$125.71	$49.17-$ 251.10	$56.95
PUNCTUM PLUG PROCEDURE:			
1985	$173.91	$35.25-$ 774.36	$193.75
1986	$189.74	$35.38-$ 566.07	$168.68
1987	$179.02	$34.34-$ 926.76	$176.16
PLETHYSMOGRAPY, VASCULAR:			
1985	$ 55.35	$18.11-$ 117.26	$24.50
1986	$ 64.43	$12.13-$ 151.86	$32.57
1987	$ 62.71	$14.92-$ 129.66	$30.85

APPENDIX C

GLOSSARY

The **cochlear implant** is an electronic device that captures sound and converts it to an electrical signal. It improves hearing by stimulating the auditory nerve.

Decompression of the median nerve at the carpal tunnel is a procedure to release tight bands of tissue that may develop and press on the nerve where it passes under the arch formed by the bones of the wrist.

Extracorporeal shock wave lithotripsy (ESWL) provides for the pulverization of kidney or gall stones by focused ultrasonic shock waves. It offers an alternative to invasive surgery or to drug maintenance therapies.

Infusade pumps are devices that dispense medication slowly and continuously into a blood vessel over extended periods of time. Implanted in the body and refilled by injection, they allow the patient to remain ambulatory and to control levels of medication.

Intracardiac electrophysiological testing is an invasive diagnostic tool that stimulates the heart beating with an electrode introduced into a heart chamber. Electrical signals are imposed out of phase with established rhythms to study the speed and quality of recovery to the heart's normal beats.

Magnetic resonance imaging (MRI) is a method of showing the size and shape of body cavities and tissues. It is capable of demonstrating a wide variety of soft tissue lesions, and it avoids use of potentially harmful radiation or injected contrast media.

Plethysmography is measurement of changes in the size of a part of the body in response to the circulation of blood. It is often used to assess blood flow in the veins of the legs.

The **punctum plug procedure** places stoppers at the openings into the drainage tubes through which tear fluid runs out of the eye. It is used to retain fluid in patients who experience "dry eye."

Real time cardiac monitoring records out-of-the-ordinary episodes of heart activity when the patient is in an ambulatory setting and about the normal tasks of ordinary life.

Tissue plasminogen activator (TPA) is a naturally occurring enzymatic protein that promotes breakup of blood clots. It is available as a genetically engineered drug for use in treating heart attack patients.

Trabeculoplasty, whether or not performed with a laser "knife", is a procedure to open the pores through which fluid drains from the front part of the eye. It allows increased flow of fluid (aqueous humor) out of the eye, helping to relieve built-up pressure in cases of glaucoma.

Transtracheal oxygen is delivered through an opening in the neck, instead of through the nose. The method can be more effective in getting oxygen to a patent's tissues, and it can consume less oxygen in achieving the same effect.

APPENDIX D

COMMENTS ON THE DRAFT REPORT AND OIG RESPONSES

In this appendix we provide the verbatim comments on the draft report by the Health Care Financing Administration (HCFA), the Public Health Service (PHS), the Assistant Secretary for Planning and Evaluation (ASPE), the Health Industry Manufacturers Association (HIMA), and the Health Insurance Association of America (HIAA). In each case, after presenting the comments, we offer our response to the comments.

With respect to HCFA, the operating agency to which each of our recommendations is directed, it is important to note that subsequent to receipt of its written comments we held meetings with HCFA to discuss the agency's concerns about the report's findings and recommendations. At these meetings HCFA officials discussed problems which exist with carrier assessment of new technologies, and indicated that the agency has taken recent initiatives to improve technology assessment.

Some of the actions we recommended are included among the HCFA initiatives. The HCFA was concerned that our findings, at least in part, may no longer be valid because of its recent efforts. It asked the OIG to conduct an additional study aimed at assessing the effectiveness of its recent initiatives.

We agree that HCFA has moved to resolve the problems addressed in this study. For this reason we have removed from this report a statement, contained in the draft report, that the current procedures for carrier coverage and pricing of new technologies constitute a material internal control weakness within the meaning of the Federal Manager's Financial Integrity Act. We have agreed to work with HCFA in evaluating the effectiveness of its efforts to improve carrier assessment of new technology.

The HCFA agreed that additional legislative authority would help it improve coverage and pricing decisions for nonphysician services. The HCFA believes that physician payment reforms recently enacted in the Omnibus Budget Reconciliation Act of 1989 (OBRA-89) will provide an appropriate framework and sufficient authority to improve coverage and pricing decisions relating to physician payments.

We agree and we have modified our legislative recommendations to focus exclusively on nonphysician services. But we are concerned about the practical aspects of the new physician payment reform provisions. In order to develop fee schedules for new and emerging treatment modalities, HCFA must identify them. We believe that the ability to identify emerging new technologies is the area of greatest weakness in the current system. We are hopeful that HCFA's recent initiatives will be effective in addressing this weakness. We will know more when our future evaluations, mentioned above, are completed.

We also remain concerned that the many Part B payments for nonphysician services, such as durable medical equipment, prosthetics, and physiological testing, are not covered by the payment reforms of OBRA-89 . We believe our legislative proposals are particularly important for these nonphysician services.

The HCFA disagreed with our recommendation for disseminating coverage and pricing information among carriers through a clearinghouse because it would not be cost effective, and because carriers do not use current clearinghouses. We continue to support this recommendation. In our survey, the carriers themselves asked for this kind of assistance. We believe the current clearinghouses are too passive and often impracticably slow because they rely upon specific requests from the carriers. What we have in mind is a more proactive and orderly dissemination of information. We think that a more proactive clearinghouse would be an effective way to do this, but we would support any other technique provided it is aggressive and systematic. We have modified the wording of the recommendation to make our intent more clear.

Following are the written comments we received on the draft report and our responses to them.

HEALTH CARE FINANCING ADMINISTRATION (HCFA) COMMENTS

We have reviewed the above draft report. OIG states that its findings demonstrate "the lack of an effective system to identify, track, and diffuse information about new technologies and to decrease Medicare payments to capture economies of scale when these flow from new technologies." According to the report, this alleged deficiency constitutes a material internal control weakness within the meaning of the Federal Managers' Financial Integrity Act and the Office of Management and Budget Circular A-123.

We do not agree with this conclusion. We believe that the report does not offer sufficient evidence to support its major findings. Also, the report does not reflect the statutory context within which carrier assessment of new technology is made. Finally, the report does not address the recent significant changes already affecting the technology assessment process, even though these were discussed with OIG staff at an exit conference on August 2.

More detailed comments on the report's findings and recommendations are attached. Thank you for the opportunity to review and comment on this draft report.

OIG states in the report, "the conditions identified in our findings collectively show a material internal control weakness...." The report has three major findings upon which this allegation of a material weakness is based. Our comments on these findings follow:

Finding 1 - Unwarranted Variation

> Extensive and apparently unnecessary variation exists among the carriers in coverage and pricing decisions involving new technologies.

Response

The mere existence of variation in coverage and pricing decisions does not necessarily indicate a problem. The Medicare program was designed from the outset, in both statute and regulations, to reflect local practice and pricing conditions. Furthermore, based on the data presented in this report, it is difficult to reach *any* conclusion regarding the degree of variation (unwarranted or not) that exists among the carriers in covering or pricing new technologies. Thus, the extent of the alleged problem cannot be addressed.

- Coverage of New Technologies

  In terms of coverage decisions, the report does not give an example of any unwarranted variation, nor does it offer any evidence as to the scope of the variations between carriers. The report finds instead that, in response to a survey question, "respondents at one-third of the carriers say that the carriers, as a group are at most minimally consistent in making coverage decisions about new technologies" (Page 12). The report does add that an equal number of carriers stated there was at least moderate consistency, and another equally sized group had "no opinion." The ambiguity of this response calls into question the effectiveness of the survey, but, more fundamentally, we would question the use of a survey as a substitute for an analysis of actual coverage data.

  The only "hard" data on carrier coverage of new technology are presented in table II-A-1. This table purports to show the number of carriers covering each of 12 selected technologies from 1985-1987. The figures presented for 1987 in this table appear to indicate that the carriers are relatively consistent in their coverage decisions.

  Moreover, in the narrative which precedes this table, OIG describes its methodology for obtaining the coverage data, i.e., the carriers were asked to give the procedure codes used for each of the 12 technologies. From this information, OIG apparently inferred which carriers covered what technologies. However, coverage decisions cannot necessarily be inferred from the presence or absence of a code. A carrier can decide not to cover an item for which a code already exists, or may cover an item or service for which no code exists by using one of several "not otherwise specified" codes available. OIG may have gathered data on carrier coding, but it is not possible to know for sure what these data say about carrier coverage decisions.

- Pricing of New Technologies

  The report does not identify any overall financial effect so that the significance of the problem can be evaluated. The only comparative figures are found in table II-C. This table has data for only three technologies, each of which shows a wide

range of carrier payment levels. However, OIG does not disclose the array of payments. This makes it impossible to tell if the variation is caused by one or two aberrant carriers, with most of the payment levels clustered near the average, or whether the randomness is broad based. Without this information, it is not possible to evaluate the significance of the range.

There are even more fundamental methodological problems with the data as presented. It would appear that OIG did not ask the carriers what their prevailing rates were for the technologies in question. Rather, according to the explanation given on page 17, they took the various procedure codes reported to OIG for the three technologies, then used HCFA's Part B Medicare Annual Data System (BMAD) to determine the allowed payments for these codes. However, according to table II-A-2, there were several codes reported for each technology (18 for real time cardiac monitoring, 9 for punctum plug procedure, and 3 for plethysmography), and these different codes may not represent precisely the same service. There are different procedures that can group under each technology and different services that could be included in these codes (e.g., technical component vs. physician services). It appears that OIG lumped the data from all the codes together. Thus, it is not possible to determine how much the variation in allowed amounts reflects an inadvertent comparison of different items, or how much is actually due to variations in carrier pricing decisions.

OIG Finding 2 - Economies Not Realized

Carriers have no system for ensuring that payments for new technologies decrease in response to decreasing costs for delivering an item or service.

Response

As OIG makes no attempt to define the financial effect of this finding, the significance of the problem is not clear. The evidence that economies have not been realized relies, first, on the opinion of "respondents at half the carriers" that the cost of delivering a new product decreases (Page 19), and second on the fact that the actual pricing of the sample technologies did not decrease. There are no concrete and factual data presented to show that the actual costs of these technologies did in fact decrease over the time period studied.

The report criticizes the carriers for not taking special initiatives to "capture savings for Medicare when the cost of providing a new technology decreases" (Page 19). OIG does not take into consideration the considerable statutory constraints that a carrier faces in taking such an initiative. Medicare law states that the criteria for determining a reasonable charge for a physician service are the customary charges for similar services made by the person furnishing the service, and the prevailing charges in the locality for similar services. Thus, it does not generally follow that the pricing of the sampled procedures would decline, as annual price adjustments are necessarily based on submitted charges.

OIG also makes frequent reference to the fact that few carriers apply inherent reasonableness to lower the pricing of technologies. The OIG ignores the statutory realities. Since 1985, Congress has acted to restrain the use of inherent reasonableness as a pricing criterion. Carriers are no longer free to apply inherent reasonableness to physician services, which would constitute the bulk of charges for new technologies. If HCFA wishes to apply factors other than reasonable charges in determining whether a charge is inherently reasonable, we must first publish a notice in the *Federal Register* to that effect.

Finding 3 - Little Guidance to Carriers

> While HCFA has made strides in specifying overall procedures for coverage decisions, it gives little practical guidance to carriers on coverage and pricing matters.

Response

Medicare law authorizes the Secretary to enter into contracts with carriers for performance of payment and coverage functions. This basic approach of Medicare operations appears to be disregarded by OIG when discussing the relationship between HCFA and the carriers. The case studies in the report indicate that the carriers often seek and receive advice from HCFA. The report also states that HCFA will make a national coverage decision binding on the carriers, when "it has become apparent that different carriers have made inconsistent coverage decisions" (Page 2). OIG has not produced evidence that HCFA has failed to fulfill the objectives of the law in this regard.

The report also fails to take fully into account the following initiatives taken by HCFA to update the coverage process and to improve and increase communication between HCFA and the carriers.

- On January 30, 1989, HCFA published a proposed rule in the *Federal Register* which describes the coverage process in detail and which makes explicit the criteria that are to be applied when making coverage decisions. This important initiative, which for the first time would include cost-effectiveness as a coverage criteria, was essentially relegated to a footnote in this report.

- HCFA is requiring that carriers must submit a copy of all medical coverage policy by September 30, 1989. This policy will be reviewed to identify carriers with widely variant policy.

- Effective October 1, 1988, carriers were required to have licensed physicians as medical directors.

- HCFA is committed to holding an annual Medical Directors' Conference, though in practice, these conferences have been held on a semiannual basis since December 1988.

During the May 1989 conference, a half day was devoted to the subject of new technology assessment.

- HCFA's Coverage and Payment Technical Advisory Group, which includes selected carrier physicians, and the HCFA Physicians' Panel both discuss emerging technology and coverage issues.

- In recent years, there has been significant pricing guidance given to carriers on new technologies. The instructions on magnetic resonance imaging and the technical component of cardiac catheterization are two examples. We are in the process of carrying out an evaluation of the reasonableness of price levels for real time cardiac monitoring. When this is finished, the results will be communicated to the carriers.

Comments on Specific Recommendations

Recommendation 1

HCFA and the Public Health Service (PHS) should cooperate in establishing a clearinghouse devoted to the compilation and dissemination of information on new health care technologies. The clearinghouse could be established either within the Department or through contract with a private entity.

Response

We do not concur with this recommendation. The report does not demonstrate that this would be a cost-effective alternative to the recent initiatives we have described above. In addition, this recommendation appears inconsistent with OIG's own findings, since the report itself suggests that carriers do not use information already available from existing clearinghouses. In this regard, the report does not mention the clearinghouse function of the National Center of Health Services Research and Health Care Technology Assessment within the PHS.

Recommendation 2

HCFA should foster greater consistency among the carriers in their coverage and pricing decisions concerning new technologies by:

- Improving communications among the carriers by fostering increased use of national and regional technical advisory groups.

- Providing the carriers with selective access to comparative Medicare payment information about new technologies.

- Reviewing on a regular schedule the performance of carriers in identifying, covering and pricing specific new technologies.

Response

We agree that we should constantly foster improvements in our carrier decisionmaking process with regard to new technologies. It is because of this commitment that we have undertaken many of the initiatives listed above. Given the extent of these initiatives, we do not believe that the specific actions included in the OIG recommendation are necessary at this time.

Recommendation 3

HCFA should seek legislative authority to broaden the bases upon which it can establish the reasonable charge for a new technology, both at the time of initial coverage and after the technology has assimilated into the marketplace.

Response

We do not concur with this recommendation. This recommendation is largely a proposal that HCFA be given increased authority to apply inherent reasonableness. However, Congress has only recently stated its position, by acting to restrict further the Secretary's authority. It is clear that Congress has no interest in easing the administrative burden that Congress itself imposed on applying inherent reasonableness.

Also, under pending legislation, the physician payment system will change radically. With a national fee schedule using a resource cost-based relative value system, carrier discretion to price physician services will be virtually eliminated. Therefore, there would be little current interest in Congress in making procedural adjustments in the reasonable charge system.

OIG RESPONSE TO HCFA WRITTEN COMMENTS

We believe that the report does offer sufficient evidence to demonstrate the lack of effective systems to identify, track, and diffuse information about new technologies and the inability of the system to decrease Medicare payments to reflect economies that flow from new technologies.

Because the systems do not exist, the information desired by HCFA is practically impossible to obtain. We therefore collected information using discussion guides and mail surveys of the very carriers who would operate any effective system. We also obtained new data about a few specific technologies to illustrate the points we raised. We believe that the carriers' experiences and observations collected in the report, along with the case studies, support the findings and recommendations.

We agree with HCFA that the report should reflect the statutory context within which carrier assessment of new technology is made. We did not mean to imply that HCFA was remiss in failing to use its statutory authority. On the contrary, we believe that HCFA has been thwarted in its efforts by ambiguous statutes and complex procedural requirements. In the final report we have made the context more explicit. Also in the final report, we have recognized more completely HCFA's recent initiatives to update the coverage process and improve communication. These are significant steps. Our report recommends additional beneficial steps derived from the carriers own experiences and perceptions.

Finding 1 - Unwarranted Variation:

The HCFA states that variation in coverage and pricing decisions does not necessarily indicate a problem; variation was designed into the program from its outset in 1965. But the OIG report speaks of unwarranted variation. Neither OIG nor the respondents to the survey finds any basis for the extent of variation perceived by the carriers. Although the extent of variation contemplated by the architects of Medicare is not defined for coverage and pricing activities, there are some guides available that allow us to place the variation in context:

- We found average amounts allowed for new technologies varying by factors of five among carriers. In contrast, economic indices such as personal income or cost price indices rarely vary by a factor as much as two between States.

- Carrier medical directors perceive the variation in coverage among carriers as well in excess of the variation on medical practice among States. They observe that medical practice today in 1989 is much more uniform nationally than it was at the outset of Medicare in 1965.

- Small and remote carriers report that they see new technologies soon after general professional acceptance. Any advantage for the major medical centers operates during the investigative phase of the technology.

- Manufacturers of new technologies operate in a nationwide market. Only rarely do manufacturers make new technologies available in limited areas of the country.

The HCFA states that the survey question on consistency is a questionable substitute for analysis ot actual coverage data. As previously mentioned, we believe that the carriers' perceptions and the case studies provide ample basis for a finding that coverage and pricing decisions are inconsistent. However, we modified our finding to indicate that some, but not all, of the variations are unwarranted. We are particularly concerned about variations in pricing.

The HCFA correctly states that the data in table II-A-1 (now table B-1a) of the draft report refer to codes used, not to coverage decisions. We have revised the table and the discussion in

the text to correct this error. But we should emphasize that the conclusion is not changed. The same item or service is treated differently by different carriers.

We found no evidence that carriers make decisions not to cover; they just do not make the decision to cover. If the data in table B-1a are taken at face value, they show extensive variation in what is supposed to be a uniform national coding scheme, and raise a question as to how well the HCPCS applies to new technologies. If, however, the implication drawn by the OIG is correct, and the absence of a code indicates absence of coverage for a new technology, that raises a question as to how equal is the access different Medicare beneficiaries have to what is supposed to be a nationally distributed new technology.

The HCFA states that the draft report does not disclose arrays of allowed amounts in table II-C (now table B-3) and does not identify any overall financial effect. We agree that the dispersion in allowed amounts should be shown more completely than through the sample in figure 8. Accordingly, we have added standard deviations to table B-3. These clearly show that the variations are substantial. Since our choice of technologies and therefore the data on average allowed amount are illustrative, we should not and do not project financial effects. We found that variation exists, and it exists for some critical new technologies. We did not attempt to audit all new technologies.

The HCFA states that there are fundamental methodological problems with the use of HCFA's Part B Medicare Annual Data System (BMAD) and with lumping together the data for different codes. We used BMAD because that gives the best available measure of what was actually paid. Prevailing charges would give what should have been paid under ideal conditions.

Similarly, the use of different codes by different carriers would have made any comparison by individual code meaningless. We asked each carrier the same questions, in the same words, and we used BMAD to translate their responses into allowed amounts. Our averages do *average* everything the carriers include under each new technology. We recognize that there are different levels within each technology but we choose to report each as a group.

Finding 2 - Economies Not Realized:

The HCFA states that no concrete and factual data are presented to show that the actual costs decreased and that the financial effect is not defined. However, since neither HCFA nor the carriers routinely identify new technologies or keep track of payment trends as these technologies mature, such data is practically nonexistent. Nevertheless, we gathered the carriers' own perceptions about cost trends for new technologies. We reported on the apparent contradiction between the large number of respondents who believe that costs decrease and the absence of any affirmative effort to reflect these perceived cost decreases in Medicare reimbursement amounts.

The HCFA states that the report does not take into account the criteria for determining a reasonable charge and the statutory constraints on HCFA and the carriers in use of inherent

reasonableness. We agree, and we have modified the background section of the final report accordingly. Because of these factors we recommended, and continue to recommend, legislative action.

Finding 3 - Little Guidance to Carriers:

The HCFA states that the evidence in the report does not show HCFA to have failed to fulfill the objectives of the law in relation to carriers as Medicare contractors. The purpose of this study is to identify ways for HCFA and the carriers to better achieve their objectives, changing the structure only when a change is needed. We found that the carriers collectively believe that they, and HCFA, can do better at assessment of new technologies. Our recommendations address the carriers' need in this area.

The HCFA states that the report does not take fully into account HCFA's initiatives to update the coverage process and to improve communication between HCFA and the carriers. We agree, and we have taken more complete note of these in the final report.

Recommendation 1 - Clearinghouse:

The HCFA rejects our recommendation for a clearinghouse stating that it is not shown cost-effective, that carriers don't use existing clearinghouses, and that the clearinghouse function of the National Center of Health Services Research and Health Care Technology Assessment (NCHSR/HCTA) is not mentioned.

We continue to support our recommendation. The carriers themselves want something existing clearinghouses do not offer, prompt access to coverage background and also pricing information. The HCFA initiatives don't give the carriers this kind of information. The means to provide such information promptly to the carriers can and should be developed more strongly. What we are advocating is a more active strategy for disseminating information to take the place of one that relies on the carriers to request information. We think that a clearinghouse can be an effective way to do this, but we would support any other technique provided it is aggressive and systematic. We have modified the wording of our recommendation to clarify our intent.

Limitations of the existing clearinghouses make it all the more important for HCFA to exercise leadership in prompt sharing of information that is useful to the carriers in assessing new technologies. If, as the carriers believe, information sharing will eliminate unnecessary duplication of effort, then carrier use of the clearinghouse would be cost beneficial. The role of the NCHSR/HCTA clearinghouse function will have to be reconsidered now that OBRA-89 has replaced NCHSR/HCTA with the Agency for Health Care Policy and Research.

Recommendation 2 - Foster Consistency:

The HCFA agrees that they should constantly foster improvements in the carrier decision making processes for new technologies. We have stated above that the HCFA initiatives are a

valuable beginning. Regional meetings and Technical Advisory Groups similar to the the New York Region's Medical Issues Technical Advisory Group (MITAG) model hold promise as effective ways to foster active and ongoing communication among carriers, with HCFA in its proper oversight role. We also recommend that HCFA continue to find ways to give carriers selective access to pricing information. The recent initiative of supplying BMAD data is a good start. This is the very data we used for our case studies. But, as HCFA has remarked, it has its limitations, especially given the discretionary nature of coding of some services. Further, we recommend that HCFA, in reviewing the carriers' performance, give special attention to new technology. The respondents to our survey (medical directors) either had no knowledge of the Contractor Performance Evaluation Program (CPEP) process or little understanding of its function. They reported that it did not relate at all to their technology assessment activities.

Recommendation 3 - Seek Broader Bases for Pricing in the Law:

The HCFA rejects our recommendation, stating that it amounts to expansion of inherent reasonableness authority, which it goes on to state the Congress wants to restrict. Also, HCFA states that the recently enacted resource based relative value system for physician payment will soon make this issue moot.

We agree and we have modified our legislative recommendations to focus exclusively on nonphysician services. But we are concerned about the practical aspects of the new provisions. In order to develop fee schedules for new and emerging treatment modalities, HCFA must identify them. We believe that the ability to identify emerging new technologies is the area of greatest weakness in the current system. We are hopeful that HCFA's recent initiatives will be effective in addressing this weakness. We will know more when our future evaluations, mentioned above, are completed.

We also remain concerned that the many Part B payments for nonphysician services, such as durable medical equipment, prosthetics, and physiological testing, are not covered by the payment reforms of OBRA-89. We believe our legislative proposals are particularly important for these nonphysician services.

PUBLIC HEALTH SERVICE (PHS) COMMENTS

General Comments

Through the Office of Health Technology Assessment (OHTA), PHS is involved in the Health Care Financing Administration (HCFA) process for making national coverage decisions for health care technologies. However, this relationship on the part of OHTA does not directly involve the activities of the Medicare carriers, particularly where pricing matters are concerned.

A review and analysis of table II-A-1, "Number of Carriers Covering Each Technology 1985-1987," in the OIG report indicates the usefulness and necessity for technology activities.

While a clearinghouse is necessary for compiling and disseminating information, completed assessment reports by PHS and subsequent Medicare Coverage Instructions make carrier coverage decisions easier and more consistent. For technologies assessment by OHTA such as Trabeculoplasty, Cochlear Device Implantation and Extracorporeal Shock Wave Lithotripsy most carriers were consistent in their coverage decisions. Also evident is the fact that even where a National Coverage Decision has been made by HCFA such as in the case of Pacing, not all carriers are aware or consistent with the HCFA Position for that technology or procedure.

The following are our comments on the OIG recommendations.

OIG Recommendation

The Health Care Financing Administration and the Public Health Service (PHS) should cooperate in establishing a clearinghouse devoted to the compilation and dissemination of information on new health care technologies. The clearinghouse could be established either within the Department or through a contract with a private entity.

PHS Comment

We concur in general with this recommendation. The OIG report makes reference to the PHS-supported Institute of Medicine (IOM), Council on Health Care Technology clearinghouse function which is already operational. The report notes, however, that few carriers draw on this resource as well as other efforts providing technology information. The availability and location of a clearinghouse devoted to the compilation and dissemination of information on new health care technologies may not be as much the issue as the need to get Medicare carriers to utilize the existing resources. Furthermore, the reliance of Medicare carriers on a national clearinghouse for their technical information will certainly address the concern raised in the OIG report for greater consistency among carriers in their coverage decisions.

Regardless of the organizational location of the clearinghouse, the Department or IOM, adequate funding for such an endeavor is paramount for a successful program. Reorganization legislation being considered for the National Center for Health Services Research and Health Care Technology Assessment (NCHSR) may place the IOM clearinghouse function within the National Library of Medicine. PHS is in full agreement with the OIG report that there is a need for a national clearinghouse; however, the support for the clearinghouse functions already operational may be preferable to seeking the establishment of a clearinghouse within the Department. Should the Department be encouraged to established a clearinghouse then consideration and funding for the operation could be given to the Division of Research Dissemination and External Liaison (Division) within NCHSR. The Division is responsible for disseminating the assessments of OHTA and has a mailing list of approximately 25,000 people and organizations.

OIG Recommendation

The Health Care Financing Administration should foster greater consistency among the carriers in their coverage and pricing decisions concerning new technologies.

PHS Comment

Even though this recommendation is directed to HCFA, PHS concurs in general with it. PHS is aware of the inconsistency in contractor coverage decisions as well as HCFA proposals to address this issue. The steps outlined by HCFA in the *Federal Register,* January 30, 1989, (54 FR 4302) regarding "The Medicare Program: Criteria and Procedures for Making Medical Services Coverage Decisions that Relate to Health Care Technology" seem appropriate and adequate for obtaining greater consistency in the coverage decisions of Medicare Carriers.

OIG RESPONSE TO PHS COMMENTS

We welcome PHS support for a clearinghouse and we agree that there is a need to get Medicare carriers to utilize existing resources more effectively. We encourage HCFA and PHS to arrange a meeting of all interested parties to discuss operating alternatives, including use and organizational location of the IOM clearinghouse function. We agree with the PHS statement that, regardless of the organizational location of a clearinghouse, adequate funding is paramount for a successful program.

We note that PHS is aware of the inconsistency in contractor coverage decisions as well as HCFA proposals to address this issue. The proposed rule on coverage decision making is an important first step, but this alone is not enough. The carriers are looking for more effective guidance from HCFA, better communications among themselves, and quicker more extensive sharing of national Medicare data with the carriers by HCFA. The MITAG discussions provide an attractive model for improving communications.

ASSISTANT SECRETARY FOR PLANNING AND EVALUATION (ASPE) COMMENTS

We have been concerned about HCFA's coverage determination process for some time and welcome and support your recommendations to improve coverage decision making.

OIG Recommendation

Establish a joint HCFA/PHS clearinghouse on new technologies.

ASPE Comment

We support a joint clearinghouse, but would prefer it to be maintained within the Department, rather than contracted out to a private entity. We believe that an in-house clearinghouse would offer significant advantages in terms of cooperation and rapid dissemination of information.

In addition, we suggest that substantive linkage among the Effectiveness Initiative, technology assessment activities of NCHSR, and the recommended HCFA/PHS clearinghouse could have synergistic effects on all three.

Since carriers do not utilize existing national technology sources, it is imperative that the clearinghouse take the initiative to communicate with the carriers and foster communication among carriers.

OIG Recommendation

HCFA should seek legislation to increase its authority to make reasonable charge determinations for new technologies both at the time of initial coverage and after the technology has been assimilated into the marketplace.

ASPE Comment

With the Congress likely to implement an RBRVS sometime in the near future, it becomes even more important that HCFA acquire and exercise authority to set reasonable charges (and presumably soon, relative values) for new technologies and other newly covered items and services as well as the authority to revise such charges and relative values as circumstances warrant.

Thank you for sharing your report with this office.

OIG RESPONSE TO ASPE COMMENTS

We welcome ASPE support for a clearinghouse which takes the initiative to communicate with carriers and foster communication among carriers. We encourage HCFA and PHS to arrange a meeting of all interested parties to discuss operating alternatives, including whether an in-house clearinghouse would offer significant advantages in terms of cooperation and rapid dissemination of information.

We agree with ASPE that HCFA needs to acquire and exercise authority to set reasonable charges, and also the authority to revise charges.

HEALTH INDUSTRY MANUFACTURERS ASSOCIATION (HIMA) COMMENTS

Thank you for your August 16 letter transmitting a copy of your "Medicare Carrier Assessment of New Technologies" August draft report (Draft Report). Medicare assessment of medical technologies, at both the national and local levels, has a significant impact on our members—manufacturers of medical devices, diagnostics and health care information systems. Since 1986, HIMA has been quite involved with the Medicare coverage and payment process. We appreciated your contacts with our organization during the research stages of this Report and we welcome the opportunity to comment on the Draft Report.

Your study is particularly important in view of the unique challenges which technology innovation presents. Continual research on medical devices and diagnostics makes innovation both rapid and incremental. The assessment process is often time consuming and results in a snapshot of medical practice. Carriers face the difficult task of keeping their policies up-to-date with current medical knowledge.

The following comments address issues in your report in the sequence they appear in the Draft Report.

A. HIMA COMMENTS ON IG FINDINGS

1. *Technological innovation has not been the major cause of Medicare Part B payment increases.* Rather, new devices have allowed many services to be performed in a more cost-efficient location—the outpatient setting—contributing to Congressional and Administration goals under the prospective payment system.

   The Draft Report states that HCFA and OTA studies show that new health care technologies account for a substantial portion of the annual increase in Part B payments (page 2). The data in the report attributed 50% of this increase to inflation and 37% to increases in utilization.

   A clear objective of Congress and the Administration in implementing the prospective payment system and the professional review organization program was to encourage a shift of medical services from more costly inpatient settings to the outpatient arena. This would save costs on inpatient care, but it would also trigger increased utilization of outpatient services.

   Technology has helped to shift services and costs to less expensive outpatient settings.

   Additionally, studies by ProPAC confirm that technology has played a minimal role in hospital inpatient cost increases.

   > Overall, the results suggest that new technology and technological advances account for only a small part of the annual increase in total Medicare expenditures for hospital operating costs. (Medicare Prospective Payment and the American Health Care System, Report to the Congress, Prospective Payment Assessment Commission, June 1988, page 22.)

   A complete examination of the role of technology in terms of Medicare Parts A and B payments reveals that technology contributes only modestly to overall increases.

2. *The section dealing with other studies and actions should include a description of the September 14, 1988 report and recommendations of the Congressionally mandated National Advisory Council on Health Care Technology Assessment.*

3. *Improved communications between manufacturers and carriers can make technology assessment more efficient.*

The Draft Report states that: "Manufacturers also create problems for the carriers by providing data that are not relevant, objective, or complete." (Page 6.) Manufacturers can provide better prepared materials for carriers if they know precisely what information carriers need in order to make reasonable coverage decisions. The information requirements are rarely spelled out by carriers. Even coverage requirements used at Medicare's national level have only been issued in proposed form as recently as January 30, 1989. (See proposed rule in Federal Register.) Carriers in some cases are quite reluctant to take the time to discuss their evaluations with manufacturers. HIMA has some evidence of carriers refusing to respond to manufacturers' inquiries. Improving the communication between carriers and manufacturers would facilitate proper assessments.

HIMA has for three years been conducting seminars to educate its members about Medicare concerns. We have featured representatives from carriers and would like to continue and even expand these programs. (These conferences have also included representatives from the Inspector General Division of the DHHS Office of General Counsel.)

4. *HIMA and its members have consistently identified the problems with cost-effectiveness as a coverage criteria.*

The Draft Report (pages 8-9) implies an endorsement by manufacturers of cost-effectiveness as a coverage criterion. HIMA has underscored the legal, methodological, and policy problems associated with using cost-effectiveness as a Medicare criterion. Some clarification of this section should be made.

B. HIMA COMMENTS ON IG RECOMMENDATIONS

1. *A clearinghouse to compile and disseminate information on health care technologies could be an asset to carrier decision-making provided the information was regularly kept up to date and that the sources of data into the clearinghouse included information from a wide range of reliable sources, including manufacturers of medical technology.*

HIMA would like to sound a note of caution that such a clearinghouse should not unduly complicate the coverage decision-making process. Creating a new entity might only add delay in decisions without improving the quality of decisions. Thus, it would be crucial, if such a clearinghouse was to be considered, that clear operating parameters be established that assure rapid and accurate acquisition and dissemination of data.

2. *Greater consistency, to the extent it is needed, can be promoted by finalizing the Medicare coverage regulation.*

The IG report recommends that HCFA should foster greater consistency among carriers in coverage and pricing decisions. HCFA has made a substantial step in this direction already with the publication of a proposed rule on January 30, 1989, dealing with Medicare coverage criteria. The criteria would apply for both national and local decision-making. Setting out the rules for coverage is the best first step in making decisions more consistent.

The Medicare program was designed to operate in a decentralized fashion. The system of carriers and fiscal intermediaries was set up to take advantage of the expertise held by operating insurance companies. The Draft Report proposes, in some respects, to reverse this principle. The carriers would benefit from a binding national mechanism that imposes decisions on them because it would relieve them from the burden of making the decisions themselves. They could in fact shift this responsibility to the federal government.

Some improvements in carrier consistency should be expected, but not the federalization of technology assessment. The question of variation in practice patterns is a complex one. There are legitimate divergences in medical care when comparing research-intensive, teaching institutions to small rural hospitals. Carriers should continue to have the responsibility, discretion, and flexibility to apply coverage rules to their own unique situations. This can assure that decisions are made with the patient's needs in mind, not just the need for national uniformity.

The finalization of HCFA's coverage rule, transmission of the rule to carriers, education of the carriers, and requiring compliance with the rule through HCFA's annual carrier performance evaluation program (CPEP) would improve performance without creating a new layer of bureaucracy.

3. *Sufficient legislative authority clearly exists for Part B payment controls.*

The IG report suggests legislative changes to allow HCFA to establish reasonable charges for a new technology, at the time of initial coverage and after the technology has been disseminated into the marketplace. HCFA currently has wide-ranging authority to establish payment amounts and to change those amounts. The legislation allowing the use of inherent reasonableness for physician services and for other Part B items, the implementing regulations, and the carrier instructions are quite detailed. They afford carriers a high degree of guidance in payment analysis. This is not to say that Part B payment mechanisms are not complex and could benefit from clarification. However, no further legislative changes should be contemplated until recent initiatives have been fully understood by the carriers and providers.

The Draft Report assumes that costs will inevitably drop as familiarity with a new technology increases. This assumption needs to be fully explored to see if in fact

"economics of scale or knowledge" occur in the medical marketplace. The concept appears to be driven by anecdotes and two procedures, cataract extraction and coronary artery bypass grafts, which may not represent the actual dynamics of technology-specific, system-wide efficiencies.

C. CONCLUSION

The role of carrier coverage decision-making has been and will continue to be an important part of the Medicare program. The Draft Report identifies some areas where improvement is needed. HIMA supports, as noted above, certain reforms that will contribute to better and more efficient decisions. We are concerned that certain recommendations made in the Draft Report would not improve the process.

We very much appreciate the opportunity to review the Draft Report and share our comments with you.

OIG RESPONSE TO HIMA COMMENTS

We agree that certain reforms will contribute to better and more efficient decisions and we welcome the support of HIMA in those areas where improvement is needed. We continue to believe that the recommendations made in the draft report would improve the process.

In response to specific concerns expressed by HIMA:

A1. The report states that technology innovation accounts for a *substantial portion* of the annual increase in Part B payments, and cites studies by HCFA and OTA in support. We are not aware of more recent studies that estimate this portion more precisely. We did not state, or imply, that technological innovation is the *major cause* of the annual increase. Indeed, we did state that inflation is the largest factor.

A2. We have added a reference to the report of the National Advisory Council on Health Care Technology Assessment to the section dealing with other studies and actions.

A3. We recognize the initiative of HIMA in conducting seminars to educate its members about Medicare concerns. But we also recognize that manufacturers ordinarily take the initiative in approaching carriers about new technologies. Although we agree with HIMA that improved communications can make technology assessment more efficient, we remain concerned that HCFA and the carriers need to take a more affirmative attitude in relating to manufacturers.

A4. The four manufacturer's representatives whom we interviewed gave their own opinions about cost effectiveness as a major criterion in making Medicare coverage decisions. It should not be inferred that they are representative of the group of all manufacturers. We

have modified the text to emphasize that these are individual opinions, and we have noted HIMA's stated concerns with cost effectiveness as a criterion.

B1. We agree with HIMA's concern that any clearinghouse provide information promptly in order to expedite coverage and pricing decision making, and we have noted the importance of time in the final report.

B2. We agree with HIMA that implementation of HCFA's proposed rule on coverage decision making is an important first step, but this alone is not enough. The carriers are asking for more effective guidance from HCFA, better communications among themselves, and quicker more extensive sharing of national Medicare data with the carriers by HCFA. The MITAG discussions provide an attractive model for improving communications.

B3. We continue to believe that the statutory authorities HCFA now has for deciding the amounts Medicare pays for a new technology are so detailed and complex as to be effectively unusable. The small number of carriers reporting use of inherent reasonableness illustrates this situation. We believe there is a need for a clearly stated statutory authority for HCFA to set national prices or price limits in those exceptional situations where HCFA believes this action warranted.

This authority should allow HCFA to go beyond charge histories (for example, to consider product development costs) in order to set a reimbursement amount that is fair to the provider of service, encourages beneficiary access to the benefits of new technology, and supports innovation by the manufacturer or other innovator. We should emphasize that we foresee this process occurring about as frequently as do national coverage decisions now, approximately 20 time a year. Carriers would continue to make almost all Part B coverage and pricing decisions.

HEALTH INSURANCE ASSOCIATION OF AMERICA (HIAA) COMMENTS

Thank you for sharing with us the draft report entitled, "Medicare Carrier Assessment of New Technologies," which provides an overview of major issues and challenges facing the Medicare Part B carriers in assessing new health care technologies. We have had an opportunity to review this draft report and we have the following comments:

1) We would support the establishment of a clearinghouse on emerging and new technologies in order to access information bearing on the identification, coverage and pricing of such technologies.

The HIAA has been discussing the desirability and feasibility of establishing such a clearinghouse for its members, and we would be very willing to meet with representatives from HCFA and PHS in order to discuss a collaborative effort.

2) We support the recommendation regarding HCFA's need to foster greater consistency among carriers in their coverage and pricing decisions concerning new technologies and to go a step further, we would recommend that such information should be shared with private sector third party payers.

3) We support the recommendation that HCFA should seek legislative authority to broaden the basis upon which it can establish the reasonable charge for a new technology, both at the time of initial coverage and after the technology has been assimilated into the market place. There are several coverage/payment level issues that commercial insurers must deal with on a daily basis, and if such information could be shared with private sector payers, it would also create greater consistency.

On page 15 of the report, it states that, "HIAA has established a Practice Assessment Center which began in 1987, with preliminary studies in small area analysis and reviews of obsolete technologies." The formal name of the HIAA technology assessment activity is called the Medical Practice Assessment Unit, which has initially developed a report on underevaluated health care technologies, which includes information on obsolete technologies and commissioned a study on quality assessment. Further, the unit plans to convene rotating panels of experts by clinical area, in order to identify emerging and new health care technologies, as well as technologies that may be becoming obsolete.

In addition to this activity, the association plans to hold a series of conferences dealing with coverage payment level issues, such as identifying sets of criteria by delivery setting, e.g., hospital inpatient care, ambulatory care, preventive services, etc. As mentioned, we are considering the establishment of a clearinghouse in order to assist our companies in identifying emerging and new technologies.

The unit does not plan to conduct any small area analysis studies at this time, and your final report should reflect that.

I believe the recommendations offered in the report would dramatically improve the operational aspects of Medicare carrier identification and assessment of new technologies, and we would be pleased to work with the Inspector General's office to improve the Medicare coverage decision-making process.

OIG RESPONSE TO HIAA COMMENTS

We welcome HIAA support for our three recommendations, and we encourage HCFA and PHS to arrange a meeting of all interested parties to discuss collaborative efforts with regard to a clearinghouse.

We misunderstood some of the information about the Medical Practice Assessment Unit that was provided by HIAA during our interviews. We have changed the final report to recognize the activity of the unit as stated by HIAA.

APPENDIX E

ENDNOTES

1. *Health Insurance for the Aged and Disabled*, Title XVIII of the Social Security Act, 42 U.S.C. 1395 et seq.

2. Section 1862(a)(1)(A) of the Social Security Act, 42 U.S.C. 1395y(a)(1)(A).

3. Section 1842(a) of the Social Security Act, 42 U.S.C. 1395(u)(a).

4. U.S. Department of Health and Human Services, Health Care Financing Administration, *Medicare Program; Procedures for Medical Services Coverage Decisions; Request for Comments*, Notice, 52 Federal Register 15560, April 29, 1987.

5. U.S. Department of Health and Human Services, Health Care Financing Administration, *Health Care Financing Notes*, September 1986.

6. U.S. Congress, Office of Technology Assessment (OTA), *Medical Technology and Costs of the Medicare Program*, Report OTA-H-227, July 1984, pp. 43ff.

7. Notes 4 and 5. From 1980 to 1985, the Consumer Price Index for all urban consumers for all items rose from 246.8 to 322.2 (31 percent), and that for medical care rose from 265.9 to 403.1 (52 percent). Data from U.S. Department of Labor, Bureau of Labor Statistics.

8. Note 6. The OTA explored the dual relationship between Medicare and health care technology. Medicare policies affect the adoption of technologies, and patterns and use of technologies affect Medicare costs. The OTA listed 18 major options, among them an option to mandate that Medicare coverage decisions include cost considerations when appropriate and an option to move to fee schedules for physician payments under Medicare.

9. Lewin and Associates, *A Forward Plan for Medicare Coverage and Technology Assessment*, Washington, D.C., 1985. Among the changes recommended by Lewin are clarifying and opening up to the public the coverage decision making process and more narrow coverage decisions by HCFA.

10. U.S. Department of Health and Human Services, *Growth in the Volume and Intensity of Physician Services*, Washington, D.C., 1989. This report is in response to Section 4056(c)(2) of Public Law 100-203, The Omnibus Budget Reconciliation Act of 1987.

11. Jameson v. Bowen, C.A. No. CV-F-83-547-REC (E.D. Cal).

12. Federal Register, January 31, 1989, Volume 54, Page 4302.

13. Griffiths et al. v. Bowen, U.S. District Court, D. Mass., C.A. 86-2556-Y.

14. U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, National Advisory Council on Health Care Technology Assessment, *The Medicare Coverage Process*, Washington, D.C., 1988.

15. Blue Cross and Blue Shield of Massachusetts, *Guidelines for Proper Submission of New Service/Product Information to Third Party Payers*, Boston, MA, no date.

16. Blue Cross and Blue Shield Association, *Coverage of New or Unusual Devices, Services and Procedures in the Absence of Written Medicare Guidelines*, Administrative Bulletin 1816, Chicago, IL, November 7, 1985.

17. Similar comments about the role of cost effectiveness were made in the comments received by the HCFA, note 4, and in the study by Lewin and Associates, note 9.

18. Joint letter to the Secretary of the U.S. Department of Health and Human Services, dated March 30, 1989.

19. See the OTA report on Medical Technology and Costs of the Medicare Program, note 6, appendix E, table E-4.

20. U.S. Department of Health and Human Services, Health Care Financing Administration, *Coverage Issues Manual*, HCFA Publication 6, Section 50-13, November 1985.

21. The idea of a clearinghouse to share information among carriers, particularly on coverage issues, has been put forward before. See the discussion in appendix E of note 6 for further comments by carriers.

22. Section 1842(b) of the Social Security Act, 42 U.S.C. 1395(b).

23. U.S. Department of Health and Human Services, Health Care Financing Administration, *Medicare Carriers Manual*, HCFA Publication 14, Part 3, Section 5000 ff, especially Section 5246, March 1987.

24. United States Department of Labor, Bureau of Economic Analysis, *Survey of Current Business, 68* (4) 75, April 1988.

25. American Chamber of Commerce Researchers Association, *Inter-City Cost of Living Index*, Fourth Quarter, 1987, Indianapolis, Indiana, 1988.

26. Kirchner, Merian, *Medical Economics*, October 3, 1988,page 126ff.