DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration
Washington D.C. 20201 – 0001

FAX COVER SHEET

HCFA'S OFFICE OF LEGISLATION

200 independence Avenue S.W. 341-H

TO: Deborah Adler ***FAX NO:*** 456-5557

NO. of PAGES: 17 ***DATE:*** 9/6

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

SEP - 5 2000

Ms. Pam Bailey
President
AdvaMed
1200 G Street, NW, Suite 400
Washington, D.C. 20005-3814

Dear Ms. Bailey:

I appreciate the opportunity to comment on your policy paper, "The Medicare Payment Process and Patient Access to Technology," which provides AdvaMed's perspective on Medicare's coverage, payment and coding processes. The Health Care Financing Administration's (HCFA's) primary goal is to assure that beneficiaries have access to high quality health care which includes access to effective medical technologies. While there is always room for improvement, we believe that we have been successful in assuring that innovations in health care are readily available for Medicare beneficiaries. As you can imagine, then, we strongly disagree with some of the conclusions presented in your paper and the assumptions on which they are based.

HCFA must balance competing interests as it strives to assure high quality health care for beneficiaries. We must act as a prudent purchaser on behalf of our 39 million beneficiaries and hundreds of millions of taxpayers, pay providers adequately and fairly under the law, and protect the Medicare trust funds. At the same time, we must incorporate the views and interests of beneficiaries, providers, manufacturers, private health plans, taxpayers and others, including members of Congress, into the decision making process.

In contrast to our multifaceted mission and approach, your position paper draws conclusions from only one perspective – the financial environment for manufacturers. From this sole perspective, it is impossible to judge fairly the effectiveness of Medicare in assuring patient access to technology. For the past 35 years, Medicare beneficiaries have had ready access to the vast majority of new technologies as they became available, either immediately through local coverage decisions or alternatively through bundled payment systems. This is appropriate because most new technologies are similar to existing technologies, or are considered integral to existing procedures. Your paper does not present compelling arguments that beneficiaries have lacked access to new technology. The paper also fails to provide a complete picture from which to examine the effectiveness of Medicare's coverage, coding and payment procedures. This is disappointing because we pointed out the narrowness of this perspective to the paper's authors at the Lewin Group early on in their inquiry.

We believe your policy paper relies on an inaccurate set of assumptions.

- Your paper assumes that Medicare beneficiaries do not have adequate access to new technology. We believe that beneficiaries do have appropriate access to beneficial technology.

- Your paper assumes that FDA approval, which establishes that a device is safe, is a sufficient standard for what is clinically reasonable and necessary. In fact, these are different standards.

- You assume that new technology, whether innovative or incremental, always improves health outcomes. In fact, some new technologies do not improve outcomes and may even contribute to negative outcomes.

- You assume that Medicare payment systems should assure coverage of manufacturers' start-up costs for new technology rather than make them compete with existing technology. We see Medicare's primary role as providing beneficiaries with access to appropriate health care.

- You assume that new technology is always more expensive. Experience demonstrates that this is not always the case.

The processes of innovation/diffusion, evaluation, clinical practice adaptation, and payment for technology are complex and interrelated. We have to make sure that our policies do not discourage the use of valuable new technologies that will improve care for beneficiaries. At the same time, our policies should not encourage the use of unproven, ineffective, or harmful technologies or create a unique advantage for new technology.

We agree that procedures for obtaining coverage, coding and payment should be as responsive, timely and understandable as possible in order to serve Medicare beneficiaries and other stakeholders. We believe that the vast majority of new technology is treated in a timely manner through its integration into existing payment systems and through the flexibility provided to local carrier medical directors. Nevertheless, there are instances when "breakthrough" technologies are also subject to our coverage, coding and payment determination processes. You have provided examples where there has been difficulty, both in negotiating multiple processes, and with the time it can take to assign national codes.

Let me first address coverage issues with regard to breakthrough technology. There often are many clinical questions about these breakthrough technologies – questions the FDA approval process was not designed to answer. These clinical issues are particularly critical for the elderly and disabled Medicare population. Thus we must carefully evaluate these technologies while making coverage and payment decisions. Since we streamlined the National Coverage Decision process last year, we have made and implemented national decisions in well under 6 months, and payment for these

technologies through local decision making can generally continue while decisions are being implemented nationally.

We are concerned that your paper suggests that Medicare should use passthrough payments more broadly. We believe determining appropriate payment amounts requires the collection of data that reflect the technology's experience in Medicare. New technologies are not always more expensive. We have found that the experience of a new technology under existing payment systems reveals the actual cost and appropriate payment amount. Moreover, our ultimate objective is to fully integrate the technology into existing payment systems so that practitioners and other providers are able to choose the most appropriate technology for the patient. You suggest that passthroughs of the costs of new technology would promote beneficiary access to new technology. We believe expanded use of passthroughs in Medicare's prospective payment systems would remove the incentive that practitioners and providers face to choose the most efficient technology where the clinical options have similar benefit to the patient. As a consequence, passthroughs would impose avoidable, significant new costs on Medicare beneficiaries and taxpayers.

Also, with regard to coding issues it is important to understand that many stakeholders are involved in the assignment of national codes and computing national payments.

- Providers, particularly hospitals and physician offices, seek stability in coding and payment. Frequent changes and updates disrupt claims processing systems, raise issues of compliance, and create uncertainty in payments;

- The medical community has an interest in assuring that coding systems are clinically coherent, and;

- Private and other public insurers often use the same coding and payment systems as HCFA.

We cannot unilaterally assign codes without consulting all of these stakeholders, and that is why these processes take time. Moreover important changes stemming from the Health Insurance Portability and Accountability Act will require greater standardization and consultation across the industry. Yet we understand that the timeframes for assigning new national codes for breakthrough technologies can be longer than the manufacturing industry would like. As we have done in the past, we welcome the opportunity to meet with you and other stakeholders to examine potential ways to speed up this process.

We agree that HCFA should take action within the structure of its organization to better assist manufacturers seeking national codes and payments in addition to what is available on our website. We are committed to working with you and would like to meet to discuss your concerns and ways we can make constructive improvements in the process. Further, I want to reemphasize our willingness to work with manufacturers when they seek FDA approval to assist in determining up front the kinds of information that would be useful in

speeding up the Medicare coverage decision process, particularly where breakthrough technologies are concerned.

I also want to point out our commitment to cover many of the costs associated with clinical trials, described recently in a proposed National Coverage Decision. Under the proposed decision, Medicare would pay for monitoring and evaluation, device implantation, and other costs, such as room and board for a hospital stay required as part of a clinical trial that meets the qualifying criteria. Assuring Medicare beneficiaries that these and other specified costs will be covered is expected to encourage them to participate in clinical trials and the knowledge gained from clinical trials will lead to better health care for our 39 million beneficiaries. In addition, this proposed decision should assist you in covering some start up costs associated with some new technologies. Your cooperation and suggestions are welcome as we implement this important new policy.

Last year we worked together to make improvements in our national coverage process. I look forward to continuing to work constructively with you, as we strive to assure high quality care for our Medicare beneficiaries.

Sincerely,

Nancy-Ann Min DeParle
Administrator

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Office of the Administrator
Washington, D.C. 20201

JUL 24 2000

The Honorable Bill Frist, M.D.
United States Senate
Washington, DC 20510

Dear Senator Frist:

Thank you for your June 5, 2000 letter concerning the volume of pages of Medicare regulations. You and I agree on many things, including the desirability of streamlining the federal government's oversight of the Medicare program wherever possible, consistent with sound management on behalf of our 39 million beneficiaries and the American taxpayers. I believe it is important that we also try to reach a common understanding on the nature and volume of the current Federal regulations relating to Medicare, because that is the starting point for any streamlining efforts we might undertake.

I believe you misunderstood my January 27, 2000 letter to Representative Stark in which I took issue with your statements about the number of pages of Medicare regulations, which were apparently based on assertions by the Mayo Foundation. I believe my letter makes clear that when this all started – with an op-ed published by Robert Waller, M.D., of the Mayo Clinic in the Washington Times – I first asked Dr. Waller the basis for his statement. He referred me to the Mayo Foundation for the specifics. My staff then contacted the Mayo Foundation, hoping they would share their methodology and calculations with us, but they never provided us with any information. We continued to try to find the source of the "110,000 pages" claim, while conducting our own research. Indeed, after your statement was published in the press release accompanying the Medicare proposal you introduced with Senator Breaux in January 2000, my staff also called your office to determine the source and derivation of the numbers you used, but again received no response.

Thus, in responding to Representative Stark in early January, I presented the results of HCFA's own efforts to quantify the number of Medicare regulations, which found that there are 1,700 pages of Medicare regulations implementing 900 pages of statutes enacted by Congress. I did not know – as you have now revealed – that the Mayo Foundation had included program manuals used by providers, suppliers and the private insurance companies that process Medicare claims in its calculation of pages of "regulations." Although manual pages are not technically "regulations," and although it is misleading to argue that every physician and every provider needs to know each and every manual provision, I agree that program manuals contain interpretive rules of general applicability. Even if manual pages are included, however, the Mayo Foundation has grossly overstated the pages of regulatory requirements applicable to the Medicare program. The 21 HCFA program manuals encompass 32,803 pages. Therefore, adding program manual pages to the pages of regulations and statutes, there are approximately

35,000 pages of Medicare statutes, regulations and program manuals – about one-third of the 110,758 pages charged by the Mayo Foundation.

I have now reviewed the Mayo Foundation's list (which we finally received at a Congressional hearing this month) and believe that it exaggerates and misrepresents the administrative requirements of the Medicare program in several fundamental ways.

- First, the Mayo Foundation significantly overstates the pages of statutes and regulations applying to the Medicare program.
- Second, the Mayo Foundation includes in its list documents that cannot fairly be characterized as part of the Medicare regulatory framework. Documents such as Federal Register preambles, newsletters, or bulletins are explanatory or educational in nature, and it is not accurate to include them in a list of regulatory requirements. Similarly, documents such as Provider Reimbursement Review Board (PRRB) decisions or Federal court rulings apply to specific provider disputes and should not be labeled as regulations or generally applicable administrative requirements.
- Third, the Mayo Foundation implies that physicians and providers must review and are held accountable for knowing each and every regulation and manual page. This is simply not the case.

I have explained each of these points in more detail below.

<u>The Mayo Foundation overstates pages of Medicare regulations and statutes.</u>

The Mayo Foundation significantly overstates the pages of regulations and statutes applicable to the Medicare program. The Mayo Foundation counts 3,574 pages of Medicare regulations, and 14,500 of "fraud and abuse" regulations. Using the Code of Federal Regulations published by the Federal Register National Archives and Records Administration (October 1999), my staff found that there are approximately 1,700 pages of regulations in Chapter 42 of the Code of Federal Regulations -- half the figure listed by the Mayo Foundation. The 1,700 figure includes the 47 pages of regulations governing the Department's Office of the Inspector General, which are published in Parts 1000 through 1008 in Chapter 42 of the Code of Federal Regulations. (There is no set of regulations entitled "fraud and abuse" regulations).

The Mayo Foundation also lists approximately 1,500 pages of statutes governing the Medicare program – the Medicare laws and the Medicare provisions of the Balanced Budget Act of 1997. However, the Medicare provisions of the Balanced Budget Act are incorporated into the Social Security Act, and actually eliminate and replace major sections of the Act. Counting these provisions separately, therefore, is duplicative.

We believe our count is the accurate one. Congress has enacted 900 pages of statutory language (including Balanced Budget Act and Balanced Budget Refinement Act provisions) pertaining to Medicare. To implement these often detailed statutory

provisions, HCFA has promulgated 1,700 pages of regulations. Although HCFA's program manuals are not technically regulations, I agree that they contain administrative requirements that are binding on physicians, providers, and suppliers accepting federal Medicare payment. Therefore, I asked my staff to review the number of pages in the 21 Medicare manuals published by HCFA. They determined that the 21 HCFA program manuals encompass 32,803 pages. Therefore, we believe that the total pages of statutes, regulations, and program manuals is 35,403, not 110,758, as asserted by the Mayo Foundation.

The Mayo Foundation includes documents that are not properly characterized as part of the Medicare regulatory "burden."

In its efforts to paint the Medicare program as overly burdensome, the Mayo Foundation seems to have included virtually every piece of paper relating in any way to Medicare. For example, the Mayo Foundation includes Federal Register preambles, newsletter guidance by carriers and intermediaries, administrative bulletins, decisions by the independent Provider Reimbursement Review Board, HCFA Administrator decisions, court decisions, and OIG compliance plan guidance documents. I do not believe it is fair to characterize any of these documents as part of the regulatory regime.

- For example, the Mayo Foundation counts 35,000 pages in HCFA and OIG Federal Register preambles. However, Federal Register preambles are explanatory documents, in which the agency responds to thousands of comments received from the public, including health care providers and their representatives. These preambles explain the agency's interpretations of the regulations – but the regulations themselves are published as part of the Code of Federal Regulations in 42 C.F.R. Indeed, part of the reason the agency must include preambles in the Federal Register is to comply with the Administrative Procedure Act's requirement to respond to each comment made by the public. While these preambles help to explain the agency's rationale for a regulation – most often explaining the agency's interpretation of the underlying statute enacted by the Congress – it is not fair to characterize preamble language as a regulatory requirement that providers must know and follow.
- The Mayo Foundation counts 27,000 pages of Provider Reimbursement Review Board (PRRB), HCFA Administrator and court decisions. These decisions relate to fact-specific cost disputes between providers and Medicare fiscal intermediaries or carriers. The decisions do not announce rules of general applicability.
- The list includes 170 pages of compliance plans. These voluntary guidance documents are issued by the OIG, working in conjunction with health care providers, and offer providers a plan to follow to protect themselves from violating Medicare law and the False Claims Act. These compliance plans cannot fairly be characterized as part of Medicare's regulatory requirements.
- The list includes 16,950 pages of carrier newsletters, intermediary communicators, intermediary bulletins, Medicare administrative bulletins and Blue Cross and Blue Shield Association administrative bulletins. Newsletters and administrative bulletins,

usually produced by private-sector contractors, are educational documents intended to assist physicians and providers and should not be viewed as part of the administrative burden. Such documents might point out common billing errors made by physicians, or provide information about how to transmit data electronically to a carrier or fiscal intermediary.

The Mayo Foundation list gives the false impression that physicians, providers and suppliers must be familiar with each page of HCFA's program manuals.

The Mayo Foundation implies that physicians and providers are held responsible for knowing each and every provision in HCFA's program manuals. This is simply not the case. Many of our manuals are specific to a certain type of provider. For example, there is a health maintenance organization manual, a home health agency manual, a hospital manual, a hospice manual, a renal dialysis facility manual, a rural health clinic manual and a skilled nursing facility manual. These manuals are designed to help those providers understand the rules applicable to them and because there is a manual specific to each type of provider, the manuals often contain identical instructions.

Similarly, the coverage manual includes coverage information applicable to each specialty, so a physician specializing in one type of medicine would not need to be conversant with the entire manual. Medicare has four DME regional carriers, each with its own manual. Therefore, if a provider submits claims to only one DME carrier, it would consult only one manual. Medicare's carrier and intermediary manuals are primarily intended to provide instructions to the private insurance companies that process Medicare claims, and not to providers, suppliers or physicians.

* * * * *

While I believe that the Mayo Foundation and those who have used their calculations have not accurately presented the administrative requirements of Medicare, I want to make clear that I am committed to reducing unnecessary or burdensome administrative requirements wherever possible. That is more difficult to do than it might seem, and I need your help, and that of your colleagues, to succeed. The Balanced Budget Act of 1997 alone contained 335 provisions related to our programs, mandating new prospective payment systems for hospital outpatient departments, skilled nursing facilities, and home health agencies. For each of these provisions, HCFA has the obligation to help educate the affected parties – whether they are physicians, hospitals, or beneficiaries – about the implementation of changes in the law. In most cases, we must issue a regulation in accordance with the Administrative Procedure Act in order to implement Congress's mandate.

Far more important than page counts are the common-sense steps we have been taking to make Medicare rules simpler. Under this Administration's leadership, HCFA has developed and implemented a number of initiatives to help providers comply with Medicare policies. For example:

- We recently sent letters to every physician participating in the Medicare program explaining how they can avoid common billing errors.
- This June, we hosted a town hall meeting to discuss our proposal for the new, simplified documentation guidelines for reimbursement of evaluation and management services.
- This fall, we will restore funding to toll-free numbers so that all providers can contact fiscal intermediaries and carriers and make general or specific billing inquiries.
- We offer free training courses that any provider or physician can use on our website at www.hcfa.gov.
- In 1998, we established the Physicians' Regulatory Issues Team (PRIT). Now led by Barbara Paul, M.D., a practicing physician from California who joined HCFA in February 1999, the team is addressing regulatory burden on a number of fronts. As part of the team's efforts, Robert Berenson, M.D., Director of the Center for Health Plans and Providers, visited the Mayo Clinic to meet with physicians there and hear their views about administrative requirements. PRIT is developing two complementary systems (Impact Analysis and Sentinel Clinicians) to evaluate every new regulation or policy. Evaluation involves assessing the real-world impact on practicing physicians, and writing/modifying requirements based on that impact. In addition, the Team reviews current regulations or policies, listens to practicing physicians' assessments of these regulations, and will simplify, clarify, change or eliminate these regulations wherever possible.
- We have refocused the Practicing Physicians Advisory Committee to consider how our regulations affect actual clinical practices.

I take very seriously your perception of Medicare's regulatory burden, and I have worked to reduce it since becoming Administrator in the fall of 1997. I want to work with you and with anyone else who is serious about reducing the administrative and regulatory burden of the Medicare program, so long as we do so in a responsible way, protecting the Medicare Trust Fund, the taxpayers, and our nation's beneficiaries. To engage in this important work, we need to be fair about the current volume of Medicare regulations and what is driving them and honest about the fact that it is neither possible nor desirable to run a national program of this magnitude without consistent, nationwide regulations.

Finally, as you know, there are different views about which regulations are necessary, and which ones are essential. Indeed, there have been cases where I have attempted to eliminate what I strongly believe are unnecessary regulations, and have met with surprising opposition from some provider groups and members of Congress. So these

issues are not as simple as you and I might like, but I hope you will bring to my attention any examples of unnecessary regulations that we should consider eliminating.

Again, thank you for the opportunity to provide my perspective on the Mayo Foundation's list. As always, I look forward to continuing our constructive dialogue and working with you to find innovative methods of streamlining regulations and assisting physicians, suppliers, and providers in understanding and complying with the Medicare rules, as we serve more than 39 million Americans who rely on this program for the quality health care they deserve.

Sincerely,

Nancy-Ann DeParle

Nancy-Ann Min DeParle
Administrator

Volume of Regulations

- Although much of the evidence of Medicare's regulatory burden on providers is anecdotal, it is known that providers must comply with almost 111,000 pages of Medicare regulations and supporting documents. These are reflected below:

CATEGORY OF REGULATION	PAGES OF REGULATIONS AND DOCUMENTS
Medicare Laws + Related Laws (SSA+Amendments)	706
Fraud and Abuse Regulation	14,500
BBA of 1997	800
Medicare regulations (42 C.F.R.)	3,574
21 HCFA Manuals	10,500
HCFA Federal Register – ('82 – '98)	34,000
Carrier Part B Manuals	500
Correct Coding Manual	340
Carrier News Letters	4,320
Intermediary Communicators	2,880
Intermediary Medicare Bulletins	2,250
Medicare Administrative Bulletins	5,000
Blue Cross Association Administrative Bulletins	2,500
Durable Medical Equipment Regional Carrier Manuals	418
Provider Reimbursement Review Board Decisions	24,000
HCFA Administrator Decisions	2,000
Court Decisions	1,000
OIG Federal Registers (1994 – 1998)	1,000
OIG Work Plan Compliance Program Guidance	170
Rural Health Clinic Billing Carrier Instruction Manual	300
Total	**110,758**

Source: Compiled by the Mayo Foundation, 1998

- This chart, which was assembled early in 1998, does not include thousands of additional pages of regulations and instructions published since then, according to the Health Care Leadership Council.
  - The additional regulations resulted from implementation of both the Health Insurance Portability and Accountability Act of 1996 and the Balanced Budget Act of 1997 – which included regulations for implementing the Medicare+Choice program.

L FRIST
NNESSEE

COMMITTEES:
Commerce, Science, and Transportation
Budget
Labor and Human Resources
Foreign Relations

United States Senate

WASHINGTON, DC 20510

Treat as Original

June 5, 2000

Ms. Nancy-Ann Min DeParle
Administrator
~~Health Care Financing~~ Administration
Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201-0004

Dear Ms. DeParle:

I have read with interest your letter of January 27, 2000 to Representative Pete Stark concerning the number of pages devoted to Medicare regulation. The letter was in response to a letter from Representative Stark in which he questioned the accuracy of representations made by myself and Senator John Breaux concerning the number of pages of Medicare regulation. You expressed "surprise" in your letter concerning our statement that federal regulations relating to Medicare are more than three times larger than the IRS code and its regulations.

As you know, the Mayo Foundation has concluded that there are 132,729 pages of federal health care regulations, laws, rules, guidelines, and related paperwork, of which over 110,000 are related to the Medicare program alone. This is substantially more than three times the 16,200 pages which your letter identifies as being devoted to the Internal Revenue Code and its implementing regulations. In fact, the over 110,000 pages of paper regulating Medicare alone is more than *six* times the number of pages you identify for the tax code. I hope that you will have an opportunity to review the attached chart summarizing the Mayo Foundation's findings.

In your letter to Representative Stark, you were apparently aware of the Mayo Foundation's statistics, but chose not to challenge their methodology. Rather, you had the "Physician Regulatory Issues Team" conduct a "review of the Medicare laws, regulations, and carrier manuals to determine the nature of the regulatory burden Medicare imposes on physicians." Your letter goes on to state that the statutory language relating to HCFA comprises 900 pages, while HCFA's regulations comprise 1,700 pages. That implies that the total number of pages devoted to federal regulation of Medicare is at most 2,600.

Your calculations apparently exclude the 21 HCFA manuals which attempt to explain the range of HCFA's regulations to providers (10,500 pages) and all of the fraud and abuse regulations (14,500 pages), among numerous other HCFA guidelines and instructions itemized in the attached chart. The omission of the manuals is particularly troubling, as your letter specifically identified "carrier manuals" as a factor in assessing the "regulatory burden Medicare imposes on physicians."

I believe that these Mayo Foundation figures may even actually understate the volume of HCFA regulations, as the study was done in 1998 and numerous regulations as well as new Medicare laws have passed since. In fact, when my staff contacted the Congressional Research Service, they were informed that there were 32,803 manual pages, more than three times the number identified by the Mayo Foundation. Thus, HCFA's manual pages *alone* may be nearly three times your calculation of the total number of pages devoted to tax regulations.

Citizens and health care providers alike are often frustrated by the HCFA bureaucracy. Minimizing the number of pages HCFA uses to regulate health care might serve to paint a more benign, but misleading, image of HCFA's regulatory reach. I am sure you agree that our important consideration of the future of Medicare requires full and fair representations of fact.

I look forward to working with you to strengthen and improve Medicare, and to try to reduce the regulatory burden the current system imposes.

With warm regards, I am

Sincerely,

Bill Frist, M.D.
United States Senator

WHF\gp

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

JAN 2 : 2000

The Honorable Fortney H. (Pete) Stark
United States House of Representatives
Washington, DC 20515-0513

Dear Representative Stark:

Thank you for your letter concerning recent questions about the complexity of Medicare, particularly the number of pages of law and regulations. I, too, was interested to read the press release that accompanied the "Medicare Preservation and Improvement Act of 1999", introduced by Senators Frist and Breaux. The press release quoted the Senators as stating that "We must change a federal program that now requires more than 132,000 pages of regulations, three times larger than the IRS code." I was surprised to read this statement, because I have spent some time looking into this issue myself. I believe that the Senators have been misinformed, and I am glad to have the opportunity to set the record straight.

Soon after I became the Administrator, I read a similar statement made by Robert Waller, M.D., then the Chief of the Mayo Clinic, in a Washington Times op-ed piece. I began investigating the matter, first by questioning Medicare staff and reviewing the regulations myself, and then by talking with Dr. Waller to find out where he had obtained his information. I also appointed a senior medical advisor, Steven Gleason, D.O., who led a Physician Regulatory Issues Team that conducted a review of the Medicare laws, regulations, and carrier manuals to determine the nature of the regulatory burden Medicare imposes on physicians. The Physician Regulatory Issues Team spent considerable time meeting with physicians around the country to discuss these issues. While there are certainly concerns among physicians about the Medicare law and regulations, we found that the volume was considerably lower than the tax laws and regulations.

The statutory language related to HCFA is located in titles XI, XVIII, XIX, and XXI of the Social Security Act, and encompasses 900 pages. HCFA's regulations that implement these statutory requirements are located in the Code of Federal Regulations at 42 C.F.R. Parts 400 to 498, and encompass 1,700 pages. In contrast, I understand that the Internal Revenue Service code, which represents the statutory language under which the IRS operates, encompasses 3,000 pages, and that the implementing regulations, located in volumes 1 through 20 of the Code of Federal Regulations encompass approximately 13,200 pages.

Our Physician Regulatory Issues Team continues to work to communicate with physicians about Medicare's requirements, and to ensure that these requirements are

appropriate. I hope that you and your colleagues will advise us of any suggestions you may have to simplify and clarify Medicare's rules.

I look forward to working with you to strengthen and improve Medicare. With best regards,

Sincerely,

Nancy-Ann DeParle

Nancy-Ann Min DeParle
Administrator

HEALTH CARE FINANCING ADMINISTRATION

ADDRESSEE: Deborah Adler

PHONE: _____

FROM: Patti Unruh
OFFICE OF THE ADMINISTRATOR
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TOTAL PAGES:	ADDRESSEE'S FAX MACHINE NUMBER:	DATE:
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REMARKS: FYI.

Letter we sent to AdvaMed in response to their report about Medicare's coverage, coding & payment process.

– Patti

The Administrator
Washington, D.C. 20201

SEP - 5 2000

Ms. Pam Bailey
President
AdvaMed
1200 G Street, NW, Suite 400
Washington, D.C. 20005-3814

Dear Ms. Bailey:

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HCFA must balance competing interests as it strives to assure high quality health care for beneficiaries. We must act as a prudent purchaser on behalf of our 39 million beneficiaries and hundreds of millions of taxpayers, pay providers adequately and fairly under the law, and protect the Medicare trust funds. At the same time, we must incorporate the views and interests of beneficiaries, providers, manufacturers, private health plans, taxpayers and others, including members of Congress, into the decision making process.

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- You assume that new technology is always more expensive. Experience demonstrates that this is not always the case.

The processes of innovation/diffusion, evaluation, clinical practice adaptation, and payment for technology are complex and interrelated. We have to make sure that our policies do not discourage the use of valuable new technologies that will improve care for beneficiaries. At the same time, our policies should not encourage the use of unproven, ineffective, or harmful technologies or create a unique advantage for new technology.

We agree that procedures for obtaining coverage, coding and payment should be as responsive, timely and understandable as possible in order to serve Medicare beneficiaries and other stakeholders. We believe that the vast majority of new technology is treated in a timely manner through its integration into existing payment systems and through the flexibility provided to local carrier medical directors. Nevertheless, there are instances when "breakthrough" technologies are also subject to our coverage, coding and payment determination processes. You have provided examples where there has been difficulty, both in negotiating multiple processes, and with the time it can take to assign national codes.

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technologies through local decision making can generally continue while decisions are being implemented nationally.

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Also, with regard to coding issues it is important to understand that many stakeholders are involved in the assignment of national codes and computing national payments.

- Providers, particularly hospitals and physician offices, seek stability in coding and payment. Frequent changes and updates disrupt claims processing systems, raise issues of compliance, and create uncertainty in payments;

- The medical community has an interest in assuring that coding systems are clinically coherent, and;

- Private and other public insurers often use the same coding and payment systems as HCFA.

We cannot unilaterally assign codes without consulting all of these stakeholders, and that is why these processes take time. Moreover important changes stemming from the Health Insurance Portability and Accountability Act will require greater standardization and consultation across the industry. Yet we understand that the timeframes for assigning new national codes for breakthrough technologies can be longer than the manufacturing industry would like. As we have done in the past, we welcome the opportunity to meet with you and other stakeholders to examine potential ways to speed up this process.

We agree that HCFA should take action within the structure of its organization to better assist manufacturers seeking national codes and payments in addition to what is available on our website. We are committed to working with you and would like to meet to discuss your concerns and ways we can make constructive improvements in the process. Further, I want to reemphasize our willingness to work with manufacturers when they seek FDA approval to assist in determining up front the kinds of information that would be useful in

speeding up the Medicare coverage decision process, particularly where breakthrough technologies are concerned.

I also want to point out our commitment to cover many of the costs associated with clinical trials, described recently in a proposed National Coverage Decision. Under the proposed decision, Medicare would pay for monitoring and evaluation, device implantation, and other costs, such as room and board for a hospital stay required as part of a clinical trial that meets the qualifying criteria. Assuring Medicare beneficiaries that these and other specified costs will be covered is expected to encourage them to participate in clinical trials and the knowledge gained from clinical trials will lead to better health care for our 39 million beneficiaries. In addition, this proposed decision should assist you in covering some start up costs associated with some new technologies. Your cooperation and suggestions are welcome as we implement this important new policy.

Last year we worked together to make improvements in our national coverage process. I look forward to continuing to work constructively with you, as we strive to assure high quality care for our Medicare beneficiaries.

Sincerely,

Nancy-Ann Min DeParle
Administrator