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MEDICARE QUALITY ASSURANCE

HEARING

BEFORE THE

SUBCOMMITTEE ON
MEDICARE AND LONG-TERM CARE

OF THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED SECOND CONGRESS

FIRST SESSION

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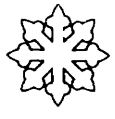

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MEDICARE QUALITY ASSURANCE

FRIDAY, FEBRUARY 22, 1991

U.S. SENATE,
SUBCOMMITTEE ON MEDICARE AND LONG-TERM CARE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 9:34 a.m., in room SD-215, Dirksen Senate Office Building, Hon. John D. Rockefeller IV (chairman of the subcommittee), presiding.

Also present: Senators Chafee, Heinz, and Durenberger.

[The press release announcing the hearing follows:]

[Press Release No. H-2, Feb. 15, 1991]

MEDICARE SUBCOMMITTEE TO HOLD HEARING ON MEDICARE QUALITY ASSURANCE; STUDY ON IMPROVING QUALITY OF PHYSICIAN AND HOSPITAL CARE TO BE FOCUS

WASHINGTON, DC—Senator John D. Rockefeller IV (D., West Virginia), Chairman, announced Friday that the Subcommittee on Medicare and Long-Term Care will hold a hearing to examine a study by the Institute of Medicine on methods of assessing and assuring the quality of health care services under the Medicare program, and on recommendations to improve the current system.

The hearing is scheduled for *Friday, February 22, 1991 at 9:30 a.m.* in Room SD-215 of the Dirksen Senate Office Building.

The Institute of Medicine recommends that the current peer review organization (PRO) system be modified to focus less on the control of utilization through the review of individual cases and to place more emphasis on assuring quality through measures of overall performance.

"In the Omnibus Reconciliation Act of 1986, Congress called for a study to design a strategy for quality review and assurance in Medicare. That study has now been completed by the Institute of Medicine and merits our close review. Understanding and improving the quality of care should be our highest priority within the Medicare program. This hearing will focus on the best approaches to achieving that end," Rockefeller said.

OPENING STATEMENT OF HON. JOHN D. ROCKEFELLER IV, A U.S. SENATOR FROM WEST VIRGINIA, CHAIRMAN OF THE SUBCOMMITTEE

Senator ROCKEFELLER. Good morning, everybody. We have our usual outpouring of U.S. Senators here. People alert to every new nuance in health care policy cannot wait to discuss quality and utilization review or some such combination. In any event, there is a number anyway who say they are going to come.

You know better than I that since 1965 the Medicare program has been serving the medical needs of a lot of elderly Americans. Through Medicare our Nation has promised to provide seniors access to a very broad range of quality and cost-effective services. The complex nature of that task requires us to review and occa-

sionally to refine specific aspects of the program in order to keep that promise.

As the purchasers of health care, we want to get the most value for the dollar. That goes without saying. Value can be measured by assessing the cost and quality of what we purchase. We, in government, spend a great deal of time addressing the never-ending escalation of cost and with good reason—Medicare being probably the best example in government—and we have achieved some successes and some not so successful results in this regard.

However, we do not, in our haste to simply assault cost containment, want to think about Medicare policies primarily in terms or only in terms of their cost and their impact on the Federal deficit. Although costs are incredibly important and will remain that—you know, we are sinking in the cost of all of this and cannot sustain the rate of our sinking at the Federal level—a very serious concern to all of us must equally be developing systems that help us improve quality in our present Medicare health care system.

Now that means we have to better understand what quality is, which is easier said than done. We must be involved in helping doctors and hospitals provide the kind of quality care that we want under Medicaid.

This is going to be a difficult task because of the need to balance utilization review with its positive effects on cost-containment with its potentially negative effects on quality and provider cooperation—a delicate balance but a very important one.

Recognizing the challenge before us, Congress in 1986 asked the Institute of Medicine to review the systems currently in place in Medicare for evaluating the quality of care and to provide us with a strategy for improving quality of care under Medicare in the future.

The report of the IOM was delivered to Congress last year. It is superb. It is not necessarily written in lay language. It has its academic aspects, but it is within the fine tradition of the IOM to explore every aspect of the issue and to present very clear, very concise scholarly analysis of available data.

This morning we are going to look at this IOM report and get the reaction of a variety of experts to the IOM Committee's recommendations. I really hope that these discussions will teach us and help us focus on how to balance this automatic, never-ending drive of government to contain costs, which is absolutely mandated by any reasonable look at our current condition, and yet at the same time somehow try to find a way to look at quality. We want to develop a system that is user friendly, not only to Medicare consumers, but also to providers who are shaking under the hassle factor. It is not easy, but I think it has to be done and that is what this hearing is about today.

Mr. Durenberger?

OPENING STATEMENT OF HON. DAVE DURENBERGER, A U.S. SENATOR FROM MINNESOTA

Senator DURENBERGER. Hello, Mr. Chairman. I compliment you on calling this hearing. I compliment the witnesses, I guess all of them have been here before in the effort, as you say, to find a ra-

tional approach to dealing with universal access, both you and they have contributed a great deal.

The Institute of Medicine report is probably one of the more important contributions that is going to be made in the long term, dealing with cost factors as it relates to access.

I have a full statement which I will ask to be made part of the record. I will recognize in the statement that the Institute took a look at what we are doing in Minnesota. In this regard, the statement will also recognize what we are doing in an ongoing basis at the project called Minnesota Clinical Comparison and Assessment Project.

The statement will reflect some of my thoughts on what we have tried to do with peer review. It will also discuss that we have probably not appropriately financed the peer review process to reach some of our objectives. I think the track that you are on with this hearing is one we ought to be on, one we ought to stay on, and one we should do everything we can to help the people that are involved in this process do a better job of forming public policy.

Senator ROCKEFELLER. Great.

[The prepared statement of Senator Durenberger appears in the appendix.]

Senator ROCKEFELLER. Our first witness is Dr. Gail Wilensky. I am very proud that she is here. Dr. Wilensky, you know that I speak well of you every single chance I possibly have to your seniors, your juniors, and to the public in general. We look forward to what you would have to say.

STATEMENT OF HON. GAIL R. WILENSKY, PH.D., ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. WILENSKY. Thank you. Mr. Chairman and members of the subcommittee, I am pleased to be here today to comment on the Institute of Medicine's report on assuring quality in the Medicare program.

Tremendous improvement has been made in recent years in the area of health care quality assurance. HCFA has been initiating and supporting many projects to enhance health care quality. As a result, we are ready to chart a new direction in monitoring and improving quality within the Medicare program.

Peer review organizations are Medicare's principal vehicle for monitoring the quality of health services provided to the elderly. Over time PRO review will change from a case-by-case review of medical records to a process that looks at the use and outcomes of various types of care.

The IOM report affirms that we are headed in the right direction. Our goal is to move the PRO program beyond detection of inappropriate care to a comprehensive system of quality assurance. PRO's need to be better equipped to identify inappropriate patterns of utilization and outcomes. They need to share such information with the medical community to help correct inappropriate behavior and improve medical practice.

HCFA has undertaken several major activities that will provide a framework for changing to a more progressive approach to quality review.

An important part of our effort to transform the peer review process is the development of a uniform clinical data set. UCDS is a state-of-the-art computer system which will permit us to gather, develop, and analyze extensive clinical data. The UCDS will standardize the initial review process.

PRO's will use the UCDS to abstract detailed clinical data from medical records under review. The abstracted clinical data would then be subjected to computerized quality screens in order to identify cases needing further review.

Based on our experience to date, several modifications have been made to reduce abstracting time and to improve the screens which prompt further medical review. We anticipate that all PRO's will be conducting review using the UCDS by late 1993.

Linking UCDS to currently available Medicare claims data will allow PRO's to evaluate patterns of care and patterns of outcome. This large data base will also provide an abundance of information to researchers in the medical community on the effectiveness of various treatments and surgical procedures.

We have contracted with several PRO's and academic medical centers to develop the computer hardware and software to analyze existing claims data and the emerging clinical data base.

PRO's are also beginning to use a new method of quality analysis. Several PRO's participated in a project which involved computer analysis of hospital utilization data by geographic area. This permits PRO's to detect variations in patient outcomes by procedure and diagnosis, with an eye toward identifying "potential" quality problems. PRO's have also shared the results of geographic variation analysis with hospitals and physicians.

We are designing quality assessment tools to be used in non-institutional settings. Several PRO's are involved in a project to characterize patient risk factors, therapeutic interventions, and the effect of care on the patient's health.

In another project, PRO's are developing an approach to review the quality of care in physicians' offices using available Medicare claims information.

We are working with the Agency for Health Care Policy and Research to determine how PRO's could assist in the dissemination and evaluation of practice guidelines.

Because HCFA has extensive Medicare data bases, we have also entered into an agreement with the Agency to transfer special data tapes for their use in outcomes research.

We are developing a new protocol for PRO review of HMO services. The current process does not produce the information needed to evaluate individual HMO's or the whole HMO program.

The proposed PRO review will use an improved sampling methodology based on enrollees who receive HMO services. This will allow the PRO and the individual HMO to better target problem areas and emphasize problem resolution.

The direction of the IOM report parallels what we have been working on for the last 4 years. We agree with the IOM report that the current PRO review process needs to focus on medical review,

on the effectiveness of care, and that additional quality and outcomes research is needed.

We question, however, two of the IOM recommendations. The IOM recommends that several new advisory councils should be created. We recognize the need for scientific and technical guidance. We have worked closely with quality experts in the development of our new review process and we surely plan to continue doing so.

Additional administrative layers, however, would complicate and disrupt the process we have made to date. Excessive oversight would hamper our efforts to remain on the cutting edge of health care quality assurance.

The IOM also recommends doubling the current PRO funding to at least $600 million per year. We do not expect to need major budgetary increases. It is also unrealistic to expect additional funding in light of our current financial constraints.

Mr. Chairman, we are challenged with ensuring the quality of health care services delivered to Medicare beneficiaries. The IOM report affirms my belief that we are on the right track in our effort to improve the PRO program.

We have demonstrated that assuring quality care to Medicare beneficiaries is one of our highest priorities. I look forward to working with the Congress, health care organizations and the PRO's to further refine our quality assurance program.

Thank you. I would be happy to answer any questions you may have.

Senator ROCKEFELLER. Thank you, Dr. Wilensky.

[The prepared statement of Dr. Wilensky appears in the appendix.]

Senator ROCKEFELLER. Do you want to start off, Dave?

Oh, good morning, Senator Heinz. Did you have any comments you wanted to make? This is a long time interest of yours.

OPENING STATEMENT OF HON. JOHN HEINZ, A U.S. SENATOR FROM PENNSYLVANIA

Senator HEINZ. I apologize for being late. I have two committees meeting simultaneously. I would like to make a brief comment, if I might.

I welcome Dr. Wilensky back to our committee and to thank her for the excellent job that she does. Nobody ever gets it perfectly, but I do not know anybody who tries harder and is more able to achieve that result than Gail Wilensky. If it is not perfect, it is not for lack of skill or effort on her part.

Senator ROCKEFELLER. It is good coming here, is it not? [Laughter.]

Dr. WILENSKY. It is my first year anniversary. Thank you.

Senator HEINZ. So it is and you have our sympathy. [Laughter.]

I cannot resist, Mr. Chairman—and Gail Wilensky knows this subject; we have talked about it; we corresponded on it; we have become pen pals on it--it has to do with one aspect of quality assurance that we will get into later today. It is the Medicare Risk HMO Program.

Whenever I think of that program I think of that television advertisement for a well-known hamburger outlet that went,

"Where's the beef?" Where the Medicare Risk HMO program is concerned, we have to ask the question, "where is the quality?"

Indeed, we are asking that of the entire Medicare program today. Because in spite of tremendous efforts made by yourself, by Dave Durenberger, and other members of this committee, we still hear too many stories about the shortcomings in Medicare's quality assurance.

Even though I think we have improved, we still have a long way to go. Whether or not we are further ahead than where we were 25 years ago when this program began, I cannot say. But I do worry that as hard as we try, we often seem to be staying in place and that is detrimental to the 33 million Medicare beneficiaries, many of whom are both old and alone.

We have today before us a very bold and comprehensive plan from the Institute of Medicine. It sets forth a long-range strategy for enhancing quality assurance under Medicare. I must say, it is very appealing to focus on a long-term, comprehensive, almost last word approach dealing with populations and demographics. However, I would not want anyone to think that even if we all loved the IOM proposal and put it into immediately, it would solve any of the quality problems we have today.

One of those quality problems has been highlighted by a recent draft GAO study on quality assurance in the Medicare HMO program. This investigation, done at my request, examines PRO review of both internal quality assurance programs of risk contract HMO's and the health care provided by those HMO's. To put it briefly and bluntly, the study's preliminary findings are very troubling and should be deeply disturbing to every member of this committee.

I will have more to say about this later. But in brief, one of the shockers in the report is that when serious deficiencies in the internal quality assurance program of an HMO were identified, the PRO lacked the authority to enforce corrective action. I see several heads going up and down in the audience signifying both knowledge and consent, I think.

Although information on problem programs was provided to the Health Care Financing Administration by the PRO's, in all but one case HCFA failed to act on PRO recommendations. or so my information indicates. If I am incorrect, I know Gail will set the record straight.

Mr. Chairman, I ask unanimous consent that the remainder of my remarks be placed in the record at this point.

[The prepared statement of Senator Heinz appears in the appendix.]

Senator HEINZ. I do want to say again to be fair to Gail Wilensky, and she knows I am her strong supporter, she inherited a great many of these problems. She has been working diligently to correct years of bureaucratic neglect. So I do not want her to take any of my criticisms of HCFA, although it is the agency which she runs, as criticism that is directed at her. It is not.

Senator ROCKEFELLER. I think she can handle it, Senator.

Senator HEINZ. And you, and David, and me.

Senator ROCKEFELLER. One of the things that you talk about is the uniform clinical data set which can be used to monitor the

quality of care. I would like to get you to talk a little more about that. I would also like to get you to respond to concerns that it is all in computer language and that we don't have an English translation yet. I understand that it takes a long time for a person to actually make use of it.

To follow up on this concept, I also understand that you have set up certain practice guidelines to assess quality. I would like to know more about those practice guidelines and how they were developed.

Dr. WILENSKY. Okay.

Let me explain a little about what the uniform clinical data set is. USDS consists of both the data set and the algorithms which are just computerized screens to go through to see whether you have got a quality problem.

The notion of the uniform clinical data set was to improve what we now do to identify a problem, which tends to be haphazard because of the way that it is structured. It is a case-by-case retrospective review by a nurse reviewer to see whether or not there is a problem in the medical record.

All the constraints you have within the human mind of how much information you can process, or what particular guidelines may be written out, and then what the individual brings into the process, is what determines whether or not the case goes on to a second level of review. There is an enormous amount of variation in terms of how well people can do the review and what it is that they pick up.

The idea behind the uniform clinical data set is to have a standardized data set. Although there is really a larger number of data elements, only a quarter or less would ever be abstracted from any particular medical record. This forms the basis of the information. Now you have, in addition to having a common type of a record to look at, a data set, a set of instructions or procedures—algorithms—to look to see whether or not there appear to be problems.

That is basically what we are up to—to get away from having an after-the-fact, case-by-case review to having information put into a computer system, abstracted from the medical record itself. Then a set of these algorithms are applied to see whether or not it appears that care was delivered in a way that makes sense.

You asked a number of questions. One of the things I think it is very important for people to understand is the uniform clinical data set—both the data elements and how the abstraction is done. What these algorithms are is an evolving process.

We have in the past couple of years, as we have developed the UCDS and used it on a pilot basis—we are about to end our phase one of this pilot phase—made a number of changes. We have found that there are certain things that were more complicated than were necessary—data elements that did not need to be there, some of the algorithms needed to be refined.

We anticipate that at the end of phase one, which formally ends in June—lots of evaluation and assessment goes on in that period—that there may well be changes made in all areas. And furthermore, the UCDS will continue to evolve. There seems to be some notion that there is a fixed-in-concrete data set and there is a fixed-in-concrete set of these algorithms.

But in fact, we view UCDS—and other people need to view UCDS—as a process that will evolve as we learn more. We certainly are far from perfection now. We have a system that allows us to modify what is going on.

Senator ROCKEFELLER. So the time it takes for the nurse to review the chart could diminish?

Dr. WILENSKY. It actually, at least initially, is going to increase, although we think that will change. Right now in this pilot phase the abstraction, in putting in all the information and being able to see if there is a problem, takes closer to 60 minutes instead of the 30 minutes in a manual review.

We think that this will decline both because we will learn how to make it more efficient and the people and the process of getting it done will be made more efficient. But mainly it will be a much more satisfactory way to see if there is a problem. This will be a more systematic way of reviewing records and seeing whether or not there appear to be problems, rather than relying only on what an individual person might be able to pick up.

So at the moment it is taking longer. I do not know whether it will be 30 minutes or not. That is really not our goal. Our goal has been to move from this after-the-fact, case-by-case review which was too idiosyncratic based on the individual review, to a way of reviewing that is much more focused on the outcome of care and on the patterns of care. We can have a consistency that making use of modern computing facilities allows.

Let me respond to one other question that you raised which is: How did we develop the data elements and the algorithms?

Again, saying it is a process that "developed" is only slightly wrong in the sense that it connotes a past term. It is: How are we developing this and who have we brought in?

There was initially a task force. In fact, there were a series of panels early on that the IOM convened for us to look at a number of issues relating to how to go about doing this business.

The actual data set was put together by groups of individuals made up both of the PRO's and academic medical community. The algorithms were also developed by the PRO's and the academic medical centers.

As we have been going through this pilot process, we have basically invited anybody who wanted to come in and assess what is going on to look at both the data and to look at the algorithms. We have had a fair amount of involvement by academic clinicians and by biostatistician.

The AMA has been very active. John Kelly, from the quality program of the AMA, has been very much involved in this process and will, especially as we end phase one, become very much involved.

We have indicated that as this phase one period is coming to a close and we will have the results. We will make sure that the research community knows that they are available. Basically, any and all parts that people would like to look at are available and will continue to be available. It is all in the public domain—the software, the hardware, and the results.

At the moment, the algorithms are computer language; if you are not into looking at algorithm talk you would probably have a

little difficulty understanding them. They will be available in the so-called English version this summer.

We have groups that are working on that for us. We certainly do not deny the need for having the algorithms in a way that folks that do not understand how algorithms are written would understand the clinical implications. But we do expect that we will have the English version available soon.

Obviously, a lot of the members of the research community, including the clinical community, are perfectly comfortable in looking at the algorithm patterns. It has been part of the work going on in the research community in clinical medicine for a long time.

Senator ROCKEFELLER. Okay. Dr. Wilensky, thank you.

I am going to get back to the practice guideline part of my question in my second round.

Dr. WILENSKY. All right. I forgot about that.

Senator ROCKEFELLER. Dave?

Senator DURENBERGER. Thank you, Mr. Chairman.

Gail, at the risk of getting another 5-minute response——

Dr. WILENSKY. He asked a lot of questions.

Senator DURENBERGER. I agree with everything else they said about you, but it is the only area that I would say together we need to work on. [Laughter.]

This is really a tough area—the quality, the outcomes, the interrelationships. What the IOM has done has offered up a definition of quality which is very broad and everybody can agree with.

What you have just illustrated is how difficult it is to implement it.

I would like to go back to where both of my colleagues were in their earlier comments—and maybe a little bit of frustration that all four of us have had because we have been working together on this now for many, many years in one way or another—and in part, it has touched on when you said your two objections to the IOM study were (1) they suggested these additional advisory councils; and (2) they were asking for an unrealistic amount of money for the Peer Review process.

I must begin by making an observation that if those continue to be our hang-ups in this process then maybe we ought to deal with and resolve the whole issue of: How should we organize—those of us who are on the governmental end of this—how should we organize to achieve a national objective of having an institutionalized means of determining what is quality health care in this country?

Last year when Phil Goodman was my Robert Wood Johnson fellow he made this very complicated looking form which got passed out last year. It is called the, "Inside the Beltway Impact of AHCPR," which is just one small little agency working on outcomes.

But it is a good illustration of how difficult it is to be Gail Wilensky or how difficult it is to be anybody in this process trying to deal with quality of health care in the specific clinical setting.

If it is possible for you to go back and examine your two objections and state for the subcommittee how we ought to institutionally organize to deal with the whole issue of quality and outcomes, I would appreciate your doing that.

I happen to think that the Peer Review organizations are an essential part of this process. But I also see value in what PROPAC has done on their part of the process, what PPRC has done on their part or what AHCPR is going to be doing.

I do not see any problem with having some advice and some contributions to getting to the end of this. But I must say that if I were you I would be really frustrated by being surrounded by all of these institutionalized contributions. Is there a better way to organize to accomplish this?

Dr. WILENSKY. Well, let me explain what the objection was. It is much more specific than the generic objection about having advisory groups and other groups.

The specific objection was to a very layered structure of groups that would review and respond to what HCFA and the PRO's were doing. There are at least two or three different formal groups that were being proposed by IOM.

HCFA and AHCPR have an exceedingly good working relationship. You are very right—what they are doing interacts very much with what we are doing. They are looking at the outcomes work. We need to incorporate the outcomes work and the practice guidelines into the PRO process. We have had a lot of conversations about how to make sure we work together. We give them data. They use the data in order to do outcomes research.

We have had, and will have in the future, a number of advisory groups coming in to advise us. We will probably have a formal TAG—a Technical Advisory Group—to come in to respond to what we are doing.

Our concern was that two or three additional administrative structures above what already exist seemed too unbalanced to be helpful. It just is hard to respond in that formalized of a structure. We think that there are ways to do exactly what the IOM wanted.

We have probably at any one time four or five contracts with the IOM giving us technical advice. But they do not have to be a formalized, in place, immutable group. They come to us and suggest, or we go to them and ask for assistance. In addition, we put together technical advisory groups, or we convene meetings of people to come in.

This process seems to do what is clearly necessary, which is to have all sorts of input from the scientific and research community, but to do it in a way that allows us to respond.

I do not have any objection to the 10-year plan that is laid out by IOM, except for a very practical problem. We have got to have quality all the time. We cannot wait 10 years to get to where we want to go. We are proposing that the UCDS get incorporated into the fourth scope of work, which is going to start coming out in the fall.

Now something is going to happen in the fall when we start renewing contracts, because the old contracts start coming off the board. So either we go back with our old way or we go in and start doing some new work. We are an operations group; we are not a research group. I have probably more sympathy than any other HCFA administrator having come out of the research world.

It is not the direction of what IOM is proposing that we have any problem with. All the way through what they are proposing, we

are in absolute agreement. There are just some very specifics that we think either are not necessary or in some cases are not helpful.

I guess at any moment in time I would like more money for almost everything we do. But I honestly believe we can convert to this new system that looks at outcomes; and we will be spending a little more, but not a whole lot more. I just do not find it very realistic to say, double the amount of money you have for this activity. I am not the Appropriations Committee and I am not going to hold my breath until the Appropriations Committee does it.

Senator DURENBERGER. Thanks.

Senator ROCKEFELLER. Senator Heinz?

We welcome Senator Chafee, also.

Senator CHAFEE. Welcome, Dr. Wilensky.

Senator ROCKEFELLER. Senator Heinz?

Senator HEINZ. Mr. Chairman, I just want to agree with what Dave Durenberger said at the outset. There is something that both Gail Wilensky and Dave Durenberger have to work on. [Laughter.]

With that uncharitable comment, I will prove that the two of you are not alone.

Gail, I am going to direct the following question to what I take to be, if not the central, at least to me the most important recommendation in the IOM study, to restructure the PRO program. In particular, I am concerned with the local or regional PRO's—MQRO's—which are supposed to obtain information on patient and population based outcomes and practitioner and provider processes of care—to analyze that data, use that data to make judgments about provider performance, feed that data back into internal QA programs of those providers as well as report it, and then where necessary carry out quality interventions and technical assistance to internal quality assurance programs.

What I interpret that to mean—in just slightly different, if no less clear language—is that IOM is proposing that we move over the next decade to a prospective, population-based analysis that should identify quality problems more accurately and more consistently.

Theoretically, I think it is true that if you focus on outcomes, you are going to learn things about the entire delivery of health care that we clearly do not know now. But I do question whether we will ever be able—I hope I am wrong—to make meaningful comparisons between providers on the various measures of quality and, therefore, whether the IOM model it will be helpful.

In particular, I am concerned that if you are looking at the individual provider—be it a hospital or a doctor—the total number of cases may be too small to have any statistical significance or validity. This is a particular problem when the data are appropriately segregated, as I anticipate they must be, by diagnosis—we currently have around 400 DRG's—and then further subdivided at a minimum for health status to take into account the fact that somebody with one diagnosis at age 21 has a different health risk than somebody with the same diagnosis at age 82; and then further, of course, subdivided by whoever the provider happens to be—a hospital or an individual practitioner.

As I recollect my elementary statistics, you have to have a fairly large number for any one of those provider-adjusted, diagnostically-

related, health status-adjusted groups for it to be meaningful in comparison to anything else. It is the so-called "N," that if it is too low, you do not have statistical confidence.

So my question is: Is what I have just described as a layman a concern that we should have about the IOM study? Has anybody simulated this particular kind of model to find out how many data points you would actually get on a provider basis in the year—hypothetically, let us say in the year 2000—if we could do everything IOM said we ought to do by the year 2000? Would we have statistically meaningful data that would lead to the next step, which is obviously doing something useful when you have the data?

Senator HEINZ. I think that is the yellow light. I just proved the point that Dave Durenberger and you are not alone. [Laughter.]

Dr. WILENSKY. This is complicated. This is hard to do in a five word answer.

Senator ROCKEFELLER. Take your time in answering.

Dr. WILENSKY. We will have enough data to answer some of those questions because there are a lot of Medicare beneficiaries. For some things, data points are not going to be a problem because even if you have a relatively rare diagnosis, you have 33 million people, or 34 million, to look at.

Senator HEINZ. Remember, the idea is to check up on individual providers—that is, to say, hospitals or practitioners. So the first thing that happens to the 33 million is they are divided by the number of hospitals or the number of physicians and those become very small numbers, indeed, to start with.

Dr. WILENSKY. Let me share a little about how we are able to help ourselves in this world. What the IOM is suggesting is what we are going to be starting in April of 1992 and phasing in by April of 1993. The uniform clinical data set is our first step to achieving outcomes oriented patterns of care analysis.

You are absolutely correct that if you want to know if an individual physician or an individual hospital is behaving in an appropriate way you need to look at what that individual physician and hospital is doing. But the issue of what is appropriate needs to be based on an outcomes of care analysis.

So it is the standard that we have set first. What we can really use all of this data in the UCDS for is making use of the internally generated data that HCFA has or could have to look at whether individuals with certain kinds of symptoms and diagnosis have patterns of care.

Senator HEINZ. Gail, what you say is incontestable. Let me stop you there and say that I agree with you entirely.

Just to conclude the discussion, because at least if I cannot control myself, I can keep others from making the same mistake I do.

Let me just conclude by saying that there is no question that understanding outcomes on the overall population it is absolutely critical to designing processes and standards of practice that result in better health care and quality.

I was taking aim, not at that proposition, but that what I understood to be the centerpiece of the IOM recommendation, which is this: The current system of PRO review is case-by-case oriented, is adversarial, is ineffective, does not result in process and system changes.

Dr. WILENSKY. Right. That is correct.

Senator HEINZ. And what IOM has recommended is over time that that case-by-case review be replaced by what I will call for want of a better term, a population-based outcomes analysis.

Dr. WILENSKY. Outcomes and patterns.

Senator HEINZ. I am simply questioning the premise that you can on a provider-by-provider basis ever substitute that for the case-by-case analysis because the statistical relevance of what you end up with is maybe in question.

Mr. Chairman, what I might suggest is that, maybe one of our other witnesses will address that, but I think maybe we need some kind of analysis either from IOM or from some other analysis as to whether on the provider basis—after you get through dividing into the 33 million Medicare population, all the providers, and all the DRG's, and all the health status adjustments, and times the number of people go through a provider—you get anything that is statistically relevant.

If the number is under 53 or whatever some statistician will tell us and we will know that that is something of a blind alley in practice even though theoretically it is correct.

Dr. WILENSKY. Right.

Senator ROCKEFELLER. Gail, if you would like to respond to that, please do.

Dr. WILENSKY. The issue is, when you have a standard you then can look to see whether you appear to have a problem.

There are going to be some cases where you are going to have problems because there is a lot of variation in predicting your outcome. You are clearly going to need at some point to go back and to review the standard against care that is given.

The point of setting a standard is to get an initial screen. Does a problem exit? If you have observed patterns of care by an individual physician over a number of patients that do not fit with what you know about outcomes, you have a feedback mechanism.

The answer to whether any one physician will have a statistically significantly sample for pneumonia or appendicitis or whatever to look at how he does individually, is maybe or maybe not.

But you can clearly look at the patterns of care either for the specific diagnosis or for the individual overall and feed back information—if you do something to a patient that has the following kind of symptoms, our analysis suggests this is what is likely to happen and this is what is not likely to happen.

So it is really a way of reorienting, which is again, we think, very consistent with what we are proposing now with this uniform clinical data set. We will move to a more uniform way to provide feedback to the individual physician and to identify patterns of care.

It is not going to remove the need at some point to have more of a specific look, but it is a first cut at whether or not you have problems. UCDS will allow us do so much more consistently and reliably and focus on outcomes and not process.

I think IOM agrees that the general strategies that we are proposing and they are recommending will do the same things. The issues that you raised are true but they are not always as damag-

ing as they might seem. I would be glad to give you more of a response in writing if you would like in a non-technical way.

[The information follows:]

Whether or not a practitioner delivers a statistically significant number of specific procedures should not matter in analyzing and monitoring practice patterns and outcomes of care. The main objective is to determine which practitioners behave differently from an established standard, either for an individual procedure or as a trend in their practice behavior. Deviations from an established standard in an individual case or, more importantly, identification of trends that deviate from the standard only gives us a first level cut at determining whether a quality problem exist. From there, it is important to proceed with a more in-depth review.

The Uniform Clinical Data Set will give the Peer Review Organizations the ability to identify patterns of care and outcomes. This will allow them to measure practice patterns and outcomes against standards of care. When problems are identified, the PRO's will then be better able to feed back information to practitioners in order to change practice behavior.

Senator HEINZ. My time expired along time ago. Thank you.

Senator ROCKEFELLER. Senator Chafee?

Senator CHAFEE. Thank you, Mr. Chairman. I apologize for being a little late.

Perhaps you have covered this. Indeed the prior question dealt with some of it. If you have covered it before, please be brief.

I hear from providers at home, and I guess we all do about the PRO in our area, as you do, and unfortunately what we hear mostly is complaints. I suppose that is typical in political life, where people rarely call us to say what a super job we are doing.

Dr. WILENSKY. Rarely.

Senator CHAFEE. I suppose you do not get many praising letters either. But you deserve them as do we. [Laughter.]

The complaint always is that the PRO is intrusive. Is there any way to avoid this adversarial relationship?

Dr. WILENSKY. Well, I think there are some things that we can do. Physicians do not like the PRO's. That is for sure.

Senator CHAFEE. Well, that is for sure.

Dr. WILENSKY. I mean I get lots and lots of negative comments.

By moving away from the case-by-case record review to a point where we are looking at patterns of care and outcomes of care and feeding back information to the physician community, we have some evidence of success. Some of the work that Jack Wennberg has done with the physician communities in New Hampshire and Maine showed that behavior could be modified when you share information such as what you are doing is way out of line with what the rest of the physician community does for somebody with a particular diagnosis or illness; or, if you were to go ahead and do a particular procedure on someone with those symptoms, we can show you that 80 percent of the time you are going to get a lousy outcome. There are some times when feedback alone will work.

That kind of information, which is the direction that we want to move to with the use of UCDS ought to make it less adversarial.

We also have to be honest though and say none of us are really crazy about having somebody else looking over our shoulder. At some point, both in terms of quality and in terms of being fiscally prudent managers, given the role of the government as both protector and financier, some element of that is going to get in.

So I think we can make it better but it is not going to be completely zero.

Senator CHAFEE. In other words outline to the doctor how other doctors are handling a patient through a course of procedures and with different providers.

Dr. WILENSKY. Right.

Senator CHAFEE. It seems to me it is going to be quite expensive for the PRO. We are talking added money.

Dr. WILENSKY. We are not. Right now we are not talking less money. What we are proposing to do will include some changes in what the PRO's currently do. Right now a lot of what the PRO's do is not worth a whole lot. So part of the changes will be to have the PRO's do things that count and have them not do things that do not give very much payoff.

There will also be computerized systems. One of the things that computers do well is move lots of information around relatively cheaply. So it is possible to do a lot of this. I mean it is not cheap and it is certainly not being done to save money.

Senator CHAFEE. Let me ask you another question. One of the findings they made in the IOM study was that the PRO program focused on finding poor care and trying to correct problems and impose sanctions, but does not recognize good performance or reward providers who render high quality care. How could the PRO's reward a provider? Send them a nice letter or give them a gold star?

Dr. WILENSKY. The first part of the phrase I do not have any problem with. I think there has been some inappropriate focus in the PRO's and we can do that part better.

I think what you want to do is make better information available to physicians so they know what happens if they do something. It is part of the whole problem we have had in this country of engaging in a lot of medical care with very little scientific basis behind it. It is why what we are trying to do with reforming the PRO's, and the whole emphasis on outcomes and policy guidelines that the Public Health Service is working on, are so integrally related.

We need to give feedback to physicians about what works. We need to alert hospitals about physicians who perform well and who do not perform well, so that we can try to have constant education. It is going to change all the time because our information changes and because the physicians practicing also will change.

Senator CHAFEE. Thank you.

Mr. Chairman, I would just like to ask one question. Am I correct in believing that the Medicare program in this fiscal year we are in, Parts A and B will spend $116 billion? Does that sound right?

Dr. WILENSKY. It is over $100 billion.

Senator CHAFEE. My figures show $116 billion.

Dr. WILENSKY. Yes.

Senator CHAFEE. That is a whopping program.

Dr. WILENSKY. Yes.

Senator CHAFEE. Even from somebody from Washington. It boggles the mind.

Dr. WILENSKY. Projected to grow at 10 percent next year too.

Senator CHAFEE. The more we can do to monitor this growth the better. I commend you, Mr. Chairman, for having this hearing. I know it is on the IOM report. But it is an oversight hearing. I am just glad we are doing it because if you look at the Federal budget and increasing programs, Medicare is where the dollars are and sometimes people forget.

Sometimes the elderly suggest that, "Well, the Medicare program is paid for by the beneficiaries." That may be under Part A, but take a look at Part B. It is coming out of the General Treasury—75 percent of it. It behooves us to pay a lot of attention to it and we appreciate the attention you are giving to it, Dr. Wilensky.

Senator ROCKEFELLER. Gail, I would like to go on but we cannot. We just have too many other witnesses. I have got eight questions I want to send you.

Dr. WILENSKY. Fine.

Senator ROCKEFELLER. I assume others do also.

Dr. WILENSKY. I would be glad to respond them.

Senator ROCKEFELLER. So I enormously appreciate your being here in this incredibly complicated job that you do so well. Thank you very much.

[The questions appear in the appendix.]

Senator ROCKEFELLER. Dr. Paul Griner is one of the fathers of the IOM study; currently he is professor of medicine and general director of the Strong Memorial Hospital in Rochester.

Dr. Griner, you will be testifying on behalf of IOM?

Dr. GRINER. That is correct, Senator.

Senator ROCKEFELLER. Please proceed, sir.

STATEMENT OF PAUL GRINER, PROFESSOR OF MEDICINE AND GENERAL DIRECTOR, STRONG MEMORIAL HOSPITAL, ROCHESTER, NY

Mr. GRINER. Thank you.

I am Paul Griner. I am the Samuel E. Durand, professor of medicine at the University of Rochester; and the general director of the University's Strong Memorial Hospital. With me is Kathleen Lohr, the deputy director of the Division of Health Care Services at the Institute of Medicine. Kathleen was the director of the study whose report we are discussing today.

I served on the Institute of Medicine's Study Committee on Quality Assurance in the Medicare program. That study, as you know, was requested by the Congress, called for an ambitious and far-reaching strategic plan for assessing and assuring the quality of medical care for the elderly during the next decade.

I do appreciate the opportunity to speak to you today about some of our major conclusions and recommendations.

Senator ROCKEFELLER. Dr. Griner, you know that I have the 5-minute light on. If you have a long speech we can enter it into the record. Right now, I would like to get you to boil it down.

Dr. GRINER. I will be within 5 minutes.

Senator ROCKEFELLER. Okay. My apologies to you.

Dr. GRINER. Let me summarize the major points of this study. First, the quality of medical care for beneficiaries, although adequate, can be improved.

Second, the current system is not very effective. It focuses excessively on detecting poor hospital care, slights issues of under use and problems that occur in nonhospital settings, lacks proof that it makes any difference for the elderly, and intrudes on the doctor/patient relationship. Because it lacks coordination among multiple oversight functions, it is wasteful of resources.

Third, there are three broad categories of problems regarding quality of care—overuse, underuse of needed service's and poor technical and interpersonal performance by practitioners in institutions.

We cannot say how much each of these three kinds of problems exist. We also cannot say which of them is likely to be the most important. Thus, the quality assurance program must be prepared to find and deal with all three kinds of issues.

Fourth, a small number of practitioners and providers account for a large proportion of serious quality problems. So we do need strong mechanisms to deal with this small fraction of the provider community. Average everyday practice, however, is not immune from quality deficiencies and a successful quality assurance program, both finds the so-called bad apples but also works to raise the level of practice of all practitioners and identifies problems in health care systems that must be addressed to promote quality.

Finally, it nurtures the best instincts and conduct of health care professionals who serve the elderly and indeed all of us.

Fifth, we need to know more about the nature, extent, and intensity of quality care problems and the potential burdens of harm they pose for the elderly. Perhaps our greatest deficit is in seeing viable solutions. We need to understand better how to change the behaviors and patterns of care of practitioners and how various approaches to financing, reimbursement and organization of services promote or constrain quality.

Sixth, no definition of quality of care guides the Medicare Peer Review Organization program today. Even more telling is that the Medicare program itself has no direct mandate to measure, assure or improve the quality of care given to the elderly or more importantly the health of the elderly.

Seventh, the Institute of Medicine defined quality of care as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. We believe this statement provides a firm basis for quality assurance in Medicare.

Let me now return to highlight the implications of these findings. We made ten major recommendations. Two of them propose expanding the mission of the Medicare program to be responsible and accountable for quality of care for, and thus the health of the elderly.

The third recommendation focuses on the needs for research in areas of clinical evaluation, such as quality of care, outcomes and effectiveness.

A fourth calls for expanded capacity building and training for health professionals in the concepts and skills of quality assurance and research.

In a fifth recommendation we call for rebuilding and restructuring the current PRO program into a Medicare program to assure

quality, and then two related recommendations regarding implementation of that new effort.

Finally, three recommendations concerning public oversight, accountability and evaluation of the new program.

In all likelihood not all of these can be acted on immediately or simultaneously. We believe, therefore, your first priority should be to consider and act upon the IOM's definition of quality of care and its call to expand the mission of the Medicare program to embrace that definition.

Such an expanded mission would aim to improve the quality of health care for Medicare enrollees by strengthening the ability of health care organizations and practitioners to assess and improve their own performance and by identifying and overcoming system and policy barriers to achieving good quality of care.

The corollary of this, the comprehensive system of quality assurance for Medicare, would include tools to help providers improve the health of the elderly and to help them monitor their own performance on behalf of Medicare beneficiaries.

Therefore, a new program like the one we described in our report to you must concentrate on improving communication between doctors and patients and on broadening its concerns for the health and well being of the elderly. Over the longer term it might also be a prototype for quality assurance systems that could serve other parts of our society as well.

Finally, it is hard to see how we can get where we want to go if we do not invest in the people, the systems and research needed to pursue the broad quality agenda set forth in our report.

Therefore, I think that great weight must be placed on our recommendations for extended research and capacity building.

I would be happy to answer any questions, Senators. And on behalf of the Institute of Medicine, we appreciate once again the opportunity to present our views and recommendations.

Senator ROCKEFELLER. Thank you, Dr. Griner.

[The prepared statement of Dr. Griner appears in the appendix.]

Senator ROCKEFELLER. It is an extraordinary work—Volume I, Volume II, and more. I do not know how you did it. It is incredible. Reports are published, some people read them, others do not, but there is an extraordinary amount of thought and work that goes into every one of these. I really congratulate you for your effort.

Basically, you would feel that the current system is not very effective since it focuses so heavily on hospital care and the overuse and underuse of procedures. The nonhospital settings, as you indicated, intrude on the doctor/patient relationship. I think you suggest that what we have now concentrates on picking out bad apples and is not very active in terms of raising the level of practice of all practitioners. That would be a fair characterization?

Dr. GRINER. That is correct.

Senator ROCKEFELLER. As I understand, you are not recommending starting over with a new quality assurance mechanism. Rather, you are recommending that we build on the PRO program already in place.

If that is true, obviously because of your dissatisfaction with current procedures, you want to see elements of that current system changed. I would ask then: What would you change? What would

you keep? Do you think that the Medicare program to assure quality the QualPAC is absolutely necessary? Or could we accomplish the same goals through an enhanced role for the PRO's? What about PROPAC and what about PPRC? Do you think they could have a role in any of this, if somehow they were expanded from their present position?

Now that is a bunch of questions but you can answer them.

Dr. GRINER. Let me perhaps, Senator, focus on the first question that we would consider to be most critical, and that is the broadening of the responsibilities relative to the Medicare program and our recommendation of the need for congressional oversight.

If one looks at issues of quality, the determinants of quality go far beyond simply the measurement of physician performance in the hospital setting. Issues of quality bear on the extent to which the financing of health care services or the organization of those services are orchestrated, in addition to how they are provided.

There are positive incentives and there are perverse incentives in our current system of health care. We do not believe that current oversight is sufficiently broadly focused to be able to give us the information needed to identify key areas where quality can be improved. For example, to what extent are problems of access to health care services, either through organizational issues or financing issues, factors contributing to under-utilization of health services.

We also know that over-utilization of services is in part related to reimbursement incentives.

This reinforces the point that Dr. Wilensky made a little earlier—namely, the need for a population based approach to the assessment of quality, one that goes beyond individual physicians and goes beyond individual settings such as hospitals or clinics. It pertains to our first recommendation of the need for broad oversight of all the elements that impact on quality of care and the need as we see it for Congress to have that direct responsibility.

Our recommendation of the creation of a Program Advisory Commission addresses this concern. We are not wedded to that particular name or to that particular commission.

Senator ROCKEFELLER. No, I understand that. I accept that.

But you do not recommend scrapping the PRO. So that there must be some parts would wish to get rid of and some parts which you wish to make stronger. That is what I was trying to get at.

Dr. GRINER. I am sorry, Senator. You are quite right.

We do not recommend scrapping the PRO. We do recommend fundamental revision of the current program. It needs to extend beyond hospital settings. It needs to have a greater level of science applied to the methods used to measure quality.

We do have some concerns about the plans to implement, early on, the uniform clinical data set and perhaps if time permits, we could discuss that concern.

Senator ROCKEFELLER. Well, give me a sense of that now.

Dr. GRINER. There are a host of factors that we feel need to be considered prior to the implementation of a systematic computer-based approach to the measurement of quality. They have to do with the need for better markers of outcome, including functional status and quality of life.

These are outcomes that occur, and can be measured, and should be measured well after hospitalization. They require direct access to the patient through surveys, either telephone or mail surveys. Such markers must be incorporated into the data base.

We also need to recognize that data must be obtained across settings. We must be sure that hospitals and other facilities providers have the wherewithal to generate and evaluate information bearing on quality. We need to recognize and anticipate long-term directions in the recording of medical information, for example, the use of computerized records and what that implies for the generation of a uniform data set.

And finally, we need to be addressing the issue of confidentiality, and the need to have a set of measurement tools that are generic in nature and apply to all patients, not just Medicare recipients. Otherwise, we will have duplication of very expensive systems.

So while we support the need for a more systematic approach and one that will look at patterns of practice among providers rather than individual case review, we do think that there is a considerable amount of work that needs to be done and pre-tested before wide implementation.

Senator ROCKEFELLER. Okay. I cut you off from the continuation of your answer on the earlier part. But my time is out. I will go now to Senator Durenberger.

Senator DURENBERGER. I have two questions, Doctor. The first is: Your suggestion for the first step in this process is to adopt the IOM reports definition of quality. The question is: How does that act standing alone change the way Medicare will approach the issue of quality?

Dr. GRINER. If I understand your question, Senator, my response would be that in order to address this more comprehensive definition of quality we really need to get a handle on the entire system of health care and all of the factors in that system that impact one way or another on quality.

So it goes beyond just an assessment of patients who are already in the system, to include those that who do not have access for one reason or another or who are not utilizing services even though they do have access.

In order to achieve all of that one needs a community-based approach to the health of the elderly, not a specific—a physician-based or a hospital-based set of measurement tools.

Senator DURENBERGER. The second question I have for you refers to the term, capacity building. What is capacity building as used in the IOM study; and what is the most efficient way for us to implement your suggestions on capacity building?

Dr. GRINER. By our definition, Senator, capacity building relates to two fundamental elements of infrastructure. One has to do with manpower; the other with information content and, the recording and analysis of data.

The data infrastructure issue relates to the comments I made just a bit ago to Senator Rockefeller. We believe an enormous amount of additional work needs to be developed prior to implementation of such a broad data base.

Manpower is another major issue. There are far too few people with health services research skills who can adequately evaluate

and improve the state-of-the-art of the tools that we must use. We need to train not only those who are actually generating information, but those who will be applying that information in the field to achieve more systematic and scientific oversight.

Currently, we have estimated that less than three-hundredths of 1 percent of the total health care budget is assigned to this capacity building function. And while we are not anticipating an increase in those funds, under times of fiscal constraint, we do suggest that it is critically important that the funds not be reduced.

As regards to the question of how Congress might facilitate capacity building, the suggestion has been made that we look at existing organizations in Federal agencies and perhaps reshape some of their missions or add to their mission.

For example, the Bureau of Health Manpower of the Health Services Resources and Administration might be a vehicle for expanding educational programs or sponsoring programs. In addition, Congress might develop incentives for academic medical centers to develop or expand graduate programs that would focus on the educational needs of people in the field.

Senator DURENBERGER. Thank you.

Senator ROCKEFELLER. Senator Heinz?

Senator HEINZ. Mr. Chairman, just one key question for Dr. Griner, who I assume heard my discussion and exchange with Dr. Wilensky. I want to be clear that I do not question the importance of outcome-related research for at least two very important purposes and which research we have not done.

Purpose number one is so that we can do a better training of medical professionals. Purpose number two is that when a provider, be it an institutional or an individual provider, is identified as needing help, the appropriate body be in a position to help that provider. You can really only do that effectively with outcomes research. It is clearly true that most physicians and hospitals are extremely well-motivated. If you can show them how to get a better result, they will not be unhappy. They will be delighted.

As I understand it the IOM proposal, anticipates over the long term—10 years from now—moving from the case-by-case kind of review that we now have under the PRO system to an outcome-oriented discipline and management information system. Under such a model, is it statistically possible to get actionable management information, if you will, either for the institution or for the provider or for some outside body when you take the Medicare population, divide it by the number of providers and then further divide that by the number of DRG's, and again by whatever it takes to have comparable demographic groups?

I will tell you why I ask. Each year, due to some legislation that we wrote in this committee, the HCFA hospital mortality data are released. Small mushroom shaped clouds form over individual hospitals at least until the air clears. Mortality is a very important health outcome. I cannot think of a more important one. And we have good statistics on who lives and dies. And yet even the release of hospital mortality data has proven to be a somewhat controversial annual exercise.

So my question is: Can you really get the kinds of good numbers you need to make this system ultimately actionable on a provider

basis? And have you done any kind of an analysis to support that point?

Dr. GRINER. Thank you, Senator.

I do believe that it is possible, through systematic evaluation of patterns of practice at a local level, to get the kind of information that highlight a possible quality problem. Such evaluations provide a first level assessment that may require additional work to separate issues of quality from outcomes that have no bearing on quality.

In my hospital we have a systematic approach to the evaluation of patterns of practice among all of our clinical services. Almost without exception, we find opportunities from those evaluations to improve our care. In some cases it is because the quality is poor; and in some cases we have a systems problem. So my answer is, yes.

Now having said as much, it is critically important that the markers of quality be sufficiently sensitive and specific to be able to point us in the direction of a quality problem as opposed to any number of other factors that may determine the outcome of care.

That gets back to the point that was made earlier of the need for a very thoughtful approach to the incorporation of all of the variables that need to be considered before implementing a system that achieves its objectives.

Senator HEINZ. The second part of my question was whether there is an analysis that supports that encouraging conclusion, a numerical or statistical kind of simulation, if you will.

Dr. GRINER. Thank you.

Let me take a page out of the book of industry in this country and suggest that the terrific accomplishments that have occurred through the application of methods of continuous quality improvement, can be applied to the field of health care——

Senator HEINZ. Remember, I come out of just such an industry which in a day turns out a million sample units of what is supposed to be an identical product.

Dr. GRINER. Yes, Senator.

The point I was trying to make was that industry has shown us the ability to improve quality at a cost that is affordable. There is no industry in the country more critically in need of these two goals simultaneously than the health care industry.

Senator HEINZ. My time has expired. I want to take a contrary point of view. The contrary point of view is not my point of view. It is that of many experts who have looked at crucial industries in this country, such as steel and automobiles, textiles, semi-conductors.

It turns out the United States is probably last in most of the industries in the ability to do good quality assurance, which is unfortunately one of the reasons people buy products that are not American made.

Secondly, one of the other tremendous problems American industry has is that we are apparently relatively incapable of integrating what is called engineering, marketing and research all at the same time. Concurrent engineering it is called. It is because, much like the medical profession, engineering schools in this country only teach engineering. They do not teach integration with manu-

facturing, with production, with marketing, with styling, with fuel economy.

So if you say, "Gee, American industry can do it, so can we," I am really worried about you.

Dr. GRINER. Well, sir, I come from Rochester, NY, the home of Xerox. The Xerox Corp. has recently won the Baldridge Award for its outstanding accomplishments in quality and cost control. We are learning from Xerox about opportunities that we have within our health system to achieve both outcomes. I am convinced that we will be able to do that.

Senator HEINZ. I hope you are right.

Senator ROCKEFELLER. Thank you, Senator Heinz.

Senator Chafee?

Senator CHAFEE. Dr. Griner, in one of your comments you said that the PRO's were focusing on the in-patient setting. And my question is: To what extent is the PRO review occurring now in out-patient settings? Could you give some thoughts as to how you could shift some of the focus from the in-patient to the out-patient setting, and how to shift from a case-by-case to outcomes?

Dr. GRINER. We expect that more and more complex and sophisticated health care will be delivered outside of the traditional hospital setting; in free standing and diagnostic treatment centers, in office practice; in long care facilities, and increasingly in the home setting. It is true that the tools we currently have available for assessing quality have been designed and limited principally to the hospital setting.

One element of our report was the caveat that greater attention be developed to the design and implementation of quality assessment methods, a cross settings, and particularly in those settings that do not currently have such tools in place. Easier said than done. But in part related to the issues that we brought up earlier about the need for careful attention to the data base infrastructure in ways that would permit us to attract patients across settings and not limit ourselves to the black box of the hospital.

Senator CHAFEE. That is so-called "outcomes research?"

Dr. GRINER. In part. Although I would say that—we strongly support the view that no amount of outcomes research alone will give us the comprehensive view of quality that we need to have.

We will still be focusing heavily on process issues. There needs to be a balance between the assessment of the process of care as well as its outcomes. In some cases processes can be poor, but outcome excellent or vice versa. We will miss the problem if we focus on only one measure.

Senator CHAFEE. Let me ask you a question. If somebody is a good doctor for 40 and 50 and 55-year-olds, would that doctor be a good doctor for people who are 70 and 80-year-olds? I guess what I am really asking is: Are gerentologists much better with the elderly? And is that a subspecialty?

Dr. GRINER. Yes and no, sir, depending on who one asks the question of. Most of us who are in what we would refer to as about primary care disciplines—internal medicine and family practice—would suggest that since the majority of our patients are over 65 then we should be, if we are not, focusing on these needs of the

elderly and expanding our skills to be certain that we are providing the level of care necessary for the Medicare population.

Most of us would take exception to the requirement or to the suggestion that specific——

Senator CHAFEE. That did not come from me. That is a question.

Dr. GRINER. Yes.

Senator CHAFEE. I am asking.

Dr. GRINER. No, I am referring to comments throughout the health care world that suggest that in order for elderly patients to receive proper care they must be cared for by geriatricians. We think that is a fairly narrow perspective.

Senator CHAFEE. Is that a recognized subspecialty, gerontology?

Dr. GRINER. Yes, it is; and with appropriate Board certification.

Senator CHAFEE. The theory is that they would deal with individuals over a certain age?

Dr. GRINER. I am not sure there is an age cutoff. There are some geriatric care problems that occur in young people. But generally the focus is on improving the functional status of people that are either aged or chronically infirmed or both.

Senator CHAFEE. Okay. Thank you very much, Mr. Chairman. This is clearly a complicated area.

One of the points you were making earlier about training a whole group of people to evaluate quality of care—and I think you call it in your statement "expanded capacity building and training for health professionals in the concepts and skills of quality assurance and research"—would they have to be M.D.s?

Dr. GRINER. No. In fact, probably most of them would not be. We would hope that they would be limiting their interests to the health field. But the whole area of health services research is one that calls on research skills that may not require an M.D. People with Ph.D.s or Master's Degrees in public health, or health care research would be included.

Senator CHAFEE. Thank you.

Senator ROCKEFELLER. Dr. Griner, without starting another line of questions, I want to pretend like I am adding on to what Senator Chafee said when he mentioned outcomes research.

The AHCPR, I would have to think, even though it does not answer all questions, as you indicated, is one of the most important agencies in the Federal Government at this point this new agency is absolutely and totally unknown by the entire Western World that it even exists.

What I mean is it is funded, and probably underfunded, I guess, out of physician payment reform to help us determine what is appropriate care, what is necessary care, what ought to be the standard of practice throughout 7,000 medical codes, et cetera. It has an enormous responsibility. It contracts with physicians to assist in these tasks.

It is run by, I think, an excellent person who is not yet fully appointed. I think this must be something of a moral problem not only for him, but for the Agency. One could argue that AHCPR is the most important and perhaps the most exciting venture going on in health care as far as the government is concerned right now. Its activities could have enormous consequences on both the cost of

care and the quality of care—the very issues we are hearing about today.

My question of you is: In your opinion, are they going at it in the right way? For example, I assume when doctors go to medical school they learn a lot. They start practice. They then run into all kinds of situations and they learn a lot more. But they must also forget part of what they learned in medical school. It is the whole question of concentric circles.

For example, a student in the sophomore year of college, because of a long summer vacation, which we insist on giving in this country, will have forgotten up to half of what he knew when he enters his junior year. That phenomenon cannot be limited to students at universities. It probably is a phenomenon with doctors too.

This is a long way of saying that one of the things I worry about in AHCPR is that they will end up codifying what it is that doctors feel at the present time and will not develop a more rigorous, disciplined, or challenged result. In fact, that they may not be being challenged sufficiently, now.

Now if I were to mention the name Dr. Lawrence Weed in this room, every single physician would get up and flee from the room and never return. But it is interesting that there are a number of people who say that his criticisms of what is going on and his approach to what constitutes necessary and unnecessary care has some useful aspects. He has his defenders.

My question to you is: What is your position, either with your physician or your IOM hat, it does not make any difference to me, on how the Agency is proceeding? Who is watching what it is doing, to whom it is accountable? Are they exercising that accountability? What is the feeling in the physician community about what it is that they are coming up with? Do you think it is going to make a significant difference in the practice of medicine?

Dr. GRINER. Thank you, Senator. Let me try to take each of these in sequence.

First of all, we believe that Congress should receive a pat on the back for having established the Agency. It is the first time that wide recognition has existed of the need to parallel basic biomedical research with the approach that will help us to apply knowledge from research in a more discriminating way.

The Agency has, we hope, a bright future. It is also funded at levels that permit a much more comprehensive approach to research and development and capacity building than ever existed before.

We do feel—that it is important for the Agency to have definitive leadership as soon as possible. Funding is available, but defined approaches, prioritization, laying out the strategic plan, developing a broader mission than currently exists, all need to be done in ways that will help to advance the goals that we are all referring to this morning. Those goals are being constrained by the lack of definitive leadership.

We also feel that it is important—and I do speak for the IOM in this regard—that we make sure that the focus of the Agency goes beyond simply the development of standards of medical practice, as important as they are. In addition studies are necessary that look at the totality of health care, its organization, its financing, and

how it impacts on the quality of care and the quality of life, not only of Medicare recipients, but of the public at large.

Senator ROCKEFELLER. Okay. I will not pursue that. Frankly, I have a number of questions I want to send you also. I would like to have you expand a little bit more on these last questions. You did not really zero in on some of them. I would like to have more of your views on them.

Dr. GRINER. I would be pleased to.

Senator ROCKEFELLER. Because their procedures are set, once they have set up the way they are going to proceed, it will be hard to change. What happens is that in the initial phase of existence the Agency will formulate its approach to these issues. If there is a mistake made or there is not enough broadness of view in these early stages we are going to be paying for it for a long time.

Dr. GRINER. We quite agree.

Senator ROCKEFELLER. So I will follow up with some other questions.

Dave?

Senator DURENBERGER. I just want to thank you for asking that. I have no questions, Mr. Chairman.

Senator ROCKEFELLER. Okay.

Dr. Griner, thanks very, very much.

Dr. GRINER. Thank you, Senator.

Senator ROCKEFELLER. You have come a long way and I appreciate it. We will be following up with questions.

It is interesting. For those of you who would be interested, the President just had a press conference. He said, "Iraq must withdraw by noon tomorrow to avoid a ground war." He also said that he very much appreciates the Soviet effort.

Next we have a panel consisting of Dr. Thomas Dehn, immediate past president of the American Medical Peer Review Association; Dr. Wolford, who comes from Louisville and represents the AHA; Dr. Robert McAfee, who is vice-chairman of the board of trustees of the American Medical Association, from Portland, ME; and Dr. Robert Kane, Minnesota chair in long-term care and aging, School of Public Health, University of Minnesota, the home of Dave Durenberger.

I do not know who is meant to begin, but I suppose I should start with Dr. Dehn, since I mentioned him first.

STATEMENT OF THOMAS G. DEHN, M.D., IMMEDIATE PAST PRESIDENT, AMERICAN MEDICAL PEER REVIEW ASSOCIATION, MILWAUKEE, WI

Dr. DEHN. Thank you, Mr. Chairman. I am Tom Dehn. I am a radiologist in practice in Milwaukee, WI; and as mentioned, the immediate past president of AMPRA. I have been involved in AMPRA's efforts to take a second look at the PRO program from the trenches. They tend to do that to immediate past presidents. It is sort of a thankless job just before I go out to pasture.

Let me mention that I have a written statement that I find relatively boring and would ask that you enter that into the record so that I will have the opportunity to make some relatively spontaneous comments.

Senator ROCKEFELLER. We will certainly do that.

Dr. DEHN. Thank you.

This IOM Report, as we have reviewed it, in the trenches, we find, really has a great deal of merit. The salient feature, we can boil it down from our perspective, is that it recognizes the integrity of the infrastructure of the PRO Program across the country, and yet recognizes that the mission may no longer be relevant.

In deference to the work that Senator Durenberger did as the father of the PRO legislation I would have to say that the PRO Program is still doing its job, but that the world has changed. We just want to applaud this group as affording us the opportunity to do some midcourse corrections.

With that in mind, concurrent with the effort by the IOM, both HCFA—and it is rare that I compliment HCFA—but both HCFA and the individual PRO's undertook simultaneous efforts to really do an examination of conscience. Are we really doing a job that is relevant to the changing health care system?

Your initial comments in the opening of this session really laid the ground work for some of the comments that I am going to make. I would like to report to you on our interim work that we have done thus far in what we call our "NuPRO Task Force," what NuPRO should be like relevant to the changing health care system; and I will show you some of the things, if I might.

This first graph represents the alarming statistics that we are all too familiar with. In fact, this shows that records indicate the $116 billion that was earlier mentioned, represents the increased costs of health care as a measure of our gross national product.

I think that the next several graphs will very directly answer some of the questions of the earlier data. The problem here is that if the PRO's did what they so far can do best, absolutely perfectly, they would be able to trim up inefficiencies in the system.

Now if this represents graphically the two greatest complaints that society has about health care—that is, that the overall cost is too high—and that the costs of health care are rising too rapidly, if the PRO did exactly what it is supposed to do now—that is turn out all the inefficiencies in the system—and we make an assumption that the inefficiencies were not a lot greater in 1950 than they are in 1990, then what we would have is just a readjustment of the overall problem.

We would adjust it down a little bit. But it really would not meet what now seems to be, and appropriately so, the most dramatic complaint and criticisms about the health care industry—first that the costs are too high—we would only have adjusted that a small amount—and that the costs are rising too rapidly.

So when I was asked to chair our NuPRO Task Force I said to our boys in the trenches, knowing what you know now, how would you do it differently, but keep within the mandate and the constraints and the reality of our changing health care system? So we did that.

We analyzed the costs of health care and the elements that go in. And as far as the Medicare program is concerned, we really cannot do much with the enrollee unless he already tackled the means test from some other aspect of the overall beneficiary group and I do not think we are at this point.

The benefits package to date has been left really untouched. And I would like to come back to that in a second.

Utilization in unit cost under the Part A program has been addressed early on during the introduction of the Medicare program by the PRO's and by the HSA's in total unit cost, both of which were judged to be relatively ineffective.

Now if you remember the history of the PRO Program, it was introduced simultaneously with the introduction of the PPS program. The prospective payment made utilization unit cost irrelevant. But the PRO Program was meant to oversee the performance of the PPS Program. I think we are doing that reasonably well, and so our mandate really begins to change.

Costs are increasing in the ambulatory sector under Part B, and clearly I have heard comments that the PRO role ought to be expanded beyond facility based review and into the ambulatory setting, as appropriate.

Now what government has done is that on the Part B you have taken a look at a freeze of the price side and have introduced resource-based relative value scale. And on the volume side, Medicare volume performance standards. You can beat those into the ground.

What is key is, what we see, whether we all like this or not, is that somewhere along the line we have to address—and I suspect to mid-decade—may I continue?

Senator ROCKEFELLER. Go ahead.

Dr. DEHN [continuing]. Address universal coverage. It would seem that it will have to happen. Now that is a political issue. But if that reality comes to be, then the costs in this system will be so high that the role of the PRO program could very well change to something considerably different, the per diem considerably different from what we are doing now, again using that infrastructure.

Utilizing UCDS—and again it is a complicated system that needs a lot of work, but it has promise—and outcome measures, what we can do is this. And this I find really interesting.

This graph helps define what I think are the three roles of the emerging PRO Program. And if you agree or do not agree, please feel free to ask. If we say that this represents—and this speaks to Senator Heinz's questions—if this represents a distribution of health care—and this being numbers of encounters—and this is some measure of efficiency, either cost or health status upon discharge, some measure of efficiency better on this side than on this side, what we have been doing in the PRO Program is beating up on marginal practitioners that are relatively inefficient and we have been trying to make them better; and we have not done a very good job.

That is mandate number one. That is what we have been doing. I think it was appropriate in the early stages. We did not really know what PPS was going to do to the system; and I think that good public policy despite the fact that it is unsavory to find bad practitioners and to beat up on them, I think that public policy will require that we continue to do that at some level. You may disagree.

What is exciting, however, I think, is the fact that if we are able to use UCDS or some system, whereby we manipulate large sets of

data, we can in Milwaukee or in Minnesota or in West Virginia do a distribution curve and find out what these practitioners are doing. What are they doing?

We can analyze this and take this information back to these doctors and make them better. We have not done that before. I think we would have better success, if we tried this, in making good doctors better than lousy doctors pretty good. We just have not been very successful at that.

Now that I think is relevant. But what is even more interesting is with regard to the variable health care costs, the one that we have not really begun to address is the benefits package. If you really want to change that curve significantly we need, I think, to attack the benefits package.

The way we can do that—again, I hope--is to be able to take a look at this distribution and say this works and we ought not to cover this. So an adequate evaluation of patterns of care, of elements of care, can be returned to those who define a benefits package and say, our data indicates that does not work—that multiplier does not work and I do not think we ought to cover it.

So in terms of an emerging, changing health care system what the PRO program can do is, continue to be vigilant, take what we are doing now, and hopefully make it better.

The third aspect, which I think will have impact on cost, is—tell you what does not work and not cover it. This is all buried in the IOM Report if you take a look pretty critically at it. And my testimony, as I indicated earlier, sort of edges up on the same thing. But if I can really demonstrate graphically what the IOM report means to me and simultaneously what a PRO Program has done individually, this is really what it is.

If you agree, I guess what we would like to request from your committee and from the Health Care Financing Administration is, in that next scope of work, that technically we would like to discuss, some support for capacity building so that we can gain the ability within the PRO Program to do this, because we cannot do it now. We do not have that expertise.

That is going to mean, I think, that the Health Care Financing Administration must be less proscriptive about what we are going to do for the next several years. I think it is really pretty exciting.

Senator ROCKEFELLER. Thank you, Dr. Dehn, very much. We could do individual questions, but I think we would be better to go through the panel.

[The prepared statement of Dr. Dehn appears in the appendix.]

Senator ROCKEFELLER. Dr. Kane, would you be willing to go next?

STATEMENT OF ROBERT L. KANE, M.D., MINNESOTA CHAIR IN LONG-TERM CARE AND AGING, SCHOOL OF PUBLIC HEALTH, UNIVERSITY OF MINNESOTA, MINNEAPOLIS, MN

Dr. KANE. Thank you, Mr. Chairman. My name is Robert Kane. I am a professor at the University of Minnesota School of Public Health. Although I was a member of the Institute of Medicine Committee on Assuring Quality Under Medicare, I am speaking today as a researcher who has applied some of the principles outlined in that report to work in Minnesota and nationally.

The IOM report calls for a redirection of effort away from a preoccupation with the structure and process of care to a more balanced prospective that places greater emphasis on the outcomes of care. Ideally, if we could fairly and accurately assess the outcomes of care and attribute them to the roles of various providers of care involved, we would be in a position to encourage some and discourage others. The task is, however, very complex. In a world where many different persons and groups are involved in delivering care to any patient, establishing these causal pathways is not easy. The good news is that in many cases, it may not be necessary. Rather than attempting to micro-manage care, the government—or other payers—may be able to monitor only those providers that show a consistent pattern of performance less than expected. To create reasonable bases from which to generate expectations requires large data sets and continual monitoring. This was the task assigned to the newly constituted PRO's—or MQRO's—in the IOM report.

In Minnesota we have taken this idea and put it to work in a slightly different context. Rather than looking to a formal system of mandated review, the several medical societies and hospital organizations in the State have formed a cooperative venture called the Minnesota Clinical Comparison and Assessment Project (MCCAP).

MCCAP is distinct because it is an ongoing program committed to improving care by using the patterns of community practice rather than relying on data generated in academic centers. It relies on a working partnership between the practicing community and the university. It depends on the active cooperation of the hospitals and the physicians. It uses information about both the clinical actions taken in the hospital and their consequences as reflected in both the hospital record and from specially conducted interviews with patients at specified times after their discharge from the hospital. The outcomes assessed then cover both clinically specific items and more general measures of their overall functioning and satisfaction with the care they received.

Under this program, several conditions are selected each year for study. A panel of clinicians is constituted to develop guidelines for the management of each condition selected. The panels also identify the parameters by which one might judge successful outcomes if the right steps had been taken. In addition to the condition-specific outcomes, more general measures of functioning and discomfort are used as well as items addressing the patients' ability to perform socially important roles. We also inquire about satisfaction with elements of care received in the hospital.

The criteria embodied in the guidelines are assembled into an abstracting form used to assess the care delivered as reflected in the medical record. Additional items are added to the record abstract to examine the severity of the patient's condition and other factors that may have influenced the outcomes of care such as other diseases the patient was suffering from.

At a time after discharge designated by each clinical panel, interviewers contact the patient by telephone to administer a brief interview addressing salient points about the outcomes of and satisfaction with care.

The information collected in this manner can be used for a number of important purposes. Used in the aggregate, this data can address the important question of the relationship between what is done and the results of that care. Once the relationship between appropriateness and outcomes is established, one can return to the same data set to see if, when the right thing was done by different physicians, the result was equally satisfactory.

Thus far, five conditions are being studied. The conditions were chosen to cover different types of patients and to represent frequently occurring treatments. The plan is to collect data on each condition for a period of at least 1 year. Another 6 months is needed to complete the followups. Thus analyzed results will not be available until about 2 years after the process begins. After a period of organized feedback through general conferences about the overall results and specific feedback on their results to individual hospitals and assistance with the development of needed educational interventions, a second cycle of data will be collected on the original topics to look for evidence of impact.

Successfully carrying this type of monitoring and analysis is a large task. MCCAP has been able to attract the voluntary cooperation of most of the hospitals in Minnesota. Virtually all of the metropolitan hospitals and a large proportion of the rural hospitals are participating.

MCCAP has been from its inception a professionally driven project. The underlying concept has been that it is better to take the responsibility for data collection and thus have a strong hand in shaping it than to wait until some outside force imposes it. Much of the financial support for the program comes from the hospitals and physician organizations, although some funds have been raised from foundations, including the Pew Charitable Trusts and the Bush Foundation. Because it is run by the hospitals and physicians, the program enjoys a high level of credibility and has been able to obtain high levels of cooperation.

Let me briefly note two other projects that also address issues raised by the IOM report but on a more national scale. The principles of the IOM report are already being applied, at least on an experimental basis, by one unit within HCFA. With support from the Agency for Health Care Policy and Research, HCFA's Office of Research and Demonstrations has contracted with the University of Minnesota School of Public Health to develop and test a mechanism to systematically obtain outcome information on Medicare patients discharged from hospitals with selected diagnoses. Four diagnoses were identified by a specially convened advisory group for study initially, two of which will be used in pilot tests. National experts in each area will assist in developing criteria for outcomes and inclusionary criteria as well as modifying factors. The system will be tested on a national sample of Medicare patients using a combination of medical record abstraction and telephone and in-person interviews.

Another study, funded jointly by the DHHS Assistant Secretary for Planning and Evaluation and HCFA is looking specifically at the outcomes of post-hospital care. This study covers over 2,600 Medicare discharges from 51 hospitals in three cities. Each live discharge with one of five DRG's was interviewed at discharge and

again at 6 weeks, 6 months, and 12 months after discharge. The purpose of the study is to understand who gets what kinds of post-acute care and what difference this care actually makes. In this case, we are trying to separate the effects of hospital and post-hospital care to pay special attention to the impact of the latter, whereas in the earlier studies we were emphasizing the former.

All of this work suggests that it is possible to collect data on the outcomes of hospital care and to relate that information to what is done to patients. The IOM report has charted the future for quality assurance. The necessary tools are already in hand and we are becoming more sophisticated in using them all the time.

Thank you.

Senator ROCKEFELLER. Thank you, Dr. Kane.

Dr. McAfee?

STATEMENT OF ROBERT E. McAFEE, M.D., VICE CHAIRMAN, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION, PORTLAND, ME

Dr. MCAFEE. Thank you, Mr. Chairman, Senator Durenberger. My name is Robert McAfee. I am a practicing general surgeon in Portland, Maine; and am Vice Chairman of the Board of Trustees of the American Medical Association.

First of all, on behalf of this panel, representing the States of Wisconsin, Minnesota and Maine, I would like to thank you for the opportunity to make a lovely southern trip this morning. I appreciate it.

Senator ROCKEFELLER. Do you know my first cousin, who is practicing medicine in Portland, ME?

Dr. MCAFEE. I sure do. He is a delightful addition to our State and our community. You would be terribly proud to see him care for his patients.

Senator ROCKEFELLER. Good. Thank you.

Dr. MCAFEE. On behalf of the AMA, Mr. Chairman, I want to express our appreciation for this opportunity to appear before the subcommittee to provide our views on the Institute of Medicine's Report, "Medicare: A Strategy for Quality Assurance." Quality medical and health care, as well as assurance for quality, are critical issues for physicians and the AMA.

Overall, the health and medical care that Americans, including the elderly receive, is of unparalleled high quality. In its report the IOM makes the statement, "The nation is generally perceived to have a solid, admirable base of good quality health care; and the elderly are usually satisfied with the quality of care they, themselves receive."

The AMA is proud of its leadership in the development and implementation of measures and policies that are effective in helping guarantee and improve such quality. As physicians we do strive to always improve our ability to provide the highest quality medical care for our patients.

We are pleased to say that there are portions of the recommendations in the IOM report with which we agree wholeheartedly. But we must also report to you, however, that the AMA cannot support the overall conclusion of the IOM study that states, "Sig-

nificant problems exist in quality of care in our present approaches as to quality assurance. They are sufficient to justify a major redirection for quality assurance in this country, and in particular a more comprehensive strategy for quality assurance in Medicare."

Quality assurance is an evolving science and such a major redirection, which would include the creation of yet another Federal agency to oversee quality of the Medicare program, would be a wasteful use of resources. It is clear that government resources are not limitless. It would be far more appropriate and cost effective for any additional resources to be directed to providing existing Peer Review Organizations (the PRO's) with the resources necessary to help them concentrate more on educational and quality programs, as Tom Dehn has pointed out this morning, and by increasing support for the activities of the Agency for Health Care Policy and Research.

Let me at this juncture thank the committee again for its role in helping create that agency. Dr. Clinton has performed marvelously as the Director of that particular agency. In my personal vision, he has done everything just right. His relationship with the private sector, with physician organizations, has been superb. There has been no attempt to duplicate what is going on in our sector, and we are made aware of plans contemplated by the agency. I think to this date the agency has been extremely well administered.

Although this hearing is not specifically addressing issues relating to peer review organizations, the AMA would like to provide for the record of the subcommittee a number of changes which we recommend in the PRO Program.

First, let me point out that the AMA and medicine have taken a lead role in the development of practice parameters consistent with the IOM Recommendation No. 9 supporting the development of clinical practice guidelines and standards of care. Today over 30 physician organizations are developing practice parameters. And in addition to the rapidly expanding activities of the National Medical Specialty Societies and others, the Agency for Health Care Policy Research is also charged with the development of practice guidelines.

The AMA's primary objective for parameters is to ensure that they are properly developed and implemented so that patients receive only appropriate, effective and necessary medical care. To accomplish this goal, the AMA's efforts are being directed primarily toward working cooperatively with other physician organizations to facilitate their efforts to develop practice parameters.

I have with me today and I will leave with the committee our current catalog on practice parameters, of which there are over 1,000 in this book; our quarterly publication on new developments; and our attributes which help organizations develop those particular parameters.

We think that appropriately developed parameters can increase the appropriateness of clinical care. For example, the guidelines on cardiac pacemakers that were produced by the American College of Cardiology and the American Heart Association have reduced uncertainty that surrounded the appropriate use of cardiac pacemakers and have reduced the use of these pacemakers by approximate-

ly 25 percent in the Medicare population from the years 1984 to 1988.

In addition, the American Society of Anesthesiology, developing standards on intra-operative monitoring which have reduced hypoxic injury, in one State, Massachusetts, from an average of six injuries to an average of one injury per year, can point to a remarkable accomplishment. These examples indicate that practice parameters can be very effective in improving the quality of medical care.

The most significant recent activity in parameters is the establishment of the AMA specialty society Practice Parameter Partnership and the Practice Parameters Forum, which provide an open and participatory process for representation of all of organized medicine.

Let me say, and in our statement, that each recommendation is addressed. Our major concerns are in 3, 4 and 5, with which we strongly disagree. The rest of the recommendations we would essentially endorse.

Finally, I would remind you, Mr. Chairman, that the AMA is a parent organization of the Joint Commission on Accreditation of Health Care Organizations. And as the IOM report notes, the Joint Commission's agenda for change and continuous quality assurance programs are important initiatives to ensure the quality of care that patients receive in accredited institutions.

Our involvement in this private, voluntary activity reflects physician commitment to assure that the needs of our patients are met. We are proud of our work and of our co-sponsoring organizations, including the AHA who is here to testify with us today.

In conclusion, Mr. Chairman, the AMA supports the goals of improved quality care and quality assurances identified by the IOM report. Physicians will support such initiatives when they are convinced that the goal is legitimate, the process is fair, and the patient's best interests is the focus. Physicians do adapt their practice when presented with credible information in a nonadversarial context.

In that regard, it has been a professional delight for me to be associated with the Maine Medical Assessment Project. Since its inception over 10 years ago, when I was fortunate enough to be President of the State Medical Association, at the beginning of that study, I remain proud of its achievements. It is as successful now as it was during its beginnings. I am totally convinced that when presented with credible information, physicians modify their behavior appropriately.

With this in mind, we urge this committee to provide oversight so that those goals can be met to the benefit of Medicare patients through the existing quality assurance mechanisms.

Thank you, Mr. Chairman.

Senator ROCKEFELLER. Thank you, Dr. McAfee.

[The prepared statement of Dr. McAfee appears in the appendix.]

Senator ROCKEFELLER. Mr. Wolford, I made you a doctor when I introduced you.

Mr. WOLFORD. I accept all honorary degrees. But I was willing to accept that one today as well.

STATEMENT OF G. RODNEY WOLFORD, PRESIDENT AND CHIEF EXECUTIVE OFFICER, ALLIANT HEALTH SYSTEM, LOUISVILLE, KY

Mr. WOLFORD. Thank you, Mr. Chairman, for the opportunity to provide my testimony on this very important issue. As you indicated, I am Rod Wolford. I am the president and CEO of Alliant Health System in Louisville, KY. And on behalf of the American Hospital Association, I wish to give support to the Institute of Medicine strategy for quality assurance.

In these times of ever increasing health care costs as is demonstrated on the charts that we just saw bold changes are required; and there are not many agencies or individuals that are prepared to step up to the plate to make bold changes. Instead they want to make incremental changes which usually results in very little change over the long pull.

The Institute of Medicine's recommendations represent a bold, a refreshing, and a creative proposal that has the opportunity to stimulate improvement and quality, not only for Medicare recipients, but for all Americans because health care policy is increasingly driven by the policies established by Medicare.

Most importantly the data accumulated and disseminated on quality through this strategy will result in first improved accountability on the part of all providers; second, a better informed consumer, which is very important for the third component that I believe will have the most significant change; and that is that I think it will ultimately lead to a new level of constructive competition based on quality and value that we do not see today.

Representing the experiences from my own organization, Alliant Health System, and paraphrasing a popular country song, I maintain we have been "looking for quality in all the wrong places."

While the PRO's are an improvement over the old PSRO's, the PRO is an inspection model. It seeks the errors and the offenders and hassles many of the innocent in the process. Unfortunately, inspection and penalties do not focus on the overall clinical process and outcome. Therefore, a sustained and long-term improvement in the outcome is sketchy and erratic at best.

Nearly 4 years ago Alliant, with its three hospitals in Louisville, charted a course of creating our own internal revolution by changing its policies, its behaviors and its culture, both of itself and its own organization and attempting to change the culture of its medical staff to view and improve quality in a different way, in a way we never had done before.

Our view of quality, much like the Institute of Medicine's report and of the quality gurus such as Edward Demming believes inspection to detect errors and variations, to then punish the offenders, is an unproductive means of quality improvement. Instead, we believe the development of clinical processes or protocols to then be used to measure and reduce treatment variation will result in continuous process improvement and ultimately improve the outcome on a sustained and repeatable basis.

To date, Alliant has developed and defined on their own volition clinical processes for over 140 different diagnosis. Remarkable improvements have occurred in utilization, outcome, resource con-

sumption. All of those areas are very important for what we are talking about today. But we are only at the beginning of where we can go.

The IOM strategy, if fully implemented, would promote this type of effort and behavior in most health care settings. That is a revolution. I am sure there will be nay sayers and doubters to the Institute of Medicine's strategy, but I encourage your adoption of the report with the caveat that some of the bureaucratic burden that is expressed in the multi layers in that report be examined very carefully so that we do not overdo it in that particular area, and that adequate resources be invested in research and in implementation to assure the success of the strategy's long-term implementation. Because I believe with that long-term implementation we will see dramatic changes in the quality and the value of services to Medicare recipients.

Thank you.

Senator ROCKEFELLER. Thank you very much, Mr. Wolford. I appreciate that.

[The prepared statement of Mr. Wolford appears in the appendix.]

Senator ROCKEFELLER. Let me just kind of scatter fire some questions here. Maybe I will start with you, Dr. Kane, if you do not mind. In regards to your MCCAP, how long has it been going? What have you reviewed so far? What have you seen in the way of practice style changes? Just give me a better sense of it.

Dr. KANE. The program began approximately a year ago. It took about 8 months to develop the first set of guidelines. The first two topics that were dealt with were hip replacements and cholecystectomies. Actually, four guideline panels were launched simultaneously and it is important to appreciate that the guideline approach that is being used in Minnesota is not so much reinventing the guidelines, because good work is being done by the AMA and a number of other organizations to really bring together the best knowledge we have in each of those fields.

What the guideline process does essentially is buy in the physicians. It involves them in developing and agreeing to in advance a set of practice principles that they are going to live by. The first results are, in fact, changes in physician behavior simply by widely distributing in advance of beginning to monitor the quality after careful review by virtually all of the physicians who would be affected within the State of Minnesota. We began to see a change in that behavior.

The second change that we noted immediately was that some of the guidelines, particularly the ones that addressed the outcomes of care, required specifically that one know how the patient was doing before the crisis that led to his or her hospitalization. That that kind of information on functional status is poorly recorded in the medical record.

We were able to recruit the nurses in each of the hospitals to now systematically collect information at both admission and discharge on the patient's functional status, some of the key symptomatology, with regard to pain and other forms of discomfort that would be particularly relevant to assess whether the patient, in

fact, benefited from the very procedure whose outcomes we wanted to measure.

Even before we have finished one round of data collection we are seeing major changes in the way that the health care system is responding to these kinds of problems and beginning to implement creative solutions in advance of even the data coming out.

We began officially collecting data on a prospective group of all admissions for elective hip replacements and elective cholecystectomies in December 1990. We are really just early into the phase of actually systematically collecting that data, and will begin the systematic follow-ups on the outcomes in approximately June of this year. We decided that 6 months is the appropriate follow-up for hip procedures, which is the first condition.

We will be following up cholecystectomies in about a month because even since the development of the guidelines we have encountered a whole new technological breakthrough with regard to cholecystectomies, namely the laparoscopic cholecystectomy, where one can now almost admit a patient in and discharge him on the same day for what used to be a fairly major operation.

This system provides a monitoring device to, in fact, look at the outcomes and the effectiveness of that care for an evolving technology, while the process is being developed and tested in a general population.

Senator ROCKEFELLER. Was the motivation that lead you to start the MCCAP a dissatisfaction with the PRO system?

Dr. KANE. No, I think that would be unfair to say that it was dissatisfaction.

The PRO system is unfortunately seen as being marginal to the major concerns of what we are concerned with with regard to quality of care.

Senator ROCKEFELLER. In other words, you would agree with that chart?

Dr. KANE. I think that Dr. Dehn has laid it out exactly right. I think, in fact, it is that shift not only in name, but in function from the PRO to the MCRO, represents a concept that moves away from an adversarial or even a conflicting system of quality.

I think this whole panel is saying that there are two major synergistic movements. One is the internal quality control that needs to go on and should be expected to go on within each of the organizations or institutions. That is the continuous improvement we have talked about. The other is an oversight function which should not be a micro-management function, but rather an oversight function which assures that if, indeed, the continuous quality improvement is going on, it will, in fact, result in better patient outcomes.

Important questions were raised earlier—the question about the statistical size of the samples needed to test those effects. We have statistical abilities to aggregate across conditions so that one can look for patterns of effect, correcting for the effects of each of the conditions and for the patient characteristics.

What is exciting about programs like MCCAP and some of the work that has been going on with the Maine Medical Association and in other parts of the country as sort of demonstration sites, is the demonstration that, even now with the present level of our

knowledge and technology, it is feasible to do exactly the kinds of programs that the IOM report was calling for.

This is not a science fiction report about some decade hence. We can begin to launch much of that work right now and are doing just that.

Senator ROCKEFELLER. Let me follow up. In your written testimony you indicated that there was a need for external monitoring.

Dr. KANE. Yes.

Senator ROCKEFELLER. The concern of this whole hearing is the tension that exists between cost containment or utilization and quality. In terms of your group, how is that handled? In a more general sense, how do you think that monitoring can be done?

Actually, let me ask another question. Who makes up the panel of the folks that do this for your program? I assume they are physicians. There must be others. Do they work with the hospital administrators as they do this? Describe the degree of coordination which minimizes confrontation and which maximizes the incentive for all to participate in your program?

People are not necessarily trained in outcomes research, I would not think. How is that instinct or that intellectual pursuit built into your panel? Then will you go on to tell me how it monitors itself or is monitored.

Dr. KANE. It is important to appreciate that the MCCAP Program is a cooperative venture. One of the things I have learned in the 5 years I have been in Minnesota is that coalitions are possible there, that may not always be possible in other parts of the country. Indeed, this is truly a collaborative process. The groups sponsoring and participating in the program represent the hospitals, hospital administrators, various health professionals—nurses and physicians primarily, but other depending on the condition that is involved—and the university, both researchers and physicians.

We have been able essentially to extract the best knowledge from each of those disciplines as it pertains to the problem. This sort of collaboration results in a positive approach, including getting the best out of administrators about how to approach the situation.

Senator ROCKEFELLER. But monitoring implies, or I think it implies anyway, that you have to keep an eye open because the hospital administrators, nurses, and physicians are all working together. They are all in the same unit. Monitoring implies that there has to be some other kind of outside viewpoint.

Dr. KANE. You make an important point here. I want to try and separate two parts of that issue. One is, monitoring does imply oversight. By collecting the data in one agency or one unit which happens to be sponsored by these organizations, we nonetheless provide data about the whole range of activities across virtually the entire State. So that one can monitor from a larger body that is representative of the participants.

I do not think monitoring necessarily has to be enforced from above or from without in order to be effective. On the other hand, were we to have the MQRO's that the IOM calls for, then the monitoring function that is currently being done by MCCAP could be done by an MQRO.

Now it is important to appreciate that under the current scope of work a PRO would not be able to do the kind of work that MCCAP

is doing. MCCAP essentially filled a void that was not being filled by any other organization. But it would not necessarily need to exist if one had this other kind of organization.

On the other hand, the great strength of MCCAP is that it is sponsored by physicians and medical organizations. It enjoys a level of cooperation that would be very hard to obtain from an external agency. When we discovered, for example, that certain critical pieces of information were not readily available in the medical record, we were able to prevail upon the nurses and the physicians to provide that information so that we could supplement the medical record and have the kind of data that we needed to really assess the outcomes.

Were we to depend on the medical record, for example, we would be in the status of the old joke about, "Will you be able to play the piano after the operation?" Well, if you do not know whether you could play it before you cannot judge your piano playing skills after.

We do not have that kind of base line information about functioning in most medical records in this country.

Senator ROCKEFELLER. As you view AHCPR, how good do you think they will be? What is the quality of their work? Do you agree with the broadness of their discipline as they set their pattern for work? Do you have any concern about them?

Dr. KANE. I am first of all very encouraged by what I have seen in the early days of AHCPR. And it is early days still for the organization. We have all pointed to the tentative nature, even of the leadership of the organization. I think they have done magnificently well for the short period of time they have been in business.

On the other hand, it is important to recognize that this kind of activity has several very critical components. One of the things we talk about in quality of care is the difference between assessment and assurance. And indeed, the task of AHCPR is to assure, which presupposes first that we have to be able to assess.

The guideline work and other kinds of things basically speak to developing criteria by which we can assess whether good things are happening; and, indeed, the emphasis on outcomes and effectiveness speaks to be able to monitor whether those things are really being achieved.

That only gets us to the necessary, but not the sufficient stage. The next big job is, in fact, to begin to change the actual patterns of behavior among the large numbers of practitioners from the individual physician level all the way up to the medical corporation level that we have heard some testimony about this morning. I think that is going to be a very difficult task.

Senator ROCKEFELLER. I am interested in that. Let me say to all of you, let's suppose that AHCPR is set up perfectly and that the world of concentric circles that I am worried about is all nonsense, and that it really does lay out what constitutes appropriateness, necessary, et cetera, how do you see the process by which it will, in fact, actually effect what happens in physicians' offices and hospital wards?

Dr. KANE. There are several steps that need to be taken; and I think the AHCPR has responded to some of them very well.

One of the important ones Dr. McAfee has spoken about is the need to involve the critical players at the beginning. You cannot impose quality from without; they have to be a part of the process. If you are not part of the solution, you are likely to be part of the problem. That, indeed, is very true here.

AHCPR has reached out very effectively to try and bring in as many participating organizations as possible.

Senator ROCKEFELLER. Are patients represented?

Dr. KANE. They are indirectly. Dr. Clinton has spoken on several occasions about his efforts to involve patient organizations, like the AARP and others in the process. Certainly their opinions, at least, have been sought. They are not represented on the specific panels that are writing the guidelines.

Senator ROCKEFELLER. Do you think that is a deficiency?

Dr. KANE. No.

We need to provide a mechanism for assessing the patient input, but it is unrealistic to ask patients to write specific clinical guidelines about the technical aspects of management. The patients really have the most to say about the defining outcome states. There we have effectively involved patients in a variety of different levels, in a number of different projects.

Senator ROCKEFELLER. Would any other of you care to comment on any of the points that I have raised?

Dr. DEHN. If I might, Senator.

The comment that Bob just made about involving the beneficiary, the patients in this case, in a measure of outcome is really critical. The professionals can take care of the process—how to perform a cholecystectomy, how to perform any kind of surgical procedure, how to treat a diabetic.

But ultimately the outcome is relatively subjective. You really have to find out what the public, what your beneficiary, what your end user of the system wants out of the system. They define the outcomes. Now there are some very objective outcomes, but there are an equal number of subjective outcomes. The involvement in the beneficiary community in defining those outcomes gives us the endpoint. It lets us know whether we are successful.

You asked earlier how we would actualize this. The patterns that have been developed, the guidelines that have been developed, under the tutelage of the AHCPR can be translated into the process by which you achieve the outcomes that you desire. So that simultaneously you are developing outcomes that you would like to see, along with the development of process by which you can reach those outcomes, and then recognizing that there are a varied way to achieve the outcomes.

You then test which is the more efficient way to do that, and you can do that with some analog of the PRO Program as we see it now. That is how I see it, going from the blue sky that we are talking in the room, through a CAP Program and the kind of experimentation that they are doing there, in the trenches by the PRO's.

Senator ROCKEFELLER. The reason I pursue that—and Dr. McAfee, please join in on this—referring to my cousin who is a physician in Portland, he says that one of the things he is now doing is that he sits together, side-by-side so to speak, with his pa-

tient, facing a computer screen. There is sort of a symbolism involved in that.

In other words, in the interviewing of the patient and trying to find out what might be wrong, he feels at least very strongly that it is important to understand that the patient can be enormously helpful to the doctor. Often however the way interviews are set up—the doctor here and the patient here looking at each other—the doctor does not get sufficient information from a patient and outcomes might be affected.

So that in a sense he works jointly with them. Let me give you an example: a fellow has something that hurts in his stomach, the doctor punches up something on the computer and the computer screen gives a whole list of questions—does this hurt, does that hurt. The patient and the doctor together go through it together.

In fact, as a result of this process the patient can take home a computer printout of what they have just been discussing and can at dinner sit with his family and review it. Often the patient's spouse or the patient's son or the patient's father will say, "Now look, I have noticed for the last 6 months that you have been doing this," which had not occurred to the patient.

In other words, the body of knowledge grows as the patient becomes involved, so to speak, in the diagnosis or whatever you want to call it. That is what I mean when I ask about patient being involved. I am trying to stretch the process. Getting back to what I referred to earlier, is AHCPR attempting to codify the way things are done. Do you understand my points?

Yes, sir?

Dr. McAfee. I think you have identified the important point. We did, as part of our Maine medical project, a small outcome study—100 patients having had prostatectomy, randomly selected. And by any parameter, as professionals looking at the quality of care, it was a superb group. The utilization, the relief of symptoms, the blood loss, the absence of complications, would stack up against anybody's series any place. They look marvelous. We asked the urologist, and to a person, they said this was the greatest operation I ever did. It was perfect.

We then followed this up for 18 months by having an independent third party visit with those patients in their home, with their families, assessing the efficacy of that particular procedure. We found that in some areas up to half the patients said, "I wish I never had that operation."

Senator Rockefeller. Could you repeat that? Half of the patients what?

Dr. McAfee. Said that, "I wish I had not had that operation at this particular time."

Now what the professionals were assessing and what we have looked at as quality issues were obviously not the issues of outcome, of quality of life, et cetera, that are so critically important to patients, to all of us.

As a consequence of that study we have then gone back, through Jack Wennberg and others, have now initiated a nationwide study that the American Academy of Urology is doing prospectively to determine which is a better operation and when should it be done.

More importantly, the informed consent package now put together for patients indicating those, let's say, with prostatectomy, with minimal symptoms, maximum symptoms and how they match their life style and at what point should surgery be considered is a much more informative process. It is informative not just to patients but to the physicians themselves who had not appreciated until one looks in depth at these outcomes and quality of life issues how one should properly select timing and procedure.

So I think you are on the right track. It certainly is part of what we need to do and continue to follow up. That is why I think some of the parameters that the Agency is looking at to begin with are not the high tech things in terms of sophisticated technology, but are pain management, are stress incontinence, are urinary incontinence. We are going to be looking at bed sores. I mean things that are critically important in terms of patient care, patient disability, and ultimately significant cost issues. But they are not the flashy coronary by-pass or prostatectomy or carotid end arthrectomies that have gotten the press in the past.

Dr. KANE. Senator, you make a very important point that I just want to underline. It is very important that we build into our quality standards patient expectations. I think what you are really speaking to is our need to develop more sophisticated mechanisms. The computer example that you give is a lovely one of how we can, in fact, encourage patients to be more active and productive participants in the whole process of not only defining how care is given, but what we expect from that care.

Senator ROCKEFELLER. Also, in narrowing the range from which one selects what the problem might be.

Dr. KANE. Very much so.

Senator ROCKEFELLER. A mutual process, so to speak.

Dr. KANE. Yes.

On the other hand, we need to recognize that we have made some rather impressive strides in a fairly short time. I mean it was certainly well within my professional career when it was considered virtually unthinkable to look beyond the walls of the hospital to talk about the outcomes of care.

Basically, if you managed to get rolled out or walk out of the hospital with a reasonable respiratory rate, that was considered a successful discharge. We are now at a stage where we are beginning to systematically follow patients at points up to 6 months or a year after the hospitalization to find out not only whether the patient is still alive, but how she/he is functioning, how she/he has readapted to her/his basic social roles, what kinds of symptoms; and, in fact, how would she/he now reassesses the experience, as has just been pointed out.

We are talking small steps, but I think we are taking the right steps in very important directions.

Now the other part of the answer, I think, to your original question—what forces shape what the health profession does—there are two major forces that drive the health system in this country. Basically, it is the rules we have for what we pay for; and the rules we have for what we regulate.

What we have right now in this country is a lack of synchrony. Essentially we are here talking about wonderful ideas about how to

do that. In fact, your cousin is not getting paid much for spending all that time sitting down in front of the computer discussing things for patients.

Senator ROCKEFELLER. He points that out to me on occasion.

Dr. KANE. We have a payment system that is not compatible with either spending time with patients or for rewarding people who produce better outcomes more than people who produce poorer outcomes.

Senator ROCKEFELLER. Actually, it is interesting, one of your other charts, the RBRVS, is a classic example of what you are speaking about. He is a family practitioner. Let us say he sits down and spends an hour narrowing the range of options as the computer keeps spitting out more questions and both patient and the physician try to hone in on the problem. This activity is highly cognitive. That's why it is important to have physicians getting reimbursed on the basis of time involved in this very long process.

Particularly if you begin to fundamentally affect not only the diagnosis but the outcomes of the whole system. I mean it really is important that physicians be reimbursed for what is often the most tedious but most important part of their job.

That was a speech; that was not a question.

Dr. KANE. Just think for a moment, if we had a system that in fact paid physicians on the basis of their outcomes. All of the concerns we have about weeding out the bad apples would suddenly now be driven out essentially by economics.

If indeed you got paid more for a successful outcome and you got charged for a bad outcome, I suspect we would need far fewer regulations and we would have a very different kind of environment.

Senator ROCKEFELLER. Can I just ask you all a broad question? It is sort of philosophical. Here we have $116 billion in Medicare and close to $50 billion in Medicaid. By the year 2000 they say that spending under Social Security will be surpassed by Medicare. In other words, cost broke State Governments, broke Federal Governments, both have enormous deficits. It is really important.

You just cannot escape from it. In fact, I think as I said in Miami, at the American Medical Association meeting, I think cost containment is almost the credibility badge, the litmus test, or the gateway through which you have to walk in order to talk about universal access to health care. You have to pass the cost containment test. It has to be credible.

The reason for this hearing is that that is only part of the story, and that Medicare has to be about better quality of health care. So that you really have an exquisite tension which is virtually impossible to resolve. You cannot have better quality, I would assume, without having more costs. Dr. McAfee I know that you do not like some of these new national monitoring groups being suggested by IOM; and I can understand that.

In fact the worse thing you can say in Washington is let us appoint another monitoring group. It almost takes everything else that you might have to say on the subject and makes it irrelevant because people just dismiss you.

On the other hand, you do have to monitor. There does have to be internal and external discipline. That is the way most of the rest of the world of work and industry, et cetera, works. So how do

you address philosophically the question of the tension between quality of care and the need for it, more emphasis on it—outcomes research and all of that—on the one hand, and on the other hand driving down the cost of everything?

Dr. DEHN. Mr. Chairman, I will give it a bit of a try. This is a personal opinion, and not representing AMPRA.

Senator ROCKEFELLER. No, no. You do not have to.

Dr. DEHN. Thank you.

It is my feeling that ultimately we are going to have to engage in a process not unlike what that is going on in Minnesota, not unlike what is envisioned by a PRO Program, that leads to not necessarily a monitoring of quality, believe it or not, but a definition of a basic health care plan.

That basic health care plan probably would be significantly less comprehensive than that which we see covered by Medicare today and that society would probably be asked to determine whether they valued care beyond that which was defined in a basic health care program. This is a social issue; it is not a medical issue.

You are probably familiar with the early efforts by the State of Oregon to assess the society in Oregon as to where they wanted limited resources to be allocated. Interestingly, there were relatively few health professionals involved in that. That suits me personally just fine.

Because right now as you saw aptly identified, we are really getting a mixed signal. We want all the health care in the world and we do not want to pay for it. What we need to do is to organize society to bring the debate on what constitutes a basic health care system into the public arena, give us a straight message, and we can do the job.

Above and beyond that should—and again this is a personal opinion—be the responsibility of the individual beneficiary recipient.

Mr. WOLFORD. Mr. Chairman, I will go second here.

There is a strong inference given by a lot of people that quality costs more money. I do not believe that is true. I do not believe that you can always say that if you have higher quality it has to cost more. As we have seen that in some of the products that we have received from foreign lands and so on, the productivity and the costs that go into those products of higher quality than what we can produce has beat the pants off of us in many of our industries.

I maintain that quality reduces the unnecessary variation of which they have done wonderful jobs in Minnesota and Maine and other locations of doing that. It reduces the waste in the system if you have a process by which you can identify the necessary processes to build the product and reduce that variation, reduce the waste going into it.

That is a different management philosophy than we have grown up with in the United States. It is different than we have been trained in our schools, regardless of what schools they are. We are making some changes in that at this point in time, but it is different.

That means that the management culture, whether it be the physicians or whether it be the hospital administrators or the

others have to change in order to adapt themselves to looking at quality in a different way, that quality does not necessarily cost more.

So that requires investment. It requires investment in the infrastructure in which we evaluate, assess or monitor quality, because we cannot do it the way we had been doing it before if we want to achieve different results. It requires investments in information technology that you mentioned a moment ago, something that we are probably lacking very much in the medical field now. Because the algorithms, the processes, and all of the different iterations that can take place in medicine can be quantified and developed into information technology that can be very useful in quality.

So all of that requires investment and we should not be afraid to make that investment if we wish to have a different level of quality.

Dr. MCAFEE. Mr. Chairman?

Senator ROCKEFELLER. Yes, Doctor.

Dr. MCAFEE. Professionals respond to good, credible data. Forgive me if I say data because in New England we reserve the term "data" to refer to our female offspring, as in our son and daughter.

Good data, as specific as it can be to that institution, to that population base, to that region, or if possible to that individual, if given in an environment of true science rather than without any punition of taking away of credentials or impacting on your licensure board or removing your liability insurance or not paying you, but just to identify you as somebody who may be an outlier, and you for the first time appreciating that what you have been so very proud of doing is now, when measured against the activities of your peers, indicates perhaps overutilization of an operation, a therapeutic maneuver of some sort.

The single greatest motivating force I have found in my part of the world with physicians has nothing to do with your credentials and your pocketbook and this sort of thing, but it is the mere fact that you may lose the mutual trust and respect of your peer by continuing to practice what you think is appropriate medicine. That, 99.9 percent of the time, affects behavior change for the better and is done in an environment without those in the periphery trying to influence that change.

So the creation of that data, the sharing of that data, the specificity of that data, and whether that is to be through the Uniform Clinical Data Set, whether it is through feedback of information such as Tom had mentioned, in whatever form, I think it is the key to continuing to implement good and better quality, and monitoring that quality down the line.

The wisest investment Maine ever made was the creation of the Maine Health Information Center; and the Maine Medical Association put up $10,000 at a time when their total budget was not much greater than that to pay for collecting data. We now have quarterly hospital discharge, 100 percent hospital discharge, data that we have had for 11 years now. We can see trends. It is the ideal monitoring system for in-patient care; and we are trying to modify this to some of the outpatient care.

Senator ROCKEFELLER. You have all been very generous. I want to ask one more sort of general, philosophical question and I would

like to hear your comments. But let me say before that, that I am going to send each of you a number of questions that I wanted to ask but did not.

[The questions appear in the appendix.]

Senator ROCKEFELLER. One of the things, Dr. McAfee, that my cousin also tells me is that a lot or a goodly number of his age group—and he is in the thirties—are getting out of medicine. They are physicians and they are getting out. They want out because of this hostile climate of which you speak, the hassle factor, which is now part of the English language.

You look at our current situation, and in a sense you could almost say, it can only get worse because we have been going along in this country assuming that whatever was needed would be paid for, that whatever new technology was made available was the right of every single American. Every single American uses it and costs go up.

We are coming to a point where the cost of health care is virtually unsustainable by at least the Federal Government. So you have this ridiculous situation where Congress in the last 10 days of a 2-year session or of a 1-year session will in its Reconciliation Bill cast about in the last few moments looking for $2 to $3 billion to cut or $4 to $5 billion to cut, and they go after the opthamalogist or the anesthesiologist. They just cut arbitrarily. We cut arbitrarily. No science. It is desperation.

We cannot sustain the increased cost of Medicare. We cannot do it. Even as we do it is still going to go up every year. When we talk about cutting Medicare, of course, it is never cutting Medicare in absolute terms; it is cutting the rate of growth. People think it is cutting Medicare. The intensity over this issue is so much stronger in the last 5 or 6 years. Obviously, we understand the reason why.

On the other hand, you have outcomes research and you have the IOM report, new groups to monitor, and different States trying different things. There is tremendous pressure on a physician. Patients are becoming more knowledgeable; consumers, generally, are becoming more knowledgeable.

The whole question of liability reform, tort reform, which I think is absolutely fundamental. A physician faces his patient, and the patient is not a patient but a potential litigant. The whole philosophy, in a sense, the souring of the relationship, taking away what it was meant to be, what it was when physician went into the practice.

My question is: Can we go through this process, all of us—public people, physicians, other private sector people—in a spirit of comedy, understanding that in a sense we all have to give something up, that we all have to change our ways of behaving. Certainly we do in Congress. We have been outrageous, really, just handing out money nonstop and then all of a sudden jerking it away without thinking.

Presumably if we ever get to the point where there is full access to care and there is no more uncompensated care, doctors and hospitals will benefit from that. So they would need at that point, probably, to give something back. The consumer is going to have to give something up. If there are more MRI's in San Francisco than there are in all of Canada that says there is something basically

wrong with our systems. Our consumers are going to either give up first dollar coverage or are going to have to pay a certain percentage of co-insurance. They have to understand they have to limit their own demand for medicine. This is their patient responsibility.

Everybody gets hurt in this process. Hospitals are closing. We have hospitals in West Virginia which I fight to keep open that have only 20 percent occupancy of their beds; and yet they are sole community hospitals. There is nothing else. There is nothing else in the area. So everyone has to sacrifice.

Do you think that there is a possibility that we can go through this agony over the next 5 or 6 years as we try to recreate, retune, or redirect and yet control costs and improve quality, and work together?

I know it is a naive question, but I think it is maybe the most important.

Dr. McAFEE. I do not think there is any question that we are going to do it, that it is going to evolve into a system that I think we are all going to be proud of at the end of that process.

I think the key, Senator, as it has been in the past and I know is well-known to you, that if we can maintain the mutual trust and respect that we have for each other, that the profession has for government and those saddled with the responsibility of providing in the public sector, if we continue to respect the professions and their role, and meeting their needs; and if we both collectively can continue to respect the needs of patients and not deny patients access and resources because of inappropriate cost decisions, then I think we will have done what we want to do.

In regard to the profession itself, yes, we see young people somewhat despondent about having finally arrived and beginning practice and it is not what they wanted it to be. But I submit to you that some of those physicians probably should not have gone to medical school in the first place, because they are being despondent about the wrong reasons.

The practice of medicine still is a marvelous, marvelous profession. The positives of it you do not see and hear because you do not have the opportunity to on a daily basis, as we in the profession do. And until you have the opportunity to operate on that young adult trauma victim who is dying before your eyes and finally grasp that splenic artery between your thumb and forefinger at 2:00 in the morning and know at that moment that you have given that kid 50 more years of life, simply by doing what you are doing at that point, regardless of what financing or where you are, et cetera, occurs, I submit to you that still is the single greatest natural high that one individual can feel for another on the face of this earth.

That is why you go to medical school; and that is why we are doctors. We will solve these other problems in some other fashion.

Dr. KANE. Senator, let me perhaps provide a slightly more pessimistic view of what I think is happening here. Your description of the American population is very accurate. America is like a fat person who goes on a series of binge diets and keeps gaining weight all the time. That is what we have done with our health care system.

We keep looking for magic bullets. We have tried the banana diet, and the grapefruit diet, and we have been taking some pills for it, and we find out we are still gaining weight all the time.

I think if we are going to really change the way that we behave we need to change fundamental behaviors. In a society where consumerism is the national pastime it is very difficult to anticipate any type of way to get out of the trap of people expecting more and more from the medical care system.

The major medical journals now have news releases on a weekly basis to inform the public about the latest medical breakthrough based on the last three cases. These reports encourage patients to demand that kind of care from their doctors. That situation is not likely to lead to active cost containment.

We need to find some very strong discipline. I think Dr. McAfee is absolutely right when he describes the wonderful sensation of operating on a trauma patient. But one of the realities of medicine today is that the probability of benefit is inversely related to the duration of the event. We do much better on trauma than we do with chronic disease.

This is a country that is facing an epidemic of chronic disease. Most of the doctors practicing medicine in this country today will work less with splenic arteries than they will with 85-year-old people in intensive care units hooked up to 14 machines.

If we are going to begin to look for ways to control our almost insatiable appetite for medicine, it has to be by resetting the appestats of the average person. We need to have very frank discussions about what we truly expect from the medical care system.

We are in some cases buying minutes of life at a very, very high price. At the same time we are neglecting literally thousands of people who are in dire need of care, because they are uninsured or because they are in long-term care facilities that are not providing a reasonable quality of life.

I certainly do not need to tell the Chairman of the Pepper Commission those problems. You have dealt with them eloquently. But it seems to me that we need to grapple with that basic redistribution. We need to find ways to give the physician who is delivering primary care to the 75-year-old person the same sense of satisfaction that the surgeon gets when he repairs the spleen of the trauma victim.

We do not have a mechanism to do that. That is why developing data on outcomes and the differences that doctors can make becomes so important. Right now most of the physicians who are practicing primary care get no system of systematic feedback about the difference they make as physicians.

That lack is one reason they are driven to doing more and more procedures because you get immediate gratification from that. That kind of a resetting of the environment of practice by providing reasonable information that can involve patients can mean both patients and physicians active participants in understanding the alternative scenarios for different kinds of outcomes that are possible by different kinds of procedures.

Good information can begin to reset this whole pattern that we have developed. It is going to take something much more substan-

tial than just forming panels of experts to write guidelines to simply change that whole situation.

Dr. DEHN. Senator, as I understand your question, it was less with regard to the process than are we going to survive the process; and what impact will that process have.

My thoughts on the issue are that the quality that makes us uniquely human is our ability to reflect on our own behavior. As a profession we are engaged in reflecting on our own behavior. That is really exciting. It may be a little painful and a lot of work for us.

But for young students, young practitioners, to be a part of a very critical moment in the practice of medicine, the opportunity to take a very critical look at yourself, and the opportunity to use that information to make changes that are for the betterment of you or your profession, while it may sound like fluff, is a very, very exciting opportunity.

I think that young students, my son included, who I encouraged to go into medicine, will grab that challenge and do a lot better job than we have done with it in the last several years. I am optimistic.

Mr. WOLFORD. Well, I guess I will fill in the last here. I am optimistic, but pessimistic at the same time. I will balanced in that and say that I believe that the American people have the will to make changes. But many times we see structural gridlock because of self-interests—self-interests that both built the very, very good medical system that we have today; and that self-interest coming back to haunt us and not wanting to change.

All we have to do is take a sampling at one of these subcommittees on health care issues and see the diversity of opinion and the host of people who will come in to render that opinion as to why they should get more of the pool of money that is out there, at this time a very massive amount. And sometimes it is reflective of a shark-feeding frenzy on that massive pool of money. It is very difficult to change that.

So I think if we are to change the health care system, we cannot look at it in just simply incremental changes. We are going to have to take a look at some of the structural aspects of the system to determine what do we need to fundamentally change in order to make it a modification of where we are today to achieve a better result.

Senator ROCKEFELLER. I really appreciate all four of you, your openness, and your honesty. You have been very helpful to me. This topic is endlessly complicated but ultimately important. I really appreciate your being here.

With that, we will adjourn the hearing.

[Whereupon, the hearing was adjourned at 12:24 p.m.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED

PREPARED STATEMENT OF THOMAS G. DEHN

Mr. Chairman and members of the Committee, I am Thomas G. Dehn, M.D., Immediate Past President of the American Medical Peer Review Association (AMPRA) and a practicing radiologist in Milwaukee, Wisconsin. I am also Chairman of the AMPRA NuPRO Task Force, an initiative within the Association to develop our own recommendations regarding the future of the PRO program. On behalf of the physician directed medical review organizations which comprise AMPRA's membership, including the federally designated Peer Review Organizations (PROs), I am pleased to have this opportunity to present AMPRA's views on the Institute of Medicine (IOM) study entitled, "Medicare: A Strategy for Quality Assurance."

Mr. Chairman, in a historical sense, the release of the IOM report has come at a particularly propitious time. Major health care policy debate and action regarding the form and substance of Medicare quality assurance activities has occurred approximately once a decade. In 1965, at the start of the Medicare program, conditions of participation were stipulated governing institutional quality assurance responsibilities. In 1974, the Professional Standard Review Organization (PSRO) program was established at the urging of Senator Wallace Bennett. In 1982, Senators Durenberger and Baucus led a successful effort to establish the Utilization and Quality Control Peer Review Organization (PRO) program. Today, with the IOM report as the catalyst, we are once again debating the overall goals and objectives of a Federal oversight program responsible for assuring the quality of care received by Medicare beneficiaries. The IOM report has stimulated all of us to think with greater clarity and purpose about ultimate goals for such a program and the best methods to achieve them. AMPRA is a willing participant in this important policy discussion. We welcome this hearing today not as protectors of the status quo but as contributors to new ways of thinking about Medicare quality assurance activities. Our comments will focus in particular on the appropriate role for external review organizations.

PRO PROGRAM: WHERE WE HAVE BEEN

Mr. Chairman, before commenting specifically on the IOM report and presenting the Committee with some of AMPRA's specific recommendations for the future, I think it important to briefly review the short history of the PRO program. In this regard, I only wish to point out that the design of the PRO program, since its inception, has been a reflection by Congress and the Health Care Financing Administration (HCFA) of concerns regarding the potential risks to quality of care and to cost containment that may arise from the incentives of the Medicare prospective payment system (PPS) for hospital services. PRO review has been specifically tailored to address such PPS concerns as: inappropriate admissions, premature discharges, and DRG coding manipulation.

In retrospect, we should not be surprised that PRO objectives were so clearly tied to PPS oversight. PPS was a largely untested hospital payment system which raised many concerns within the Medicare beneficiary community regarding the impact on patient care. Seen from this perspective, the PRO program has met many of the original objectives set for it. Quality of care in hospitals, as PROs have observed and the recent RAND DRG Study on the Impact of DRGs on Quality of Care validates, has not deteriorated but has actually improved as a result of the PPS system. Instability at discharge has increased as a result of PPS, but this problem is more a reflection of the limited Medicare benefit structure for post acute care treatment than

a responsibility of the hospital to provide non acute care services. Admission rates for hospitals have declined even though the economic incentives of PPS reward increased admissions. A study from Project Hope concludes that a major causal factor for this drop in admissions is the fact that hospitals now screen all their Medicare admissions to prevent retrospective denials of hospital payment from the PRO.

My point, Mr. Chairman, is that the PRO program has been guided by a narrow and limited, albeit understandable, set of objectives. These objectives have been to oversee the introduction of the PPS system and to project some level of confidence to Congress and the public that quality of care has not been compromised. The original PRO statutory objective, articulated by Senators Durenberger and Baucus, to empower local review organizations to innovate and to focus their activities on a broad range of quality and utilization objectives gave way to succeedingly prescribed PRO Scopes of Work, both in terms of the cases to be selected and the method by which review would be performed. As I have commented before this Committee on previous occasions, PROs are limited to a "snapshot" look at Medicare services. As we near the first decade anniversary of the implementation of PPS and with the broad success of PPS in terms of introducing incentives for hospital efficiency, it is now an appropriate time to move beyond this solitary focus and begin to pursue a more ambitious agenda. It is with this understanding in mind, that I turn now to a discussion of the IOM report.

THE IOM REPORT

At the outset, Mr. Chairman, let me take this opportunity to compliment the IOM Committee and staff on a thoughtful and innovative report. The IOM Committee took seriously its charge to outline a long term strategy for Medicare quality assurance and set a direction for the future that we can steer by in the years ahead. It is a very ambitious and difficult course that the IOM has chartered but let me state with confidence that it is a course that the PRO community can follow with enthusiasm.

AMPRA is particularly appreciative of the report's conclusion that now is not the time to start over but to strike a balance between new emphases and responsibilities for Medicare quality assurance activities and retaining elements of the current system. Not surprisingly, AMPRA agrees with one of the report's conclusions that the current PRO program provides a valuable infrastructure of committed quality assurance professionals that will be needed even as the roles and functions of local review organizations change significantly in the days ahead.

To briefly summarize our position, Mr. Chairman, AMPRA is supportive of many of the conclusions and recommendations of the IOM study. We support the study's strong call for the development of a comprehensive database on patient care outcomes The PRO community would like to be in the position in the future of linking more empirical evidence of medical effectiveness with the promulgation and dissemination by the PRO of more explicit process of care standards. We support the IOM strategy to feedback information to providers and patients to help inform clinical decision making as a preferable alternative to regulatory oversight and the imposition of sanctions and penalties. The study's emphasis on continuous improvement as a means to shift provider behavior to a higher performance standard is laudable. It is true that too much time and too many resources have been expended in the PRO program chasing a relatively few provider outliers in the system. We are in agreement that identifying and rewarding provider performance needs to be encouraged in any Medicare quality assurance system. AMPRA fully supports the need to assure quality of care in all care settings and the call for additional funding to reach this goal. As previously mentioned, too much of the present PRO focus is on oversight of PPS at a time when services and technology are being dramatically shifted to the ambulatory setting. These and other recommendations of the IOM study are applauded by AMPRA, and as an Association we are committed to their implementation. The challenge is now to translate bold thematic goals and objectives into programmatic specifics. The PRO community is committed to assisting HCFA in realizing this difficult transition because we believe the end result will be a more efficient and effective external review system.

AMPRA's stated goal in embracing IOM's new direction is to rid the perception if not the reality that PROs are nothing more than government policing and enforcement agencies. We must begin to create state level review organizations that are first and foremost valuable information and education resource centers for both providers and consumers at large. In spirit and mission we must begin to think of ourselves as patient advocacy organizations understanding that the ultimate goal of peer review activities is to improve the quality of care for beneficiaries. At the same time, we must be true to our calling to improve provider/practitioner practice be-

havior through a peer review process that protects the confidentiality of peer deliberations.

To realize this shift of focus in Medicare quality assurance activities, nothing less than a change in culture and attitude must govern the relationships between PROs, providers, beneficiaries, and the government. Trust and cooperation must replace suspicion and penalty as the guiding principles between all parties, not the least of which is the relationship between HCFA and its PRO contractors. New lines of communication and new methods of communicating with all parties must be developed to handle the new kind of information that will be demanded in the future.

As the IOM report expressed, another critical element of success in the future will be the willingness and ability of all participants to build new skills and capacity. While clinical judgment will remain an important ingredient in quality of care evaluation, much of our work in the future will be guided by epidemiologic science, clinical decision analysis, information science, and statistics. Major resources must be devoted to training of individuals at all levels in the Medicare quality assurance system, including hospital, PRO, and HCFA staff.

Mr. Chairman, while AMPRA is in strong report of the report's basic recommendations, we do wish to take issue with a couple of the report's conclusions and address two perceptions occasioned by the report's release. Let me elaborate.

The report concluded that PRO review to date has been a hindrance to the goal of self-monitoring and internal organization improvement. While we agree that too much of PRO review has been characterized by a regulatory and inspection model, approaches that need to be deemphasized in the future, we believe, nonetheless, that the primary impact of the PRO program to date has been to provide incentives for hospitals and other providers under review to invest in developing their own internal systems of quality and utilization management. The PRO community has observed a pronounced increase in such institutional activity since the introduction of PRO review. We are disappointed that the report did not explore more thoroughly this sentinel impact of PRO review. AMPRA does not believe, as the report itself concluded, that it is time to relinquish PRO authority to sanction or penalize; these interventions can be needed stimulants to positive changes in behavior when other appeals to the provider community have not worked.

The IOM report also concluded that the PRO program is overly attentive to utilization and cost containment issues at the expense of quality of care. AMPRA would be the first to acknowledge that over time the scope of work assigned to Federally designated PROs has changed in important ways. While quality of care issues did take a back seat in the first PRO scope of work, PROs now focus a great deal of time and effort on activities geared to monitoring and improving the quality of care. The development of generic quality screens for use in the second contract cycle, and the development of HCFA's mandated quality intervention plan in the current contract cycle give evidence of the change in emphasis from utilization review to quality review.

Philosophically, we also believe that quality and utilization are inextricably linked. For example, good surgical outcomes in terms of mortality and morbidity rates in patients for whom the surgical procedure was not medically required certainly would give a distorted view of the quality of care provided to the patients in question. In addition, we believe that considerable efficiencies are possible when a single entity concurrently reviews care for both medical necessity and quality.

As I noted earlier, AMPRA is also concerned about two perceptions that might be occasioned by the report. The first of these is that external peer review should be abandoned in favor of data analysis, practice guideline dissemination, and providing feedback to providers, all of which is intended to improve outcomes. While many PROs are actively involved in all of these activities, AMPRA strongly believes that, given the current state of knowledge about outcomes of care and the use of data to monitor these outcomes, it is entirely premature to consider abandoning the concept of peer review.

As an example of this imperfect state of knowledge, I refer the Committee to an article published July 25, 1990 in the Journal of the American Medical Association. This article, entitled "Explaining Variations in Hospital Death Races: Randomness, Severity of Illness, Quality of Care," was co-authored by one of the members of the IOM panel which produced the Medicare quality study. This recent article concluded:

> "Our analyses of a representative sample of patients with CHF [congestive heart failure] and AMI [acute myocardial infarction] in four populous states [California, Illinois, Minnesota, and New York] have not produced much evidence that hospitals with higher than expected death rates based

only on administrative data actually, on review of their medical records, provide lower-quality care."

By citing this study, I do not wish to imply that AMPRA or its members believe that mortality and other outcomes data are useless. AMPRA, its research and education affiliate, the American Medical Review Research Center (AMRRC), and individual PROs have been pleased to be in the forefront of research and demonstration activities relating to small area analysis, outcomes of care and medical effectiveness.

On the other hand, my reference to this study is intended to make the point that even in the case of outcomes data with which quality of care experts have had the most experience, there are many unanswered questions. Unfortunately, some casual readers of the IOM study apparently have come away believing that peer review activities will be, or should be, discontinued as soon as possible, and replaced by an alternative, off-the-shelf quality assessment tool. Among other things, they have failed to note that the IOM report itself calls for a 10 year implementation strategy.

Mr. Chairman, AMPRA strongly believes that there will always be a role for the peer review process. Physician peer review of medical records must continue to play a central role in the Medicare program's ability to validate outcome data and to make definitive judgments about provider performance and the quality and appropriateness of medical care. In our view, outcomes data, effectiveness research and practice guidelines will supplement and complement—rather than replace—peer review activities. They offer additional tools to monitor and assess the quality of care provided to Medicare beneficiaries and other patients. As noted above, they are also likely to help focus these review activities.

PRO PILOT INITIATIVES

Mr. Chairman, it is important to note that work has already begun in the past several years to operationalize review methods that are consistent with the IOM vision of the future. Under HCFA's direction, AMPRA and the PRO community have been participating in a number of pilot projects and special programs toward this end. For example, seven PROs are now involved in a project to design an approach to assess the quality of care provided to patients in noninstitutional settings. This pilot project is focusing on 16 medical areas and is intended to enable PROs to evaluate variations in effectiveness among interventions and among providers, and to provide useful feedback in order to stimulate continuing improvement in patient care.

Since 1987, AMRRC and 12 PROs have been involved in a HCFA-funded project which makes use of a small area analysis tool to compare the utilization and outcomes of care in various locales. This special project was intended to develop PRO capabilities to feedback data on patterns and outcomes of care to the practitioner and provider community and to evaluate the impact of such feedback on patient care.

Both AMPRA and AMRRC continue to bring attention to recent developments in quality assurance, effectiveness research, and practice guidelines. In November 1989, AMRRC hosted The National Working Forum on Outcomes and Quality of Care. A considerable portion of AMPRA's April 1990 Legislative Policy Conference was devoted to effectiveness research and practice guidelines including a presentation by Dr. Jarrett Clinton, Acting Administrator of the Agency for Health Care Policy and Research (AHCPR). We are participating actively in AHCPR's ambitious agenda to promote outcome research and develop practice guidelines.

In short, the PRO community supports and has been actively involved in pilot projects and programs aimed at improving our review and other quality assurance activities. We believe that these types of projects and programs should proceed, subject of course to careful design and thorough evaluation. These initiatives offer great promise for the future of the PRO program and quality assurance activities generally. They are indicative, Mr. Chairman, of work now being performed that is complementary to the quality assurance activities advocated in the IOM report.

AMPRA RECOMMENDATIONS

As Chairman of the AMPRA NuPRO Task Force, I am pleased to take this opportunity to present some of our preliminary thinking regarding the future of the PRO program. The Task Force will be completing its deliberations and issuing a final report to Congress in the early Spring of this year. Based on discussions to date, particularly an AMPRA NuPRO Membership Forum recently conducted in Albuquerque, New Mexico, AMPRA offers the following five recommendations for Committee consideration:

Medicare Part B Review—AMPRA was a strong supporter of the recent passage of OBRA 1990 provisions that mandate a coordinated strategy of PRO and Part B Carrier review in physician offices starting on January 1, 1992. This date, as you are aware Mr. Chairman, coincides with the introduction of the Resource Based Relative Value Scale (RBRVS) physician payment reform. AMPRA concurs with Congress that it is imperative that targeted review strategies be introduced to address quality and access concerns that might surface as a result of the new payment incentives. For this reason, AMPRA recommends, as a modest starting point for evaluation of care provided in physician offices, the review of certain inpatient "sentinel" conditions that might represent a failure of ambulatory management or access problems. We note that this is the same approach that AMPRA recommended for the review of HMOs/CMPs.

Pattern Analysis and Information Feedback—As mentioned previously, AMPRA strongly supports the emphasis in the IOM report on pattern analysis and information feedback. The AMRRC project on the use of small are analysis was a strong signal that data analysis and feedback of information can capture the attention of the practitioner community while casting the PRO in the role of information and education resource rather than enforcement agency. Unfortunately, just as momentum was building for this approach throughout the PRO community, the project was abandoned when the special project monies ran out. AMPRA believes that this activity is too important to the future of the PRO program to be delegated to a special project category. AMPRA, therefore, recommends that pattern analysis, starting with small area analysis, and information feedback be formally incorporated into the PRO Scope of Work. We further believe that a fixed percentage of each PRO budget be earmarked for these important functions, including financial support for the training of personnel and the recruitment of health services researchers needed for this new work.

PRO Flexibility—AMPRA believes that it is an appropriate time to embrace the original Senator Durenberger and Senator Baucus vision of the PRO program encouraging local PRO flexibility to innovate and to focus review activities. The HCFA national prescription for case selection ignores the fact that quality and utilization problems are unique to state and local areas. PROs are in the best position to use their data profiling capabilities, review experience, and knowledge of the local medical resources and personnel to determine where review activities should be concentrated and, for the better performers, relieved. AMPRA recommends, therefore, that a certain percentage of overall PRO case review be left to the discretion of the PRO. For the sake of national consistency and to maintain the principle of minimum compliance monitoring, this approach should be balanced with a mandate that PROs review a random sample of cases in every hospital. AMPRA is confident that greater PRO discretion in case selection will lead to a higher yield in identified quality and utilization problems and PROs would be willing to be evaluated on this premise.

Uniform Clinical Data Set—AMPRA supports HCFA's decision to develop a Uniform Clinical Data Set (UCDS). We understand the need to have an ability within our quality assurance system to risk adjust for patient characteristics. Risk adjustment will enable us to distinguish between patient outcomes that are driven by the patient's condition or the quality of the medical intervention. UCDS also holds promise for making individual case findings more consistent as the system builds a more structured protocol for implicit review by peers. We do recommend, however, that HCFA move carefully and cautiously towards UCDS implementation across the country. In particular, much work needs to be done to refine the clinical algorithms that are an integral part of the UCDS system. Given the extraordinary implications of the UCDS system for the medical care industry, we need to be certain that UCDS represents the best adaptation of current clinical knowledge to computer science.

PRO Contract Administration—Mr. Chairman, you might wonder why I bring the issue of PRO contract administration before you today. I do so because the PRO community strongly believes that without a sound infrastructure of stable administration of PRO contracts, our efforts are seriously compromised even with the best laid plans of the IOM report or AMPRA's NuPRO proposals. In the 1987 Omnibus Budget Reconciliation Act (OBRA 1987), Congress recognized that HCFA had an obligation to provide due notice and adjustment to PRO contracts when it is necessary to change or add new functions or activities not included as part of the original agreement. OBRA 1987 therefore required the Secretary of Health and Human Services to "negotiate the necessary contractual modifications, including modifications that provide for an appropriate adjustment (in light of the cost of such additional function) to the amount of reimbursement" to the PRO. Regrettably, a number of recent HCFA-directed change orders, including modifications to PRO

data reporting requirements and other administrative changes with financial impact, have been issued without contract modifications. HCFA has taken the position that these change orders are not changes in review functions, and therefore not subject to the OBRA 1987 provision. AMPRA finds this interpretation of current law to be inconsistent with the intent of Congress. We believe that this issue merits further consideration by the Congress, especially in light of the findings and recommendations of the IOM study. AMPRA recommends that any proposed change in the PRO contract be formally negotiated by HCFA with the PRO before implementation of the new provision is required.

SUMMARY

AMPRA appreciates this opportunity to present our views about the IOM Medicare quality study. We believe that establishing a long term strategy for Medicare quality assurance is a policy imperative that all parties must now work together to achieve. The IOM study has made a valuable contribution to designing a framework and setting a direction for the future. The challenge, as AMPRA sees it and the study concludes, is not to "start over" but to strike an appropriate balance between adding new tasks and responsibilities and retaining features of the current system that are needed to meet the future goals of a Medicare quality assurance program.

RESPONSES OF DR. DEHN TO QUESTIONS SUBMITTED BY SENATOR ROCKEFELLER

On behalf of the American Medical Peer Review Association (AMPRA), the organization which represents federally designated Peer Review Organizations (PROs), I appreciate the opportunity to respond to the following questions.

Question 1. What is your perception of your members roles in quality review, distinct from their roles in utilization review?

Answer. The design of the PRO program, since its inception, has been a reflection by Congress, the Health Care Financing Administration (HCFA) and the Medicare beneficiary community of concerns regarding the potential risks to quality and appropriateness of care that may arise from the incentives of the Medicare prospective payment system (PPS) for hospital services. The PROs quality review function has been specifically tailored to address such PPS concerns as inappropriate admissions, premature discharges, and DRG coding manipulation. Utilization review, particularly PRO oversight of hospital admissions, has significantly contributed to cost containment while arresting the per capita admission rate. "From 1983 through 1989 the per capita admission rate decreased by 15%, from an all time high of 431 per 1,000 beneficiaries in 1984 to 368 per 1,000 beneficiaries in 1989."

At the start of PRO review, activities largely focused on review of the utilization of services. In 1986, the PRO scope of work was dramatically altered to increase emphasis on quality review. With this shift, AMPRA believes that a balance between quality and utilization has been achieved.

Question 2. How effective do you think the development of outcomes research and practice guidelines will be in not only assuring quality, but also in continuing to monitor utilization?

Answer. AMPRA has been in strong support of the work of the AHCPR. AMPRA is hopeful that the results of the guideline activity can be translated into medical review criteria for use in the evaluation of quality care as well as in the decision-making process of what should and should not be covered under the Medicare program. The guideline development work, coupled with the development and use of comprehensive data bases by PROs as outlined in the IOM recommendations on Quality Assurance should enhance quality and utilization review activities.

Question 3. How do we go about establishing, implementing and revising practice guidelines for use in a quality assurance program?

Answer. AHCPR, through contract, will manage the development of practice guidelines. As these are developed, work must begin to translate the guidelines into medical review criteria. Once established, such guidelines can be disseminated and utilized by providers in their treatment decisions. Criteria, once established, can be used in the review process by PROs at the local level. Results can the be utilized to feedback information to practitioners and to enhance/update the guideline development process.

Question 4. How accurate is data gathered retrospectively from the medical record? What can we do to improve our clinical data gathering?

Answer. Data gathered retrospectively from the medical record is only as good as the documentation provided by the attending physician on the record. Clinical data gathering could be improved by improving documentation on the medical record.

Question 5. Please expand on your concept of how your members can modify the current PRO program to detect underutilization that effects quality?

Answer. Much work has gone on in the PRO community relative to suggestions to enhance to future scope of work. AMPRA is in strong support of the future directions of PRO review as recommended in the Institute of Medicine report on "Quality Assurance" and as articulated by Dr. Gail Wilensky, HCFA Administrator. We support a shift in program emphasis from a largely regulatory and enforcement oriented system to one that emphasizes epidemiologic oversight, focused peer review, and education interaction with the medical community. Specific recommendations to the next statement of work in the form of an AMPRA Program Policy Statement are attached.

AMERICAN MEDICAL PEER REVIEW ASSOCIATION PRO PROGRAM POLICY STATEMENT

In October 1991, the PRO program will enter its fourth contract cycle. This new contract period represents a valuable opportunity to improve the present program and introduce both a new program philosophy and new approaches to peer review. The Health Care Financing Administration (HCFA) recently released a draft of the 4th Scope of Work that sends uncertain signals about how the PRO program will move from a largely regulatory and enforcement orientation to a system that emphasizes epidemiologic oversight, focused peer review, and educational interaction with the medical community.

The American Medical Peer Review Association (AMPRA), representing Peer Review Organizations (PROs), offers the following recommendations and commentary to HCFA, Congress, and other interested parties to facilitate discussion regarding the best short term strategies for the PRO program. Our input builds on the framework of the 4th Scope of Work as outlined by HCFA but with important modifications that we believe will improve overall program effectiveness.

Recommendation One—Add needed flexibility to the PRO program and encourage local initiative by supporting PRO-determined focused case sampling (both for developing more extensive clinical data for categories of interest and for following up on questions raised by broader data analysis).

The PRO program will suffer if national uniformity in cases selected for PRO review is pursued as a preeminent goal. Rather, HCFA should not only permit but encourage PRO discretion to select areas of inquiry and review, recognizing that opportunities for quality improvement are dynamic and variable. In turn, Regional Office oversight and final evaluations should pay attention to the plans for and results of these focused selections to ensure PRO accountability.

The importance of promoting PRO innovation by granting PRO authority to focus review was recognized by the architects of the original PRO legislation. Section 1154(4)(A) of the PRO statute stipulates:

> The organization **shall** (emphasis added), after consultation with the Secretary, determine the types and kinds of cases (whether by type of health care or diagnosis involved, or whether in terms of other relevant criteria relating to the provision of health care services) with respect to which such organization will, in order to most effectively carry out the purposes of this part, exercise review authority under the contract.

This explicit legislative objective could be easily accomplished within the context of HCFA's present draft of the 4th Scope of Work. The proposed 10% random sample would be maintained as presently envisioned by HCFA The random sample would represent a basic level of compliance monitoring for hospitals operating under the Prospective Payment System (PPS) and would entail the full complement of PPS review (DRG validation, admission, quality, discharge, outlier, readmission, intervening and coverage review). It would also represent the minimum review sample to which the Uniform Clinical Data Set (UCDS) system would be applied, once the new methodology is ready for national implementation.

In addition, a PRO would be permitted to select a focused sample of up to 10% of hospital discharges as additional cases for review. PRO flexibility to focus review would be incorporated into the required "Pattern Analysis" section of the 4th Scope of Work. This section of the Scope of Work, which AMPRA and the PRO community strongly supports, outlines PRO responsibility to explore data regarding medical practice variation. Such investigation will necessarily prompt questions best answered through reviewing or abstracting additional targeted cases. The capability to select cases for special focus is particularly important because of the need to understand patient risk factors contributing to outcomes and use rates observed. The basic 10% random sample will not produce sufficient data on a condition-specific basis for most practitioners and many facilities.

Focused review is also needed to provide clues to the link between patient outcome and process of care and to provide needed opportunities for the application of specific peer review interventions. For example, a PRO might decide that a prior authorization program is needed in response to a medical condition or surgical procedure under study, particularly where the challenge of addressing wide variations in practice leads to a search for better appropriateness criteria. Finally, it is recommended that this focused review strategy take the place of the "PRO Objectives" section of the Scope of Work.

In summary, we believe that focused case selection by PROs is a natural and essential corollary to UCDS and pattern analysis in order to: validate conclusions drawn from PRO data analysis; establish PRO credibility in their required information feedback efforts with providers and practitioners; provide opportunities to implement specific review interventions in response to unexplained practice variation; define expectations for PRO performance in terms of results rather than rigid process requirements. Most importantly, it will imbue PROs with a sense that they are full partners with HCFA in Medicare quality assurance activities and not mere executors of central mandates.

Recommendation Two—Redefine the requirements for PRO quality review and Intervention to encourage non-punitive and educational feedback to care givers aimed at catalyzing self-determined improvements.

The 4th Scope of Work as drafted represents an uneven mix of old and new assumptions about PRO interaction with the provider and practitioner communities. This is particularly noticeable with respect to the required quality intervention plan with its skewed point system. For three years, physicians and hospitals nationwide have complained that the HCFA model is too punitive and rigid. Yet, it has been retained in the 4th Scope of Work. A rewrite of the PRO Quality Intervention Plan is needed to reconcile these philosophical differences in the 4th Scope of Work. The goal of this effort would be to blend the current statutory requirements with the future, balancing the mandate for protecting the beneficiary with the model of non-punitive and educational feedback to providers and practitioners.

Recommendation Three—Plan carefully for UCDS implementation to assure that all necessary steps are first taken to evaluate and refine the system clinically and to build effective training and support systems. When those steps have been taken, implement UCDS through contract modification.

AMPRA and the PRO community supports HCFA's development of UCDS as a tool of patient risk adjustment and as a methodology to standardize case findings for individual record review. The system holds extraordinary promise for building a needed national clinical database that will permit meaningful outcome assessment while, at the same time, improving peer review. However, even supporters of UCDS must conclude that much work needs to be done to:

- ensure inter-abstractor reliability;
- refine existing clinical algorithms;
- create new algorithms for areas not covered;
- reduce unnecessary referral rates;
- refine the system for its ultimate use as a tool of risk adjustment;
- build administrative mechanisms to support training and system maintenance at a national scale.

The system is also, as presently configured, very expensive; in the current form, UCDS triples the unit cost of PRO review. Its high cost led directly to HCFA's decision to reduce by half the projected volume for review in the 4th Scope of Work

To be hopeful that in April 1992 a reasonable next step toward national implementation can be taken, these concerns will need to be addressed in concrete ways, with full consideration of the experience of the initial PROs involved. AMPRA does not subscribe to the view that there is no alternative to the immediate implementation of UCDS. The move toward pattern analysis, focused peer review, and feedback as suggested in Recommendations One and Two above will move the PRO program substantially forward even if extra time is needed for UCDS to be properly and carefully developed. We believe that UCDS implementation must be timed to: ensure a quality product in the long run; increase the likelihood that UCDS will establish needed credibility in the medical and health care services research communities; permit HCFA to accurately predict the costs associated with UCDS; and be consistent with articulated HCFA management policy to await completion of special projects before implementation of new review methodologies.

Recommendation Four—Assure that HCFA contracting mechanisms support, rather than distract from, PRO effectiveness.

AMPRA has expressed strong opposition to the HCFA decision to switch from a fixed price to a cost reimbursement contracting arrangement with PROs for the fourth contract cycle. We believe the decision was hasty and has several negative ramifications. PRO accountability to a set of negotiated set of contract deliverables and objectives, mandated by the original authors of PRO legislation, can best be assured under a fixed price arrangement. Cost reimbursement will require more administrative effort for both the government and the PROs (see attached AMPRA letter to HCFA). We recommend that developmental activities, involving changing unit costs, be temporarily reimbursed as a cost reimbursement add on to a base fixed price contract until the specifications of desired work and expected effort are stabilized enough for incorporation into the base contract. To the extent that some form of cost reimbursement is deemed necessary by HCFA to deal with developmental activity, clear commitments to minimizing the administrative burden and to assuring that PROs have adequate operating cashflows are essential.

Recommendation Five—Establish a new position within HCFA's organizational structure—Associate Administrator for Medical Review. This position would be filled by a physician knowledgeable in the field of quality assurance. The medical review components of both the Bureau of Program Operations and the Health Standards and Quality Bureau would be responsible for reporting to this position.

Recommendation Six—Establish within DHHS a National Council on Medicare Quality Assurance to assist in the implementation, operation and evaluation of Medicare review activities. This is a recommendation of the Institute of Medicine in their recent study entitled, "Medicare: A Strategy for Quality Assurance."

Recommendation Seven—Establish a private, freestanding, technical assistance center for Medicare review contractors. This recommendation is based on a recommendation to Congress by the Physician Payment Review Commission.

The new emphasis in the PRO program on epidemiologic oversight will demand new clinical and technical capacity not presently evident to the degrees required within HCFA or within the PRO community. The recommendations above are presented to: elevate the importance of review activities within HCFA while institutionalizing needed expertise at the highest level; establish a panel of outside experts to oversee and guide the increasingly complex nature of Medicare review activities; and create a technical resource center for PROs and other Medicare contractors to assist in the challenge ahead to build new capacity within review organizations.

Policy Statement adopted by the Board of Directors of the American Medical Peer Review Association on May 11, 1991

AMERICAN MEDICAL PEER REVIEW ASSOCIATION (AMPRA),
810 First Street, N.E., Suite 410, Washington, DC 20002, 202-1371-5610.

MEMORANDUM

TO: Institutional Membership
FROM: William Moncrief, Jr., M.D., AMPRA President
SUBJECT: Meeting with HCFA Administrator, Gail Wilensky, PhD.
DATE: July 18, 1991

The purpose of this communication to the AMPRA Membership is to report on my recent meeting with HCFA Administrator, Gail Wilensky, PhD., held on July 16, 1991. AMPRA had requested the meeting to discuss Association concerns with the 4th Scope of Work, both in terms of program design and contract administration. AMPRA's recently issued *PRO Program Policy Statement* had been formally sent to Dr. Wilensky prior to the meeting and was used as the focal point of our discussion

I was accompanied by James Cannon, CEO Section Chairperson, and Andy Webber, AMPRA Executive Vice President. HCFA was represented at the meeting by: Louis Hays, Associate Administrator for Operations; John Spiegel, HSQB Deputy Director; Michael Hudson, Deputy Administrator; and Nancy Gary, M.D., Medical Advisor to the HCFA Administrator. The meeting lasted an hour.

Relying principally on the concerns and recommendations in our Policy Statement, we raised the following issues with Dr. Wilensky: the need for PRO flexibility

to focus individual case review as required by the PRO statute; the need to rewrite the PRO Quality Intervention Plan (QIP); the need to further refine the UCDS system and gradually introduce PROs to UCDS review by incrementally building towards higher volumes of UCDS review rather than having all review shift to UCDS at a date certain; AMPRA's surprise that HCFA would shift to cost reimbursement given both the risks such a contract arrangement imposes for the government and the administrative burden and costs it creates for HCFA and PROs; the need to extend the existing PRO contracts in the First Cycle given the extreme delays in the release of the RFP. We concluded our remarks to Dr. Wilensky by expressing the opinion that the PRO program will only by successful to the extent that HCFA and the PRO community begins to establish a genuine partnership. We raised the above concerns one at a time, asking for a HCFA response after we completed each discussion item. As is Dr. Wilensky's style, she turned to Mr. Hays and Mr. Spiegel for many of the HCFA responses. HCFA's responses can be summarized as follows:

PRO Flexibility to Focus Review—Mr. Hays and Mr. Spiegel took the lead on responding to this recommendation. Mr. Hays asked why we did not think that a 10 percent random sample was sufficient. We answered that such a sample size will not yield sufficient data to permit profiling of practice patterns at provider/practitioner levels. We also expressed the conviction that a focused approach will increase the likelihood of identifying quality and appropriateness concerns. Mr. Spiegel acknowledged that HSQB has been in discussions with AMPRA/AMRRC on this point and that HSQB would be open to receiving proposals from individual PROs that outline a rationale for taking the results of individual case review and pattern analysis to focus review.

AMPRA strongly recommends to its membership that we collectively test HCFA's willingness to look seriously at PRO proposals that incorporate a focused review strategy into our responses to the next scope of work. This is particularly important for the First Cycle PROs who have been asked to build their business proposals based on a 15% random sample in year one and a 10% random sample in years two and three. While UCDS implementation is anticipated for introduction in month eighteen, nothing is certain given delays in contract administration. Therefore, it becomes important to build a rationale, at the very least in years two and three, to maintain a 15% review volume. This will allow PROs to keep needed staff. Most importantly, it will improve our product

Quality Intervention Plan—In response to our call for a rewrite of the QIP, Dr. Wilensky turned to Dr. Gary and asked whether the "Hassle Factor" Committee that Dr. Gary chairs had heard concerns about the QIP. Dr. Gary answered in the affirmative and expressed the opinion that many doctors feel that they are being hit with a PRO hammer for rather minor concerns that are raised by the PRO. There was general agreement in the discussion that ensued that PROs must maintain their authority to take punitive action when needed but better ways must be found to make PRO-medical community dialogue over individual case issues more educational. Dr. Wilensky expressed her view that the most meaningful educational interaction with the medical community will come with the feedback of PRO information on population based analysis. We had referred in our introductory remarks that AMPRA has established a QIP Task Force and Mr. Spiegel stated that HSQB will take seriously any recommendations that AMPRA puts forward.

UCDS Development and Implementation—Dr. Wilensky expressed HCFA's continued support for UCDS. She did not comment on HCFA's specific plans to further refine the system before PRO implementation. She stated that a more gradual implementation of UCDS would have budgetary implications. Mr. Spiegel commented that the 4th Scope of Work is specifically designed to allow PROs to gear up for UCDS implementation over a six month period, inferring that a gradual phase in approach is not necessary.

Cost Reimbursement Contracts—After listening to our concerns, Dr. Wilensky expressed genuine surprise at hearing the HCFA had made the decision to shift to cost reimbursement. She emphatically stated that "this goes against the principle that I have been trying to espouse here at HCFA," namely the interest in shifting economic risk for the provision of services from the government to providers/practitioners and other contractors doing business with the Medicare program. It was clear from her response that she was not made aware of this decision and she immediately asked Mr. Hays and Mr. Spiegel to explain. Both Mr. Hays and Mr. Spiegel commented that they were sympathetic with AMPRA's position on this issue but stated that the final decision was in the hands of HCFA's Office of Management and Budget. Mr. Spiegel explained to Dr. Wilensky that Management and Budget's rationale for changing the contract arrangement was the uncertainty of predicting the costs associated with the new activities of the 4th Scope of Work, particularly

UCDS. Dr. Wilensky responded that she could understand a short term (we assume she meant by this a single contract cycle) switch to cost reimbursement but reiterated her strong position that this arrangement is not in the government's interest.

We are assuming that this is a issue that Dr. Wilensky will pursue as a follow up to our meeting, although her final comment suggests that she will permit this decision to stand, at least for the 4th Contract Cycle. Whatever the outcome, it was important that AMPRA raised the awareness of the HCFA Administrator. We cannot help but raise the question: if the program side of HCFA was sympathetic to AMPRA's view on this issue, why did they not contest Management and Budget's decision by going directly to Dr. Wilensky with their concerns?

First Cycle PROs—In response to our concern that there is no time to negotiate 4th Cycle contracts given the October 1 start date for PROs in the first round and our recommendation that existing contracts be extended, Dr. Wilensky again turned to Mr. Hays ad Mr. Spiegel for a reply. They responded by stating that HCFA General Counsel interprets the law as not giving them this option. We commented that unlike PROs in the other contract rounds, first cycle PROs did not receive a one time contract extension. We believe the law is permissive on this point. Mr. Hays expressed sympathy for the difficult position first cycle PROs are in and asked that AMPRA convey HCFA's regret for the delays. He went on to state, however, that, while time is short, HCFA believes that it can meet the October 1 deadline for completing contract negotiations.

In summary, while it is hard to gauge the ultimate outcome of our discussions with Dr. Wilensky in terms of changes in the PRO program, we do believe that it was necessary that our concerns be expressed at the highest level within HCFA.

PREPARED STATEMENT OF SENATOR DAVE DURENBERGER

Mr. Chairman, I want to express my appreciation to the Institute of Medicine for its three year effort in response to the Congressional mandate to address issues of quality assurance in the current Medicare Program.

I particularly want to praise the Institute's efforts to define important and fundamental CONCEPTS of QUALITY and QUALITY ASSURANCE. The Institute's Report addresses themes that have concerned me for a long time, such as the importance of what I have identified as the FIVE ACTORS—consumers, providers and hospitals, insurers employers, and government—and the need for all participants to become engaged in and informed about quality health care.

To involve all the actors and to ultimately improve the quality of care, we need INFORMATION. I agree with the Report's recommendations that we need to refine our *methodologies* for evaluation of quality. As the costs of medical care continue to rise, it is imperative that we fund studies on outcomes and effectiveness, engage in careful technology assessment and work to develop practice guidelines. It is false economy to ignore the importance of information in the pursuit of quality care. I have supported and continue to support the efforts of the *Agency for Health Care Policy and Research*, and I am pleased that the Institute's Report recognizes its importance in this enterprise.

Minnesota's health care community has always been at the forefront of the quest for quality. In fact, one of the Institute's site visits was to Minnesota where a vanguard consortium of hospitals have looked at issues of underutilization and overutilization of hospital services, and skill in the delivery of health care.

The Report provides us with excellent definitions of the problems we face. Now the issue is not WHY, but HOW and WHEN do we develop reforms to assure quality in the Medicare program. How shall we STRUCTURE institutions to accomplish the goal of quality assurance? I am particularly proud that Minnesota is the home to an innovative voluntary project, the *Minnesota Clinical Comparison and Assessment Project*, which serves as a model for many such reforms. The large-scale data gathering and outcomes research of this consortium of medical and hospital societies, along with the University of Minnesota, can point us in the right direction. I am glad that Dr. Robert Kane, of the University of Minnesota School of Public Health, is here with us today to talk about Minnesota's pioneering efforts in this endeavor.

I note that the Report is critical of the present structure of the Peer Review Organizations (known as the PROs). I was one of the authors of the original legislation creating these entities. I acknowledge that the PRO system does make an important contribution to the Medicare program, but believe the role must be continually improved and fortified to keep up with the pace of technology and the future changes in the Medicare structure. The challenge for those of us in the Senate is to consider

HOW we can improve our review of those who provide services to the elderly under the Medicare program.

The next question is WHEN do we act? In this era of budget constraints, we cannot ignore the costs of a major restructuring of quality review. We must constantly search for ways to remove redundancies, and improve the efficiency of these programs, while improving quality.

Finally, we must think about the FUTURE. This Report looks only to the Medicare program, but it has much broader ramifications. It is important that we, as policymakers, "get it right" with Medicare quality assurance because we can serve as a model for discussion of quality and value that will ultimately affect non-Medicare beneficiaries as well.

PREPARED STATEMENT OF PAUL F. GRINER

Thank you, Senator. My name is Paul Griner. I am the Samuel F. Durand Professor of Medicine at the University of Rochester and General Director of the University's Strong Memorial Hospital and I served on the Institute of Medicine's study committee on quality assurance in the Medicare program. That study, as you know, was requested by the Congress and called for an ambitious and far-reaching strategic plan for assessing and assuring the quality of medical care for the elderly during the next decade. I appreciate the opportunity to speak to you today about some of our major conclusions and recommendations, and I have also submitted three additional materials for the record.

Let me summarize the major points of the study.

1. The quality of medical care for Medicare beneficiaries, although adequate, can be improved.

2. The current system to assess and assure quality is not very effective. It focuses excessively on detecting poor hospital care, slights issues of underuse of services and problems that occur in nonhospital settings, lacks proof that it makes any difference for the elderly, and intrudes on the doctor-patient relationship. Because it lacks coordination among multiple oversight functions, it is wasteful of resources.

3. There are three broad categories of problems regarding quality of care: Overuse of unnecessary and inappropriate services, underuse of needed services, and poor technical and interpersonal performance by practitioners and institutions. However, we cannot say *how much* each of these three kinds of problems exists. We also cannot say which of them is likely to be the most important. Thus, a quality assurance program must be prepared to find and deal with all three kinds of issues.

4. A small number of practitioners and providers accounts for a large proportion of serious quality problems, so we need strong mechanisms to deal with this small fraction of the provider community. Average, everyday practice, however, is not immune from quality deficiencies. A successful quality assurance program both finds the so-called "bad apples" and works to raise the level of practice of all practitioners, and it identifies problems in health care systems that must be addressed to promote quality. It nurtures the best instincts and conduct of health care professionals who serve the elderly and, indeed, all of us.

5. We need to know more about the nature, extent, and intensity of quality-of-care problems and the potential burdens of harm they pose for the elderly. Perhaps our greatest deficit is in seeing viable solutions. We need to understand better how to change the behaviors and patterns of care of practitioners, and how various approaches to financing, reimbursement, and organization of services promote or constrain quality.

6. No definition of quality of care guides the Medicare peer review organization (PRO) program today. Even more telling is that the Medicare program itself has no direct mandate to measure, assure, or improve the quality of care given to the elderly or, more importantly, the health of the elderly.

7. The Institute of Medicine defined quality of care as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." We believe this statement provides a firm basis for quality assurance in Medicare.

Let me return now to highlight the implications of these findings. We made ten major recommendations. Two of them propose expanding the mission of the Medicare program to be responsible and accountable for quality of care for, and thus the health of, the elderly. A third recommendation focuses on the needs for research in areas of clinical evaluation, such as quality of care, outcomes, and effectiveness, and a fourth calls for expanded capacity building and training for health professionals in the concepts and skills of quality assurance and research. In a fifth recommenda-

tion, we call for rebuilding and restructuring the current PRO program into a Medicare Program to Assure Quality, and two related recommendations address implementation of such a new effort. Finally, three recommendations concern public oversight, accountability, and evaluation of the new program.

In all likelihood, not all of these can be acted on immediately or simultaneously. I believe, therefore, that your first priority should be to consider and act upon the IOM's definition of quality of care and its call to expand the mission of the Medicare program to embrace that definition. Such an expanded mission would aim:

- to improve the quality of health care for Medicare enrollees, by strengthening the ability of health care organizations and practitioners to assess and improve their own performance, and by identifying and overcoming system and policy barriers to achieving good quality of care.

The corollary to this—a comprehensive system of quality assurance for Medicare—would include tools to help providers improve the health of the elderly and to help them monitor their own performance on behalf of Medicare beneficiaries. Therefore, a new program, like the one we described in our report to you, must concentrate on improving communication between doctors and patients and on broadening its concerns for the health and well-being of the elderly. Over the longer term, it might also be a prototype for quality assurance systems that could serve other parts of our society as well.

On another front: it is hard to see how we can get to where we want to go if we do not invest in the people, systems, and research needed to pursue the broad quality agenda set forth in the IOM report. Therefore, I think that great weight must also be placed on our recommendations for extended research and capacity building in this field.

I would be happy to answer any questions you may have about these profound issues and about the IOM's report. On behalf of the Institute of Medicine, thank you again for the opportunity to present our views and recommendations.

Attachments.

MEDICARE: A STRATEGY FOR QUALITY ASSURANCE
BACKGROUND FOR THE SENATE FINANCE COMMITTEE HEARINGS

At the twenty-fifth anniversary of the Medicare program, Congress and the nation can be justifiably proud of the accomplishments of the Medicare program in providing access to a generally high level of quality of care for the elderly. Near universal coverage by the Medicare program gives elderly people better access to health care than any other age group. Nevertheless, care is neither uniformly accessible nor uniformly good. Gaps in coverage and financial barriers exist and affect quality adversely. Reports of excessive care and care of poor technical or interpersonal quality in hospital, office, and community settings continue to be reported.

Since nearly the beginning of the Medicare program, the federal government has tried to ensure that services reimbursed through the program are medically necessary, appropriate, and of a quality that meets professional standards. The two main efforts in this arena have been the Professional Standards Review Organizations (PSRO), in operation between 1972 and 1981, and now the Utilization and Quality Control Peer Review Organization (PRO) programs. The success of those programs in meeting those goals has been, at best, mixed. Furthermore, since the implementation of Medicare's Diagnosis-Related Group (DRG) based prospective payment system (PPS) for hospitals, Congress has heard from many quarters that the quality of inpatient care was being undermined, yet few data are available to support or refute such claims.

In response to congressional concerns that quality of care was deteriorating under PPS and that the PROs and other mechanisms for monitoring or maintaining quality were inadequate, the Omnibus Budget Reconciliation Act of 1986 directed the Department of Health and Human Services (DHHS) to request that the National Academy of Sciences "design a strategy for quality review and assurance in Medicare." In 1987, the Institute of Medicine (IOM) of the National Academy of Sciences appointed a distinguished committee to conduct the requested study, with funding from the Health Care Financing Administration (HCFA).

In March 1990, the IOM released a two-volume report -- Medicare: A Strategy for Quality Assurance -- on the work done to meet the congressional mandate. Volume I of the report contains the IOM committee's findings, conclusions, and recommendations for a comprehensive strategy to improve the quality of health care services delivered to the nation's Medicare population; the executive summary is appended to this background document. Volume II of the report, a major compilation of information on quality measurement and assurance, records the study's many data collection and outreach activities.

An article in the March 8, 1990, issue of the New England Journal of Medicine by Kathleen N. Lohr and Steven A. Schroeder (respectively the study director and chairman of the IOM committee), outlined the major findings and recommendations of the report. They noted, based on the full study, that: although the current quality of medical care for Medicare enrollees is not bad, it could be improved; the current system to assess and ensure quality is in general not very effective and may have serious unintended consequences; and exciting opportunities are now emerging to set in place a comprehensive system of quality assurance that can address itself to improving the health of elderly people.

A BRIEF HISTORY OF MEDICARE QUALITY REVIEW

Successive federal activities have included Experimental Medical Care Review Organizations (EMCROs) of the early 1970s, PSROs, and PROs. These activities were among the more visible examples of a grassroots professional interest in the quality of medical care delivery that emerged following the World War II. The structure and purposes of a quality assurance system for Medicare in the 21st century, therefore, build on organized quality assurance

efforts that started as a professional effort and that has a modern-day history half a century old.

PSRO PROGRAM

Professional Standards Review Organizations (PSROs) were established by the Social Security Amendments of 1972 (P.L. 92-603) to assure that physicians and institutions met their Medicare obligations, namely, that services provided or proposed to be provided to Medicare beneficiaries were medically necessary, of a quality that met local professionally recognized standards, and were provided in the most economical manner consistent with quality of care. PSROs were voluntary, not-for-profit, local physician organizations; HCFA, in administering the program, awarded annual grants to PSRO entities that consisted partly of congressionally appropriated general revenues and partly of Medicare Trust Fund monies. PSROs carried out a number of activities, including hospital utilization review, development of hospital discharge data (the PSRO Hospital Discharge Data Set), profile analysis, and Medical Care Evaluation studies.

The PSRO National Standards Review Council was appointed by the executive branch, consisted of 11 physicians not in the federal government who could represent or were recommended by practicing physicians, consumer groups, and other health care interests, and was charged with reporting to the Secretary of DHHS (then Health, Education and Welfare) and to the Congress on its activities. The Council provided, albeit imperfectly, for some accountability of the program, and it gave some opportunity for early review and consideration of program plans and advice to HCFA by a well-disposed, but external, group of experts.

The PSROs faced conflicting emphases -- contain costs but maintain quality. The framers of the PSRO legislation and program intended primarily that the program lower the inappropriate or unnecessary use of services, as the alarming increase in the cost of medical care at that time was assumed to arise largely from overuse of services. Program evaluations focused mainly on PSRO impacts on costs. This divergence in expectations for the PSRO program -- namely, the congressional expectations that they were getting a cost-control program, the PSRO belief that they were doing quality assurance, and HCFA's view that the program did both -- persisted throughout the program, and it set the stage for disappointment in all quarters with PSRO performance.

Evaluations of PSRO impacts on quality of care were never accorded a status equivalent to that directed at its effects on costs of care, and they were not conducted with equivalent sophistication, although experts regard a report in the late 1970s by the HCFA Office of Research and Demonstrations as a landmark effort. A major lesson of the PSRO program was that the conflict between using such agents simultaneously to contain costs and to maintain quality will almost surely short-change the latter unless strong programmatic steps are taken to protect and emphasize the quality-of-care assignment.

Overall, the PSRO program probably saved as many resources as it consumed, but in an era of rapidly escalating health (and Medicare) expenditures, this was not perceived as an adequate level of performance. PSROs did appear to have a slight positive impact on quality of care as measured by documented changes in medical practices rather than by dollar savings. Again, however, in an environment concerned chiefly with rising expenditures, these effects were not persuasive as regards the success of the PSRO program.

PRO PROGRAM

Disappointment at the limited effectiveness of the PSRO program prompted calls for its abolition or restructuring, and it was phased out in the early 1980s as the PRO program was slowly put into place. Despite rhetorical emphasis on assuring quality of care, the new PRO program focused initially on use of services and costs, and the tie to the new DRG-based PPS reimbursement scheme for hospitals was quite strong. For instance, the PPS legislation

charged the PROs with responsibility for reviewing the validity of diagnostic information; the completeness, adequacy, and quality of care provided; the appropriateness of admissions and discharges; and the care given in so-called day and cost outlier cases.

Structurally, much about the earlier PSRO program was revamped. The ability of PROs to act against overuse of services and to curtail expenditures was strengthened. Administrative and financing arrangements were changed so that the program could, at least in theory, be better managed at the federal level. Still, many of the difficulties facing the PSRO program remained.

Congress modified and added to the responsibilities of PROs nearly every year since first enacting the program. Apart from extensive expectations for reviewing the use, costs, and quality of inpatient hospital care, for instance, Congress has called for review of care provided in risk-contract health maintenance organizations (HMOs), post-acute care provided by nursing homes and home health agencies, and physician office-based care. (Only the HMO review is at all extensive, and fee-for-service physician outpatient care has not yet been implemented except through very recent pilot projects.) PROs also have considerable professional and community outreach responsibilities. The complex review and intervention tasks expected of PROs are specified in great detail in the "scopes of work" of their contracts, and PRO performance is evaluated on the basis of how well they meet these specifications (not on their impact on costs or, especially, on quality of care).

Contemporary Critiques of the PRO Program

On the basis of other, partial evaluations of the PRO program and its own activities, the IOM committee drew several conclusions about the current PRO program. Among the more telling were the following:

- Congress has invested the PRO program with responsibility for the quality of care of an appropriate range of health services, but definitional, operational, and strategic problems remain. The IOM report stressed the importance of defining quality of care as a means of directing the efforts of a quality assurance program, with particular emphasis on health outcomes quite broadly defined. The present PRO program has no guiding definition of quality, and it is not in a good position to concentrate on health outcomes important to patients or to focus on populations (apart from the small HMO enrollee population).

- The program is not as well focused on quality review and quality assurance as might be desired or expected, in contrast to continuing emphasis on direct cost and utilization control and PPS matters.

- The program is excessively oriented to inpatient hospital care. It is ill-equipped to deal with issues of continuity or episodes of care through time or across different settings of care.

- The program has little or no open or public mechanism for program planning, oversight, evaluation, and accountability. PROs individually and the program more generally do a poor job of documenting their impact on quality of care, and they are not in a good position to defend their program planning, decisionmaking, or past record. Better evaluation criteria and procedures are needed, with quality of care a significant part of the scope of work on which PROs are assessed.

- The PRO program is almost entirely oriented toward finding poor care and trying either to change the behavior and performance of a small fraction of providers or to sanction very poor providers (i.e., remove them from the Medicare program). It cannot easily recognize good (or excellent) performance or reward providers and practitioners when they render high quality care and mount successful quality assurance programs. Indeed, it cannot even say much about average care or about how to improve everyday practice.

- Certain legal aspects of sanctioning (for both PROs and the DHHS Office of Inspector General, to which PROs forward recommendations for sanctions) remain fuzzy, and the options open to the PROs and the OIG are narrow. The PRO program's sanctioning process has not been a successful remedy for severe problems in quality. This is true despite the considerable antagonism directed at the PROs because of their perceived adversarial and punitive attitude toward providers.

- Regulations presently forbid or constrain innovation (such as alternative approaches to in-hospital chart review). Difficulties with data sharing and data release continue.

- The present approach to "peer review" may not give PROs state-of-the-art professional knowledge or the highest levels of specialist expertise. Despite two decades of staunch leadership from those in the medical community committed to quality assurance and peer review, many physicians remain suspicious of and hostile to PRO activities, continuing to perceive it at one and the same time as intrusive, arbitrary, and punitive -- and fundamentally irrelevant to improving quality of care.

- The level of funding for the PRO program is no greater, proportionally, than it was for the PSRO program nearly a decade ago, yet the peer review program assignments have been appreciably expanded (not entirely for quality-of-care concerns, however). The IOM committee viewed this overall investment in a program intended to monitor and improve the quality of care for the elderly as likely to be too low ever to accomplish the expected tasks adequately. Funding individual PROs through extraordinarily detailed contracts and contract modifications was seen as too limiting; it seems to foster evaluations of contract performance rather than impact on quality of care and to constrain innovation and flexibility to meet local conditions and problems.

Despite the foregoing comments, the IOM committee judged the program to be sufficiently well-established that it should be improved and built on, not dismantled, in part because of the financial and psychological costs inherent in taking apart an existing program and creating a new one. Moreover, the existing program has procedures and organizational relationships that should be brought to bear on any future Medicare quality assurance program. The cadre of committed and experienced professionals, including physicians, nurse reviewers, and administrators, is a particularly valuable asset. (Much of this experience and manpower dates to PSRO and earlier peer review efforts.) In addition, PROs can operate on the basis of better Medicare data sets than were available during PSRO days, and they have a considerable advantage in computer technology compared to the earlier program.

THE IOM REPORT

RECOMMENDATIONS

The IOM committee asserted, first, that a strategy for quality assurance must be guided by a definition of quality and an understanding of the burden of harm attributed to poor quality care. It defined quality of care as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." This definition emphasizes:

- health services, not just patient services or medical care;
- the care of populations, not just single episodes of care of patients;
- outcomes desired by patients, thus accentuating the role of informed patients in sharing in decisionmaking about their care; and
- professional competence and continuous professional growth for physicians and other clinical providers.

Moreover, the committee contended that assessing quality of care requires understanding at least three dimensions of quality: poor technical or interpersonal performance, overuse of unnecessary and inappropriate health

services, and underuse of needed and appropriate services. Current systems of quality assessment cannot provide reliable national estimates of the burden of poor quality attributable to any of these three problems, and for this reason they cannot answer congressional concerns about the effect of PPS or other financial or regulatory initiatives. For instance, understanding the quality implications of underuse of services that might result from closing of hospitals or restrictions on coverage calls for measuring the health of the elderly population, but current quality assurance activities under Medicare could not provide such information.

The committee's proposed program for quality review and assurance aimed to shift the emphasis from current PRO directions or tasks to ones that more fully reflected its vision of a quality assurance program, in six different ways. First, the PRO program is inclined toward reaction, external inspection, and regulation; the future Medicare quality assurance program would be more proactive in data collection and feedback and would vigorously foster professionalism and internal quality improvement. Second, the present system heavily emphasizes providers and the process of care; the future program would give more attention to patient and consumer concerns and decisionmaking and would adopt an aggressive outcomes orientation. Third, PROs rely heavily on monitoring information and on data collected for other purposes (such as billing) and do little constructive feedback to providers; the IOM program would generate new knowledge from clinical practice and return that information to providers in a timely way that improves clinical decisionmaking.

Fourth, although any quality assurance program must be concerned with individual providers and specific incidents of care, as is presently the case, the future program would place stronger emphasis on systems of care, on joint production of services by many different providers, and on continuity and episodes of care. Fifth, the Medicare peer review programs have traditionally focused on hospital inpatient care and have been able to do little or nothing with ambulatory, office-based care or care in other nonhospital settings; the program for the 1990s would make quality assurance in all major settings in which the elderly receive care a high priority. Sixth, a major deficiency of the present program is lack of evaluation and public oversight and a consequent inability for people to know what the nation is getting for the Medicare resources presently devoted to the peer review program or which parts of that program are successful (or not); the committee thus placed considerable emphasis on public accountability for its proposed program.

In line with these points, the committee made ten major recommendations, which are more thoroughly presented in the attached executive summary. Briefly, two recommendations proposed expanding the mission of the Medicare program to be responsible and accountable for quality of care -- i.e., the health -- of the elderly. Special note should be given to the IOM's definition of quality of care and its call to broader the Medicare mission to embrace that definition. Such an expanded mission would aim:

- to improve the quality of health care for Medicare enrollees,
- to strengthen the ability of health care organizations and practitioners to assess and improve their own performance, and
- to identify and overcome system and policy barriers to achieving good quality of care.

The corollary to this -- a comprehensive system of quality assurance for Medicare -- would include tools to help providers improve the health of the elderly and to help them monitor their own performance in behalf of Medicare beneficiaries. Therefore, a new program, like the one described in the IOM report to Congress, must concentrate on improving communication between doctors and patients and on broadening its concerns for the health and well-being of the elderly. Over the longer term, it might also be a prototype for quality assurance systems that could serve other parts of society as well.

Thus, in a third recommendation the IOM panel called for rebuilding and restructuring the current PRO program into a Medicare Program to Assure Quality (MPAQ), with a redefinition of its functions to emphasize outcomes of care and feedback of clinically relevant information to health care providers. The MPAQ would use organizations like the PROs (renamed Medical Quality Review

Organizations, or MQROs) as the basis for more systematic data collection, analysis, and feedback to providers and practitioners. In the committee's words, "the MPAQ would be explicitly oriented to quality of care, not to utilization or cost control," and it called for a 10-year implementation period that would include testing methods of quality assurance and time for building professional capacity to apply the new tools that are being developed. Two related recommendations dealt with transition to the MPAQ.

The MPAQ would plan and administer the quality assurance effort for Medicare. It would have three major responsibilities: (1) long- and short-term program planning for MQROs (e.g., to define the program guidelines for the MQROs, to review applications and make awards to MQROs, and to provide or arrange for technical assistance to MQROs); (2) monitor and evaluate MQRO operations and performance; and (3) aggregate, analyze, and report data on use of services, processes of care, and health status and outcomes of care to a far greater extent than is now done.

MQROs would have several primary responsibilities: (1) obtain information on patient and population-based outcomes and practitioner and provider processes of care; (2) analyze these data, making appropriate adjustments for case mix, patient characteristics, and other pertinent information by various types of providers; (3) use these data to make judgments about practitioner or provider performance; (4) feed such information back to the internal quality assurance programs of practitioners and providers (as well as report it to the MPAQ); and (5) carry out quality interventions and give technical assistance to internal, organization-based quality assurance programs.

Three additional recommendations from the IOM committee concerned reliable public oversight, full accountability, and rigorous evaluation of the impact of the new program. This aspect of the study included oversight of the new program partly through new advisory bodies, including a congressional oversight commission ("QualPAC") comparable to ProPAC or PPRC and an executive branch National Council comparable to the earlier PSRO Council.

Finally, two other recommendations focused on the needs for research in areas of clinical evaluation, such as quality of care, outcomes, and effectiveness, and on expanded capacity building and training for health professionals in the concepts and skills of quality assurance and research. The committee underscored the great importance of investing in the people, systems, and research needed to pursue the broad quality agenda set forth in its report.

REACTIONS TO THE REPORT

A useful debate about the mission of the Medicare program and its quality assurance effort is now under way. Policymakers and legislators are confronted with many difficult issues about how to maintain and improve the quality of health care for the elderly through a reformulated program that emphasizes outcomes and effectiveness of care, minimizes external inspection and regulation, encourages organization-based, professional quality assurance, and is accountable to the public. The IOM committee's findings and recommendations are widely regarded as a significant contribution to that debate, although no consensus on the proposed directions of the program has emerged in the short time since the report has been issued. The hearings of the Senate Finance Committee will be a constructive step toward better understanding and accord on appropriate directions in which to head.

SPECIAL REPORT

A STRATEGY FOR QUALITY ASSURANCE IN MEDICARE

THE Institute of Medicine of the National Academy of Sciences has just released a report on quality assurance for the Medicare program.[1] The legislation authorizing the study called for an ambitious and far-reaching strategic plan for assessing and ensuring the quality of medical care for elderly people during the next decade. The deliberations and fact finding of the study's 17-member committee included the review of commissioned and staff-produced papers, public hearings, panels, site visits, focus groups, and many meetings.

The resulting report indicates that although the current quality of medical care for Medicare enrollees is not bad, it could be improved; that the current system to assess and ensure quality is in general not very effective and may have serious unintended consequences; and that exciting opportunities are now emerging to set in place a comprehensive system of quality assurance that can address itself to improving the health of elderly people.

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MAJOR FINDINGS AND CONCLUSIONS OF THE STUDY

What does it mean to say that one will ensure the quality of care? Believing that any quality-assurance program for Medicare should be guided, first of all, by a clear definition of quality of care, the study committee defined quality of care as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." This definition is similar to those offered by groups as diverse as the Joint Commission on Accreditation of Healthcare Organizations[2] and the congressional Office of Technology Assessment.[3] However, it refers broadly to health services, not just to patient or medical care, and it focuses on both individual patients and larger groups comprising those who seek and use health services and those who do not. A critical aspect of the definition is its emphasis on outcomes of care that are desired by patients, with a crucial assumption that patients will be informed and will share appropriately with their physicians in decision making about their care. Finally, with its emphasis on health services that are consistent with current professional knowledge, this definition highlights traditional notions of continuous professional growth and evaluation for physicians and other clinical practitioners.

What important factors about elderly people should a quality-assurance program take into account? It is not news, of course, that the population of elderly people in this nation is growing (both in absolute numbers and as a proportion of the entire population) and graying (as the average number of years lived after the age of 65 rises). An increasing number of elderly people live with chronic illness and disabling conditions. All these factors suggest that demands for well-coordinated, highly technical, and compassionate supportive care will increase in the next decade. What is not clear is whether the nation and the professional communities will be able to provide it.

Near-universal coverage by the Medicare program gives elderly people better access to health care than any other age group. Nevertheless, gaps in coverage and financial barriers do exist and affect quality adversely, as many of those giving testimony to the com-

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mittee attested. Furthermore, health care costs continue to rise independently of increasing demand or the per capita use of services.[4,5] With the spiraling expenditures come ever-stronger pressures for cost containment and calls for the rationing of health care,[6] perhaps on the basis of age.[7] The reform of physician-payment mechanisms[8] may presage considerable shifts in the types of care available to elderly people, even as the use of inpatient hospital care remains at lower levels than a decade ago and as the use of other sites of care, such as outpatient and long-term care facilities and home settings, continues to expand. These financial and organizational factors, whose directions over the coming decade are not entirely predictable, pose threats to the quality of health care. In our judgment, a successful quality-assurance program for Medicare will have to be able to respond flexibly to them.

What are the problems a quality-assurance program should address? Poor quality of care can be categorized in terms of the overuse of health services, the underuse of services, and poor technical or interpersonal performance. Evidence of overuse, especially of procedures and certain types of medications, such as psychotropic drugs, is substantial. For example, in a review of almost 5000 hospital records of Medicare patients, 17 percent of coronary-angiography procedures and 32 percent of carotid endarterectomies were judged to be inappropriate, and an additional 9 and 32 percent, respectively, were judged to have been performed for indications that were equivocal.[9] Many physicians with whom the Institute of Medicine committee spoke recognized overuse as a prevalent problem.

Underuse is harder to detect under existing surveillance systems but is widely believed to be considerable, especially for certain groups of elderly people (for instance, those who are poor or whose access to care is poor because of geography) and for certain poorly covered services, especially long-term care. Background papers for the Institute of Medicine study[1] reported the substantial underdiagnosis of conditions such as treatable incontinence, curable infections, gait disorders, metabolic disorders, and psychiatric problems, especially depression. Examples of underuse included the underprovision of rehabilitation services and of home care nursing services.

Many diverse examples of poor performance have been documented and were mentioned to the study committee and staff during extensive site visits. For instance, one study of hospital mortality found that 14 percent of deaths were probably or definitely preventable, and explanations included errors in diagnosis and management.[10] Antibiotics were also widely misused according to one community-hospital study, in which only 72 percent of therapeutic uses and 36 percent of prophylactic uses were found to be appropriate.[11]

We cannot say that any one of these three aspects of poor quality of care is most important. Different problems are evidently more or less important according to the setting in which care is rendered and whether reimbursement is through a fee-for-service system or a prepaid system of capitation. Again, quality-assurance programs must be able to detect and respond appropriately to very different types of problems, in many different settings of care, and for various types of practitioners.

Various pieces of evidence suggest that a small number of outlier (very poor or aberrant) practitioners and providers account for a large proportion of the very serious problems in quality; they occupy what can be called the tail of the quality distribution. For example, at a public hearing a representative of the Medicare peer-review organization (PRO) in California estimated that perhaps 6 to 8 percent of the state's 50,000 physicians had serious, recurring problems in quality. The medical director of a PRO in another state reported that about 5 percent of the practicing physicians in that state accounted for 95 percent of the identified problems in quality. More than a decade ago, the California Medical Insurance Feasibility Study reported an "injury rate" of 4.65 per 100 hospitalizations, of which 17 percent were due to negligence.[12]

Average, everyday practice — the large central portion of that quality distribution — is not, however, immune from deficiencies in quality. A successful quality-assurance program cannot focus on only one part of this distribution. It must be able to detect and correct, if not prevent, problems in quality among outliers at the same time as it seeks to improve average practice — a task some refer to as shifting the curve upward to better performance. External regulatory mechanisms may be needed to address the outlier problems, educational efforts based on better data about peer practices and patient outcomes may be preferable in shifting the curve. The Medicare quality-assurance program must be able to support both regulatory and educational efforts.

Instances of truly superior care make up the other tail of the quality distribution. In the rush to attend to deficiencies, quality-assurance programs often ignore the exemplary practitioners and institutions, thereby losing an important opportunity to highlight and reward outstanding models of high-quality care.

What is Medicare doing now to ensure the quality of care for elderly people, and how successful are those activities? The PRO program is Medicare's existing effort to address many potential or real problems in the care of elderly people. Congress created the program in 1982, essentially as a replacement for the professional standards review organizations (PSROs).[13] The PROs have had major responsibilities for monitoring the implementation of the Medicare prospective-payment system since its inception in 1983, and Congress has added many other assignments to the PRO agenda in the intervening years.

The statewide PROs, which are overwhelmingly nonprofit, physician-based organizations, constitute a

potentially valuable infrastructure for quality assurance. Many have an institutional history dating to the PSRO program and earlier. They have a committed and experienced cadre of physicians, nurses, administrators, and technicians with considerable understanding of the tasks that need to be accomplished in quality assurance. They are also gaining an experience in the use of computers and data analysis that did not exist a decade ago.

The present configuration of the PRO program, however, has several limitations, evidenced in published reports and in many comments heard by committee members during public testimony and site visits. An important drawback is that the PROs still appear to give primary attention to control of utilization and to aspects of the implementation of prospective payment rather than to quality of care. Whether this is true is a matter of debate, but the belief that it is continues to prejudice the acceptance of PROs by physicians and hospitals. Many commentators perceive the PROs to be adversarial and punitive and to impose excessive burdens on providers. Others believe that despite their intrusive and regulatory characteristics the PROs have little real influence on quality of care.

The focus of the PROs is on individual events and, often, outliers rather than on episodes of care or average practice, and their attention remains mostly on hospital care. Although the PROs require many programs of corrective action for physicians and hospitals with poor records, the sanctioning process for more serious problems seems to be largely ineffective. The PROs are constrained (sometimes in counterproductive ways) by regulatory and legal systems, and they have no ability to spotlight exemplary performance.

Debate over the sanctioning process has been acrimonious. Among the issues are whether PROs have to demonstrate that physicians are "unwilling and unable" to correct unacceptable practices, the wording and timing of so-called "quality denials" for substandard care and the notification of patients about such denials, and the use of monetary penalties instead of exclusions from the Medicare program. Some of these issues (such as matters concerning the quality denials) appear to have been settled by the recent Omnibus Budget Reconciliation Act of 1989, but others linger as irritants to both practicing providers and the PROs.

It was the committee's strong impression that interventions attempted by the PROs to remedy severe problems in quality were for the most part unsuccessful. Although the PROs institute many thousands of lesser interventions — such as notifying physicians or hospitals of possible problems or requiring various forms of continuing medical education or mandatory consultation with specialists — they have recommended relatively few full-sanction proceedings. The Health Care Financing Administration reports having forwarded little more than 100 recommendations for sanctions to the Office of Inspector General in recent years, more telling is that by one count only 8 of 18 sanction cases that reached the level of an administrative-law judge were upheld in favor of the Medicare PRO program.

Some observers criticize the low level of public oversight and accountability of the PRO program. The program does not appear to follow recommended procedures of public administration (e.g., certain formal procedures for rule making) as much as some experts think desirable,[15] and there is little opportunity for patient or provider groups to have a useful and systematic role in program planning. The highly detailed contract specifications through which the program supports the statewide PROs seem to render them relatively inflexible and unable to address local or changing problems in quality, and individual PROs are evaluated on the basis of how well they meet rigid contract requirements, not how well they improve the quality of care. Finally, no one can say what effect the PROs have had on the quality of care in the nation as a whole because the program (unlike the PSRO program) has not been formally evaluated in that or any other area.

What concepts and practical tools might best serve a quality-assurance effort for Medicare? The complex factors outlined above imply that no single approach or conceptual framework is likely to suit all purposes. The classic model of structure, process, and outcome expounded by Donabedian has guided quality-assurance efforts for almost a quarter-century.[16,17] It is a robust basis for the Medicare quality-assurance effort, but it has often been applied in ways that make quality assurance seem reactive, punitive, and excessively regulatory. For better than a decade, proponents of process-of-care measurement and advocates of outcomes measurement have engaged in a rather unproductive debate about the merits of their approaches. The consensus appears to be that successful quality assurance will always have to concern itself with both the processes of care and patient outcomes.

Newer models of continuous quality improvement emphasize internal, organization-based, professionally led efforts to improve many small processes of care in a ceaseless cycle of examination and change.[18,19] These approaches emphasize ongoing, prospective self-examination and professionalism, often focus on problems in systems of health care delivery rather than the problems of individual patients, and target average, everyday performance much more than the identification of outliers. Little experience is yet available, however, to indicate whether this will be a viable approach to tackling clinical quality-of-care problems. Nevertheless, different approaches to quality assurance may be necessary for different sites of care (e.g., the hospital, the home, or ambulatory care settings) and for different organizational structures, such as health maintenance organizations and fee-for-service practices. The continuous-improvement models deserve careful testing and experimentation.

What methods exist to detect problems in quality of care? Problems in quality can be detected through many

mechanisms. For instance, large administrative or insurance-claims data bases may be used to create indicators of potentially poor outcomes (or sentinel events) and the provision of inappropriate services; small-area-variation analysis to determine differences in the use of services per person is another approach that uses such large data bases. At an institutional level, hospitals or large group practices may adopt systems that track indicators such as patterns of nosocomial infections or unusual occurrences according to physician, unit, shift, or service. In addition, physician and nurse reviewers can examine medical records retrospectively, against either explicit written criteria or implicit professional norms, to judge the quality of the process of care. Cases of problems in quality can also be uncovered by applying generic quality screens to patient records.

The criteria according to which quality of care can be judged or improved belong to at least three different classes. One type of criteria comprises guidelines for clinical practice, which are now a major focus of concern in the public and private sectors and among physicians.[5] A second type of criteria includes those that lay out ways to manage patient problems or to evaluate care that has been given for specific patient problems. These criteria can be fairly simple descriptions of good (or not so good) clinical care, or they can be very elaborate criteria maps and decision trees that attempt to cover many possible clinical factors.[6,7] A third type involves criteria used to find cases that appear to warrant further professional review. These different types of quality-of-care criteria have very different characteristics, and the study proposes some properties they should have if they are to be used as guidelines or yardsticks for acceptable quality of care.

What methods exist to remedy problems in quality once they are detected? Approaches to correcting problems in quality can emphasize a considerable array of professional and educational activities, regulatory mechanisms (financial penalties or program exclusions, for instance) such as those employed by the Medicare PRO program, and indirect methods based on beliefs about competition and the forces of health care markets. No quality-assurance program can be successful without a mix of approaches, yet most programs to date lack a full spectrum of proven techniques for correcting identified problems in quality.

What broad problems challenge the nation's ability to make progress in quality of care? The present structure of our health care system does not have the capacity to achieve a comprehensive and maximally effective quality-assurance program, either for Medicare or for the nation more generally. Research is needed in several areas: basic methods of quality review and assurance, the application of techniques of quality assurance and continuous quality improvement, and the dissemination of information necessary for improving the performance of health care professionals. It will also be necessary to train professionals in research skills and in techniques of quality assurance and continuous improvement. In addition, patients and their families must be enabled to share more fully in decision making about their own health care.

Major Recommendations of the Study Committee

The committee recommended a number of steps for a strategy of quality review and assurance for Medicare. One called on Congress to expand the mission of Medicare to include an explicit responsibility for ensuring the quality of care of Medicare enrollees. Thus, any new Medicare quality-assurance program must give more attention to the processes of patient–practitioner interaction and decision making, to broad health and quality-of-life outcomes, and to patient satisfaction and well-being. Three goals for a Medicare quality-assurance program were stated: continuously improving the quality of health care for Medicare enrollees, strengthening the ability of health care organizations and practitioners to assess and improve their own performance, and identifying and overcoming systemic and policy barriers to good quality of care.

The committee's central recommendation was that Congress restructure the existing PRO program, redefine its functions, and implement a new program — the Medicare Program to Assure Quality, or MPAQ. Regardless of the criticisms that can be raised about the PROs, the committee generally believed that an abrupt end to or shift away from the complex existing program, with its historical ties to earlier Medicare peer-review efforts, was neither desirable nor feasible; the MPAQ would therefore build on the present structures. It would, for instance, continue to use local (but not necessarily statewide) organizations like the PROs (now to be called Medicare Quality Review Organizations) for more systematic data collection, analysis, and feedback to providers and practitioners.

More important, the MPAQ would be explicitly oriented to quality of care, not to utilization or cost control. It would be charged to facilitate programs of quality improvement within provider organizations and physician practices through the dissemination of useful data, technical assistance, and other actions. It would also attempt to make the Medicare Conditions of Participation for hospitals more consistent with and supportive of the overall federal quality-assurance effort.

The aim is a system of quality assurance that focuses on health care decision making and the health outcomes of Medicare beneficiaries, that enhances professional responsibility and capacity for improving care, that uses clinical practice as a source of information to improve quality, and that can be shown to improve the health of elderly people by attending to problems of overuse and underuse of services as well as poor technical quality. A more basic goal is to have a fully functioning program in place by the year 2000 (with many of its parts operating successfully well before then) that can respond flexibly to changing health care needs, health care delivery and financing mechanisms, and social realities. The committee's report describes in some detail potential approaches the

MPAQ and its Medicare Quality Review Organizations may take, but it calls for implementation of the new program over a 10-year period, during which appropriate methods can be tested for all major settings and systems in which elderly patients receive care.

To address the concern about lack of public accountability and oversight, the committee advised that Congress establish two new advisory groups. The first is a quality-program advisory commission similar to the congressional commissions for Medicare prospective payment for hospitals and physician payment; it would oversee the activities of the MPAQ and report to Congress on them. The second, a national council on Medicare quality assurance, would advise the Department of Health and Human Services and would assist in the implementation, operation, and evaluation of the MPAQ. The committee also recommended that Congress authorize and appropriate the funds needed to implement its other recommendations — an amount roughly estimated to be twice the present investment in the PRO program. Then, to make the program more answerable to the public for the expenditure of public monies, the committee called for a periodic (e.g., every two years) report to Congress from the Secretary of the Department of Health and Human Services on the quality of care for Medicare beneficiaries and on the effectiveness of the MPAQ in meeting the program goals.

Issues for the Future

Many issues about quality of care and quality assurance remain to be considered. For instance, how good is the United States at delivering health care to its citizens and ensuring the quality of that care? Many in policy-making and professional circles severely criticize this nation's health care system and point to other countries, often Canada, as models for reform. These points are likely to be debated for some time, and they may accurately reflect the reality that we provide adequate health care for some but by no means all of our citizens. The criticism of quality assurance is not valid, however, because the United States (and its medical community) is the world leader. Although other countries have quality-assurance mechanisms in place, often imported from the United States, none approach the degree of sophistication or the acceptance and leadership by physicians that is apparent here.

The ambiguity of the relation of quality of care to access, costs, and use of services persists, and the appropriate relation between the review and management of utilization (on the one hand) and quality review and assurance (on the other) remains clouded. It is very difficult to distinguish between utilization review and management as mainly cost-cutting measures and as useful tools for quality assurance (for instance, if procedures requiring previous authorization curtail manifestly unnecessary surgery), and it is therefore difficult to determine what sorts of agencies should carry them out. We share the concern that assigning a quality-assurance program responsibility for controlling use and costs will undermine goals of quality of care, and we reiterate the committee's strong preference for making the major goals of the MPAQ those of quality assurance and improvement.

Assuming that the criticism of the PRO program has substance and that its difficulties are real, what is the threat to the success of the MPAQ in bottling new wine in old wineskins? In other words, is it sensible to start a new program with agents who are viewed today with a mixture of hostility and disdain, and is the committee's decision to emphasize transition rather than starting over a mistake? The MPAQ will be a far-reaching and complex program, and successful implementation will require every possible advantage. Our reading of the practical and political climate is that building on the history and strengths of the peer-review community, of which the PROs are the most visible manifestation, is a far more attractive proposition than trying to invent new entities to carry out the MPAQ mandate.

How can society know it is getting value for its investment in quality of care? In general, this country does not subject major social programs to much public oversight and accountability or systematic, quantitative evaluation. Should this public program be accountable to the public and be required to justify itself by demonstrating an effect on things as difficult to pin down as health outcomes and quality? We believe the answer to that question is yes; public oversight and accountability and rigorous evaluation are critical aspects of this effort.

What are the critical problems in quality the MPAQ should address? Despite considerable effort, the Institute of Medicine study was not able to say that particular problems, such as the overuse of procedures or hospital inpatient care, were more or less important than the underuse of, say, home health care, or that they were more or less important than, for example, poor diagnostic or therapeutic decision making on the part of office-based physicians. It seems clear that problems of all three sorts can be found, with differing degrees of frequency and severity, in all settings of care. This means that the nation must develop a better epidemiology of quality of care to guide the allocation of resources in quality assurance. The MPAQ is intended to capture information about clinical practice that can be used to develop this picture more fully, but efforts beyond Medicare and elderly people will be needed.

The growing enthusiasm for the models of continuous quality improvement should be of special interest and appeal to the community of practitioners. Their emphasis on self-examination and self-correction is in accord with traditional views about the learned professions, and their focus on systems of care made up of many small processes reflects a practitioner's daily activities more than do patient outcomes, which may be remote in time and place. Nevertheless, information about successful applications is scant; these approaches have yet to be shown capable of coping ade-

quately with problems of the overuse of services, underuse of services, or poor technical or interpersonal skills. Moreover, the continuous-improvement programs are difficult and time-consuming to implement. They are very much oriented to complex organizations such as hospitals and prepaid group practices, and they do not lend themselves to quality assurance in the office of the average private practitioner.

What is the proper role of outcomes in measuring and improving quality of care? Little empirical research, let alone practical experience, gives confidence that patient outcomes can be the primary basis of a quality-assurance or continuous-improvement effort. Yet outcomes and outcomes management became the watchwords of the 1980s,[23,24] and they are likely to remain a dominant refrain in the 1990s. In short, outcomes are not a completely proved approach to quality assessment and assurance, but as the committee's definition of quality makes clear, they cannot and must not be ignored. We concur with the committee's effort to temper unbridled enthusiasm for outcomes with the practical appreciation that, for many aspects of monitoring and improving health care, the process of care is the key.

Regardless of the weight accorded processes or outcomes in quality assurance, it will be important to understand and acknowledge that patients differ in their preferences for types of health care and for the results they may reasonably expect from that care. The landmark work of Wennberg and his colleagues comparing surgery with watchful waiting in men with benign prostatic hypertrophy[25,26] is only the opening chapter, and many questions remain. How should physicians elicit patient preferences and take account of them in health care decision making? When the values and preferences of individual patients conflict with broader social values and preferences, which take precedence, and what is the role of the physician in this regard? Physicians face difficult choices in balancing their traditional obligations of beneficence (the duty to do good) and nonmaleficence (the duty to do no harm) with the more recently espoused rights of patient autonomy (the duty to respect the rights of patients to independent self-determination) and concerns about equity and distributive justice (the combined duty not to discriminate among people or groups on the basis of irrelevant characteristics and to distribute resources fairly, not capriciously or arbitrarily). We hope that these issues can be more fully addressed during the implementation of the MPAQ.

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EXECUTIVE SUMMARY

MEDICARE

A Strategy for Quality Assurance

Volume I

Committee to Design a Strategy for
Quality Review and Assurance in Medicare
Division of Health Care Services
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Volume I of this report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

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Committee to Design a Strategy for Quality Review and Assurance in Medicare

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Contents

The contents of the second volume of this report are listed below.

Preface

Medical care in the United States presents a paradox. At its best, U.S. medicine is a marvel, featuring state-of-the-art diagnostic and surgical technology augmented by sophisticated pharmaceutical agents. Most citizens report that they are happy with their medical care. Yet, at the same time our health care system merits serious criticism: it is by far the most expensive in the world, consuming almost 12 percent of the nation's gross national product; its health status, as measured by such standard indices as life expectancy from birth or infant mortality rates, lags that of most developed countries; its organization and distribution of health care resources are unbalanced, with a serious skew toward technology-intensive services, sometimes at the expense of primary care, preventive services (especially for the poor), home care, and long term care; and more than 30 million persons lack any form of health insurance, thereby posing severe problems of access and equity.

By contrast, the elderly enjoy comprehensive coverage and usually excellent access to hospital and acute care facilities under the Medicare program. Coverage for ambulatory care is also good, although benefits for home and long term care are limited. By international standards, the U.S. elderly enjoy excellent health status. As judged by life expectancy from age 65, and especially from age 75, the U.S. ranks among the countries with the best longevity in the world.

Driven largely by concerns about relentlessly rising expenditures for medical care, many health policy analysts now believe that explicit rationing of health services is the appropriate strategy for medical cost containment. The prospect of rationing, however, must be viewed in the context that, for the elderly in the United States, utilization of services such as coronary artery bypass surgery, prosthetic replacements of diseased hips,

and treatments for end-stage renal disease already greatly exceed levels occurring in any other country.

As a result of these conflicting trends and forces, the current health care system in the United States presents a confusing picture:

- Despite the comparatively high use of medical services, there are strong pressures to increase access and use of virtually every type of health care, including organ system transplants, treatment for AIDS, and long term care.
- At the same time, employers, employees, federal and state government, and the elderly are increasingly vocal in their opposition to paying more for medical care for themselves and others.
- Governmental and industrial efforts at medical cost containment have been persistent, incremental, and largely ineffective in their overall effect on the costs of medical care. Previous and current efforts include incentives for health maintenance organizations, hospital prospective payment, utilization review, limitations on benefits and eligibility, imposition of copayments and deductibles, mandated local entities to ensure planning of new facilities and technologies, and limits on medical malpractice awards. These cost containment strategies have had, at best, marginal effects on the ever-increasing costs of medical care, and essentially no impact of the quality of care. It is not unreasonable to expect that the current "hot prospects" for medical cost containment, such as physician payment reform and the promulgation of practice guidelines, will be equally ineffective.
- An unintended but increasingly intrusive result of the cumulative efforts at medical cost containment has been the establishment of an administrative bureaucracy to review medical care delivered in all sites—hospital, office, home, and nursing home. Although it is unclear that the procedures that have resulted from this effort have reduced the cost of medical care, it is clear that they have introduced a layer of complexity for patients and providers and have contributed to a mounting sense of frustration among physicians.
- The advent of sophisticated data collection and analytic techniques, made possible by computer technology, offers the opportunity to measure and compare the outcomes of medical care for certain conditions across comparable settings. In addition, newer ways of conceptualizing the approach to quality measurement and improvement provide the stimulus to reassess our goals and efforts.

Emerging from this tangle has come an increasing concern about the quality of medical care, particularly focused on the question of whether cost containment efforts (both successful and unsuccessful) will harm quality. To address that question it is necessary to define quality of medical care, to measure it, to assess its current state, and to understand how it can be

improved and how it might be jeopardized. From concerns and questions such as these comes this report. Requested by the Congress, the authorizing legislation called for an ambitious and far-reaching strategic plan for assessing and assuring the quality of medical care for the elderly during the next decade. Emboldened by the scope of this charge, the Institute of Medicine study took a broad and comprehensive view. Its deliberations and fact-finding included commissioned papers, public hearings, panel meetings, site visits, focus groups, and many meetings.

The resulting report indicates that although the current quality of medical care for Medicare enrollees is not bad, it could be improved; that the current system in place to assess and assure quality is in general not very effective and may have serious unintended consequences; and that exciting opportunities—still to be tested in the field—are now emerging to set in place a comprehensive system of quality assurance that can address itself to improving the health of the elderly population.

STEVEN A. SCHROEDER
Chairman, Committee to Design a Strategy
for Quality Review and Assurance in Medicare

Introduction to the Study and This Report

CONGRESSIONAL CHARGE

The commission from the Congress of the United States to "design a strategy for quality review and assurance in Medicare" was contained in Section 9313 of the Omnibus Budget Reconciliation Act of 1986 (OBRA 1986). It called for the Secretary of the U.S. Department of Health and Human Services (DHHS) to solicit a proposal from the National Academy of Sciences (NAS) to conduct the study that would address eight legislative charges, namely "among other items," to:

(A) identify the appropriate considerations which should be used in defining "quality of care";
(B) evaluate the relative roles of structure, process, and outcome standards in assuring quality of care;
(C) develop prototype criteria and standards for defining and measuring quality of care;
(D) evaluate the adequacy and focus of the current methods for measuring, reviewing, and assuring quality of care;
(E) evaluate the current research on methodologies for measuring quality of care, and suggest areas of research needed for further progress;
(F) evaluate the adequacy and range of methods available to correct or prevent identified problems with quality of care;
(G) review mechanisms available for promoting, coordinating, and supervising at the national level quality review and assurance activities;
(H) develop general criteria which may be used in establishing priorities in the allocation of funds and personnel in reviewing and assuring quality of care.

STUDY METHODS

Studies undertaken by the NAS and the Institute of Medicine (IOM) are conducted by expert committees. These committees comprise individuals selected for their expertise who can provide information and insights from all disciplines and social sectors that are important to the topic of the study. The 17-member IOM committee for this study included experts in medicine, nursing, home health and social services, law, economics, epidemiology and statistics, decision analysis, and quality assessment and assurance. Committee members also represented major consumer, purchaser, and business interests. The committee had a broad representation by age, sex, and geographic location.

The OBRA legislation required consultation with specific organizations and representatives of major groups with an interest in this issue. To this end, a 14-member Technical Advisory Panel (TAP) was appointed; it met twice during the study, and IOM staff maintained regular contact with TAP members.

Review of the congressional charges reveals that the scope of this study could have been extraordinarily, and possibly unmanageably, broad. The committee thus decided to constrain the breadth of the work in several ways. First, it considered quality issues only as they relate to elderly Medicare beneficiaries. Second, it focused on three major settings of care: inpatient hospital care, outpatient physician-office-based care, and home health care. Collectively, those locales and types of care provide important insights in problems of and opportunities for quality review and assurance not only in their own right but for other settings (such as ambulatory surgery) that could not be studied in depth. Third, the study included both fee-for-service and prepaid group practice but did not look in detail at different types of prepaid, capitated, or managed care arrangements.

Another decision was to emphasize long-range issues, that is, specifically to respond to the congressional call to ". . . design a strategy . . . ." The committee elected to consider the elements of a strategy that might be put in place over the decade of the 1990s; the aim was to articulate a goal for the year 2000 and the major steps that need to be taken to reach that goal. Thus, the emphasis of this study is on strategy, not immediate tactics, although some recommendations deal with nearer-term changes and activities.

The study was conducted in three phases: planning (summer 1987 through January 1988); data collection and report preparation (February 1988 through February 1990), and dissemination (through May 1990). The work was financed by two grants from the Health Care Financing Administration (HCFA), one for the planning phase and one for the remainder of the study. HCFA also asked that the IOM undertake a second effort, mandated in Section

9305 of OBRA 1986, to examine the capacity of standards used for hospitals to meet the Conditions of Participation for Medicare to assure the quality of hospital care. The IOM included this work in the larger effort.

The committee and IOM staff carried out several major activities during this study; they fall into the general categories of convening, gathering background information, consulting broadly with groups across the country, and acquiring or producing technical documents (some of which are in Volume II). The committee met nine times for two-to-three-day meetings. A total of 10 background papers was commissioned; in addition, several papers and reports were produced by IOM staff or consultants on various specific activities of the study.

Early in the study two sets of focus groups were conducted. Eight focus groups were carried out among elderly Medicare beneficiaries in four cities (New York City, Miami, Minneapolis, and San Francisco); an additional eight groups were done among practicing physicians in five cities (Philadelphia, Chicago, New Orleans, Los Angeles, and Albuquerque). A public hearing process was also carried out in the early months of the study. It featured two formal public hearings, one in San Francisco and the other in Washington, D.C., at which a total of 42 groups gave oral testimony before the entire committee; in addition, written testimony only was received from nearly 100 groups (of nearly 575 contacted).

The most extensive study task was a series of site visits across the country. In the major site visits (two-to-three-day trips to the states of California, Georgia, Illinois, Iowa, Minnesota, New York, Pennsylvania, Texas, Virginia, and Washington), committee and staff visited Medicare Peer Review Organizations (PROs), hospitals and hospital associations, home health agencies and aging groups, health maintenance organizations (HMOs), state departments of health, and other organizations; in addition, meetings with practicing physicians, hospital administrators, and other individuals were organized. The shorter site visits were to specific organizations (e.g., multispecialty clinics or HMOs) that appeared to offer particular insights into approaches for quality assurance. Altogether, site visitors spoke with more than 650 individuals.

To address the congressional charge of prototypical criteria and standards, a special expert panel was convened late in the study to develop recommendations concerning the criteria by which quality-of-care criteria and appropriateness or practice guidelines might be evaluated. Other consultants were used to advise on different study topics, such as legal and regulatory issues. For instance, we acquired data on staffing and costs of quality assurance programs from a survey that was being conducted at the same time by a large multihospital system. Additionally, at several of its meetings, the committee heard from a range of experts in quality assurance and related topics. Finally, committee and staff consulted with staff at

HCFA and at several federal and congressional agencies with interests in the Medicare quality assurance program.

ORGANIZATION OF THIS REPORT

This report first examines concepts of quality of care and of assessing, assuring, and improving quality of care. Chapter 1 presents the committee's definition of quality of care and examines the topic of the quality of health care as a public policy issue. Chapter 2 focuses on a conceptual framework and models for implementing quality assurance and continuous improvement programs and explores the key attributes of a quality assurance program.

The report then turns to a description of the context and environment for quality assessment and assurance in Medicare. Chapter 3 discusses aspects of the elderly population. Chapters 4, 5, and 6 examine the Medicare program and its quality assurance efforts (hospital conditions of participation in Chapter 5 and the peer review programs, particularly the PRO program, in Chapter 6).

Chapter 7 examines quality problems and the burdens of harm they pose to the elderly; these include poor technical or interpersonal performance of practitioners, overuse of services, and underuse of services. Conceptual and practical issues posed by setting and payment systems are dealt with in Chapter 8, and Chapter 9 discusses certain strengths and limitations of key quality measurement and assurance approaches. Chapter 10 deals with the special topic of desirable characteristics of quality-of-care criteria sets, practice guidelines, and case-finding tools. Chapter 11 presents the committee's views about long-range needs for research and for capacity building for quality assurance.

Finally, Chapter 12 presents the committee's quality assurance strategy for Medicare. It highlights the committee's conclusions about the current program, states the committee's recommendations about new directions for a Medicare quality assurance program, and suggests the steps and the timetable by which such a new program might be put into place. Volume II of this report contains major background documents.

We expect this report to be of interest to a wide audience. Its principal purpose is to address the strategic concerns of Congress about a viable approach to maintaining and improving the quality of care for the elderly. We believe it will be useful for those who lead the development of quality assurance programs at the local level, by documenting the wide array of tools and the rich store of quality assurance experience in the country today. The considerable research agenda called for by remaining unanswered questions about the measurement and assurance of quality should be of value for investigators in health policy, health services research, and educa-

tion. Finally, we believe it will provide guidance for policymakers responsible for designing a farsighted yet pragmatic quality assurance program for Medicare.

KATHLEEN N. LOHR
Study Director, Study to Design a Strategy for Quality Review and Assurance in Medicare

MEDICARE

A Strategy for Quality Assurance

Volume I

Summary

Good health is a highly valued attribute of life. It is also difficult to define; it means different things to different people. In general, however, Americans would cite similar goals for their health and principles for health care. The nation has long held a common concept of what constitutes desirable health services.

What is different today is a broad concern among the health professions about the quality of health care. This is coupled with rising dissatisfaction about the health care system on the part of the public and policymakers, unremitting pressures for cost containment, and uncertainty about the effect of future cost containment on quality of care.

Focusing these concerns on the elderly, the Congress of the United States, through the Omnibus Budget Reconciliation Act of 1986, called on the Secretary of the Department of Health and Human Services (DHHS) to request the National Academy of Sciences to conduct a study "to design a strategy for quality review and assurance in Medicare." The Academy's Institute of Medicine (IOM) appointed a 17-member committee to undertake the study. In response to the congressional mandate this committee report covers four main themes:

- appropriate definitions of quality of care and quality assurance;
- the range and adequacy of methods for measuring quality and for preventing, detecting, and correcting quality problems;
- needed research and building of a professional cadre; and
- a strategy for implementing a program to assure the quality of health care for Medicare beneficiaries.

The remainder of this summary first describes the methods of the study and summarizes the committee's findings and conclusions. It then gives the committee's 10 major recommendations and describes the main operational features of a Medicare Program to Assure Quality (MPAQ), as the committee denotes the new program it recommends be established. Finally, it outlines a three-phase, 10-year implementation strategy, during which time many details of the program will evolve.

FINDINGS AND CONCLUSIONS

The nation is generally perceived to have a solid, admirable base of good quality health care, and the elderly are usually satisfied with the quality of care they themselves receive. Contrasting with this positive perception of the overall quality of care in the nation is a large literature that documents areas of deficiencies in all parts of the health sector. Some of these relate to the overuse of unnecessary and inappropriate services, some to underuse of needed services, and some to poor technical skills, interpersonal care, or judgment in the delivery of appropriate services.

Significant problems exist in quality of care and in the nation's present approaches to quality assurance. These problems are sufficient to justify a major redirection for quality assurance in this country and, in particular, a more comprehensive strategy for quality assurance in Medicare.

Our major findings and conclusions include the following:

- A quality assurance program should be guided by a clear definition of quality of care.
- No single approach or conceptual framework to quality assurance is likely to suit all purposes.
- Regarding the elderly,
  —their population continues to grow, both in absolute numbers and as a proportion of the entire population,
  —the average number of years lived after age 65 continues to increase, and
  —an increasing number of the elderly live with chronic illness and disabling conditions.
- Regarding Medicare and the elderly,
  —health care costs continue to rise,
  —pressures for cost containment increase, and
  —use of sites of care other than inpatient (i.e., outpatient, long-term-care, and home) continues to expand.
- Near universal coverage of the elderly population by the Medicare program gives them better access to health care than any other age group; nevertheless, gaps in coverage and financial barriers do exist and adversely affect quality.

- Regarding the burden of poor quality,
  —evidence of overuse of health services is substantial,
  —underuse is hard to detect under existing surveillance systems, but we suspect it is considerable, and
  —numerous examples of poor performance have been documented.
- Different approaches to quality assurance may be necessary for different sites of care (e.g., hospital, home care, and ambulatory settings) and for different organizational structures such as health maintenance organizations (HMOs) and fee-for-service practices.
- Criteria by which quality of care can be reviewed or assured
  —can be classified into three main groups—appropriateness (or clinical practice) guidelines, patient management and evaluation criteria, and case-finding screens, and
  —vary considerably in internal and external validity.
- Those groups of quality-of-care criteria can be described in terms of substantive (or structural) attributes, such as scientific grounding, latitude for clinical and patient judgment, design, and efficiency and implementation (or process) attributes such as feasibility of use, ease of use, ability for special cases to be appealed, and dynamic aspects of review and updating.
- Currently available methods of quality assurance
  —suggest that a small number of outliers account for a large number of serious quality problems,
  —are inadequate in coping successfully with outlier providers,
  —tend to focus on single events and single settings,
  —may not identify underuse and overuse of services,
  —are constrained (sometimes in counterproductive ways) by regulatory and legal systems, and
  —are of questionable value in improving average provider behavior.
- Medicare Utilization and Quality Review Peer Review Organizations (PROs) constitute a potentially valuable infrastructure for quality assurance. Nevertheless, it is the perception of the committee that Medicare PROs
  —give primary attention to utilization rather than quality,
  —focus on outliers rather than the average provider,
  —concentrate on inpatient care,
  —impose excessive burdens on providers,
  —do not use positive incentives to alter performance,
  —are perceived as adversarial and punitive,
  —use a sanctioning process that is largely ineffective,
  —are rendered relatively inflexible by program funding arrangements,
  —use methods that are redundant with other public and internal quality assurance programs, and
  —have not been evaluated with respect to their effect on quality.

- Mechanisms for ensuring that hospitals meet the Medicare Conditions of Participation are generally sound in terms of the concept of "deemed status" but warrant strengthening in several aspects, especially the survey and certification procedures for hospitals that are not accredited.
- The present structure does not have the capacity to achieve a comprehensive and maximally effective quality assurance system. Required research and capacity building include basic methodological research, applications research, research on methods of diffusion, training of professionals in research and quality assurance, and methods to improve patient decision making.

A MODEL OF QUALITY ASSURANCE FOR MEDICARE

On the basis of these findings and conclusions, the committee outlined its vision of a quality assurance system for Medicare. It focuses on health care decision making and health outcomes of Medicare beneficiaries, enhances professional responsibility and capacity for improving care, uses clinical practice as a source of information to improve quality of care, and can be shown to improve the health of the elderly population. This "ideal" system stands in sharp contrast to the existing quality assurance system: the latter relies too heavily on provider-oriented process measures, regulation, and external monitoring, contributes little new clinical knowledge to improve the quality of care, and has not been evaluated in terms of impact on the health of the elderly. We believe that any future quality assurance program requires a better balance than exists today between regulation and professionalism, provider orientation and patient orientation, and processes of care and desired health outcomes.

DEFINING QUALITY OF CARE

The committee identified critical dimensions of quality of care and adopted the following definition:

> **Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.**

According to this definition, the health care services provided are expected to have a net benefit (to do more good than harm, given the known risk when compared to the next-best alternative care). That benefit is expected to reflect considerations of patient satisfaction and well-being, broad health status and quality-of-life outcomes, and the processes of patient-provider interaction and decision making. The values of both individuals

and society are explicitly to be considered. How care is provided should reflect appropriate use of the most current knowledge about scientific, clinical, technical, interpersonal, manual, cognitive, and organizational and management elements of health care.

RECOMMENDATIONS

In responding to the congressional charge to design a strategy for quality review and assurance in Medicare, the committee has three aims. The first is to have in place a fully functioning program by the year 2000. The second is to have many of its parts operating well before that time. The third is to create a system that itself can grow and mature well into the next century, when health care needs, health care delivery systems and financing mechanisms, and social realities may be vastly different from those we encounter today. In furtherance of these aims, the committee agreed on 10 recommendations, which are based on its findings and conclusions and its vision for a new quality assurance program for Medicare.

Medicare Mission and Quality Assurance

RECOMMENDATION NO. 1. Congress should expand the mission of Medicare to include an explicit responsibility for assuring the quality of care for Medicare enrollees, where quality of care is defined as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

A critical requirement of a quality assurance program is that it respond conceptually to an accepted definition of quality of care. For this report we have adopted the definition offered above, which implies a markedly stronger and broader mission statement for the Medicare quality assurance than appears in the legislation that presently guides the Medicare peer review program. A more explicit commitment to quality is needed to counter the perception that monitoring efforts in Medicare are primarily concerned with cost containment.

By focusing on health services, desired health outcomes, and levels of professional knowledge, our definition of quality calls for broad action by provider organizations and by the Medicare program in the collection, analysis, feedback, and dissemination of data and in the initiation of creative quality interventions. This definition implies a considerably expanded and richer conceptualization of the outcomes about which data will be acquired than has been evident heretofore in any (external or internal) quality assurance efforts. It also implies greater attention to the scientific knowledge base, to health care technology assessment, and to the actual processes of

everyday practice. It requires that better use be made of what is known about the effectiveness of health care services and about the links between process and outcome. Finally, by highlighting the need for attention to both individuals and populations, this definition underscores the importance of requiring the Medicare program to take responsibility for understanding the health outcomes of the populations for which they are accountable, not just for the persons actually served.

Quality Assurance Goals of the Medicare Program

RECOMMENDATION No. 2. Congress should adopt the following three goals for the quality assurance activities of the Medicare program:

- **Continuously improve the quality of health care for Medicare enrollees, where quality is as defined in our first recommendation;**
- **Strengthen the ability of health care organizations and practitioners to assess and improve their performance; and**
- **Identify system and policy barriers to achieving quality of care and generate options to overcome such barriers.**

We recommend below an ongoing evaluation of the quality assurance program and its impact. The goals for which that program should be held accountable are improved health, enhanced capabilities of providers in quality assurance, and better understanding of broad system obstacles to high quality of care. These goals are at once more explicit and more comprehensive than the status quo.

Medicare Program to Assure Quality (MPAQ)

RECOMMENDATION No. 3. Congress should restructure the PRO program, rename it the Medicare Program to Assure Quality (MPAQ), and redefine its functions.

To discharge the responsibilities implied by earlier recommendations, Medicare will need a revised and expanded quality assurance program at the federal level. To underscore this point, Congress should deliberately shift the focus and responsibility of this new program—the MPAQ—to functions more explicitly oriented to quality of care. In addition, Congress should authorize the Secretary of DHHS to support new local entities—Medicare Quality Review Organizations (MQROs)—in the performance of the MPAQ activities. To build on the personnel and skills already available, these local entities would in many instances be (or be similar to) the organizations with which the Health Care Financing Administration (HCFA) presently contracts through the PRO program. Responsibilities and functions of these organizations are discussed below.

Public Accountability and Evaluation

RECOMMENDATION No. 4. Congress should establish a Quality Program Advisory Commission (QualPAC) to oversee activities of the MPAQ and to report to Congress on these activities.

RECOMMENDATION No. 5. Congress should establish within DHHS a National Council on Medicare Quality Assurance to assist in the implementation, operation, and evaluation of the MPAQ.

RECOMMENDATION No. 6. Congress should direct the Secretary of DHHS to report to Congress, no less frequently than every two years, on the quality of care for Medicare beneficiaries and on the effectiveness of MPAQ in meeting the goals outlined in recommendation no. 2.

In addition to the MPAQ and its MQROs, we have recommended that two other entities be created to form a comprehensive structure to promote, coordinate, and supervise quality review and assurance activities at the national level. Because of the importance of these public accountability and oversight activities, we also suggest that the Secretary of DHHS establish a Technical Advisory Panel to assist in the evaluation efforts. These bodies will have four major purposes, namely to bring a greater degree of public and scientific oversight and input into the quality assurance program, provide a way for both the MPAQ and the MQROs to avail themselves of the most advanced techniques available through the private sector, provide a basis by which the program itself can be more effectively evaluated, and assist the program in management and operations.

Hospital Conditions of Participation

RECOMMENDATION No. 7. Congress should direct the Secretary of DHHS to initiate a program to make the Medicare Conditions of Participation consistent with and supportive of the overall federal quality assurance effort.

This report emphasizes the use of process-of-care information and especially patient outcomes data in evaluating quality of care. Nevertheless, all conceptual frameworks of quality assurance emphasize the importance of the *capacity* of an organization to render high quality care—essentially a structural measure. Indirectly, such capacity is measured through mechanisms such as accreditation. For the hospital sector and Medicare, this translates into "deemed status" for those facilities accredited mainly through the Joint Commission for Accreditation of Healthcare Organizations and certification through state survey and certification agencies for those not so accredited.

Our recommendation is intended to prompt HCFA to strengthen its current program for survey and certification of hospitals and for delegating certification of unaccredited hospitals to state agencies. Four aspects of this program deserve attention. First, HCFA should update the Conditions of Participation, and their related standards and elements, within the next two years and continually thereafter (no more infrequently, say, than every three years). Second, HCFA should continue to support the concept of deemed status for hospitals. The agency should encourage the Joint Commission in its efforts to develop a state-of-the-art quality assurance program and in its program to disclose information to the agency about conditionally accredited and nonaccredited hospitals in a timely fashion. Third, HCFA should increase the capacity of the survey and certification system to encourage and enforce compliance with the conditions (i.e., for those hospitals not meeting them by virtue of deemed status). Finally, HCFA should improve the coordination of federal quality assurance efforts by developing criteria and procedures for referring cases involving serious quality problems from the MQROs to the Office of Survey and Certification (and vice versa).

Research and Capacity Building

RECOMMENDATION No. 8. Congress should direct the Secretary of DHHS to support, expand, and improve research in and the knowldge base on efficacy, effectiveness, and outcomes of care and to support a systematic effort to develop clinical practice guidelines and standards of care.

RECOMMENDATION No. 9. Congress should direct the Secretary of DHHS to establish and fund educational activities designed to enhance the nation's capacity to improve quality of care.

We applaud recent developments in the attention and support that Congress and DHHS have given to effectiveness and outcomes research and to efforts to stimulate the development of clinical practice guidelines. We endorse expanded funding for all of these efforts. DHHS should also undertake broad efforts to improve coordination of data systems and data collection efforts within the Department.

Long-term financial and other support for research and special projects is needed in many areas:

- variations, effectiveness, and appropriateness of medical care interventions;
- practice guidelines and the mechanisms by which they can be developed, refined, disseminated, and updated;
- better measures of the technical and interpersonal aspects of the process of care;

- more and improved measures of health status and health-related quality of life;
- effectiveness of methods for changing provider and practitioner habits, behaviors, and performance;
- data and information management systems (computer hardware and software); and
- improved methods of program evaluation.

Capacity building is that set of activities that will enhance the ability of professionals and patients to assess and improve quality of care. If quality assurance is to move forward aggressively, it will require a corps of professionals prepared to provide both technical skills and leadership. At present we lack such a group in anything like adequate numbers to staff a national set of organizations for this purpose. An early priority must be, therefore, to establish training programs to prepare these health professionals, taking account of the following circumstances and needs:

- Educational programs would likely require an extended period of study (e.g., a year);
- They can be built on existing programs in epidemiology, health services research, and biostatistics;
- Education for the existing staffs of facilities and those senior professionals already in, or just about to enter, this work will have to use techniques of intensive continuing education and technical assistance;
- More organized programs of training with field experience will be needed to prepare a new cadre of health workers with the tools needed to collect and apply information based on outcomes in quality assurance;
- Resources will be needed to underwrite the curriculum development and to support the education of these professionals; and
- Ways to make quality assurance more of a profession with a clear career path should be developed.

In addition, it will be important to educate patients and consumers about how best they can contribute to evaluating and improving the care they receive and participate in informed decision making about their health care.

FUNDING

RECOMMENDATION No. 10. Congress should authorize and appropriate such funds as are needed to implement these recommendations.

The MPAQ must be adequately funded from the start, if it is to be successfully implemented and operated. We propose a considerably expanded data collection and evaluation effort in the new MPAQ and assume

that Congress and HCFA will continue to expect the MPAQ to do much, although not all, of what the PRO program now does. For those reasons, we concluded that an increase in the MPAQ budget over present PRO levels is necessary. In addition, we advised that the MPAQ shift from a purely competitive contracting mechanism for MQROs to a funding mechanism that relies more heavily, if not exclusively, on grants or cooperative agreements.

This recommendation is potentially costly, but an underfunded quality assurance program cannot discharge its responsibilities effectively and thus wastes the funds it is provided. It earns little respect from providers, and it cannot demonstrate any meaningful impact on either quality of care or health of the beneficiary population.

The program we are proposing is intended to avoid some of those pitfalls. It is also intended to provide a considerably enhanced body of knowledge about the health and well-being of the elderly and to improve the mechanics of quality review and assurance in all major settings of care. Furthermore, we have built into our proposals a rigorous evaluation component, so that society can know what it is getting for its investment. In our view, the MPAQ simply will not be able to accomplish its objectives with funding that remains at customary levels, and we thus advocate an appreciable increase in support.

We have not specified a target amount, however. Implementation of this proposed program will take time, and many details will emerge only with time. Moreover, internal and external quality assurance efforts have an element of joint production, and not all the activities envisioned in this plan may involve new federal costs. Nevertheless, a reasonable estimate of the costs of this program might be that it would eventually double the investment in the present PRO program, but it should be recognized that this is an order-of-magnitude estimate not a detailed point estimate.

ORGANIZATIONAL AND OPERATIONAL FEATURES OF THE MEDICARE PROGRAM TO ASSURE QUALITY

Starting Points

The conceptual foundation of the MPAQ approach is the classic triad of structure, process, and outcome. We also draw on five constructs of the continuous improvement model: (1) differentiate external quality monitoring from internal quality improvement and assurance efforts; (2) emphasize increased use by internal programs of data on outcomes, systems, and processes of care; (3) reward providers that implement successful internal quality improvement programs; (4) focus on a broad range of "customer" outcomes that include those of patients, practitioners, and the broader community; and (5) foster cooperative communication and negotiation between many different pairs of actors in the health care delivery setting.

The practical starting point for the MPAQ is the existing Medicare program and the private, local, peer review organizations that presently do (or could) carry out the current PRO agenda. We emphasize transition, not starting over, and we believe that many elements of the PRO program can and should be retained. At the same time, we have renamed the program to emphasize the substantial changes in concept and function that we have recommended.

Structure

The Federal and Local Levels

MPAQ. The first level of our model of quality assurance is that of the federal program, the MPAQ. It might also embrace other organizations that operate nationally and that might be considered complementary to this effort, such as the accreditation programs of the Joint Commission.

Briefly, the MPAQ would be responsible for the planning and administration of the quality assurance program for Medicare. It would have three major responsibilities: (1) to engage in long- and short-term program planning for MQROs (e.g., to define the program guidelines for the MQROs, to review applications and make awards to MQROs, and to provide or arrange for technical assistance to MQROs); (2) to monitor and evaluate MQRO operations and performance; and (3) to aggregate, analyze, and report data.

MQROs. The middle level is that of local or regional entities, the MQROs. They would have several primary responsibilities: (1) to obtain information on patient and population-based outcomes and practitioner and provider processes of care; (2) to analyze these data, making appropriate adjustments for case mix, patient characteristics, and other pertinent information by various types of providers; (3) to use these data to make judgments about practitioner or provider performance; (4) to feed such information back to the internal quality assurance programs of practitioners and providers (as well as report it to the MPAQ); and (5) to carry out quality interventions and technical assistance to internal organization-based quality assurance programs.

The Internal Organization-Based Level

We have given considerable recognition to the emerging concepts of continuous quality improvement and organization-based, internal quality assurance efforts. Self-review and self-regulation remain the hallmark of the healing professions. Therefore, our third level is one based on internal, organization-based quality assurance.

We do not prescribe the approach to quality assurance that such institutions, agencies, or practices might take. Some internal programs may pur-

sue traditional efforts; others may implement advanced continuous quality improvement models; still others may experiment with novel review and assurance efforts tailored to their particular needs and circumstances. The MQROs should encourage and assist in the development of all such internal efforts. Internal programs will no doubt use outcome data for their own purposes, but they will also need to emphasize the actual systems and processes of care as a means of knowing where to act when problems arise or to improve care more generally. Finally, these internal programs will have to document that their surveillance systems identify and attempt to solve important quality problems.

If internal programs cannot document their quality assurance procedures and impact, or if the results of the external MQRO monitoring suggest that these activities are not being done well, then the MQRO will have to become more actively involved. Such MQRO interventions might involve abstracting process-of-care information on-site, consulting in the planning of quality assurance activities, imposing corrective actions of the sort now available to PROs, and pursuing new intervention strategies developed during the implementation of the MPAQ.

Operational Overview of the Proposed Model

An Emphasis on Outcomes

A central theme of our recommendations and the proposed MPAQ is a greater emphasis on the outcomes of care. Attention to outcomes offers several advantages. It allows monitoring of the system while leaving providers able to undertake their own quality improvement efforts. It collects systematic data that can be used to inform the field about how process components are related to outcomes. It provides a means to look across time and to appreciate the temporal and service linkages within episodes of care. It emphasizes aspects of care that are most relevant to patients and to society.

The MPAQ and MQROs must choose outcomes that are easily and reproducibly defined, can be practically obtained, and are important to Medicare beneficiaries. These outcomes should include mortality and medical complications; relevant physiologic measures; functional outcomes such as patients' mental and emotional status, physical functioning (for instance, ability to walk), and social interaction; activities of daily living; placement of the patient at home or in a long-term-care facility; and the patients' and their families' satisfaction with care.

A difficult aspect of outcome-directed quality assurance efforts will be to adjust outcomes for the risk factors present in the population being studied (e.g., case mix, severity of illness, and demographic factors). The choice of conditions to be monitored in this new program must reflect the availability

of information about known risk factors. Furthermore, the size of this undertaking means that not all discharges could be monitored for outcomes. At least some conditions would be studied nationally for periods of time to acquire adequate comparative data. In other cases, local or regional topics (perhaps based in part on variations in performance) might be used as the basis for selecting conditions.

Adjusted, comparative information would be returned to the appropriate providers. In addition, providers in a region can be evaluated according to the relative outcomes of their patients. Those whose performance was significantly poorer than the mean would be asked to examine their activities carefully—to identify the specific systems or processes of care that contributed to these results and to make appropriate corrections. Follow-up studies should be performed to assess the impact of these corrections. Failure to improve would result in closer monitoring and potentially more stringent actions, including public disclosure of their status.

Aggregate information would be shared with provider groups to serve as a basis for better understanding of the processes of care. This information would form part of a national data base to be used to improve clinical decision making.

The Importance of the Process of Care

This attention to outcomes is not intended to slight the importance of process-of-care measurement. Process measures have strengths missing in an outcome focus, including the lack of sensitivity of outcome measures for detecting certain rare but catastrophic events. Process measures may need to be used as proxies for outcomes for patients with complex medical conditions, when the many variables that influence outcomes of care cannot be controlled. Further, the long lead time required for some adverse outcomes is such that process surrogates are needed.

Identifying key processes of care and responding to them are best done by internal quality assurance programs of these institutions, organizations, or provider groups. Related activities, such as the development of clinical practice standards and appropriateness criteria, will be best done by national groups drawing on data generated by this quality assurance program as well as the increased interest and research in effectiveness and outcomes of care. The MPAQ and MQROs should encourage, stimulate, and participate in this work as much as possible.

Continuity of Quality Assessment

The emphasis on care beyond a single setting is a new direction in quality assurance. It is essential if ultimate outcomes are to be understood and affected. Superb inpatient care followed by poor post-hospital care, for

instance, cannot be acceptable. Each care provider and institution is part of a system of care. Each must recognize a responsibility to ensure that the continuum of the process of care results in a good outcome for the patient.

Potential Problems

It is appropriate here to acknowledge real or potential drawbacks with this model. This ambitious design will be more difficult to develop in the ambulatory and home care setting than in the institutional one. The data and methods to implement such a system today are inadequate or not easily transferable from other research applications; furthermore, assessment techniques to identify problems are more advanced than techniques to intervene successfully once problems are identified. It is this dearth of off-the-shelf methods that necessitates the research agenda and the proposed 10-year implementation strategy. Any system has the potential for "gaming" by providers; a program as invested in promoting internal quality improvement efforts as this one is more at risk for such gaming. There is little experience to draw on to evaluate a program as complex and ambitious as this one, and it therefore may run a considerable risk of seeming to be ineffective, inefficient, and wasteful of the public's dollars. Relying on self-review, delegated review, and self-regulation are problematic approaches, and they deserve careful study.

IMPLEMENTATION STRATEGY AND PHASES

Our 10-year implementation strategy is divided into three phases from 1991 to 2000. The major activities that should be undertaken are outlined below. Activities beginning in one phase need not end in that phase; for instance, special studies begun in Phase II may well continue into Phase III, and certain efforts to be started in Phase I (such as public oversight or capacity building) are expressly intended to continue throughout implementation and beyond.

Phase I: Years 1 and 2

Congress or DHHS, or both, should take the basic steps to establish the MPAQ. These include establishing the program and the entities in the first five committee recommendations and providing the appropriate authorizations and appropriations, and beginning operations of QualPAC and the National Council. PRO program activities, financing instruments, survey and certification procedures for Conditions of Participation for hospitals, and other aspects of existing programs should be reviewed and revamped as necessary to meet MPAQ goals. MPAQ public oversight and evaluation activities (e.g., articulating specific goals for the MPAQ, appointing the

TAP) should be begun and the first program evaluation report should be submitted. Research and capacity building efforts should be started.

Phase II: Years 2 through 8

The middle phase of implementation entails data collection, data analysis, information dissemination, and four areas of special projects. These activities focus on the design, testing, and implementation of major components of the MPAQ model. We assume that these activities would be started in the second or third year of the MPAQ and generally would take anywhere from three to six years to complete. We assume further that the best of the approaches would then be incorporated into the full MPAQ in Phase III, taking into explicit account the advice and consent of QualPAC, the National Council, or both.

Data Collection

We have consistently emphasized the importance to this Medicare quality assurance program (and to the Medicare program more broadly) of a greatly enhanced data base on use of services, patient outcomes, and the process of care. To create and maintain such an information base—only the foundations of which are in place—and to make it useful for assuring the quality of health care for the elderly over the long run is a massive undertaking. We expect that getting this data collection effort underway will take the middle part of this 10-year strategy because the development and testing of such a system is necessarily evolutionary and must be responsive to environmental and technical factors.

Data Analysis Capabilities

The data analysis capabilities that would be needed in a program with the level of information gathering just described exceed those available in contemporary quality assurance programs, both public and private. Thus, HCFA will need to begin early in implementation to expand and improve its internal data analysis capacity and, more importantly, the data analysis capacity of the MQROs. Specific attention should be given to strengthening several key elements, especially analytic personnel and computer capability, and initiating a technical assistance effort (use of outside expert consultants on an advisory or contracting basis).

Information Dissemination

Our proposed program calls for a sophisticated approach to feeding useful clinical-practice and quality-related information back to practitioners

and provider institutions of all types. Few good models of such feedback loops exist, so a considerable effort will be needed to design, test, and refine such models. Also, formal, external studies of issues relating to public release of information and data sharing might be undertaken, with a focus on their legal, regulatory, and policy ramifications.

Special Projects

Distinguishing providers on the basis of quality and outcomes. If the MQROs are to be able to respond differently to providers according to their capacity to render superior, acceptable, or only poor care, they have to be able to create "quality distributions" of providers, so that performance along that distribution can be acknowledged and acted upon. To overcome the enormous conceptual, practical, and political difficulties of this, we recommend studies to test different methods for creating such quality distributions for the major types of Medicare providers.

Improving the average level of performance. Improving average performance ("shifting the curve") is, in our view, a critical aspect of the MPAQ; so is fostering better internal, organization-based quality assurance programs. Because this is such a new area, various research and demonstration studies (including current PRO pilot projects as appropriate) will be needed during this phase. These projects might be done through joint efforts of the MQROs and individual providers, focus on geriatric-specific quality concerns, be community-wide, and/or involve several providers in either similar or different care settings.

Incentives for good and exemplary performance. Early in Phase II, the MPAQ should study ways to identify and reward both good and exemplary (or superior) providers. These might include lowering the amount of intrusive external review to which they might be subjected, publishing superior rankings, giving special recognition for performance and innovation, selective contracting, and sharing information on exemplary providers with private third-party purchasers.

Dealing with outliers. Providers not meeting the criteria of satisfactory performance on the quality indicators will be subjected to more intensive review and other quality interventions; we have noted in the report that more innovative approaches to these quality interventions will need to be developed. Better mechanisms also need to be devised for real-time intervention in the event of catastrophic malfeasance or poor performance.

Phase III: Years 9 and 10

Our aim is a functioning quality assurance program at the end of a 10-year period, one that can respond creatively to changing environmental circumstances. Some of these circumstances can be foreseen (even if their particulars cannot be specified), such as a larger and older elderly population and different Medicare payment systems. Others are a matter of speculation, such as the strength of the nation's economy. Most of the reforms suggested for the first two phases of this implementation strategy are intended to provide a firm foundation for this program, and we expect them to continue into Phase III.

Thus, in Phase III, we expect to see a shift from demonstrations to full-scale implementation, continued improvement in quality of care and in the conduct of quality assurance, and a major reassessment to determine if the MPAQ is on target. The report highlights four other sets of activities in this third phase because of their very broad and long-range public policy implications: research, capacity building (both discussed earlier), public oversight of the Medicare quality assurance effort, and program evaluation.

A consistent theme of the report is engagement of patients and consumers in quality assurance. A corollary is that the public is entitled to know and have some voice about public monies spent on quality assurance programs. The public also needs a way to bring quality-related problems to the policymaker's attention. The report suggests that efforts be coordinated among all the Medicare commissions (especially ProPAC, PPRC, and QualPAC), so as to avoid duplication of effort and forestall major policy difficulties. Among the issues that might be monitored is the likelihood and severity of quality problems confronting the MPAQ as reimbursement mechanisms and Medicare benefits change over the 1990s, but other issues may well arise.

We clearly put very strong emphasis on rigorous evaluation (of the program itself, not only its agents). We have suggested that HCFA devise and test various program evaluation techniques, including ways to assess the cost-effectiveness of a quality assurance program. We suggest that a formal, operational program evaluation effort (outside the MPAQ) be in place by the time the MPAQ itself is fully operational.

CONCLUDING REMARKS

This report presents a strategy for a quality review and assurance program for Medicare.

It envisions an evolution from the present Medicare PRO program but

with several different emphases that present extraordinary challenges. It looks more to professionalism and internal quality improvement than to regulation and external inspection. It gives more attention to patient and consumer concerns and decision making, and it adopts an aggressive regard for outcomes. It seeks to generate new knowledge from clinical practice and to return that information to providers in a timely way that improves clinical decision making. It places stronger emphasis on systems of care, the joint production of services by many different providers, and continuity and episodes of care. Related to this, it moves more forcefully into settings not traditionally subjected to formal quality assurance, such as physician office-based care and home health care. It becomes far more publicly accountable through an extensive program oversight and evaluation effort. It intends to be responsive to a changing environment, with principles that will stand the tests of time and change. Finally, it is grounded in a clear definition of quality of care.

The Medicare program has a large responsibility to assure the quality of care for the elderly population. By no means does it have the sole responsibility. Patients, providers, and societal agents must work together if we are to meet the challenges inherent in this strategy for quality review and assurance.

RESPONSES OF PAUL F. GRINER TO QUESTIONS SUBMITTED BY SENATOR ROCKEFELLER

Question No. 1. Could you elaborate on the concepts of the process of care and the need for the continuity of quality assessment? Why did the committee feel that these elements are so important to a quality program in Medicare?

Answer.—

PROCESS OF CARE

More than 25 years ago, Avedis Donabedian formulated three ways to approach the assessment of quality. They included examination of the *outcomes* of care, which can be understood broadly as the result of efforts to improve the health of patients and the population served; the *structure* of health care organizations, which includes their policies, procedures, staffing, equipment and other organizational determinants of how care is delivered; and the process of care. *Process of care refers to the decisions and actions taken during the care of an individual patient, ranging from preventive care to acute, chronic, and rehabilitative or supportive care.*

The Institute of Medicine defined quality of care as " . . . the degree to which health care services [i.e., processes of care] for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." This definition underscores the important link between process of care and outcomes, and suggests that both processes and outcomes of care can give important information about quality. Exactly how these aspects of quality might be dealt with in real life are suggested by the following "cases."

A 60-year-old man suffers an acute heart attack at home. He is taken to an emergency room within half an hour, where a diagnosis is established using the patient's history and classical physical findings. He is promptly treated with a clot-dissolving agent. The process of care throughout the hospitalization (both observations and treatments) was appropriate, and he is discharged after 10 days with specific plans including cardiac rehabilitation after convalescence. Quality assessment in this case would indicate that both the process and short-term outcome of care were good, and a quality assessment program might be able to use measurements of either processes or outcomes to determine the quality of the health encounter.

A 5-year-old girl is brought to the family physician's office with a high fever, cough of several days' duration, and a very "sore throat." The nurse-

practitioner in the office takes her history, vital signs such as temperature, and a throat culture; based on this information, she recommends appropriate symptomatic care and that the mother call the office late that afternoon for results of a rapid strep test that will determine whether an antibiotic should be given. The test is positive, and the mother is notified and given instructions. The family physician calls in a prescription to the pharmacy. A two-day strep test that will confirm the results of the earlier test is conducted. Quality assessment here would show that the process of care was good. Knowing something about the outcomes of care, however, depends on whether the mother calls back (or is called by the physician or nurse-practitioner); if care has been successful, however, it is entirely possible that that fact will not be known to the clinicians. Thus, in this case, care cannot easily be judged on the basis of outcomes, and an evaluation must rest nearly exclusively on measures of the process of care.

The conclusion to be drawn from these definitions and examples is that measuring both processes of care and outcomes is important for a comprehensive understanding of quality of care. In some instances, however, measuring outcomes may be difficult; in those cases, assessing the processes of care is the pivotal evaluation technique.

CONTINUITY OF CARE, ITS IMPORTANCE FOR MEDICARE

Continuity of care refers to patients being seen by the same health care provider for each visit or being given consistent and coordinated medical advice by several health care practitioners. It can also refer to the goal of a system of care that permits providers in different settings to have access to medical record information from sites of care as diverse as physicians' offices, acute care hospitals, freestanding laboratories, nursing homes, and homes. In this formulation, any health care provider is able to use this information in his or her care of the patient for an entire episode of care, regardless of changes in the setting of care. For instance, during an episode of illness an elderly patient may move from home to an emergency room, to a hospital, to a nursing home for rehabilitation, and back home where he or she may receive home care. Care for chronic illness may span many patient visits and necessitate the coordination of many actions by health care providers within a complex (even if single setting) system of care; thus, the quality of care cannot be adequately assessed by reviewing single events or the actions of single providers. Although quality assessment is typically conducted by a given organization focusing on the care within a single setting, the process and outcomes of care must be tracked and assessed across settings and over time if a program of quality assessment is to draw accurate conclusions about the care. Although this need is generally true of quality assessment methods, it is particularly important in assessing and improving the care of the Medicare beneficiary with several chronic diseases.

Question No. 2. Who should be responsible for the establishment of practice guidelines and how do we ensure their validity? How can we be sure they are updated appropriately?

Answer—.

DEVELOPMENT OF PRACTICE GUIDELINES

In October 1990, the IOM published an initial report on clinical practice guidelines in response to a request from the Agency for Health Care Policy and Research (AHCPR); the IOM is now engaged in a second study that should be published at the end of this year. Although the first report focused on AHCPR, it also noted that government's role in arranging for the development of practice guidelines may in the end be fairly modest. Indeed, the contemporaneous efforts of many different organizations in the private sector may significantly outpace what this one agency can do. The committee did not recommend any single source of responsibility for guideline development.

Regardless of the specific society, government body, or other organization sponsoring the development of guidelines, the IOM committee strongly recommended that the development of guidelines should be a *multidisciplinary process;* that is, practice guidelines must be developed by a process that includes participation by representatives of key affected groups. participation may include serving on panels to develop guidelines, providing evidence and viewpoints to the panels, and reviewing draft guidelines. Such participation increases the likelihood (1) that all relevant scientific evidence will be located and critically evaluated; (2) that practical problems with using the guidelines will be identified and addressed; and (3) that affected groups will see the guidelines as credible and will cooperate in implementing them. Partici-

pation by physicians, nurses, patients, payers and others can be achieved in several ways, including membership on the development panel, testimony at public hearings, participation in focus groups, consultation during site visits, and provision of comments on draft guidelines.

Within the government, meeting the challenge of developing good practice guidelines cannot be solely the responsibility of the AHCPR Forum. For instance, the AHCPR's Medical Treatment Effectiveness program (MEDTEP) will generate information of immediate importance for practice guidelines. Moreover, holes in data identified during the guidelines development process should highlight areas that AHCPR can target for research funding. Outside AHCPR, the work of other agencies in the Public Health Service (PHS), most notably the randomized controlled trials of the National Institutes of Health, will be essential to the long-term utility of guidelines, especially insofar as those trials include broad measures of outcomes important to patients. Outside the PHS, the agency has established some links with the Health Care Financing Administration (HCFA), in part because of provisions of the Omnibus Budget Reconciliation Act of 1989 but more importantly because HCFA's data on the Medicare population (and, to a lesser extent, on the Medicaid population) should be valuable for developing, implementing, and evaluating guidelines. In addition, the Medicare peer review organizations may be valuable sites for disseminating guidelines, using them as quality review criteria, and evaluating their practical utility.

ENSURING THE VALIDITY OF PRACTICE GUIDELINES

The IOM committee placed a great deal of emphasis on the concept of *validity* of guidelines, by which it meant that "practice guidelines are valid if, when followed, they lead to the health and cost outcomes projected for them." Further, a prospective assessment of validity will consider the projected health outcomes and costs of alternative courses of action, the relationship between the evidence and recommendations, the substance and quality of the scientific and clinical evidence cited, and the means used to evaluate the evidence. This emphasis on validity reflects the IOM's concern for finding a way to judge the soundness of guidelines themselves rather than just the acceptability of the development process. The IOM committee is now drafting a practical instrument to assess the soundness of practice guidelines prospectively and will deliver a provisional version to the AHCPR at the end of the summer.

Developing practice guidelines is a challenging task that requires diverse skills ranging from the analysis of scientific evidence to the management of group decisionmaking to the presentation of complex information in understandable forms. As is the case for the acquisition of any medical information knowledge, those who develop and seek to ensure their continued accuracy as well as those who seek to improve the methodology of guideline development, implementation and evaluation, will need firm financial support, specifically, through AHCPR extramural grant programs.

UPDATING OF GUIDELINES

Little formal attention has been given to updating guidelines. Once guidelines have been published, it is presumably the responsibility of the developing organization to see that they are updated and updates republished as new technologies or literature emerge. The IOM report recommends that all guidelines have published along with them *scheduled review dates* based on the authors best judgment about the rapidity of movement in the subject and allowing for earlier review in the event of unanticipated major changes in the field. Others have suggested publishing a "sunset" date after which guidelines would either be updated or automatically withdrawn. As guidelines become disseminated and adapted for various uses within organizations, however, the task of and responsibility for updating becomes correspondingly complex, diffuse, and problematic. Better information and decision support systems can help but problems with updating are likely to continue, a situation not unique to guidelines. As AHCPR generally investigates the dissemination issues on its research agenda, some ideas for updating as well as initially disseminating guidelines will likely emerge.

GENERAL OBSERVATIONS

The field of guidelines development is a confusing mix of high expectations, competing organizations, conflicting philosophies, and ill-defined or incompatible objectives. It suffers from imperfect and incomplete scientific knowledge, as well as imperfect and uneven means of applying that knowledge. Despite the good intentions

of many involved parties, the enterprise lacks clearly articulated goals, coherent structures, and credible mechanisms for evaluating, improving, and coordinating guidelines development to meet social needs for good quality, affordable health care.

This situation will not change overnight, even though many promising activities, including those sponsored by AHCPR, are under way. Thus, expectations of quick results should be restrained.

The IOM committee believes that the AHCPR's practice guidelines effort has substantial potential to advance the state of the art in this field, strengthen the knowledge base for health care practice, and, hence, improve the appropriateness and effectiveness of health care. The conditions for such success are demanding but not out of reach. In particular, expectations for the agency—and for practice guidelines per se—must be realistic regarding timetables and results. Strict regard for the scientific rigor of the process is critical, as is avoidance of premature closure on a single method of guidelines development. Attention to implementation and evaluation needs to be factored into the development process at an early stage.

In May 1990, a new IOM committee began an 18-month study of the development, implementation, evaluation, and revision of clinical practice guidelines. Many of the issues raised in the first report on guidelines are being examined in greater depth during this second project, which is supported by the John A. Hartford Foundation, Inc. and the U.S. Public Health Service. A particular focus of this study is the implementation and evaluation of practice guidelines. The IOM committee is examining how guidelines are (or are not) integrated into programs of quality assurance and improvement, health benefits design and administration, and risk management. It is also considering other issues such as the bioethical aspects of guidelines and the status of guidelines in determining malpractice liability.

Question No. 3. The IOM report made specific recommendations concerning public accountability, evaluation, and oversight of the Medicare quality assurance effort. What organizations could undertake efforts to ensure public oversight and accountability for these efforts and what role should Congress play in this process?

Answer. As noted in the response to question 4, we regard these issues with special concern. The committee felt that evaluation and oversight functions are critical to a strategy for quality assurance in Medicare, and our report had, of course, suggested the creation of two new organizations (the "QualPAC" and a "National Council") as mechanisms for ensuring appropriate public oversight. If such a commission is not feasible, however, it is still crucial that this function be performed. Other existing organizations might well be considered. For instance, on its own behalf the U.S. Congress might give the mandate to monitor Medicare quality assurance efforts (or quality of care across all segments of the population) to, an existing commission such as ProPAC or PPRC. Congress might also consider expanding the responsibilities of some existing HCFA physician advisory panels, perhaps mandating that representatives of clinical professions other than physicians be added as well as representatives of consumers and patients. Congress might, instead, want to direct a different part of the Department of Health and Human Services (for instance, the offices of the Assistant Secretary for Planning and Evaluation or of the Assistant Secretary for Health) to undertake a formal evaluation of the Medicare PRO program, with the results of that evaluation to be reported both to the Secretary of HHS and the Congress.

Alternatively, the Congress might wish to direct the National Academy of Sciences and the Institute of Medicine to revisit the issues (appropriately 11 updated) originally raised in the OBRA 1986 legislation that called for the study on which we testified at your hearings in February.

Finally, as implied below, Congress might wish to schedule regular or periodic "oversight" hearings specifically on issues related to the Medicare PRO program or on broader quality of care concerns. These might be made part of, or held as adjuncts to, other oversight hearings on different aspects of Medicare administration.

Question No. 4. What issues raised by the report are likely to need follow-up or could be the topic of a future hearing?

Answer. By the very nature of the IOM's response to its congressional mandate, we see many topics and steps warranting follow-up over the next few years. Recalling some of our major concerns with the current system, it seems reasonable to revisit the following specific issues. First, how well the Medicare PRO program, and the PROs themselves, are discharging their current responsibilities and how well they are moving in the direction of greater attention to (a) patient outcomes, (b) continuity of care and the quality of care through episodes and across settings, and (c) adequate analysis and feedback of clinically relevant information to providers and practitioners. In addition, our discomfiture with the lack of public evaluation and public accountability is undiminished. To address all these issues, we believe that

one or more "oversight" hearings specifically on the PRO program would serve many purposes.

Second, the groundswell of interest in continuous quality improvement and total quality management has grown into a significant movement, both in the private sector (in health and non-health industries) and in the Federal government. We believe it is time for a more informed examination and debate of this very appealing approach to quality assurance because it promises to replace the punitive approaches to quality assurance that are currently in place with more positive approaches that more likely would simultaneously achieve both quality of care and cost containment.

A third related arena is that of outcomes, health status, and health-related quality of life. The IOM report placed heavy emphasis on a broad definition of outcomes and health status—stressing in particular those quality of life outcomes that matter to patients in contrast to the clinical or biophysiologic measures that tend to matter to clinicians. This field has become considerably more sophisticated in just the last two or three years, and we believe a hearing on this topic (which relates as well to effectiveness and outcomes research and to the development of practice guidelines) would prove useful to the health subcommittee.

PREPARED STATEMENT OF SENATOR JOHN HEINZ

Mr. Chairman, there was a television commercial a few years ago that asked "where's the beef?" That same question is appropriate today some 25 years after the enactment of the Medicare program asking—"where's the quality?"

Despite years and years of hearings, legislation, and horror stories from Medicare recipients about HCFA's failures to ensure the quality of care, we may not be any further ahead than we were 25 years ago. Harsh words? Yes! But true.

There are more then 34 million Medicare beneficiaries, many of whom are old and alone. They are often a lone voice in the crowd. While their principle protector is Congress, many of us had hoped that the Health Care Financing Administration (HCFA) would be their advocate. It is tragic that this has been a myth.

Before us today is a bold and comprehensive plan from the Institute of Medicine setting forth a long range strategy for enhancing quality assurance in the Medicare program. While it is appealing to focus on the long term potential of Medicare's quality assurance program, we must act now to address its serious shortcomings.

I am particularly concerned about a recent draft GAO study on quality assurance in the Medicare HMO program. This investigation, done at my request, examines PRO review of both the internal quality assurance programs of the risk contract HMOs and the health care provided by these HMOs.

I was horrified by the study's preliminary findings. Less than one-quarter of HMOs that participated in the Medicare risk contract program had their internal quality assurance program reviewed by a PRO. HCFA has never required a review and there is little or no incentive for an HMO to voluntarily subject itself to a review.

More than half of the HMOs whose quality assurance programs were reviewed did not prove they could identify and correct quality of care problems. The draft report suggests that many of the quality assurance programs had serious weaknesses that were contrary to Federal regulations.

The real shocker is that when serious deficiencies in the internal quality assurance program of an HMO were identified, the PRO lacked the authority to enforce corrective action. Although information on problem programs was provided to HCFA by the PROs, in all but one case HCFA failed to act on PRO recommendations.

The bottom line is that HCFA spent more than $10 billion in the last three years on the Medicare risk contract program, but they cannot tell us whether our senior citizens received quality care.

To be fair, Gail Wilensky inherited a great many of these problems. She has been working diligently to correct years of bureaucratic neglect and I look forward to working with her to achieve the goal of quality of care for every Medicare beneficiary.

The Institute of Medicine's plan offers great promise for achieving real quality assurance in Medicare by the year 2000. Mr. Chairman, a decade is too long to wait!

RESPONSES BY ROBERT L. KANE TO QUESTIONS SUBMITTED BY SENATOR ROCKEFELLER

Question No. 1. How do you translate practice and patient data into practice guidelines?

Answer. We are presently forced to fall back on expert opinion as the basis for generating most of what we use as practice guidelines. The type of systematic data I am advocating, when analyzed, would provide the basis for determining what kinds of treatments produce what kinds of results in what kinds of patients. The decision about what to recommend would depend on the weights given to alternative outcomes. For example, one might conclude that there was only a modest difference in outcomes when a given type of patient was treated in two quite different ways, one of which was much more expensive. The practice guideline might opt to favor the less expensive treatment, or at least hold the payment equal for both.

With the rich data base possible, the current way of using practice guidelines will change. Instead of coming up with recommendations for what should be done for whom, the system will be able to operate in a query mode. The practitioner can enter the patient characteristics and proposed treatment, and the machine can indicate if there are more cost-effective approaches; or he can indicate a condition and patient characteristics and the machine will provide the most cost-effective approach. Because the definition of cost-effectiveness depends on how one values various outcomes, it will be essential to either agree in advance on those weights or to choose a dominant outcome for the calculation.

Question No. 2. How do you monitor the practice guidelines after they are developed?

Answer. The system envisaged is constantly self-correcting. As new information or more observations become available, better predictions of outcomes and correlations with patient and treatment characteristics are possible. Rather than talking about annual reviews of guidelines as might apply to traditional approaches to practice guidelines, we are suggesting a continuous process. The answer given today might change tomorrow if new data justified such a shift.

Question No. 3. What data do you have that relate the development of practice guidelines to the improvement in quality?

Answer. MCCAP has not yet reached the stage where we can even point to any changes in physician behavior, let alone claim a causal relationship. We do, however, have some anecdotal information suggesting that physicians informed about the statewide guidelines have already become more thoughtful about what they are doing. I am not sure that guidelines will lead to better quality. Much seems to depend on the trust the physicians have in the guidelines. It is important to get them to buy in by making them part of the process rather than having it thrust upon them. We have noted for example, that the Minnesota Blue Cross introduction of the Value Health Sciences approach to guideline use, which is based on a sophisticated expert system, has engendered a great deal of discussion and controversy, but not clear evidence of behavior change. I think the best evidence of how physicians respond to data (as opposed to guidelines) comes from the Maine experience with TURs.

Question No. 4. What are the legal implications of using practice guidelines?

Answer. I am not a lawyer but I sense that they are concerned about these guidelines becoming the standard against which malpractice is judged. There is a special irony in guidelines developed by expert panels. I have always wanted to see how well the panelists follow the guidelines they develop. If they do not, there is a real risk that physicians will be held accountable for unrealistic standards. Presumably the guidelines would also be used to determine what is paid for and hence could become the subject of suits by patients as well as physicians. What happens to the patient who has a strong preference for a given outcome but the guideline is not designed to maximize that outcome? If the procedure is excluded, he is denied access to that care. That may become the basis for a law suit.

Question No. 5. What is the cost of your program?

Answer. We have not been in operation long enough to get a firm feeling on the operational costs. There will undoubtedly be some economies of scale as the program gets experience in developing the guidelines and setting up data collection. Right now, we estimate that it will cost about $125,000 to develop the system and collect the outcomes data and record abstracts for one condition in Minnesota. We propose to add $50 to the cost of every admission. (This represents about 6% of the cost of one hospital day.) Because not every problem will be studied at any single time, that "tax" will more than cover the costs of data collection and analysis. It is important to appreciate that the cost is much lower because the physicians work for free as do the nurses who collect the data from patients in the hospital. The nurse

collected data is invaluable in getting information otherwise not well documented in the medical records.

Question No. 6. Will the use of practice guidelines detect over/under-utilization of procedures?

Answer. They should detect both depending on how one defines the condition being studied. For example, if the definition of a condition is a procedure, one will never identify those who have the indications but did not get the procedure. One would miss cases of underservice this way. If one can identify all persons (even all persons admitted to hospital) with a specific characteristic and follow them through the medical record to see how many did better or worse to compare those treated according to the guidelines and those not, one can begin to estimate whether following the guidelines made a difference. It is easier to look for overservice, because selecting by a procedure will include those inappropriately (or potentially inappropriately) treated. The more basic the question (i.e., the more generic the definition of a condition), the harder it is to identify the correct population to study, because some of them will not get into any formal care at all and others will not get into the hospital.

PREPARED STATEMENT OF ROBERT MCAFEE

Mr. Chairman and Members of the Subcommittee: My name is Robert McAfee, MD. I am a practicing general surgeon in Portland, Maine, and Vice-Chairman of the Board of Trustees of the America Medical Association. Accompanying me are Hilary E. Lewis, JD, and Ross N. Rubin, JD, of the AMA's Group on Legislative Activities and John Kelly, MD, of the AMA's Office on Quality Assurance. On behalf of the AMA, I want to express our appreciation for this opportunity to appear before the Subcommittee to provide our views on the Institute of Medicine's (IOM) report: "Medicare: A Strategy for Quality Assurance."

Quality medical care as well as quality assurance are critical issues for physicians and the AMA. Overall, the health care that Americans, including the elderly, receive is of unparalleled high quality. In its report, the IOM acknowledges that:

> "The nation is generally perceived to have a solid, admirable base of good quality health care, and the elderly are usually satisfied with the quality of care they themselves receive."

The AMA is proud of its leadership in the development and implementation of measures and policies that are effective in helping assure and improve such quality. As physicians, we continually strive to improve our ability to provide the highest quality medical care for our patients. Still, improvement in the quality of medical care is always possible, as is possible with all human endeavors. Efforts to facilitate such improvement are welcomed and vigorously pursued by the profession.

For this reason, the AMA supported and participated in the IOM's examination of quality assurance under the Medicare program. (Congress mandated this study in the "Omnibus Reconciliation Act of 1986" P.L. 99-509). For example, we shared our quality assurance guidelines developed for medical peer review systems, and many of these principles are incorporated in the IOM's report. With the report now completed, we are pleased to say that there are portions of the IOM's recommendations with which we agree wholeheartedly.

We also must report to you, however, that the AMA cannot support the overall conclusion of the IOM study that:

> "significant problems exist in quality of care and in our present approaches as to quality assurance. They are sufficient to justify a *major* (emphasis added) redirection for quality assurance in this country and, in particular, a more comprehensive strategy for quality assurance in Medicare."

Although quality assurance is a rapidly evolving field, such a major redirection, which would include the creation of yet another Federal agency to oversee the quality of the Medicare program, would be a wasteful use of limited government resources. With the already strained Federal budget and with the new budget process, it would be far more appropriate and cost effective for any additional resources to be directed to providing existing Peer Review Organizations (PROs) with the resources necessary to help them improve existing quality assurance programs and by increasing support for the activities of the Agency for Health Care Policy and Research (AHCPR), a recently established Federal agency that shows great promise in identifying means to improve the quality of medical care. (The Administration's budget calls for an increase of $119 million in outlays for PROs and $7 million in additional spending for the AHCPR.)

A central question that you must contend with in addressing the recommendations in the IOM Report is whether improved quality assurance can be achieved through existing quality assurance systems, including PROs, or whether an entirely new system is needed to achieve this goal. It is the AMA's position that, given the may resource constraints now being imposed on the nation's health care system, current quality assurance mechanisms have proven themselves effective enough to strongly argue against the increased level of expenditures that would be needed to establish a wholly new quality assurance system. PRO experience to date has demonstrated that the overall quality of care provided to Medicare beneficiaries is good. HCFA reported that the PROs found few "significant quality problems," with only 2.32 percent of all inpatient hospital cases reviewed identified as having a quality problem and many of these problems were minor. The fact is that Medicare beneficiaries receive high quality medical care primarily due to the competence and commitment of medical professionals. A variety of mechanisms already in place help to guarantee professional competence and commitment, such as physician credentialing through state medical licensure and disciplinary boards, voluntary specialty certification, sound educational programs, continuing education, and independent peer review.

This is not to say that the PRO program is not without faults and cannot be improved. Operationally, the PRO program affords different procedures in different locales and does not uniformly provide adequate due process for the protection of practitioners. We have, and we will continue to discuss issues of due process and other operational concerns with the Health Care Financing Administration. Finally, the AMA is concerned with the expansion of PRO review into physician office practice. The size, scope and complexity of such a massive endeavor needs to be thoroughly examined to determine whether such review is even feasible with the current state of the art in review. Congress should revisit this issue when reports from current demonstration programs are available.

IOM RECOMMENDATIONS AND AMA RESPONSE

At this point, I will address the ten recommendations set out in the IOM report.

Recommendation 1—Congress should expand the mission of Medicare to include a explicit responsibility for assuring the quality of care for Medicare enrollees, where quality of care is defined as the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge

An explicit, statutorily expressed commitment to quality already exists in the Social Security Act within the legislation authorizing the PRO program. Section 1154(a)(1)(b) of the Social Security Act clearly states that a purpose of the PROs is to determine whether "the quality of such [medical] services meets professionally recognized standards of health care . . . ." In addition, placing a greater emphasis on a definition of quality that includes outcomes, and establishing the appropriate balance between quality and cost containment efforts in the Medicare program are goals that the AMA and individual physicians support.

Recommendation 2—Congress should adopt the following three goals for the quality assurance activities of the Medicare program:

- *Continuously improve the quality of health care for Medicare enrollees, where quality is defined as in the first recommendation;*
- *Strengthen the ability of health care organizations and practitioners to assess and improve their performance; and*
- *Identify system and policy barriers to achieving quality of care and generate options to overcome such barriers.*

These are excellent goals within the context of any quality assurance system. In generally supporting these goals, we also point out that they are appropriate for use in strengthening existing quality assurance systems.

Recommendation 3—Congress should restructure the Utilization and Quality Control Peer Review Organization (PRO) program, rename it the Medicare Program to Assure Quality (MPAQ), and redefine its functions.

The American Medical Association strongly disagrees with this sweeping recommendation. This recommendation is based on the assumption that the current system is not working, an assumption that we do not share and which we believe is wrong. Nothing in the IOM report provides compelling evidence that it is necessary to establish a totally reorganized quality assurance system.

This recommendation calls for a radical departure from the current PRO system, which has been in effect for only five years. While the AMA agrees that improvements in the PRO program need to be made, it is still too early to judge fully, let alone condemn, the program's effectiveness. The PRO program should be allowed to mature and be administered in a stable manner. Only then should it be evaluated in light of alternatives.

We are concerned that the proposed Medicare Program to Assure Quality (MPAQ) suggests a return to the Professional Standards Review Organization (PSRO) program. The PSRO program was discarded largely because it lost the focus on quality and placed too much emphasis on cost control. Moreover, if a return to the style of the PSRO program results, evaluation of quality will be more fragmented and inconsistent than already exists among the nation's 53 PROs.

The report proposes that the MPAQs obtain and use data to assess practitioner or provider performance and feed such information back to practitioners and providers. Those recommendations reflect recently established PRO activities, such as physician profiling, small area analysis, and the Uniform Clinical Data Set (UCDS). The proposals contained in the Report with regard to data collection and analysis and interpretation, moreover, remain largely untested. Because data collection and analysis is fraught with enormous technical complexity and expense, it would be premature to establish a new bureaucracy to collect more data when the potential benefits of such efforts are unclear.

HCFA is finalizing the Uniform Clinical Data Set (UCDS) and has accepted the offer of the AMA to participate in a meaningful evaluation of the UCDS components and proposed applications prior to the full implementation of the UCDS. The AMA is pleased to participate in this activity, as existing programs have often failed to include adequate physician involvement during the planning and testing phases, or to afford the necessary feedback to physicians regarding the findings and significance of data. The Maine Medical Assessment Program provides a model for appropriate data collection and feedback, achieving its success with the active involvement of the physician community. Only through the participation of the medical profession will such efforts result in the compilation of meaningful information similar to the success achieved in Maine.

Recommendation 4—Congress should establish a Quality Program Advisory Commission (QualPAC) to oversee activities of MPAQ and to report to Congress on these activities

Establishment of QualPAC is unnecessary and redundant because both the Physician Payment Review Commission and the Prospective Payment Advisory Commission routinely address quality issues as part of their activities. In addition, Congress has established numerous independent Commissions that also have addressed health care quality concerns, such as the Advisory Council on Social Security and the "Pepper Commission."

In opposing the creation of OualPAC, we also note that OualPAC would require considerable time and resources that, as we have already described, would be better applied to improving existing quality assurance capabilities.

Resources necessary to fund QualPAC could be better used in support of the AHCPR which was created by Congress (Omnibus Reconciliation Act of 1989; P.L. 101-239) to:

> promote improvements in clinical practice and patient outcomes through more appropriate and effective health care services; promote improvement in the financing, organization, and delivery of health care services; and increase access to quality care.

The AHCPR funds research in numerous areas, including: efficiency, effectiveness, and quality of health care services; outcomes of health care services; and clinical practice. The AHCPR research agenda provides a foundation to improve both quality of care and internal and external quality assurance programs (such as the PRO program). We believe that the AHCPR is accomplishing much of the research agenda proposed by the IOM for QualPAC.

One method by which quality assurance and cost containment goals can best be achieved is through the kind of research being proposed and now being undertaken by AHCPR and the widespread dissemination of the results of such research. We believe that the AHCPR is administering its activities well, and that a restructuring of the Federal administrative programs or the creation of new Federal structures certainly are premature and unnecessary at this time.

Recommendation 5—Congress should establish within the Department of Health and Human Services (HHS) a National Council on Medicare Quality Assurance to assist in the implementation, operation, and evaluation of the MPAQ

The creation of still another oversight body cannot ensure that quality assurance activities will be carried out any better than are current activities. Given the cost of establishing such a body, the climate of limited health care resources, and the unsubstantiated need for such redundant oversight, this recommendation should be rejected.

Recommendation 6—Congress should direct the Secretary of HHS to report to Congress, no less frequently than every two years, on the quality of care for Medicare beneficiaries and on the effectiveness of MPAQ in meeting the goals outlined in Recommendation 2

The AMA agrees that it would be beneficial for the Secretary to report to Congress on the existing quality of care for Medicare beneficiaries. However, the AMA suggests that such a report should be used first in assessing the strengths and weaknesses of the current system, including the effectiveness of PROs in meeting their current goals, before a restructuring of the quality assurance system is undertaken. Only if it is determined that the goals outlined in Recommendation 2 are not being met by current quality assurance activities would it be appropriate for the Secretary to recommend massive changes within the existing system.

Recommendation 7—Congress should direct the Secretary of HHS to initiate a program to make the Medicare Conditions of Participation consistent with and supportive of the overall Federal quality assurance effort

The AMA supports the four steps recommended to improve the Medicare Conditions of Participation. We note, however, that the report focuses only on the Conditions of Participation for Hospitals. Given the role of Conditions of Participation in setting minimal standards for various types of health care providers and facilities, we believe that such Conditions should be continually subject to review.

Recommendation 8—Congress should direct the Secretary of HHS to support, expand, and improve research in and the knowledge base on efficacy, effectiveness, and outcomes of care and to support a systematic effort to develop clinical practice guidelines and standards of care

Recommendation 9—Congress should direct the Secretary of HHS to establish and fund educational activities designed to enhance the nation's capacity to improve the quality of care it receives

Recommendation 10—Congress should authorize and appropriate such sums as are needed to implement these recommendations

The AMA supports the intent of each of these recommendations. (We believe that the AHCPR will help to accomplish many of the goals of recommendation 8.) The AMA believes, however, that funding for research should be supported for medical care recipients in all age groups, not just for Medicare beneficiaries. Funding should be used to support professionally directed research efforts to improve the quality of care throughout the spectrum of life, especially during the prenatal period and infancy, given our nation's relatively high rate of infant mortality.

QUALITY INTERVENTION

Under the Third PRO Scope of Work, all of the nation's 53 PROs were required to implement a Quality Intervention Plan (QIP) to identify the source of a confirmed quality problem and to profile physicians and providers involved in confirmed quality problems. Under the QIP's prescribed plan, each PRO is required to perform a quality review and implement interventions when quality concerns are identified. Once identified and confirmed, the quality concern is assigned a weight by a PRO physician based upon the degree of harm or potential for harm to the patient according to a three-level severity index. Each category carries an assigned weight. The PRO profiles the total weights accumulated for reviews completed quarterly for each physician or provider. The total weight then determines the type of corrective action to be implemented. The QIP also requires that interns and residents (those individuals participating in a graduate medical education program accredited by the Accreditation Council for Graduate Medical Education and the American Osteopathic Association) be given QIP points when problems are confirmed that are attributable to them.

The IOM Report addresses the issue of quality intervention under the new structure it envisions. It recognizes the necessity of balancing the need for predictable

and equitable intervention strategies for all providers, with an emphasis on local decision making, flexible responses to different problems, and support for emerging internal quality improvement programs. The Report takes the view that explicit bases or common factors for choosing among intervention options must be articulated, leaving individual decisions to Medicare Quality Review Organizations. This approach, as acknowledged in the Report, would be similar to the current PRO quality intervention plan. It would give broad authority for different types of interventions, from notification of concern about a quality problem, through mandated continuing medical education, to intensified review, and ultimately to various legal and financial sanctions. The development of other innovative interventions is also recommended. In noting that innovative options for responding to quality problems have not been fully developed by any Federal quality assurance program, the Report suggests that some demonstrations or quasi-experiments be conducted to explore the feasibility and effectiveness of various approaches to quality interventions.

Although the AMA believes that the concepts underlying the QIP have some merit, the AMA has favored modification of specific elements in the QIP, such as the number of severity levels, severity level definitions, and the application by PROs of severity levels and specific interventions. In addition, the AMA recommends that PROs should provide expanded feedback to state and local medical societies regarding the range of identified quality deficiencies in a manner that adequately protects confidentiality.

With regard to assignment of QIP points to interns and residents identified as the source of a confirmed quality problem, we find it inappropriate to have these points allocated to residents who provide care in supervised settings. The AMA recommends that (1) the attending physician of record not be assigned QIP points; (2) the PRO notify the responsible training program and resident regarding the quality problem; (3) the residents participating in an accredited training program not be assigned any QIP points for activities within their training program; (4) the resident and program director receive notification from the PRO which serves to initiate a specific corrective action plan by the residency program director; and (5) that such corrective notifications by PROs to residents be used only within the training programs and remain confidential from all other parties.

Finally, the AMA urges the establishment of adequate due process protections for physicians and providers who are designated through the Problem Identification Process. The levels of appeal currently in place with respect to PRO utilization review under the Medicare program provide a model for appropriate notice, reconsideration, clarification, hearing and review.

AMA QUALITY INITIATIVES

The AMA and medicine have taken a lead role in the development of practice parameters, consistent with the IOM recommendation supporting the development of clinical practice guidelines and standards of care. Today, over thirty physician organizations are developing practice parameters. In addition to the rapidly expanding activities of the national medical specialty societies and others, the AHCPR is charged with the development of practice guidelines.

The AMA's primary objective for practice parameters is to ensure that they are properly developed and implemented so that patients receive only appropriate, effective, and necessary medical care. To accomplish this goal, the AMA's efforts are being directed primarily toward working cooperatively with other physician organizations to facilitate their efforts to develop practice parameters.

Appropriately developed practice parameters can increase the appropriateness of clinical care. For example, guidelines on cardiac pacemakers, produced by the American College of Cardiology and the American Heart Association, have reduced uncertainty surrounding the appropriate use of cardiac pacemakers and have reduced the use of cardiac pacemakers by approximately 25% in the Medicare population between 1984 and 1988. In addition, the American Society of Anesthesiology developed standards on intra-operative monitoring which have reduced hypoxic injury in Massachusetts from an average of six injuries a year to an average of one injury per year. These examples indicate that practice parameters can be very effective in improving the quality of medical care.

The most significant recent activity in encouraging the development of practice parameters is the establishment of the AMA/Specialty Society Practice Parameters Partnership and Practice Parameters Forum, which provide an open and participatory process for representation of all of organized medicine.

In addition to the activities of the Practice Parameters Partnership and Forum, the AMA has produced various products to encourage and facilitate further development of practice parameters by physician organizations. The AMA has published a

Directory of Practice Parameters developed by national medical specialty societies and others. The Directory contains bibliographic information on over 1100 practice parameters. The AMA also published *Attributes to Guide the Development of Practice Parameters.* These documents have been well-received by the medical profession as useful products to assist them in their development of practice parameters. The AMA also publishes, on a quarterly basis, *Practice Parameters Update,* which lists practice parameters under development and recently completed practice parameters.

CONCLUSION

While the AMA supports a significant number of the recommendations contained in the IOM report, we do not believe that the report adequately documents a need to restructure the entire quality assurance system to improve quality as opposed to implementation of incremental changes in the existing quality assurance system. There is little evidence and no guarantee that a new quality assurance program under Medicare will be less problematic or "adequately" funded from the start, especially in the current economic climate in which programs that we know improve the delivery of quality health care are competing for limited Federal funds.

Although Americans, including the elderly, generally receive high quality medical care, we must continue to expand our efforts to improve the quality of medical care. Improved systems of quality assurance are an important part of this effort. However, strategies to improve quality assurance must acknowledge the complexities inherent in patient care, including the enormous variability among patients, patient clinical status, and patient preferences.

Physicians have long played an active role in efforts to improve the quality of medical care. Future efforts to improve quality assurance must involve physicians and physician organizations in every aspect of the planning and implementation of quality assurance systems. There is no denying that data analysis and outcomes assessment are important. But data will never substitute for clinical judgment or medical peer review. The AMA stands ready to participate in all efforts to identify mechanisms to improve quality of care.

Finally, we believe that many of the recommendations of the IOM study are already being addressed through the efforts of individual physicians, hospitals, the AMA and other physician organizations, the Agency for Health Care Policy and Research, and others. The American Medical Association recommends that the views outlined herein be incorporated in the upcoming Fourth Scope of Work.

RESPONSES OF DR. MCAFFEE TO QUESTIONS SUBMITTED BY SENATOR ROCKEFELLER

Question No. 1. What aspects of the PRO program need to be revised to allow us to concentrate on quality review as well as utilization review?

Answer. Efforts to obtain and use data to assess practitioner and provider performance, with the active involvement of the medical profession, can aid in quality review. Better use of data should be a goal of the PRO program. Existing programs have, heretofore, failed to afford the necessary feedback to physicians regarding the findings and significance of data. As the Maine Medical Assessment Program has demonstrated, the participation of the physician community will result in the compilation and dissemination of meaningful information that may be used to identify and correct existing problems.

The American Medical Review Research Center project, addressing small area analysis of variation in utilization and outcomes of hospital care across geographic areas, is another activity which the AMA supports. The pilot programs engaged in by 12 PROs to review, interpret and provide information to physicians on identified practice patterns will serve to enhance the educational role of the PROs. In addition, we commend HCFA for its focus in the Fourth Draft Scope of Work on geographic analysis of variation in use and outcome which will provide better aggregate information on which to base review decisions. The AMA also has been pleased to accept the invitation to participate with the Health Care Financing Administration (HCFA) in evaluating the components and proposed application of the Uniform Clinical Data Set (UCDS) prior to its full implementation. The UCDS will allow a consistent set of rules and criteria for reviewing medical records.

The AMA is concerned, however, about review activities that have proven to be ineffective, such as preprocedure review. We strongly support the elimination of 100 percent PRO preprocedure/preadmission review of ten surgical procedures as proposed in the Fourth Draft Scope of Work. We further recommend that provisions in the Federal law which authorize such preprocedure review be repealed.

The AMA also recommends modifications to the Quality Intervention Plan (QIP), so that the program may be implemented to achieve educational rather than punitive goals. Under the current model, each PRO is required to perform a quality review and implement interventions when quality concerns are identified and confirmed. Each confirmed quality problem is assigned a weight based upon the degree of harm or potential for harm to the patient according to a three-level severity index. The AMA believes that the creation of five levels of severity, rather than the current three levels, will provide greater flexibility in reflecting interventions that are more appropriate and fair to physicians and their patients.

The AMA has strongly opposed elements of the proposed "quality denial" regulations which would permit the denial of Medicare payment for services that do not meet professionally recognized standards of care. We have called for the establishment of adequate due process safeguards to ensure that quality denials, when made, are warranted. We also oppose notification to beneficiaries of PRO determinations of payment denial based on failure to meet professionally recognized standards of care prior to any reconsideration of the determination which might be requested by the physician. The AMA has additionally urged HCFA to establish an expedited reconsideration process for quality denials. Until the cited practitioner has obtained a timely PRO reconsideration of the determination and exhausted rights to provide additional information and judicial review of an adverse reconsideration decision, a beneficiary should not be notified of a quality denial.

Question No. 2. Do you think that physicians feel that our current PRO program is concerned at all about quality or do they feel it is entirely budget driven as a cost containment device?

Answer. In November 1989, the AMA conducted a survey of physicians' opinions on Peer Review Organizations. The sample revealed that 60 percent of the physicians polled were of the opinion that their local PRO emphasizes cost containment, 10 percent stated that it emphasizes quality, and 30 percent said that the emphasis is balanced between cost containment and quality. These results would indicate that a majority of physicians regard PROs as placing an emphasis on cost containment, rather than quality.

We think the program needs to change this perception, and we laud ongoing efforts. The AMA commends HCFA for a number of proposed changes in the review program which will highlight quality issues. We have, however, raised several concerns regarding a number of aspects of quality review as proposed in the Draft Fourth Scope of Work. In order for the PRO activity to act as an educational mechanism, enhanced efforts focusing on quality must become paramount.

Question No. 3. Can you enlighten me further on where we stand with the development and implementation of practice guidelines?

Answer. Establishment of processes for the development, dissemination and implementation of practice parameters is well under way. The first step toward advancing these goals was the establishment of the American Medical Association/Specialty Society Practice Parameters Partnership and Practice Parameters Forum. The Practice Parameters Partnership, comprised of the fourteen largest medical specialty societies and the AMA, establishes a cooperative activity for the purpose of guiding and coordinating the activities of the medical profession in practice parameters activities. The Practice Parameters Forum, with active participation of over 65 medical specialty and state medical societies, provides the broad base of scientific and clinical expertise necessary for the development, dissemination, and implementation of practice parameters.

As part of its initial activities, the AMA, in conjunction with the Practice Parameters Partnership and Practice Parameters Forum, developed *Attributes to Guide the Development of Practice Parameters.* The *Attributes* describe the components of scientifically sound, clinically relevant practice parameters that are applicable in the day-to-day practice of medicine. To facilitate relevant physician organization review and comment on practice parameters during their development, the AMA compiles and distributes "Practice Parameters Update," a quarterly publication that identifies: practice parameters recently completed by physician organizations; plans of physician organizations to develop practice parameters; and recently rescinded practice parameters. The most recent issue of the "Update" identified 200 practice parameters currently under development by physician organizations and others.

To further enhance dissemination and implementation of practice parameters, the AMA compiles and publishes the *Directory of Practice Parameters.* The *Directory* is a bibliography, organized by subject matter, sponsoring organization, and publishing source, of over 1100 medical practice parameters developed by physicians' organizations and others.

As the efforts of the AMA and other physician organizations to develop and disseminate practice parameters progress, practice parameters will provide an important foundation for the review criteria and clinical algorithms used by PROs.

Question No. 4. In what way is organized medicine willing to help us control the concerns about over/under utilization of services?

Answer. The AMA and medicine have taken a leading role in the development of practice parameters, as indicated in the response to Question No. 3. The primary objective of this activity is to ensure that clinical practice parameters are properly developed and implemented so that patients receive only appropriate, effective and necessary medical care. Over 30 physician organizations are developing practice parameters designed to increase the appropriateness of clinical care. For example, guidelines on cardiac pacemakers, produced by the American College of Cardiology and the American Heart Association, have reduced uncertainty surrounding the appropriate use of cardiac pacemakers and have reduced the use of cardiac pacemakers by approximately 25 percent in the Medicare population between 1984 and 1988.

The AMA supports HCFA's efforts to make the PRO program's assessment of quality more systematic and consistent. We encourage PROs to provide pattern analysis feedback in aggregate form to the physician community for educational purposes at the national, state and local level so that appropriate educational programs can be created.

Additionally, the AMA is working with HCFA to develop guidelines that will ensure that the content of medical records will provide the most accurate documentation by incorporating improved methods of recording patient information. This approach will ensure that payment decisions are based upon sound medical record data.

Question No. 5. How can we adapt the process of quality review to the post-hospital, ambulatory setting without increasing the "hassles" to physicians?

Answer. The AMA opposes mandatory PRO review of ambulatory care. However, the AMA believes that if PROs undertake review of physician office care, it should be targeted and cost-effective rather than all inclusive in nature. The AMA has proposed several ways to focus ambulatory review. First, Medicare carriers could monitor claims of ambulatory services to target for PRO review physicians for whom the frequency or type of claims deviate significantly from those of their peers. Second, PROs could review the office care of patients who have required hospitalization because of suspected improper ambulatory care. Third, PROs could review office records of physicians whose care of their hospitalized patients has been formally judged to be deficient. Last, PROs could review office records of physicians who have been identified as providing care of substandard quality, e.g., those who have been the subject of formal disciplinary action by a state medical licensure or disciplinary board, or by a hospital review committee.

If any system of physician office review is implemented, the AMA strongly believes that it must be done in a form that: (1) results in minimal intrusion in the care process and the physician-patient relationship; (2) avoids markedly increased administrative burdens and costs to physicians; (3) avoids inappropriate disclosure of confidential medical information; and (4) emphasizes education rather than punitive interventions. It has been documented that to be successful, results of focused review need to be followed by effective, thoughtful and strongly supported interventions to reduce unnecessary use and enhance quality. If ambulatory review efforts are funded by Congress, the AMA urges that such funding be allocated for non-punitive educational interventions which address quality and utilization concerns.

Question No. 6. What alternatives are there to extending the quality review process to the ambulatory setting that still allow us the opportunity to enact a program that will improve quality and efficiency in this setting?

Answer. As indicated in the response to Question 4, the AMA supports efforts to provide pattern analysis feedback in aggregate form to physicians in order to create educational programs at the national, state and local levels. The involvement of practicing physicians in all aspects of data evaluation is critical in order to ensure the reliability and credibility of data collection efforts. The type of information that can be gleaned from this approach will be far more effective than efforts targeted toward physician office review. Those demonstration projects which are being conducted currently in physicians' offices will require careful analysis before any consideration can be given to the expansion of physician office review.

The AMA also is active in another private sector quality review process, as a parent organization of the Joint Commission on the Accreditation of Health Care Organizations. The Joint Commission has launched an Agenda for Change with the goal to restructure its survey and accreditation procedures. The AMA has also been involved in the Joint Commission's continuous quality assurance program to assure

that quality of care is received by patients in accredited institutions. Our involvement in this private, voluntary activity reflects physician commitment to seeing that the needs of our patients are met.

PREPARED STATEMENT OF SENATOR DAVID PRYOR

Good morning. Chairman Rockefeller, I would like to commend you for holding this very important hearing on the issue of quality assurance in the Medicare program, and on the Institute of Medicine's report: *Medicare: A Strategy for Quality Assurance.*

There is no question that we have a long way to go to ensure that we have quality care across the board for Medicare beneficiaries. As Chairman of the Special Committee on Aging, I continue to receive alarming reports of poor care, inappropriate and premature discharges from hospitals, and other quality complaints.

The Institute of Medicine is to be commended for a thorough evaluation of the adequacy of our current methods for measuring, reviewing, and assuring quality of care. I look forward to working with this Committee to review the recommendations of the Institute of Medicine report. It is a valuable document and deserves close study.

Medicare's Peer Review Organizations (PROs) review the services provided under the Medicare program. Since their creation in 1982, the role and responsibilities of PROs have expanded from a primary focus on inpatient hospital services to services provided in other settings. I believe that the time is ripe for the Congress to review the past performance of the PROs as well as their future role.

With my Aging Committee and Finance colleagues, I intend to work to study the role that PROs can and should play in monitoring care in the Nation's hospitals and doctors' offices, as well as in nursing homes and other long-term care settings.

I am pleased to join you, Chairman Rockefeller, in this important effort. I look forward to hearing the testimony of all of our witnesses today.

PREPARED STATEMENT OF GAIL WILENSKY

Mr. Chairman and Members of the Subcommittee: I am pleased to be here today to comment on the Institute of Medicine's report on assuring quality in the Medicare program.

Tremendous improvement has been made in recent years in the area of health care quality assurance. HCFA has been at the forefront—initiating and supporting many projects to enhance health care quality. As a result, we are poised to chart a new direction in monitoring and improving quality within the Medicare program.

Peer review organizations (PROs) are Medicare's principal vehicle for monitoring the quality of health services provided to beneficiaries. To meet the changing needs of our health care system, we plan to transform the PRO review process as we know it today. Over time, case-by-case review of medical records will be replaced by a process that looks at the use and outcomes of various types of care. The PROs will disseminate the utilization and outcomes information to the medical community as part of their feedback and education efforts. Providers could then use the information to modify practice behavior and to improve internal quality assurance operations.

The Institute of Medicine (IOM) report, "A Strategy for Quality Assurance in Medicare," affirms that we are headed in the right direction. The IOM recommends that the PROs stop performing medical record review in favor of an approach that includes monitoring and analyzing the health status, utilization patterns, and outcomes of care for the Medicare population. These recommendations are entirely consistent with our efforts to move the PRO program beyond detection of inappropriate care to a comprehensive system of quality assurance. We have made considerable progress in developing the framework and scientific tools which are needed to institute these changes.

BACKGROUND

Our current efforts continue the evolution of quality assurance activities under the Medicare program. Initially, the utilization review committees of individual hospitals were responsible for quality concerns. In 1972, Congress created the Professional Standards Review Organization (PSRO) program to add a level of peer oversight to the process.

The PSRO program was phased-out in the early 1980s and replaced by the Utilization and Quality Control Peer Review Organization (PRO) program. PROs are charged with ensuring that services delivered to Medicare beneficiaries are necessary, appropriate, and meet standards of quality. When Congress enacted the PRO legislation, Medicare's hospital reimbursement mechanism was changing to prospective, diagnosis-related payment. As a result, the PROs' early efforts were aimed at detecting inappropriate utilization of services and premature discharge.

The PRO review process continued to evolve throughout the 1980s. PROs lessened their initial emphasis on inappropriate utilization and started to pay more attention to quality issues. For example, in 1984, PROs began to focus review on identified problem areas rather than broadly reviewing the general use of services. In 1986, generic quality screens were instituted to identify cases that were potential quality problems. Generic screens look at cases involving the medical instability of patients at discharge, unscheduled returns to surgery, trauma suffered in the hospital, and deaths.

Congress intended that the PRO program use local review by peers. It was noted that local physician Practice patterns, the availability of resources, topography, and social norms resulted in geographic variation in the provision of health care. Today, wide variations in practice patterns are being questioned PROs need to be better equipped to identify inappropriate patterns of utilization and outcomes, and to be better able to help correct inappropriate behavior and improve medical practice by sharing such information with the medical community.

We have invested a great deal of time and energy into pursuing a long term strategy for the PRO program. HCFA has undertaken several major activities that will provide a framework for changing to a more progressive approach of quality review.

EFFORTS TO IMPROVE MEDICARE QUALITY REVIEW

For this new approach to be successful, the PROs will rely upon new, comprehensive data bases and sophisticated data analysis. The PROs will use the results of their analysis to support their provider communication and education efforts. We are encouraged by our progress and would like to share with you our activities to date.

Uniform Clinical Data Set.—An important part of our effort to transform the peer review process is the development of the Uniform Clinical Data Set. The UCDS was designed by a task force, which included representatives from the American Medical Association and the American Hospital Association. UCDS is a state-of-the-art computer system which will permit us to gather, develop, and analyze extensive clinical data.

Currently, the initial screening of medical records is done manually by nurse reviewers and may vary from PRO to PRO. In the near future, PROs will use the UCDS to abstract detailed clinical data—up to 1600 relevant data elements—from medical records under review. The UCDS would then subject the abstracted clinical data to computerized quality screens in order to identify cases needing further review by a PRO physician. The UCDS will standardize the initial review process and provide PRO physicians with more organized information on which to base their decisions.

In 1989-90, the UCDS was field tested in 9 PROs. Based on this experience, several modifications were made to reduce the abstracting time and to improve the screens which prompt further medical review. Currently, the UCDS is being phased in at 7 PROs, and we expect that the system will undergo further development before it is implemented in additional PROs. We anticipate that all the PROs will be conducting review using the UCDS by October 1993.

In addition to screening for quality problems, the UCDS data base will also serve other functions. Linking UCDS to currently available Medicare claims data will allow PROs to evaluate patterns of care and patterns of outcomes, adjusted for the condition of patients. This large data base will also provide an abundance of information to researchers and the medical community on the effectiveness of various treatment modalities and surgical procedures.

Medical Epidemiologic Software and Hardware Tools.—A major part of our transition to an outcomes-oriented approach to quality review is the development of extensive computer capacity to do the necessary analysis. PROs will need the capability to analyze existing Medicare claims data as well as the emerging clinical data base.

We have entered into contracts with the Wisconsin PRO and its subcontractor, the Medical College of Wisconsin, and the New Hampshire PRO and its subcontractor, the Dartmouth School of Medicine, to develop and test standardized computer hardware and software. In addition, we are exploring the feasibility of establishing,

in certain areas of the country, lead PROs to become what in effect will be regional analysis and training centers.

Analysis of Geographic Variation.—In 1987, we started a project to familiarize the PRO community with a new method of quality review using geographic variation analysis. Twelve PROs participated in the project which involved computer analysis of hospital utilization data by geographic areas in their individual State. This geographic variation analysis permits PROs to detect variations in patient outcomes by procedure and diagnosis, with an eye toward identifying "potential" quality problems.

The project also was intended to acquaint the PROs with the use of geographic variation analysis as a feedback mechanism to educate the medical community. The PROs gained experience in using the results of geographic variation analysis to inform hospitals and physicians of how their utilization and outcomes differed from the norm in order to modify practice patterns.

We are also using geographic variation analysis with other health data to identify quality problems. For example, we have begun analyzing mortality rates, readmission rates, duration of hospitalization, and hospital expenditure data for 38 conditions and procedures. This information will be analyzed by hospital market areas, metropolitan statistical areas, counties, and entire States and provided to the PROs to be used in conjunction with their current review efforts. It is our hope that the PROs will have the capability to conduct this type of analysis for themselves in the rear future.

These projects are the cornerstone of our transition to an improved PRO program. The formation of an extensive clinical data base, the linking of Medicare claims data, and the development of epidemiological hardware and software are essential to a comprehensive, systematic approach to quality review.

There are other benefits in transforming the current PRO review process. A standardized review process improves the reliability of measuring and comparing PRO performance, and the effect PRO review has on the delivery of high quality health care.

OTHER QUALITY EFFORTS

I would like to briefly touch upon a few of our more recent quality activities.

Quality Review in Noninstitutional Settings.—We are also in the process of designing quality assessment tools to be used in physician offices. Currently, we do not review the quality of care Medicare beneficiaries receive over time or in noninstitutional settings such as physician offices.

Seven PROs are involved in an extensive project, which began in 1989, to characterize patient risk factors, therapeutic interventions, and the effect of the care on the patient's health in noninstitutional settings. Thirteen medical conditions are under study. This project will be completed in late 1991.

In another project, we contracted with 3 PROs last September to develop an approach to review quality of care in physicians' offices using available Medicare claims information. The project also will develop methods to review the adequacy of medical records documentation and to conduct broad-based assessment of clinical performance for common conditions, tests, and treatments. This project will be completed in three years.

Coordination with AHCPR.—We are also coordinating several activities with the Agency for Health Care Policy and Research (AHCPR). AHCPR is responsible for outcomes research, technology assessment, and development of practice guidelines. We are working with AHCPR to determine how PROs could assist in the dissemination and evaluation of practice guidelines. However, practice guidelines are only effective if they are broadly applicable to and used, as with outcomes research, by the medical community to educate and improve practice behavior.

Because HCFA has extensive Medicare data bases, we have also entered into an agreement with AHCPR researchers to transfer special data tapes for use in their outcomes research. We are working with AHCPR to further investigate building and maintaining data for use by the Department and the public.

Managed Care.—PROs are also responsible for monitoring quality in HMOs that contract with the Medicare program. HCFA is developing a new protocol for PRO review of HMO services. The current process of using Medicare hospital claims, or "no-pay" bills, does not produce the information needed to evaluate individual HMOs or the HMO program.

The proposed PRO review of HMOs will replace "no-pay" bills as the data source with an improved sample methodology based on enrollees who have used HMO services. The new review process will allow the PROs and individual HMOs to target problem areas and to emphasize problem resolution. This approach will maintain a

quality standard for HMOs consistent with the standard applied by PROs to other institutions.

IOM REPORT ON MEDICARE QUALITY ASSURANCE

The direction of the IOM report parallels what we have been working on for the last four years. We agree with the IOM that the current PRO review process needs to focus medical review on the effectiveness of care, and that additional quality and outcomes research is needed.

We question two of IOM recommendations. The IOM recommends that, in order to improve oversight of Medicare quality review, several new advisory councils should be created. We work with researchers, academicians, and medical interest groups as needed because we recognize the need for scientific and technical guidance in the development of our programs. Additional administrative layers would needlessly complicate and disrupt the progress we have made to date. I believe that additional oversight would hamper our efforts to remain on the cutting edge of health care quality assurance.

The IOM recommends doubling the current funding to at least $600 million per year. We do not expect that our continued efforts will need major budgetary increases. We believe that it is both unrealistic to expect additional funding in light of current financial constraints, and unnecessary given the progress we have already made under current funding levels.

CONCLUSION

Mr. Chairman, we are challenged with assuring the quality of health care services delivered to Medicare beneficiaries. The IOM report affirms my belief that we are on the right track in our efforts to improve the PRO program.

Achieving an effective, comprehensive quality review system within Medicare may have implications for our nation's health care system as a whole. Improving and building upon existing structures will avoid needless disruption in the progress we have already made in the area of health care quality. I believe that the speed with which we can make some of these changes will only increase as we move forward with implementation.

We believe HCFA and the Department have demonstrated that assuring quality care to Medicare beneficiaries is one of our highest priorities. I look forward to working with Congress, interested health care organizations, and the PROs to further improve the quality of health care for our nation's elderly and disabled.

Thank you. I will be happy to answer any questions you may have.

RESPONSES OF GAIL R. WILENSKY TO QUESTIONS SUBMITTED BY SENATOR ROCKEFELLER

Question No. 1. Can you specifically address the IOM definition of quality and how you see the PRO providing that degree of quality review now and in the future?

Answer. The Institute of Medicine defined quality of care as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." The IOM includes very specifically within its definition of quality the importance of outcomes. Most quality review today, including PRO review, focuses on structure and process.

The Health Care Financing Administration is engaged in developing a systematic approach of quality assessment to address deficiencies in the current process, which is not uniform or consistent. The new process will give the PROs the capacity to analyze all care, not just a sample of cases, in ways which focus on the outcomes of care. The objective is to enable the PROs to characterize patterns of use and patterns of outcome in their jurisdictions and to draw inferences about the performance of providers of medical services.

The analytic techniques under development will assess the risk of particular outcomes for patients with various clinical conditions and the extent to which those outcomes are different from the national experience for similar patients. Outcomes will be analyzed using survival models which assess long term and short term outcomes as well as the extent to which the risks of those outcomes change over time. A variety of outcomes will be analyzed including, mortality, morbidity, readmission to the hospital, length of stay, use of nonhospital ambulatory services, disability and expenditures. Other outcome measures can and will be developed over time; however, for the initial work these measures were chosen because they are readily available from existing Medicare data files.

Such a system will allow us to measure the impact of treatment options on the health outcomes of patients and to determine which treatment interventions produce appropriate outcomes, or conversely which services provided to Medicare

beneficiaries are appropriate—as judged by the outcomes produced. Without a systematic approach to analysis, the judgment about appropriateness of services—be they hospital admission, or particular surgery, or various medical services—can not be made reliably.

Question No. 2. Do you think that the Medicare program should become responsible for guaranteeing quality in the Medicare program as defined by the IOM?

Answer. Assuring the quality of care for Medicare beneficiaries is one of the Health Care Financing Administration's main responsibilities. We are confident that the direction we have chosen for the PRO program will ultimately result in a quality assurance program based on health outcomes and current professional knowledge regarding treatment modalities and technology.

Question No. 3. What can we do to more meaningfully promote quality and efficiency among health care providers in a positive manner?

Answer. For the short term, we plan to supply PROs with data about outcomes of care in their State. The PROs will share the data reflecting geographic variations with the physicians and providers in the community. We believe that this sharing of information about practice patterns and outcomes, as opposed to information about individual occurrences of poor quality, in a cooperative manner will lead to promotion of better quality health care.

In addition, we are working out an agreement with the Agency for Health Care Policy and Research to involve the PROs in the development of review criteria based on clinical practice guidelines and the dissemination of both guidelines and review criteria to the health care community. These practice guideline, and the criteria developed as a result, will do much to improve the quality of care.

Question No. 4. What elements of the current utilization review mechanism should be kept and which should be modified to achieve the goals outlined in the report?

Answer. We are in the process of developing the PRO fourth scope of work which will go hand-in-hand with our efforts to redirect the PRO program. As part of the fourth scope of work, we plan to implement the Uniform Clinical Data Set (UCDS). This "expert system" is a data collection and case review system for capturing inpatient hospital clinical data. The objective of the UCDS is to systematize the first level of the peer review process, and make it more consistent, objective, and reproducible.

Implementing UCDS as part of the fourth scope of work will move us to a more outcomes-oriented review as recommended by IOM. Redirecting the PROs to look at patterns of care and outcomes will allow them to use the information to improve the average level of performance of providers, another recommendation of IOM. Therefore, the current method for informing providers of their performance will be modified so that it is less adversarial and more cooperative.

In terms of modifying specific review categories, we are reviewing the third scope of work to determine what changes should be made to eliminate those categories which have not been productive. For example, the Office of the Inspector General has recommended that preadmission review be eliminated as not productive and we are considering this recommendation. There are also other, more minor, review categories that have not been effective as we would have liked and so we are also considering eliminating them.

Question No. 5. The IOM states the need for monitoring the continuum of quality of care, including post-hospitalizations. Where do you stand with the pilot projects you instituted to monitor this phase of the health care system?

Answer. We strongly agree with the IOM that it is essential to redirect PRO review to look at the continuum of care, rather than individual episodes of treatment. This will be accomplished through requirements in the fourth scope of work as well as through pilot projects. For example, in the new scope of work, the PROs will be reviewing a beneficiary-specific random sample of cases, instead of a provider-specific sample. This will enable the PRO to track beneficiaries over time and arrive at valid conclusions about the health care they receive. All of the care those beneficiaries receive, except for care rendered in physician offices, is subject to review.

Similarly, the first group of PROs will begin using the UCDS beginning April 1, 1992. The UCDS will enable us to match clinical data with data from other Medicare files, thereby enabling the PRO to perform detailed longitudinal analysis. This will, over time, lead the PRO program toward a broader based epidemiologic analysis of health outcomes as envisioned by the IOM.

Our pilot programs clearly are designed to provide data necessary to study patients over the continuum of care. We have two projects well underway which we expect will give us the necessary information to review patient care provided in

physician offices and other ambulatory settings. In both cases, PROs have joined with academic medical experts to develop this information, and in both cases the approach is educational rather than regulatory.

The Wisconsin Peer Review Organization has a two-year contract to review care in ambulatory settings, which will be completed in September 1992. Data will be abstracted from patient records on 13 medical conditions that are commonly found in the Medicare population. Evaluation of risk-adjusted outcomes for these conditions will provide clues as to which patterns of interventions are likely to affect patient outcomes significantly.

The Delmarva Foundation for Medical Care (the Maryland PRO) was awarded a three-year project on December 1, 1990 to do claims profiling and medical record review in physician offices. Primary care physicians will be compared to their peers on the adequacy of record documentation and performance of routine clinical functions such as testing, prescribing and monitoring drugs, procedures and diagnoses. We believe that the results we obtain from these two projects will enable us to implement an effective system of ambulatory care review.

We have recently funded a pilot project with the Massachusetts PRO and 3 leading clinics (Cleveland, Lahey, and Ochsner) that will conclude in March 1992. The purpose of the project is determine whether specific interventions can be identified that maximize the quality of outcomes for beneficiaries with diabetes and hypertension. The emphasis in the project is evaluating the continuum of care, including ambulatory care and related inpatient admissions, in the clinics.

In addition to these projects, we have pilots that will enable the PROs to obtain the hardware and software necessary to conduct epidemiological analysis. In November 1990, we began a three-year project with the New Hampshire Foundation for Medical Care. That PRO is working with the Dartmouth Medical School in designing a "Biostatistical/Epidemiologic Workstation" which will help the PROs perform longitudinal outcome studies. In addition, the Arizona and Connecticut PROs are working with the Medical College of Wisconsin to design and test a hardware and software system that could enable PROs to perform longitudinal analysis more effectively.

We will continue to encourage the PROs to submit innovative proposals for pilot projects in this area.

Question No. 6. Has there ever been a formal review of the PRO program to evaluate its effect on either utilization and/or quality of care in the Medicare program? Do you think that such a review would be worthwhile?

Answer. HCFA formally evaluates the accuracy of PRO reviewer determinations through the Peer Review Organization Monitoring Protocol and Tracking System (PROMPTS). PROMPTS, is used to evaluate ongoing contractual performance.

HCFA further validates PRO reviewer determinations by means of a contract with the "SuperPRO," an organization of health care professionals whose responsibility is to review the accuracy of PRO determinations and provide HCFA with an independent, professionally recognized evaluation of PRO medical determinations.

In addition, there have been several ad hoc evaluations, performed by the Office of Inspector General, the General Accounting Office, and others. However, there has never been a systematic, thorough evaluation of the impact of the PRO program on the utilization and quality of care or on the health status of the Medicare population. Such an evaluation is the only way to assess the true impact of the program. The changes that we are making to the program at this time will enable us to assess the impact of PRO review on the outcomes of care received by the Medicare population.

Question No. 7. What are your plans for the next scope of work of the PRO?

Answer. We are in the process of developing the fourth scope of work. We are performing a zero-based analysis of the various review categories of the third PRO scope of work to determine whether or not they are productive in finding quality problems. Review areas may be retained, modified, deleted, or added. For example, areas which have not produced satisfying results, such as review of some specific DRGs, could be dropped.

The UCDS and requirements to engage in analysis of geographic variations in patterns of use and outcome will be implemented during the fourth scope of work. The implementation of these tools will move the PRO program into the arena of analyzing outcomes of care on a longitudinal basis.

Question No. 8. Do you think that ProPAC and PPRC could be of assistance to you in developing a quality of care evaluation and research program for Medicare?

Answer. The Prospective Payment Assessment Commission considers issues related to maintaining quality of care as a significant part of its mission. ProPAC examines the effect of the prospective payment system on quality and access. Therefore,

ProPAC already plays a important role in helping identify issues related to payment that may affect quality within the Medicare program.

The Physician Payment Review Commission has not focused on a quality objective. However, due to the Omnibus Budget Reconciliation Act of 1990, the PPRC has been given the role of investigating issues related to utilization review and quality of care, including the effectiveness of peer review procedures and other quality assurance programs applicable to physicians. PPRC's new responsibility for making recommendations to Congress regarding quality issues will give us additional insight into ways to improve quality programs in Medicare in the future.

Question No. 9. What role do think AHCPR can or should play in developing and monitoring a strategy for improving quality in the Medicare program?

Answer. The Agency on Health Care Policy and Research is responsible for outcomes and medical effectiveness research, technology assessment, and development of practice guidelines. We are working with them to determine how the information on appropriate medical practice reflected in the clinical guidelines can be incorporated into PRO review. We have also entered into an agreement with AHCPR researchers to transfer Medicare data tapes for use in their outcomes research. Their work in practice guidelines and outcomes research is essential in the development of a quality program which mirrors what was recommended by IOM.

Prepared Statement of G. Rodney Wolford

INTRODUCTION

Mr. Chairman, I am G. Rodney Wolford, President of the Alliant Health System in Louisville, Kentucky. I am pleased to be here today on behalf of the American Hospital Association and its nearly 5,500 member hospitals to lend our support to the recommendations in the report entitled Medicare: A Strategy for Quality Assurance, prepared by the Institute of Medicine's Committee to Design a Strategy for Quality Review and Assurance in Medicare (the IOM Committee).

This is an important and timely study. Quality management has moved to the center of healthcare concerns for both the purchaser and provider. New resources are becoming available to hospitals and more are needed to allow them to analyze their own performance, compare their performance to other hospitals, and improve their management of quality. The Committee report is an excellent survey of these exciting changes and fashions a stimulating vision for the future efforts of the Federal Government to support provider efforts to enhance the quality of health care offered to Medicare beneficiaries.

Medicare has traditionally approached quality assessment through structural and procedural standards—two of the three classic components (structure, process, and outcome) of traditional quality assessment. The Conditions of Participation, which prescribe the organization of institutional resources, are meant to provide insight into the facility's potential to furnish good quality care. The Peer Review Organization (PRO) program, using detailed review of individual medical records by trained reviewers, assesses the appropriateness of care. Missing has been an analysis of the processes and variations in treatment along with the actual outcomes of care. The centerpiece of the IOM Committee's report is the incorporation of process and outcomes studies into Medicare's quality assurance program so that the three components of quality are integrated.

By placing effectiveness at the core of Medicare's assessment activity, this new strategy would allow Medicare to develop coverage policies that reflect what is known about effectiveness and appropriateness. The generation of a body of reliable clinical information that describes institutional performance would enable Medicare to initiate competitive reforms that would make the system more efficient.

The Committee's recommendations sketch a long-term vision of the development of a Medicare quality assurance program. We endorse this vision. The 10-year implementation proposed by the Committee will be required along with a solid commitment of resources. Adequate resources for research and demonstration projects are essential for the construction of this new process. The difficulty of developing and perfecting the techniques of outcomes analysis, and of building the necessary expertise throughout the health care system, at hospitals and among PROs, to analyze and use the data, should not be underestimated.

We believe the IOM's recommendations could be positive but may be more elusive than the Committee seems to expect. In the following statement we would like to:

- discuss some implications of the more far-reaching recommendations;

- describe a few private sector activities that are moving the hospital community in a similar direction;
- discuss briefly some HCFA initiatives that appear to be working toward the goals outlined in the IOM study, but note a few of their limitations; and
- note some general concerns about expectations for what outcomes research can do at the present time.

We close by highlighting some of the short-term strategies recommended by the IOM that we believe would be productive for Congress at this time.

IOM RECOMMENDATIONS

A New Mission for Medicare

The most far-reaching of the Committee's recommendations is its first: to broaden Medicare's quality assurance mission. The Committee proposes that the goal of the Medicare program be to "assure the quality of care for Medicare enrollees."

This is a major departure from the traditional role laid out in the Medicare statute. Medicare was conceived as an insurance program, not a health program. Providers are not compelled to participate, but do so under an agreement as willing, independent, autonomous "contractors." The health and safety standards in the Medicare "Conditions of Participation" are contractual obligations. They are designed to avoid payment for substandard services but keep a respectful distance from the private practice of medicine and the independent management of private organizations.

The PRO program reflects the economic model that has driven Medicare's approach to quality review. PROs make a medical judgment about whether a specific statutory coverage criterion has been met—whether individual cases are medically reasonable or necessary and therefore warrant payment by Medicare.

The IOM Committee's proposal would change the relationship Medicare and providers. It would change the expectations Medicare has for providers and would change public expectations for the Medicare program.

The IOM Committee expects Medicare to take an active role in directing and molding the evolution of medical practice, but not by interfering in clinical decisionmaking. The Committee intends Medicare to analyze and evaluate the overall impact of Medicare services but leaves to providers and practitioners the responsibility for assuring that quality care is provided to individual patients. This is fitting. Medicare would monitor, evaluate, and provide information to providers about the overall effect of their performance on patient outcomes.

The Committee chose its words carefully in defining quality as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." It proposes to look at the quality of "health services" rather than provider services; to evaluate the overall impact of these services on the Medicare population rather than rely on the microanalysis of individual cases as is currently done by PROs; and to judge medical decisions on the basis of their "likelihood" or probability of improved outcomes.

Because the IOM Committee's strategy is patient-centered rather than provider-centered, it would require Medicare to follow beneficiaries through the continuum of care and would not allow the current fragmentation of Medicare's quality assurance activities according to arbitrary provider classifications.

While the Committee appears to call for a shift from utilization review to quality assurance, quality assurance is defined to include the notion of clinical appropriateness. Utilization review would still be performed, but it would rely on standards of clinical appropriateness and would consider the underuse of services as well as overuse. Thus access would become an explicit component of Medicare quality assessment.

We support the definition of quality proposed by the IOM Committee but would emphasize one point. The Committee deliberately declined to consider resources as a factor in the definition of quality, arguing that Medicare should not feel constrained to work within existing resources because added resources may be called for to improve the overall ability of the Medicare program to meet the health care needs of its enrollees.

We agree that resources should not be part of the quality definition but wish to emphasize resources as an important dimension of quality. Although many quality issues are not related to resources, a deficiency in resources to acquire the necessary services can create a quality problem for the beneficiary. This is precisely why we believe resources should become an explicit dimension of the definition of quality—not to accept those constraints, but to understand their effect. Resources must be

considered in the evaluation of clinical decisions because resources can constrain patient care decisions and the future creation of knowledge.

Making Efficient Use of Institutional Quality Assurance

The American Hospital Association has long advocated an approach to external monitoring that builds on, rather than substitutes for, the hospital's internal quality assurance mechanisms. The IOM Committee's proposal would implement such a system, monitoring differently at the system level than at the institutional level. This stands in marked contrast to the system that exists today.

PROs review the medical appropriateness of individual cases in the same way hospital medical staffs review their own cases in their utilization and quality review committees. Consequently, Medicare duplicates the physician's decisionmaking process (with the advantage of hindsight) and questions the management of individual patients rather than assessing the overall performance of the institution with respect to its patient population. This is the source of understandable resentment among clinicians.

By contrast, the IOM Committee's strategy would use the positive overall performance of providers as the foundation for external monitoring. It would respect the capability of the institution to control the process of care internally, however the thrust of the proposal would encourage hospitals to intensify their efforts to identify and improve their processes of care. The strategy calls for epidemiologic monitoring of provider performance through the analysis of outcomes data. The result of these analyses would be shared with providers, leaving to them the responsibility for reviewing it and taking appropriate corrective action. The external review organization's role would be to assess the ability of the institution to manage quality effectively and to intervene only when the institution appears unwilling or unable to do so.

This model would substitute an educational model of continuous quality improvement for the conventional attempt to "inspect" quality into the system by isolating and eliminating the individual provider or practitioner who performs badly. It will be asked whether this approach can be reconciled with the current regulatory mindset that measures its effectiveness in sanctions and penalties. Clearly we need a process for identifying the egregious violation and eliminating those providers and practitioners who are a danger to their patients or are unwilling or unable to better themselves. But building a quality assurance system solely on inspection and enforcement is likely to be less effective than a model based on the open sharing of information and consensus development about the best approaches to improving the process of care.

Administrative Oversight of HHS

The Committee recommends that Congress create two new entities to supervise, coordinate, and support Medicare's quality review and assurance activities at the national level. Analogous to the Physician Payment Review Commission and the Prospective Payment Assessment Commission, the proposed Quality Program Advisory Commission would report to Congress on Medicare's quality assurance activities. To assist in the implementation and evaluation of the new quality review program, the Committee also suggests the creation of a Rational Council on Medicare Quality Assurance within the Department of Health and Human Services.

While we are concerned about the many administrative layers proposed by the IOM Committee to support, oversee, and evaluate Medicare's quality assurance activities, we do believe there is merit to the creation of an external body accountable to Congress through which the issues of access, affordability, and effectiveness would be publicly confronted and debated. Such a Commission would provide information about the impact of cost-containment measures on the ability of providers to furnish high-quality care and could provide guidance to Medicare as it seeks to make its coverage rules more cost-effective.

PRIVATE SECTOR INITIATIVES

A great deal is being done in the private sector to develop the techniques and resources that are necessary to make the IOM Committee's strategy possible. The hospital community is eagerly embracing new techniques for quality management derived from industrial models of quality assurance. These methods of "continuous quality improvement" place quality enhancement at the top of the organization's management priorities and use statistical profiles and analysis of variance to identify areas where quality review activities can most profitably be focused.

My organization, Alliant Health System, has successfully implemented such a system. We have seen it work. Our medical staff has developed consensus on 140

clinical protocols to define the process of care and guide physician decisionmaking. We have reduced variations in clinical practice among our medical staff and in doing so have improved the quality of care. At the same time, we have reduced length of stay and charges per case. Group action and knowledge sharing produce better care, less expensively, than our old inspection model ever did.

At the same time, several national programs are developing the techniques of outcomes analysis. For the past two years the Quality Measurement and Management Project (QMMP) of the AHA's Hospital Research and Educational Trust has demonstrated the commitment of the hospital community to exploring new ways to address practical issues of quality management. Sponsored by a coalition of multihospital systems representing nearly 2,000 hospitals, QMMP has been developing tools to help hospitals monitor and measure quality. QMMP member hospitals have received a model for "integrated quality assurance;" a management model for "continuous quality improvement;" and risk-adjusted comparative outcomes reports for acute myocardial infarction (heart attack) and transurethral resection of the prostate, along with a videotape and case studies to help them learn how to use the data.

This idea is already taking hold in the private sector. The Joint Commission's "Agenda for Change" will restructure its survey process using a similar feedback model. Institutions will be provided with information about clinical outcomes to raise their awareness of where their problems might lie and will then be judged on their ability to resolve identified problems.

In a similar vein, the Joint Commission's Agenda for Change would shift its focus from assessing the institution's potential to assessing its actual performance on the basis of selected outcome measures. The Agenda for Change calls for development of clinical indicators, data base development, development of mechanisms for data feedback to providers, and new standards and survey processes that focus on overall effectiveness of the institution's quality management.

Also encouraging hospital use of outcomes is the Maryland Hospital Association's clinical indicator project, which now has enlisted over 400 hospital subscribers in several states as well as some hospital systems. MHA collects information on such indicators as infections, mortality, and readmissions and reports back to hospitals their own and average rates for hospitals of similar size and type.

These projects are at the forefront of the movement to integrate outcomes into hospital quality assurance programs, but they are in their infancy. These projects are demonstrating how difficult it is to determine what sort of information will be most useful to institutions in managing the quality of the services they provide. Although enormous progress is being made, the time line for the process of developing the techniques, testing them, and evaluating their effectiveness is likely to be long.

HCFA INITIATIVES

HCFA has undertaken several activities that appear consistent with the epidemiologic approach to quality monitoring outlined by the IOM Committee, including the annual analysis of patterns of mortality and the ambitious Uniform Clinical Data Set (UCDS), which will automate case selection and standardize current methods of peer review, and will generate a sizable clinical data base for outcomes research.

For the past five years, Medicare has used its administrative data base to analyze hospital mortality rates. Mortality is easy to measure and certainly an important outcome, but even this is difficult to analyze and interpret. Although everyone would agree that death is an important outcome to measure, no one really knows how good a marker it is for institutional quality, nor how much it helps to identify problems that could not be identified otherwise using standard case review techniques.

The UCDS is two projects in one: a software program for compiling clinical information that can be used to adjust outcome measures for differences in patient severity and a computer algorithm for standardizing the medical record review currently conducted by PROs. PROs will abstract medical records to collect clinical information and then use the algorithm to screen those data and select cases for review. There are problems with it, however, that are well known to HCFA. It requires abstraction of enormous amounts of clinical information on each case (about 1,600 data elements), yet uses only about one-third of them in its algorithm for case selection. The clinical information collected would also be used to form a data base for large scale data analysis, but no one knows which of these clinical details will prove useful in adjustment of outcomes for patient condition. Meanwhile, the clinical logic of the algorithm, which has not been updated since 1988, is inefficient in its selection of cases for intensive review by physicians, so HCFA has wisely chosen in its initial implementation to allow nurses to override these decisions. To our knowl-

edge, no formal evaluation of earlier test phases of the UCDS has ever been completed or made available to the larger community of clinicians and providers.

The Health Care Financing Administration deserves credit for its pioneering work, but these tools are largely untested and by no means ready for widespread implementation. Although HCFA's plan appears to move in the general direction of the recommendations made by the IOM Committee, it is by no means a complete realization of the Committee's vision of a comprehensive, integrated quality assurance program, and its deficiencies reveal the difficulty of developing and testing these tools and updating them to keep them current.

REALISTIC EXPECTATIONS FOR OUTCOMES RESEARCH

Health services researchers have made enormous progress identifying appropriate statistical techniques for analyzing clinical data, developing ways to adjust for patient risk, and identifying appropriate outcome measures. But major obstacles remain. First, we have to be able to obtain valid measures of health status for analysis. While everyone agrees that this must be done, we have few incentives and little practical knowledge and experience utilizing outcomes research to improve institutional quality. Researchers have a good theoretical idea of how to go about it and have made a great deal of progress developing instruments for health status measurement, but no data set or data vehicle exists for collection of sensitive measures of health status. Second, we have to know how to resolve the attribution problem facing all outcomes analysis: to what extent are institutional differences in outcome the result of the clinical care provided, and to what extent are they the result of differences in how ill the patients are. Researchers are still seeking to understand what clinical information would be most useful to describe the patient's condition in order to isolate these effects. It is expensive and time-consuming to collect it. Which of these clinical data are most relevant and necessary, and which of the available repertoire of statistical techniques is most appropriate? What is the relationship between outcomes and the process of care? These questions remain to be resolved. Outcomes research is not the magic bullet that resolves all quality assurance concerns.

From data collection, to analytic techniques, to selection of outcomes, we have not reached a level of sophistication sufficient to implement a system such as the IOM proposes. The IOM Committee, recognizing the deficiencies in the current state of the art, proposes a 10-year plan to realize its vision. We would encourage Congress to provide funding for research and demonstrations to develop these techniques and to build adequate data sets.

Outcomes analysis will make no difference without better-articulated and shared standards of care and more consensus about patient care management. Without such standards, it is as difficult for the institutions as it is for external reviewers to conduct a meaningful, objective review. As the IOM Committee acknowledges, outcomes research can help identify areas of potential concern, but it cannot identify what the problem is or how to resolve it. The challenge that lies ahead is training our providers on identifying and improving their clinical processes to improve the outcome. Peer review, although helpful, is not the entire solution. Many times those areas with the greatest amount of unexplained variation are those with the least consensus about standards and protocols of appropriateness and therefore are the weakest grounds for PROs or anyone else to question the judgment of the treating physician. Without well-articulated standards of medical practice, there can be no standards of medical review. The development of practice guidelines is difficult, laborious, and expensive, but it is ultimately the key to meaningful change.

In the long term, we expect outcomes and effectiveness research to contribute to development of appropriateness standards, and we would expect the Federal government to take an active role in supporting effectiveness research. However, as a practical matter, practice guidelines must be developed through a process of consensus development, by clinicians in their relevant specialty areas.

SHORT-TERM STRATEGIES

If the IOM Committee's vision seems remote at this time, it will never be realized unless we begin to build toward it. The IOM Committee suggests several short-term strategies that the American Hospital Association supports.

1. *Use Incentives to Improve Quality.* Medicare's current quality assessment program makes no attempt to reward or create positive incentives for good performance. The IOM Committee recommended several incentives that should be explored, including reduced levels of intrusive review, special recognition for superior results, or selective contracting.

2. *Develop the Capacity for Data Analysis Among Hospitals and PROs.* The IOM Committee recommendations call for a sophisticated approach to feeding useful clinical detail and quality-related information to practitioners and providers and relying on the ability of the providers and practitioners to make productive use of it. We believe such a mechanism will work, but at the present time there are few successful models of such systems, and neither hospitals nor PROs have the analytic capabilities necessary to deal effectively with clinical outcomes data. We are working on building that capacity now. The American Hospital Association is cosponsoring a program for hospitals and PROs developed by the American Medical Review Research Center designed to heighten the level of awareness of statistical approaches to quality assurance and new methods of outcomes measurement. But this is only the beginning. We are especially concerned about the implementation of this model in small or rural hospitals, where staff frequently perform more than a single task, and where the likelihood of acquiring a staff person devoted entirely to data analysis is remote. Their special problems will need to be addressed.

3. *Fund Demonstrations and Program Evaluations.* Much of what the IOM Committee proposes is uncharted territory. We need to experiment, and we need to evaluate projects systematically to find out what works. In particular we would urge support for demonstration projects with PROs and providers to test the data feedback model and to enable hospitals to develop their analytic capabilities. With the current severe constraints on hospital finances, we cannot afford the expense of implementing untested approaches that later fail to provide the desired information or effect.

CONCLUSION

The American Hospital Association appreciates this opportunity to present its views on the Institute of Medicine's report and looks forward to working with this committee to fashion a progressive, efficient, and effective quality assurance program for Medicare.

RESPONSES OF G. RODNEY WOLFORD TO QUESTIONS SUBMITTED BY SENATOR ROCKEFELLER

Question No. 1. Who helps to establish the practice guidelines used in your program?

Answer. Information for the practice guidelines come from a variety of sources. First, various physician specialties are working to establish national guidelines. As critical paths are written, this information is often incorporated into the path.

We have found that our staff nurses, through observation of physicians, can do the initial development of the critical paths. They are familiar with various practice patterns and can organize the data for presentation and final review.

The physicians most involved in a particular diagnosis are asked as a group to then evaluate and establish the steps and processes in the critical paths (practice guidelines).

Finally, ongoing collection of data is used to continuously improve the critical path.

Question No. 2. What positive incentives can be instituted to reward providers for good performance?

Answer. Public recognition through measuring clinical quality and costs, and publishing those results, should have a positive impact upon providers. A second approach would be financial rewards. Perhaps providers who produce better outcomes should be paid more.

Incentives are a natural outcome when the provider stands at financial risk under various citation models.

Question No. 3. How can we integrate the concept of resource consideration into a quality model without the process becoming Just a utilization review program?

Answer. Until the health care system becomes more integrated with the providers, and collectively focused on the overall outcome, this question is very difficult. Utilization review is an inspection model and the quality model infers continuous improvement. The payment system will drive the use of these models.

Question No. 4. Good data is key to having a quality assurance program. The medical record has been often criticized as not being particularly accurate. (A) How can we work with hospitals and physicians to improve medical records and; (B) What other sources can be used to gather good data that can be used for a quality and utilization review program?

Answer. (A) The medical record itself is a great opportunity for quality improvement. However, our information indicates that most information required to meas-

ure quality is in the medical record and is accurate. The problem is capturing the information on a real time basis, and having the information available in databases that can be used effectively for improvement processes.

Technological improvements such as bedside terminals, electronic medical records, and systems which help physicians in diagnoses and treatment will eventually help improve the medical record. Consistent state laws permitting electronic medical records should be pursued to allow this technology to develop.

Answer. (B) We are not aware of any other significant sources of data beyond the medical records that can help with quality and utilization review. However, the missing component is the aggregation of an individual's medical history. The medical record tends to be on an episodic basis for services provided by one provider. A full evaluation of the quality would require an aggregation of all records for a patient.