ASSESSING HEALTH CARE QUALITY

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTH CONGRESS

SECOND SESSION

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THURSDAY, FEBRUARY 26, 1998

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:10 a.m., in room 1100, Longworth House Office Building, Hon. William Thomas [Chairman of the Subcommittee] presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
February 19, 1998
No. HL-18

CONTACT: (202) 225-3943

Thomas Announces Hearing on Assessing Health Care Quality

Congressman Bill Thomas (R-CA), Chairman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee will hold a hearing on health care quality. **The hearing will take place on Thursday, February 26, 1998, in the main Committee hearing room, 1100 Longworth House Office Building, beginning at 10:00 a.m.**

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

There is intensifying interest at both the State and Federal level in legislative initiatives intended to promote health care quality and provide protections for consumers enrolled in health plans. Dozens of bills have been introduced during the 105th Congress and hundreds have been considered in State legislatures across the country that are designed to give both providers and patients more clout in dealing with private-sector managed care plans.

Private-sector purchasers have devised their own strategies for holding health plans accountable for delivering quality care in addition to lowering health care costs. There also is a wealth of accreditation and other voluntary private-sector initiatives aimed at measuring and improving health care quality. For example, in recent years, both the Joint Commission on Accreditation of Healthcare Organizations and the National Committee for Quality Assurance have made considerable progress toward implementing performance and outcome measures. In addition, the American Medical Association recently developed a standardized process for certifying the quality of physician services.

At the same time, the Federal government has focused increasingly on exercising its purchasing power to promote health care quality in government programs. Medicare reforms included in the Balanced Budget Act of 1997 (BBA) (P.L. 105-33) broadened significantly the patient protections already in place in Medicare law, including a requirement that health plans cover emergency services that a "prudent layperson" would deem necessary, a provision prohibiting health plans from interfering with physician communication about treatment options, and a requirement that plans consider appeals from denials of care in emergency and urgent care situations within specified time frames. The BBA also strengthened the authority of the Health Care Financing Administration to collect, monitor, measure, and disseminate information about the quality of care provided to beneficiaries enrolled in Medicare+Choice plans.

Aside from last year's Medicare reforms, relatively little legislative attention has been paid to measuring and ensuring quality of care across a wide range of delivery systems and practice settings, and very few of the recent initiatives are based on clinical evidence of health outcomes. Moreover, there is an inherent tension between government requirements and ensuring access to affordable private health coverage in a voluntary market. It has been estimated by the Congressional Budget Office and private economists that premium increases of one percent resulting from government mandates cause between 200,000 and 400,000 Americans to lose their health coverage.

(MORE)

In announcing the hearing, Chairman Thomas stated: "We need to get a realistic assessment of the state of our nation's health care quality. Before rushing to enact legislation that may do more harm than good, we should set aside politics and sloganeering and figure out how we can help empower consumers to make better health care choices based on clinical data and outcomes measures. Any effort to provide increased protections must be balanced carefully against the risk of increasing the number of uninsured Americans and making health coverage more costly and more unattainable."

FOCUS OF THE HEARING:

The hearing is designed to take a broad look at issues of quality and accountability in the nation's health care system, to help identify current measures of quality and to examine the role of the private sector, the government, and developing information technologies in promoting health care quality.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Any person or organization wishing to submit a written statement for the printed record of the hearing should *submit at least six (6) single-space legal-size copies of their statement, along with an IBM compatible 3.5-inch diskette in ASCII DOS Text or WordPerfect 5.1 format only, with their name, address, and hearing date noted on a label*, by the close of business, Thursday, March 12, 1998, to A.L. Singleton, Chief of Staff, Committee on Ways and Means, U.S. House of Representatives, 1102 Longworth House Office Building, Washington, D.C. 20515. If those filing written statements wish to have their statements distributed to the press and interested public at the hearing, they may deliver 200 additional copies for this purpose to the Subcommittee on Health office, room 1136 Longworth House Office Building, at least one hour before the hearing begins.

FORMATTING REQUIREMENTS:

Each statement presented for printing to the Committee by a witness, any written statement or exhibit submitted for the printed record or any written comments in response to a request for written comments must conform to the guidelines listed below. Any statement or exhibit not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All statements and any accompanying exhibits for printing must be typed in single space on legal-size paper and may not exceed a total of 10 pages including attachments. At the same time written statements are submitted to the Committee, witnesses are now requested to submit their statements on an IBM compatible 3.5-inch diskette in ASCII DOS Text or WordPerfect 5.1 format. **Witnesses are advised that the Committee will rely on electronic submissions for printing the official hearing record.**

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. A witness appearing at a public hearing, or submitting a statement for the record of a public hearing, or submitting written comments in response to a published request for comments by the Committee, must include on his statement or submission a list of all clients, persons, or organizations on whose behalf the witness appears.

4. A supplemental sheet must accompany each statement listing the name, full address, a telephone number where the witness or the designated representative may be reached and a topical outline or summary of the comments and recommendations in the full statement. This supplemental sheet will not be included in the printed record.

The above restrictions and limitations apply only to material being submitted for printing. Statements and exhibits or supplementary material submitted solely for distribution to the Members, the press and the public during the course of a public hearing may be submitted in other forms.

Note: All Committee advisories and news releases are available on the World Wide Web at "http://www.house.gov/ways_means/".

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202-225-1721 or 202-226-3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

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Chairman THOMAS. The Subcommittee, such as it is, will come to order.

I want to welcome everyone to today's hearing, assessing health care quality. Today, the subcommittee will hear from witnesses who will help us better understand how health care quality is defined—or not defined, measured—or not measured, and, hopefully, assured across a wide array of delivery systems and practice settings.

We'll also hear about what is being done to promote quality in both the private sector and in Federal government health care programs.

Last week, President Clinton issued an executive order requiring all Federal health care programs to initiate a timetable for complying with the recommendations of the President's Advisory Commission on Quality and Consumer Protection in the Health Care Industry. We all agree that Americans should have access to the highest quality health care. The challenge, of course, is to assure quality without stifling innovation, increasing the number of uninsured Americans, making health coverage more costly and more unattainable, and expanding government bureaucracy. Those are not desirable side effects from the changes.

That's why I sent a letter to Secretary Shalala last week requesting information, including cost analysis, that I assumed the administration would have assessed very thoroughly before launching such a major initiative. I received an answer to my letter, I believe this morning, and without objection, I'd like to put in the record at this point both my letter and Secretary Shalala's response.

[The information was not available at the time of printing.]

Chairman THOMAS. The concern that I have is that the administration's response fails to provide us with any estimates of the cost impact of the executive order on seniors and those enrolled in other public programs, or on the providers, practitioners, and health plans providing those services to patients. In fact, the Secretary's letter—page 1 and at the top of page 2—indicates that these estimates simply don't exist. In the words of the Secretary that "although the Office of the Actuary has not completed the analysis of these estimates," they believe they will not have any significant impact.

My concern is that by using the executive order process, the President has avoided these new requirements of submitting to the Office of Management and Budget for assessment their impact on the American public. It's doubly disturbing because the President challenged Congress to extend the requirements in the executive order to the private sector so that, as he said, they will become the law of the land for all Americans. Obviously, when Congress considers the President's challenge in actual legislative language, it will have to be fully analyzed by the Congressional Budget Office. In the past, CBO and private economists have estimated that premium increases of one percent resulting from government mandates cause between 200,000 and 400,000 Americans to lose their health care coverage. I don't know whether the Secretary assumes one percent is not significant or not, but clearly the costs are a concern.

While I recognize there's an opportunity for partisan advantage in the debate over health care quality and consumer protection legislation, I had hoped we could begin to address this issue by building on the bipartisan health care reforms enacted during the past two years to, for example: one, save the Medicare program from bankruptcy for over a decade; two, provide Medicare beneficiaries with greater choice of private health plans; and three, expand preventive care for seniors; four, fight health care waste, fraud, and abuse; and five, limit preexisting conditions and guarantee affordability of private health insurance.

Specifically, there is a recent history of bipartisan quality protections on which to bill. We strengthened Medicare consumer protections in the 1997 Balanced Budget Act by one, guaranteeing access to emergency coverage under a "prudent, layperson standard"—Ben Cardin has been very helpful specifically in moving that issue forward; and two, allowing physicians to discuss all available treatment options with patients regardless of the cost; three, requiring health plans to consider appeals from denials of care in emergency and urgent care situations within specified timeframes; and four, more importantly and more fundamentally, strengthening the authority of the health care financing administration to collect, monitor, measure and disseminate information about the quality of care provided to beneficiaries in Medicare Plus Choice plan and fee-for-service.

Instead of entering into a substantive discussion about how best to ensure quality of care based on sound clinical data in the private sector, however, it appears the administration is more interested in playing partisan politics without fully analyzing the issue. It is unfortunate.

Before rushing to enact legislation that may do more harm than good, stifle innovation, and increase the number of uninsured Americans, we need to set aside politics and look for ways to empower consumers with clinical data and outcomes to allow them to make better health care choices. We've assembled a group of witnesses today that will help us do just that.

I'm very concerned about movements that are occurring in States, I'm concerned about what the Federal Government is or is not doing, and I look forward to today's testimony to assist us in making, what I consider to be, some extremely important decisions for all Americans over the next several months and years.

[The opening statement follows:]

Statement of Chairman Bill Thomas
Ways and Means Subcommittee on Health
Hearing on Assessing Health Care Quality
February 26, 1998

Welcome to today's hearing on assessing health care quality. Today, the Subcommittee will hear from witnesses who will help us better understand how health care quality is defined, measured, and assured across a wide array of delivery systems and practice settings.

We will also hear what is being done to promote quality in both the private sector and in federal government health care programs.

Last week, President Clinton issued an executive order requiring all federal government health care programs to comply with the recommendations of the President's Advisory Commission on Quality and Consumer Protection in the Health Care Industry. We all agree that Americans should have access to the highest quality health care. The challenge is to assure quality without stifling innovation, increasing the number of uninsured Americans, making health coverage more costly and more unattainable, and expanding government bureaucracy.

That is why I sent a letter to Secretary Shalala last week requesting information and cost analysis that I assumed the Administration would have assessed very thoroughly before launching such a major initiative. I ask that a copy of that letter be placed in the record at this time along with Secretary Shalala's response.

The letter I received from Secretary Shalala last nite fails to respond to several key aspects of my request. Importantly, the Administration has failed to provide the Subcommittee with any estimates of the cost impact of the executive order on our seniors and those enrolled in other public programs, or on the providers, practitioners and health plans providing services to these patients. In fact, the Secretary's letter states that these estimates simply do not exist. By using the executive order process, the President has avoided having these new requirements submitted to the Office of Management and Budget (OMB) to assess their impact on the American public.

This is particularly disturbing because the President "challenged" Congress to extend the requirements in the executive order to the private sector so that they "will become the law of the land for all Americans." When Congress considers the president's challenge, actual legislative language will have to be fully analyzed by the Congressional Budget Office (CBO). In the past, CBO and private economists have estimated that premium increases of one percent resulting from government mandates cause between 200,000 and 400,000 Americans to lose their health coverage.

While I recognize that there is an opportunity for partisan advantage in the debate over health care quality and consumer protection legislation, I had hoped we could begin to address this issue by building on the bipartisan health care reforms enacted during the past two years to: (1) save the Medicare program from bankruptcy for over a decade; (2)

provide Medicare beneficiaries with greater choice of private health plans; (3) expand preventive care for seniors; (4) fight health care waste, fraud, and abuse; and (5) limit preexisting conditions and guarantee portability of private health insurance.

Specifically, there is a recent history of bipartisan quality protections on which to build. We strengthened Medicare consumer protections in the 1997 Balanced Budget Act by: (1) guaranteeing access to emergency coverage under a "prudent layperson" standard; (2) allowing physicians to discuss all available treatment options with patients regardless of the cost; (3) requiring health plans to consider appeals from denials of care in emergency and urgent care situations within specified timeframes; and (4) strengthening the authority of the Health Care Financing Administration (HCFA) to collect, monitor, measure, and disseminate information about the quality of care provided to beneficiaries enrolled in Medicare+Choice plans.

Instead of entering into a substantive discussion about how best to ensure quality of care based on sound clinical data in the private sector, however, it appears the Administration is more interested in playing partisan politics without fully analyzing the issue.

That is unfortunate. Before rushing to enact legislation that may stifle innovation and increase the number of uninsured Americans, we need to set aside politics and look for ways to empower consumers with clinical data and outcomes to make better health care choices. We have assembled a group of witnesses today who will help us to do just that. I look forward to today's testimony.

-30-

And with that, I'd recognize my colleague from California, Mr. Stark, for any comment he may wish to make.

Mr. STARK. Mr. Chairman, thank you. Thank you for holding this hearing on health care quality and what I'd like to think of as the search into medical outcomes. But, I notice an undertone in your opening remarks that I think was perhaps present in your press release. I just want to come back to that. It deals with an event which Mrs. Morella and I attended in Wheaton, Maryland last Friday to join with the President in announcing his executive actions to implement laws which we passed last year under your direction and with your support.

Now, you had referred to that as a political stunt and I'll stipulate to that. There were lots of press and people out there. I like to take credit for the sun coming up every morning, but I can't get any press to observe it with me. But, I want to say that those were commission recommendations that applied to Medicare and Medicaid beneficiaries. Recommendations requiring that beneficiaries have more complete information; they have a choice of providers within plans, access to emergency services; full participation in medical treatment decisions; no discrimination based on race, sex, and age; privacy of medical records; a system for handling complaints and appeals as you suggested; and a call for consumers and patients to become more involved in the health—to guide their own destinies by quitting smoking, exercising, those sorts of things.

Now, these recommendations were basically the Medicare section of the Balanced Budget Act. And, I guess what I'd like to ask my Republican colleagues is, and it's a challenge, which one of those would you repeal? Which one of those rights for our senior citizens or the Medicaid beneficiaries would you like us to deny?

Now, I'm prepared this morning to ask unanimous consent to give you all the right to vote on any one of them or all of them. But, I don't think that that's going to get us where we want to get. We've got a couple of hundred cosponsors on the Norwood Bill. I presume we'll get the same number on a bill that Mr. Dingell will be introducing. We're prepared to move.

I hear that our Speaker does not want to move ahead this year to give patient protection in the form that either Norwood or Dingell are proposing. There may be an alternative to that, but I think that we're missing a bet. We may not get the expansion of Medicare into the younger people; that's a tough one to pass and I don't know if the public is pushing us that much. But, the public is pushing us on. They are pushing us from both sides of the aisle, in movies, on television, in the press, in States—in California they have a ballot initiative—and I think we could move ahead.

And I'd like to challenge my Republican colleagues not to move backward on what the President has done, but to move ahead. Once more, while Mr. Houghton and Ms. Johnson are in the room, I'm perfectly willing to ask unanimous consent to have a vote today to remove any one of the privileges or rights that the President bestowed by executive action for Medicare and Medicaid beneficiaries last Friday. I think those were all things that we all voted on—I know the Chairman did. Everybody supported those in the Balanced Budget Amendment of last year. We ought to say, Mr. President, you did it expeditiously and let's us go on and do whatever

else we have to do. Change it if you want, but I think we ought to move ahead.

I'm sorry to be so negative because I do really want to get into what Dr. Eisenberg wants to talk about in terms of outcomes research and things that will help make these decisions more empirical and less subjective as I am making comments this morning. But, I want to give some credit, where it is due. As you know, Mr. Chairman, I tend to think you do a better job in health care, generally, than the President does. So, I am no fan of the President or his former advisor in that area, as you well know. But, I do want to give credit in this case where credit is due and it has bipartisan support. Thank you, Mr. Chairman.

[The opening statement follows:]

Statement of Congressman Pete Stark
Subcommittee on Health
Committee on Ways and Means
February 26, 1998

MANAGED CARE QUALITY: WE KNOW THERE ARE PROBLEMS--AND IT IS TIME TO ACT, NOT WAIT

Mr. Chairman:

Thank you for holding this timely hearing on health care quality.

The press release announcing today's hearing suggests that Congress should adopt a go-slow approach toward quality legislation that would help millions enrolled in managed care plans. I'm afraid I disagree. With 222 Members supporting Dr. Norwood's bill and a hundred or so on legislation being developed by the Democratic Caucus, it is clear that Congress and the voting public wants managed care reform -- this year.

Last Friday, Connie Morella and I went to Wheaton, Maryland, to add support to the President's call for federal agencies to translate the Quality Commission's recommendations into concrete policy. I was shocked to read your comments that this was nothing more than a "political stunt," and that the President must think it is "too bothersome to work with Congress." Tuesday's press accounts quote you as saying that the executive order was mere "grandstanding."

The President's announcement builds on the work of the Advisory Commission on Quality in the Health Care Industry -- a group that included members of the business community and managed care representatives -- and that operated by consensus. After months of deliberation and dozens of public meetings, the commission called for managed care plans to make changes in eight key areas to give consumers a measure of real control over the quality of their health care. Here's what the commission recommended:

> 1--More complete and understandable information -- up front -- about the terms and conditions of what a plan covers and what it doesn't;

These are important steps the program should take over the next several months.

Legislation is needed to accomplish other goals. All five of the Subcommittee's Democratic Members support the President's call for legislation to amend Medicare so that women have the option to choose OB-GYNs for their primary care doctor and to ensure continuity of care. We invite you to, Mr. Chairman, to be the chief sponsor of this legislation or to join us in cosponsoring it.

Back to your reported statements about "grandstanding" and "political stunts."

Exactly which of these Commission recommendations, Presidential regulations, or requests for legislation do you call a "political stunt" Mr. Chairman?

On behalf of the Democratic members, I ask unanimous consent that the Subcommittee be permitted to bring up and vote, right now, on a resolution to block any or all of the Commission's recommendations; or any one of the President's administrative directives I just spoke of.

I have a draft House Joint Resolution right here expressing the sense of the Congress against whatever regulation or legislative proposal you object to. All you have to do is fill in the blank with the item you think is a "stunt," and we can vote on it right now.

I challenge the Members to rescind any one of these rights. If you object, then you must feel that the President has not done anything inappropriate and that the Subcommittee therefore explicitly endorses the President's actions of last week.

Does any Republican member have a motion to disapprove any of these items?

Mr. Chairman, we should not wait to extend to all Americans the same level of quality that we require for public-sector plans--the plans that we as Members of Congress use.

There's plenty of evidence that right now, health quality is uneven, sometimes bad -- and almost always worse for minorities. The American Medical Association's National Patient Safety Foundation reported last fall that 180,000 people die each year from medical injuries, "the equivalent of

Chairman THOMAS. I don't want to prolong the discussion but I do believe a brief response would be appropriate.

Pretty obviously, where we came together in a bipartisan agreement and implemented quality aspects under the Balanced Budget Agreement, I have no quarrel, obviously, with going forward in that area. But, the gentleman's statement as to what occurred, I believe, needs a slight correction. What the President was referring to was the commission that he created several months before the election, before we passed the Balanced Budget Agreement, and which include a number of items that are not in the Balanced Budget Agreement and which apply to something more than Medicare and Medicaid in terms of all Federal Government health programs.

The gentleman himself mentioned that there should be no discrimination on the basis of age, sex, or race. I have a difficult time figuring out how that gets implemented, for example, in the Medicaid program based upon who current recipients are in the Medicaid program. Does that mean that able-bodied males can now sue to get the same kind of benefit that pregnant women or women with children get in a Medicaid program? That's my point about the politics of it. It looks good and it sounds good, but as far as trying to advance a comprehensive quality program, it didn't help a whole lot.

And, as far as the gentleman's statement about the Speaker not wanting to move quality legislation in this Congress, then why in the world was I up at a 7:30 quality care task force meeting of all of the key chairmen of the Commerce Committee, the Ways and Means Committee, the Education and Workforce Committee, and all of the pertinent committees that would deal with this legislation to try to take a look at putting together a decent package of legislation and not one based upon anecdote? The last thing we ought to do is legislate by myth, rumor or anecdote.

One of the reasons we're holding this hearing, and I'm glad we got it early in the session and that we have the kind of quality people that we have here today, is to get an understanding of what real-world problems there are; what we need to do to be able to get the tools to measure quality—if, indeed, we can measure quality, which I believe we can and I hope out of this hearing I'll get some support for that argument; and what are the practical and appropriate steps to take both legislatively and administratively to ensure real quality, lasting quality, in a structure that will evolve over time and not be one designed to last between now and November of 1998. And that's the context in which I made my statements.

Any other member of the panel wishing to make statements can certainly submit a written report. It is now my pleasure to turn to the first panel, and it's good to see with us someone who's been with us a number of times before, Dr. John Eisenberg, who is currently the Administrator of the Agency for Health Care Policy and Research, an important agency which will assist us in this task, and I believe, for the first time, Dr. Jeff Kang who is the Chief Medical Officer, Center for Health Plans and Providers, the Health Care Financing Administration.

I want to thank you both for being here. Any written statement you have will be made a part of the record and you may address

us in any way you see fit on this important subject. Should we start with Dr. Eisenberg.

STATEMENT OF JOHN EISENBERG, ADMINISTRATOR, AGENCY FOR HEALTH CARE POLICY AND RESEARCH

Dr. EISENBERG. Thank you very much. I'm pleased to be back and to join you to address these issues that you've raised. In your invitation to us to testify today, you asked that we talk about how health care quality is defined and how it's measured, what the role of Government and the private sector are in promoting health care quality, and how legislation might affect quality costs and access.

As you mentioned, I address these questions not only from my role as Administrator of the Agency for Health Care Policy and Research but from my experiences working with you as Chair of the Physician Payment Review Commission and having recently left the position of chief of the medical services at Georgetown, where these issues were really quite real.

Most importantly, I think we need to emphasize that health care is a personal decision. It's a decision that's made by individuals and, although many of these decisions are made with some help from doctors and from nurses and from our loved ones, they remain personal and they remain very individual decisions. But, they are decisions that get made in the context of a very complicated health care system——

Chairman THOMAS. John, I'm going to ask you to move that microphone just a little bit closer. Something happened——

Dr. EISENBERG. Okay.

Chairman THOMAS [continuing]. To it during the break, I don't know——

Dr. EISENBERG. I apologize.

Chairman THOMAS [continuing]. What it is but it's very hard to hear and so you're going to have to get very close to it. I apologize.

Dr. EISENBERG [continuing]. I will do that.

I was alluding to the fact that our decisions about health care are very personal ones, they're made with some help from our family, from our friends, from our clinicians, but they're made in the context of a very complicated health care system where patients and clinicians deal with decisions for which they often have inadequate information. I think the bottom line for us is that our job, whether we're emphasizing the powerful role of the market to reward quality or whether we're emphasizing public policy that more directly promotes quality care, is that we need to determine how we can assure that quality care is delivered in this country.

Government can assure that consumers have their rights protected, as you've mentioned in your opening comments, and that's important. But, I think what is also very important is what you both mentioned in your opening comments and that is that once those rights are protected, what is the health care to which people have access? I want to discuss how we as public servants can be sure that the health care to which we do have access is high quality health care.

Let me mention six ways in which I think we can address your question of how Government can play a role here. The first is that we can protect consumers' rights. Secondly, we can be sure, as Dr.

Kang will address, that we purchase high quality health care for our beneficiaries, through Medicaid, through Medicare, through the Office of Personnel Management. Another way in which we can assure quality care is the care that we provide through the uniformed health services—the VA, the Defense Department—care that is directly provided by Government. So, those are three ways; we can protect consumers, we can purchase care of quality, and we can provide care of quality.

But, as the head of a research agency, I want to emphasize three other roles that I think are very important for Government in assuring high quality care. First, we need to be sure that we're sponsoring and that we're conducting research that's going to give us knowledge about what works, that's going to give us knowledge about what new tools we can use to improve the quality of care, and provide us with tested and proven ways of improving quality. That takes more research. Secondly, we should be tracking the quality of care in this country. We should be doing a better job of monitoring where there's a need for improvement and where there's an opportunity for us to do better, to identify where there are gaps between what we know how to do and what we are doing. And third, we need to be providing very clear and very unbiased information to the public so that when they choose a plan or they choose a provider, hospital, or clinician, or with their clinician they choose a diagnostic test or as treatment, they can make an informed decision.

You established this agency, AHCPR, in 1989 to do just that; to be sure that that knowledge is available. We sponsor, we conduct, we translate research in the science of health care. We apply the same kind of rigorous evaluation that is applied at the NIH.

What we mean by quality, when we sponsor this research, is usually thought of in three ways: structure, process, and outcome. And it's probably familiar to you; by structure, we mean, what's the basic construct of the health care system—for example, with breast cancer, do we have the right mammography equipment out there? With coronary disease, are clinicians or cardiologists board-certified? Are they well-trained?

But, even if the structure is right, it doesn't mean we're practicing right. We need to be looking at the process of care. The process of care asks questions about how we deliver it. In breast cancer, it asks questions such as are we getting mammography to the women who need it when they need it, to women at high risk? For coronary disease, it asks questions such as are we giving people clot-dissolving drugs when they come in with myocardial infarctions?

Even if we have the right structure and we have the right process, though, you don't do much for people unless they get good outcomes, unless the end results of their care are good. Just having the right structure, just having the right process isn't going to be sufficient. We need to be asking questions like, was the breast cancer treated at an early stage when we could treat it effectively? And, did the patient survive the heart attack with a high level of functioning?

You know well because of your concerns about the AAPCC how much variation there is in practice in this country. We need to un-

derstand that practice better. We need to understand why, in Miami, the AAPCC is $8,000 and why, in Allegheny County in New York, it's $4,400 and why those variations exist. One big reason is because of the uncertainty that clinicians have and patients have about what works and when it works. We know from Wennberg's work and others that when the uncertainty is the greatest, the variation is the greatest and the opportunity for improvement is the greatest.

One other area which I'd like to emphasize where information may help both public policymakers and consumers is by giving them information about what consumers think about the quality of care that they're getting.

We have a big poster here about the consumer assessment of health plans survey (CAHPS) which we, at AHCPR, have sponsored with collaboration from HCFA, NCQA, and others. HCFA announced recently that it will be adopting CAHPS as has the Office of Personnel Management. This means that we as Government employees and Medicare beneficiaries will know what other consumers think about the plans. CAHPS gives them information that they previously didn't have.

So, Mr. Chairman, I think we're making progress. We're making progress towards an effective system of quality measurement. We know that consumers, physicians, managers, and other leaders—public policymakers—need information about what works and what doesn't. Neither the public nor public leaders are going to be able to make decisions about the quality of care without the knowledge about what works, how to measure it, and how to improve it. Unless we develop better measures of quality and better ways of improving the information that guides both choices about care and programs to improve it, we're not going to be able to do what the public wants us to do: to be assured that the care they have is high quality care. Thank you.

[The prepared statement follows:]

Statement of

John M. Eisenberg, M.D., M.B.A.

Administrator

Agency for Health Care Policy and Research

before the

House Ways & Means Health Subcommittee

February 26, 1998

Mr. Chairman, thank you for giving me the opportunity to address the Committee on the very timely and important issue of health care quality. AHCPR's mission is to provide science-based information that will improve decision making at all levels -- from patients, to clinicians, to health care system leaders, to public and private policymakers. AHCPR's goal is to ensure in an increasingly market-based health care system that unbiased, state-of-the-science information drives informed decisionmaking.

Today, I would like to provide you with my perspective on quality, not only as the Administrator of Agency for Health Care Policy and Research (AHCPR), but also as someone who has spent his entire career in clinical medicine. My perspective on the quality of health care is also shaped by my experiences as the Chair of Medicine at Georgetown University, as the Chair of the Physician Payment Review Commission (PPRC), and as a professor of medicine.

What is Quality?

Most health professionals see quality as having three dimensions: structure, process, and outcome. Structure represents the basic characteristics of physicians, hospitals, other professionals, and other facilities. It describes whether there are well-trained health professionals; appropriate hospitals, nursing homes, and clinics; and well-maintained medical records, as well as good mechanisms for communication between clinicians. For example: Is the mammography equipment up to date and maintained properly? Are the cardiologists well-trained and board certified?

Structure is the framework in which we practice, and although the education of professionals and the facilities in which we practice are among the best in the world, let us never take them for granted.

If the structure is solid, we can concern ourselves with the process of medical care. Concern for process suggests that quality is determined not just by having the right people and facilities available, but it also means the right things must get done in the right way. Process includes questions like: Was the mammogram done for a woman at risk for breast cancer? Was the heart attack treated in the most up-to-date manner?

The third dimension, outcome, reflects the end result of care. Did people get better? Was disease or disability reduced? Was it reduced as much as it could have been, given what we know is scientifically possible? This is an area of increasing interest but one in which what we don't know is striking. We need to be able to measure the outcomes of care so that we know which types of care really help patients and so that we can look to instances of poor outcome for opportunities for improvement. For example, outcomes tell us whether breast cancer was detected early enough for the treatment to be effective. Did the patient survive the heart attack with the highest possible level of functioning?

I have felt for years that we need to ensure we are protecting the quality of the health care provided to this Nation's citizens by developing science-based, reliable quality measurement and improvement tools.

Patients' Concerns About Quality

The context of our discussion about quality is that our country has a market-oriented health care system. Whether publicly or privately financed, a basic element of market-oriented health care is the opportunity for informed choices by purchasers and patients and by those acting on their behalf. An essential part of health care quality improvement is to empower with information the ultimate consumer of health care -- the patient. And we know that Americans are concerned about the quality of care they receive.

A recent Kaiser Family Foundation poll found that a majority of Americans rate their health plans a "B" or higher. However, 55 percent of respondents in managed care plans and 34 percent with traditional insurance responded "yes" to question about whether their plans "would be more concerned about saving money than about what is the best medical treatment."

We need an infrastructure in place that will provide consumers with information on health care quality. This information should include outcomes of treatments, patient assessments, and other quality indicators.

Clinicians' Need For Information on Quality

Today I would like to concentrate on the clinical aspects of quality once a person has gained access to care.

Clinicians want to do the right thing. Physicians and other health care professionals need better scientific information about which treatments are most appropriate for which patients and at what point during the course of their care. I cannot overstate the importance of building the evidence base for clinical practice. It gives health care professionals the unbiased information they need to make effective, timely diagnoses and provide appropriate treatment. Physicians need to know what works in order to provide quality health care, and their patients deserve no less.

The ever-changing, ever-growing medical literature is making it difficult for busy physicians and other health care professionals to keep up with the latest scientific evidence. For example, it is estimated that if a physician reads two peer-reviewed journal articles each night, at the end of the year, he will be 800 articles behind in his reading. While it is good to have a large body of information, we need to provide this information in a useful format.

Having a readily accessible evidence base for treatment also will help improve the communication between patients and their doctors. Together physicians and their patients can use this information to find the most effective, appropriate, and least burdensome treatment. This sharing of information and communication is the foundation of a good doctor-patient relationship.

Variation

In my role as the head of a federal health agency, I see the importance for providing a sound evidence base for clinical practice in order to assure and improve its quality. This is invaluable to a health care system that is faced with the critical issue of which care is appropriate.

Medical practice varies widely in this country. The issue of variation is not new to you. Dr. John Wennberg's work has documented the wide geographic variation in health care that occurs in this country. AHCPR has sponsored a substantial portion of Dr. Wennberg's work in the area of prostate disease. His research team found that the rate of radical prostatectomy for Medicare patients in Fort Worth, Texas is twice the rate in Dallas, Texas (3.1 per 1,000 Medicare enrollees versus 1.9 per 1,000). Variations also occur region to region, State to State, and within States. For example, the rate for radical prostatectomy for Medicare patients in Baltimore, Maryland is approximately three times the rate in Salisbury, Maryland.

Variation provides us an opportunity to study which care is appropriate, how much is enough, and what is fair. I should point out, however, that variation is not inherently bad. In some cases, variation is caused by geographical, epidemiological, or cultural factors. For example, we expect to have a higher rate of skin cancer in the South and therefore more treatment for skin cancer in that region. In other cases, variation may point to areas of uncertainty in medical practice.

The fact that there is variation demonstrates that there are inconsistencies in how health care is delivered in this country. What these inconsistencies mean is a subject for further research and data collection; they underscore the need for better information on what works, when, and for whom. We need more research on and knowledge about health care outcomes to understand whether variation in medical practice should be celebrated or eliminated.

An important component of variation is personal preference and values. Patients and their clinicians must weigh personal preferences when making health care decisions. For example, research has indicated that some patients with laryngeal cancer would rather risk living fewer years than undergo a procedure that would cause them to lose their voices. For them, the issue is not the length of their lives but the quality of their lives. That is a decision about outcomes that patients make reflecting their own priorities, their own values, and their own choices.

Although individual preferences are important, we know there are some essential issues of quality that are common to all patient encounters. We know that certain drugs and certain immunizations should be given in certain clinical circumstances. Our challenge is to provide consumers with information on quality that will help them make decisions about the care they receive according to their individual needs and desires.

These decisions about the clinical services that will serve patients' needs represent one level of choice which requires valid information. When we decide on a health plan and a clinician or hospital we deserve the same kind of detailed information that is available to us when choosing a car, a home, and most other products and services that we use our limited resources to buy.

A survey cosponsored by AHCPR and The Kaiser Family Foundation found that a large majority of Americans (nearly 90% in every case) feel that quality information --such as how a plan cares for its members who have health problems, ease of getting care, and success in treating or managing disease -- is "very important" when choosing a health plan.

With the growing complexity of the marketplace, the demand for this kind of information is growing. We cannot leave the other health care stakeholders out of the mix. We also must ensure that health system leaders and policymakers also have the information they need to make good decisions.

Quality Measurement and Improvement

Certainly a key element in quality health care is to assure that the three elements are in place -- that the structure of the system is strong and that clinicians know what to do and are able to do it with skill and expertise. We also need to measure how well we do in the structure and process of care, measure the outcomes we achieve, and identify areas where there is opportunity for improvement. We need to develop more and better methods for measuring quality. We also need to communicate the results in useful, understandable formats that help improve health care decisionmaking. And, it is critically important that this information be made available in the public domain.

We have been successful in doing this in the automobile industry. For instance, if I am buying a car, I know that I can find data on the safety, efficiency, and reliability of different car models. This information is based on accepted measurements, such as crash tests, service records, and fuel efficiency.

Like the automobile industry, we must make it the goal for our health care system to provide similar information on the quality of health care services. To that end, we must strive to

develop accepted measures and instruments that can be used to gauge and improve the quality of health care services.

Last Friday, the Secretary of Health and Human Services announced the release of AHCPR's Consumer Assessments of Health Plans Survey (CAHPS), a series of questionnaires designed to be used by public- and private-sector health plans, employers, and other organizations to survey their members and employees. The information from CAHPS questionnaires presented in the CAHPS report formats can help consumers and group purchasers compare health plans and make more informed choices based on quality. Both the questionnaires and report formats have been tested widely in demonstration sites around the country.

We know that consumers select health plans based on the recommendations of their families, friends, and colleagues at work. While this is a good start, CAHPS provides information on the experiences of hundreds of people who are already in a particular plan. This provides a view of a health plan that is more representative and more reliable than the view captured in the opinions of a few individuals. Since CAHPS allows for comparisons among similar plans and across different types of plans (managed care vs. fee for service), consumers will be able to get a complete picture of the what each option provides and how it stacks up to what else is available.

CAHPS already is being used by a wide range of private sector organizations, including Ford Motor Company's Department of Health Care Quality, which is testing CAHPS in two markets, and five large health plans, including NylCare and United Health Care. The surveys have been used by more than 20 states, including California, Maryland, New Jersey, Washington,

Texas, and Florida.

The Secretary also announced last Friday that HCFA will begin fielding a CAHPS survey, developed in partnership by AHCPR and HCFA, to assess the quality of care in Medicare managed care plans.

In the near future, you will get an opportunity to use CAHPS to choose your health care coverage for you and your family. The Office of Personnel Management will be using CAHPS to help federal employees select health plans based on information on quality.

I am not suggesting that all providers and plans in every clinical setting and every region in this country be evaluated using the exact same measures. Measures and instruments should not be one-size-fits-all; instead, they should reflect the diversity of needs and uses that exist across the country. What I am advocating is a "department store" of accepted quality measures--all based on science and validated for reliability and usefulness--where users of measures can pick the set that fits their need, whether that need is to compare health plans or providers or to conduct a hospital quality improvement project.

The Public Role

As a physician experienced in providing care for patients in a Veterans Affairs hospital and for Medicare beneficiaries, I have had the opportunity to gain insight into the public role in

providing and paying for care. Our responsibility for quality includes government's role as purchaser and provider, but it goes beyond this level to help the health care market work as effectively as possible for all Americans.

In my view, it is the responsibility of Government, in partnership with the private sector, to ensure that the science of performance measurement matures in a way that promotes effective, efficient, and reliable measurement and reporting. Government's contribution in this partnership plays out in four critical areas.

One, the Government supports and conducts the basic research underpinning the science of quality measurement and quality improvement. Resting on the strong foundation of outstanding biologic research by our colleagues at the National Institutes of Health and elsewhere, AHCPR supports health services research about the effectiveness and outcomes of medical care that serves as an essential building block for quality measurement.

As you know, AHCPR is not a regulatory or enforcement agency, but instead it is an agency that sponsors, conducts, and translates research. We follow the same rigorous evaluation and peer review standards for awarding research grants as does the National Institutes of Health. Three-quarters of AHCPR's research funds are used to support researchers throughout the country. This research provides the evidence needed about what works and doesn't work in health care practice and hence what can be measured and improved.

Two, the Government can put science into practice by developing measurement tools and instruments and testing them on an ongoing basis to ensure their reliability, validity, and usefulness in improving the quality of health care services.

A third and unique contribution by Government is that the research, measures, and tools developed by us and our partners are in the public domain and available for all to use. There were many times during my years of practice and as Chief of Medicine at Georgetown that I wished we had better access to a toolbox of quality measures which would have enabled us do a better job on measuring quality and patient outcomes.

Last, but by no means least, the fourth major role of Government is the implementation of quality measures within Government-supported health programs. The Government is the largest purchaser of health care in the Nation, accounting for more than 43 percent of health care dollars spent at the local level. It is entrusted with the care of many of this nation's most vulnerable citizens.

The Government has an interest in ensuring quality, partly because it is a purchaser and provider of medical services, but also because it has a general responsibility to help make the health care market work as effectively as possible for all Americans. How can we achieve these goals? By developing, testing, and using science-based measures and applying the results to improve quality either through consumer choice strategies or quality improvement projects.

Conclusion

Mr. Chairman, while measuring quality of care is difficult now, we are making progress in that direction. We know that consumers, physicians, and the health care system as a whole need information on what works and what doesn't work in health care. This information is critical, and as I have seen through my career it is essential to improving the quality of care provided in this nation.

Thank you.

Chairman THOMAS. Thank you very much, Dr. Eisenberg.

Dr. Kang, welcome to the Subcommittee.

STATEMENT OF JEFF KANG, CHIEF MEDICAL OFFICER, CENTER FOR HEALTH PLANS AND PROVIDERS, HEALTH CARE FINANCING ADMINISTRATION

Dr. KANG. Thank you, Mr. Chairman and members of the committee. I'm very pleased to be here to describe HCFA's efforts working to ensure that Medicare and Medicaid beneficiaries receive high quality health care services.

By way of introduction, since this is the first time I'm here, I am an internist and a geriatrician who practiced clinical medicine for 10 years and ran a private-group practice. I also am very familiar with managed care as a provider who took capitated payments, but also worked for plan management for utilization management and quality assurance. As a practicing physician, I am pleased to be here to talk to you about quality.

But, before I begin, I would like to recognize you and Representative Stark and thank you for your strong leadership in passing consumer protection and quality protections in last year's Balanced Budget Act.

Because this Subcommittee has jurisdiction over Medicare, I will focus my comments on that program. With regard to Medicare, I would like to focus on managed care first because this is where HCFA's thinking and its programs, with regard to quality assurance, are most matured.

Our strategy in managed care has two components, as Dr. Eisenberg suggested, and I'm going to spring off of his comments: the first really is performance measurement, and then the second is consumer protection. With regard to performance measurement—and by performance measurement, I'm referring to the processes and outcomes, as Dr. Eisenberg discussed—performance measurement has two purposes in it also; the first is for plan-to-plan comparisons, the second is for internal quality improvement.

With regard to plan-to-plan comparisons, this requires standardized measurement systems. Here we have three efforts in process: the first, as you know, is HEDIS 3.0 measures. In 1997, we required Medicare managed care plans to report this information to us and we soon hope to be able to publish this data for consumer information. The second, as Dr. Eisenberg referred to, was the consumer satisfaction survey, or CAHPS. We are currently in the process of surveying over 130,000 Medicare managed care beneficiaries and we'll be able to get this information back to them with regard to their plan performance sometime in the fall. The last effort is the Foundation for Accountability. FAcct endorses and promotes a common set of patient-oriented measurement systems and we anticipate that some of these measures will be incorporated in future versions of HEDIS.

But, with plan-specific comparative data from these standardized measurement systems, what can we do with them? Well, as purchasers, we can do four things: we can set minimum performance level, we can set contractual targets, we can reward good performance, and we can assist beneficiaries in making health plan choice to create market competition based on quality, not cost.

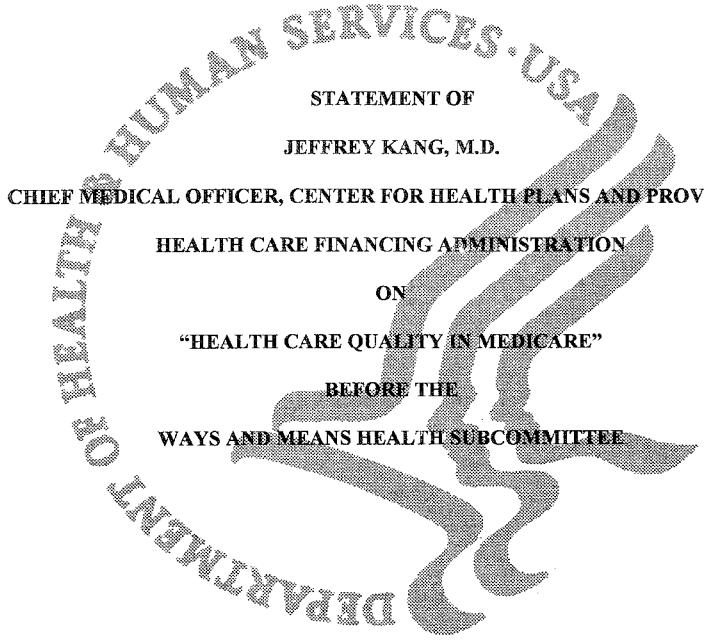
The second use of performance measures I'd like to briefly touch on is for the purposes of internal plan quality and improvement; not for the purposes of comparison, but for the purposes of internal improvement. Here, through a contractor, HCFA developed what we are calling QISMC, Quality Improvement Standards for Managed Care. Plans will be required to show measurable improvement in specified broad, clinical and non-clinical areas of measures of their own choosing. So, they have the flexibility of choosing their own measures and the requirement is that they just show demonstrable and measurable improvement over time.

Now, let me just briefly mention the second component of our quality strategy, which is consumer protection. As the members—as Representative Stark and yourself have discussed, as a result of the Balanced Budget Amendment, I'm happy to report that much of what's in the President's Consumer Bill of Rights is or will be available to the Medicare beneficiaries and Medicaid beneficiaries. As you've already mentioned, there's appeals of grievances, the physician incentive regulation, and the prudent layperson standard.

In conclusion—oh, I should mention the—I did promise to talk a little bit about fee-for-service. Just as we're interested in getting performance measurement and improvement and accountability in managed care, we can do the same in fee-for-service. We are looking at doing HEDIS measures in fee-for-service, we're developing an OASIS measurement system for home health providers, the MDS system for nursing home providers, and the joint commission has the ORIC system for hospitals. We are also looking at developing a member satisfaction survey instrument to be used in fee-for-service. Finally, we are revising our conditions to participation for providers to reflect the same emphasis as in QISMC for managed care on minimum performance level and demonstrable and measurable improvement.

In conclusion, there is much work to be done but I think we've gotten a good start. The difficulty really is in developing good performance measurements and outcomes. But, as quality measurements improve, HCFA will be well-positioned in its strategy of emphasizing performance, accountability, and quality improvement. I'd like to thank the Chairman and Mr. Stark and other members of the committee for working to enact the quality-related provisions in the Balanced Budget Act and I agree very much with the Chairman's notion of empowering consumers to make better health care choices based on clinical data and outcome measures and we look forward to continuing to work with you on this vital issue.

[The prepared statement follows:]



STATEMENT OF

JEFFREY KANG, M.D.

CHIEF MEDICAL OFFICER, CENTER FOR HEALTH PLANS AND PROVIDERS,

HEALTH CARE FINANCING ADMINISTRATION

ON

"HEALTH CARE QUALITY IN MEDICARE"

BEFORE THE

WAYS AND MEANS HEALTH SUBCOMMITTEE

FEBRUARY 26, 1998

HCFA
MEDICARE • MEDICAID
Health Care Financing Administration

INTRODUCTION

Mr. Chairman, I am very pleased to be here to describe how the Health Care Financing Administration (HCFA) is working to ensure that Medicare and Medicaid beneficiaries receive high quality health care services. This is a priority for the President and the Administration as a whole. Mr. Chairman and Rep. Stark, I would like to thank you for the leadership you provided in passing strong consumer and quality protections for Medicare beneficiaries in last year's Balanced Budget Act (BBA). Our goal is to become a value-based, beneficiary-centered purchaser. We are striving to enhance performance and accountability in a quality health care delivery system -- one that is affordable, effective and safe, while protecting and improving enrollee health and satisfaction, and responding to the specific health needs of individuals.

As the nation's largest purchaser of health care, we want to effectively use market forces to obtain the best value for our beneficiaries. We have developed a unified approach in regard to quality measurement and improvement for both Medicare and Medicaid. We know through our participation in a variety of public private partnerships that this approach is consistent with the strategy of many of the large private and public purchasers. However, given that this Subcommittee has jurisdiction over Medicare, I will focus my testimony on our efforts in regard to that program. In addition to discussing our quality initiatives, I want to highlight some of the quality- related consumer protection provisions in the Medicare program. These provisions were strengthened as a result of the work of this Subcommittee in the Balanced Budget Act of 1997.

QUALITY INITIATIVES

The argument for the potential of managed care to improve quality is well known. The capitated prepayment made to managed care allows plans to organize care and re-allocate resources to address, in a coordinated and systematic way, the needs of each patient. In managed care, the organization is accountable for improving the well-being of the patient. This provides both an opportunity and an incentive to improve the quality of care being furnished and emphasizes preventive care rather than acute care.

The flip side to the argument is also well known. In managed care, there is the potential for "under-service" and poor quality, if plans try to maximize short-term profits by not delivering appropriate care. The goals of our quality initiatives are to measure performance and to hold plans accountable for their performance and for quality improvement.

Performance Measurement

We have two approaches towards performance measurement. The first approach is to identify those clinical intervention processes (tests, medications, procedures, surgeries) that, based on scientific evidence, we know are linked to desired health outcomes. Examples of these processes are mammograms for breast cancer screening, flu shots, use of beta-blockers after myocardial infarction.

Some (not all) of the measures of these clinical processes can come from plan administrative or encounter systems. While this approach has limitations (good outcomes is not the sum of known clinical processes), process measures provide significant insight into the quality of care and provide opportunities for measurement and improvement.

The second, preferred and potentially the most efficient strategy for clinical performance measures, is to move toward outcome measures, which reflect the health status of the beneficiary. The problem is that the science of outcomes measures is in its infancy. The movement towards better outcomes measures is critical for HCFA, like-minded purchasers, and beneficiaries in order to hold plans and providers accountable for the care they deliver. HCFA and the Agency for Health Care Policy Research (AHCPR) have been active in promoting research to identify these measures. With such measurements in hand, HCFA and the public will be able to objectively compare managed care plans as well as fee-for-service, and to determine whether managed care plans are living up to their potential to improve the quality of care.

In June of 1996, a Quality Initiative Team was commissioned within HCFA to develop a comprehensive quality strategy that would transform HCFA's efforts from that of carrying out a group of quality-related functions to that of operating an integrated quality program that is accountable for the health and satisfaction of its beneficiaries. The goal of this strategy is to improve care consistently across the Medicare and Medicaid programs, for managed care as well as fee-for-service, and for special populations as well as the beneficiary population as a whole. Based on the recommendations of the Quality Initiative Team, a permanent Quality Council was created within HCFA to coordinate implementation of the quality strategy.

Accountability -- Quality Improvement System for Managed Care

Historically, HCFA's review of Medicare managed care plans has focused on structural standards that looked at a plan's infrastructure and capacity to improve care, as opposed to looking at whether the plan actually improved care. The trend among purchasers of managed care, however, is to demand performance measures in order to hold managed care organizations "accountable." To provide for this accountability within Medicare and Medicaid, HCFA working though the National Academy of State Health Policy in consultation with State Medicaid agencies and regulators, quality measurement experts, managed care plans and beneficiary groups has developed the Quality Improvement System for Managed Care (QISMC). QISMC will help us to assure that care is improving and that plans are accountable in regard to objective, measurable standards.

QISMC adds two major changes to the quality assurance standards that exist in Medicare managed care.

- First, plans will be required to meet minimum performance levels on standardized measures (see HEDIS and CAHPS below). Such minimum performance levels are to be set by HCFA on an annual basis and will be based on local or national observed historical experience.

- Second, plans will be required to show demonstrable and measurable improvement in specified broad clinical areas (e.g., preventive services, acute ambulatory care, chronic care, hospital care, etc.) based on performance improvement projects that each plan will identify.

With QISMC, we will shift from looking at whether plans have the infrastructure to improve care to whether plans demonstrate measurable improvement. The question is not whether plans are able to improve, but rather did they improve. QISMC will define in advance for plans what is acceptable, demonstrable, and measurable improvement. These definitions will also serve as the basis for HCFA reviewers to monitor plan performance and compliance based on data.

The current draft of QISMC has been sent out for comment. NASHP will then incorporate those comments and give us a completed report by June. This will serve as the basis for HCFA to have further discussions with the various stakeholders.

HEDIS 3.0

One of the sources for standardized measures under QISMC will be the Health Plan Employer Data and Information Set (HEDIS) 3.0. This choice, in part, is an effort to move toward standardization with other purchasers. HEDIS 3.0 reflects a joint effort of public and private purchasers, consumers, labor unions, health plans, and measurement experts, to develop a comprehensive set of measures for Medicare, Medicaid, and commercial populations enrolled in managed care plans. Four measures that impact on Medicare beneficiaries were added to the "effectiveness of care" category in HEDIS 3.0, including: mammography rates, use of retinal examinations for diabetics, outpatient follow-up after acute psychiatric hospitalization, and utilization of beta blocker in heart attack patients. HEDIS 3.0 will facilitate comparison of plan performance measures. It will also permit HCFA to establish minimum performance levels for these standardized measures, thus, holding plans accountable for the quality of the care they provide.

Last year, HCFA directed all Medicare managed care plans to report date for 1996 on 32 HEDIS 3.0 measures to the National Committee for Quality Assurance (NCQA) by June 30, 1997. These 32 HEDIS 3.0 measures cover: effectiveness of care, access/availability of care, satisfaction, health plan stability, use of services, cost of care, informed health care choices, and descriptive information. Since many of the specific measures break down by age and other demographic characteristics, there are up to 850 data elements per plan.

HCFA, working with the HEDIS Committee on Performance Management, was instrumental in adding functional status for enrollees over age 65 as a measure in the "effectiveness of care" category in HEDIS 3.0. The "Health of Seniors" functional status survey will be the first outcome measure in HEDIS that will longitudinally track and measure functional status. It addresses both physical and mental status through a self-administered instrument which determines whether the beneficiary perceives that his or her health status has improved, stayed the same, or deteriorated. This measure will be administered by independent venders beginning in May of this year.

HEDIS 3.0 data is self-reported by plans and is unaudited. Many purchasers and consumers are making judgements and comparisons based on this data. Given the importance of the data and HCFA's leadership role as the largest purchaser of managed care in the country, we contracted with the Island Peer Review Organization (IPRO, which serves the state of New York) to perform an audit of the HEDIS data. The purpose of the audit was to ensure that valid, accurate, and comparable HEDIS summary data for services provided in 1996 were obtained. Data validation was twofold: (1) to quantify the accuracy of the information collected, and (2) to quantify its completeness. The audit was divided into two parts. The first was a baseline assessment of all 284 contract markets reporting HEDIS to determine the effect of their information management practices on their ability to report accurate data. In addition, IPRO performed an onsite audit of 79 contract markets covering 65% of Medicare beneficiaries enrolled in managed care.

Last December, IPRO discussed its preliminary audit findings with HCFA staff. The final IPRO report is due to HCFA within a few weeks. We do know that there were serious problems with data accuracy due to immature plan information systems and ambiguous measurement specifications. HCFA is conducting its analysis of 1996 HEDIS data based on the preliminary audit findings. We are committed to making the HEDIS data and the results of the IPRO audit publicly available as rapidly as possible. However, such a release must be consistent with our public responsibility and the competing interests to make data widely available, be fair and accurate to plans, and to inform the public. We will get back to the Committee on how we plan to proceed with the data release.

In the meantime, HCFA is working to receive more accurate HEDIS data in the future and toward that end will be working with NCQA and the health plans. We are considering mandating a pre-submission audit of HEDIS data by all plans for this year. We do expect that, over time, the information systems that health plans use to provide HEDIS data will advance from their current developmental stage. HCFA also expects that other management systems, such as provider contracting, will be better structured for easier provision of performance data. Finally, we believe that the HEDIS measure specifications will improve as NCQA continues to refine them through feedback from current implementation.

Accurate HEDIS data is necessary but not sufficient for the effective use of quality information. HCFA, like many purchasers and consumer groups, continues to struggle with how particular measures should be used for plan comparison. Much work remains to prepare Medicare beneficiaries to use plan comparison data, as well as quality of care and satisfaction data as these become available. At present, we are still learning about which measures or groups of measures and what methods of presentation for these measures Medicare beneficiaries would find most informative and usable. Both accurate data and a meaningful framework are necessary to meet BBA requirements for broadly disseminating information to Medicare beneficiaries to promote active, informed selection among options.

Consumer Assessment of Health Plans Study (CAHPS)

In cooperation with HCFA, AHCPR designed the Consumer Assessment of Health Plans Study (CAHPS) to design a Medicare beneficiary survey. This survey quantifies Medicare enrollees' evaluation of key elements of their health plans, including how easy it is to get access to appropriate care, how well the clinicians communicate with them about their health status and treatment options, and the quality of care provided. Survey results, which will provide extensive information about every Medicare managed care plan, will be available this fall and will help beneficiaries make informed decisions about their health plans. We are pleased that OPM will work with us to have FEHBP enrollees participate in this initiative. HCFA plans to administer the survey through an objective single third party vendor in order to ensure comparability. The survey was just mailed out for the first time earlier this month, and results are expected to be available to consumers for use in their decision-making this fall.

Encounter Data

HCFA's research office recently completed an investigation of whether encounter data can be used to measure access to and quality of care for Medicare beneficiaries enrolled in managed care plans. The results of this study, which used data from a large HMO and from fee-for-service, successfully demonstrated that using encounter data in this fashion is possible. Encounter data would obviate the need for many current HEDIS measures. However, there are many clinical processes and outcomes that are not captured by claims-based encounter systems, thus there will be a continued need for NCQA or FAcct - like efforts.

Accountability and Quality Improvement In Fee-for-service Medicare

The movement toward performance measurement and accountability for quality improvement is not limited to managed care. We are currently revising our conditions of participation for hospitals, end-stage renal disease facilities (ESRD), home health agencies, hospices and ambulatory surgical centers in order to move away from process requirements and instead require that providers monitor the quality of care that they provide, improve that quality and document that improvement. The new requirements do not mandate the structure or processes that must be used to accomplish the expected outcome, unless those requirements are predictive of quality and patient safety (i.e. infection control, life safety code standards).

In order to evaluate and improve quality, health care organizations must have data that will inform them about the quality of care that they provide. Our standards will require the collection of quality indicator data in those areas where the science is available and consensus exists on the value of the information. The state of quality indicator development varies by provider type. We are requiring collection of OASIS data that supports outcome measures in home health, indicators of the efficacy of dialysis for ESRD facilities, and MDS data in skilled nursing facilities. Providers such as hospitals, hospices and ambulatory surgical centers do not yet have quality indicators that are supported by

science and industry consensus. For those providers, our standards will require that they select a set of the many measures available to them.

HCFA's Clinical Measures group is working with other public and private partners to develop measures in those areas that need them and to improve and converge the quality indicators already developed. As the health care environment continues to change and the science evolves, our standards will be modified to reflect and support our continuous efforts to improve the way we improve quality.

Foundation for Accountability

The Foundation for Accountability (FAcct) is a non-profit organization dedicated to helping purchasers and consumers obtain the information they need to make better decisions about their health care. As Federal Liaisons to the FAcct Board of Trustees, HCFA is joined by other public and private sector partners, including the American Association for Retired Persons, the AFL-CIO, the Department of Defense, the Office of Personnel Management, Ameritech, and American Express. FAcct is uniquely situated to integrate the perspectives of purchaser and consumers of health care in regard to quality measurement. Specifically, FAcct endorses and promotes a common set of patient-oriented measures of health care quality.

Last August, President Clinton announced a major collaboration between FAcct, NCQA, ADA, HCFA and several other organizations to develop a common set of performance measures for person with diabetes. This important initiative should lead to improved quality of care. We anticipate that HEDIS will include some of the measures coming out of this collaboration for implementation in 1999.

PRO Activities

From January 1994 to present, PROs have initiated 1044 cooperative improvement projects and completed 359 of these. Of the projects initiated during the 4th PRO contract cycle (1993-1996), eighty-seven percent resulted in improvements in care that have been documented.

- Cooperative Cardiovascular Project (CCP) is a national effort to improve the quality of care for Medicare beneficiaries who have had heart attacks. The project began as a pilot program in 1992 in four States using quality indicators based on guidelines published by the American College of Cardiology and the American Heart Association. In 1995, CCP was expanded to a national project focusing on quality indicators when a patient arrived in the hospital and at discharge. Results in the pilot States showed: a significant improvement in all indicators; a 10 percent drop in 30-day mortality and reduced length of stay.

- There have been over 60 recent PRO Projects on community acquired pneumonia involving 37 states focusing on improving timing of antibiotics. A HCFA-sponsored study conducted by the Connecticut Peer Review Organization established a linkage between early

administration of antibiotics and mortality. Thirty-seven percent of completed pneumonia projects demonstrated improvements in reducing average length of stay. Twenty-two percent of the completed pneumonia projects demonstrated improvements in reducing mortality.

The Medicare Managed Care Quality Improvement Project (MMCQIP) is designed to enhance HCFA's ability to assess how well the ambulatory care process in managed care is meeting the needs of beneficiaries. At this time, we are evaluating the care received by Medicare managed care plan enrollees diagnosed with diabetes mellitus, and the incidence of screening mammography in a sample of enrolled beneficiaries. The PROs in five states (California, Florida, New York, Pennsylvania and Minnesota) and 23 Medicare-contracting HMOs are collaborating on MMCQIP. In addition, an on-going sister project, utilizing the PROs in Maryland, Iowa and Alabama, will analyze the same measures in the fee-for-service setting. The initial finding is that there is room for improvement in both managed care and fee-for-service in these two areas.

QUALITY-RELATED CONSUMER PROTECTIONS

Quality improvement initiatives are an important part of our general effort to assure adequate consumer protection for beneficiaries enrolled in managed care plans. It is worth noting that Medicare has other structural provisions that protect beneficiaries. In fact, many of the protections available to Medicare beneficiaries are not available to most commercial enrollees.

Last fall, the Advisory Commission on Consumer Protection and Quality in the Health Care Industry presented the President with a *Consumer Bill of Rights and Responsibilities*. On November 20, the President directed the Secretaries of Defense, Labor, Health and Human Services, Veterans Affairs, and the Director of the Office of Personnel Management to assess the extent of current compliance with the Bill of Rights, consistent with the missions of our agencies, and to identify the process for resolving any impediments to further compliance.

Just last week, these agencies reported back to the President, through the Vice President, on the degree to which they are currently in compliance, administrative steps that could be taken to come into compliance, and statutory barriers to prevent these Federally-administered health plans from coming into compliance. HCFA reported to the Vice President that both Medicare and Medicaid are largely in compliance with the Consumer Bill of Rights.

With the *Consumer Bill of Rights and Responsibilities* in mind, let me briefly highlight some of Medicare's quality-related consumer protections. As I noted earlier, these provisions were strengthened as a result of the work of this Subcommittee on the BBA.

- **Unrestricted Medical Communication**: The Medicare statute requires that contracting health plans must make all covered services available and accessible to each beneficiary as determined by the individual's medical condition. In fee-for-service, Medicare beneficiaries are made aware of the full range of treatment options by their physicians. In November of

1996, we sent a policy letter stating that managed care enrollees are entitled to the same advise and consultation. The Medicare+Choice provisions of BBA included such a so-called "anti-gag clause" provision.

- **Beneficiary Appeals**: In this area, Medicare's protections are significantly beyond those generally available to managed care enrollees in the private sector.

  Under the BBA, Medicare+Choice plans must have a procedure for making determinations regarding whether an enrollee is entitled to receive services and the amount the individual is required to pay for such services. The explanation of a plan's determination must be in writing, and must give the reasons for the denial in understandable language and must describe the appeals processes. Determinations must be made on a timely basis; i.e., within 60 days after the request by the enrollee. Reconsiderations of the denial coverage based on lack of medical necessity must be made by a physician with expertise in the relevant field of medicine.

  Plans are also required to have an expedited review process in cases for which the normal time frame for making a determination or reconsideration could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. Either the beneficiary or the physician may request an expedited review. Requests for expedited reviews made by physicians (even those not affiliated with the organization) must be granted by the plan. Expedited determinations and reconsiderations must be made within time periods specified by the Secretary, but not later than 72 hours after the request for expedited review, or such longer period as the Secretary may permit in specified cases.

  An independent entity with which HCFA contracts is responsible for reviewing and resolving plan reconsiderations not favorable to the beneficiary. If the independent review is unfavorable to the beneficiary, the beneficiary has the right to the ALJ and judicial review.

- **Physician Incentive Plans**: Effective January 1, 1997, the Physician Incentive Plan Final Rule required managed care plans with Medicare or Medicaid contracts to disclose information about their physician incentive plans to HCFA or the State Medicaid agencies, before a new or renewed contract receives final approval. Plans whose compensation arrangements place physicians or physician groups at substantial financial risk must provide adequate stop-loss protection and conduct beneficiary surveys. Current law requirements for physician incentive plans are maintained in the BBA.

- **Emergency Services**: The BBA clarified the obligation of Medicare and Medicaid managed care plans to pay for emergency services rendered to their enrollees. "Emergency services" are defined from a "prudent layperson" perspective. Medicare+Choice plans and Medicaid managed care organizations are required to pay for emergency services without regard to prior authorization or whether the provider has a contractual relationship with the plan. These provisions will be implemented for Medicare when the BBA regulations are issued this

summer. However, HCFA is sending a letter to State Medicaid directors to clarify this new policy.

There are, however, a few rights for which HCFA has determined that additional appropriate administrative actions could be taken to bring the program into compliance with all of the major elements of the Consumer Bill of Rights. Last week, the President directed the Department to bring Medicare and Medicaid into compliance in these few areas. These include ensuring that Medicare and Medicaid beneficiaries with complex and serious medical needs have access to specialists and to some of the rights regarding participation in treatment decisions, as contained in the Commission's recommendations.

- The Department's implementation of the BBA, combined with our commitment to implementing the *Consumer Bill of Rights and Responsibilities*, will ensure that Medicare will be in substantial compliance with the Commission recommendations by next year. Additional authority is needed to bring the program into full compliance with regard to confidentiality, transitional care, and choice of provider for women for their routine and preventive women's health services. The Department has already released a report that outlined new privacy protections that are needed to ensure appropriate confidentiality of medical records.

- As a result of recent guidance to states and new consumer protections enacted in the BBA, the Medicaid program is quickly moving into compliance with much of the Consumer Bill of Rights, and will soon be in substantial compliance. As with Medicare, additional authority is needed to bring the program into compliance with regard to confidentiality, transitional care, and choice of provider for women for their routine and preventive women's health services.

CONCLUSION

We are well aware that there is still much work to be done to ensure that Medicare and Medicaid beneficiaries receive high quality care. With advancements in quality measurement, our strategy will change from monitoring processes to assuring minimum quality performance and measurable quality improvement. Our work with managed care will assist us in addressing the question of quality in original fee-for-service Medicare. We thank Chairman Thomas, Mr. Stark, and other members of the Committee for working to enact the quality-related provisions that were included by the Congress in the Balanced Budget Act of 1997. We look forward to continuing to work with this Subcommittee on this vital issue.

Chairman THOMAS. Thank you very much, Doctor.

Probably to both of you, but more directly to Dr. Eisenberg, you know, given the direction and tone of his testimony because pretty obviously—and Dr. Kang, you're correct, we're focussing primarily on Medicare—but I've discovered that since this committee is one of the few that actually puts together the product that's moved through the system, we've had to drive a lot of the system through the Medicare structure. But, when we talk about quality health care, as Dr. Eisenberg indicated clearly, it ought to be open to all.

And I was heartened to a certain extent by the President's Commission concern about patient protections in the use of the term "confidentiality," rather than privacy because I believe if you use the terms "right to privacy," it tips over into an area that oftentimes is not viewed in a way commensurate with our job of collecting data. And so, the confidentiality term is one that I am appreciative of having been used.

My concern about our ability to collect data which is critical to outcomes, research, and quality comparisons is that there apparently is a move-on in the States and I happen to be over the break in Minnesota at the Mayo Clinic and got firsthand evidence and information of the difficulty in complying with the Minnesota State law in restricting the collection and dissemination of data.

My question directly is over what I understand to be the administration's position that they would not be interested in restricting States who passed laws which are more stringent than the Commission's proposal for confidentiality. If indeed that is the case, how could we possibly move forward in a broad-based, multistate data collection structure if we allow the States to devise privacy laws similar to Minnesota's which requires an affirmative sign-off with a 60-day window for the use of material?

Dr. EISENBERG. Well, we share your concern. In fact, I often think about this problem and think about the metaphor of a key and a lock. I think that we do need to lock up the data that we have—confidential information for our health care—but we can't throw away the key. And the question, of course, that you ask is, who's going to control that key and who's going to control access to that data.

The Secretary, on September 11, sent the Congress a proposal from the Department on privacy and emphasized in that letter that there were several elements that must be maintained and available because they're public goods; they include research and quality of care evaluation. And, I think your point, especially in the context of this hearing, is very, very important. We need to be sure that we have not only consistent data but good data that's available so that we can evaluate the quality of care and so that we have access to information for research. Now, given that——

Chairman THOMAS. But, Doctor, is my understanding correct, that the administration has indicated notwithstanding that floor, that States could go below it if they so chose and that there was no interest in dealing with that issue? Is that understanding correct or not?

Dr. EISENBERG. The Department's and the administration's comments to the Congress were just that; that this would be a floor of stringency and if the States decided to be more stringent, they

could do so. I think what we need to do as we work through this process is for the Congress and the administration to work together to be sure that those public goods are preserved, especially in the context of this hearing, research and quality. We could do that in a variety of different mechanisms, including model legislation for the States, but we do share your concern that those public goods continue to be available and would look forward to working with you as this legislation goes through to be sure that they are available——

Chairman THOMAS. Well, I'm sorry to press you on this but I think it's a fundamental point and I want it to be very clear. If States have the ability to create more stringent restrictions on the use of patient records than as advocated by the administration, is that going to be a concern to those people who are trying to establish computer-based information networks for quality control?

Dr. EISENBERG. Yes, it will, and like every element in this confidentiality debate, there are two edges to the sword. As we try to prevent inappropriate use of these data, we have to be sure that we preserve the appropriate use with the right safeguards. And, what we need to do is to work together to be sure that your concerns are taken into account.

Chairman THOMAS. I appreciate your response. It is a difficult one. I know both of you are in a difficult position on this, but I think at this point we have got to be as honest as we can about what the job is with full protections of individual confidentiality of records but the absolute necessity to collect statistically quantitative data.

Dr. KANG. Mr. Chairman, if I may, give a real live example on this—and I'm not a legislator so I don't know how to get out of this problem, but it is a problem. Medicare is a Federal program. We're requiring HEDIS measures for the purposes of ensuring quality. We did have some problems—in HEDIS, there is a measure with regard to follow-up care for mental health after an affective disorder and there are some places, States, where we've run into problems where we could not collect that information because of confidentiality laws with regard to mental health records. And, this is an issue and, again, I don't know exactly how to solve this but I think you've identified a very important issue.

Chairman THOMAS. Dr. Kang, recently I was somewhat disturbed to find out that your agency's trying to, for want of a better term, "water down" some of the beneficiary-centered BBP provisions like the national toll-free number for seniors to report fraudulent activities, toll-free number for seniors to ask questions about their private plan choices. There was an attempt to phase it in or to create something other than what we had requested in the BBA. Do you perceive any difficulties in implementing the additional, beyond the BBA requirements in the President's proposal since, apparently, the agency's having some difficulty swallowing all of the stuff that we asked them to do?

Dr. KANG. With regard to that, I assume you're referring to the Consumer Bill of Rights. As I suggested, much of the protection proposed in the Consumer Bill of Rights are already present in Medicare so the incremental changes that are being proposed really will not present a major administrative problem.

Chairman THOMAS. If, in fact, that's the case, I don't expect any additional slippage of any of the items that are critical for consumer information. If you are willing to make that statement about being able to accept the President's additional workload, then I don't expect any additional concerns about phasing in or not implementing in full the provisions that we agreed to on a bipartisan basis and I appreciate your statement on that.

I have some concern, and I don't normally do this but, there's a witness that's coming and this is the last question that I'll ask, there are additional witnesses and, frankly, some of the testimony is very good and I think this is important to get out, especially in the context of the debate that we're going to be engaging in in the House and, I guess, in the Senate, on the question of quality and where should it be applied.

A member of a panel to come makes this statement in a summary way, if I can find it. I'm looking for it and I can't find it. I apologize.

This is a phrase used both as a summary in one of the future panel participants and from a February 1998 National Healthy Policy forum briefing paper "Health Care Quality: From Data to Accountability" by Mary Darby and I was struck with the similarity of the phraseology and one, which I think is absolutely critical as we move forward in this debate. And his statement, Dr. Chassin's statement is this: "Very large numbers of Americans are harmed by exposure to the risks of health services from which they cannot benefit. Equally large numbers of Americans fail to receive health services that save lives and prevent disability. More are injured when avoidable complications of heath care are not prevented. Quality of care is the problem, not managed care. These problems occur in small and large communities in all parts of the country with about equal frequency in managed and fee-for-service systems of care." That was from his summary.

And, from the Health Care Policy forum statement, "The quality of care, it appears, has always been inconsistent. It is only recently that awareness of inconsistency has become widespread. This observation runs counter to a popular tendency to associate poor quality with the spread of managed care and its perceived limited on consumer choice. In fact, evidence can suggest that managed care is as good as, worse than, or better than fee-for-service care, depending upon which research one turns to."

And, in that context, my question would be, Dr. Kang, I have available information that you are now going to send out a questionnaire and it, interestingly enough, is going to about 130,000 Medicare beneficiaries is, as the release indicates, Medicare will use the consumer assessment of health plans, the CAHPS proposal, this month to conduct a first-ever survey of beneficiaries in every Medicare managed care plan to assess their experiences with managed care. Have we done this with the fee-for-service program?

Dr. KANG. We haven't but we are actively working with AHCPR to develop a similar instrument to be used in a fee-for-service program.

Chairman THOMAS. What percentage of Medicare beneficiaries are fee-for-service versus managed care?

Dr. KANG. Right now, in the Medicare program, it's 16 percent in the managed care program.

Chairman THOMAS. So, we have 85, roughly 85, percent of the beneficiaries in the fee-for-service program. Unless you with to disagree with Dr. Chassin or the report survey that quality of care is unequal in both areas, and why haven't we been trying to do assessments on quality in fee-for-service and why are we launching the first ever in only the 15 percent portion of the beneficiaries of Medicare? And this is the concern I have about, in part, politics driving rather than policy driving a discussion of this issue. Quality care is quality care. But, what's occurring is a political wave to focus only on managed care on a quality concern, rather than across the board, including 85 percent of the beneficiaries in the fee-for-service. When are we going to have the fee-for-service questionnaire out and in the field?

Dr. KANG. I agree with Dr. Chassin's position completely. This notion of tremendous variability in quality of care, whether its managed care or fee-for-service or whether whatever State we're in, it has been known for years. It's unfortunate, though, that the movement to managed care has actually brought it to the public's attention so this is actually where we've started. But, in reality, HCFA's viewpoint on this is that we need similar measurements and accountability in the fee-for-service program——

Chairman THOMAS. Then why aren't we doing fee-for-service? Why are we doing managed care first?

Dr. EISENBERG. Let me—since we're the guys who developed this instrument, I should help out here.

Chairman THOMAS. Yes, but you're not the ones who decided to apply it to managed care before you applied to fee-for-service. That was HCFA.

Dr. EISENBERG. But we——

Chairman THOMAS. Now, I need to know why HCFA decided that it was more appropriate to move on 15 percent of the beneficiaries rather than assist quality care for 85 percent of the beneficiaries. What was the decision structure that led to the movement to push this out as a survey to managed care rather than fee-for-service?

Dr. EISENBERG. If I may, the main reason we developed this instrument is because people making choices among plans wanted help in choosing among those plans. And, in fact, much of the debate that has gone on in this committee in previous years has been to give people that choice. They didn't have choice of plans within Medicare part A and part B and so therefore——

Chairman THOMAS. Yes, but they have choice of doctors——

Dr. EISENBERG. They do, and——

Chairman THOMAS [continuing]. And, frankly, when you talk about quality in fee-for-service, it is a comparison of folks who were doing the same thing in different ways.

Dr. EISENBERG. And you're right on target because the next phase of the development of this CAHPS instrument is to develop measures among providers. But, the first step was to address what people were complaining about, which was now that we have choice among plans, how to choose——

Chairman THOMAS. The only point I want to make is we have to be careful in terms of what we're doing because we may drive

through politics the belief that quality of care is, in fact, a "problem" only with managed care when, in fact, quality of care is a concern for all in all of medicine. And that's my primary concern. And, from a policy point of view, we should be sensitive to that.

Dr. EISENBERG. Can I just make one other comment on that? And that is to say that we—AHCPR sponsored a conference this year during which the theme was the question of what the quality of care is in managed care, and the conclusion was very much what you stated, which is managed care is so diverse and so, there's a term we use in medicine which is pleomorphic, multi-forms. It's a great word for managed care because it comes in so many different forms. You can't compare managed care versus fee-for-service anymore.

And, we, as an agency, believe that the right research question to ask is the one that you're asking; not whether managed care is better than fee-for-service, but what aspects of managed care are good in health and which ones might not be. And that's the reason why the CAHPS program is designed to try to tease apart those element.

Chairman THOMAS. Thank you.

Mr. STARK. Mr. Chairman, I thank you for letting me inquire. I'd like to follow up on that to suggest that the complaints that I'm getting, and I think my colleagues are also getting are all about managed care. I'm not getting any complaints that people in the fee-for-service system are being denied access to specialists, or are not having their emergency room bills paid, or can't appeal. They can just walk out of one doctor's office and into the next doctor's office and Medicare will pay. The major part of all of our constituents' unhappiness is coming from managed care. And, I tend to grease the squeaky wheel.

Second, we're paying $500 a month for everybody in managed care, healthy and sick. If you're in fee-for-service and you're not going to the doctor, it doesn't cost us anything. So, that 100 percent of the people in managed care are clipping the system for, let's say, an average of $4,000, $5,000, $6,000 a year, depending upon where they live. That is an area in which we have a responsibility because the individual has no choice in managed care.

In a fee-for-service plan, Medicare is the broadest choice plan in the country. There is no facility or no physician, almost, that is denied to a person in the Medicare fee-for-service system. There is a caveat in that they ought to have Medigap insurance, which could be a little bit expensive. Nonetheless, some 70 percent of Medicare beneficiaries have that.

So, I think from this member's standpoint, going first to managed care makes sense. It is new, it is confusing, it is unusual and it's generating a lot of complaints. We might as well start there and hopefully we would build those efforts.

I wanted to ask Dr. Kang a question regarding this issue of the HEDIS—is that how you pronounce the acronym?

Dr. KANG. [Witness nods affirmatively.]

Mr. STARK. In your report, you're suggesting, if I can read into your report, that many of these plans are not responding accurately. I'm going to be generous. They're not lying, I don't think you would say, but they aren't responding very accurately. And, I'm

guessing that the reason they're not responding very accurately is that, rather than fibbing to you, they're just not keeping good records. Or, they're not able to keep good records. For example Oxford health plan. Their computers are down and they're not able to pay the doctors, much less respond to your inquiries. But, is there a legislative action that must be taken to achieve accurate HEDIS reporting? Should we kick plans out of medicare if they can't respond? If somebody was honing up their HEDIS figures, would you suggest kicking them out of the system? Or, do you think given time, these systems will start providing you with more accurate information?

Dr. KANG. I'd like to take an opportunity to briefly just talk a little bit about this managed care fee-for-service issue and then I'll just——

Mr. STARK. Okay.

Dr. KANG [continuing]. Speak to the HEDIS issue. I think that there is some confusion with regard to quality care——

Chairman THOMAS. Dr. Kang, as a first time visitor, you need to know that in terms of the lights and the members' times, they get antsy. But, obviously, you want to respond to a question that I asked and so, it won't come out of the gentleman from California's time.

Dr. KANG. Okay.

Mr. STARK. Take your time.

Dr. KANG. There is some confusion between the access to care and consumer choice in the fee-for-service system as being a proxy for quality of care. What we really need to do is actually have good performance measures. And, it turns out that the peer review program has done a managed care to fee-for-service diabetes quality improvement project where the initial measurement shows that there are no differences between managed care and fee-for-service with regard to those diabetes outcomes.

So, we have to be a little bit careful in terms of how we define quality of care but it really explains why we need good performance measures and outcomes measurements.

Chairman THOMAS. Could I ask you just a followup? Did you read the magazine U.S. News rating of America's top HMOs? That their rating—they used HEDIS figures, did they not, in putting that together? Did they do a pretty good job of rating? Not in terms of—systematic, I mean, as their procedure. Is that a good way to build a—it may not be accurate—go ahead. You can criticize U.S. News and World Report or you can praise them.

Dr. KANG. Let me—shall I answer this question or your first question?

Chairman THOMAS. Well, either one. I just—[Laughter.]

Dr. KANG. With regard to the HEDIS measures, I do want to say that HEDIS measures are self-recorded and, given the fact that the Balanced Budget Amendment calls for us to publicly report these measures, we felt that our responsibility to make sure that these measures were accurate and with what confidence that we could publish these. So, therefore, we did this audit of measures. The purpose of the audit was not to actually catch fraud or lying. It turns out we did not see any. But we did find measurement problems and they really speak to the immaturity of this science.

There are information system problems, and there are measurement specification problems. There's ambiguity in those specifications. I believe, though, over time that they will improve.

Now, the problem with some of these U.S. News and Reports is that there is an issue of what is the underlying accuracy and validity of the measures. And I think that we need to be a little careful with what we publish as we move forward.

At the same time, though, these kinds of things begin to dialog and begin to push the importance of quality in the public's mind, rather than just comparing plans based on costs and benefits.

Mr. STARK. Let me now jump to the last holiday season——

Chairman THOMAS. Would the gentleman yield on that point?

Mr. STARK. Yes.

Chairman THOMAS. My assumption is, since you're now into HEDIS 3.0, as you move to HEDIS 4.0 or 5.0 or 6.0, your shift will be away from the process analysis aspect and more into outcomes so, although this kind of a comparison in U.S. News and World Report might be premature and you wouldn't be able to get a full reading, clearly you anticipate that as you go forward on this it will be a much more useful tool in comparing the quality aspects between HMOs. So, they're a little premature, would that be fair to say?

Dr. KANG. That is true——

Chairman THOMAS. That your later models will be better in helping us?

Dr. KANG. That is true. In fact, there is a true outcomes measure in HEDIS for the Medicare population called the Health of Seniors measure. The problem is this is a longitudinal measure for which we won't have data——

Chairman THOMAS. Okay.

Dr. KANG [continuing]. For the next 3 or 4 years.

Chairman THOMAS. Thank you. Thank you.

Mr. STARK. Let me add—Mr. Chairman——

Dr. EISENBERG. May I add just a quick comment to that?

Mr. STARK. Well, I want to ask you a question first. Not knowing that all the television would be over at the Kyoto hearing this morning, I have prepared this chart which I'll share with my colleagues.

[Chart.]

Mr. STARK. But, really, it's Uwe Rheinhardt's Christmas card. [Laughter.]

That's true. And what it shows, and John Eisenberg has already seen this, is that between Minneapolis (which is in the neighborhood of the Mayo Clinic), and New York or Miami and probably San Francisco, there's an almost 50 percent difference in the AAPCC. In other words, we're paying four grand a year for the average health care cost in Minneapolis and we're paying $8,500 in Miami. What we need to encourage Dr. Eisenberg to do is to change this. It isn't right. There's no reason why Medicare we couldn't fly somebody from Florida to Minneapolis, give them a pass on Northwest Airlines to do so, and spend half as much. We'd save money for the Government and make a little money for the airlines in the bargain.

I want to ask Dr. Eisenberg to comment on how the research that we hope you're going to do is going to help us to straighten this out, to make this differential less extreme. And maybe you could comment on where these numbers came from, Doctor, and how you would see AHCPR's ability to address this. I can't make that part of the record but it's a new Christmas card. Thank you, Mr. Chairman.

Dr. EISENBERG. Many of these numbers about variations among small areas come from the work of Jack Wennberg who looks at Medicare data and looks at how we can compare the utilization of services across areas. It's not always the case that one region is high in everything or is low in every area. What is almost always the case, as I mentioned in my prepared testimony, is that when there's variation, there's uncertainty. And when the uncertainty is reduced, we can often improve the quality of care, sometimes reduce it's costs.

AHCPR is sponsoring projects now to try to test that but it's only a hypothesis at this point. We believe, given the evidence that's available, that if we can get more information to doctors and patients about what works and what doesn't work, we can both get rid of the unnecessary services and, have some resources so that we can provide some services that aren't being used now that should be.

Experts in this area say that about 30 percent of services that are provided to Americans don't help them, and these services don't enhance the quality of their care. There are other services we know would enhance the quality of their care if they received them. So, our job is to figure out which is which and then to get that information to the decisionmakers.

Mr. STARK. Thank you, Mr. Chairman.

Chairman THOMAS. Certainly. The gentlewoman from Connecticut is not available. Does the gentleman from New York wish to inquire?

Mr. HOUGHTON. Thank you, Mr. Chairman. Gentlemen, good to have you here. Thanks very much for your testimony.

Just picking up a little bit on what Mr. Stark was saying, I think dollars do make a great deal of difference. You mentioned, Dr. Eisenberg—I forget whether you mentioned Miami or Houston or Dallas, but also you did mention Allegheny county, New York, which is something which I represent—a big, big difference in the AAPCC. And if I understand correctly, that the higher the amount, the more frequent the use.

But, I guess the basic question that I was searching for is this: with all of your testimony and, you know, you're talking about standards and you're talking about peer review and information and followup and reports and things like that, where is the incentive for quality, for better quality? I know what it is in business, it's in terms of higher price.

Dr. EISENBERG. Right.

Mr. HOUGHTON. Or, it's in terms of greater profit margin. But where is the incentive for somebody in Allegheny county, New York, who in many cases has to pay the same costs because they are in the greater Buffalo, New York area. And, I'm sure that the Buffalo Children's Hospital, or something like that, gets a far dif-

ferent payment. Where is the incentive for this? As a matter of fact, where is the incentive—I don't quite put my fingers on it—with all the standards and the reviews and things like that, what is the incentive really to do what you want?

Dr. EISENBERG. Well, let me just comment first on the statistics. You're absolutely right about the difference between Allegheny county and Miami and that would suggest that there's either underservice in your area or overservice in Miami, or both. But, we wouldn't imagine that all services should be the same across the country. In fact, we would hope it would be the case that there would be more skin cancer being treated in Miami than in Allegheny county, New York.

But, that notwithstanding, your question about where we're going to provide incentives is really a quite fundamental one because, by and large, right now we have incentives on what we can measure and we can measure cost easily. And so, the incentives today say all of the studies that are being done are, by and large, on cost. But, we find that when we survey Americans, 90 percent of them say that quality is a key issue. Over 40 percent of Americans say that quality is the most important issue, but over 60 percent say they've never seen any information on quality.

Mr. HOUGHTON. Yes.

Dr. EISENBERG. Now, consider the U.S. News and World Report example, as a sort of consumer's report approach. If I'm buying a car, I'm going to go to Consumer Reports so I can see what the quality of that car is going to be based on unbiased observers measures. The U.S. News and World Report measure in some ways was unfortunate because it amalgamated all the different measures that NCQA looks at. If I'm looking at a car, I want to know how fast it goes from zero to 60. I also want to know how comfortable it is, as well as its cost. If I'm choosing a plan or a doctor or a hospital, I want that information as well.

We don't have that information yet but Americans want it and the answer to your question, unfortunately, right now is the incentive is on cost and next it's on image and after that it's on something which we can't give them, which is quality.

Mr. HOUGHTON. Yes, well, maybe Dr. Kang, you'd like to answer. But, I really think in the final analysis if we talk quality, at least from any experience I've had through my life, that there has to be some sort of a push, an internal incentive, and I don't see it there. I mean, for example, just little things like a quality emphasis in business and having a Malcolm Baldrige award. I don't even see that here.

Maybe you'd like to comment.

Dr. KANG. I think the problem is there is no market for it. (a) we're not able to measure quality, but (b), there is no market for quality. So, I think that—but we're in somewhat of a chicken and egg situation. If consumers don't have information, then they make their choices based on costs. If we start giving them information on quality, the demand for that information will increase which will then put pressure on creating this information.

Mr. HOUGHTON. But, if I could just interrupt a minute, but whenever I've seen quality work, it just doesn't come from one source. Let's say that all the information is available early on to

a patient so that they are able to make intelligent decisions about their own health. And let's say all those things that you've talked about here in terms of the standards and the peer review, things like that, are available to the doctors. It still doesn't——

Chairman THOMAS. Right.

Mr. HOUGHTON. It doesn't really quite match.

Dr. KANG. There is another thing that HCFA's interested in. We do not have the statutory authority for it, but other purchasers do this, which is the notion of beginning to pay for better quality care. Just like your car manufacturer or something, you may choose to pay for better quality parts or whatever. So, I think that as we begin to develop quality measures and create a market for quality, the notion of economic incentive for good quality of care gets put on the table. I think we need to begin to move in those directions.

Chairman THOMAS. Right. Thank you.

Mr. HOUGHTON. Thank you, Mr. Chairman.

Chairman THOMAS. Thank you. I believe this is the last vote of the day and I would ask the panel if you would indulge us, the subcommittee will adjourn until 25 after. Then we can come back and continue with the questioning. Is that okay with you?

Thank you very much. Subcommittee stands adjourned until 11:25.

[Recess.]

Chairman THOMAS [presiding]. Does the gentleman from Maryland wish to inquire?

Mr. CARDIN. Thank you, Mr. Chairman. First, let me thank you for this hearing on quality issues. I think it's an extremely important subject and one that will become even more dominant in the health care debate in the very, very near future. I very much appreciate the testimony of our witnesses and the response to the questions so far.

I'm just curious as to the appropriate role between the Federal Government and the States here. I know that in my State of Maryland, we have had some State efforts in regard to trying to give consumers more information on selection of HMOs. The State of New Jersey has also had a performance report in regards to helping their consumers on selection of HMOs. The Federal Government, obviously, has a responsibility as it relates to the Medicare population in trying to give better guidance to consumers on selection of HMOs based upon quality. And the Chairman raises a very good point, that quality goes well beyond just a managed care program, such as the fee-for-service is also Medicare.

So, how do we handle the relationships between what the States are doing—they're closer to their people and to the beneficiaries, they have a better network of getting information out—and to the work that you all are doing? I appreciate any guidance you might be able to give us on that issue.

Dr. EISENBERG. Let me start by saying that there is a critical role for the States in this area and, as an agency, our feeling is that our methods, our tools ought to be used by whoever is going to take the lead. In this area, the States in many instances have taken the lead.

One example is the one you mentioned which is that the consumer assessment of health plan survey, which this poster depicts,

is used in the Maryland report on managed care plans and there's a booklet that the State puts out, as you know, that's a side-by-side comparison of managed care plans along these lines.

I applaud the States for doing this. I think given that we are experimenting and that we're trying to find the best way to get information to patients, we need to have as much innovation at the State level as we can. There are certainly some economies of scale in the area of research and measurement that we ought to be taking advantage of at the Federal level and, to the extent that many of the plans cross State boundaries, we need to be considerate of that factor as well. But I'd like to see the States do as much as they can and would like to continue to work with them in that area.

Mr. CARDIN. Are you working with the States?

Dr. EISENBERG. We do. We, as an agency, have not only supported the development of tools like this, but we have a program called the User Liaison Program, which is one of our most popular, in which we meet with State governments, both administrative and legislative sides, to help them understand what health services research is bringing forth that they might apply in addressing questions related to the cost, use, access, quality, and outcomes of health services. We get very good reviews for that program and look forward to continuing it.

Mr. CARDIN. Dr. Kang.

Dr. KANG. I'd like to just add one other thing: in addition to the issue of the efficiency with regard to the standardization of measurements and the science of outcomes and performance, I think there is a role for the Federal Government working with States on data infrastructure issues and data collection issues and this will be critical because we want that standardized to the extent that plans or providers cross States lines.

Mr. CARDIN. It seems like that almost all the work is being done in trying to give consumers information on a health care plan, more so than individual providers. Can you just give us any hope that the technology will ultimately give guidance not just on the plan itself but to the individuals that participate so that the consumer can not only make a choice on plans but can also know about the individual components of the plan?

Dr. EISENBERG. We are working on that. In fact, and there is a plan to move this consumer assessment to the provider level as well as to deal with the importance of gaining data from large data sets about providers, both within plans and across plans, to see how well they do.

One of the challenges, though, is the problem of the sample size and severity adjustment, which are technical problems but very tough problems. We don't want to penalize physicians or hospitals who take on the toughest cases who then might have poorer outcomes and we don't want to infer that that's poor quality care. You wouldn't want that to happen to Hopkins in Maryland and we don't want it to happen to any hospital in the country that takes care of the sickest patients.

And so, we don't yet have the technology, the methodology, to be sure that we can correct for severity and risk in that area. We do, though, have good enough data to give back to providers so that

they can look at it and they can say, here's an area where we might be able to improve. And, I'm distinguishing here between the use of data for choice by consumers or employee benefit managers, and the use of data for quality improvement. The data for quality improvement should be corrected as much as possible for severity but that kind of judgement can be made internally by the organization as well.

Mr. CARDIN. I understand it's very difficult and I think you need to go slowly on it. You don't want to put out material that could disadvantage those that are willing to really take on the more difficult assignments in our health care delivery system. So, I encourage you to take your time, but it is important that we do make progress and provide greater guidance.

Dr. EISENBERG. Well, it's critically important to us, as a department, as an agency, as well.

Mr. CARDIN. Thank you, Mr. Chairman.

Chairman THOMAS. I thank the gentleman. The terms comes up over and over again, risk assessment, the ability to judge risk in a number of different areas and I'm just hopeful if we can push forward in some kind of some crude measuring device in a number of areas dealing with risk assessment; here, in terms of responsibility taken on heavy cases, others, in terms of a fair and equitable load among similar patients and that sort of thing. It's very frustrating. Several times in the past if we'd had it, we could have moved forward in a little bolder way. Good luck to you.

Does the gentlewoman from Connecticut wish to inquire?

Mrs. JOHNSON of Connecticut. Thank you very much, Mr. Chairman. I want to just raise two issues. First of all, I'm interested in your comments about the need for standard and objective measures and I respect that need. I also was very reassured by your comments a few minutes ago about the need to correct for severity and type of illness in a lot of this public information that we're going to distribute.

I would also like to raise the issue, because I hope you're thinking about it but it's never been thought about very well, and that is legitimate variation. You do point out in your testimony, Dr. Eisenberg, variation is not inherently bad. Now, it's more than that. Often, the best ideas are not popular at first.

I know we all move from anecdotal evidence but my husband was trained as an Obstetrician in California and, when he moved to the East Coast, no one in the hospital had done any delivery by natural childbirth and he had never done one under general anesthesia. I mean, this is polar variation. You know, he stuck to his way of practicing and, over time, there has been change, but, if you look at what's happened in the public conversation about caesarian sections, it's not healthy. It wasn't good. A lot of the advice that's been given to women on that issue has not been good for them, nor good for the child that they were about to give birth to.

So, there's a certain fadism in our public conversation about what treatments are best and the standardization could easily sock-in current practice as best practice. So, that's a problem. Now, I don't want to spend all of my time having you talk about that because it's really just a problem that we all understand but you've really got to make sure that somehow we build in a space for new

approaches that aren't popular at first, and that may even be picked up by a group and dramatized as dramatically bad when, in fact, in the long run, they may be dramatically good.

The more important issue that I wanted to bring up and Dr. Kang, you referenced capitation—you know, you need to think about, because we need your guidance, on how do we merge our research on best practice with our commitment to reimbursement rates.

Now, a perfect example is the problem we're having now in oncology—the RBR'S does not reward the physician for the delivery of the drug and the wholesale price, the Inspector General says, is the price we're paying is way too high because he doesn't take into account the cost of delivery. And, when you're talking infusion therapy and OSHA regulations and insurance to cover things that have to be refrigerated for a wide range of kinds of cancer patients, it's really wrong for Government not to be able to see this. So, we have to think honestly about reimbursement rates. Reimbursement rates destroyed Medicaid. When Medicaid did usual and customary, it was a one-kind of system. When it stopped doing usual and customary, it was a different kind of system and a lower quality system. And, I personally believe that we're moving this direction in Medicare.

So, I think it's unrealistic for you guys to be "quality" in Government and in the administration and not be willing to talk about cost of quality. Both cost and reimbursement rates, cost and capitation—I mean, some of the capitation rates I see HMOs proposing are scandalous and, at some point, the Government has to be able to say quality care—we don't see at this point that quality care can be delivered for that.

Then, lastly, I'd just like to mention to you that our own approach to fraud and abuse is now reducing the very kinds of care that we want to hold physicians and HMOs accountable for. In my area, it has eliminated annual physicals because the OIG only lets you get reimbursed for what it specifically you are supposed to look at, at that moment, with that patient. And doctors used to say, fine, you're in for this, but we'll also just do all this checkout to be sure you're okay. Can't do that anymore. Fraud and abuse investigations won't let you.

So, are we going to hold them, then, to the quality standard of you didn't get it early enough? Well, you didn't get it early enough because you already had your mammogram a month ago or four months ago or eight months ago or nine months, ten months ago and it wasn't quite time for your next one. So, yes, you didn't get it early enough. So, I think we have to deal honestly with the conflict between quality as you academicians, in a sense, professionals, look at it and what we are actually reimbursing for and allowing. So, are you running into those kinds of problems in your work?

Dr. EISENBERG. Let me respond to one of your first comments about the variation issue. I couldn't agree with you more. There needs to be healthy and legitimate variation to reflect cultural differences, geographical, epidemiologic differences. My response to you in brief is that variation is not the answer; variation is the question. We have to follow up to find out why those differences exist and whether they are legitimate differences.

Let me let Dr. Kang address the issues that are specific to HCFA except that I would say this: that one way in which we reward providers for providing high quality care is through the attraction of patients. It's the market share issue so that—and I recall my days when I was on that side—the fact that there were fees that were constrained or limited didn't stop us from trying to provide high quality care or in other ways attract patients because we needed more patients, more market share. So, that I think your question does raise some very important issues but it doesn't preclude the attraction of patients through a market mechanism.

Mrs. JOHNSON of Connecticut. Well, all I'm saying is there's a point at which it does. If the market—if the reimbursement rate is so low that your volume has to get so high that you literally don't have time to listen for that hour, then it does. And that's what you also having to be willing to speak up about and think about.

Dr. Kang.

Dr. KANG. I'll answer briefly. I think what you're really raising is what we're after, which and what society's after is value from the health care system. And it's really quality divided by cost. So, you're absolutely right; we cannot talk about quality in the absence of cost and the dilemma that we have—I think the Balanced Budget Amendment has given us a lot of tools to look at the cost side of the equation. What we're really wrestling with is the quality side of that equation such that we can have an open discourse on the tradeoffs between quality and costs, i.e., value of what we're trying to get.

Mrs. JOHNSON of Connecticut. Just in conclusion, Dr. Eisenberg, you mentioned geographic, culture, and those kinds of differences. That's the least of our problems. When you get down to outcomes for a surgeon, you say, given all of that, this works better and that means you're not going to reimburse for this other thing that right now doesn't look as good because the majority of physicians don't do it and don't like it and for one reason or another, you know, don't think it's the right thing. If you don't allow that, you don't find out in 5 years that, in fact, it was the right thing. That's the kind of narrowness that I fear losing. So, these are just warning thoughts and particularly on the reimbursement issue, we have to be far more honest or we'll destroy the system. Thank you.

Chairman THOMAS. I thank the gentlewoman. Does the gentleman from Louisiana wish to inquire?

Mr. MCCRERY. Now, Dr. Kang, when your agency is considering a payment or a coverage policy change that has clinical implications, what types of experts do you consult with?

Dr. KANG. Actually, I'll let Dr. Eisenberg answer that question because we do very much rely on much of the evidence-based practices that AHCPR works on.

Dr. EISENBERG. There is in the organization of AHCPR, the Agency for Health Care Policy and Research, a mechanism whereby when HCFA asks a question like you just asked, it will say: is this the kind of question where we can ask the medical directors of the carriers' intermediaries to deal with this issue or is this something where we do need to go to the evidence and get an approach that looks at what the real evidence is?

And when that's the case, HCFA has several options, one of which is to come to us and ask us to do an evaluation. Sometimes we do those internally within the agency but increasingly, we ask one of our evidence-based practice centers to take on that project, 12 centers around the country that have expertise in this area. They write a report that then would go back to us and we'd then go to HCFA after we're confident that the report is of the highest quality. That helps HCFA to make that decision.

The coverage decision is HCFA's but what we are able to do is to provide an arms-length analysis of the science that underlies the question of whether a service should be covered or not; that is to say, whether its effectiveness is demonstrated or not.

Mr. MCCRERY. Well, the reason I asked the question, in September, this last September, there was a payment policy change regarding EPOGEN that was issued by the agency and we're told by a specialist in that area that this decision could have a dramatic impact on some of their patients.

When the staff—I'm told when our staff asked HCFA if the agency had consulted with leading nephrologists about this, they were told that HCFA did not and the rationale for not consulting with leading nephrologists was that, well, they're likely to give us a biased answer because of financial interests.

Couldn't you have found some retired nephrologists? [Laughter.]

Or an academic, someone that didn't have a financial interest that could give you a specialist's view of this change?

Dr. KANG. Well, I think that we actually consulted the available literature. The dilemma here with regard to EPO is there is scarce literature on this issue and then we have to make a decision. We need to make a decision, whether we actually refer this for some sort of practice or evidence-based practice center evaluation. The dilemma here is there really is little literature. Then, we have to make some sort of coverage decision based really on whatever efficacy information that we might have and also, though, there are cost implications. So, it's a balancing act here. The dilemma with EPO is there's very little information really available on either side.

Mr. MCCRERY. Well, but, I mean, that just underscores the need to consult, at least to me it should underscore the need to consult, some leading nephrologists and we're told that you did not do that, that the agency didn't do that. So, what's the rationale?

Dr. KANG. I understand that we're in the process of reevaluating our EPO policy so I'll have to get back to you——

Mr. MCCRERY. We hope so.

Dr. KANG [continuing]. On this issue for the record.

Mr. MCCRERY. We keep asking this question and we don't get a good answer really. We're hopeful that HCFA will undertake an expeditious review of this policy and get back to us soon with some specifics rather than a general answer that you're looking into it because that's all we've gotten so far. Thank you.

Chairman THOMAS. Does the gentleman from Nevada wish to inquire?

Mr. ENSIGN. Thank you, Mr. Chairman. I'd like to just briefly follow up on the EPOGEN situation and just give you an anecdote,

and being a veterinarian, we're not supposed to just give anecdotes when we're in the medical field.

But, my Aunt is in end-stage renal failure, has been for some time, and as a personal story there, the EPOGEN policy for her was almost disastrous recently and it does not take into account—and we know in medicine, medicine is an art every bit as much as it is a science. And just like body temperature varies, hematocrit varies between people. What's normal and healthy for one person is not necessarily what another person needs. Your policy does not take that into account and I would urge you, as a personal request for people like my Aunt and the many people out there, that your policy may work for 80 percent of the people but for the 20 percent that it doesn't work it can have disastrous consequences.

And it has to cost a lot more money to get somebody back to bring regulated and get them up to feeling well because they can end up in the hospital and all kinds of things if they end up, you know, becoming sick because their hematocrit levels are not high enough. So, I would definitely add my voice to the other people on the committee who I would like to see HCFA do this as expeditiously as possible.

Do you have a date when you think that you will—at all, that HCFA will be finalizing their change in policy?

Dr. KANG. I'm sorry. I'm not close to this particular issue so I would have to get back to you for the record.

Mr. ENSIGN. Okay. I would appreciate that.

Dr. KANG. I do have a general comment, though, which is that having worked for other plans, the way other plans will deal with this issue is that they'll have a general policy that works for 80 or 90 percent of the population. But, to actually waive that policy for the 1 or 10 percent individuals who are special cases causes a dilemma for us as an agency. To administer an exceptions policy has tremendous administrative costs and, quite frankly, we're not funded to do that.

Mr. ENSIGN. And yet——

Dr. KANG. That's a major dilemma for us.

Mr. ENSIGN. The other exception—I visited one of these clinics in Las Vegas and Las Vegas has a lot of people that travel and they're not quite there to authorize their next EPOGEN shot but they need it and that's another thing I'd like you to look into, is that you don't want to restrict people that would like to enjoy that quality of life, to be able to travel like other people. So, that is another consideration I'd like you to look into.

Dr. Eisenberg, I'd like to ask you a question on measuring quality. Once again, kind of anecdotally, this seems to be one of the most difficult things to measure because some of the things along the line that Nancy Johnson was talking about—once again, this gets back somewhat to the art of science, the art and science of medicine and what a doctor's particular experience may be in a particular area may be different than somebody else's.

A very good example is my son has gastric reflux. We're working with a gastroenterologist, we're working with a surgeon. This surgeon has done, probably as much work as anybody in the world on this particular disease process in kids and his recommendation right now is to do surgery. Her recommendation—and they have

different standards by which they measure these recommendation—her recommendation is to go the conservative approach.

And, to measure which one of those is the quality is very, very difficult and, it's real judgement call. There are pluses and minuses whichever way you go and whichever route you turn out, if it turns out wrong, then that's going to be negative against that judgement.

But also, along similar lines to that, if you have—for instance, caesarian rates. You measure caesarian rates across the country and they vary somewhat, depending upon the plan, and things like that. My wife and I just went through the Bradley method of natural childbirth.

Now, under the Bradley method, they have about a 4 percent caesarian rate, okay, even with past caesarian operations. But, that's a minor technique used across the country; very few people use that on a comparison number, although there are significant enough numbers nationwide. But, that's not going to be a particular procedure that you all are mostly going to be measuring. You see what I'm saying?

Dr. EISENBERG. Yes.

Mr. ENSIGN. In other words, depending on who's giving you the measurements will depend on, are going to depend on whether or not something affects their measure of quality.

Dr. EISENBERG. You hit one of the toughest nails on the head which is that when we make choices about our health care, they're individual choices. In making a decision about how to treat reflux, making a decision between medical and surgical therapy, you don't have a simple yes/no question. It's a question that weighs the advantages and disadvantages, the risks and potential outcomes of each.

Our belief, and I haven't seen Dr. Mulley's testimony but I bet he'll talk about this, is that if we can get information to patients about what the expected outcomes are of the alternatives facing them, they can make a choice which best meets their individual needs. Some people will say, I'll take the chance of surgery, and some will say, I just don't want to take that chance. We can let them make those individual decisions. But without the data about what the expected outcomes will be, we can't give them that choice. That's the first level.

Now the second is the level of trying to improve quality. We talk a lot about quality, like it's a scorecard, and we're trying to develop scorecards of quality. But it's not just a scorecard for others to look at and grade us. It's a way of our grading ourselves. You know, when I and you used to get report cards in school, it was okay because your parents knew how you were doing, but it was most important because you knew how you were doing, and you knew the areas in which you had to work the hardest to improve.

So what I hope we can do is to recognize this individualism in health care and give the community, the medical community, the hospitals, the information so that they can improve themselves. And as this data gets better and more solid, we can also use it for people to make choice. But your point is well taken—it's at all of those levels of decisionmaking that we need to have the data for people, and we can't lock ourselves into one single way of getting to the outcome.

Mr. ENSIGN. The only caution I would make is when we're providing these various statistics, and you get the oncologist that will take on the absolute worst cases, and so his mortality rate is going to be much higher than somebody else's that won't take——

Dr. EISENBERG. Right.

Mr. ENSIGN [continuing]. On those real bad cases. It may be a disincentive for that oncologist then to take on the bad cases or any oncologist to want to take on the bad cases in the future. We have to be careful when we're reporting these things because the press, you can't expect them to be physicians or scientists; they aren't. So when they can take something and make a particular group or a hospital or a particular part of the country look very, very bad, and what they're not doing, not based on good evidence, but based on the way that they read it in an unscientific way.

Dr. EISENBERG. Absolutely. In fact, the old HCFA mortality data is a good example of that, I think. I think HCFA, quite rightly, stopped presenting that data because it was so misunderstood by people who were making the comparisons in the way that you are describing them—mistakenly.

But as a chief of a service at a hospital, it was immensely useful to me to see how we compared to our peers, and I could then look at that information and say, is there an opportunity for improvement here? There was somewhere it was easily explained because we had the toughest cases; there were others where there were really some things we could have done that were better. So I think what we're saying together is that this data is important, but it's got to be used appropriately, when it is used.

Mr. ENSIGN. Thank you.

Chairman THOMAS. I thank the gentleman.

Before I call on Members of Congress who aren't on the subcommittee, Dr. Kang, in your response to the EPOGEN question, you indicated that you were somewhat removed from it. So I want to ask you a question I assume that you are not removed from, although I'm interested to hear.

When Nancy Anne-Min DeParle talked to us on her first occasion as the Administrator, I had referenced a GAO discovery that the Technology Advisory Committee had violated five major provisions of the Federal Advisory Committee Act, and she had indicated that she understood that, and was canceling the next scheduled meeting, which I believe was supposed to be sometime this month.

IPOGEN is one particular of the high-tech aspect. A lot of it are devices that are coming in. This committee, Technology Advisory Committee, obviously, makes assessments to provide opportunities for the latest technology to be part of Medicare's basket of services. What are you doing to make sure that you can continue to make evaluations, notwithstanding the fact that you were in violation of the Federal law previous? You're a member of that committee, aren't you?

Dr. KANG. Yes. No, I am.

Chairman THOMAS. Has it met?

Dr. KANG. It has not met since that——

Chairman THOMAS. Does it have a scheduled meeting?

Dr. KANG. It does not. What we're trying to do is figure out a different process for obtaining the expert opinion that we actually need to make our coverage decisions.

Chairman THOMAS. Well, aren't we concerned about any extensive time of not meeting that we can't advance new medical technologies which, in fact, would be part of the quality issue?

Dr. KANG. I am concerned about this, and we're trying to figure out another vehicle for us to get expert——

Chairman THOMAS. Do you have any timetable for figuring out the other vehicle?

Dr. KANG. I will have to get back to you on that.

Chairman THOMAS. Yes. I am concerned about it. I just want to know that you're resolving it. It doesn't have to be in any—I'd be concerned if it was six months from now, but I am concerned about getting up and running on this important aspect. I'm sorry they were in violation of the law. I appreciate Ms. DeParle's voluntary cancellation of the continued process, which was in violation of the law, but we've got to figure out how to get within the law, so we can continue to do what you and I both think is an important part of evaluation.

The gentleman from Washington I believe wishes to inquire. Mr. McDermott?

Mr. MCDERMOTT. Thank you, Mr. Chairman. The chairman and I had a discussion walking across the street about the whole question of privacy versus data. I know you're both aware of the Stanford-Harvard study of the misuses of medical data that have been accumulated. There are now in the Congress probably six or eight different approaches to this whole question of privacy—I think driven at least in part by the Human Genome Project, which is just about to come to completion. It's going to give us enormous data beyond what we already have. The proposal that makes the most sense to me—obviously, one that I dropped in—is one in which it would require a patient to sign off that the data was going to "X" place, and if any other use of that was going to be made, they would have to come to the patient, explain, and make a second signoff for shifting the data, except for research in which, if it was going to be a part of a statistical basis, not personally identified, it could be sent on without a personal signature.

Now I would imagine that a patient in Medicare would send in their documents to Dr. Kang for payment. You would have the data, and that you could send it to Dr. Eisenberg for statistical analysis with no problem under that procedure. I can't see why that procedure isn't the best one for us to adopt in the Federal Government in terms of protecting the privacy of that information. If HCFA were to release it to the HIAA, then that would be a violation of the law unless the patient were notified of that. And I can't see—I would like to hear a dialog from you about why that is not an effective and simple mechanism to deal with it now, because we all come from the same basis, believing that we need data. I believe we need data. We can't run this thing without data. So we're on that. Now let's figure out how to protect the patient.

Dr. EISENBERG. Let me add one item before I start, which is to say, no matter which solution we conclude is the right approach for making information available for research, I'd like to add quality

improvement and quality assurance activities to that list, because if we're going to have oversight groups that look at doctors' quality, hospitals' quality, plans' quality, we need the data, and that may be individualized data, in order to do that. Because it's not literally research, it might get lost. It might fall through the cracks.

So, first, I hope that we can include quality improvement/quality assurance activities. Secondly, one of the difficulties that we face in the research community is the need to link data across different databases. To do that, we need to have some identifier. It doesn't have to be the patient's name. It could be an encoded and encrypted identifier, but we do need to have an identifier to link data across different datasets, maybe an interview that——

Mr. MCDERMOTT. Something other than the social security number, for instance?

Dr. EISENBERG. Well, the social security number is one simple proposal. There are problems with that. We are, as is the Congress, working on what the right identifier ought to be, but it would be an identifier. We need to be sure that it's adequately encrypted or somehow adequately protected and that there are firewalls available, so that those people who get these data can't identify the individual.

Some have pointed out to us, though, that even with a few pieces of information about an individual, especially for unusual people, you could figure out who that person is, even if it's encrypted. So there are technical challenges to this, and I hope that, no matter what we do in solving the confidentiality problem, that we maintain the ability to link different databases, so that we don't throw out some identifier of people in order to make that linkage.

And then the final comment I would make is that I think that we need to do a better job of helping institutional review boards who have the responsibility for overseeing the ethics of research, understand better how they can assure that the investigators in these research projects to which you refer have adequate controls for confidentiality. I think if we can develop standards for them and we can help them, then we probably could allow more data to be available to investigators, but still to have appropriate safeguards for that kind of data.

Mr. MCDERMOTT. Do you foresee a problem with saying to a patient who's submitting their data to Dr. Kang for payment, in your submitting information, you signed that this will be available for encryption for research in the agency that you head?

Dr. EISENBERG. I see two problems with it. One is that we may want to undertake studies that are retrospective, whereby the waiver that the patient signed would not cover the kind of research that we might want to do 5 or 10 years later on old data. We ought to at least leave room for new kinds of questions and new kinds of research to be done.

My biggest concern is the second, though. I don't think that most patients, especially in the heat of arriving in a hospital emergency room, pay much attention to those waivers, frankly, and I'm not sure that's the right time to ask a person whether they want to waive their privacy rights.

We had a staff person in our agency who told me the story about going to an emergency room in a hospital out of town, and after

she signed the form, she went back to see what she had signed, because she just didn't even know what she had signed.

If we are going to have these waivers signed, we have to be absolutely sure they're being signed with full knowledge of what people are signing, and I'm concerned that in most instances it's not the right time in a person's life to be asking them to waive that information, especially when they fear that they might not have access to care if they don't sign the waiver.

Dr. KANG. Actually, with regard to our claims data, that's basically what's happening right now. We get the claims data in. If someone like John Eisenberg wants to use it, we strip it of all the patient identifier information, and then he can use it. The dilemma is he can't link data with other sets. That's one issue.

There is one other issue, that is the medical record itself—we do not have this in claims data. The medical record itself is a rich source of clinical data for outcomes and performance measure, quality assurance, quality improvement, all this stuff. Your proposal speaks to the issues that we have the data in-house to do claims, but what about the confidentiality or privacy issues around the medical records, which prevents people from access to that needed data? So there is that issue also.

Mr. MCDERMOTT. It seems to me that in the bills we passed a year or so ago, we required every physician to report what's in the chart, including what was called "encounter" data, which to me is a major source of information, but also a major source of potential abuse. If you were to tell your physician that you thought you were having a problem with X, Y, or Z, if somebody can retrieve that data and use it, as the Stanford-Harvard study suggests, to deny loans or employment or all the other reasons or the other ways it's been used, it seems to me that there has to be a way to gather that chart data, but still protect it.

Dr. EISENBERG. Well, one mechanism is to be sure that those who have access to the chart understand the restrictions, that there are penalties for those who misuse the information, and that the protocol that's used has been approved by an oversight group. I recall having sent medical students to the record room to do research for me, to go through charts, and in retrospect, I wonder if I had instructed them adequately on their responsibilities about the privacy of that information. And I'm sure as a psychiatrist that there were times when you didn't write things on the chart that you might have otherwise written, and you had to write some kind of code, so that you knew what it was, but nobody else might. I think the problem that you're describing is a critical one.

But we do need a mechanism in place where we have adequate oversight and protections, but where we don't throw away the key to the data that's going to be so helpful for understanding health care.

Mr. MCDERMOTT. Do you think the mechanisms that were in place in Maryland, where the employees of their Medicaid system were selling cases to HMOs, so that they could do selection of which patients they wanted to approach—do you think those mechanisms are sufficient?

Dr. EISENBERG. Not knowing the specific details, let me respond in a general way. I think we need to have restrictions and fire-

walls, protections, in place, but there will always be people who undertake criminal activity. My feeling about this is that we ought to be sure that if people violate the standards that the Congress establishes, that there are penalties in place for those people.

Mr. MCDERMOTT. Thank you, Mr. Chairman.

Chairman THOMAS. I thank the gentleman.

Any additional inquiries?

[No response.]

Then I'll just ask one, Doctor, to try to sum up the concerns that we have in the directions that we're going, because we all want a measure of quality. But just as the gentleman from Nevada indicated, you can get into a definition, but there are other levels that you have to deal with.

HCFA has worked with the National Academy of State Health Policy to develop what you call your QUISMC System, and you've got seven clinical focus areas that you're dealing with in beginning to examine managed. And I guess they're as good as any other seven you might be able to evaluate, but what I've looked at, and my immediate reaction to it was, that this could easily be applicable to the fee-for-service area, and that what my concern would be, if you created a kind of a cookie-cutter seven focus, have you taken into consideration severity of a problem area in terms of numbers that have occurred, degree?

Clearly, you've got down, for example, mental health or substance abuse. That may or may not be an important area, and you may want to focus more on an area—you know, lousy jobs of fixing hips or something else that would be far more critical to the senior population. How are you dealing with weighting these kinds of inquiries on quality? So that we're getting answers that are useful for more people and not just we've now done a quality check and we can put seven checks in seven boxes. By the way, how many boxes could you currently check off in managed care if this system were in effect?

Dr. KANG. There are actually plans that could satisfy this requirement for the prevention measures, the acute ambulatory, and the chronic measures here. Let me——

Chairman THOMAS. There are seven. Could any of them comply with all seven?

Dr. KANG. At this point, no, that's the reason for the phase-in. There is a phase-in such that the requirement for seven doesn't go into effect until six years out. So there is a very gradual phase-in to this.

I do want to speak to this. Actually what I think is that there is a very important issue. What we had to do is balance what I would call the distribution requirements for performance improvement projects versus trying not to be specific. Health care is local in nature, and these performance or quality improvement projects need to be local, based on the local conditions, who are the stakeholders, who are the interested parties, et cetera. So we came up with this notion of here's a general distribution, but then within these categories you have great latitude to pick the project that you're interested in. So in the chronic condition one, giving you an example, you could pick hip fractures for the Medicare population. I do think that in the Medicare population that the prevalence of

mental health and substance abuse is quite high. So from a distribution requirement standpoint, you'd probably want to have something in that area. That's how we came to this.

I do think, though, that this is part of—this has been the source of great public comment, and with regard to distribution requirements, we are open to getting into dialog to see——

Chairman THOMAS. And what are you doing in the fee-for-service area, since I guess six years out, when this thing is supposed to be implemented, the fee-for-service will have shrunk from 85 percent down to about 80 percent of the beneficiaries? Are we doing anything in the fee-for-service area such as this?

Dr. KANG. Yes. Again, actually, these QUISMC requirements—we're calling them QUAPI—this particular domain, quality assurance performance improvement, is being built into our conditions of participation for hospitals, nursing homes, home health agencies, et cetera.

Chairman THOMAS. Okay. I guess you're getting my drift, and that is I'm concerned about quality across the board, not just in those areas that are politically-hot right now, because those winds blow warm and blow cold, and quality ought to be of concern in any aspect of medical delivery services.

I thank both of you very much.

Dr. EISENBERG. Thank you.

Chairman THOMAS. You've been a great help.

I would ask the next panelists to come forward, and thank you for your patience. The next panel consists of Dr. Mark Chassin, who's chairman of the Department of Health Policy, Mt. Sinai School of Medicine, New York, New York, and probably more important, he's co-chair, Institutes of Medicine's National Roundtable on Health Care Quality; and Dr. Albert Mulley, who's an associate professor of medicine and health policy at the Harvard Medical School.

Thank you both for accepting our invitation. Any written material you may have will be made a part of the record, and you can address us in any way you see fit in the time provided to you.

Dr. Chassin?

You've done this before. Thank you for the summary. I read all this stuff, but it's nice to have it right out in front. I appreciate it.

STATEMENT OF MARK R. CHASSIN, M.D., CHAIRMAN, DEPARTMENT OF HEALTH POLICY, MT. SINAI SCHOOL OF MEDICINE, NEW YORK, NY, AND CO-CHAIR, INSTITUTE OF MEDICINE'S NATIONAL ROUNDTABLE ON HEALTH CARE QUALITY

Dr. CHASSIN. You're very welcome.

Mr. Chairman, Members of the Subcommittee, thank you very much for inviting me to talk with you this morning about health care quality. I'd like to make four points. The first is that quality of care can be precisely defined and accurately measured.

The second is that research using well-defined and documented measures has shown serious and extensive quality problems in American medicine.

Third, though some quality improvement programs have succeeded in substantially improving health outcomes for patients, these efforts generally are sporadic and limited in scope. Much

broader efforts are needed if we are to realize the full potential value in improved health of the trillion dollars we spend every year on health care.

And, fourth, the recent flurry of legislation and regulation aimed at managed care is important to establish due process and other procedural rights for managed care enrollees, but it will not materially improve health care quality. Quality is the problem, not managed care.

As the chairman mentioned, I co-chair with Bob Galvin of Motorola the Institute of Medicine's National Roundtable on Health Care Quality, which has deliberated for about two years. The Roundtable and the IOM are presently considering statements about health care quality. Those are in process. So my remarks this morning are not to be construed as conclusions of the Roundtable or the Institute of Medicine; rather, they come from my experience of about 20 years working in the field of health care quality in various forms.

Start with the definition of quality, and I think it's useful to articulate a specific definition. The best one I know of was created by the Institute of Medicine in 1990, and it defines quality as, "the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." It's a definition I believe consumers, providers, and health plans can agree on and use productively.

The research on quality the last 20 years is clear and compelling. We have, as I said, serious and extensive problems in quality in American medicine. These problems come in three varieties: overuse, underuse, and misuse. Many studies have documented substantial amounts of overuse of health services. I believe a conservative reading of that literature supports the conclusion that 20 percent of what we do constitutes overuse; that is, it could be eliminated safely because patients would be spared the unnecessary risk of those procedures and those services; quality would improve.

One recent study, for example, showed that in 1992 12.6 million Americans received antibiotic prescriptions for colds and other upper respiratory infections caused by viruses in which antibiotics are entirely useless. This represented 21 percent of all adult ambulatory antibiotic use in that year. Overuse of antibiotics is the major preventable cause of the very serious problem we face now with bacteria growing increasingly resistant to current treatment and causing life-threatening illness.

Underuse, too, is very common. Research has documented underuse of virtually every effective health care service that's been studied. These include immunizations, inhaled steroids for patients with asthma, treatment for early-stage breast cancer, the identification and treatment of patients with depression or high blood pressure, on and on.

Large numbers of patients in many of these studies, as many as 50 percent—5-0 percent—failed to receive these effective interventions. Research has documented that underuse about equally prevalent in managed care and fee-for-service systems.

Let me just give you one example of the magnitude of these failures. A variety of treatments for heart attacks, when used appro-

priately, saves about 80 lives for every 1,000 patients treated. While as many as 60 percent of heart attack victims may be eligible for these treatments, the research shows that we currently reach only about half. Since more than 750,000 Americans suffer heart attacks every year, when you do the math, it works out to about 18,000 preventable deaths every year, just because we don't do what we know already works. Put another way, that death toll is the equivalent of one TWA Flight 800 plane crash every five days, and that's the quality failure for just one disease.

Misuse problems, unfortunately, are also very common. They occur most commonly in the form of preventable injuries from the use of medications or from the use of medical and surgical procedures. Patient injuries from medications, for example, alone occur at a rate of about 2,000 per year at the average large hospital. Over 500 of those are entirely preventable with current knowledge, and each one adds about $5,000 to the cost of hospital care.

These problems clearly need to be addressed by a wide variety of methods directed at their root causes, including improving patient and physician knowledge, creating support systems that remind physicians and other caregivers about when and exactly how to administer effective treatments, and engaging clinicians in ongoing efforts to measure and improve the quality of care that they render.

Improvement efforts are being made today, and I don't want to minimize them, and some are, indeed, producing impressive results, but, over all, particularly when stacked up against the magnitude of the problems, their impact is small.

Current legislation and regulation aimed at managed care will not fix these quality problems. Now let me be clear. I do believe it's important to establish these procedural rights and other benefits for managed care enrollees, but there is no evidence that those kinds of rules will affect the kinds of quality problems that I've just described. Improving quality requires a far more concerted and widespread effort than we're currently making. Government can play a vital role, for example, by investing in the development of specific quality measurement approaches and by disseminating, evaluation and dissemination, effective improvement methods, as the Agency for Health Care Policy and Research has been doing. Government can, and I think should, promote the collection of standardized data on quality to stimulate improvement by showing providers where they stand compared with their peers, a comparison that is extremely difficult for individual providers to obtain on their own.

Creative regulation could improve health outcomes by facilitating regionalization, particularly of services where we know that high volume is associated with much better outcomes. We've known that for quite some time, but we still permit very low-volume facilities to do these procedures.

However, Government should be one part of a much more multifaceted approach that includes components of competition, voluntary and professionally-led quality improvement, and payment incentives. At its best, health care in the United States is the finest in the world. Unfortunately, it is very often not at its best, and Americans bear a great burden because of these failures, a burden

that's measured in lives lost, reduced functioning, and wasted resources. Addressing these problems vigorously should be among our very highest priorities.

Thank you, Mr. Chairman.

[The prepared statement follows:]

SUMMARY

The quality of health care can be precisely defined and measured with a degree of scientific accuracy comparable to that of most measures used in clinical medicine. A growing body of rigorously done research has documented serious and widespread quality problems in American medicine.

Very large numbers of Americans are harmed by exposure to the risks of health services from which they cannot benefit. Equally large numbers of Americans fail to receive health services that save lives and prevent disability. More are injured when avoidable complications of health care are not prevented. Quality of care is the problem, not managed care. These problems occur in small and large communities in all parts of the country with about equal frequency in managed and fee-for-service systems of care.

Exemplary measures of quality can be and are being used in improvement efforts that result in better health outcomes for patients. Such efforts, however, are rare. Improving quality requires a far more systematic and concerted effort than we are presently making. Realizing the most value in improved health from our investment in health care requires a major overhaul of how we deliver health services, educate and train clinicians, and assess and improve quality of care. While these tasks will be complex and difficult, the challenges we must meet to improve quality of care are simple:

1. To always deliver effective care.
2. To always avoid providing ineffective services.
3. To eliminate preventable complications of health care services.

Mark R. Chassin, M.D., M.P.P., M.P.H.
Professor and Chairman
Department of Health Policy
Box 1077
The Mount Sinai Medical Center
One Gustave L. Levy Place
New York, NY 10029-6574
TEL (212) 241-5379

The Need for Urgent Action to Improve the Quality of Health Care

Statement Submitted to the Subcommittee on Health of the
Committee on Ways and Means

Mark R. Chassin, M.D., M.P.P., M.P.H.

Professor of Health Policy and Medicine
Chairman, Department of Health Policy
Mount Sinai School of Medicine

Co-chair, Institute of Medicine
National Roundtable on Healthcare Quality

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"Like Beauty, quality of care is in the eye of the beholder.
It can't be defined or measured."

"Quality of care is like the weather; everyone talks about it,
but you can't do anything about it."

Both of these statements are often heard in discussions about health care quality, and both couldn't be more wrong. Quality can be precisely defined and accurately measured. A growing body of rigorously done research has documented serious and widespread quality problems in American medicine. Exemplary measures of quality can be and are being used in improvement efforts that result in better health outcomes for patients. Such efforts, however, are rare. The recent flurry of legislation and regulation relating to perceived abuses of managed care is important in establishing due process for health plan members, organizational accountability, and insurance coverage rules. However, it does little, if anything to ameliorate health care quality problems. Quality of care is the problem, not managed care. Improving it requires a far more systematic and concerted effort than we are presently making.

The Institute of Medicine's Special Initiative on Quality

In 1994 the Institute of Medicine of the National Academy of Sciences began a Special Initiative to focus attention on the crucial importance of measuring, monitoring, and improving the quality of health care in the United States. A central activity of that Initiative is the National Roundtable on Health Care Quality. The Roundtable is a diverse group of individuals who represent business, consumers, government health programs, expertise in health care quality, managed care, nursing, and academic and practicing physicians. The aim of the Roundtable, which has been deliberating for 2 years, is to identify and examine the issues most central to improving quality of care. It has heard from many experts, held a series of wide-ranging discussions, sponsored conferences, and convened a separate liaison panel to deliberate on the many issues specific to quality in managed care.

Initial discussions revealed a variety of differing perspectives on health care quality. Some believed that quality could not be defined or measured. Some believed that quality problems were serious and extensive; others did not share that view. Some believed strongly that market forces would inevitably improve quality, while others believed equally strongly that regulation is required.

The Roundtable is a work in progress. No conclusions about quality have been formally endorsed by this body. The remainder of this statement discusses 2 milestones in the Roundtable's work, the 2 sponsored conferences. The Roundtable is currently actively considering the precise content of specific statements it may wish to make.

Defining and Measuring Quality of Care

The Roundtable sponsored a 2-day conference in September 1996, entitled "Measuring the Quality of Health Care--State of the Art." At that conference a large number of presentations focused on describing exemplary measures of quality, their development and testing, and their uses to assess and improve quality. The general conclusions emerging from the participants at the conference were that the quality of health care could be defined and measured with scientific accuracy comparable to that of most measures used in clinical medicine and that a number of exemplary measures have been developed and used to improve health.

The Institute of Medicine (IOM) developed a most useful definition of health care quality in 1990:

> 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.[1]

The definition recognizes that our old way of thinking about quality as being limited to assessments of care provided in hospitals and doctors' offices is incomplete. We must also be concerned about people who could benefit from effective health services but are not currently receiving them--hence the emphasis on populations. The definition also emphasizes the probabilistic nature of health care. Good quality cannot be equated to good outcomes; disease too often defeats the best health care. So an important dimension of quality requires attention to what specific services are provided to patients in what specific circumstances.

The phrase "desired health outcomes" reminds us that we must broaden our thinking about assessing the impact of health care. In addition to mortality and medical complications, we must ask patients and consumers what kinds of outcomes they value, and we must measure them when we assess health care quality. The final phrase, "current professional knowledge," is a warning that quality measures must be continually assessed to assure they incorporate the most up-to-date scientific knowledge about effective health care.

This definition has two very important implications for what kinds of measures we consider to be valid measures of quality. Two different kinds of measures can qualify: processes or outcomes of care. A process is a specific patient care activity. Examples of processes of care include giving a drug to control high blood pressure, getting a patient out of bed and walking after a hip fracture repair, and educating a patient with diabetes about how to monitor her own blood sugar at home. Outcomes include death, clinical complications (infections, adverse drug reactions), and functioning of various kinds (physical, social, and emotional).

Some processes and some outcomes are valid measures of quality, but many are not. Understanding which are which goes to the heart of the definition of quality. For a process of care to be a valid quality measure, it must bear a definite relationship to a health outcome we care about. The stronger the relationship, the more proved it is, the better. Controlling high blood pressure is a good example of a process measure that is a valid quality measure, because research has demonstrated that successfully controlling hypertension reduces the frequency of stroke and death. For many processes of care the strength of this relationship is weak or nonexistent. For an outcome to be a valid measure of quality, it must bear a definite relationship to specific processes of care that we can modify to change the outcome. Death following heart attack is a valid quality measure, because there are numerous effective treatments that reduce mortality. On the other hand, the development of distant metastases following the diagnosis of inoperable lung cancer is not a valid quality measure, because no known processes of care affect that outcome.

Using the IOM definition of quality and these rigorous criteria for validity, it is possible to summarize the state of the art of quality measurement. As the September 1996 conference made clear, the experience of the last 25 years demonstrates that we have at present a substantial number of well-studied, validated methods for measuring many different dimensions of the quality of health care. Further, we understand a great deal about how to create new measures to address specific areas of medicine and health care that have thus far received little attention. Some of these methods include: techniques for summarizing and combining evidence of effectiveness, methods for structuring consensus processes for experts to agree on guidelines for how particular kinds of care should be provided and under what circumstances, quantitative approaches to measuring physical, social, and emotional functioning, and methods of risk-adjustment that allow outcomes for populations with different characteristics to be compared.

Research Assessing the Magnitude of Quality Problems

A large number of studies have employed valid quality measures to assess the magnitude of various quality problems. These problems come in three varieties: overuse, underuse, and misuse. Overuse occurs when a health service is provided in circumstances when its risks outweigh its benefits and, therefore, harm is more likely to result than benefit. Underuse is the failure to provide a health service that would have produced benefit. Misuse occurs when a

beneficial health service is provided poorly; the patient experiences a preventable complication and therefore fails to receive the full potential benefit of the service. The message from this research is clear and compelling: We have serious and widespread quality problems in all three of these areas. The problems exist in all delivery systems, populations, and communities in the United States.

Overuse is very common in American medicine. A large volume of studies has documented substantial amounts of overuse across a wide variety of health services, from the simplest diagnostic and therapeutic interventions (e.g., ankle x-rays and antibiotic prescriptions) to the most complex (coronary angiography and carotid endarterectomy). A recent study showed that 21 percent of all antibiotic prescriptions, a total of 12.6 million, received by adult ambulatory patients in 1992 were used to treat colds, other upper respiratory infections, or bronchitis, conditions in which antibiotics are entirely ineffective.[2] Practices like these have undoubtedly contributed substantially to the rising frequency with which disease-causing bacteria are developing resistance to currently available antibiotics.

Another study documented that Medicare patients underwent inappropriate procedures 17 percent of the time for coronary angiography, 32 percent for carotid endarterectomy, and 17 percent for upper gastrointestinal endoscopy.[3] Other investigations have shown 16 percent inappropriate hysterectomies in a group of 7 HMOs, with individual plans varying between 10 percent and 27 percent,[4] 23 percent of children proposed for tympanostomy tube insertion, which requires general anesthesia and is the most common surgical procedure in childhood, for inappropriate reasons,[5] and 20 percent of cardiac pacemakers inserted for clearly inappropriate indications.[6] Interestingly, although proponents of managed care argue that it reduces cost by eliminating overuse, this claim has never been substantiated by rigorous research. No studies have directly measured overuse in managed care and fee for service settings and compared the results. Nor do we understand how much of any cost reduction managed care achieves is due to reductions in overuse.

If overuse is common in American medicine, underuse is ubiquitous. Whether the subject is childhood immunizations, prenatal care, inhaled steroids for patients with asthma, the detection and treatment of high blood pressure, radiation therapy following breast-conserving surgery for early-stage breast cancer, or a variety of treatments for heart attacks, the research is consistent. Large numbers of patients, often as many as 50 percent, fail to receive interventions that have been conclusively proven to improve outcomes. One recent study found that 79 percent of elderly heart attack patients failed to receive indicated treatment with beta blockers and experienced a 75 percent higher death rate than those who were so treated.[7] The consequences of these failures are measured in major lost opportunities to improve survival, health, and functioning.

Four treatments for acute myocardial infarction have been proved effective in improving survival. Research has demonstrated that timely provision of thrombolytic agents, aspirin, beta blockers, and angiotensin converting enzyme inhibitors to appropriate patients can save approximately 80 lives for every 1000 patients treated.[8] But all of these treatments are dramatically underused.[9] In 1994, 759,000 Americans were hospitalized with heart attacks.[10] If only 60 percent of these patients were eligible for these treatments (e.g., had no conditions contraindicating their use) and as many as 50 percent of those eligible now receive them (likely an overestimate), then more than 225,000 patients fail to receive these effective interventions every year. Considering the results of the efficacy research, these failures lead to more than 18,000 preventable deaths each year--from just one disease.

We also know that substantial underuse exists in both fee-for-service and managed care practice settings. Comparative studies have found high levels of failure (ranging from 40 percent to 60 percent) to diagnose and treat depression, to control hypertension, to obtain recommended mammograms, and to provide appropriate eye care to patients with diabetes in both kinds of financial arrangements.[11] Quality is the problem, not managed care.

Underuse problems are made much worse by the lack of health insurance that more than 40 million Americans currently experience. The barriers to access created by this lack have been directly implicated increasing the risk of dying and increasing disability. One study found that

those without health insurance had a 25 percent greater chance of dying within 12 years, controlling for age, race, education, income, and comorbidity.[12] Other work has confirmed these findings and extended them to show that lack of insurance is associated with poor functional status and that loss of health insurance, particularly Medicaid, can be associated with deterioration in chronic disease secondary to reduced access to effective care.[13-16]

Unfortunately, misuse problems, too, are highly prevalent. Injuries from preventable adverse reactions to medications and avoidable complications of medical and surgical procedures are the major classes of misuse problems. Recent work from Boston suggests that patient injuries due to medication use occur at a rate of about 2000 per year even at the best large teaching hospitals, with 28 percent being entirely preventable.[17] Further, each of these preventable adverse drug events adds about $4700 to the cost of the hospital stay during which it occurs.[18]

The Harvard Medical Practice Study estimated that over 27,000 patients hospitalized in New York State suffered injuries due to negligence in the provision of medical care in 1984.[19] The RAND study of prospective hospital payment showed that Medicare patients with congestive heart failure who received medical care of poor quality were 74 percent more likely to die within 30 days of hospital admission, compared with those who received good quality care.[20] We also know that large numbers of complex and risky surgical procedures continue to be performed at hospitals and by surgeons with very low annual volumes, a condition which has repeatedly been demonstrated to result in worse outcomes, with death rates often more than twice as high, compared with higher volume providers.[21] We do not know whether misuse is more or less prevalent in managed care compared with fee for service arrangements.

The evidence is compelling. Very large numbers of Americans, perhaps millions are harmed by exposure to the risks of health services from which they cannot benefit. The health of the public is jeopardized by some of these practices, such as the indiscriminate use of antibiotics. Equally large numbers of Americans fail to receive health services that save lives and prevent disability. More are injured when avoidable complications of health care are not prevented. These problems occur in small and large communities in all parts of the country with about equal frequency in managed and fee-for-service systems of care.

Improving Quality of Care

Recognizing the seriousness of our quality problems in health care should not trigger a search for individuals to blame. The causes are more complex. In no small part, these problems represent the opposite side of a remarkable scientific achievement. Over the last 25 years, we have generated an enormous amount of new knowledge about the efficacy and effectiveness of health services. It is sobering to realize that the first randomized controlled trial (RCT), the gold standard in research for assessing the benefit of health services, was published only in 1952. The number of articles publishing the results of RCTs increased from about 100 in 1966 to nearly 10,000 in 1995. In the 5 years between 1991 and 1995, more articles from RCTs were published than in the previous 25 years combined.

As the speed with which rigorous scientific knowledge accumulates has increased, our methods and systems of educating young physicians and other clinicians and supplying health care practitioners with the information they need to provide high quality care have not kept pace. We have not yet succeeded in crafting education and training curricula that prepare physicians and other clinicians to be effective life-time learners, constantly seeking new data on efficacy and effectiveness and incorporating them into their practices. Too many training programs are still mired in the medieval apprenticeship approach to professional education. We have been even less successful in supporting clinicians in practice by ensuring that the systems in which they deliver care make maximum use of available scientific knowledge and are constructed to anticipate human error and render it harmless.

In light of these observations, the Roundtable began to investigate our current approaches to improving quality of care and how effective they are or could be.[22] A participatory 2-day conference was convened in October 1997, at which invited papers assessed each of 4 major quality improvement strategies: continuous quality improvement, regulation, market competition, and payment incentives. An extraordinarily diverse group of about 60 interacted energetically in debating the evidence that each of these strategies has actually improved quality, the strengths and weaknesses of their potential impact, and how they might fit together in a more integrated approach. Participants included business leaders, physicians, health care quality experts, consumer representatives, health economists, health lawyers, managed care executives, academic policy experts, government officials, and members of the Roundtable.

By the end of the conference, a remarkable consensus had emerged among conference participants around the following 4 propositions:

1. Health care quality problems (or opportunities to improve) in the United States are of major significance. Variations in quality are unacceptably large. Collectively, they demand urgent attention.

2. Taken together, our current approaches to quality improvement are unlikely to produce rapid progress.

3. A small number of hospitals, health plans, and integrated delivery systems have made notable efforts to improve, and some successes have been documented. These efforts, however, have been limited in their impact. We have no exemplary role models of health plans, medical groups, hospitals, or integrated delivery systems that provide care that is consistently and uniformly free of quality problems.

4. Realizing the most value in improved health from our investment in health care requires a major overhaul of how we deliver health services, educate and train clinicians, and assess and improve quality of care.

Each of the 4 major strategies proposed to improve quality of care has important strengths and at least equally important weaknesses. Continuous quality improvement (CQI), or the adaptation of industrial quality management methods to health care, offers important tools and methods for well-motivated providers and institutions to do even better. As currently applied, however, few organizations make maximal use of its potential. Its use tends to focus narrowly

on administrative (as opposed to clinical) aspects of care, and overuse problems are rarely addressed. Further, data documenting its impact on health are scant. Future experience may be more positive. Regulation is the only method we have at present for protecting consumers from individuals or institutions who perform so poorly that they endanger patients. Unlike CQI, it can reach every corner of the delivery system. However, it is rigid, difficult to change, and particularly ill-suited to motivating even mediocre providers to do better.

Marketplace competition currently fuels change at many levels of health care financing and delivery. Proponents believe it will be a major force for quality improvement. Skeptics note that today competition takes place almost entirely around price, no market exists in which quality is the focus of competition, little in economic theory suggests that it will occur, and there is no evidence that it is happening. While there is wide agreement that payment affects behavior, there is less agreement about whether such incentives can be used to drive quality improvement. At present, fee-for-service payment encourages overuse and capitation encourages underuse. No payment system effectively and consistently rewards excellence.

Specific examples of quality improvement efforts resulting in improved health are available, but they are so noteworthy in large part because they are rare. While a growing literature documents the incidence and harm of adverse drug events (ADEs), few studies document substantial improvements. Such change is possible, however, as illustrated by the report from LDS Hospital in Salt Lake City describing a series of computer-assisted programs to help physicians avoid antibiotic-related ADEs. Among other impacts, the study demonstrated a 30 percent decrease in the frequency of antibiotic ADEs, a 27 percent decline in the mortality of antibiotic-treated patients, and a 58 percent drop in antibiotic costs per treated patient.[23]

Currently, quality improvement efforts are sporadic at best. They usually occur in large institutions, most often in hospitals. They focus disproportionately on misuse problems when they address clinical issues at all. Long-term, multi-institutional, or regional efforts to improve are rare. The New York State program of measuring risk-adjusted mortality rates for coronary artery bypass surgery (CABS) patients, publishing these data annually, and using them to facilitate quality improvement has reduced mortality statewide. [24] This program now includes data on risk-adjusted mortality following percutaneous transluminal coronary angioplasty. Another effort in the 3 northern New England states has also reduced mortality following CABS[25], and Pennsylvania has published data on risk-adjusted mortality following CABS and acute myocardial infarction.[26] These efforts stand out precisely because they are so unusual.

Finally, the diverse group of people at the quality improvement conference agreed that whether one discusses health plans, medical groups, hospitals, or integrated delivery systems, there are no exemplary role models that uniformly and consistently provide the highest quality care. Room for improvement is ample in all institutional settings. We will have to devote much more effort than we have thus far to rethinking how we deliver health services, the ways we educate and train physicians and other clinicians, and how we measure and attempt to improve quality. While these tasks will be complex and difficult, the challenges we must meet to improve quality of care are simple:

1. To always deliver effective care.
2. To always avoid providing ineffective services.
3. To eliminate preventable complications of health care services.

While public attention is now turning to quality of care in some ways, much of the debate fails to address the nature and magnitude of the quality problems delineated above. The focus on managed care, while understandable, is inconsistent with the data demonstrating problems of similar magnitude in fee for service settings. The various new laws and proposals to regulate managed care may establish important principles and rules for due process, coverage determinations, and organizational accountability. They do not, however, address the multiple, serious quality problems that inflict considerable harm on the American public whether they are enrolled in managed care plans or not.

An Urgent Need for Rapid Change

At its best, health care in the United States is the finest in the world. Unfortunately, it is very often not at its best. Americans bear a great burden of harm because of these failures--a burden that is measured in lives lost, reduced functioning, and wasted resources. The magnitude of these problems calls for urgent action. Left alone, our current approaches to improvement do not offer the promise of rapid change. Addressing these problems vigorously should be among our very highest priorities in health care. The IOM Roundtable is currently deliberating over the findings of the conferences it sponsored. The IOM will, in the future, issue conclusions and statements following its internal and external review procedures.

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Chairman THOMAS. Thank you very much, Doctor.

Mr. Mulley.

STATEMENT OF ALBERT MULLEY, ASSOCIATE PROFESSOR OF MEDICINE AND HEALTH POLICY, THE HARVARD MEDICAL SCHOOL

Dr. MULLEY. I, too, want to thank you, Mr. Chairman and committee members, for having me here today. Let me begin by introducing myself. I am a practicing physician and chief of the General Medicine Division at Massachusetts General Hospital, as well as associate professor at Harvard, as you mentioned. I'm also cofounder, with Dr. Jack Wennberg of Dartmouth Medical School, of the Foundation for Informed Medical Decisionmaking, which was established in 1989, expressly——

Chairman THOMAS. Doctor, excuse me. You're really going to have to talk directly in the microphone.

Dr. MULLEY. Okay, thank you.

Chairman THOMAS. It's very hard to pick it up. Thank you.

Dr. MULLEY. The Foundation was formed expressly to promote research and to develop educational interventions, with the goal of improving the quality of medical decisionmaking.

I believe that there are some reasons to feel good about American health care quality, but, as we've heard, there are also compelling reasons to be concerned. I'd like to make a distinction between two forms of variation that raise many of the questions that we've been addressing so far today.

First, there is variation when the same interventions are used by different providers and produce very different outcomes. For instance, four-to five-fold variation in rates of mortality after prostate surgery or as much as ten-fold variation in rates of mortality after cardiac surgery to treat coronary artery disease. These kinds of outcome variations raise serious questions about the processes of care and suggest that there's variation in these processes, often unrecognized, that leads to inadequate quality, or misuse, to use Dr. Chassin's term.

But even more striking than these differences in outcomes when the same intervention is used by different providers, are differences in the rates at which interventions are used in seemingly similar populations. This form of variation raises questions about decision quality, and that's what I want to focus on this afternoon.

Why is it that a man in Washington State is six times more likely to have radical surgery for prostate cancer than a man living in Connecticut? Why is it that a resident of New Haven is twice as likely to have coronary artery bypass surgery than a resident of Boston, and that a resident of Boston is twice as likely to have carotid endarterectomy? Why is it that a woman living in Pittsburgh is 15 times more likely to have breast-conserving surgery if she has breast cancer than a woman living in Ogden, Utah?

There are many explanations for practice variation. Dr. Eisenberg has focused on professional uncertainty, but there are also enormous geographic variations in capacity to deliver certain services. There are variations in the ways physicians interpret the same evidence. And different professionals bring different preferences and attitudes to patients' decisions. And sometimes the

professionals' preferences and attitudes seem to overrule or override the preferences of a particular patient.

The result from the perspective of policymakers and payers is concern about underutilization and overutilization of services, as we've just heard, but the result from the perspective of patients is that the care received may depend more on where you live and who you see than who you are and what you care about.

The implication for the profession is that we need to pay far more attention not only to doing something right, but to doing the right thing, and I would term that "decision quality."

Consider what that means for a man with benign prostatic hyperplasia, something that all of us men will experience if we live long enough. Whether or not he has surgery should depend on how bothered he is by his symptoms of urinary dysfunction, but it also should depend on how bothered he is by the prospect of compromised sexual function, which may follow surgery.

Practice variation tells us that these personal preferences, more often than not, are overruled by professional conventional wisdom that may vary from place to place, but does not vary sufficiently from patient to patient. Now, we've tried to respond to this by developing guidelines, and improvement in decision quality does require reduction in the variation in professionals' access to, interpretation, and application of clinically-relevant scientific information. Guidelines have been developed that can accomplish this. But decision quality also requires that the variation among patients with regard to preferences and attitudes be recognized and honored in the decision process. Guidelines can rarely accomplish this.

More often, they rely on assumptions about average preferences and average values. If these guidelines are followed, interventions will be given to people who, if informed, would not choose them, while they are withheld from patients who would choose them. This is bad medicine and it's bad economics.

Approaches to decision support can make a difference. Some approaches have been developed and have been subjected to extensive evaluation, including randomized trials. The results are noteworthy. Patient satisfaction with care and decisionmaking is generally increased. Confidence in treatment choice is generally increased, and patients' participation in prospective outcome studies has been facilitated, thereby producing new knowledge to better support decision quality.

Also importantly, utilization rates of some costly interventions have fallen. Most noteworthy is evidence that programs to support decisionmaking shared by doctors and patients together produce very strong associations between what patients care about and the treatments they get. For example, with shared decisionmaking, men who are very bothered by symptoms that can be relieved by surgery are seven times more likely to have surgery. Men who are very bothered by the prospect of having their sexual function compromised are one-fifth as likely to have surgery.

These kinds of measures applied broadly could assure that health plans and providers deliver care that is consistent with the wants and needs of the patients who live with consequences. Given that we live in a time of constrained resources, the potential impact

of this approach on utilization and the cost of care deserves some emphasis.

When shared decisionmaking was used among men in staff model HMOs who were being operated upon at a rate that was 40 percent below the national average, the rate fell 40 percent. If this rate of surgery existed in the 306 hospital referral areas in the country, there would have been 160,000 fewer operative procedures done in the Medicare population. Similarly, if we look at coronary artery bypass surgery in New York, we see that it's done about twice as often per capita in New York as it's done in Ontario. If we look at clinical characteristics and look at people based on their coronary anatomy, those who are least likely to benefit because of the location and extent of their blockages, and are most likely to be harmed because of their age and the concomitant risk of stroke, are 17 times more likely to have surgery in New York than in Ontario. When this approach to decision support was used in a randomized trial in Toronto, despite the much lower baseline rates, the rate of surgery fell 22 percent.

The relative inattention to decision quality and health care is a serious problem with enormous consequences in the trillion dollar health care economy. The dual challenge is to raise the level of awareness about the problem among all stakeholders, especially patients, while developing tools to measure and improve decision quality.

The common thread that runs through the problems and challenges that I've talked about is the need for unbiased, objective, and balanced information. This information and its flow to patients and doctors, when they need it to improve the quality of decisions, are enormously important public goods.

Thank you.

[The prepared statement follows:]

Subcommittee on Health of the Committee on Ways and Means
United States House of Representatives
Hearing on Assessing Health Care Quality
February 26, 1998

Mr. Chairman and Members of the Subcommittee, I am grateful for this occasion to appear before you and offer testimony regarding opportunities for more meaningful assessment of health care quality.

My name is Albert Mulley. I am a physician and Chief of General Internal Medicine at Massachusetts General Hospital, and Associate Professor of Medicine and Health Care Policy at Harvard Medical School, where my research for the past fifteen years has focused on applications of decision theory and epidemiology designed to improve the quality of medical practice. I am also co-founder, with Dr. John Wennberg of Dartmouth Medical School, of the Foundation for Informed Medical Decision Making which was established in 1989 to promote research, and to develop educational interventions, with the goal of improving the quality of medical decision making.

Over the past decade, Americans have witnessed a vast restructuring of the health care economy. The changes have been stimulated by concerns about both the cost and the quality of health care. Among the most compelling signs of inefficiency and suboptimal quality are the dramatic differences in outcomes when the same interventions are delivered by different providers. These outcome differences imply that there is substantial variation in processes of care, much of which goes unrecognized. Even more striking are differences in the rates at which alternative interventions are used in seemingly similar populations. These practice variations suggest need for improvement in the way choices are made among available alternative processes of care, i.e., the clinical decisions that determine which interventions are used for whom. Understanding and addressing these phenomena are major challenges in health care.

Some elements of health care's restructuring have been reassuring. Applications of quality improvement derived from industrial quality management sciences have led to development and use of process performance measures, including patients' reports and ratings of processes and outcomes of care. Guidelines have been developed and disseminated to assure the availability of knowledge necessary to support good clinical decision making. Market competition has created new incentives for providers and health plans to use these new tools to compete not only on cost, but also on quality, to the extent that it can be measured.

These problems and the predominant policy responses are summarized in Table 1.

Table 1. Quality Challenges in Health Care

The Problems:	Outcome Variation	Practice Variation
Examples:	Hospital Mortality Surgical Mortality	Hospitalization Rates Surgery Rates
Causes:	Variation in Processes	Variation in Process Selection
Responses:	Process Performance Measures	Guidelines Access Restriction

Modified from Mulley AG. Industrial quality management sciences and outcomes research: responses to unwanted variation in health outcomes and decisions. In Blumenthal D., ed. Industrial Quality Management Sciences in Health Care. San Francisco: Jossey-Bass. 1995.

But process performance measures designed to monitor and reduce outcome variation, and guidelines and access restrictions designed to reduce practice variation, have serious limitations that may or may not be recognized and/or acknowledged by different stakeholders. Market competition places a high premium on availability of accurate, objective information which in turn places a new and heavy burden on payers and patients accustomed to relying on providers' sense of professional agency to understand their needs. Failure to recognize the limitations of process performance measures and guidelines put patients' welfare at risk. Failure to anticipate the unintended negative consequences of market incentives magnify that risk.

Quality Challenges: Responding to Outcome Variation

Much of the recent emphasis on quality improvement in health care has focused on identifying and reducing variations in processes of care that are known to, or presumed to, result in variations in outcomes among providers. The outcomes of concern may be objective or subjective, and they may, or may not, be uniquely related to health care.

Differences in mortality and complication rates following surgical procedures or hospitalization are objective measures that have been examined and reported by health services researchers for decades. Such findings attracted little attention from providers, policy makers or patients until the highly publicized release of hospital mortality data by the Health Care Financing Administration in 1986. This was followed by release of statewide surgical mortality rates for institutions in Pennsylvania, New York, and elsewhere. The validity of inferences drawn from the comparative outcome rates were questioned, and these questions were often well justified. But in a newly consumer-oriented health care market place, the data could not be dismissed. Patients and payers, sensitized to possible differences in quality, sought "centers of excellence". Providers, many for the first time, examined the outcomes of their care in an effort to support claims of excellence or, at least, deflect any perceptions about poor quality care.

Relief of pain and other subjective symptoms, and the impact that such symptoms have on quality of life are equally important measures that are uniquely related to health and health care. Clinical scientists have generally avoided measurement of such subjective outcomes, preferring more objective anatomic or physiologic measures that may or may not be associated with what concerns patients most. The recent investment in outcomes research has produced well validated measures of symptoms and patients' response to them. A prominent example is development of the AUA-7 and the associated measures of "bothersomeness" for patients with benign prostatic hyperplasia by the AHCPR-funded Prostate Disease Patient Outcomes Research Team.

Many objective and subjective measures that may contribute substantially to patients' satisfaction with health care encounters are not unique to health care. Waiting times, the ambiance of facilities, personnel responsiveness to clients or customers are common to all service industries.

Subjective measures are technically more difficult to develop and implement than objective measures. Outcome measures that are uniquely related to health care are more difficult than more general measures of service satisfaction for political rather than technical reasons. The relative ease of using objective measures not uniquely related to health care has created a tendency for health plans to measure outcomes that may be least indicative of their presumed core competence. Accumulating evidence indicates that much of what we measure in an effort to promote competition among health plans misses the mark. We've stressed satisfaction with amenities and paid too little attention to how well we communicate with patients about diagnosis, prognosis and treatment, and how well we engage them in their own care.

Competition based on quality measures that distract providers and patients from what is the core function of health care is a serious problem. The dual challenge is to develop valid and reliable measures of the condition-specific subjective outcomes that often matter most to patients and overcome the political barriers to use of outcome measures,

objective as well as subjective, uniquely related to health care. Congress could help fashion a constructive response to the challenge by funding and promoting research and development in the following areas:

- Measurement instruments that focus on patients' subjective responses to elements of health care uniquely related to maintaining and improving health-related quality of life; and
- Consumer education about what constitutes quality health care, and about incentives health plans face that might threaten the validity of inferences made about quality.

Even when outcome measures do focus on health, and are seemingly uncontroversial because of their objectivity, there are difficulties. Patients (as well as payers and policy makers) may pay too little attention to limitations of measures. Comparison of unadjusted or crudely adjusted hospital and postoperative mortality data noted above is an important example, not only because of the controversy it produced, but also because of the perverse incentives created for providers. Consider the predicament of the cardiovascular surgeon in New York or Pennsylvania who understands the limitations of severity and comorbidity adjustments, and also understands well that the net expected benefit of surgery is greater for patients with higher expected operative mortality. Consider the unrecognized predicament of patients who rely on that surgeon for objective information about harms and benefits of surgery, as well as counseling about what level of risk might be reasonable given the prognoses with alternative treatments.

Consider further the implications of expanding "report cards" to include multiple relevant clinical outcomes including symptom relief. A seemingly reasonable measure of performance for orthopedists and neurosurgeons who perform back surgery is the proportion of patients who are relieved of their sciatica and/or back pain following surgery. Note that candidates for surgery most likely to improve the score of a particular surgeon are those patients who are most likely to improve over the next several months with or *without* surgery.

That such incentives affect clinical decision making has not been documented. But policy makers should be aware that the inadequate recognition of the limitations of outcomes measures (and adjustment techniques) in the marketplace can create an environment that works against the most scrupulous providers and against patients who are misled by faulty outcome comparisons.

This is not an argument against outcome comparisons designed to stimulate quality improvement by focusing attention on measurement and improvement of care processes. This work needs to be done. However, outcome comparisons to make inferences about quality comparisons, and thereby influence purchasing decisions, or choice of personal physician or surgeon, requires a higher standard of evidence--a standard we have not yet reached for many of the measures of outcomes most uniquely related to health.

The potential for misleading inferences to be made from comparison outcome measures is a serious problem. The perverse incentives created for clinical decision making, largely unrecognized by patients and purchasers, is a more serious problem. The dual challenge is to develop better measures and adjustment techniques, while educating consumers about inherent limitations. Congress could help fashion a constructive response to the challenge by promoting research and development in the following areas:

- Disease severity, comorbidity and other adjustment techniques for clinically relevant outcomes measures;
- Education of consumers, payers and policy makers about limitations of clinically relevant outcome comparisons with resulting incentives with a strong potential for a negative impact on clinical decision making; and
- Quality improvement strategies that acknowledge different standards of evidence for 1) using outcome comparisons to stimulate process measurement and improvement and 2) using outcome comparisons to make inferences about quality and thereby guide purchasing and provider decisions.

Quality Challenges: Responding to Practice Variation

Quality improvement in American health care has emphasized improvement of processes of care, doing something (whether an office visit for secondary prevention of coronary disease or coronary artery bypass surgery) right. The phenomenon of practice variation tells us that we need to pay far more attention to whether or not we are doing the right thing. Why is it that not too long ago residents of New Haven were twice as likely to have coronary artery bypass surgery as residents of Boston? Why is it that a man in Washington State was six times more likely than a man in Connecticut to have radical surgery for prostate cancer? Why does the proportion of Medicare beneficiaries with breast cancer who receive breast-conserving surgery vary more than fifteen-fold among major hospital referral areas? These variations in specific treatments, as well as comparable geographic variations in per capita hospital resources, Medicare spending, and the physician workforce, have been well documented in The Dartmouth Atlas of Health Care, edited by Dr. Wennberg.

Many forces contribute to practice variation: geographic variations in capacity to deliver certain services; variations in interpretation of evidence; and different professionals' different preferences and attitudes regarding harms, benefits, risks, and discount rates. These factors contribute to a local professional conventional wisdom that drives decision making. The result from the perspective of policy makers and payers is concern about underutilization and overutilization of services. The result from the perspective of patients is that the care received may depend more on where you live and who you see than on who you are and what you care about.

Patients too differ in their preferences and attitudes toward harms, benefits, risks and discount rates. For example, some men with benign prostatic hyperplasia are very bothered by symptoms of urinary dysfunction. Other men with equally severe symptoms when measured reliably are not bothered. Some men are very bothered by the prospect of compromised sexual function which may follow surgery. Other men are not bothered by this prospect. But these differences do <u>not</u> explain the practice variation described by Wennberg and others. Unless there were striking geographic differences in populations' distributions of preferences and attitudes, care tailored to individuals would result in the same rate of interventions among those populations.

Development of guidelines (or "practice parameters", "clinical policies", "appropriateness criteria", etc.) to educate physicians and to administratively restrict access to certain interventions has been the principal policy response to the problems with decision quality evidenced by practice variation. But the response has been inadequate. Methods used to develop guidelines can address problems with professional uncertainty at the level of the individual professional who may not be aware of existing evidence, or have the time and the capacity to interpret and apply that evidence to practice. They can also identify areas of collective professional uncertainty, where no adequate evidence exists to guide decision making. Guideline development can thereby target areas for needed, high-leverage outcomes research.

But consensus conferences and other methods for guideline development cannot reduce uncertainty in the absence of evidence. At best, they can substitute authoritative opinions. The risk here is the patients and others may believe the opinions to be scientifically supported when they are not.

A greater risk of guidelines is that they imply that scientific evidence is sufficient to drive a clinical decision toward one choice or another. More often than not, clinical decisions depend as much or more on the preferences and attitudes about harms, benefits, risks and discount rates that vary significantly among doctors and among patients, and systematically between doctors and patients. True decision quality requires reduction in variation in professionals' access to, and interpretation and application of clinically relevant scientific evidence. Guidelines can accomplish this. But decision quality also requires that the variation among patients with regard to preferences and attitudes be recognized and honored in the decision process. Guidelines rarely accomplish this.

More often, they rely on assumptions about *average* preferences and average attitudes. If these guidelines are followed, interventions will be given to people who, if informed, would not choose them while the same interventions are withheld from those who would. Evidence-based medicine is necessary to decision quality, but it is not sufficient.

Guidelines and similar efforts to improve decision quality have been handicapped by failure to distinguish between warranted and unwarranted variation. Approaches to decision support that do make the distinction have been developed. The approach developed by the Foundation for Informed Medical Decision Making, which encourages doctor and patient to participate in shared decision making, has been subjected to extensive evaluation including randomized trials. The results have been noteworthy: patient satisfaction with care and decision making has generally increased; utilization rates of some costly interventions have fallen, sometimes dramatically; patients' confidence in treatment choice has increased; and patients' participation in prospective outcomes studies has been facilitated, thereby producing new knowledge to better support decision quality.

Perhaps most noteworthy is evidence that programs to support decision making shared by doctors and patients produces very strong associations between patients' stated preferences among outcomes and the care that they actually receive. For example, with the shared decision making form of decision support, men who are very bothered by symptoms that can be relieved by surgery are seven times more likely to have surgery than those with the same level of symptoms who are not so bothered. With shared decision making, men who are very worried about the impact that a loss of sexual function will have on their quality of life are one-fifth as likely to have a procedure that could result in sexual dysfunction than men who are not so worried about that same prospect. These kinds of measures, applied broadly, could assure that health plans and providers deliver care that is consistent with the wants and needs of the patients who live with the consequences. As already noted, such an emphasis on decision quality could also significantly decrease utilization and costs for many illnesses.

The potential impact of this approach on utilization and costs of care can be illustrated with two examples. First, shared decision making was implemented in two staff model HMOs that already had rates of surgery for this condition that were substantially below the national average. With the adoption of shared decision making, rates fell fully 40% to a level comparable to the lowest rates among hospital referral areas within the United States. If surgery were performed at the shared decision-making rate in all hospital referral areas in 1992-93, 160,000 fewer prostate operations would have been performed among Medicare beneficiaries. Second, shared decision making was implemented in a randomized trial among men and women with coronary artery disease in Toronto. The rate of coronary bypass surgery in Ontario is about one-half that in New York. (Patients who are least likely to benefit because of the extent and location of their coronary artery blockages, and most likely to me harmed because of older age and greater risk of stroke, are much more likely to receive surgery if they reside in New York rather than Ontario.) Despite the lower baseline rate, patients in Toronto who participated in shared decision making were 22% less likely to undergo surgery than those who didn't.

Implementation of decision support programs has been problematic. Some of the obstacles have been technical. The technology to support decisions made by patients and doctors with computer-based multimedia representations of unbiased information and vicarious experience is changing rapidly, creating risk barriers to adoption. The greater obstacles, however, have been political and cultural. Sophisticated decision support programs require that both physicians and patients adjust roles and change behavior. Most of the unwarranted variation in the processes of clinical decision making is found in elements of the decision for which providers are responsible. Yet professionals generally resist interventions that feel like standardization or regimentation, in part because of their legitimate concerns about preserving warranted variation. Most of the warranted variation is found in elements of the decision that should come from patients. It is their preferences and attitudes that matter most because they will live with the decision's consequences. Yet many patients, not recognizing the role of their preferences and

attitudes, resist decision making responsibility. The result of the resistance from both sides is often poor decision quality leading to suboptimal health-related quality of life for individuals and inefficient allocation of health care resources for populations.

The relative inattention to decision quality in health care is a serious problem with enormous consequences in the trillion dollar American health care economy. The dual challenge is to raise the level of awareness about the problem among all stakeholders, especially patients, while developing tools to measure and improve decision quality. Congress could help fashion a constructive response to the challenge by funding and promoting research and development in the following areas:

- Measurement of health professionals' and patients' preferences among different health outcomes that follow alternative treatments for common health problems, as well as analysis of patterns of variation in these preferences among and between professionals and patients;
- Measurement of professionals' and patients' risk attitudes and discount rates as they apply to common clinical decisions, as well as analysis of patterns of variation in these attitudes among and between professionals and patients;
- Approaches to providing, to both clinicians and patients, patient-specific outcome probabilities for alternative clinical strategies;
- Approaches to providing to patients unbiased vicarious experience to establish accurate expectations of potential health care outcomes following choice of alternative treatments;
- The impact of unbiased, objective decision support on (1) utilization of interventions, (2) patient satisfaction with decision-making and subsequent care, and (3) health outcomes;
- Methods for using the clinical decision "aperture" as an opportunity to capture clinical information that facilitates entry into prospective trials, including randomized-control trials; and
- Methods for measuring decision quality including associations between patients' preferences and attitudes and the care they receive.

In addition to promoting research along these lines, Congress might charge HCFA with development of demonstration projects to test implementation strategies for improving decision quality, with greater participation of Medicare beneficiaries in treatment choices.

A common thread that runs through the problems, challenges and potential solutions presented in this testimony is the critical need for accurate, unbiased information about provider performance in delivering health care interventions, and about what can and cannot be accomplished with those interventions. Inherent limitations in the accuracy of such information and the freedom with which it flows have always presented obstacles to those who would improve the quality of health care. The new emphasis on market competition has, however, substantially raised the stakes.

Current policies create strong incentives for providers to exploit these limitations to compete for market share on the basis of *perceived* rather than actual performance quality. There are equally strong financial incentives for providers to influence demand for services by overstating or understating net expected benefits. Availability of accurate, unbiased information, interpreted with full appreciation of inevitable remaining limitations can provide needed checks and balances. Better measures to improve the accuracy of information, better systems to support its flow, and more effective education to assure knowledgeable interpretation are critical public goods. At stake is not only the effectiveness of health care and the efficiency of the largest segment of our economy, but also the integrity of the social contract of the healing professions and the trust of patients in need.

Portions of this testimony were prepared for an "Expert Meeting" on Quality Measurement sponsored by the Agency for Health Policy and Research on February 10, 1997.

Massachusetts General Hospital receives federal funding for biomedical research. In 1997, the total funding level was $119.8 M which represents a 9% increase over the previous year. The Foundation for Informed Medical decision Making has not received federal funding.

Chairman THOMAS. We thank both of you very much.

As you know, we're engaging in what some folks in Congress believe is a major debate over quality. I'm just looking at the press table and all of the empty seats over there, so perhaps it may not be as burning an issue as some folks thought. Or I guess the way in which we approach trying to deal with legislative remedies is not nearly as exciting as some other folk who aren't trying to get to the bottom of it and solve it in a way that I think is the only way to deal with these issues. I don't know which, but they're not here.

Interestingly enough, both of your testimony is just about 180 degrees off of what I hear on the floor or in the cloakroom or see as what the argument is when I read the legislation that we're supposed to be looking at, because you've clearly indicated—I mean, choice is a term that everybody is using now. Quality—if you have choice, you have quality, and what you've said is that more isn't necessarily better. In fact, it can clearly be harmful.

But my problem is I've still got to deal with what some folks believe is an issue, and that perhaps we can get outfront in doing it right. Dr. Mulley, your decision quality statements could be fairly defeatist if what I took away from what you said was, gee, we need a clean sheet of paper; we need different folks going through medical school; we need different patients coming to those doctors. I mean, it's pretty fundamental that a lot of these problems apparently are political, cultural, or geographic, and that's darn tough to get to from a legislative point of view.

So I want to try to see if you can give us some pointers here that we can take away and apply directly to what we're going to have to be doing over the next several months. You heard the earlier questions and testimony from people who are more in the public sector. If you gave us the three most important things that we needed to do to provide quality—I mean, I'm kind of focused on the collection and dissemination of data, so that we've got the outcomes, so that we can talk about guidelines and maybe we would also need to deal with enforcement, but that gets into some sensitive areas.

You've seen also a great concern, and I think rightly so, about patient records in terms of how they're used and what they're used for, beyond the patient's approval, but if you have a patient approval, you'll never be able to get to the collection and dissemination of data.

So if I'm a legislator who's got to put a bill together that would disregard all of the arguments that are being made by folks as to what quality is because most of them are Trojan horses protecting particular interests, and they are getting to the fundamental question of improving quality. What would you like to see us do within the realm of what we're able to do from a legislative point of view? And if you've got more than three, I'll take them, but I didn't want to create too long a list for you.

I am very concerned about the movement in States' denying the access to data. I'm very concerned about creating a system which, in fact, allows businesses in Maryland to mail to you based upon what folks thought were confidential medical lists. Is the collection of data critical? How can we get to it? What other things can be

doing, if that's not the most important thing? Give me one, two, three, four, or what do you think—from a legislative point of view, not from your point of view, because we've got to legislate?

Dr. MULLEY. Well, let me begin by saying that I think that the kind of research necessary to collect data, both on quality and on outcomes and effectiveness, is critically important, and let me just say that I think supporting the kind of research that has led us to where we are in being able to measure quality research done by AHCPR, and research of the same kind done by NIH, is critically important.

But for the hearing now——

Chairman THOMAS. Could you submit—you don't have to do it now—some example, a list of the kind of research that is most useful in moving forward in that kind of approach?

Dr. MULLEY. Yes. It's included in my written testimony.

Chairman THOMAS. It's in your presentation?

Dr. MULLEY. Yes.

Chairman THOMAS. Okay.

Dr. MULLEY. What I focused on in my written presentation is the kind of research that brings patients more into the quality equation, because I really do believe that there is an enormous patient choice dividend in the health care economy that addresses many of the cost issues that we're all concerned about.

Second, I would also say that there are opportunities to test this model of patient involvement in treatment choice. Certainly trying to develop some demonstration projects in the Medicare population, and seeing the extent to which attention to quality decisionmaking would have the same kinds of results it's had in these experiments that I've described to you—that is, increases in the quality of outcomes, increases in patient satisfaction, decreases in utilization. To be able to intervene on a broader scale and further test the hypothesis will be very important. And it would certainly be consistent with the current focus on patients' involvement in treatment choice.

I want to make the distinction between choice of plans, choice of doctors, and the fateful choices that people make about the treatment they get, because they live with the consequences. With ischemic heart disease, we don't, that's right. With ischemic heart disease, we're talking about an enormous knowledge gap among patients because there's enormous knowledge gap among professionals, about the risk of cerebral vascular events when people have bypass surgery, because we did the randomized trials in people who are younger than 65 and people who are over 65, who now often get the surgery, are the ones who are at greatest risk for this complication.

So I think that if we could find ways to create some demonstration projects where people in the Medicare population, in particular, are given balanced, objective information about the potential harms and benefits of procedures that are used 800,000 times a year in this country, that we would really learn something important.

Third, I want to pick up on something that Mr. Houghton mentioned, and that is the need for incentives that encourage decision quality. And by that, I mean decision quality with the information

that we currently have available, but also incentives that reward providers who capture collective experience, so that we can improve future decisions. I could cite many examples; Dr. Chassin could cite many examples of databases that have provided more information to professionals in this country and around the world than all of the collected randomized trials in the area.

In finding ways to award fee-for-service physicians in academic centers or in large settings to participate in those kinds of objective, balanced, prospective cohort studies, so that we're learning from collective experience, rather than not learning from it, is something that I would like to see in legislation.

Those are three responses.

Dr. CHASSIN. I think I have four maybe. I think certainly the protection of the ability to collect clinical information and use it properly and appropriately, with appropriate confidentiality safeguards, is of the highest priority, and I have followed this issue as it's developed over the last many months, and some of the solutions that have been proposed are extremely worrisome. I would certainly agree with Dr. Eisenberg that exceptions for properly-overseen research and quality assurance and quality improvement activities that have also been duly constituted should be in any consideration of legislative action there.

I would distinguish between the kind of research support, which I think clearly needs to increase, of the kind that the agency has done and sponsored in the past with respect to finding out better what works and what doesn't work. We need an awful lot more of that. But the kind of research that I think we also need is how to do what we already know works when we ought to be doing it, and that has lagged even further behind the effectiveness and efficacy research that tells us more about what does work and what doesn't work.

We've known that antibiotics don't help colds ever since there were antibiotics and we understood colds were viral infections, and yet, 50 percent of adult office visits for colds result in an antibiotic prescription, leading to the problem that I mentioned.

We don't know how to solve that problem. We haven't figured out how to measure it very well and how to intervene to improve it, and yet we know from a couple of small examples in other countries where massive programs have been put in place that not only is that problem solved, but this problem with growing bacterial resistance is also greatly helped. So there are tremendous gains to be had here, if we were to focus research efforts on specific measurement and improvement attempts, and then even more important, disseminate those, make them easy for others to do.

One of my jobs, in addition to my academic job, is to lead our hospital and health systems' quality improvement efforts that are clinically directed and focused on improving outcomes. Now when we try to figure out how to improve treatment for women with breast cancer or for patients with heart attacks, we almost have to start from scratch. We ought to have an easily-available library of tools, of instruments, of methods, of materials that others have used, that are proven to be effective, that we can pull off the shelf and just use. That does not exist, and I think it would facilitate improvement enormously.

Chairman THOMAS. I know you haven't finished your list, but on that point, let me ask you a quasi-loaded question, because I don't know the answer to it, and it may not be appropriately phrased. But it gets back to this question of quality, because what you have talked to me a little bit about is, okay, obviously, I agree we've got to get informed patients; the first-dollar, third-party payment system created a bunch of ignorant consumers, and we've got to get the material to them and let them—but it just seems to me it starts also with those professionals who went through professional training, who perpetuate myths and failures to collect data that's most recent and most appropriate.

Which system has the better chance of propagating the better materials, a managed care structure or a fee-for-service structure?

Dr. CHASSIN. Well, I think looking at——

Chairman THOMAS. Or is that an unfair question because, as I said——

Dr. CHASSIN. I think both have opportunities in slightly different ways. A managed care setting has, if it's tightly controlled—I mean, as Dr. Eisenberg said, there is no such thing as managed care anymore. There's so many different varieties, it's hard to know what one means by that.

Chairman THOMAS. I guess I don't mean it that way. Let me put it slightly differently, and that is, if we have all these problems in a system in which doctors were totally in control, I think the political and cultural tends to dominate almost as much as the scientific. To what extent have we broken down the great man concept, and is that a help or a hinderance in terms of trying to move forward?

Dr. CHASSIN. Well, I think that a number of things have been changing at the same time over the last, say, 10 or 15 years, including the tremendous and dramatically-accelerating weight of new information about what works and what doesn't work. It is simply not possible anymore for an individual physician practicing on his own or her own to keep in his or her head everything that they need to know to practice good medicine, but that was not true 20 or 25 years ago. It was possible. We haven't kept pace with that enormous explosion of information, with the systems to provide information that is necessary at the right time, and we haven't yet trained up our physician and other care-giving workforce to understand that working together in teams is going to be a much more effective way of making use of this information.

Chairman THOMAS. And I apologize for getting you off the track.

Dr. CHASSIN. No.

Chairman THOMAS. You gave us our second one. I'm looking forward to your third and fourth.

Dr. CHASSIN. So the second one I think is to recognize that there is an enormous public education effort that needs to go along with the professional education effort. I think one of the problems that we have faced in trying to combat—I go back to the antibiotic example, antibiotics for colds and other overuse problems—is a pervasive belief on the part of a lot of the consuming public that more is, in fact, better, and that's not, certainly not always true in health care. It may not be true most of the time.

And I, going back to Mr. Houghton's comment of earlier, I think we do need a Baldrige Award in health care, and I understand that that is in process. I think that highlighting in that very public, very visible way voluntary, professionally driven efforts to improve could make a big difference.

Chairman THOMAS. Does the gentleman from California wish to inquire?

Mr. STARK. Gentlemen, thank you for your work in this area.

The only thing I've thought about as I've gone through your testimony Dr. Mulley, is a story I often use anecdotally. It is a managed care plan in Florida that was hustling male patients into castration rather than giving them a costly drug that is the alternative therapy castration. And I always say, I don't know what castration costs because every time I ask doctors, they all volunteer to do it for free. So, I get a biased opinion of what it would cost. But I suspect its lot less then the drug therapy. It saves a lot of money, $7,000 to $8,000 for every patient they can castrate rather than put on a regimen of drug at $300 a month. But it doesn't seem proper to me. I gather both are effective in stopping testosterone. So I don't know what you do about that. However, if that patient knew their options I think that that health plan might not have had such a high degree of members of their plan electing surgery.

My question to both of you is that I have not seen in your testimony—and maybe I didn't read it as thoroughly as I should have here—any reference to free markets or competition. Now I know Jerry Austin in your institution took the same economics course I did when we were both students a thousand years ago. So he knows all about competition and free markets. I don't know whether every other member at Mass General hospital does, Why is that? How does competition help you? You guys didn't mention it but the AMA is going to talk about it. They say that their members should have the benefits of competition. I think that just means more money, which is usually all the AMA is interested in. But what does the free market do for us? What does competition do?

The poster child of competitive models would be Columbia Hospital. They are the best at doing what they learned to do at the Harvard Business School and applying free market and competitive business practices to the delivery of medical care. How does that factor into your studies?

Dr. MULLEY. Well, I think that free market competition has provided very strong incentives for providers and provider organizations to compete on costs, but on also perceived quality. And the problem is that we haven't been able to measure more than perceived quality. To a great extent, health care organizations have competed on the basis of amenities. We've measured satisfaction with food or with quality of the rooms or the ambience of the facilities that people see rather than measuring the core issues that really are unique to health care. That's one area where I think we need to do a good deal more work, and some of that work is research and some of it is demonstration projects using what we already know.

I think that the ability to compete on perceived quality without adequate measures is potentially dangerous for lots of reasons. Some of it was referred to earlier today—when the wrong incen-

tives are put in place for providers to compete on the basis of scorecards, when outcomes are measured only for people who get a surgical intervention as opposed to all people with the condition. Obviously, there's an incentive to not take on the riskier patients. If the denominator includes all of the people with the condition, then you're able to monitor that kind of change in behavior and really provide more accurate measures of quality.

With regard to the focus that I brought to the committee, decision quality, I think there are some enormous opportunities to create competition in the marketplace with individual providers and provider organizations demonstrating their ability to provide care that is most consistent with what patients care about. As I've said, the story about the care you're getting depending more on where you live and who you see than who you are and what you are about is compelling to individuals. And if one plan was able to show strong associations between what people said they cared about and the treatment they received, and another plan wasn't, the marketplace would reward the plan that tailored care to what people really cared about and what they defined as quality of life. And the kinds of measures that I cited earlier could do that and could allow plans to compete on that kind of attention to patient wants and needs.

If we were to talk to Jerry Austen about this, Jerry might say, "Well, what about decreasing the rate of bypass surgery as a result of providing this information to patients? I think the answer to that, for some who are into competing in the marketplace, is that the absolute number of operations that are done depends not just on the rate at which you do them; it depends on your denominator; it depends on your market share. I think there are lots of leverage points in the health care economy now whereby one can increase their market share by virtue of decreasing their rate, because of the overutilization and supplier-induced demand that drives decisionmaking.

Mr. STARK. We have an example in The Washington Post today. George Washington wants to build a new hospital, 400 new beds. We've got more hospital beds around here than we know what to do with. But the key is—and one of the things they mentioned—is that every room is going to be private with its own shower or bathtub. They don't talk about better equipment or better lighting in the surgical amphitheater or any of that. I'm not sure what that does for outcomes as opposed to sharing a room. It's nicer, I suppose, particularly if somebody snores like I do. Nonetheless, for us to be building these huge new hospitals when the use of hospitals is decreasing is exactly what Dr. Mulley is talking about, I think.

Dr. MULLEY. Yes, exactly.

Mr. STARK. They're building bells and whistles and extra chrome grills when they should be looking to put in seatbelts and anti-lock brakes.

Dr. MULLEY. That's what I was referring to when I was talking about competition and amenities.

Mr. STARK. Yes. That's a perfect example. Well, I don't want to belabor this, and my colleagues would like to inquire. Thank you both for your work in this area, and godspeed. Do it faster, wouldn't you? We need it.

Chairman THOMAS. Does the gentleman from New York wish to inquire?

Mr. HOUGHTON. Mr. Stark, I'm sitting next to a very distinguished physician here, and he has told me that an alternate word to castration is orchiectomy, and you might want to consider using that at another time. [Laughter.]

Well, anyway, gentlemen, I'm delighted to be here with you and to hear your words of wisdom. I really have sort of two basic questions.

One—and this is something we've been talking up here about, about the basis information system which Dr. Chassin was talking about—that it seems to me that, my impression—and most of this comes from rural America—is that doctors are so involved in caring for patients, they do not have the information of what's going on in the rest of the world, and they don't have time to look it up. They're not next to a teaching or a research university, and therefore, they do the best they can.

But that information is available, and the vehicle for it is there, as long as somebody does it. I mean, whether it's Microsoft or whether it's HCFA or what—I mean, I can't imagine a local doctor developing his own software for something like this. It's just impossible.

But that information is available, and then it feeds right into what Dr. Mulley is saying, being able to share that with a patient. So the question is, it's there, but how do we get it here? And that's something I think that might lend itself to understanding and legislation. So maybe you'd want to comment on that.

And then I've got another question for Dr. Mulley.

Yes?

Dr. CHASSIN. Sure. I think you're absolutely right, that we have the technology, the technical know-how to build support systems that really are quite effective, and in fact, we know from the isolated cases where they've been used and evaluated that, in fact, they can have dramatic effects. One LDS hospital in Salt Lake put in a series of programs to reduce antibiotic adverse drug events, injuries due to antibiotics, reduced the frequency by 30 percent, reduced mortality by 27 percent, and reduced antibiotic costs by 58 percent for every treated patient. So these systems can work; they require enormous investment, and they require organizations, not, as you've pointed out, individual physicians or small, one- or two- or three-person practices to be able to do that.

Where we've now started moving away from hospitals, and in places like the Northwest, where big, multi-specialty physician groups don't exist by culture or tradition, those organizations are few and far between. Hospitals are harried because of competition and reduced reimbursement.

So finding the capital to make those investments is one problem, and then adapting the culture of physicians and other caregivers to an understanding that they need that information is another part of the problem. The current generation of physicians I think, by and large, still believe they ought to be carrying everything in their heads and that requires an educational effort that will take some time.

But, technically, you're absolutely right; we have the technical know-how to build systems that could make an enormous difference.

Mr. HOUGHTON. Yes, because I think we're searching for ways to increase quality; we're searching for ways to increase coverage; we're searching for ways to help those people who are the suppliers, and it's all there. The question is, how can we put it together?

And I don't know whether you gentlemen would like to make some sort of proposal to us—it doesn't have to be long, just some general thoughts, but, I mean, of all the things we're talking about, this may be one of the most important things we can do, and it's possible; it's not technically impossible.

Now the other thing is what Dr. Mulley was talking about, is—the chairman is now on the phone—but my sense is that what you're talking about doesn't have anything really to do with law. It doesn't have anything to do with data. I mean, it's really a matter of standard operating procedures. It's really a matter of attitude.

But when you talk about a process which reduces cost and helps the customers, it saves assets, and doesn't cost very much, it's very attractive. And it is really just sharing information not on a post-operative basis, but on a pre-operative basis, with people, and the willingness to take upfront time and knowledge and care, rather than having all the downstream complications which come. Some of the statistics you mentioned, the coronary issue with something like 17 times more whatever the procedure was in New York versus Toronto, those are very compelling figures.

So I don't know whether it takes a tremendous investment, whether it takes law, or what it takes, but it just seems to me that there, again, that's all there to do, if the attitude is changed. Maybe you could help me on that?

Dr. MULLEY. Yes, I agree with everything you've said. It's a very simple idea with a lot of compelling implications. I'd come back to something that the chairman raised a couple of times, which is that social and political issues sometimes really get much more complicated than the actual idea that you're trying to implement. In order for this approach to decision quality to work, there really has to be a recognition of a change in roles on the part of both providers and patients. Patients are often very happy to defer decisions to doctors because they're feeling very vulnerable, and they anticipate that there might be a bad outcome, and they might not want the responsibility for the decision that led to the bad outcome.

So there needs to be, I think, a major educational effort, as Dr. Chassin has also suggested, to help people understand their role in a health care economy, particularly since we've unleashed some market forces in that health care economy.

I want to come back to the issue that you raised with Dr. Chassin because it's related to this. We certainly have the wherewithal with information technology today to deliver existing information and to inform decisions. We can give people probabilities of good and bad outcomes, and give them vicarious experience of what other patients have gone through, so they can recognize their role and make choices with regard to the quality-of-life implications of

the different available treatments. But that same technology gives us the wherewithal to capture their experience, so that the next generation of decisions are even better informed.

And the point I want to make is that, yes, we do have some information that we could do a better job of delivering, but we don't have nearly enough information about the most common conditions and the most common procedures that we do. We do 400,000 coronary artery bypass operations a year in this country. We do about 400,000 angioplasties a year. I estimate that worldwide we've randomized about 1 in 5,000 patients who've had coronary artery bypass surgery, and as a result of that, the few, 1,400 or so, who have been randomized aren't nearly as representative of the population we treat as we would like. You've heard some examples of the problems this creates already.

We should have ways of capturing experience that patients have as they make treatment decisions and after they make treatment decisions, regardless of which treatment they end up having. And, again, information technology makes it possible for us to do that and dramatically improve what we know about what works, at the same time we're improving decision quality at the outset.

The reason I think that's important—and to some extent related to the issue of confidentiality and privacy that keeps coming up—is that the feasibility of this kind of research, when it's focused on a particular condition, and the alternative treatments for it, has been shown over and over again. Patients are happy to participate in focused outcomes research. It's very different than the vague, administrative database research. Over and over, patients have been asked to participate, and they do it. In fact, when they're given a choice between one therapy or another therapy, or perhaps randomization, which gives us the strongest evidence, they're happy to participate in that kind of study as well. That's been shown in the UK repeatedly, and more recently, it's been shown here.

So I'm just agreeing with what you said and what Mark said. We have the technology to deliver the best available current information, but that technology also gives us the capacity to continuously improve it in ways that we haven't been organized to do in medicine in the past.

Chairman THOMAS. Does the gentlewoman from Connecticut wish to be recognized?

Mrs. JOHNSON of Connecticut. Yes, briefly, thank you.

I appreciated your testimony very much. I'm sorry I had to be so in and out during the question period.

I just wanted to ask you if you are working in any areas like nutritional services. One of the problems that we're going to have is focusing on those things that hit you in the face, like the difference between New Haven and Boston in certain areas, and regionally, and things like that. But the ability of nutritional services to either improve the quality of recovery, reduce the cost of recovery, or prevent surgery, that kind of thing, is increasingly interesting to me. Are you doing anything looking at those new areas? Because, eventually, if we're going to turn the system around to a more preventive approach and a higher-quality approach, we have to start

thinking about those kinds of ancillary services that may not be so clearly related to illness, treatment, the model of medicine.

Dr. CHASSIN. Well, I think you're right, and I think you point to an area that has been understudied greatly. But particularly I think in recent years with the development of our capacity to better measure functional outcome, that nutrition will become an increasingly important ingredient in producing better functional outcomes. A study that we're doing, for example, now, funded by AHCPR, is looking at the effect of a variety of inpatient interventions on risk-adjusted functional outcome after hip fracture repair, and nutritional services, along with physical therapy and rehab and a lot of others, are in that mix. I think as we do more with measuring functional outcomes in the course of disease following treatment or in the course of chronic disease, we will need to pay more attention to nutritional services and other services that have to date been very underevaluated.

Mrs. JOHNSON of Connecticut. There's, I think a new Lewin Study, or fairly recent Lewin Study, on just the Medicare population of access to nutritional services on a cost-free basis. It's had some very interesting implications. So there's somewhat more work being done in this area than there has been, but I think some of those things that are systemic we need to be looking at, as well as the particular things, because those we need to be building into the coverage network of Medicare, so that the system can evolve in a way that's comprehensive.

Dr. MULLEY. I'm certain that access to nutritional services varies enormously across the country in terms of the manpower available to provide those services, but that, too, I think is something that we can expect to change with the availability of new information technology and access to information. My guess is that the whole structure, and our very definition, of nutritional services and health care will look radically different five years from now because of available information technology.

Mrs. JOHNSON of Connecticut. And then, just lastly, I'd just like to comment. In your work, does it come to your attention, the relationship between decisions and reimbursement rates? Aren't we driving——

Dr. CHASSIN. All the time.

Mrs. JOHNSON of Connecticut [continuing]. Patient care decisions yet by reimbursement rates?

Dr. CHASSIN. Well, I think that reimbursement, in whatever form it occurs, is a very powerful motivator, and like competition, another very powerful motivator, we haven't yet figured out how to use financial incentives and line them up with quality incentives, so that excellence gets rewarded. We have fee-for-service, which encourages overuse—one kind of quality problem; capitation encourages underuse, another kind of quality problem. We don't have a payment system that consistently and effectively rewards excellence, like competition. Competition now occurs on price. It's a wonderful motivator. If we could only figure out how to harness it to quality improvement, potentially it could be very effective, but that doesn't exist in any market in health care that I'm aware of. So we've got a lot of challenges before we can make these motivators

that work in other areas, particularly in business, very well work to improve quality.

Mrs. JOHNSON of Connecticut. At a very crude level, I do see employee dissatisfaction resulting in employers looking not just at the price of a plan, but also quality issues and what the plan can tell them about response to consumers and appeal procedures, and things like that. I see some bottoming-out of price being the only consideration, and I think that brings the market back into quality issues. Do you see that?

Dr. CHASSIN. Well, I hope you're right, although with the current trend up again in premiums, I don't think it takes much to get people thinking again about cost. I don't yet see a market where quality considerations are even a significant part of the purchasing decisions.

Mrs. JOHNSON of Connecticut. Thank you.

Chairman THOMAS. My only concern in that conversion of ideals to reality is that some bureaucracy and some Congress will create a link between you get more money if you do this procedure, legislate it. I'm very concerned about the collection of data to be used as required behavior procedure to receive specific amounts of money. Incentives are good; collection of data and outcomes research is good, but it's a very tempting governmental role to link the two produce, quote-unquote, "quality medicine" as defined by the last majority vote of Congress. That's what really worries me as a down side on all of this, and it's just now come up in a form that I could capsulate it.

Dr. CHASSIN. Yes, I'm not at all sure that Federal legislation or legislation anywhere is the right way to use payment incentives. I think that provider organizations and other structures that are much closer to where patients actually receive care are probably better, although there may be some exceptions to that, where the data are really excellent and could support payment incentives.

Chairman THOMAS. I'm quite sure that it would be the exception to the rule rather than the rule where it should be done.

Not a member of the committee or the subcommittee, but someone who, obviously, as the gentleman from New York indicated, has an interest in what we're doing—it's a pleasure to have with us once again the gentleman from Louisiana, Dr. Cooksey. Do you wish to inquire?

Dr. COOKSEY. Thank you, Mr. Chairman.

Dr. Chassin and Dr. Mulley, I assume you're both internists, right?

Dr. CHASSIN. Training, but specialty——

Dr. COOKSEY. What do you have in your own department in terms of computerized medical records, and what's available in the rest of your respective universities? And what departments utilize computerized medical records? Or do you still use pen and paper?

Dr. CHASSIN. We, I think like most places, still use largely paper records. There are information systems that are helpful in a number of specific areas, in the laboratory and radiology, and some others, but we have not gotten even to a minimal implementation of a computerized medical record. It's in the planning, but it hasn't arrived yet.

Dr. MULLEY. A colleague of mine at MCH, Dr. Barnett, is a leader in medical computing and has been for decades. So that in our ambulatory practices we have something called COSTAR, which he invented some time ago. It needs major modification, major simplification, but we use that.

Some of the modification and simplification that's necessary has been accomplished for one service now. The obstetrics and gynecology service has an entirely electronic record; it's paperless. And the plan is to move that throughout the hospital and throughout the partners' system.

Dr. COOKSEY. Good. The Mayo Clinic in Phoenix was the first clinic to put a system like this in place. I mean, it was really a software company from Wisconsin that developed the software, and it was all, you know, a Windows-based system.

You might be interested to know that I've had my medical records on a computer since 1985, and the software company was Computers in Medicine from Boston. It was a Digital, a DEC outgrowth, and it works very well. I have a specialty that lends itself to it.

I happen to think that the solution to the quality problem is exactly what my colleague from New York said: information systems. As physicians, we have been very provincial in taking advantage of the information age. There's some wonderful physicians out there who are very well-educated and very skilled technicians, and still limping along without taking advantage of the information age. And I think that's a travesty.

I think that HCFA has got the same problems. They have archaic information systems. It contributes to their problems, our problems. But the ultimate solution to the quality issue is to have the information available out there, have it available to the patients, to the physicians in different geographic areas of the United States, and even around the world. It should be out there on the internet. You do have the problem of confidentiality, confidentiality is important, but I think it can be done, and I think it would really be worthwhile for those of you that are still making an honest living in the medical profession to go back to your respective medical schools and do whatever you can to jump-start that process. I think it will help us, as Members of Congress, to address the quality issue.

You know——

Dr. MULLEY. I agree.

Dr. COOKSEY. [continuing]. I look at the health care profession now as comparable to what the airline industry was in the late seventies. It was a regulated industry with a lot of bureaucrats in Washington and a lot of politicians in Washington, not my two colleagues here, but the other politicians in Washington, and they were running an airline system. The airlines were not available to everybody; they were only available to the people that had the money to afford them. And there were some problems in the industry, and there was some problems when we went through deregulation. None of us has flown Braniff Airlines lately, or none of us has flown PanAmerican, and I'm not saying that Braniff is the HMO or PanAmerican is fee-for-service, but deregulation and devolving the power back to the patients with good, quality information is the

ultimate solution. I don't have a lot of confidence in politicians and bureaucrats and insurance companies coming up with a solution. Do you?

Dr. MULLEY. I agree with you. I think that a friendly qualification would be that the information that's provided to doctor and patient needs to mesh, and that it needs to be balanced and objective, and its source and its auspices must not have clear interests behind it to decrease utilization or perhaps increase utilization, depending on where it's coming from. And that, too, is a difficult social and political accomplishment.

Dr. COOKSEY. Yes, Dr. Chassin? I am from Louisiana. We would pronounce your name "Chessae" in Louisiana. How do you pronounce it?

Dr. CHASSIN. Chassin.

Dr. COOKSEY. Chassin.

Dr. CHASSIN. Chassin, yes.

Let me give you an example of a program that was initiated by government, but that facilitated quality improvement that would not have been possible otherwise. It's a program that, when I was Commissioner of the New York State Health Department, that we inaugurated as a quality improvement effort. It involved collecting clinical information in order to produce risk-adjusted data on mortality after coronary bypass surgery—by hospital and by physician. Since 1990, those data have been made public on an annual basis.

But that wasn't really the innovation of the program, although it is the oldest, ongoing program of public release of that kind of information in the country. The innovation was to make that information usable for cardiac surgery programs and hospitals to find out how to improve problems that they didn't know existed until they were able to compare their results with that of their peers. One hospital, for example, in Albany, for two years running, had the highest, statistically the highest mortality rate in the State; looked at their data, used the standard peer review surgical mortality and morbidity conference; couldn't find a problem. And it was only when we helped them parse those data that they found that, for their emergency cases, their mortality was 26 percent compared with the statewide average of 7 percent. That clue allowed them to look in great detail at how they were managing those emergency cases, completely overhauled it, and the very next year their mortality rate dropped from 11 in 42 to 0 in 54.

In case after case now, we've discovered using this dataset, where hospitals didn't even know there was a problem. Now these data, which are collected by each program, but are audited and really centralized in terms of accuracy and quality and viability of the data by a State government agency, have been enormously helpful in actually resulting in improvements. Now New York, in recent research, has the lowest mortality rates across the State for Medicare patients and the most rapid rates of decline. So that program has really been very effective.

Dr. COOKSEY. Well, that's the kind of result that we will get with open and comprehensive information systems. I think it's there; the technology is there. I don't really have confidence in government's ability to develop the system. I think that some entrepreneurial private sector company that can write software should develop it,

and do it in concert with physicians, not necessarily politicians, maybe a few regulators.

But thank you, Mr. Chairman.

Chairman THOMAS. I'd tell the gentleman I've been tempted to try to work a deal with Microsoft in exchange for whatever help we might be able to deal with their group, but we could get some software. [Laughter.]

Dr. COOKSEY. That would be a good start.

Chairman THOMAS. That might be useful.

We thank both of you very much. It's clear that an informed consumer is going to be an important link, but when you tell me that health care professionals don't have the time to stay up with what's going on—I mean, we've got to look at realistic roles for informed consumers as well. But your information, I just want to assure you, is going to be very, very helpful to us, as we begin talking about, quote-unquote, "quality health care" legislation. Thank you very much.

And I also want to thank our panelists on the last panel for being patient. My belief is we're not going to get too many opportunities to have a full and complete hearing on this subject, and so I appreciate your patience.

I'd ask now that Dr. Graham—excuse me, Diane Graham, who's chairman/chief executive officer of STRATCO; Jill Kanin-Lovers, who's vice president of Global Operations, Human Resources, IBM Corporation; Dr. Jeffrey Rideout, who although he's the medical director and vice president of Quality Management of Blue Cross of California, he's here on behalf of the American Association of Health Plans; Ron Pollack, executive director of Families USA Foundation, and Dr. Randolph Smoak, vice chairman, Board of Trustees, American Medical Association.

We thank all of you for coming. I would indicate that any written testimony that you may have will be made a part of the record, and that you can in the time that you have address us in any way you see fit. Could we just start, Ms. Graham, with you, and then we'll move across the panel.

And as I indicated to other panelists, you have to talk directly into these microphones or other folk can't hear you.

STATEMENT OF DIANE GRAHAM, CHAIRMAN AND CEO, STRATCO, INC.

Ms. GRAHAM. My name is Diane Graham, and I am chairman and CEO of STRATCO, a chemical and mechanical engineering company serving mainly the refining industry. My small business has become the worldwide leader in alkylation technology, a chemical process essential to the creation of high octane and reformulated gasoline. Though we compete against three Fortune 100 companies, we are now number one in market share.

Mr. Chairman, I want to thank you for giving me the opportunity to testify today and to add my voice to the congressional debate about health care quality. I am here today wearing several hats. I sit before you as a small business owner; a mother of 4 children, and as an employer who provides health insurance for more than 50 people and more than 100 of their dependents. I also sit before you as someone who is honored to be asked by President Clinton

to serve on his Commission on Health Care Quality and Consumer Protection. And, finally, I sit before you as the only member of that commission to dissent from its recommendation that Congress should pass a consumer bill of rights. With your permission, I would like that a copy of my dissent be included in the record.

Chairman THOMAS. Without objection.

Ms. GRAHAM. I would like to use my time here to explain why. I will do so by telling you why my company provides health insurance; what it's like to provide health insurance, and why my personal experience makes me deeply concerned with all proposals to pass Federal mandates on private health plans. STRATCO is celebrating our 70th year in business. My company has provided health insurance for our employees for decades because the previous owner including my father and I believe it is good business to treat employees as if they were our extended family, and I try to offer a health plan that best meets the needs of my employees. An employee with good benefits is a loyal, productive employee.

But health benefits are not cheap. Next to direct payroll, they're the greatest business cost we incur. Over the last decade STRATCO's health care costs have grown far more quickly than any other cost of doing business. Do we keep providing health insurance despite cost increases? Yes. Is it a struggle? Definitely. Is there a limit to how much my company and our employees can afford to stay covered with the kind of plan we want? Of course. And here's my big question: Do I want Congress to do anything at all that would make this struggle of health insurance affordability worse? Absolutely not. In fact, two years ago, we had to reduce the company paid coverage from 100 percent to 75 percent.

I believe that many in Congress and the administration are giving the affordability issue minimal attention. I am concerned that in the rush to protect consumers we may protect them right out of their coverage, and there is plenty of evidence that Government mandates on private health plans raise costs and reduce coverage.

The Chamber of Commerce says three out of four insured working Americans receive their health care coverage through their employers. Ninety-six percent of businesses have 50 or fewer employees. At a time when 42 million Americans do not have any health insurance and when small businesses are still identifying the cost of health insurance as their number one business problem, I do not want Congress passing mandates on private health plans.

Some of you may say you just want to pass a few small mandates to keep the costs down. You may seek out harmless mandates that you will say nobody can or should disagree with. I ask you not to go down that road either. It will only take you to where the States are; over 1,000 coverage mandates from coast to coast. This does not take in account future mandates that may be imposed on the States by Congress.

Do I want quality health care protected? Of course. After all, I am not just a business owner, employer, and commissioner, I am a mother and occasionally a patient. We all support quality; it's just a question of who gets to preserve it and improve it. I, myself, vote for the private sector: for small business owners, providers, health plans, and benefit managers to work hard to meet the needs of consumers; different consumers with different needs in different

parts of the country. Please stick with this formula and avoid costly one-size-fits-all Government solutions. And please, whatever you do, make the affordability issue a key component in all your deliberations. Thank you.

[The prepared statement follows:]

STATEMENT OF S. DIANE GRAHAM
CHAIRMAN AND CEO, STRATCO, INC.

TO: Subcommittee on Health
Committee on Ways and Means

DATE: Thursday, February 26, 1998

RE: Health Care Quality

Good Morning, Mr. Chairman.

My name is Diane Graham, and I am Chairman and CEO of STRATCO, Inc., a petroleum engineering and grease technology company. Our small business has become a worldwide leader in alkylation technology, a chemical process essential to the creation of high octane and reformulated gasolines. STRATCO employs more than 50 employees.

Mr. Chairman, I want to thank you for giving me the opportunity to testify today and to add my voice to the congressional debate about health care quality. I am here today wearing several hats. I sit before you as a small business owner, a mother, and as an employer who provides health insurance for more than fifty people and more than 100 of their dependents. I also sit before you as someone who was fortunate to be asked by President Clinton to serve on his Commission on Health Care Quality and Consumer Protections. And finally, I sit before you as the ONLY member of that commission to dissent from its recommendation that Congress should pass a Consumer Bill of Rights.

I would like to use my time here to explain why. I will do so by telling you why my company provides health insurance, what it's like to provide health insurance, and why my personal experience makes me deeply concerned with ALL proposals to pass federal mandates on private health plans.

My company has provided health insurance for our employees for decades because I believe it is good business to treat employees as if they were my extended family. And I try to offer a health plan that best meets the needs of our employees. An employee with good benefits is a loyal, productive employee.

But, health benefits are not cheap. Next to direct payroll, they are the greatest business cost we incur. Over the last decade, STRATCO's health care costs have grown far more quickly than our other costs of doing business.

Do we keep providing health insurance despite cost increases? Yes. But is it a struggle? Yes. Is there a limit to how much my company and our employees can afford to stay covered with the kind of plan we want? Of course. And here's the big question – do I want Congress to do anything at all that would make the struggle of health insurance affordability worse?

ABSOLUTELY NOT!

I believe that many in Congress and the Administration are giving the affordability issue minimal attention. I am concerned that in the rush to protect consumers, we may "protect" them right out of their coverage. And there is plenty of evidence that government mandates on private health plans raise costs and reduce coverage:

- State benefit mandates have raised premiums on the average family by up to $1,050 (National Center for Policy Analysis). Do we really want Congress to start heading down that road?

- 6 million Americans have refused health coverage from their employers largely because of high costs (Health Affairs).

- One bill before the House, the Norwood bill, is estimated to increase premiums by on average 23%, according to the actuarial firm Milliman and Robertson.

- We know there is a direct link between cost and coverage. Every time premiums go up 1%, anywhere between 200,000 (CBO Mental Health Parity estimates) and 400,000 (The Lewin Group) lose their health insurance.

At a time when 42 million Americans do not have ANY health insurance and when small businesses are still identifying the COST of health insurance as their number one business problem (National Federation of Independent Business), I do not want Congress passing mandates on private health plans.

Some of you may say you just want to pass a few small mandates to keep the cost down. You may seek out "harmless" mandates that you will say nobody can or should disagree with. I ask you not to go down that road either. It will only take you to where the states are – 1,000 coverage mandates from coast to coast. This does not take into account future mandates that may be imposed on the states by Congress.

Do I want quality health care protected? Of course I do. After all, I am not just a business owner, employer, and commissioner, I am a mother and occasionally a patient. We all support quality – it's just a question of who gets to preserve it and improve it. I myself vote for the private sector – for small business owners, providers, health plans, and benefit managers to work hard to meet the needs of consumers – different consumers with different needs in different parts of the country. Please stick with this formula and avoid costly, one-size-fits-all government solutions.

And please – whatever you do – make the affordability issue a key component in all your deliberations.

Thank you.

Chairman THOMAS. Thank you very much.
Ms. Kanin-Lovers.

STATEMENT OF JILL KANIN-LOVERS, VICE-PRESIDENT, GLOBAL HUMAN RESOURCES OPERATIONS, IBM CORPORATION

Ms. KANIN-LOVERS. Mr. Chairman and members of the committee, my name is Jill Kanin-Lovers, and I am vice president for global human resources operations for the IBM Corporation.

Before I get into the specifics about my testimony, I would like to reach back to something from the other panel and let you know IBM would love the opportunity to come back and share with you the tools that are available to manage data and assess quality programs. Those things do already exist, and we would certainly be willing to share that with you.

Chairman THOMAS. I'm more than willing to take you up on your offer, and I've also been very pleased that a number of managed care companies, although that information may be somewhat proprietary, are willing to share as well, I'm concerned about the inability to have a clearing house available for maximum collection of this data. I appreciate your offer.

Ms. KANIN-LOVERS. Great, thank you. I don't have to explain what IBM is all about; I think most people know that, but we operate in a very intensely competitive and rapidly changing technology environment. We are totally committed to attracting and retaining the highest caliber work force and by offering high quality cost effective health care benefits that cover our employees and their families is one important way that we do that. This is part of our work force strategy.

We are a major purchaser of health care. We currently provide health care benefits for over 500,000 people in the United States. That includes our employees, our dependents, and retirees. Last year, we paid over a billion dollars in premiums for health care, so we are very much an aggressive purchaser.

I am here today on behalf of the Corporate Health Care Coalition. This is a group of 26 large self-insured, multi-State corporate purchasers of health benefits who joined together in 1993 to address health care reform issues. Our coalition members have really been in the forefront of efforts to provide high quality, cost effective benefits for employees. What I want to do today is to talk about four different things. First, I want to talk about the purchaser's role. I want to use that——

Chairman THOMAS. Ms. Lovers, if you'll talk directly into that microphone, it's going to be easier for people to hear you.

Ms. KANIN-LOVERS. I'm sorry. Okay, I apologize. Thank you.

Chairman THOMAS. No, it's a lousy microphone. [Laughter.]

Ms. KANIN-LOVERS. I want to talk about the corporate purchaser's role in general, and then I want to talk about IBM and what we do. I want to talk about the importance of ERISA and ERISA preemption and then the harm that we believe could be done by some of the pending legislation.

As long as our health care system remains voluntary, employers will play a critical role, we believe, in pooling risks; making coverage affordable; demanding quality, and informing and advocating for our employees. That is a very important role that we play. It

would be impossible to replicate this in an individual purchasing system without extensive Government intervention. We view managed care as an important tool for quality. It helps us in organizing health care providers to gain accountability at the plan level. We think it helps to learn what treatments have worked. It helps in modifying them and continually improving patient outcomes. Our goal is to move toward evidence-based medicine.

We demonstrate our commitment to quality at IBM everyday. We offer a very wide range of plan choices including a fee-for-service plan, and this year we offered 183 HMOs to our employee population. What's interesting about that is 50 percent of our employees have chosen to be in managed care options. They can choose either one, and they go into managed care. On our own and through a national purchasing coalition of 11 major companies, we have set extensive purchasing requirements; we monitor plan performance, and we encourage improvements in quality. We think we play a very important role in moving the ball on quality.

We offer employees access to a substantial amount of information. I can't emphasize how much employee education is critical to making sure that they get the right type of care that supports their specific needs and that supports the needs of their families. We've provided you with samples of what we call our HMO fact sheets, that is materials that go out to employees every single year so they can make reasoned decisions about what plan they should be in. We also provide our employees with access to a 24 hours a day, 7 days a week nurse hotline. In addition our employees have access to a telephone service if they've got questions about health care if they have any problems. We also have a lot of information available on IBM's internal internet side which employees can access. Recently, we launched a disease management program—it's a pilot project for us—to help employees in managing diabetes when they're chronically ill. That's the framework of what we're doing in the context of quality and how we go about offering health care to our employees.

ERISA is extremely important to us as corporate purchasers of health care. We think it was a brilliant stroke. When there was no requirement to have a plan in the first place, it did not make sense to regulate the contents of plans. Congress, instead, provided participants through ERISA with something that we call a tool kit. Its rights and responsibilities are laid out for us. It includes information disclosure, fiduciary obligations for the employer, internal review, and external Federal remedies. ERISA preemption of State law is a critical part of the overall structure. We think we are then able to operate with a single plan. IBM wants to be one employer in the United States. We have employees in all 50 States of the Union. We want to be able to have the same plan regardless of where our employees and their families live and work. ERISA has done more to protect the voluntary system of benefits and quality assurance than any other law.

This brings me to my last point. We are concerned about legislation like PARCA. We believe it would harm employer efforts to improve quality. This is for two reasons. First, Federal health plan standards would mandate benefits for voluntary plans. We think that's going to result in a huge enforcement bureaucracy. We think

it will duplicate efforts that are already underway in private sector accreditation and would freeze current treatment preferences that are in place.

Second, we believe any proposal that creates liability under State tort law for benefit coverage decisions of health plans is troubling. People in Federal and private sector plans now have access to internal reviews and Federal remedies, not to State torts or jury trials, and punitive damages. We administer millions of claims each year, and very few of those need to be resolved in court. We have an internal review process that works quite effectively. Cases are rarely appealed. When they are, more than likely, it is the result of lack of medical consensus. In some cases employees are looking for an answer that isn't even out there in the medical profession. We believe State tort liability would put juries in a position of deciding treatment and interfering with the move to evidenced-based medicine. Patients deserve to have evidence-based reviews in real time, not in a protracted legal battle.

Let me just conclude with some comments. It appears that there may be some action on health care this year. If this process moves forward, I would caution you to keep in mind the basic framework for any activity in this area. First of all, we would like to see you build on accreditation, quality measurement, and employee education efforts that are now underway. We think the Federal Government could really help here as the significant purchaser of health care.

We also would like to see ERISA's federal framework preserved. We think that any issues that are raised should be in this framework of the tool kit which is already provided in Federal law, and we should reaffirm preemption of State regulations and remedies.

We'd like to see you focus on the real issue which is solving the problems for the patient. The patient wants a quick decision to get appropriate treatment when needed. Neither litigation nor Federal health care standards meet this need.

We'd like to retain and reinforce the reliance on evidence-based decisions, systems of care, and accountability.

And, lastly, we would like to entitle participants to a fair process, not a perfect result. Hold plans accountable for a fair process to resolve disputes; don't punish them for adverse outcomes that modern medicine cannot prevent. Thank you for the opportunity to address you.

[The prepared statement follows:]

Statement of

Jill Kanin-Lovers,

Vice-President, Global Human Resources Operations

IBM Corporation

on behalf of the

Corporate Health Care Coalition

before the

Committee on Ways and Means

Subcommittee on Health

United States House of Representatives

February 26, 1998

Statement of
Jill Kanin-Lovers, Vice-President, Global Human Resources Operations
IBM Corporation
on behalf of the
Corporate Health Care Coalition

before the
Committee on Ways and Means
Subcommittee on Health
United States House of Representatives
February 26, 1998

Mr. Chairman and Members of the Committee:

My name is Jill Kanin-Lovers. I am Vice President for Global HR Operations for the IBM Corporation.

IBM voluntarily offers health care coverage to 540,000 employees, dependents and retirees and spends $1.09 billion on health benefits per year. As an employer with operations and employees in all 50 states, IBM manages and administers a single health care plan that arranges for the delivery of consistent, high-quality health care to our employees and their families, regardless of where they live and work. We are able, under a single plan, to provide coverage for a mobile workforce. IBM's ability to respond to our employees' needs for quality health care and tailor our plans to meet their needs is due in large part to the flexibility that the Employee Retirement Income Security Act of 1974 (ERISA) gives us. We are able to operate under ERISA's uniform system of federal regulations rather than 50 different sets of state laws.

I am here today representing the Corporate Health Care Coalition (CHCC). The Coalition is an alliance of 26 companies formed in 1993 to reflect the views of large, multi-state, self-insured companies on national health care policy. Coalition members operate health benefit plans for employees and their families as well as retirees, covering over 5 million lives and providing over $ 8 billion in benefits annually. We have been in the forefront of efforts to provide high quality and cost-effective benefits for employees. Coalition members have extensive experience in designing, administering and delivering employee health benefits, and are a major force today in ongoing efforts to improve the health care system.

Today, I would like to talk to you about health care quality from an employer purchaser perspective. First, I am going to describe the intense and diverse activity underway in the private sector to improve the quality of health care plans and protect consumers - who are our employees. I will give you an overview of how the members of the CHCC purchase and implement high quality health care benefits and services. Then, I will use IBM's health care plan as an example of how one company operates in today's health care market place. Second, I will discuss the importance of the Employee Retirement Income Security Act of 1974 (ERISA) to what we do. Finally, I will comment on the very serious harm that could be done to these private-sector initiatives by some of the legislation now before the Congress.

I. Employer Purchasing and Quality

A. Managed Care and Accountability

As advocates for our employees' health care, the Coalition's commitment to quality begins with our commitment to managed care. Managed care evolved in an effort to improve the accountability of health care providers. Early managed care plans were designed to improve the coordination of health care to patients by integrating physician and hospital care and establishing a financial incentive for preventive services and health maintenance. HMOs shifted the focus of medical care from body parts to the whole patient, and from disease reaction to health promotion.

Employers moved decisively to managed care plans in the mid 1980s to find efficiencies in health care that could lower double digit cost increases and improve quality. Researchers found very high rates of unnecessary and inappropriate care and high levels of excess facility capacity in the indemnity system. Financial incentives in fee-for-service medicine encouraged over-utilization. Employers believed that better patient outcomes and investment in more cost effective care would result from a change in the financial incentives to encourage management of care delivery.

The basic ideas behind the move to managed care are consistent with consumer protection initiatives at the state and federal level today. They included:

* ***Creating a single point of accountability*** - In an indemnity world, patients coordinate their own care, moving from provider to provider. In a managed care environment, a health plan can be accountable for the procedures and outcomes for its enrolled population. Purchasers can set targets for the health plan and expect the organization to manage its members to meet those targets. Patients can have a single primary physician coordinating their care. This single point of accountability has created a more intense focus on health care quality than existed in a purely indemnity/fee-for-service environment.

* ***Shifting the focus from input to outcome*** – Services in an indemnity system were evaluated on the basis of the input -- the volume and type of service provided -- without being able to know the ultimate impact on the patient's health. The service integration and improved patient record keeping of managed care makes it possible to manage and evaluate patient care on the basis of whether the patient's condition improves.

* ***Shifting from static quality to dynamic quality*** – Quality in an indemnity system was a state of practice that remained unchanged once attained – it was a function of the physician's training or the character of the health care facilities. The shift to organized service delivery with performance and outcome measures, has made quality a constantly evolving goal. Providers are encouraged to share information, learn from their collective experience, rethink their practices, and respond to new guidelines and protocols.

* ***Reliance on "benchmarking" and "best practices"*** - In the competitive world of managed care, no organization can assume that they are doing the best possible job. Plans can be compared to one another, and plans that have done the best job of treating a particular illness or attaining a particular health status for their population can be held out to others as an example. Purchasers can require visible progress on specific health problems as a condition for being awarded a contract. The whole concept of quality-based competition requires an organized system that can pursue strategies to achieve specified results.

Purchasers see in managed care the opportunity to improve the value they receive for their health care dollars. With a single point of accountability, employers and employees can compare the performance of plans, select plans that show evidence of meeting certain performance targets, choose the more effective plans and providers, and encourage ongoing improvements in quality and efficiency.

B. CHCC Member Company Activities in Purchasing Health Benefits

CHCC member companies are in the forefront of efforts to purchase health benefits on the basis of quality. Given the diversity of industries and types of workers in CHCC companies, a "one size-fits-all", "cookie-cutter" approach does not work. Member companies approach quality purchasing in a variety of ways that give testimony to the innovation that has developed among private purchasers. The following provides only a sample of the quality-based purchasing activities of CHCC member companies.

1. Accreditation

Many companies require health plans to have National Committee for Quality Assurance (NCQA) accreditation or be in the process of pursuing accreditation as a condition for purchasing. A number of companies also require or review Utilization Review Accreditation Commission (URAC) and the Joint Commission on Accreditation of Healthcare Organizations (JACHO) accreditation.

2. Purchasing Standards

Some companies set performance standards for health plans with which they contract. These standards may be extensive - covering such things as standard benefits, governance, financial solvency and fiscal operations, access, credentialing, network requirements, data monitoring and evaluation, UR and claims processing, grievance and appeals processes, quality assurance processes, and a number of other factors. Some companies require health plans to operate a program of continuing quality improvement or continuing targets for quality.

3. Employee education - plan comparisons

Employers in the CHCC offer choices to their employees and provide their employees substantial comparative information to select plans. Some companies provide a benchmarking process in which they compare each plan's results to results for a designated "preferred plan" on a number of dimensions, including: employee satisfaction, provider access, network coverage, and HEDIS

(Health Plan Employer Data and Information Set) measures. Other companies provide an HMO fact sheet or simplified report card, with exceptional plans identified.

4. On-Going Quality Improvement Activities

Some companies work closely with their plans on efforts to identify best practices and modify plan practices to meet agreed upon performance targets. Others help their plans develop an action plan for correcting problems identified in employee satisfaction surveys. One company provides incentives for health plans that meet their targets, works on improvement plans with the health plans that are mediocre, and eliminates poor plans from their group of suppliers.

5. Prevention and Disease Management Programs

Some companies require that plans adopt specific preventive services and disease management programs. Others develop preventive and disease management programs in conjunction with their plans. Disease management programs have been effective in dramatically improving health outcomes and reducing medical costs for chronically ill patients with specific medical problems.

6. External Review

Most companies provide for external review by qualified outside medical groups in cases where an employee contests a coverage decision with regard to significant medical treatment issues. The external review addresses medical treatment issues raised by the case and is advisory to the plan in making a final coverage decision.

7. Centers of Excellence and Specialized Providers

Most employers have contracts with treatment centers that have specialized in specific procedures and have a high volume of cases, evidence of high quality, and a willingness to contract for comprehensive treatment of particular illnesses. These centers can improve patient outcomes and manage overall costs of expensive medical care.

C. IBM's Experience in Purchasing Health Benefits

As a company in an intensely competitive and rapidly changing technology and services industry, IBM is committed to attracting and retaining the highest-caliber work force. Offering high quality, cost-effective health care coverage for our employees and their families is one important way we do that.

Today, IBM is able to offer our employees a variety of health care plan choices, which include the following:

* Fee-For-Service Indemnity Plan
* HMOs (IBM contracts with 183 plans nationwide)
* Dental Plan (3 choices, including fee-for-service and managed care)
* Vision Plan

* Managed Mental Health Plan
* Prescription Drug Network
* Catastrophic Case Management
* 24-Hour Nurse Hotline
* Long-Term Care Program
* A Wellness Website linked to medical information sites relevant to specific employee needs
* A subsidized "Life Planning Account" for our employees which covers the purchase of wellness products and healthy living activities

1. IBM Selection of Quality Health Care Plans

IBM has a highly-developed program for selecting quality health plans. First, IBM submits a Request for Information (RFI) Questionnaire to competing HMOs, carriers, and other entities. The Questionnaire includes 900 Points of Information, focused on the following 3 key areas:

✓ Quality: clinical data, utilization, provider management, credentialing, quality improvement;

✓ Administrative Effectiveness: member services, access to providers, ID card issuance, retiree coverage; and

✓ Organizational Stability: provider compensation, plan's financial stability, how long in operation, membership, NCQA accreditation

Second, we examine the satisfaction survey data we have received from our employees and add it to the questionnaire information we have received from the plans. Lastly, we factor in premium rates. By combining all these sets of information, we then develop a total numerical **Quality Score** for each plan. We use these **Quality Scores** to

1. determine with which HMOs we will contract;
2. provide feedback to the plans on their strong and weak points;
3. determine IBM's annual employee cost-share for each plan option; and
4. focus our efforts on improving each plan's overall performance each year.

We use this process to ensure that IBM employees and their families have a choice of high-quality, cost-effective health care options that meet their needs. Currently, 50% of IBM employees have chosen managed care options.

2. IBM Communication with Employees

We believe that our employees and their families should have access to easily understood information about their health plan options that allows them to make more informed health care choices. The information we provide gives them valuable comparative data that shows the significant differences in various plans' design, benefits and quality. Much of this information is gathered from our employees through employee satisfaction survey data.

IBM conducts employee surveys, both for fee-for-service and managed care participants, to determine an employee's overall satisfaction with their health care plan. Some of the Survey questions include:

- Major reasons for choosing the option
- Quality of and access to providers
- Quality of service
- Claims processing
- Overall satisfaction rating

As part of our yearly employee enrollment package, IBM provides our employees and their families with ***HMO Fact Sheets*** which help employees better understand the HMO choices available to them and the distinctions between each plan offering. For example, each ***Fact Sheet*** reports the following:

- ✓ Quality data: HEDIS results, NCQA status;
- ✓ Provider access: numbers of physicians & hospitals, board certification rates, accredited facilities;
- ✓ Key plan facts: type of HMO, years in operation, etc.;
- ✓ Customer service: hours, telephone response time, referral processing time; and
- ✓ Plan design summary

We also provide our retirees with separate ***Fact Sheets*** for Medicare-Risk HMOs. Attached is a sample ***HMO Fact Sheet*** which we sent to active employees. In addition to ***Fact Sheets***, we routinely provide our employees with information on coverage and exclusions, cost-sharing requirements in and out of network, and information on available providers.

IBM employees and retirees can also use computer and phone technology to access health benefit information. Twenty-four hours a day, seven days a week, comprehensive information on health care benefits and wellness programs is available on our Intranet, our internal communications network. For additional information and immediate answers to specific questions, IBM employees can call a 1-800 number to speak with our National Human Resource Service Center (NHRSC). NHRSC not only provides information on HR policies and processes, but can also handle a wide variety of HR transactions for employees.

3. IBM Health Care Quality Initiatives

As the health care marketplace continues to evolve and change over time, employers such as IBM and the companies in the Corporate Health Care Coalition constantly seek new ways to deliver high-quality health care choices to our employees. Because of our purchasing power as large employers, we are able to drive innovation in many ways.

One of our key quality initiatives has been through the National HMO Purchasing Coalition. This is a group of 10 like-minded companies (including American Express, British Petroleum, Gannett, ITT-Hartford, Marriott, Merrill Lynch, Mobil, Pfizer and Sears), formed in 1996 to improve health care quality on a local level by collectively selecting and partnering with locally competitive HMOs that promote a high degree of clinical quality, member access and patient satisfaction.

The HMO Purchasing Coalition considers some of the same factors as IBM's own plan selection process to determine which HMOs to offer to employees and retirees. The Coalition's Quality Review Criteria include the following:

- Commitment to continuous quality improvement
- Employee access
- Employee satisfaction data
- Employer survey data
- Ability to manage sick members
- Data submitted on RFP
- Consultant database information
- Capability for medical management
- Plan design compliance

In addition, the Coalition conducts site visits of the various HMOs to review and assess quality through the following:

- Credentialing/recredentialing files
- Provider profiling/outcome analysis
- Utilization Review case reviews (25 to 50)
- Review of QA minutes including medical records
- Clinical algorithms
- Outcomes studies

Another IBM quality initiative deals with disease management for chronic or long-term illnesses. We are jointly piloting a program in diabetes management with Intracorp, an independent external review organization. The program is designed to reduce the severity of the employee's medical problems and reduce long-term consequences of the disease by: educating employees with diabetes about ways to manage their disease; encouraging them to have regular interaction with their physician; and improving the quality and consistency of their treatment.

Instead of intervening only when there is a medical event or episode (admission or procedure), specially trained RN care specialists will reach out to the employee volunteers and their physicians to provide proactive, ongoing contact, education, counseling and access to available resources.

Employee response has been enthusiastic. When employees in the IBM indemnity health care option were offered an opportunity to participate in the program, the response was so positive that the pilot was filled almost immediately. Word of our pilot project has spread to the Centers for Disease Control; where we have been invited, with Intracorp, to make a presentation in April, 1998. If this project proves to be successful, IBM will consider extending it to other chronic diseases.

The role of IBM in purchasing quality health plans and overseeing the delivery of benefits to employees comes to life best through real cases. We have included two case studies from our employees in the Appendix.

II. The Importance of ERISA and Employer Plans

A. ERISA was a Brilliant Stroke

Some people today believe the application of the Employee Retirement Income Security Act of 1974 (ERISA) to employer-sponsored health plans was an accident or an afterthought. The legislative history of ERISA makes clear that its application to employee welfare benefits including health plans was intentional. More importantly, ERISA's structure was intentional and effective.

The purpose of ERISA was to protect "contractually-defined" benefits. Congress acknowledged that in a voluntary system of health benefits, the agreement to provide benefits was a matter between the parties - the employer and employee. Congress's role was not to specify what was in that agreement - but to ensure that if there was an agreement, it had to be understandable to the parties and enforceable. In short, ERISA was intended to provide a "toolkit" to employees: information and disclosure, fiduciary obligations of the sponsor, rights to benefits and remedies for participants.

Congress in 1974 knowingly declined to regulate the health plan itself, appropriately deferring this issue to the expected debate over national health insurance. Without a law mandating a plan, they reasoned, it would have been absurd to pass a law mandating the contents of the plan.

The focus on the ERISA "toolkit" and the avoidance of federal health plan regulation was a brilliant stroke. Congress did not need to create a massive federal bureaucracy to register and regulate tens of thousands of health plans in America. Instead it could rely on a relatively lean Department of Labor to supervise the "toolkit" and its "participant-enforced" rights. Further, the avoidance of federal health plan regulation enabled health plans to innovate and evolve easily in response to rapidly changing medical practice and technology.

Imagine the structure we would have in place today had Congress in 1974 elected instead for federal regulation of the contents and operations of every health plan in America.

* Plans would annually send their plan documents to the Federal Bureau of Health Plans where endless rows of clerks would pore over their benefits packages to confirm they were in compliance with the law.
* Standards adopted in 1974 (e.g. mandatory 8-day stays for maternity care) and occasionally amended by Congress would be rigorously enforced.
* Swarms of health care lobbyists would annually descend on Capitol Hill in attempts to convince the Congress to cover the latest in drugs, devices, and procedures or to rectify the latest perceived inequities in contracting, payment, or due process rights for particular subspecialties, ancillary providers, facility operators, or disease groups.
* Teams of federal health plan auditors would spread out across the country, springing surprise audits and lengthy site visits to review plan policies and procedures, contracts, facilities and operations.

With national health plan standards, how quickly would Congress have acted to update coverage guidelines to keep up with changing practice standards or dealt with difficult political issues when large medical interests were at stake? ERISA's structure has kept our government from getting bogged down in the kind of detailed treatment and coverage issues European national health systems are mired in every day.

B. Employer Sponsorship is Necessary

Employer sponsorship of health benefits plans has been criticized by some for limiting individual choice and hobbling pure market forces that could improve quality and reduce cost. The capacity of individual choice to drive the health care market is more of a theory, however, than a reality. Employers are expanding the options they provide to employees and are encouraging employees to exercise more choice among that array of options. At the same time, many employers are developing ways to clarify the differences between options and make them more intelligible to individuals.

The biggest problem with individual choice without employer sponsorship is the adverse selection risk that it creates and the resulting difficulty in providing any insurance coverage for people with serious medical conditions. Employer sponsorship solves easily and naturally for more than 145 million workers and their dependents the most difficult problem in health insurance - the pooling of risk. Without employer sponsorship, the Congress would have to establish a complex and intrusive government mechanism to ensure that people could get affordable health insurance coverage at all.

Employer sponsorship also provides important advocacy for participants. Employers screen plans, provide information to employees, oversee enrollment activities, act as a fiduciary in the interests of plan participants, and respond to employee concerns about plans. This sponsorship role serves an intermediary function that would otherwise have to be met through an organization created for this purpose - some kind of Regional Alliance.

C. ERISA and ERISA Preemption are Important for Employers

A critical element of ERISA's structure is its broad preemption of State laws. Congress recognized in 1974 that if its intent was to not burden voluntary health plans with extensive federal requirements, then it was counterproductive to allow states to move into the vacuum and impose excessive and varied state requirements.

ERISA preemption is grounded in the fact that health benefits are part of a total compensation package and an employer-employee relationship that is not altered as employers or employees cross state lines. ERISA preemption enables an employer to operate a consistent plan for employees throughout the company, with uniform employee rights, and consistent claims administration and interpretation of benefits, as ERISA's fiduciary obligations require.

ERISA preemption has also provided employers the flexibility to encourage national and regional market competition through active purchasing. Regulation often protects those carriers, plans, and providers already in the market from outside competition. When local health care

markets become concentrated and regulated entities resist price and quality demands of purchasers, ERISA enables employers to encourage new entrants or purchase from groups outside of the local market to restore competition. Competition has been critical in creating greater accountability of providers and plans for consumer satisfaction and outcomes.

ERISA preemption has also made it possible for health plans to introduce systems to coordinate patient care, improve quality and manage costs without the excessive financial liability that would arise from litigation of medical standards and coverage rules in state courts.

Without broad ERISA preemption, employers would be constantly torn in reconciling health benefit issues between the demands and interpretations of competing state jurisdictions. Employers would be too distracted by the demands of understanding and complying with conflicting state requirements to worry about developing sound benefit plan design. In addition, prior to enactment of ERISA, courts often had difficulty even determining which state had jurisdiction on a benefit issue when the participant, provider, employer, plan, and utilization review agent were all located in different states.

D. ERISA Provides Consumer Protection

States occasionally portray ERISA and ERISA preemption as an impediment to consumer protection. This is ironic because ERISA was enacted to give participants strong tools to protect themselves. One of the reasons for broad preemption was that Congress was concerned when ERISA was enacted that the states might try to weaken its participant protections.

Many of the provisions in consumer protection bills that have been considered at the state level in the last few years would actually duplicate existing ERISA requirements. It is also common practice for employers to initiate programs or establish procedures that go beyond ERISA requirements in informing participants, providing choices, overseeing plan operations, responding to complaints, or remedying difficulties with the plan. Employers provide the plan as a benefit to employees, and view it as worth little to the company if employees do not value it as a benefit.

III. The Impact of Pending Legislation

A number of bills have been introduced or are being drafted to respond to perceived concerns about health plans in general and managed care plans in particular. Most of the provisions in the introduced bills would broadly affect all kinds of health plans, not simply managed care plans. Much of this legislation would do serious harm to our efforts to provide high quality health care for our employees.

Rather than discuss a particular piece of legislation (such as H.R. 1415, the PARCA bill, which the Corporate Health Care Coalition opposes) -- I would like to comment on two issues that I believe are the focal point of most of the bills. These issues are threshold issues for the Congress. I would urge you in the strongest terms not to underestimate the very serious damage the Congress can do to health care coverage and benefits in the United States through legislation on these issues.

A. Federal Health Plan Standards

PARCA and most of the other bills would mandate a number of federal standards for health plan operations and benefits. Prior to the enactment of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Congress was not in the business of legislating health plan standards. ERISA did not contain plan standards. The federal government had no regulatory authority over health insurance contracts - either individual or group. The Federal HMO Act of 1973 applied qualifications only for HMOs that were seeking federal start-up grants. Medicare's standards (§1876 of the Social Security Act) applied only to the Medicare contracts.

With the enactment of HIPAA, the Congress started down a new regulatory path -- one for which the federal government is poorly organized and prepared. Given the comparatively simple requirements of this act, it is instructive to see the complicated regulatory maze the team of federal agencies has managed to construct. Three states have now thrown up their hands on their part of the implementation and asked the federal government to administer the Act for them. It is also instructive to see how unproductive some of the regulatory effort has become. One of our member companies, for example, that had never had a preexisting condition exclusion in the history of its health plans, must now spend $300,000 a year on consultants to prove to the federal government that they comply with the new law. Imagine how complicated and expensive this regulatory process would become if Congress were to enact more extensive plan standards.

Particularly troubling in the wake of HIPAA, was the enactment at the end of 1996 of laws that set plan rules for treatment. While the CHCC had no specific problem with the underlying medical policies of a 48 hour hospital stay for maternity care and "parity" of mental health and non-mental health treatment, what was troubling was that that the Congress would begin to instruct health plans on how to treat patients.

In a day when we and other purchasers are pressing for the application of better medical and scientific evidence in making treatment and payment decisions, it is anachronistic for the Congress to preempt this effort by creating its own judgment on medical questions. Congress can protect patients better by supporting the ongoing research and guideline development necessary to ensure coverage of the most effective treatments, than it can by passing ironclad laws that slow down the emergence and adoption of new technologies.

Many of the health plan standards being proposed in pending bills have very little to do with consumer protection. A number of them are aimed at protecting providers in their dealings with managed care plans. Some provisions are even aimed at protecting one class of providers from another. As various medical specialists, ancillary providers, and hospitals experience growing financial pressures, Congress will increasingly become the focal point for relief bills. The case will be made for protective legislation without regard to whether the protection is ultimately of any value to patients. I would urge you to avoid opening a route through legislation for reversing the effects of the health care market and rewarding ineffective treatments, inefficient procedures or outdated technologies.

Corporate purchasers and the health plans themselves already have the means to address many of these health plan standards issues through private-sector accreditation and auditing of health plans. Accreditation of health plans is still in its early years, and has a few more years to go before it begins to cover most plans or adequately addresses all of the significant issues in the operation of managed care plans. Nevertheless, the private sector is years ahead of where the Congress and federal agencies can hope to be in developing or implementing extensive health plan standards. The Congress, rather than attempting to develop a regulatory infrastructure to duplicate the work of private accrediting organizations, should take a look at how it can effectively build on the private-sector infrastructure that is already in place.

The government as a purchaser of health plans for Medicare, federal employees, and military personnel has a substantial amount of leverage to influence health plan operations and benefits. Before extensive federal standards are adopted and regulatory agencies created to dictate health plan standards through private employers, Congress should explore ways to coordinate the activities of federal purchasers to influence health plan operations.

B. Health Plan Liability for Coverage Decisions

Legislation, such as the PARCA bill would eliminate ERISA preemption of state laws to permit litigation under state tort law against health plans for any harm related to an adverse coverage decision of the plan.

The vast majority of participants in employer sponsored health plans today are provided rights and remedies under federal law, and cannot bring an action for benefits in state courts under state tort laws for denial of plan benefits. Medicare beneficiaries, federal employees, military personnel, and private-sector employees all have remedies available under federal law, with access in certain circumstances to federal courts once internal appeals are exhausted.

PARCA and other liability provisions would enable cases now heard in federal court to go forward in state courts, with access to jury trials and punitive damages. They would expose employer-provided plans to significant liability for day-to-day coverage and benefit decisions. This change would put much of the movement toward accountability and evidence-based medicine at risk.

The core issue is what will the plan pay for. To understand the significance of this issue, it is important to bear several facts in mind:

* Private-sector health plans are voluntary - there is no law that an employer has to have one.

* The health care market is unusual because the consumer is split in two separate parts - the purchaser and the payer. In most markets, the combination of purchaser and payer in a single person exerts a discipline on the purchasing decision. In health care, the purchaser is not constrained by the limits of the payer's resources. As a result, the payer has to set limits. Without limits, there would be no way to control spending on high cost cases to ensure plan resources were sufficient to meet the needs of all participants. Without limits, many sponsors would also be unwilling to continue sponsoring a plan.

* In the process of designing reasonable limits, employers have shifted from indemnity coverage, where every covered benefit and dollar amount was spelled out in detail - to comprehensive benefits, where all appropriate or necessary treatment is covered as it is adopted under norms of community practice. The change was an effort to provide coverage that was more responsive to evolving medical practice, and would encourage the development of new technologies.

* The challenge for health plans is how to put limits on payment that are consistent with good medical care - how to define "medically necessary" care in ways that ensure that care that is known to work is provided in lieu of excessive treatment, unnecessary services, and poor quality care.

The move toward "evidence-based medicine" is the effort to subject coverage and medical treatment decisions to the test of what has been shown to work best. Evidence-based medicine is the best hope that patients with chronic, rare, or difficult conditions will get the best treatment available and actually improve.

The conflict between the move to accountability and "evidence-based medicine" on the one hand and the autonomy of the treating physician on the other is being fought out over the issue of liability for plan coverage decisions.

The coverage decisions at issue are the most difficult decisions to make in health care. They relate to treatments that may have a very small chance of success for a critically ill patient with little hope of survival, at a very substantial cost to the plan. They relate to treatments where experts disagree and there is no consensus of widely accepted standard of care. They relate to emerging untested treatments where there is no evidence of success and questionable value for a patient.

Adding substantially to the liability for claims decisions and enabling patients to bring these questions before juries with large punitive damage awards is the wrong way to resolve these difficult questions. It is often after-the-fact – of little value to the patient. It is punishing the plan for what medical science cannot do.

This liability would enable physicians who resist plan guidelines and accountability to encourage retaliatory lawsuits for adverse coverage decisions. It would encourage physicians with a financial stake in untested new treatments to encourage suits to discourage plan denials of coverage. Indeed, any effort of a health plan to bring a more systematic and disciplined approach to medical decision making could conceivably be challenged.

* Patients could sue a health plan if they believe that a better outcome would have resulted from a different treatment, regardless of whether the treatment they received was the most effective known therapy for their condition.
* Patients could sue over the use of protocols or guidelines, no matter how well designed they were, if treating physicians could be found to disagree with them.

* Patients could sue to punish plans that followed the right process in making medically-based decisions, if the provider or patient disagree with the decision.

This added liability for benefits decisions may well put the treating physician - no matter how competent - in the drivers' seat, not only on treatment but on payment as well.

Most importantly, creating new avenues for litigation would not begin to solve the immediate problem for the patient - the need to get the best treatment when it can still do some good. Litigation can only offer the patient or their survivors hope after-the-fact.

C. Guidelines for Legislation

If the Committee concludes there is a need for legislation this year, we propose some guidelines you may want to consider:

1. Build on Accreditation, Quality Measurement, Employee Education Efforts

Private-sector quality improvement efforts are well-established and beginning to work. Rather than develop a new federal regulatory capability that is duplicative of private-sector efforts, the Committee should support existing private plan accreditation as a mechanism to instill standards for disclosure, access, provider networks, and other matters that are the subject of proposals for federal legislation. The federal government already has the capacity as a purchaser to influence the development of accreditation standards. Accrediting bodies can develop appropriate standards on the basis of sound professional judgment and medical evidence, removed from the pressures of the legislative arena.

The federal government already funds and participates in efforts to develop patient outcome measures. Continued support for this research offers the best hope for increasing the quality of medical care and ensuring that patients have access to the most effective treatments.

Another important part of the equation is to equip consumers with appropriate information to make educated plan choices and participate more effectively in treatment decisions. ERISA already requires disclosure of substantial amounts of information, and employers and plans voluntarily provide additional information and educate employees in how to make effective use of the information they get. It is important that consumers have access to information that will reveal significant differences in plan benefits or quality, and that they learn how to use it. However, we would urge the Committee to avoid requiring disclosure of excessive amounts of information or types of information that would do more to confuse consumers than enlighten them.

2. Preserve the ERISA framework

The distinction between regulation of the ERISA "toolkit" of rights and responsibilities and the regulation of the employer-employee agreement or health plan itself is significant. The Committee should strive to confine federal regulation to areas of the "tool-kit" that are consistent with traditional federal regulation and would not expand the regulatory scope of the

government. In the process, the Committee should reaffirm the exclusivity of federal regulation of the ERISA "tool-kit" and its preemption of state regulations and remedies. The Committee should avoid expanding federal regulation into areas that would reach the operations and benefits in the health plan itself.

3. Focus on the Real Issue - Solve the Problem for the Patient

The issue for the patient is to get the most appropriate treatment that is covered by the plan, and to have a coverage decision rendered quickly enough to ensure the treatment is provided in a timely fashion. Any legislation should focus on promptly resolving concerns about treatment options. The need for a prompt decision is not addressed through litigation, nor is it addressed through federal standards that mandate provider relations or treatment or coverage rules.

4. Keep our Reliance on Evidence-Based Decisions, Systems of Care, and Accountability

The best decision for patients who face difficult treatment decisions is one that has shown to be effective, suitable for the patient, and based on the best medical evidence. The Committee should reaffirm its support of the effort to improve the scientific basis for managing patient care and making treatment decisions. Proposed legislation should be carefully reviewed for its effects - intended or otherwise - on the movement toward evidence-based medicine.

5. Entitle Participants to a Fair Process, not a Perfect Result

Congress cannot guarantee what modern medicine is not always capable of providing - an optimal patient outcome. Many of the lawsuits that are brought by patients and survivors seek damages for adverse outcomes that modern medicine could not prevent. Making it possible to sue a health plan for a coverage decision in cases where the patient has an adverse outcome begs the question of whether the denial of a particular treatment was actually the direct and sole factor causing the outcome. Participants should have a right to a fair process for reviewing decisions and to a well-informed decision. It may be reasonable to punish parties that deny a participant a fair process. It is not reasonable to punish parties that provide a fair process because that process does not yield a particular result.

Thank you for the opportunity to today to share our concerns.

Appendix: IBM Case Studies

In the vast majority of cases, the plans we pick address treatment issues satisfactorily through in-house reviews and their own appeals processes. In very rare instances, where the science is unclear, IBM has a procedure for resolving some of their difficult treatment questions. Here are a few of IBM employees and their families who have benefited from this review:

Case Study

One employee, who has worked with IBM in various locations and positions since 1966, shares her experience:

> "In September 1993 I was diagnosed with Stage II breast cancer. What followed for the next 11 months was a journey of medical uncertainty, life-threatening health experiences, and support from an extensive personal community, including IBM. At the time of my diagnosis, I was told by my doctor that if I wanted to be alive in five years, I would need an autologous bone marrow transplant (ABMT). He also told me not to discuss it with my employer as companies were reluctant to pay for ABMT's for breast cancer because of the expense. This was quite scary because I wanted to pursue all options.
>
> "IBM had an established relationship with a large case management firm, Intracorp, who assisted them in handling individual cases such as mine. This was a huge relief to me. I could now concentrate on understanding my disease, research my options and make the difficult decisions for treatment without having to worry about whether or not my insurance would pay for my care. Individuals faced with such devastating circumstances need all their emotional and physical resources to fight their health battle, not their insurance company.
>
> 'Several weeks of chemotherapy followed two surgeries to remove the cancer in my breast and lymph nodes. During this time, I tried to keep up with what was going on at work via my home computer, but much of my time was spent researching breast cancer and where I would have my ABMT done. No one is prepared to enter the confusing, frightening and political world of medicine. Doctors tell you what to do, but they also have differing opinions. It took a lot of time, energy and research to become an educated consumer and patient.
>
> 'Intracorp, IBM's large case management firm was invaluable to me. A case worker was assigned who understood my disease. She directed me to many cancer-related resources such as the National Cancer Institute, an ABMT newsletter, etc. In addition, because IBM has special arrangements with several medical "centers of excellence", she was able to provide information about them, arrange for me to contact them and, at one point, schedule an interview with another IBM employee who had gone through one of the centers I was considering. I did visit one of the centers; however, I decided to have my ABMT at a regional facility close to my home so I would have much needed support. All during these months, the Intracorp case manager was available to me. She was able to arrange for a home health aide to show me how to self-inject medication. I

also had wonderful support from my colleagues at IBM. Many people called, visited, prayed and even cooked for my family, stocking our freezer on occasion.

'Today, I am fully engaged in an exciting career. It is hard to find words to express my gratitude for the kind of support I received from IBM. I live my gratitude everyday as Plan Administrator for the IBM benefit plans, ensuring that IBM employees and their families are given the most thorough consideration of their issues within the intent of the plans."

Case Study

Another IBM employee in an HMO plan that operates as a point of service network system received a recommendation from her network primary care physician that she go to Memorial Sloan Kettering Cancer Center for treatment of a tumor in the bone of her right leg. This out-of-system request was denied by the plan and she was instead referred to Albany Medical Center for treatment, which is an in-system hospital. The employee ultimately chose to go to Sloan, received the necessary treatments, and was reimbursed at out-of network rates for her claims. The plan could have approved the out-of-system care at in-network reimbursement rates but chose not to.

The employee appealed to IBM and we obtained an independent review from an oncologist as to the appropriateness of the referral by the employee's primary care physician to Memorial Sloan Kettering Cancer Center to evaluate an aggressive bone neoplasm which at the time of diagnosis was thought to be a possible osteogenic sarcoma. The independent review indicated that because of the rarity of the condition and because it is a potentially curable condition, it necessitates expert management by multiple medical specialties and it is sufficiently rare such that even large medical centers rarely treat the condition. He felt that referral to a facility like Sloan for this type of condition is perfectly appropriate. The plan ultimately paid the claim at the in-network rates. In investigating this case, it was determined that the number of situations where the plan denied paying out of system care at in-system rates where the physician approved the care were very limited in number.

In many situations, IBM uses case management, which consists of assessment, coordination and evaluation of IBM employees' and their families' medical needs to assist employees and their families. When employees in need are identified, case managers look to establish a rapport with the patient, recognize the needs and coordinate the care with the attending physician, and thus help to relieve the patient and family of additional stresses. The nurses in our network also negotiate with providers regarding home care, and durable medical equipment, etc. This provides the patient/family with access to discounts on services that they may not have otherwise received.

Chairman THOMAS. Thank you very much.
Dr. Rideout.

STATEMENT OF JEFFREY A. RIDEOUT, M.D., MA., MEDICAL DIRECTOR AND VICE PRESIDENT, QUALITY MANAGEMENT, BLUE CROSS OF CALIFORNIA, ON BEHALF OF THE AMERICAN ASSOCIATION OF HEALTH PLANS

Dr. RIDEOUT. Mr. Chairman, members of the Subcommittee, my name is Dr. Rideout. I am the medical director for quality management for Blue Cross of California, a diversified managed care organization which serves over 5 million members in California through a range of medical and specialty products including HMOs, PPOs, medicare supplement pharmacy plans, and medicaid plans. Today, I am testifying on behalf of the American Association of Health Plans which represents over 1,000 HMOs, PPOs, and similar network plans, providing care to over 150 million Americans.

Blue Cross is also a member of the Blue Cross and Blue Shield Association and the Health Insurance Association of America. HIAA and BCBSA strongly support consumer protections in the marketplace, and their members have agreed to consumer protection principles that preserve the private health care system while improving quality.

In addition to my position at Blue Cross, I serve on several committees and organizations devoted to health care quality such as the Technical Advisory Committee for the State of California's Office of Statewide Health Planning and Development. I am a board certified internist and maintained a part-time medical practice at the University of California at San Francisco until December of last year.

As a physician that was largely educated, trained, and practiced exclusively in a managed care environment and as a consumer who has also been treated almost exclusively in managed care delivery systems, I've always considered the most important question not, should care be managed but how should care be managed to improve quality? While quality means different things to different audiences important attributes must include timely access to appropriate care; prevention of illness; continuity and coordination of high quality care; a respect for patient's rights; a mechanism to respond to patient concerns; the availability of health care information for patients, and a commitment to research and technology assessment.

My goal, today, is to highlight several examples of voluntary, innovative, and collaborative approaches for quality improvement that already are occurring in the current health care delivery system. Each example has had a significant, positive impact on the quality of care received by consumers and has taken place without legislative mandates.

The first is the California Cooperative Health Care Reporting initiative which seeks to disseminate preventive health care information using HEDIS measures. For the last five years, the California industry represented by purchasers such as GTE; physician organizations such as the California Medical Association, and health plans operating in California have cooperatively collected, audited, and publicly reported comparative preventive health information

for things such as mammography screening and childhood immunizations. The primary goal of this effort is to provide consumers credible information to assist them in their selection of a health plan. The rigor of comparability used in CCHRI has been a model for many other areas of the country as well as organizations such as NCQA and also HCFA, and it's also significantly reduced the cost and burden on physicians compared to individual plan efforts to collect similar information. Given the success and the cooperation of the original process, 15 health plans and over 50 medical groups have voluntarily agreed to participate in an additional quality improvement initiative for California members with diabetes.

The second is Blue Cross' own outreach to diabetic members. In 1997, we directly contacted nearly 4,000 members with diabetes to assess their individual status regarding critical screening exams. The members contacted report high rates of screening ranging from 65 percent for foot exams and 88 percent for glycemic blood sugar testing. This says a lot about the quality of care delivered everyday by the physicians and other practitioners in California. Through this effort, we have also been able to identify select groups at higher risk, which include those where English was not the primary language and those that have not had any previous health education about their disease. Altogether, Blue Cross had to use interpretive services for over 30 different languages in order to reach our members with diabetes and discuss clinical education.

The third example is a collaborative research project with the University of California-Berkeley and Blue Cross. Initiated in 1997 through a Robert Wood Johnson grant, this public, private collaboration between a health plan and a major university is increasingly common, and it's an excellent example of innovation at work in the current environment. The research project is attempting to find out if first dollar coverage of nicotine replacement and smoking cessation counseling generates better quit rates in current smokers. Of note, we are using smoking cessation guidelines developed by AHCPR in this study. The physicians and other clinicians affiliated with Blue Cross already have an excellent track record regarding smoking cessation counseling. This study seeks to modify quality improvements already in place.

With these three examples, I hope the committee can appreciate at least some of the innovation and collaboration effort that exists in the current environment. I believe all participants in health care delivery share a common goal: that the quality of care and service delivered to consumers must be exceptional. As a clinician, I believe that, and as a health plan medical director, I promote that.

As you consider the testimony given, I would ask that you also consider that the more efficient coordination of existing oversight already in place through Federal, State, and private sector organizations may, in fact, be a more rapid and significant and long lasting step in improving the quality of care delivered to individuals.

Thank you for your consideration of my comments. I look forward to answering any questions you may have.

[The prepared statement follows:]

American Association of
HEALTH PLANS

STATEMENT ON
HEALTH CARE QUALITY

By

Jeffrey A. Rideout, M.D., M.A.

Medical Director and Vice President, Quality Management

Blue Cross of California

ON BEHALF OF
THE AMERICAN ASSOCIATION OF HEALTH PLANS

BEFORE THE

HOUSE WAYS AND MEANS HEALTH SUBCOMMITTEE

February 26, 1998
Washington, D.C.

1129 Twentieth Street, NW • Suite 600 • Washington, DC
(202) 778-3200 • Fax: (202) 331-7487 • http://www.aahp.org

Mr. Chairman and members of the Committee, my name is Dr. Jeffrey Rideout, and I am the Medical Director and Vice President of Quality Management for Blue Cross of California.

Today I am testifying on behalf of the American Association of Health Plans (AAHP) which represents more than 1,000 HMOs, PPOs, and similar network plans providing care to more than 150 million Americans. AAHP member plans are dedicated to a philosophy of care that puts patients first by providing coordinated, comprehensive health care.

Wellpoint Health Networks, the parent company of Blue Cross of California and UNICARE Life and Health Insurance Company, is also a member of BlueCross BlueShield Association (BCBSA) and the Health Insurance Association of America (HIAA). HIAA and BCBSA strongly support consumer protections in the marketplace, and their members have agreed to a set of consumer protection principles to preserve the private health care system while improving quality initiatives.

I appreciate the opportunity to participate in today's hearing, which focuses on an important issue facing federal health policy makers today: how to address consumer needs for high-quality health care, while at the same time promoting continued innovation and competition in the health care market. I have enclosed with this testimony a document citing several Blue Cross of California's original and innovative quality improvement initiatives.

My comments today focus on three areas:

- Understanding quality
- Examples of quality improvement by plans
- Why current proposals may not be the answer to quality health care.

I. Health Plan Quality

Health Plan Mechanisms to Promote Quality

The current debate on health care has often overlooked important dimensions of quality of care and how it can continually be improved. We welcome the opportunity to describe some of the important ways that health plans are improving health care quality.

Because of their mission, health plans undertake quality-enhancing activities that simply cannot be done in other systems of care, such as traditional indemnity insurance. For example, plans have established formal internal programs to monitor the quality of care provided to health plan members. The internal quality improvement programs are an organization-wide process to assess quality in a broad range of settings. To a large extent, these programs rely on providing information and services to physicians to help them evaluate, and when necessary, improve the quality of care they provide. Specific quality improvement programs are described below:

- **Coordination of Care.** The coordination of care by appropriately trained physicians helps to promote the right care at the right time in the right setting. Primary care physicians are key to this system, maintaining an ongoing relationship with their patients and helping to arrange for services such as specialty treatment, hospital care, and home health care as needed.

- **Health Promotion.** Health promotion activities improve quality by identifying members at risk of certain illnesses or eligible for certain services and reaching out to those members to educate them and encourage them to seek care. For example, nearly all plans have implemented postcard or phone call mammography reminder systems for their adult female members.

- **Disease Management**. Disease management activities improve quality by identifying members who have been diagnosed with certain chronic conditions and coordinating and monitoring their care. Disease management focuses on the comprehensive care of the patient over time rather than on individual episodes of care.

- **Clinical Quality Improvement and Research Programs**. Many health plans operate quality improvement and research programs. These programs monitor trends in health care, determine which treatments produce the best health outcomes, establish quality improvement goals, and define the process for making any needed improvements. Health plans not only help individual patients manage their own health, but also are able to study and improve the health of entire populations through comprehensive programs of data collection and analysis.

- **Member Satisfaction.** Nationwide, well over 90 percent of all health plans conduct member satisfaction surveys. Based on members' input, health plans modify their operations to meet members' changing needs. Health plans have adapted member orientation programs, providers' office hours, referral procedures, health education classes, and many other plan design features to accommodate member preferences.

- **Exemplary Practice Guidelines.** Health plans use and disseminate practice guidelines to inform network providers about evidence-based exemplary practices. The plans then monitor practice patterns, relaying the results back to the physicians. These strategies have been effective in improving the quality of care for members.

  As Robert Brook of the RAND Corporation, has noted, "medicine is largely practiced from memory, in chaotic systems without built-in safeguards. It is simply not realistic to expect a physician to recall the full breadth of his or her training and knowledge at any given time" (*The Lancet*, July 15, 1995). Health plans' ability to provide information to physicians is critical to improving the quality of care.

- **Utilization Review**. Through utilization review, plans assess the medical appropriateness of a suggested course of treatment for a particular patient for the purpose of coverage decisions. In doing so, plans discourage the provision of inappropriate care.

- **Credentialing**. Before health plans contract with providers, they examine their credentials to determine the clinical competence of the provider and to ensure that the provider meets the organization's criteria. The credentialing process involves a review of the provider's educational background and verification of board certification and licensure. Plans also check a physician's hospital privileges, malpractice history, and malpractice insurance. A health plan also recredentials providers regularly, typically every two years. This process is a key factor considered by individuals and employers when evaluating health plans.

- **Profiling.** Many plans use practitioner profiling as a method of quality improvement. Profiling focuses on an individual practitioner's patterns of care rather than that practitioner's specific clinical decisions.

II. Examples of Quality Improvement by Plans

Through these types of internal mechanisms, health plans are continuously developing innovative programs and services that enhance the quality of care delivered to members. Such innovation, while a foundation of health plans' quality improvement activities, is rare in traditional indemnity insurance.

A. Health Plan Quality Care Initiatives

The following are just a few of the many areas where health plan initiatives have resulted in improved quality.

Women's Health. Health plans have outperformed traditional indemnity plans in virtually every area of women's health.

- ***Annual gynecological and physical exams***. Health plans have responded to consumer input by facilitating access to OB/GYNs, including self-referral for routine care. Studies show that 99 percent of HMOs cover annual gynecological exams, compared to only 49 percent of large-group indemnity plans.

- ***Cancer screening***. According to a study of cancer screening among women conducted by the federal Centers for Disease Control and Prevention (CDC) and the National Center for Health Statistics, women in HMOs are more likely to obtain mammograms, pap smears, and clinical breast exams than women in traditional indemnity plans.

Care of Chronic Conditions. Many health plans have disease-specific education and management programs that provide a comprehensive approach to management of the disease, including treatment, preventive testing, and education on self-care techniques. A few examples include:

- ***Asthma.*** Asthma affects approximately 15 million Americans. It accounts for one million days of lost work, an estimated 10 million missed school days, and more than 500,000 hospitalizations a year. Located in Milwaukee, Wisconsin, PrimeCare Health Plan's "Home Asthma Education Program" is one example of an asthma management program that examines clinic and hospital record information to identify children with asthma who are missing an inordinate number of clinic appointments and have high hospital admission rates. Working with the children's pediatricians, the plan involves the children and their families in an asthma education and management program that has initially resulted in a 30 percent reduction in emergency room visits and a 60 percent reduction in hospital admissions for participants of the program.

  In addition to plan-specific asthma programs, a three-year, collaborative initiative, ZAP Asthma, has been undertaken by seven Atlanta-area health plans, AAHP, and local public health partners to reduce avoidable morbidity and mortality due to childhood asthma and to foster a more productive relationship between health plans and community-based public health services. The project integrates clinical care, environmental intervention in the home, and significant community involvement to help children and their families better manage and avoid complications.

- ***Diabetes.*** Approximately 16 million Americans have diabetes mellitus, although approximately 50 percent are unaware that they have the condition and are receiving no medical care for it. Health plans have undertaken various initiatives to improve patient and provider education about the importance of diabetic screening and treatment. Group Health Cooperative of Puget Sound, for instance, has developed two new strategies to improve the skills of its primary physicians in caring for over 14,000 diabetics. The plan utilized a team of endocrinologists and nurses to visit its clinics and assist primary

caregivers in treating diabetics. Also, each clinic reserves blocks of time for diabetics only, based on the view that when caregivers see a number of cases back-to-back, it increases awareness of the different aspects of the disease.

Harvard Pilgrim New England is another example of a plan that has developed a comprehensive diabetes management program, directed at case management, and regular vision screenings. As a result of the program, the plan was able to increase retinal exams by 26 percent, eliminate diabetes-related newborn major malformations, and decrease the incidence of low blood sugar reactions in patients receiving insulin therapy.

Care for the Elderly. Health plans offer senior members a variety of services designed to meet their specific health needs and improve their overall health. For example:

- ***Cancer diagnosis.*** A HCFA study found that Medicare HMO patients were diagnosed at considerably earlier, and therefore more treatable, stages than traditional indemnity plan patients for four types of cancer: breast, cervix, melanoma, and colon. Among elderly women with breast cancer, 72 percent of Medicare HMO patients had their cancer diagnosed at the two earliest stages, compared with 66 percent of traditional indemnity plan patients.

- ***Cancer screening.*** Mathematica Policy Research found that Medicare HMO enrollees were more likely than fee-for-service beneficiaries to have received a mammogram during 1995. Sixty-two percent of Medicare HMO enrollees received a mammogram versus only 39 percent of traditional indemnity plan beneficiaries.

- ***Overall care.*** In their comprehensive review of research studies on managed care, Robert Miller and Harold Luft found that the eight HCFA-sponsored studies that focused on the Medicare population determined that quality of care was approximately equal for HMO and traditional indemnity plan enrollees with similar treatment processes and outcomes for patients with heart failure, colorectal cancer, diabetes, hypertension and other conditions.

B. National Initiatives

In addition to these individual plan efforts to improve the quality of care for their members, health plans have joined together through their membership in AAHP to undertake a number of

national initiatives, such as:

Putting Patients First. To underscore our members' long-standing commitment to quality of care and accountability, AAHP has embarked on an important nationwide initiative called *Putting Patients First*.

AAHP's *Putting Patients First* sets forth specific health plan policies that promote high-quality care in a manner that meets the needs of individual patients. It is an ongoing, comprehensive program to let patients, doctors, and purchasers know what they can expect from health plans in a number of areas. Under this initiative, a task force of AAHP's Board of Directors is charged with identifying and highlighting issues that should be addressed, and each policy statement that is included in the initiative is approved by the Association's full Board of Directors. Policies adopted to date include: physician-patient communications; consumer information; appeals; emergency care; quality assessment and improvement programs; practice guidelines; utilization management; confidentiality; choice of provider; specialty care; and transfer of care between practitioners.

To demonstrate their commitment to this effort, AAHP's Board of Directors and member plans have decided that health plans joining or renewing membership in AAHP will be required to uphold the *Putting Patients First* policies. Health plans will be expected to continue to uphold these policies in order to maintain membership in AAHP.

Research on Chronic Care and Quality. AAHP has created a public-private partnership with

the Agency for Health Care Policy and Research (AHCPR) in a $7 million research initiative to give grants to researchers to assess the association among features and organization of managed care organizations, health outcomes, and quality of care for patients with chronic diseases. Chronic diseases to be studied include diabetes, cardiovascular disease, and HIV/AIDS. The research will also focus upon special populations, such as children and minorities, who suffer from these diseases.

National Guideline Clearinghouse. The development and use of clinical practice guidelines has grown markedly in the past five years. This growth is due to increased interest in improving the quality of health care, reducing uncertainty and variability in health care decision making, and stemming rapidly increasing health care costs. Many providers, health care delivery systems, purchasers, and consumers have difficulty gaining access to and keeping abreast of the many guidelines in use. In response, AAHP, in partnership with AHCPR and the American Medical Association (AMA), is sponsoring the development of a World Wide Web-based National Guideline Clearinghouse (NGC). The NGC will promote more widespread and comprehensive access to guidelines than is currently available to the general public.

III. Regulatory Atmosphere and Shortcomings of Proposed Expansion of Regulation

A. Current Regulation of Health Plans

Health plans are subject to regulation by numerous entities at the state and federal levels as well as by private-sector entities. For example, state regulators include insurance and health

departments in addition to labor and personnel departments. In addition to the four major federal regulatory agencies -- Department of Health and Human Services, Department of Labor, Department of Defense, and Office of Personnel Management -- other federal agencies have regulatory responsibilities over health plans. Also, health plans are increasingly meeting standards established by private accrediting organizations and specific employer requirements.

Health plan regulators have addressed a number of aspects of plan operations, including quality improvement/utilization review, solvency, benefits, enrollment rules, enrollee information, access to care, provider contracting, premiums and rating practices, grievances and appeals, management/organizational structure, reporting/disclosure, and confidentiality. Since regulatory authority is dispersed among various agencies and organizations, health plans must often comply with multiple standards in each of these areas.

B. Many Proposals May Not Be the Answer to Quality Care

Each proposal to increase government's regulation of health plans should be evaluated with respect to its potential to improve the quality of care. Will the proposal address the fundamental issues of quality, such as over-and under-utilization of care, wide variations in practice patterns across the country, and lack of access to needed care? Will they result in more eye exams for diabetics, greater adoption of state-of-the-art therapies, patient education programs that allow patients to manage chronic conditions while living active lives? These are the critical issues that must be addressed in order to continue to improve health outcomes and status.

Health plans have introduced new and successful strategies to address these issues as described earlier in this testimony. Continuous innovation and quality improvement are hallmarks of our system of care.

We are concerned that many of the proposals offered in the current debate would contribute very little to the goal of quality improvement. In fact, because many of these proposals would micromanage plans, innovations that could result in better consumer service and quality care may be stifled. As a result, our efforts to improve quality could be slowed while both consumers' costs and the number of uninsured Americans could rise.

For example, under the following proposals we find no reason to expect health care quality or access to care to improve.

- **Provider Participation Rules.** The Patient Access to Responsible Care Act (PARCA), introduced by Senator Alfonse D'Amato and Representative Charles Norwood, would prohibit health plans from taking into account the hospitals with which a physician has admitting privileges when determining whether to include the physician in the plan's network. This provision would prohibit health plans that selectively contract with hospitals from limiting their networks to physicians who practice at those hospitals. Far from improving care, this proposal could result in patients having physicians who could not treat them in a participating hospital --forcing patients to either switch physicians at a critical time or pursue treatment out-of-network and potentially incur greater expense.

- **Personal Health Professional Selection**. Legislation has been introduced to permit each enrollee to select a personal health professional from among all participating providers, including medical specialists, as well as podiatrists and chiropractors. The selection of personal health professionals who are not trained to evaluate primary health needs and develop health promotion programs, such as cholesterol and preventive screenings, will impact negatively on the reduction of risk factors, diagnosing early stages of disease, and the potential elimination or improvement in the progression of chronic disease.

- **Coverage of Care by Terminated Providers.** Several pieces of legislation, including both PARCA and the Health Insurance Bill of Rights Act of 1997 introduced by Senator Kennedy and Representative Dingell, include provisions requiring plans to continue to provide coverage during a "transition period" for a provider that is no longer in the plan's network. Because concern may have already existed regarding the quality of care, and because health plans could not monitor extensively the quality and coordination of care provided by those physicians (who may have been terminated for cause), mandating such coverage would not lead to improved care. For example, if a provider is terminated because he or she continually misdiagnoses patients, should those same patients continue to see this practitioner?

- **Clinical Mandates**. Several pieces of legislation would impose mandates on health plan coverage of care, including length of stay restrictions. These mandates are frequently motivated by misinformation rather than by the evidence on quality care. These

mandates can create unfounded public fears and they set a clinical standard that could inhibit innovation and improvement in medical care.

III. Conclusion: Consumer Satisfaction

Mr. Chairman, AAHP's member health plans promote high quality care to 150 million Americans today, and are working to continue to improve the care that we promote in the future. Health plans, working within the current regulatory framework, have demonstrated their commitment to meeting the needs and concerns of patients and purchasers, by participating in private-sector programs promoting quality of care and accountability, and by developing innovative ways to coordinate patient care.

Consumer Satisfaction Studies. Consumers' recognition of the quality of care available through their health plans is reflected in consumer satisfaction surveys. A study of 167,000 households conducted by the National Research Corporation found that HMO, PPO, and traditional indemnity plan members reported similar high satisfaction levels with their health plans whether in good-to-excellent or poor-to-fair health. Of respondents under age 65 who said they were in either poor or fair health, 79 percent of HMO members, 75 percent of PPO members, and 78 percent of traditional indemnity plan members were satisfied with their plans. Among respondents age 65 and over in poor-to-fair health, 90 percent of HMO members, 92 percent of PPO members, and 86 percent of traditional indemnity plan members were satisfied.

Satisfaction with quality of care has resulted in a greater number of people enrolling in health

plans. Large numbers of workers with an indemnity option have chosen to enroll in PPOs, HMOs, and point-of-service products. Employees have made this change even though employer premium subsidies favor indemnity plans.

On a personal level, one health plan enrollee wrote in a letter to her health plan that her plan,

> *". . . is the real answer to what every person in this world needs for medical coverage. You have given my entire family such extraordinary care on every level that I am absolutely and unequivocally grateful to all of you. You have attended to my scoliosis and my family members' allergies beautifully. You have cared for the two younger children. But most of all, you have just recently cared for my bout with cancer so well that there are no adjectives to describe my overwhelming thankfulness..."* (AAHP, *Straight Talk about AAHP's Member Health Plans*)

Mr. Chairman, AAHP is pleased to continue to work with the committee as you examine the issue of quality in health care. AAHP and its member plans have demonstrated that they are committed to upholding high standards of patient care, which include responding to consumers' needs. We welcome the committee's interest in these issues, and we thank you for providing us the opportunity to testify today.

BLUE CROSS OF CALIFORNIA - EXAMPLES OF QUALITY IMPROVEMENT ACTIVITIES

I. Academic/Public Sector Partnerships

Blue Cross of California is actively involved with a number of publicly sponsored initiatives that have the potential to positively impact the health of our members. Two examples:

UC Berkeley: Blue Cross of California and another northern California HMO are participants in this study that is funded through a Robert Wood Johnson research grant. The overall objective of the proposed randomized controlled trial is to assess the impact of first dollar coverage of a comprehensive smoking cessation treatment benefit for smokers enrolled in IPA model HMOs.

The benefit will be offered through Blue Cross of California and the other HMO involved in the study for those participants in the randomized to the treatment group. The smoking cessation treatments that will be covered include a behavioral program that meets the clinical practice guidelines established by AHCPR for effective smoking cessation interventions, and nicotine replacement therapy (gum and patch).

The specific research questions to be answered include:

- Does the benefit increase use of smoking cessation programs?
- Does the benefit increase readiness to quit or progression along the stages of quitting?
- Does the benefit increase quit attempts?
- Does benefit increase quit rates at 6 and 12 months?
- Does the benefit increase physician counseling for smoking cessation?
- Does the benefit increase provider referrals to smoking cessation treatment? and
- What is the cost per quit for this benefit?

UCLA: Blue Cross of California is involved in a controlled research study of the effectiveness of various cancer screening outreach methodologies with an emphasis on colorectal cancer. Through the project the researchers hope to identify and understand barriers to preventive screening among an insured population.

Specific focus points of the first phase of the research included exploring:

- colorectal cancer screening rates;
- barriers to screening;
- motivation to learn about prevention; and
- access to appropriate screening services.

II. Annual Assessment of Planwide Health Statistics

Description

In early 1995, Blue Cross of California implemented a population-based needs assessment to prioritize quality improvement and preventive health program selection. The assessment involves an annual review of planwide health statistics (including inpatient, outpatient/ emergency, pharmacy, and demographic information) through which clinical areas for quality improvement and population targets for preventive health are identified. The goals of this program are to (1) understand membership demographics so that preventive health initiatives will be appropriately targeted, and (2) apply claims and utilization information to identify the most common diseases or conditions impacting the health of Blue Cross's membership.

The theoretical basis for this program is that comprehensive claims and encounter information can be used as a proxy for disease incidence and prevalence within a population. Each year, assessment findings serve as a roadmap for the development and design of quality improvement and preventive health programs and, through remeasurement, as a marker for progress in disease state management.

Preventive Health Interventions

HEDIS serves as a useful starting point for measuring preventive health performance. Blue Cross has also worked to extend its preventive health measurement to clinical areas not addressed in HEDIS, and to actively remind members and providers of needed screenings in a timely manner. Based on this commitment, in 1995 Blue Cross initiated a comprehensive member preventive health postcard outreach and screening performance measurement program that has been repeated annually.

The program is designed to accomplish several tasks simultaneously. First, by sending out targeted preventive health reminders to the entire membership, outreach is accomplished. Second, by including a postage paid response card, Blue Cross has created a secondary database of screening performance that is much larger than any chart review process, and more accurate than reliance on encounter data. Finally, the postcard program allows employer and medical group specific rate information to be available based on responding members.

In 1997, over 900,000 members received direct mail postcards, each targeted to one of seven specific clinical areas based on age, sex, and disease specific identifiers. The seven areas were:

- Childhood immunizations
- PAP smear screening
- Breast self exam and mammography screening
- Adult cardiovascular risk screening, including smoking habit questioning, cholesterol screening, and high blood pressure screening
- Senior health screening, including vaccinations
- Secondary screening for diabetics
- Colorectal Cancer screening

Improving member preventive health screening also involves targeting corrective action and understanding barriers to screening. Overall screening rates for key screening exams have increased on average 5-12% over the last three years (based on HEDIS measurement), and much

of the improvement is attributable to member education efforts such as the postcard reminder program.

Blue Cross has also calculated medical group and IPA specific response rates, which gives each provider group comprehensive response rate information. PMGs were assessed regarding how they performed in following up on the members who reported not being screened for the services. In this way the focus is not only on which PMGs screen at high rates, but also what do all PMGs do about members reporting that they have not been screened. Cohort improvements in excess of 50% have been routinely documented based on the provision of this information.

Diabetes Care

In addition to member education regarding preventive health, Blue Cross has several initiatives designed to improve the care of members with chronic disease, including those with diabetes. In 1997, Blue Cross undertook a comprehensive educational outreach to every member with diabetes, which provided basic screening information based on the California Diabetes Coalition Guidelines, solicited current screening status for several key tests, and identified the primary care giver and dates for all screenings undertaken in the last year.

In total, Blue Cross completed initial outreach to nearly 4000 members with diabetes over a three month period in 1997. Questions were designed to specifically identify HA1c and retinal testing, rather than general blood work or general vision exams, as well as foot exam screening.

Analysis of member responses to the outreach suggests that overall screening rates are high, but primary language spoken and patient education were significant drivers of screening rates.

Table 1-Diabetic member reported screening results

Member attribute	HgA1c	Retinal exam	Foot exam
All participants	88.2%	77.1%	64.5%
English as the primary language	89.3%	80.3%	68.1%
Spanish as the primary language	93.5%	64.7%	47.9%
Some formal diabetes education	86.4%	67.9%	51.0%
No formal diabetes education	91.1%	82.7%	71.6%

These results suggest that barriers to screening can and should be identified in order that targeted and appropriate interventions are undertaken. Blue Cross is using this information by focusing on the highest risk members, typically those where English is not the primary language spoken, and formal health education has not previously occurred. In all, over 30 different languages were represented in this sample of diabetic patients.

III. The Blue Cross of California/CaliforniaCare Medical Group/IPA Quality Scorecard and Delegation Oversight

For Blue Cross's HMO product, health care services are delivered primarily through large integrated medical groups and IPAs (PMG/IPAs) located throughout the state. These PMG/IPAs typically are best positioned to deliver quality health care services given their direct relationship with the physicians and hospitals that serve members in that area. In order to ensure that the quality of care and service delivered to members is appropriate, Blue Cross has developed several programs to monitor and positively intervene with PMG/IPAs when performance issues arise. These programs include Blue Cross's Quality Scorecard, and a variety of infrastructure and performance monitoring activities directed by the QM department.

Overview of the Quality Scorecard Components

Indicator	Description
Administrative Grievance Rate	Number of administrative concerns, typically related to unauthorized emergency room visits, coverage issues, etc., that CaliforniaCare has received from members regarding medical groups (per 1,000 member months.
Quality Grievance Rate	Number of quality concerns, those related to access, service and care, that CaliforniaCare has received from member regarding medical groups (per 1,000 member months).
Grievance Performance Index	Index includes two components: 1. Grievance turnaround time - average response time to member. 2. Grievance overturn percent - frequency of disagreement between CaliforniaCare and groups regarding grievance decisions.
Voluntary PMG/IPA Transfer Rate	Index based on the number of PMG/IPA transfers for the following reasons: 1. Member unsatisfied with provider's quality of care or service 2. Access: Member not seen by physician in a timely manner
Medical Group Satisfaction	Percentage of members who were "satisfied" or "very satisfied" with the care delivered by the medical group. Index derived from the 1996 Medical Group Patient Satisfaction Survey.
Last Visit Satisfaction	Score measures how satisfied members were with their last visit to their chosen medical group. Multiple question index derived from the 1996 Medical Group Patient Satisfaction Survey.
Satisfaction with Access to Care	Score measures how satisfied members were with access to medical care at their chosen medical group. Index derived from the 1996 Medical Group Patient Satisfaction Survey.

Indicator	Description
Preventive Screening Performance Audit • Smoking habit inquiry • Evaluation of preventive screening performance for mammogram & PAP exam	Evaluate medical group performance based on: • CaliforniaCare membership survey response data • Preventive services claims and encounter data: 1996 Preventive Health Postcard Reminder Program response data
Site Visit Audit Score	Applying results of the 1996 PMG/IPA site visits, weighted scores will be applied to the Utilization Management, Quality Management, Credentialing, and Member Rights components of the 1996 CaliforniaCare Audit and Review Tool.

Results of interventions undertaken on performance outlier PMG/IPAs in 1997 demonstrated a more rapid rate of improvement versus the network in quality performance. In addition, more than 50% of the PMG/IPAs where intensive intervention occurred stated they made operational changes as a result of the interventions by Blue Cross.

Medical Group/IPA Oversight

In addition to quality performance measurement, Blue Cross is highly committed to thorough oversight of medical group/IPA quality management activities such as credentialing and quality improvement. For some areas such as credentialing and utilization management, PMG/IPAs are eligible for delegation. For other areas, such as quality improvement, delegation does not occur, but thorough review of PMG/IPA activity is required to assure compatibility with Blue Cross program objectives, and to ensure PMG/IPA operations are built on quality improvement principles.

In order to accomplish this degree of oversight, Blue Cross maintains a full Quality Management staff dedicated to PMG/IPA review and education. During 1997, over 500 visits were made to 150 PMGs by 14 Quality Management staff. PMG/IPA reviews performed by this staff translated to over three visits to each PMG/IPA per year on average, and a total of over 9000 physician credentialing files were reviewed to determine eligibility for delegation. This review staff is complemented by full credentialing and case management departments, which take on those activities for individual PMGs that are not eligible for delegation. During a recent NCQA review, Blue Cross's oversight of PMG/IPAs was found to be fully compliant with NCQA standards.

IV. Physician Profiling

The Blue Cross of California *StopWatch 97©* program is one of several programs used to monitor the clinical performance of participating physicians. The *StopWatch 97©* program uses claims data to identify aberrant physician practice behaviors. The program is designed to *watch* provider practice behavior, and *stop* possible fraud, abuse, or inappropriate practice. The *StopWatch 97©* program consists of an on-line computer database consisting of a practice profile for each participating physician (or group). A "point-and-click" Windows interface allows the user to query and display statistics for individual physicians or groups.

In addition to the *StopWatch 97©* program claims analyses performed, additional information from member complaints, state licensing agencies, federal Medicare sanctions, malpractice

settlements, and other public sources are used to evaluate participating providers through the credentialing process. The claims and encounter data used for *StopWatch 97®* analyses is derived from a very large claim database. Currently, this consists of approximately 35 million Blue Cross claim and encounter records and over 20 million pharmacy claim records. The analysis database is updated on a quarterly basis.

V. Senior Health Risk Assessment Programs

A variety of studies have demonstrated that a small minority (5%) of the elderly population accounts for a majority of hospital days (up to 55%) and inpatient services (up to 60%). Blue Cross Senior Secure (BCSS) in 1996 evaluated a variety of screening questionnaires designed to identify those seniors at-risk and in need of aggressive case management support. Blue Cross elected to adopt a validated screening questionnaire developed by the HMO Work Group on Care Management to provide a standardized, validated screening methodology to enable comparisons between medical groups and other organizations using the same survey instrument. The survey is used under copyright license issued by the Regents of the University of Minnesota. The risk score is derived from a list of factors which have been shown to be predictive of frequent and costly service use. These factors include the following:

- Age
- Gender
- Self-reported health status
- Self-reported chronic illnesses (Coronary/Diabetes Mellitus/Pulmonary)
- Functional status
- Psychosocial functioning and support
- Prior Service use (hospital stays, MD visits, ER use)

The New Member Survey Tool is administered upon enrollment by BCSS case management staff. It uses a limited number of directed questions and composite score designed to accomplish the followir

- Identify new members in a high-risk category who may be candidates for more intensive services coordinated by case management
- Provide the Case Manager with information regarding the member's functional status and living arrangement to be used in the development of the care plan
- Early identification of members who qualify for "institutional" Medicare rate cells or with Coordination of Benefit issues; i.e., ESRD (dialysis)/Hospice
- Identify appropriate candidates for Disease Management outreach programs
- Identify member education/wellness programs appropriate for the new enrollee

The survey is performed by mail by a case manager unless telephone follow-up is needed to improve response. New enrollee eligibility files are down loaded monthly into a PC based Access program developed by BCSS. This program is supported on a client server and has the capability of automated risk scoring, letter writing, and reporting capabilities.

"High Risk" members identified are reported to the member's medical group to ensure immediate needs are met and a case management evaluation is expedited. A telephone contact is

made with the member within two weeks to verify a visit to the primary care provider has occurred and address any remaining new enrollee issues. Targeted members identified in this survey process are also enrolled into active plan level case management programs when appropriate.

VI. Blue Cross Pharmacy Quality Management Programs for Seniors

The elderly are at significant clinical risk compared to younger populations from under, over, and inappropriate use of prescription medications. Blue Cross senior members are supported by a number of pharmacy quality management programs designed to identify and intervene when care is not appropriate.

The **MediCare Rx Program** provide clinical providers and BCSS staff quarterly reports of physician and member specific drug utilization data designed to address issues of:

- Drug/Drug Interaction
- Duplicate Therapy
- Inappropriate Utilization

The **MediCare Pharmacy Rx** program also serves a critical role in support of Disease State Management programs and provider performance reporting. Pharmacy utilization data is used to identify members with targeted medical conditions/diagnoses and linked with additional claims and encounter data sets. Examples of 1997 QI programs pertinent to seniors and driven by this program are listed below:

- Depression Medication Surveillance (Duration/Compliance)
- CHF Medication Surveillance (ACE Inhibitor)
- Anterior AMI Medication Surveillance (Beta Blocker)
- Asthma Medication Surveillance (Beta Agonist/Anti-inflammatory Rx)

The **Seniors At Risk (SAR)** program identifies seniors with chronic medical conditions at risk for potential medication complications and poor compliance. Currently the program identifies members potentially at risk in the following chronic disease categories:

- Cardiovascular
- Diabetes Mellitus
- Asthma/COPD
- Rheumatoid Arthritis

Patients are identified with >20 Rx/quarter and >5 therapeutic classes. Data are provided to the PCP and the PMG/IPA medical director which include the entire prescription drug regimen of targeted members. The reports allow the treating physician to verify compliance and review the entire prescription history of all providers caring for the member to minimize the risk of drug-drug interactions and therapeutic duplication.

The **Senior Brown Bag Medicine Review** program outlines a member/physician education process by which new enrollees are encouraged to have a systematic review of all existing medications on hand at home. The initial intake visit with the PCP includes a review of the member's current medications, determination of continued need, and discard of outdated, duplicative, or no longer indicated pharmaceuticals.

VII. Industry Standardization Activities

For several years, Blue Cross of California has been an industry leader in the development of coordinated quality measurement and improvement. While the industry in California is very competitive, Blue Cross is committed to competition based on performance, not proprietary data capture capabilities. Many purchasers, providers, and other health plans share this view, including the Pacific Business Group on Health, AMGA, CalPERs, the California Medical Association, and the National IPA Coalition. Like Blue Cross, they recognize that voluntary efforts to organize the market will lead to competition based on valid comparisons of performance. "Cooperate on standards, coordinate on implementation, compete on quality" has become a key theme for many California organizations involved in health care.

Blue Cross of California is aggressively participating and leading several voluntary industry efforts related to quality. Following is a list of the primary industry cooperative efforts that Blue Cross of California is currently participating in:

- The California Cooperative Healthcare Reporting Initiative (CCHRI). Now in its fifth year, CCHRI is a voluntarily industry cooperative that is committed to producing valid, comparative quality performance information including HEDIS, member satisfaction, access, and outcome indicators. Blue Cross was a founding health plan member, and continues to sit on the Executive Committee which equally represents plans, purchasers, and providers, and includes PBGH, CalPERs, Southern California Edison, GTE, Chevron, CIGNA, Kaiser Permanente, HealthNet, PacifiCare, Health Plan of the Redwoods, AMGA, the CMA, CHA, and the National IPA Coalition.

- The Health Data Information Corporation (HDIC). HDIC is the California community health information network, dedicated to establishing an open architecture system for the exchange of membership and clinical information among all health care delivery participants. Blue Cross is a founding member and sits on the Board of Directors.

- The California Cooperative Credentialing work group. Dedicated to eliminating the waste of redundant physician credentialing and led by the California Medical Association, this voluntary group has developed a standard industry application in use by several health plans and provider groups and is working to develop a coordinated cycle time for credentialing of physicians. Blue Cross of California is one of three health plan steering committee members.

- Member of the State of California's Office of State Health Planning and Development (OSHPD) Technical Advisory Committee representing the California Medical Association.

- Member of the American Association of Health Plans (AAHP) Quality and Accreditation Committees.

- Member of the Blue Cross/Blue Shield Association Quality Performance Measurement and Accreditation committees.

- NCQA Physician Organization Certification (POC) task force member.

- UC Berkeley School of Health Care Management Advisory Council.

- UCSF Center for Health Professions Advisory Council.

Though these efforts are technically "voluntary", they help standardize industry processes regarding quality. The innovation and commitment of the industry participants in all of these efforts is significant, and in many cases, these voluntary efforts have been used to model solutions for other areas of the nation. Blue Cross of California is proud to be a leader regionally and nationally in quality improvement efforts.

Chairman THOMAS. Thank you very much.
Mr. Pollack.

STATEMENT OF RONALD F. POLLACK, EXECUTIVE DIRECTOR, FAMILIES USA FOUNDATION

Mr. POLLACK. Mr. Chairman, thank you for inviting me to this hearing, and thank you for your perseverance at this late hour. I wanted to focus on the need for consumer protections as part of the arsenal of achieving quality of care, not as the exclusive vehicle for achieving that. And in doing so, since people characterize regulations in so many different ways, I really would like to make sure that we don't exaggerate what we are talking about in terms of consumer regulations in this context.

I'm referring, specifically, to two types of documents that the committee undoubtedly has in front of it. First, the recommendations of the President's commission of which I was a member, and I was a member of the subcommittee that drafted the bill of rights and, secondly, the agreement that Families USA together with AARP reached with three very distinguished HMOs: Kaiser Permanente, HIP, and Group Health Cooperative of Puget Sound. I've provided a copy of that agreement to you. I want to stress these because with respect to the President's commission, the reasonableness of what was presented was really the product of a virtually unanimous panel that was extraordinarily diverse. It involved four to five health plans, insurance companies, provider organizations, business, labor, academic people, and consumer organizations, and the product of this was the result of all those organizations working together.

Having said that, what I'd like to do is present five reasons why we need these kinds of modest regulations. First of all, I believe that we need these kinds of modest regulations because the public very much needs it as part of the process of rebuilding public confidence in our evolving health care system. With respect to that, I would refer your attention to a survey that was released last November by the Henry J. Kaiser Family Foundation and the Harvard School of Public Health which surveyed the public's attitudes about our health care system and, in particular, managed care, and, clearly, the findings are not something any of us in this room are particularly happy about. The majority of Americans say that managed care plans make it harder for sick people to see medical specialists. Over half say managed care has decreased the quality of care for people who are sick. Over three out of five say managed care has reduced the amount of time doctors spend with patients, and over half say they are at least somewhat worried that if they are sick their health plan would be more concerned about saving money than about what is the best medical treatment. That is not to say that any of us, including myself, want to go back to fee-for-service health care, but it does show that we really do have a lack of confidence, and this lack of confidence is growing on the part of the public. I think the modest public regulations embodied in the President's advisory commission and the Kaiser Permanente agreement, are needed. Certainly, we're seeing more and more States find that this is true, and I think that's very reflective of the views of grassroots constituency.

Second, is the real alternative to this is a market-driven approach, and I would suggest to you that, from a theoretical standpoint, a market-driven approach might make a great deal of sense. Unfortunately, it flies in the face of reality in terms of what exists in today's health care system. The way a market-driven system would work is that consumers, in effect, would vote with their feet, and they would drive quality by going into good plans and leaving bad plans. Unfortunately, today, half of the people who get their health coverage through an employer do not have a choice of plans, so that the market system simply does not exist to hold plans accountable. If we had such a system, that would be a meaningful alternative to regulations, but the reality is we don't have that today.

Thirdly, to the extent that we have some kind of a market system in some areas—and let me illustrate through the Medicare program where there are some choices, particularly, in some of the States where there has been greater penetration of health plans, I would tell you that I don't think the marketplace has actually driven quality and weeded out the bad plans from the good plans. Let me illustrate. We released a study—I don't know whether the committee has it—that looked at the disenrollment rates, literally, of every HMO in the country serving Medicare beneficiaries. This was the first time such numbers were released. They are provided by the HMOs themselves, and we took a look at the disenrollment rates. Particularly, we looked at every one of them in every one of the States, but we examined very carefully the HMOs in Texas and in Florida. The reason for that is that there were a significant number of HMOs serving Medicare beneficiaries in those States, and those two States had the highest disenrollment rates. And, so, what we did was we took a look at those plans that had extraordinarily high disenrollments rates—and my definition, it's an arbitrary one, of an extraordinarily high disenrollment were those plans that had a disenrollment rate in excess of 20 percent, meaning more than 1 out of 5 of the enrollees disenrolled during the course of the year.

In Texas, there were five such plans. Every one of those five plans in Texas, notwithstanding the extraordinarily high disenrollment rate, had a higher enrollment at the end of the year than they had at the beginning of the year. Every one of those plans had a higher market share at the end of the year than they had at the beginning of the year. In Florida, we saw something very similar. There were 14 plans in the State of Florida that had disenrollment rates in excess of 20 percent. Nine of those 14 had a higher enrollment at the end of the year than they had at the beginning of the year, and, clearly, what this is indicating is that these plans did a very good job of marketing and luring people into plans, but they were not doing the same kind of job of servicing those people and retaining them. I suggest to you that this is reflective that the market, even where there is some market, has really not held plans adequately accountable in driving quality.

The fourth reason is that we do have a regulatory system today, but it's a patchwork quilt that is absolutely indecipherable by the American public. We have one set of rules for people in Medicare. We have a different set of rules for people in Medicaid. We have another set of rules for people in fully insured plans; another set

of rules for people who are in self-insured plans. You cross State lines and you don't know what kind of protection you receive. Even within the same State if you get your coverage through an employer who's fully insured versus an employer who's self-insured, there's a vast disparity in the protection that you receive. I suggest to you that it is only this Congress that can establish some kind of rationality among these very diverse plans, and it is this Congress that I believe that can provide greater predictability by establishing a floor under which nobody can fall through, and I think that would be a very valuable service.

The last point I want to make goes to the question of cost and cost effectiveness. I believe that the kinds of provisions that are embodied in the President's commission and that are embodied in the Kaiser Permanente agreement are extraordinarily cost effective. Now, I've heard some wild numbers about different bills. I'm not here to talk about PARCA or any other bill. I'm here to discuss what's recommended in the President's commission as well as in the Kaiser Permanente agreement, and I would suggest to you that any reasonable cost analysis would show that consumer proteciton legislation makes a great deal of sense.

Now, let me just illustrate that. With respect to one of the key agreements in the President's commission, we recommended the procedural right of an external appeal. That is, if you're denied a service, if you're denied a referral if you're terminated for a specific service, there should be some opportunity to have that heard by an external body that's independent of the original decision-making body and that is dispassionate and has a competence to render a decision in a reasonably prompt manner. We did receive estimates on the cost of this, and the health plans that were part of the President's commission played a very important role in helping the Lewin Group develop the numbers for this. What the Lewin Group gave to the President's commission is that the cost of this very important recommendation ranges from three-tenths of one cent per person per month to seven cents per person per month. If you take the upper end of that range, we are talking about 84 cents per person per year. I suggest to you that this modest but very important procedural protection would do a great deal for consumers to give them greater confidence that when they are denied care, they have some recourse and that they're not totally disempowered. Let me suggest a couple of the other issues that——

Chairman THOMAS. Mr. Pollack, I understand that you have a written testimony which has been made a part of the record, and I've let you go over twice the time, so if you can begin to move toward a wrap-up.

Mr. POLLACK. I'd be happy to, Mr. Chairman.

Chairman THOMAS. Thank you.

Mr. POLLACK. Let me just take two last issues about costs, and then I'll conclude. With respect to emergency care, the prudent layperson rule, that's not an issue resulting in new costs. The cost is incurred when somebody goes to an emergency room. The regulation that's at issue is who pays that cost, not whether there is a new cost. The question is should the hospital which provided that service eat that cost or should the patient eat that cost or should the plan that has received a premium for the care of that enrollee

pay for that cost? I believe that the allocation of that cost is more properly located with the plan that has received a premium to provide health services.

With respect to one last issue, the question of direct access to specialists, say to an Obgyn is very important for women. I suggest to you that this proposal saves money. It doesn't cost money, it saves money, because for a woman who wants to see an obstetrician or a gynecologist, now she only needs to make one visit rather than two visits for the exact same service. So, I suggest to you that what we're talking about here is extraordinarily cost effective. We are not talking about mandates here. We are not talking about the kinds of services that States require with respect to a whole bunch of services. We're talking about procedural protections. Thank you, Mr. Chairman.

[The prepared statement follows:]

TESTIMONY BY RONALD F. POLLACK

EXECUTIVE DIRECTOR, FAMILIES USA

BEFORE THE U.S. HOUSE OF REPRESENTATIVES

HEALTH SUBCOMMITTEE OF THE COMMITTEE ON WAYS AND MEANS

THURSDAY, FEBRUARY 26, 1998

Families USA
1334 G Street, N.W., Third Floor
Washington, DC 20005
202/628-3030

Mr. Chairman and Members of the Committee:

Thank you for the opportunity to testify at this hearing related to quality of care, especially within the context of dramatic growth of managed care financing and delivery systems in both the public and private sectors. As the Executive Director of Families USA -- the national organization for health care consumers -- and also as a member of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, I have come to the conclusion that there is a need for *reasonable* federal regulations providing important procedural protections for America's health care consumers.

As you may know, this past year Families USA, along with the AARP, reached an extraordinary agreement with three distinguished HMOs about the need for "nationally enforceable standards" to protect *all* of America's health care consumers. This agreement, which we reached with Kaiser Permanente, HIP Health Plans, and Group Health Cooperative of Puget Sound, established 18 specific areas for consumer protections. I have appended the agreement to my written testimony and hope you will incorporate it in the published record of this hearing. The agreement which we reached is similar in many respects to the recommendations embodied in the President's Advisory Commission's Consumer Bill of Rights.

At the outset of my testimony, it is important that I underscore my support for *reasonable, procedural federal regulation* -- regulation that is designed to ensure that health plan enrollees receive the care they were promised by their health plans. This is significantly different than so-called regulatory "mandates" that require that certain services be provided. Such mandates may or may not make sense, depending on the details, but the *procedural* regulations I will be testifying about today do not create such new mandates or services. Hence, it is significant that we emphasize how the recommendations embodied in the Kaiser Permanente/HIP/Group Health of Puget Sound/AARP/Families USA agreement as well as the President's Advisory Commission's Consumer Bill of Rights are important but limited in scope.

It is also important for me to emphasize at the outset that the recommendations made by the President's Advisory Commission in the Consumer Bill of Rights were the product of near-unanimous agreement. Indeed, with the exception of one panel member who missed half of our meetings and raised her objections only at the last meeting just before the vote, there was unanimous agreement among the 34 very diverse panelists (including leaders from for-profit and nonprofit health plans, insurance companies, provider organizations, business, labor, academe and consumers) concerning the content of the proposed Consumer Bill of Rights. I believe that this is a clear sign that the legislative proposals embodying these recommendations are reasonable and deserve the most serious consideration by the Congress.

Obviously, a key underlying issue in this hearing and in future legislative consideration of pending and soon-to-be-introduced consumer protection bills is whether there should be any federal regulation at all in this area. Some have argued that there is no need for such regulation and that, instead, we should depend on the health care marketplace to drive health care quality and consumer protections. Others, as I strongly believe, feel that there is a clear need for such regulation that embodies the types of principles set forth in the Kaiser Permanente agreement and the President's Advisory Commission's Consumer Bill of Rights.

Permit me to explain why it is clear that we need reasonable consumer protection legislation. I believe that five reasons compel such a conclusion. Those reasons are:

- first, the American public very much wants and needs such protection, and such protection is needed to restore public confidence in our evolving health care system;

- second, there is no true marketplace today to drive health care quality and consumer protections;

- third, even where consumers can "vote with their feet," the market does not seem to be weeding out the good plans from the bad ones;

- fourth, consumer protection legislation today is a veritable patchwork quilt and only federal legislative intervention can ensure predictability and minimum national standards of protection for everyone; and

- fifth, by any reasonable cost-benefit analysis, the procedural protections being considered make very good policy and economic sense.

Let me amplify briefly on each of these points. With respect to the American public's desire and need for such legislative protection, it is instructive to reflect on the findings in the November 1997 public survey conducted by The Henry J. Kaiser Family Foundation and the Harvard School of Public Health. That survey found, among other salient conclusions, that:

- a majority of Americans (59%) say that managed care plans make it harder for sick people to see medical specialists;

- over half say managed care has decreased the quality of care for people who are sick;

- over three out of five say managed care has reduced the amount of time doctors spend with patients; and

- over half (55%) say they are at least "somewhat worried" that if they are sick their "health plan would be more concerned about saving money than about what is the best medical treatment."

An obvious manifestation of this public will is that more and more states are adopting consumer protection legislation, indicating clear grassroots sentiment for such protection. Indeed, the legislation being adopted in state after state has strong bi-partisan support from state officials in the legislative and executive branches of government. The measures being adopted reflect the panoply of rights that have been recommended by the President's Advisory Commission and in the Kaiser Permanente agreement.

It is also clear that there is no true market place to drive health care quality and consumer protections. Theoretically, the market place could drive quality if people increasingly chose to enroll in high-quality plans and disenrolled from low-quality plans. Unfortunately, however, a very large portion of the American public has no opportunity to make such choices. As a 1997 Kaiser Foundation/Commonwealth Fund National Health Insurance Survey found: "*The majority of working Americans do not have a choice of plans* provided by their employers." Simply stated, most consumers can't drive health care quality and consumer protections because they do not have the opportunity "to vote with their feet."

Equally important is our finding recently that, even where people have more than one choice of plans, the market does not seem to be weeding out the good plans from the bad ones. This appears to be clearly illustrated in a report that Families USA issued in December 1997. Our Families USA report provided the first-ever nationwide statistics concerning Medicare HMO disenrollment rates; the report focused on literally every HMO that served over 1,000 Medicare enrollees in 1996. The plan-by-plan disenrollment rates reflected a wide disparity in the percentage of plan enrollees who voluntarily left their plans during the course of the year -- a range from a low of two percent to a high of 81 percent.

In our report, we carefully examined the disenrollment rates in Florida and Texas, the two states with a relatively high number of health plans that had the highest disenrollment rates in the nation. What we found was rather startling. Focusing on the plans that had the highest disenrollment rates -- those plans where more than one out of five enrollees (over 20%) voluntarily disenrolled -- we learned the following. In Texas, there were five plans with disenrollment rates in excess of 20 percent. Yet every one of those five plans – notwithstanding their incredibly high disenrollment rates -- had a higher enrollment at the end of the year than they had at the beginning of the year, and every one of those plans had a higher market share at the end of the year than at the beginning of the year. In Florida, out of 14 plans with disenrollment rates in

excess of 20 percent, nine of those plans had a higher enrollment at the end of the year than they had at the beginning of the year.

It appears that some clear assumptions flow from these numbers. Obviously, these plans were far better at marketing and luring people into their plans than they were in servicing and retaining people. These plans operated like a revolving door. Even though a very high percentage of enrollees left those plans, an even larger number entered these plans. The marketplace may have taught these plans how best to market their plans to people, but the market certainly was not establishing service quality or consumer protections desired by plan enrollees.

Federal legislation is needed because the protections that do exist today constitute a veritable patchwork quilt that is undecipherable by the public. Enormous differences exist today in the protections that are afforded to people based on the accidental happenstance of a consumer's state of residence and the payer and form of their health plan. Enormous differences also exist in the protections provided for people in Medicare, those in fully insured plans, those in self-insured plans, and people in the Medicaid program. Enormous differences exist in the protections provided by one state versus other states. Finally, enormous differences exist among people within the same state, especially between those who get their coverage from an employer who is fully insured or those who self-insure.

Consumers need greater certainty about the basic protections that are guaranteed to them. Such greater predictability and uniformity can only be created, without stifling state-by-state innovation, by establishing national floor standards applicable to everyone. National standards should establish a basic foundation that nobody can fall through.

Lastly, it must be emphasized that, by any reasonable cost-benefit analysis, the reasonable consumer protections set forth in the President's Advisory Commission's Consumer Bill of Rights and the Kaiser Permanente agreement are *not* costly and are cost-effective. The President's Commission engaged the services of the Lewin Group to analyze two of the most discussed recommendations, the provisions relating to an external appeal and information disclosure. The Lewin Group found that the requirement of external appeals will have a de minimis effect on costs: the external appeal requirement was projected to cost three-tenths of one cent to seven cents per enrollee per month -- a maximum of 84 cents per enrollee per year. Similarly, the Lewin Group found that the information disclosure requirement would cost 59 cents to $2.17 per enrollee per month *minus uncalculated savings for cost efficiencies created through consumers having more and better information.*

An examination of some of the other proposed protections would show that some of the proposals would add no costs to the health care system *or could result in cost savings.*

For example, the so-called "prudent layperson" rule for the provision of emergency room care would add no costs at all. The costs of such care occur when a person receives emergency care in an emergency room. The "prudent layperson" rule merely guarantees that the hospital providing such care does not have to swallow those costs and that the enrollee does not have to pay those costs. The rule allocates those costs to the only entity that is paid a premium to provide emergency care -- namely, the enrollee's health care plan.

The proposal that women should have the right to visit an obstetrician/gynecologist without first going to a primary care physician will actually save money. This is obvious because a woman will now only need one doctor's visit to receive her obstetric and/or gynecological care rather than two visits -- the first one made solely to receive a referral. The same is true about recommendations relating to standing referrals to specialists treating a patient with a serious health condition, like cancer, heart disease or stroke. In sum, the recommendations embodied in the President's Advisory Commission's Consumer Bill of Rights and the Kaiser Permanente agreement are extraordinarily cost-effective.

It seems ironic that some in the industry are simultaneously saying that they will implement the proposed standards voluntarily and yet the enactment of such protections will be costly. Clearly, the industry seems to be speaking out of two sides of the mouth. Simply put, if these standards are being voluntarily established, how can one reasonably argue that compelling their implementation among all plans is costly? The two combined arguments are obviously disingenuous.

I believe, however, that there is at least one proposal that can serve as a bridge between adherents of a market-driven, voluntary approach to consumer protection and proponents of reasonable federal regulation. Under either approach to consumer protection and health care quality, there is an overwhelming need for consumers to have a much better understanding of crucial information so that consumers are better equipped to pursue their health care choices, rights and responsibilities. To facilitate this, it is very important that we establish non-regulatory consumer assistance programs through non-governmental, nonprofit organizations. Some people call these "ombuds" programs. Without such assistance, I believe that it is manifestly clear that neither a market-driven nor regulatory approach can reasonably work because consumers will neither be able to make thoughtful market decisions nor be able to pursue their regulatory rights.

The need for such consumer assistance programs was recently reenforced by the national survey released last November by The Henry J. Kaiser Family Foundation and Harvard School of Public Health. The survey found that more than half of the public either never heard of or knew the meaning of "managed care" or "fee-for-service" -- terms that are used virtually every day by people in this room. As America's health care

system becomes increasingly complex, and as the health care "alphabet soup" (such as PPOs, PSOs, MSAs, NCQA, HEDIS, etc.) proliferates, there is little wonder why the American public is bewildered about health care choices, rights and responsibilities. Simply stated, the American public is currently caught in an extraordinarily difficult position to function well in either a market-driven or regulatory system.

This must change -- and all sides in the debate about Congressional legislation should come together on the need for consumer assistance programs. Consumers need help in figuring out how to choose health plans (if they have more than one alternative available to them); they need to know where to take their complaints and grievances; and they need to know where they should go for specific help (including the State Insurance Commissioner, an employer benefit relations administrator, the Department of Labor's regional office, HCFA, the state Medicaid agency, etc.). Receiving such assistance would help to demystify managed care and the growingly complex health care system. It also would help to resolve problems at earlier, less formal stages and obviate the need for more contentious proceedings, such as litigation.

I believe that consumer assistance programs should provide the following types of services. First, they should help consumers make choices about health plans by providing information and answering relevant questions by potential enrollees. Second, once enrollees join a plan, they should be available to help enrollees understand their rights and responsibilities within their plans. Third, they should set up toll-free, 1-800 phone numbers to respond to questions and potential problems. Fourth, they should assist enrollees with their *non-litigative* appeals, both in appeals handled internally within health plans as well as external administrative appeals. Fifth, they should make referrals, as appropriate, to health plan administrators, employers and regulators. And sixth, they should keep accurate information about, and report on, the help provided to consumers so that everyone has good data and information about consumer inquiries and concerns.

To work well, these consumer assistance programs should be nonprofit, non-governmental organizations that are independent of plans, providers, regulators and payers. However, since these programs can only work if they have a reasonable resource base, they should be supported with public funds -- preferably by a block grant to states that would issue requests for proposals from qualified nonprofit organizations. It is my hope that the Congress will give serious consideration to such a proposal and that all Members will consider such an effort a bridge between two different approaches to consumer protection.

Let me hasten to add that there is significant precedent for such consumer assistance programs. For approximately two decades, ombuds programs have operated effectively on behalf of families of nursing home residents. The Institute of Medicine, in

a thoughtful analysis released in 1995, found that these ombuds programs have played an important role in improving quality of care in nursing homes around the country. Similarly, we have seen fledgling programs provide such assistance to some Medicare and Medicaid beneficiaries. And most recently, the Center for Health Care Rights has established an ombuds program for people in the Sacramento area -- a program currently supported with funding from three California philanthropies.

Consumer organizations consider the creation and support of consumer assistance programs a top priority. The Kaiser Permanente agreement very clearly stated that "Consumers should have access to an independent, external nonprofit ombudsman program." The President's Advisory Commission's Consumer Bill of Rights said that "some [consumers] require assistance" and that "desirable characteristics of such programs" include "[s]ponsorship that assures accountability to the interests of consumers and stable, adequate funding." I urge your most serious consideration for this approach to consumer protections.

We at Families USA look forward to the coming dialogue in Congress about the need for consumer protection legislation. We believe that such legislation would constitute a very helpful first step towards reassuring the American public that high-quality health care can be compatible with a health system that relies increasingly on managed care plans for health care delivery.

PRINCIPLES FOR CONSUMER PROTECTION

PRELIMINARY STATEMENT OF PRINCIPLES FOR CONSUMER PROTECTION

Representatives of the American Association of Retired Persons, Families USA, Group Health Cooperative of Puget Sound, HIP Health Insurance Plans and Kaiser Permanente have been engaged in joint work to develop principles for consumer protection that we believe should form the underpinning of national standards that would apply to health plans. The attached Preliminary Statement of Principles for Consumer Protection is intended to provide timely guidance about regulatory protections that should be made available to America's health care consumers.

Together, we are seeking to address problems that have led to a decline in consumer confidence and trust in health plans. We believe that thoughtfully designed health plan standards will help to restore confidence and ensure needed protection.

Important objectives of this work are to achieve greater equity in consumer protections across the states and more consistent enforcement of health plan standards that are grounded in sound public policy principles.

We have reached agreement on principles for the following subject areas: accessibility of services; choice of health plans; confidentiality of health plan information; continuity of care; disclosure of information to consumers; coverage of emergency care; determinations of when coverage is excluded because care is experimental; the development of drug formularies; disclosure of loss ratios, prohibitions against discrimination; ombudsman programs; out-of-area coverage; performance measurement and data reporting; provider communication with patients; provider credentialing; provider reimbursement incentives; quality assurance; and utilization management.

The undersigned organizations have reached agreement about the principles in the attachment. We believe these principles should be communicated now to inform timely consideration of consumer protections. However, this work should be considered preliminary because there are continuing discussions about a number of issues that are not covered in the attachment, including appropriate mechanisms for member grievances and appeals and the appropriate locus for oversight of health plan standards. We are committed to continuing joint work on these complex issues and intend to include agreements that we reach in the principles for consumer protection.

We hope that our work will be given serious consideration in efforts that are undertaken to strengthen rights of consumers and improve health plans.

PRELIMINARY STATEMENT OF PRINCIPLES FOR CONSUMER PROTECTION

It is intended that these principles will be incorporated into standards that will be legally enforceable and that an appropriate government entity will have adequate resources and sanction authority to ensure proper implementation and oversight.

ACCESSIBILITY OF SERVICES

Consumers should have access to affordable, comprehensive, culturally and linguistically appropriate health care and a reasonable choice of primary care physicians and specialty physicians. Therefore, health plans should be required to do the following:

- Have sufficient numbers of physicians, specialists and other providers to adequately serve their enrolled members.
- Provide direct access to obstetricians/gynecologists for enrolled women.
- Provide timely, appropriate care to members 24 hours a day, seven days a week.
- Ensure that the health plan's physicians, physician specialists and facilities are reasonably available to members.
- Provide enrollment materials, membership services and translation services during medical care, in the language of any population whose primary language is other than English, when such population comprises five percent or more of the population of the geographic area served by the health plan.
- Designate appropriate licensed medical specialists (including OB-GYN's who agree) as primary care providers.
- Provide referrals to specialists affiliated with the plan or recognized specialty care centers affiliated with the plan pursuant to treatment plans. Provision for standing referrals, if appropriate, should be included in the treatment plans.
- Provide an out-of-network referral at no additional cost to the enrollee if the health plan does not have a network physician with appropriate training and experience or affiliation with a recognized specialty care center to meet an enrollee's covered medical needs.

Decisions regarding access to specialty care should be made by primary care physicians and specialists so that patients are provided access to specialty care through the plan in a manner that is appropriate to their condition.

CHOICE OF HEALTH PLANS

Individuals should be given a choice of health plans.

CONFIDENTIALITY OF HEALTH PLAN INFORMATION

There should be strong protections against improper disclosure by health plans of information pertaining to individual health plan members, patients, and providers. Provisions specified in law should address:

- Appropriate use, confidentiality, and security of information, as well as protection of individual privacy.
- Appropriate circumstances under which persons may be given access to individual level information. Such information should not be disclosed to any person except:
  - For purposes necessary to perform required quality assurance functions, to meet requirements of purchasers and providers (e.g., to determine entitlement to coverage and to administer payments), or to conduct approved, bona fide clinical or health services research. These data should not contain patient identifiers which could lead to violation of individual privacy and harm to patients.
  - Upon the express consent of the covered person.
  - Pursuant to statute or court order for the production of evidence or the discovery thereof or other legally mandated disclosures.
  - In the event of claim or litigation between the covered person and the health plan.

A health plan should have written policies and procedures governing confidentiality and should ensure that the confidentiality of member or patient information and records is protected.

CONTINUITY OF CARE

To assure appropriate continuity of care, it is important for a member to select a primary care physician who will provide, or through referral, will arrange for the provision of all medical care needed by a member. Because a good relationship between the member and the primary care physician is important, a health plan member should have the right to choose a personal primary care physician within the plan and to change a personal primary care physician at any time.

With regard to in-network services, it should be the responsibility of a health plan or its provider network to:

- Coordinate the provision of health care to members and monitor their overall health status.
- Establish a system to promote the achievement of needed preventive health services for all members.
- Ensure that members' medical records are complete and consistently maintained.
- Provide members and their plan providers with reasonable and timely access to the medical records maintained by plan providers and the providers to whom the plan makes referrals. (This requirement should not apply to the medical records maintained by out-of-plan providers who provide services under a point-of-service plan or any other plan permitting services to be provided by out-of-plan providers.)
- Make a copy of medical records available to a member and, as authorized by the member, to all health plan physicians and providers that provide care to the member.

To further promote care transitions:

- Health plans should adopt processes to promote continuity and quality of care when members change from one physician specialist to another. This should include provision for a compassionate, smooth transition to a new physician specialist when consumers change health plans.

- Members who are undergoing an active course of treatment for a life-threatening disease or condition or a degenerative and disabling disease or condition, or those who have entered the second trimester of pregnancy at the effective date of enrollment should be able to continue to receive covered medically necessary care from their physician specialists for up to 60 days (or through post-partum for care related to delivery) if:
    - in the case of new members, they belong to a group and do not have the option of continuing with their previous physician specialists because their former health plan was replaced or
    - in the case of existing members, their previous physician specialists' contracts were terminated by the health plan for reasons other than unacceptable quality, fraud, patient abuse, incompetence, or loss of licensure.
    - In either case the previous provider agrees: (1) to accept reimbursement from the health plan at rates established by the health plan as payment in full, which rates shall be no more than the level of reimbursement applicable to similar providers within the health plan's group or network for such services; (2) to provide the health plan necessary medical information related to such care; and (3) to adhere to the health plan's policies and procedures including, but not limited to, those regarding referrals and preauthorizations, as well as to an approved treatment plan.

DISCLOSURE OF INFORMATION TO CONSUMERS

In order to evaluate and compare their health plan choices, consumers should be provided with information by health plans on:

- The health plan's structure and provider network, including the names and credentials of physicians in the network.
- A description of the types of methodologies (including capitation, financial incentives or bonuses, fee-for-service, salary and withholds) the health plan uses to reimburse physicians, including the proportions of physicians who have each of these types of arrangements. Upon request, the health plan should provide information on the reimbursement methodology employed by plans or medical groups for individual doctors. Specific reimbursement rates need not be disclosed.
- Coverage provided and excluded, including out-of-area coverage.
- Procedures for utilization management.
- Procedures for determining coverage for investigational or experimental treatments.
- A description of any restrictive formularies or prior approval requirements for obtaining prescription drugs. Upon request, the health plan should provide information on whether or not specific drugs are covered.
- Member cost-sharing requirements.
- Use of voluntary or mandatory arbitration.

- Disenrollment data.
- Procedures for receiving emergency care and medically necessary out-of-network services when those services are not available in the network.
- How to contact agencies that regulate the health plan.
- How to contact consumer assistance agencies, such as Ombudsman programs.

In addition, health plans should provide members regularly (at least annually) information on:

- How to obtain medically necessary covered services under their plans.
- How to receive preventive health services and health education.
- How to select providers and obtain medically necessary referrals.
- How to appeal health plan decisions and file grievances.

COVERAGE OF EMERGENCY CARE

All health plans should be required to cover emergency services. Specifically:

- Coverage for emergency care should include coverage for services provided where the member presents to an emergency department with symptoms (including severe pain) that a prudent layperson would reasonably believe to be an emergency medical condition.
- The emergency department treating the member should be required to call the health plan within 30 minutes of the point that the member is stabilized to discuss any proposed services not necessary to stabilize the patient, and the health plan should be required to respond to a request to provide care within 30 minutes from the initial call from the emergency department, unless this process is waived by the health plan. This is in order to assure appropriate follow-up care as well as to protect the member from liability for payment from uncovered services.
- Health plans should educate their members about the availability, location and appropriate use of emergency and other medical services, any cost sharing provisions for emergency services, and the availability of medical care outside an emergency department.

DETERMINATIONS OF WHEN COVERAGE IS EXCLUDED BECAUSE CARE IS EXPERIMENTAL

Health plans should have an objective process for considering experimental treatments. Therefore, health plans should:

- Adopt a technology assessment process for reviewing new drugs, devices, procedures, and therapies.
- Establish an external, independent review process to examine denials of coverage for certain experimental treatments for individual members who have a condition that has a high probability of causing death within two years.
    - The external review should be conducted by a panel of experts selected by an impartial, independent accredited entity.

DEVELOPMENT OF DRUG FORMULARIES

Health plans and other providers of prescription drug benefits should cover the prescription drugs that a member's physician believes are medically needed, while at the same time working to make prescription drugs less expensive., Plans and pharmacy benefit management providers using restrictive formularies in providing drug benefits should:

- Ensure participation of plan physicians in the development of the formulary.
- Disclose the nature of formulary restrictions.
- Make allowance for formulary exceptions when medical necessity dictates that a non-formulary alternative is needed.

These principles should apply to all providers of managed pharmacy benefits, not only HMOs.

DISCLOSURE OF LOSS RATIOS

Consumers have an interest in knowing how much of their premium dollar is going for health care delivery costs rather than for plan administration, profits, or other uses. Therefore, the formula for calculating the loss ratio and the loss ratio of each health plan should be uniformly calculated and disclosed to the public.

PROHIBITIONS AGAINST DISCRIMINATION

Health plans should be prohibited from engaging in practices that would lead to discrimination in the provision of health care services to members on the basis of age, gender, race, national origin, language, religion, socio-economic status, sexual orientation, disability, genetic make-up, health status, or payer source. (This should not be interpreted as prohibiting plans from providing care that is designed to meet special needs of targeted populations.)

In addition, health plans should engage in recruiting, hiring, contracting, and retention strategies that help assure a health care provider network that is culturally competent and sensitive to the needs of the diverse communities it serves.

Health insurance reform should address discriminatory practices that discourage enrollment of high risk, high cost, or vulnerable populations in health plans. Under a reformed health insurance system, pricing, underwriting, and marketing should be structured so that such populations do not face discriminatory barriers to enrollment or care.

OMBUDSMAN PROGRAMS

Consumers should have access to an independent, external non-profit ombudsman program. Health plans should cooperate with independent, external non-profit ombudsman programs that would assist consumers in understanding plans' marketing materials and the coverage provisions of various health plans, educate members about their rights within health plans, help to identify and investigate member complaints, assist members in filing formal grievances and appeals, and report to appropriate regulatory bodies on issues of concern to consumers.

OUT-OF-AREA COVERAGE

Consumers who have purchased health benefits coverage should have the security of knowing that when they are temporarily away from home and are within the United States, unforeseen urgent medical needs can be attended to and will be covered by their health plan. Therefore, health plans should:

- Cover emergent and urgently needed out-of-area medical services when a member is traveling outside of the health plan's service area, other than services that were foreseeable prior to commencing travel outside of the service area.
  - International travelers, students and others who live for extended periods outside of a health plan's service area should obtain separate coverage for their non-emergent out-of-area medical needs.

PERFORMANCE MEASUREMENT AND DATA REPORTING

Health plans should be required to meet nationally developed and promulgated standards for performance measurement and for reporting of data and information. There should be a nationally recognized core data and information set to measure and compare the performance of health plans. There should be standardized measures of the effectiveness and appropriateness of care (including the setting and treatment), access and availability of care (including referrals), satisfaction with the experience of care, and the stability and financial performance of plans. Specifically, measures should:

- Be outcome oriented and address the full spectrum of health care, including home health and post-acute care services.
- Be valid and scientifically based; applied in a consistent and comparable manner; efficiently administered; designed to minimize redundancy and duplication of effort, and to ensure appropriate confidentiality and protection of individual privacy.
- Build upon HEDIS 3.0 (Health Plan Employer Data and Information Set) and other measures under development, e.g., by FAcct (Foundation for Accountability).
- Data on performance measures supplied by health plans should be subject to independent audit to ensure accuracy of measures and responses.

Consumers, purchasers, providers, plans, regulators, and policy makers should work collaboratively to develop these national performance measures that will broadly serve common purposes and diverse needs of private and public interests. Plans should disclose the quality and satisfaction assessments used, including the current results of such assessments.

PROVIDER COMMUNICATION WITH PATIENTS

Patients must have full disclosure of information in order to provide informed consent regarding their treatment. To provide full disclosure to patients:

- Physicians and other health care providers should, within the scope of their practice, communicate openly and freely with their patients regarding their medical condition and treatment options.

- Contracts with physicians and other health care providers should not limit the exchange of information between a provider and patient regarding the patient's medical condition and treatment options.
- Providers should not be penalized for advocating on behalf of their patients.
- Health plans (and their contractors and subcontractors) should be prohibited from retaliating against providers or health care workers if they, reasonably and in good faith, report quality concerns to appropriate state or federal authorities, or if they bring such concerns to the attention of the most appropriate management official.
- Providers should not be penalized for providing letters of support to or in any way assisting members who are appealing a denial, termination, or reduction of service.

PROVIDER CREDENTIALING

Health plans which use a provider panel should develop, and comply with, objective, written standards of quality in consultation with appropriately qualified health care providers, similar to those used by the National Committee for Quality Assurance, for hiring and contracting with physicians, other licensed independent practitioners, and health care facilities. The standards should:

- Apply to groups of physicians and other licensed independent practitioners that contract directly with a health plan, or indirectly through a provider group, to provide health care services to members of a health plan.
- Allow a health plan, or a group of providers, to utilize practice profiling as a factor in credentialing a health care provider if the practice profiling takes into consideration case mix, severity of illness, age of patients and other features of a provider's practice that may account for higher or lower than expected costs. A health plan, or provider group, would be prohibited from discriminating against physicians and other licensed independent health care providers on the basis that their practice contains a substantial number of patients with expensive, long term or chronic medical conditions.

PROVIDER REIMBURSEMENT INCENTIVES

Neither health plans, nor provider groups that subcontract with other provider groups to provide covered services to health plan members, should use payment methodologies that directly encourage providers either to overtreat patients or to limit medically necessary care. The integrity of the provider-patient relationship should be protected by the implementation of standards that help to assure a provider's freedom to make clinical decisions without consideration of the provider's personal economic advantage. These standards should apply to health plans and to provider groups.

- Where capitation is used for an individual provider, it should only apply to services directly provided by that provider. Full-risk capitation should not be used for an individual provider.
- Appropriate safeguards, such as reinsurance or stop-loss coverage, should be used when individual providers or small groups of providers are capitated or when providers are placed at substantial financial risk.
- General information about the types of reimbursement methodologies used for providers should be disclosed.

QUALITY ASSURANCE

Comprehensive quality assurance standards are essential to enable proper evaluation and improvement of the quality of health care services provided by health plans to their members. Therefore, all health plans should:

- Be subject to comparable quality assurance requirements which are consistent with nationally developed and promulgated standards.
- Implement comprehensive quality assurance programs which include the same core elements.
- Develop and maintain the infrastructure and disclosure systems necessary to regularly measure and report the quality of health care services provided to plan members.
- Adopt quality assurance programs that promote continuous quality improvement.

The specific standards should:

- Provide latitude to health plans in the types of specific methods and activities they employ to meet quality standards, to reflect differences in how health plans are organized.
- Be non-duplicative and uniformly applied.
- Be periodically reviewed and updated to reflect changes in health care delivery.
- Provide for external review of the quality of care, conducted by qualified health professionals who are independent of the plan and accountable to the appropriate regulatory authority. External review by a private accrediting agency should not be deemed to be sufficient to meet requirements unless an appropriate regulatory authority has confirmed that the review is consistent with the nationally developed and promulgated standards for quality assurance.

UTILIZATION MANAGEMENT

Appropriate regulation of utilization management (UM) activities used by health plans should be supported, including requirements that health plans should:

- Be responsible for monitoring all UM activities, including the activities of any entities with which it contracts to perform UM functions.
- File an annual summary report of its UM methodologies with its regulatory agency.
- Ensure that its UM activities are administered by qualified health care professionals and that appropriately licensed providers evaluate the clinical appropriateness of adverse decisions.
- Use documented clinical review criteria based on sound clinical evidence which are evaluated periodically to assure ongoing efficacy.
- Issue UM decisions in a timely manner, expedited when appropriate.
- Provide members and providers with access to appropriate staff by a toll-free number.
- Provide written notification of an adverse determination, which should include the principal reason for the determination and instructions for initiating an appeal.
- Be prohibited from compensation arrangements for UM services which contain incentives to make adverse review decisions.

Chairman THOMAS. Thank you very much.
Dr. Smoak.

STATEMENT OF RANDOLPH D. SMOAK, JR., M.D., VICE CHAIR, BOARD OF TRUSTEES AMERICAN MEDICAL ASSOCIATION, CHICAGO, ILL

Dr. SMOAK. Thank you, Mr. Chairman and members of the committee. I appreciate your perseverance in hearing all this testimony, and I'll wrap mine up in five minutes.

My name is Randolph D. Smoak, Jr., and I am a practicing surgeon from Orangeburg, South Carolina and vice-chair of the American Medical Associations' AMA Board of Trustees. I'm also Chair of the governing body of the AMA's program that establishes qualifications and performance standards for individual physicians, known as the American Medical Accreditation Program, or AMAP. On behalf of our 300,000 physicians and medical students, I want to thank you for the opportunity to testify on this issue of health care quality and patient protection and the AMAP program.

For many years, the cost was a major concern with America's health care system. Efforts to control cost through utilization management, managed care, and a variety of regulatory and market-based incentives have dominated the public policy agenda for quite some time. Today, however, the focus has shifted to quality, but we want to preserve quality and also to continuously improve it. For that reason, we welcome the attention of Congress and the President to this issue.

The AMA's committed to setting standards for all physicians and measuring and evaluating physician qualifications. To achieve these goals, the AMA established AMAP. It is designed to set national standards of physician performance through accreditation of individual physicians. AMAP is also a private sector initiative undertaken in conjunction with other private sector organizations and Government agencies. It seeks to find solutions to problems in the delivery of health—quality health care by eliminating redundancy; focusing on quality, and improving patient care.

AMAP works by measuring and evaluating individual physicians against national standards criteria and peer performance in five areas: credentials, personal qualifications, environment of care, clinical performance, and patient care results or outcomes. AMAP provides the first credible, consistent, comprehensive national standard and physician quality; a standard that is meaningful not only to physicians but also for patients and purchasers.

The AMA is engaged in a number of other quality initiatives such as the Clinical Practice Guidelines Recognition program. This program identifies guidelines that meet criteria developed by the AMA, national medical specialty societies, AHCPR, AHA, and the Joint Commission. In particular, the program identifies those practice guidelines that are evidence based. The AMA is especially pleased to be adding to the work of the AHCPR along with the American Association of Health Plans. Together, we are working to develop the national guideline clearing house, a comprehensive, internet-based source of clinical practice guidelines. Further, the AMA has developed a bulletin we believe will improve physician clinical performance. This quality care alert will be a periodic mail-

ing to alert physicians to major quality issues. Finally, the AMA has issued a document entitled, Essential Characteristics of a Quality Health Plan that describes the elements all quality health managed care plans should actually meet. We urge Congress to carefully consider these workable private sector initiatives as it evaluates existing legislation.

Mr. Chairman, while discussing quality I would be remiss if I did not mention the importance of patient protections. The AMA believes that certain basic rights are essential if all patients are to receive quality care from health plans, and these include comparative information; access to emergency services; external appeals; prohibition against gag practices, and the elimination of incentives to limit necessary care. After all, what good is quality care if you cannot access it.

The Federal Government expanded patient protections and Medicare Plus Choice plans when it passed the BBA in 1997. States, too, have passed patient protection laws to protect their citizens. ERISA, however, has literally preempted States from protecting their citizens with the same patient protection laws enjoyed by all other privately insured individuals in the State. The AMA supports legislation that removes ERISA preemption so patients could recover damages for personal or financial injury or wrongful death. Specifically, the AMA supports Representative Norwood's bill, H.R. 2960, the Responsibility in Managed Care Act of 1997 and urges Congress to expedite its consideration of this bill.

I appreciate the opportunity to appear before you today and would be happy to answer any questions. Thank you, sir.

[The prepared statement follows:]

American Medical Association
Physicians dedicated to the health of America

1101 Vermont Avenue, NW
Washington, DC 20005

Statement

to the

Subcommittee on Health
Committee on Ways and Means

U. S. House of Representatives

Re: Quality of Health Care and Patient Protections

Presented by Randolph D. Smoak, Jr., MD

February 26, 1998

Division of Legislative Counsel
202 789-7426

Statement

of the

American Medical Association

to the

Committee on Ways & Means
Subcommittee on Health
United States House of Representatives

Re: Quality of Health Care and Patient Protections

Presented by Randolph D. Smoak, Jr., MD
Vice Chair, Board of Trustees

February 26, 1998

Mr. Chairman, Ranking Member Stark, and Members of the Subcommittee: My name is Randolph D. Smoak, Jr., MD. I am a practicing surgeon from Orangeburg, South Carolina, and a member and Vice Chair of the American Medical Association's (AMA) Board of Trustees. I am also Chair of the Governing Body of the AMA's program that establishes qualifications and performance standards for individual physicians, known as the American Medical Accreditation Program (AMAP). The AMA thanks you for inviting us to testify before you today on the issue of health care quality and patient protections for individuals enrolled in managed health care plans. We are especially pleased to have the opportunity to highlight the AMAP program, as well as discuss other AMA initiatives to improve the quality of health care.

The AMA is aware of the many important quality and patient protection issues being considered by Congress and the President, and we hope our statement today will shed

some light on the important quality activities underway at the AMA that are intended to enhance physicians' delivery of quality, patient-centered care.

I will add that the AMA's Board of Trustees Chair, Thomas R. Reardon, MD, serves on the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, which will be releasing its final report in March. Significant work on delineating a quality improvement agenda for the nation is being accomplished by the Quality Commission. The AMA believes that the Commission's work will add a considerable body of expertise and a number of key recommendations on specific initiatives that must be considered and undertaken to advance the quality of health care in this country. We eagerly await the Commission's final report and hope that it will aid Congress in its deliberations.

WHAT IS QUALITY?

Many in our society have come to define quality in health care as "I know it when I see it." The AMA believes, however, that quality can be defined as the degree to which patient care services influence the probability of optimal patient outcomes, and contribute to the improvement or maintenance of the quality of life. These definitions drive a variety of AMA programs and initiatives as well as our public policy advocacy efforts.

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THE QUALITY ENVIRONMENT IN HEALTH CARE

For many years, the major focus of concern with America's health care system was its growing cost. Efforts to control cost through utilization review, managed care, and a variety of regulatory and market-based incentives have dominated the public policy agenda for quite some time.

Today, however, the focus has shifted to quality. While cost is still of concern, and restricted access to care is an ongoing issue, quality of care and patient protection are clearly of greatest concern to Americans today.

Few would dispute that managed care and market forces have cut fat out of our health care system. But both patients and physicians are increasingly concerned that a singular focus on finances and the bottom line may now be cutting into muscle and bone. The AMA firmly believes that the United States is blessed with the most highly skilled physicians and other health care workers, and with the highest quality hospitals and other health care organizations, in the world. But, we are very concerned that we preserve that quality, and continuously improve it. For that reason, we welcome the attention of the Congress and the Administration to this issue.

As the nation's oldest and largest professional association of physicians, the AMA has a firm commitment to quality standards, quality measurement and quality improvement. That commitment is grounded in our belief in professionalism and professional responsibility. It is a hallmark of any profession that it:

- Set standards for its members' education, training, behavior and delivery of care;

- Measure and evaluate its members qualifications and performance using those standards; and

- Educate and assist its members to meet those professional standards.

The AMA has taken up this challenge through our new American Medical Accreditation Program (AMAP), as well as through a variety of other quality initiatives.

AMERICAN MEDICAL ACCREDITATION PROGRAM (AMAP)

The American Medical Accreditation Program (AMAP) is designed to establish national standards of physician performance through accreditation of individual physicians. AMAP is a private sector initiative through which the AMA is working with other private sector organizations and government agencies to seek solutions to problems in the delivery of quality health care. The goals are the elimination of redundancy, a focus on quality, and improved patient care.

Since early 1995, the AMA has been studying the assessment of physician performance, consistent with its role as an organization responsible for establishing and maintaining professional standards. This work was motivated by the AMA's historic role in setting standards for the profession of medicine; by growing requests from patients and

employers for information about their physicians; the profession's need for public accountability; and the fact that no organization was evaluating and accrediting individual physicians and their practices.

Managed care organizations have responded to patient and employer demands for quality evaluation by implementing credentialing and office and medical record reviews, and by profiling physician practice patterns. But there is no standardization of these processes or methods from one plan to the next. The average physician in the United States participated in 11.6 different health plans in 1996. As a result, the average physician deals with almost 12 different credentialing applications; 12 different office reviews and 12 different sets of quality measures. Current managed care quality review processes are fragmented, duplicative, and inconsistent from one plan to the next, resulting in unnecessary confusion and expense. In contrast, AMAP offers physicians and purchasers of health care a standardized accreditation program that will reduce cost to the health care system and hassle to the individual physician, and that has the added benefit of providing meaningful feedback to physicians that they can use to improve the quality of care they provide to their patients.

AMAP evaluates each physician who applies for accreditation, utilizing uniform national standards to evaluate his or her qualifications and performance. These evaluations are intended to become the primary source of trusted information for the entire health care industry. In addition, AMAP emphasizes continuing enhancement of physicians' clinical performance, providing them with information and practical assistance in improving the

quality of patient care. AMAP aims to become the physician quality standard for public and privately funded health plans, hospitals, and the public at large.

AMAP measures and evaluates individual physicians against national standards, criteria and peer performance in five areas:

1. Credentials, which includes medical education, licensure, disciplinary actions, residency training, board certification and recertification, professional liability, and disciplinary action. This component consists of primary source verified information.
2. Personal Qualifications, which addresses ethics, continuing medical education, peer review, and self-assessment of knowledge and performance.
3. Environment of Care, which encompasses the practice site review of office operations and medical records.
4. Clinical Performance (process), which includes standardized measures of key patient care processes and comparative feedback to the physician on his or her performance.
5. Patient Care Results (outcomes), which includes standardized measures of clinical results, patient satisfaction, and health status and benchmarking data, which create opportunities for continuous quality improvement.

Meeting and maintaining AMAP's high standard earns a physician AMAP Accreditation—a new benchmark of quality. AMAP provides the first credible,

consistent, comprehensive national standard in physician quality—a standard that is meaningful not only for physicians, but also for patients and purchasers.

OTHER AMA QUALITY INITIATIVES

The AMA has engaged in a number of other quality initiatives, related primarily to clinical practice guidelines, improving clinical performance, and analyzing what makes for "good" managed care.

There has been an explosion in the availability of clinical practice guidelines: between 1975 and 1980, about one publication annually was classified as a practice guideline, compared to 454 annually between 1993 and 1997. Since 1990, the AMA has published a *Directory of Clinical Practice Guidelines,* which currently lists 1,700 clinical practice guidelines.

A survey of physician medical groups and independent practice associations found that 87 percent were developing or implementing guidelines to accomplish either cost containment or quality improvement goals. The proliferation of guidelines and concerns about the scientific basis for guidelines in general led the AMA to create the Clinical Practice Guidelines Recognition Program, which identifies guidelines meeting a set of criteria developed by a partnership between the AMA, national medical specialty societies, AHCPR, AHA, and JCAHO. The program in particular identifies those practice guidelines that are evidence-based.

In addition, the Agency for Health Care Policy and Research (AHCPR), the American Medical Association, and the American Association of Health Plans are working jointly to develop a comprehensive Internet-based source for clinical practice guidelines. The National Guideline Clearinghouse (NGC) will make available a full range of current guidance on treatments for specific medical conditions. The NGC will provide full text clinical practice guidelines, guideline abstracts, summaries, and comparisons to every physician, health plan, provider, purchaser, and consumer with access to the Internet. It is anticipated that the NGC will be launched on the Internet in the fall of 1998.

Further, the AMA has developed a bulletin that we believe will improve the clinical performance of physicians. This Quality Care Alert will be a two page mailing to alert physicians to major quality of care issues where there is a well-documented gap between the state of medical knowledge and current clinical practice (e.g., low rates of use of beta-blockers in patients discharged from hospitals after myocardial infarction). The Alert will be sent on an as-needed basis.

Finally, the AMA has issued a prospectus on a set of health plan characteristics that we believe to be essential to the operation of a quality managed health care plan. The document, *Essential Characteristics of a Quality Health Plan,* describes what makes for "good" managed care. The AMA is conducting a case study, working with a number of health plans to show that these characteristics can be and are currently in operation in the marketplace. The study will be available in the summer of 1998.

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AMA RELATIONSHIPS WITH ACCREDITATION AND OTHER HEALTH CARE ORGANIZATIONS

Since its founding in 1954, the AMA has been a corporate member of the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO, or Joint Commission). Through the Joint Commission we participate in setting standards and evaluating the performance of a variety of health care organizations and health care networks. Hospitals, home care agencies and other organizations that meet these standards earn JCAHO accreditation. The National Committee for Quality Assurance (NCQA) is the primary private sector organization which evaluates and accredits managed care organizations (MCOs), and the American Accreditation HealthCare Commission/URAC accredits utilization review organizations. However, AMAP is the only program that evaluates individual physicians and their practices.

Taken together, these private sector bodies have created a comprehensive web of standards, evaluation activities and improvement initiatives. Their activities complement one another and form an important safety net upon which the public today relies, so long as they seek out accredited doctors, hospitals, and health plans.

We have recently communicated to the President, as well as to the leadership of the House and the Senate, the commitment of AMA (through AMAP), the Joint Commission and NCQA to work together in developing better quality measures to meet the information needs of those who must make informed decisions about health care –

patients, doctors, health plans, and purchasers. The private sector accrediting bodies are working together, to eliminate duplication, and to standardize quality measures that will enhance decision making.

We recognize that one issue that the Congress must address is the need for governmental oversight and coordination of the various quality measurement and accreditation activities underway in the private sector. The proper role of the federal and state governments is also crucial to this discussion. The AMA believes that private sector oversight has yielded great benefits and information for consumers. **We strongly urge Congress to resist the temptation to replace existing private accreditation entities or to add an additional layer of government oversight to a system that is evolving in the right direction.** Any activities undertaken by government should be complementary to, and not duplicative of, the creative and innovative activities taking place currently in the private sector. Meaningful quality oversight is not inexpensive, and the alternatives—an expensive, over-reaching, new government entity or an under-funded, ill-equipped, and ineffective new government entity—are equally unappealing. The AMA encourages Congress to move thoughtfully and realistically so that the work already brought to fruition through the private sector can be encouraged to the continued benefit of consumers.

The AMA is committed to reducing redundancy in all aspects of the quality review and improvement process. The AMA pledges that it will continue to work with other

accreditation organizations and the federal government, as the largest purchaser of health care, to avoid duplication, eliminate unnecessary costs, and foster cooperation.

THE ROLE OF GOVERNMENT AND THE PRIVATE SECTOR IN HEALTH CARE QUALITY

We believe that government must set minimum standards to protect the public health. But we also believe that premature government intervention into a field that is in a state of rapid evolution can be damaging. The state of the art of quality measurement is in just such a period of rapid development. The AMA, Joint Commission, NCQA, FACCT and others are making major strides in advancing the state of the art. And we are all beginning to collaborate and coordinate to further accelerate the pace of quality measures development.

Government should encourage and facilitate this process, but take great care not to stultify it. The most effective means of advancing the state of the art of quality and the standards met by health insurers, physicians, and other providers is to hold private oversight mechanisms or bodies accountable for their (and their industry's) performance. It is conceivable that direct governmental review and standard setting might be appropriate if private mechanisms have failed and are judged incapable of doing the job, but there is no evidence that this has happened in oversight of quality in health care.

The private entities that oversee the health care industry and that work to set standards, measure performance, and improve performance are growing in scope and effectiveness. NCQA, JCAHO, and other accreditation organizations have made substantial advances in the effectiveness of their work to oversee and support quality assessment and performance improvement in health plans and health care organizations. AMAP has tremendous potential to set standards for individual physicians, whether within the context of managed care or not, and to engage the medical profession in setting standards, measuring and assessing performance, and improving care and service. The government should not impede this progress by issuing another set of standards.

PATIENT PROTECTION STANDARDS—ESSENTIAL ELEMENTS

The AMA believes that while choice should be at the heart of the health care system, health plan standards and empowering patient protections should be its backbone. In other words, if patients are allowed a choice, they must also be given the appropriate information to make these choices in an informed manner. Plans must also be given the appropriate clinical information to improve quality and reduce costs. The AMA urges that all plans be guided by the following principles, which enjoyed bipartisan support in the past Congress, particularly in the design of the new Medicare+Choice program. In general, plans should:

- disclose to patients plan information, rights, and responsibilities;
- provide for appropriate professional involvement in plan medical policy matters;
- disclose utilization review plan policies and procedures;

- provide reasonable opportunity for patient choice of plans and physicians; and
- provide reasonable access to physicians (primary care and specialist care).

DISCLOSURE

More specifically, plans should disclose information on plan costs, benefits, operations, performance, quality, incentives and requirements to potential and current enrollees. In selecting plans, individuals need information to understand how the plan operates, what they get in benefits, what they must do to ensure that services are covered, and where and from whom they get services. Patients also need to know how plans compare on items such as quality indicators, patient satisfaction, cost control programs, disenrollment rates and grievance and appeals procedures.

Under no circumstances should "gag clauses" or "gag practices" be tolerated. As the AMA has testified in the past, physicians have a legal and ethical duty to provide patients with all the information they require. We believe that patients should no longer fear that third-party payors could interfere with crucial medical information. For these reasons, we continue to strongly support Representative Ganske, MD's (R-IA) bill, H.R. 586, the "Patient Right To Know Act of 1997," as well as its counterpart in the Senate, S. 449, introduced by Senator Kyl's (R-AZ).

The AMA also strongly supports efforts to provide beneficiaries with comparative information on health care plans. For example, HCFA has issued a Medicare Beneficiary

Advisory Bulletin entitled, *What Medicare Beneficiaries Need To Know About Health Maintenance Organizations (HMO) Arrangements: Know Your Rights*. The AMA has urged every managed care plan to provide risk contract enrollees with a similar booklet upon enrollment in an HMO and annually thereafter. HCFA's advisory bulletin is an excellent example of the type of important information managed care enrollees should have made available to them. We look forward to working with Congress and others in finding opportunities to provide patients with similar information in the private sector.

Furthermore, there are legitimate concerns regarding market segmentation and marketing practices designed to attract healthy enrollees. While plans should be allowed to benefit from competition and their ability to constructively improve the health care delivery process, they should not be allowed to seek out and cover only relatively healthy individuals while avoiding sicker, more costly, individuals. Marketing practices need to be evaluated as well, and insurance companies should not be allowed to offer physicians and physician groups inducements to reduce or limit medically necessary services provided to patients. The AMA believes that there should be a minimum set of provisions that plans must meet and enrollment procedures that plans must comply with that are fair and avoid inappropriate market segmentation.

RISK ADJUSTMENT

We are pleased that the Balanced Budget Act of 1997 requires Medicare to risk adjust beginning on January 1, 2000, for the Medicare+Choice plans. Adverse selection under capitation is a serious threat to the quality of any managed health care plan. Patients with

chronic or serious illnesses are at risk of being underserved unless capitation rates are appropriately risk adjusted. The current adjustment of capitation rates by some plans by age and sex explains only a small percentage of utilization and cost variation among individuals and is inadequate for protecting the most vulnerable patients. Without adjustments in capitation rates for health status, physicians who have a sicker than average pool of patients may find that the capitated rate does not cover the costs associated with providing all necessary care for their patients. By setting capitation rates at levels that are too low to cover the cost of services provided to sicker patients, there is a greater risk of plans engaging in a form of systematic discrimination which may lead to rationing of care. Thus, it is critical that capitation rates for all managed health care plans be adjusted for health status, and health plans should allow carve-outs from capitation payments for high-cost patients and treatments, such as AIDS, organ transplants, and end-stage renal disease.

GRIEVANCE AND APPEAL PROCEDURES

In order to guarantee fairness and the provision of necessary medical services, procedures must be established that provide managed care enrollees and physicians with a system to resolve disputes within the plan. In cases where the grievance or appeals cannot be resolved within the plan, participants should be able to seek independent means to address the problems.

APPROPRIATE PROFESSIONAL INVOLVEMENT

We believe that it is the duty of physicians to ensure that their patients receive necessary and appropriate care regardless of the setting or method of payment in which that care is delivered. To make certain that physicians are able to meet this obligation, plans need to provide a process, such as a medical staff model, for meaningful physician involvement in the development of medical policies of the plan, including drug formularies, to assure quality. It is also necessary for plans to have procedures and methods that assure that high quality care is provided; yet, plans should also be given some degree of flexibility in order to achieve these standards and to encourage innovations in quality improvement and cost-effective care.

At the same time, we are pleased that Congress is considering the appropriateness of certain medical decisions being made by health plans across the country. We believe that the reports of "drive-through" deliveries, "drive-through" mastectomies and "drive-through" appendectomies are not the problem, but only the symptom of a broader issue. The real problem is that health plans, in efforts to increase savings, have ignored certain fundamental principles that must be followed to assure appropriate medical decision making. The problem that the "drive-through" bills seek to remedy is the failure to integrate good medical science with the appropriate involvement of practicing physicians and the medical circumstances of their individual patients.

UTILIZATION REVIEW

The AMA believes that plan quality management systems and utilization review programs must operate to enhance patient care and be based on sound scientific and medical information. Cost alone cannot be allowed to drive quality. Those who are involved in final decisions should be knowledgeable and qualified in the area they are reviewing, as well as being licensed to practice medicine in that jurisdiction. Procedures need to be fair and prompt.

FREE MARKET VERSUS GOVERNMENT INTERVENTION

We note that the physician community is all too familiar with overregulation. We have been subjected to more regulations than we care to think about. We support these patient protections not because we believe in more regulations, but because we believe that the recent opinion polls clearly demonstrate the loss of public support and faith in the health care system. When the insurance and managed care industries confront us on "anti-gag clause" legislation, "drive-through deliveries and mastectomies," we cannot help but think of our own experience in the health care marketplace where significant barriers exist to giving individual patients the care that they need.

ERISA PREEMPTION

In addition to the federal government's efforts to improve patient protections in health care plans, especially Medicare+Choice plans, states have also passed patient protection laws to protect their citizens. Many states have enacted laws that make it illegal for any health care plan to include gag-clauses in contracts with physicians. States have also

enacted health care plan disclosure laws, patient access laws, and emergency care access laws. The Employee Retirement Income Security Act of 1974 (ERISA), however, has created a regulatory black hole for those enrolled in self-insured plans, literally preempting states from protecting their citizens with the same patient protection laws that were deemed essential to all other privately insured individuals in the state. The AMA strongly urges Congress to amend the ERISA statute to provide a level foundation of patient protection laws for all.

The most egregious example of the inequity of ERISA is the preemption of self-insured health plans from state remedies when a patient is harmed. It is unconscionable that ERISA plan enrollees who are injured as a direct result of a managed health care plan's cost containment or utilization review policy can only recover the value of lost medical benefits. The AMA supports legislation that would remove ERISA preemption provisions on causes of action against all managed health care plan administrators to recover damages for personal or financial injury or wrongful death. Specifically, the AMA supports Representative Norwood's (R-GA) bill, H.R. 2960, the Responsibility in Managed Care Act of 1997, and urges Congress to expedite its consideration on this bill.

CONCLUSION

The AMA strongly supports the need for appropriate patient protections and quality assessment across all health care plans. Improving medicine and the health of the public will always be our focus, and we pledge to continue our effort to promote the art and science of medicine and the betterment of public health. The AMA stands ready to work with you, Mr. Chairman, and Members of the Subcommittee, to improve the quality of health care in our nation. I would be pleased to answer any questions at this time. Thank you.

Chairman THOMAS. Thank you very much, doctor.

Mr. Pollack, if the President's proposals were limited to prudent layperson in the emergency room, anyone has to look at the BBA and realize that we worked that problem out for Medicare and it's pretty obviously going to be part of that package. Had we had a working cooperative relationship, it would have been done sooner. You also need to know that I don't normally do personal stuff in making points, but I'm a member of an HMO, and one of the reasons I selected it is because in that HMO my wife would be able to have her OB/GYN who she had collected prior to that as her doctor to be her primary care provider, and, obviously, there are enormous benefits to doing that, and that, again, is certainly an item that makes all kinds of sense; it's overdue. After all, this President's been President for six years, and he could have issued an executive order at any time during those six years. The commission you served on was appointed just prior to the last election, and as we heard in earlier testimony, Medicare has no problem at all conforming to it, because, after all, in conforming to the "President's proposal," quote, unquote, they will be implementing what we passed in a bipartisan way in legislation. So, my early comment about the degree of politics that have been involved in trying to move forward in this area, I think, is only underscored by some of the comments that have been made.

A couple of other specific questions, and then I want to ask you some general ones so all of you can respond, because you come from a number of very interesting directions on some of my broader questions. Ms. Kanin-Lovers, in IBM's portfolio, do you currently offer MSAs? Are you thinking about offering them? Is that a product that you haven't looked at? That you've looked at and rejected? Medical Savings Account.

Ms. KANIN-LOVERS. Medical Savings Account, thank you very much. I thought, "Oh, my goodness."

Chairman THOMAS. Sorry. I don't like jargon, and I apologize.

Ms. KANIN-LOVERS. That is not something that we currently have available although we do have something called life planning accounts, which is an amount of money that we have put aside for employees to use in certain areas, if they want to join a health facility or something like that. But, we evaluate our plans every single year and we will be looking at design again and again to see what's appropriate for the workforce. The workforce has been changing a lot and so their issues are very different.

Chairman THOMAS. Well, as the workers have been changing, the whole concept of employment—who's an employer and how people work jobs—is also changed since the ERISA was written into law. One of the problems we've dealt with over the last several Congresses are what are sometimes called the MEWAs, the Multiple Employer——

Ms. KANIN-LOVERS. Right.

Chairman THOMAS [continuing]. Associations which don't fit well under the current ERISA structure and some of the members who are interested in making changes in this area see the basic ERISA concept as a kind of a model to try to bring more in and what that does, of course, is remove a State particulars and allow interstate corporations to function in a more reasonable way.

My problem is when I listen to the President in terms of the changes that he believes need to be made by Government with Government-initiated programs because people, for example, in the near-senior group don't have jobs or people who are 55 and retired don't have jobs—over and over again the problem with health care.

And, Ms. Graham, you pointed it out in terms of the number of people who get their health care through their employer. One of the discussions that's beginning to come to the fore is to what extent is this concept written into the Tax Code that the employer is the one who gets the exclusion and carries out the various procedures and, Mr. Pollack, I think you alluded to it.

Why can't we change the Tax Code and have the provision available to an individual who then may use the employer as a collection site, and, obviously, Ms. Lovers, with the attraction that you have and the program, that you're willing to offer and if you wish to continue it, would certainly be a magnet for folks to use that as the collective group. But, it could be other groups that could be utilized as well.

And that—I can't go through all the particulars in the time that we have—but that concept of taking it away from something that really was a World War II development and currently is significantly mal-distributed as a benefit in the society, to some people who work for a corporation and don't have it and others do, and create a more equitable redistribution of benefit availability through the Tax Code.

What is the interest, approach, concern about Congress doing that kind of a radical change instead of waiting for folks to come up with here's a group who have a problem and let's have a Government program go into solve that problem. Any reaction from any of you?

Ms. KANIN-LOVERS. I——

Chairman THOMAS. Let's just start with Ms. Graham and go across——

Ms. KANIN-LOVERS. I'm sorry.

Chairman THOMAS [continuing]. So everybody gets it in kind of a—in turn.

Ms. GRAHAM. Well, I would really like to explore, learn more about that idea. I just know what the different State involvement, Federal involvement has done to our company and, again, I think that the private sector—when I look at—we have to go out and buy steel for our reactors that go into refineries and we do that by going to the marketplace and finding the best suppliers. We've done the same thing in the health care; however, every year for the smaller companies, it just gets harder and harder to find affordable and quality plans. And when we and several of the States have pooling available, I think that if there was more pooling available, that could be one solution. And certainly a lot less liability and malpractice—-malpractice reform would be wonderful, also.

Chairman THOMAS. Well, obviously, malpractice reform, I think, is part of that package. But, my concern is that you will be loaded with so many requirements that eventually you simply say Uncle and then there's a problem because here are people who have joined the group of the uninsured and, to a certain extent, the group of uninsured are an artificial creation because of the Tax

Code structure of how benefits are distributed. And, if we address the underlying problem, I think we can solve some of the others and I'm pleased to hear there is someone who takes it on as a personal responsibility, not just a corporate one, and I think that's the best way to look at it.

These individuals could, then, deal with an approach which might allow for a more responsive marketplace, if they were the ones making the choices, including employers being more responsive because you'd have to offer what the employees wanted or they would go someplace else.

Ms. GRAHAM. Right.

Chairman THOMAS. Ms. Lovers?

Ms. KANIN-LOVERS. I'd like to answer that question in two parts.

Chairman THOMAS. Sure.

Ms. KANIN-LOVERS. First of all, I do want to confess that I can't give you any comment on the Tax Code.

What I would like to talk about is kind of the employer view and the——

Chairman THOMAS. I won't ask why. [Laughter.]

Ms. KANIN-LOVERS. I don't think I'm quite the expert there.

But, I think that what we need to recognize is the role that the employers play in defining quality and I do think that we are very actively involved in improving quality of health care in the United States. When IBM goes out to bid to the 183 HMOs that we currently offer, we are very aggressive in setting standards, in telling them the records we want to see, we're looking at outcome, we're really pushing hard to make sure that that bar is raised every year. I believe that's not something that an individual employee, if they were operating as a sole person buying health care, could do. And so, we are able to do that and I think it benefits the entire United States. That's kind of one part.

The other part that's important to recognize is, as a major employer, I do not view my benefit strategy as a snap-on; it's not an add-on thing. What I do for health care is very much focussed on the needs of my employees; it's part of my strategy. When I go out to recruit—last year, IBM hired 15,000 people—we're out there fighting for the top-quality people and we're actually doing that through the design of our benefits plan. That's one component of it.

And, I've also mentioned that the workforce is changing a great deal. One observation that I wanted to make is, you know, we're hiring what's been called the "Generation Xers" now. You know that group? That's actually a group that has a stronger affinity for managed care than our longer-term employees and so we've had to change our plan to be responsive to those kinds of shifts. And, I think that's something we can do more effectively as a major negotiator for health care coverage; that we could allow our employees to do. We also can improve quality more effectively than they can.

Chairman THOMAS. I agree with that in the current environment, but if you then gave the power to each individual, you would have to compete for their attentions because they're still your employees and you want to do what you're doing. But, why can't you be an icebreaker then so that other groups can say, we want what IBM has and if someone doesn't provide it either through the insurance

agent writing it, they would go to some other group and you can then get collections of groups. And, of course, in California we have the group purchasing structures, which could utilize what these large corporations have been very successful in doing, in terms of packaging health care, and say, I want what they have or we'll go to someone who will give it to us.

I don't see why that doesn't create a more competitive market for a better quality product for more people than just those who work at IBM because there's someone else in the computer software field who has no insurance whatsoever through no fault of their own but because of the mal-distribution of benefits in the Tax Code. That's the way I'm trying to get folks to look at it. I never said you guys have not done a great job of pushing quality; I just want to try to figure out a way that more people can share in it.

Dr. Rideout, a comment?

Dr. RIDEOUT. My main comment on that would be that, at least in California, in my experience the purchaser cooperatives have been the primary driving partner of the quality initiatives that we undertake, although it's very much a two-way street. And, just as an example, they were very instrumental in pushing, say, HEDIS in preventive health rates as a standardization activity but it was the plans and the medical groups that said, hold on, the way we're organized here, we need to do this cooperatively and we would be willing to audit that data five years before it was ever done by HCFA or anybody else in this country to do that.

I think the other thing that I would add to that is the enormity of the data problem is real. And in the State last year, we had to audit 80,000 medical records in a three-month period in order to meet the combined requirements of 23 HMOs trying to supply information to their commercial purchaser partners, as well as HCFA. And, also, in our State, we need to do Medicaid reporting and sometimes it may be on a contractor county specific basis. So, the problem is enormous and I think the purchaser community has been, at least in California, instrumental in bringing this together and they are willing to take on the real issues and make solutions out of them for us.

Chairman THOMAS. Well, I would be remiss if I didn't compliment the California Blues for the very aggressive way you've gone into the purchasing cooperatives and, in fact, were a leader to make sure that it worked.

Mr. Pollack.

Mr. POLLACK. Mr. Chairman, what you raise is a question of an individual-based system and let me first start where theoretically I think that I have some common views with you. Then let me express my concerns about what you propose.

Theoretically, I do believe that ultimately we have an individual-financed system. When employers purchase care, it ultimately is individual-purchased care because it results in wages that actually subsidize care provided by an employer.

My concern about the proposal that you're suggesting is really two-fold. The first concern is from a political standpoint and the second from a substantive standpoint. From a political standpoint, I believe one of the things that has made health reform an intractable difficulty is that, when you deal with such significant change,

you wind up having a massive redistribution of resources. Moving from an employer-based system essentially to an individual-based system would involve an enormous redistribution of resources. I suggest to you, from just a political standpoint, that kind of massive redistribution has confounded all attempts at significant change.

The more significant problem that I'd like to raise is substantive. That is, if you move towards an individual based systems, there's a concomitant step that must occur. We need to have a regulatory framework to enable that to work. An essential component of that framework is we need to have serious insurance reform so that those people who are sicker, those people who are older, those people who are less desirable from an insurance company's standpoint are protected so that they can purchase health coverage. I suggest to you that, to the extent that such a proposal is viable, what must go with it is significant insurance reform.

I was slightly bemused at the first question relating to MSAs and I don't want to talk about MSAs. But, there was an interchange that I thought was very instructive that relates to an important issue here. Ms. Kanin-Lovers, who is obviously a very distinguished, knowledgeable, and thoughtful person working for a very distinguished company, was for a moment a little lost by the MSA alphabet soup. She is probably in the 99th percentile of knowledge in the country. I suggest to you that one of the things that those people who wish to promote a market-driven system to ensure quality vis-a-vis those who lean more toward a somewhat greater regulatory approach have in common is that we need to have a better system of information for consumers and ways to help consumers. If we don't have that, the marketplace cannot work.

I would like to suggest what I hope is a bridge between these two approaches, an ombudsprogram run by a non-governmental organization. It's being tested in a variety of ways in California, so you're probably as familiar about this as anyone. Such a program is often called a consumer assistance program. Others call them an ombudsprogram. I think this is an extraordinarily important non-governmental organization approach to providing assistance that would help the market-based approach as well as the regulatory approach.

People simply are bewildered today about the choices that they have. They are bewildered about their choices, their rights, and their responsibilities and they need help. I think this role should be done through non-governmental organizations.

Chairman THOMAS. I'm familiar with the argument that you make, Mr. Pollack.

Dr. Smoak, did you want to comment on that?

Dr. SMOAK. Yes, Mr. Chair. MSAs certainly are a tag line to the AMA in terms of our Medicare transition plans and I won't go into the specifics as to why but we certainly wholeheartedly endorse that concept and believe that it's a way to afford some alternate in terms of the financing mechanism of some of our health insurance needs.

I would suggest that the individually-owned as well as the individually-selected plan would be an excellent choice because it gives a patient the opportunity to have additional choices that he or she

might not have otherwise, which leads me, then, to the idea of a defined contribution which would merit a lot of value in terms of government, employers, et cetera, knowing what their outlay is and would have a particular benefit, I think, overall in our planning for financing of care.

I, myself, am a small businessman. I offer options to my employees and I think that the trust that we develop in our patient-physician relationship—this is the cornerstone, right here, of quality health care and given them a choice and opportunity to properly balance the quality, the cost, and the access to appropriate care.

Chairman THOMAS. I appreciate your comments and to pick up some points that you made, Mr. Pollack. I didn't want to continue to intervene. There's no question that you're going to have to deal with insurance reform; the question of risk adjustment is a critical one.

As was mentioned by Ms. Graham, malpractice reform needs to be involved. Clearly, with the current Tax Code mal-distribution where there are individuals who have, in essence, open-ended opportunities for fringe benefits based upon negotiating with an employer and others who don't, one of the key restrainers would be that beyond some amount that's determined, additional health care would be after-tax dollars and, until we get a fringe benefit dollar equated to a wage dollar, you're never going to get reasonable control of health care cost in this country, in my opinion.

The defined contribution is clearly one way to approach that dollar amount, especially when it's other people's money. My colleague from Louisiana on the subcommittee is fond of saying that people will consume as much health care as other people are willing to pay for and what is long overdue, frankly, in this society is a debate in a budgetary way of how much money we're willing to spend in that area and make it a policy debate.

Currently, in Medicare on part B, 75 cents out of every dollar is a subsidized dollar but you don't really see it; it should be a public policy debate as to how much that should be. I think in the long run that's the only way we're going to operate and, of course, the easiest device to do that is a defined contribution above which taxpayers dollars would be purchasing health care.

If you say that, then, you have to look at the other end of the spectrum of those who are not able either through a tax credit structure by not having an income tax, or a low enough income not to be able to deal with that issue, that there's got to be a way to make sure that they're participants in the system as well at whatever the defined contribution level is.

So, yes, it's a fairly radical discussion but I don't know any other way to get to the fundamental problem of dealing with it and maximizing the private sector's involvement in that ultimate health care structure because the current approach is wait for some group that either has a real or apparent problem and, for political purposes, create a plan which almost inevitably stretches a Government proposal to cover them, or, perhaps even worse under the current system, figure out a way to pony it up on the back of the employers either to cover those that are directly employed or, through increased tax schemes, get money to cover them as well.

So, what I'm looking at is a way to try to maximize the private health care market while answering, I think, legitimate critics about the maldistribution of benefits currently today. And, while we're doing all that, of course, we will be looking at questions of quality and providing consumers with tools that allow them to make those decisions. But, it is a massive, massive undertaking and to talk about it is not to do it and the two are worlds apart right now.

The gentlewoman from Connecticut?

Mrs. JOHNSON of Connecticut. Thank you and thank you very much for your testimony today. I am going to have to leave fairly soon so I just wanted to ask a couple of questions.

First of all, Ms. Lovers, you provide a lot of choice to your employees. You talked about a single plan but you also provide—talked about all the choices?

Ms. KANIN-LOVERS. Yes.

Mrs. JOHNSON of Connecticut. How does that work? Very briefly.

Ms. KANIN-LOVERS. We go through an open enrollment period every year and, before enrollment starts, we send out to all employees information about the way the indemnity plan works and——

Mrs. JOHNSON of Connecticut. Kind of like the Federal Government does.

Ms. KANIN-LOVERS. Sorry?

Mrs. JOHNSON of Connecticut. Kind of like the Federal Government does.

Ms. KANIN-LOVERS. I'm not sure what the Federal Government does but I assume that they would send out information on how the plan works, and then there would be information on the HMOs that are in your specific neighborhood, what those look like. We've provided copies of what we call our fact sheets——

Mrs. JOHNSON of Connecticut. Yes, that was very helpful——

Ms. KANIN-LOVERS [continuing]. And it kind of——

Mrs. JOHNSON of Connecticut. Because I don't have much time, do most Fortune 500 companies provide choice, to your knowledge?

Ms. KANIN-LOVERS. Yes. To my knowledge, yes.

Mrs. JOHNSON of Connecticut. Do you know anything about the group just below you? Do they generally provide—the bigger companies in America generally provide more than one plan?

Ms. KANIN-LOVERS. That would be my suspicion, yes.

Mrs. JOHNSON of Connecticut. Ms. Graham, do you provide more than one plan?

Ms. GRAHAM. We used to about five years ago. In the last few years, we've changed and now we—everyone has a PPO. But, we have—we employ 57 people in 7 different States so each plan—and that's not a lot of people to spread over 7 States, and so we've come up with the best plan that our managers spend a lot of time on evaluating and they're saying it's the fairest for all 7 States——

Mrs. JOHNSON of Connecticut. And why did you go from a number of plans to one plan?

Ms. GRAHAM. It was really cost and it was also taking so much time to evaluate different plans that—I mean, we're a small company and we just don't hire anybody to just review the plans so it's whatever——

Mrs. JOHNSON of Connecticut. I just think it is very important in looking at the Norwood, some of the bills before us to recognize that Government provides multiple choices; that's all Federal, State and local governments, to my knowledge. All the big companies do, and a lot of the little companies that no longer do don't because they can't afford it. So, I think you have to be very careful about this issue of mandating because a lot—some of the most destructive changes that are going on are coming as the result of mandating.

I just want to ask you one other question about your analysis of disenrollment rates. Now, my friend, Lynn Martin, went to work for one of the big accounting firms and one of her first tasks was to figure out why, when they were making such an aggressive effort to hire very, very talented women, that had so few women moving up the ladder. And, when they—when she first got the data together and she went to the CEO, he basically said, well, I guess they're retiring to have children. And that was it. The firm simply assumed that these women were leaving the firm because they had worked a number of years and now they were starting families and blah, blah, blah.

In fact, they weren't doing that. When Lynn went back and looked and did all the exit work, they found out they were going to other firms because they were not getting good choice of assignments. There was a glass ceiling and their private—all I'm saying is it really doesn't tell me anything for you to say there's a 20 percent turnover disenrollment rate because I see too much of that out there.

Seniors don't know to be sure their own physician is in the plan first. It is confusing. It's happening very fast in my part of the country. I need to know far more about that and I can't conclude from the numbers you give me that service was the problem, that they were better at marketing than they were at serving. Unless you have some better information than you've given in your testimony, we shouldn't be drawing those kinds of conclusions from that kind of data.

Mr. POLLACK. Congresswoman Johnson, let me say a couple of things about this. First, in our report, we were very clear in saying that disenrollment rates are not determinative of quality; we were very clear about that.

Mrs. JOHNSON of Connecticut. But, you're putting an awful lot of weight on it——

Mr. POLLACK. But, let me finish the point. However, there really is a conundrum, I think, for those who believe in a market-driven system who feel that a market-driven system is a better way to achieve quality. I think it is ironic that when people disenroll, say that this tells us nothing about quality.

The whole notion of a market-driven system is that people can vote with their feet and, by people voting with their feet, the market drives quality. And then, when one makes an observation about that, the very person who——

Mrs. JOHNSON of Connecticut. I'm absolutely not suggesting that we not be concerned about that data. But, to draw the conclusions you do from it, I think, is unwarranted. And, the other thing I would point out is that the market-driven health care system we

have is doing more about quality than the fee-for-service market-driven system ever did. For the first time, we are looking at patterns of practice. For the first time, we were looking at outcomes. The fee-for-service system never stimulated that.

That isn't to say that there aren't problems but I think, you know, one of the reasons we see these statistics about people feeling, say, 55 percent can't get access to care is because we talk about the fears. We don't talk about the reality. And this body has got to look at the reality. It's helpful to us that almost all the States have passed the very same consumer protection provisions that we passed last year. I think that's true; we're going to try to document that. But, we've got to be careful that we don't legislate on the basis of rather slippery information.

Let me just say one thing to Dr. Smoak. It does concern me that you have so little concern about the liability provisions in the Norwood bill. In my estimation, and I think this is universally accepted, it was, in a sense, malpractice, our malpractice laws driving very defensive medicine; driving the kind of medicine that didn't look at whether you needed the care, just whether this could possibly be something you might a few years later look back and say, we should have done. That really, in a sense, bankrupted the fee-for-service system.

So, unfortunately, in some of the legislative proposals before us, some of my colleagues are trying to solve the problems of managed care by bringing all that liability stuff back into this system which will have exactly the same effect. So, I don't see that as the answer, as important as I think rectifying the balance between the physicians and restoring to the physician the control over the care decisions. But, I don't think exposing systems to malpractice in the way we expose individual physicians to malpractice is going to be a constructive part of the answer.

So, I'm much more interested in other things that will restore power to physicians and the physician-patient relationship but maintain and oblige the physician to be accountable for the kind of discipline that we know can produce better quality care, as we heard from the earlier panel. So, I would hope that you would help us rethink what's constructive about the proposals before and what is really either terribly premature and terribly, possibly destructive because we are in a period of change and we don't want to truncate evolution; at the same time, we want to protect American health care consumers from possible significant disadvantages.

I'm sorry. I have to leave and thank you, Mr. Chairman.

Chairman THOMAS. The gentlewoman's time has expired.

For a brief final intervention, the gentleman from Louisiana.

Mr. COOKSEY. You know, I think that we all have the same motivation and that's to come up with an economic system of delivery of health care and we need straight answers, we need people to look at it objectively, people need to leave off their own biases. As a physician, I need to leave off some of mine. As managers of insurance companies, you need to leave off some of yours. And we need to look at it with a whole new perspective.

You know, in this century, we've gone from health care being a cottage industry—one solo practitioner—through a corporate entity through a Government-regulated entity—corporate in World War II

with people getting health benefits instead of—in lieu of salary increases. And, it became corporate-oriented and in Government-oriented, in 1965 with the passage of Medicare, and then you interspersed labor unions, labor unions' leaders, you interspersed regulators with Government care.

And it just—the chain gets longer and we need to get back to that patient-physician relationship. We need to get away—clear out all the regulators and we need to use information systems much better than what the health care profession and the insurance companies are doing. And then we need to get all the people out that are out there, just, in the health care system just to make money. They're too many of them making too much money and not contributing anything to the quality of health care.

Thank you, Mr. Chairman, and good day.

Chairman THOMAS. Thank you very much and I thank all of you for your patience and, more importantly, for your testimony. This is a critical area that we may very well be legislating and we need all the help we can get.

So, the hearing stands adjourned.

[Whereupon, at 2:30 p.m., the Subcommittee was adjourned subject to the call of the Chair.]

[Submissions for the record follow:]

STATEMENT of the American Academy of Family Physicians

Submitted to the

Committee on Ways & Means
Subcommittee on Health

Concerning The

Quality of Service in Managed Care Health Plans

February 26, 1998

AAFP Headquarters
8880 Ward Parkway
Kansas City, Missouri 64114-2797
(816) 333-9700

AAFP Washington Office
2021 Massachusetts Avenue, N.W.
Washington, DC 20036
(202) 232-9033 (202) 232-9044 (FAX)
(E-mail) fp@aafp.org

Introduction

This statement on health care quality is being submitted today on behalf of the 85,000 practicing family physicians, family practice residents, and medical students who comprise the membership of the American Academy of Family Physicians (AAFP).

The Academy's policy on public health, medical ethics, scope of practice and marketplace issues are unified around the patient's best interest. Quality health care is best delivered where there is an ongoing relationship with a primary care physician.

Family Practice and the Context for Managed Care Regulation

The delivery of coordinated, high quality and cost-effective health care is the norm for many managed care plans. However, the Academy readily acknowledges that some health maintenance organization (HMO) business practices pose serious access, treatment and quality problems. Over three quarters of all practicing family physicians are involved with managed care plans, and so are especially troubled by news of HMO patients facing inappropriately denied medical treatment or by reports of hassles by unresponsive or uninformed HMO personnel.

However, as an organization committed to outcomes-based medicine and the centrality of the physician-patient relationship, it is difficult for the Academy to accept solutions that are based not on science, but on the exigencies of public pressure. We are greatly concerned about spread of congressional intervention into medical practice. While decisions by managed care plans that adversely affect patients are unacceptable, we must carefully evaluate the appropriateness of solutions based on legislative mandates. We do not believe that legislation or regulation of any sort should interfere with clinical decision-making. This is the core principle upon which the Academy bases its stance on proposals to regulate the practice of medicine or the managed care industry. For instance the Academy opposed efforts to regulate post delivery hospital length of stay when they were passed last year. Similarly, the Academy also will carefully evaluate managed care administrative reforms to determine where legislative intervention appears appropriate.

The need for unfettered medical communication is another core position the Academy advocates in relation to manged care. This position is the basis for the Academy's endorsement of H.R. 586, the Patient Right to Know Act, introduced last year by Representative Greg Ganske (R-IA) and Representative Ed Markey (D-MA). Some health plans have been alledged to "gag" their health care providers by forbidding them from communicating freely with their patients about their medical or mental condition, treatment options, or health plan policies that may influence payment for a medically necessary service. Unfettered medical communication is, undeniably in the best interest of patients; it is absolutely essential for the delivery of the highest quality health care. It is also intrinsically linked to upholding the code of medical ethics that all physicians must follow. The Ganske-Markey bill would correct any problem with gag clauses that hinder physicians-to-patient communication about clinical decisions , and it is for exactly this reason that the Academy wholeheartedly endorses H.R. 586.

AAFP Commitment to Quality Health Care

The Academy is committed to preserving and promoting high quality, cost-effective health care by family physicians with (1) scientifically valid and relevant continuing education; (2) programs and tools to assess and improve the quality of health care provided to patients; (3) representation and partnerships with other organizations dedicated to providing quality care to patients.

The Academy is also committed to taking an active role in developing and implementing strategies to improve the quality of care provided by health plans. The Academy has worked closely with a variety of entities such the US Preventive Services Task Force,

Agency for Health Care Policy and Research, the Foundation for Accountability, and the National Committee for Quality Assurance's Practicing Physicians Advisory Panel, Diabetes Quality Improvement Program and Pediatric Measurement Advisory Panel in the development of evidenced-based clinical guidelines, and the American Medical Accreditation Program. In addition to evidence-based measurement, the Academy is committed to developing patient centered measurements. By concentrating on issues that are paramount to the patient, such as quality of life concerns, health care quality initiatives can have a greater effect.

- The Academy's partnership with these public and private sector groups is subject to the following specific principles:
- All quality improvement and measurement efforts must be patient-centered, evidence-based, and practicing-physician friendly;
- The advice and counsel of practicing physicians must be sought from start to finish as part of quality improvement and measurement activities;
- Solutions to quality problems in the health care system, or with health plans, must be outcomes-based and developed by patients, physicians and health plans, preferably without Congressional intervention;
- Board certification must not be used as the sole criterion for physician exclusion from health plan participation--participation decisions should be made on the basis of training, demonstrated competence, continuing medical education experience and other relevant information; and
- The activities of the Agency for Health Care Policy and Research (AHCPR), and in particular for primary care research, deserve explicit support and adequate funding to carry out is work, which is entirely consistent with efforts to improve the quality of health care services delivered to Medicare+Choice enrollees and other managed care patients.

The Academy is especially committed to the promotion of primary care research funded through the AHCPR. While most medical care is provided in the outpatient setting, ambulatory medicine is the least researched mode of patient care. Over 95% of all medical conditions have been evaluated and treated outside of hospitals over the last 30 years. Nevertheless, physicians today are educated and trained using research information that has largely been derived from hospitalized patients, or patients with conditions in an advanced state. What may appear promising in the laboratory or in highly controlled clinical trials undertaken in university centers may not be practical when attempted in the real world, or may work differently in different settings or with different population groups.

According to the 1996 Institute of Medicine (IOM) report on primary care, *Primary Care: America's Health in a New Era*, federal investments in primary care research today total between $15 and $20 million annually. The IOM report recommended an immediate fourfold increase in primary care research. We believe that U.S. research facilities must complement their understanding of high-tech research with a similar dedication to applying state of the art medicine to understanding primary care.

In light of the Academy's committment to health care quality, below are outlined the Academy's policy in five broad categories related to ensuring an accessible, appropriate and confidential health care system. These broad categories represent the basics of a patient-centered system, however, it is equally true that these categories may best be achieved through means other than legislative mandate.

Choice

The AAFP believes patients should have the ability to select a health plan from among several different options.

The AAFP has historically supported freedom of choice for both the physician and the patient as a fundamental principle when selecting health care delivery plans. Ideally, a patient should be able to choose from among several health care delivery options. The AAFP believes that it is consistent to support a variety of health care delivery methods, while calling attention to those practices that might suppress quality care in favor of profits or market share.

As you know, recent research by S. Robinson and M. Brodie, Understanding the Quality Challenge for Health Consumers: The Kaiser/AHCPR Survey, published in the May 1997 issue of *Journal on Quality Management*, reports that 46% of those surveyed would pay more to have direct access to any subspecialist and 51% would instead choose a lower-cost plan that coordinates care through a family physician. Patients have different preferences and should be offered a choice of plans. To this end, plans should provide sufficient information, in a manner appropriate to the population being served, about plan terms and conditions to allow prospective enrollees and patients to make informed enrollment decisions. Likewise, plans must be able to charge appropriate, actuarially justified premiums and higher patient cost-sharing requirements for "out-of-network" care. However, no plan should ever discriminate against individuals with expensive, long-term or chronic medical conditions.

In a related matter, family physicians are concerned about being viewed as "gatekeepers," a term that inaccurately implies that family physicians want to withhold needed care. Rather, the family physician serves in the role of patient advocate, diagnosing and treating the patient, making referrals and obtaining consultations as appropriate. Family practice is the medical specialty that provides continuing and comprehensive health care for the individual and the family. Indeed, the gatekeeper concept is completely at odds with the team approach to care espoused by family physicians.

Specifically, family physician care is comprehensive and not limited by age, sex, organ system or type of problem, be it biological, behavioral or social. Family physicians emphasize disease prevention and health promotion and utilize knowledge of the patient in the context of the family and the community. Finally, family physicians refer the patient when indicated to other sources of care while preserving continuity of care.

Access

The AAFP believes that every patient should have freedom of choice at all times, and that the extra cost of choosing direct access to specialty care outside of a coordinated care network should be borne by the patient.

The AAFP has supported a patient's freedom of choice as a matter of Academy policy for the past fourteen years. This support remains strong, even while the Academy remains certain that as an advocate for the patient, the family physician is in the best position to recommend a care setting and care regimen best suited to their patient's needs.

However, AAFP recognizes that some patients will choose to self-refer. This may not always be in the best interest of the patient and self-referral options should impose additional, actuarially justified premium and higher out-of-pocket expenses for "out-of-network" care. The AAFP believes that family physicians, in consultation with their patients, should guide referrals to other health care professionals. Similarly, AAFP feels that "any willing provider" requirements leave health care plans without the necessary flexibility to choose providers willing to practice under their protocols and plan structure, or quality assurance criteria.

Benefits

The AAFP believes that health plans should have a defined comprehensive benefits package emphasizing preventive primary care services.

The AAFP has developed a model benefit structure that emphasizes preventive primary care services (which includes health promotion, disease prevention, health maintenance, counseling, patient education, diagnosis and treatment of acute and chronic illnesses). Primary care is that care provided by physicians specifically trained for and skilled in comprehensive first contact and continuing care for persons with any undiagnosed sign, symptom, or health concern.

The AAFP also believes health plans should have sufficient financial reserves and infrastructure to ensure proper and timely payment for covered services. Utilization review medical directors should make coverage decisions based on clinically sound guidelines. Physicians should, however, have the right to appeal adverse coverage decisions and have such decisions reviewed. Health plans should respond to requests for prior authorization of a non-emergency service, upon receipt of complete information, within two business days.

Information

The AAFP believes that patients must be able to receive any information, clinical or financial, necessary to make informed decisions regarding their medical care.

Health plans should not restrict communication between a patient and their caregiver in any way. In December of 1996, the American Association of Health Plans (AAHP) announced their "Patient's First" initiative, which is supported by the Academy. The AAFP agrees with the AAHP that health plans should not, by contract or policy, prohibit physicians from communicating with patients concerning medical care and medically appropriate treatment options, whether covered or not.

Confidentiality

The AAFP believes that a confidential relationship between physician and patient is essential for the free flow of information necessary for sound medical care.

The right to privacy is personal and fundamental. Physicians understand that to be able to diagnose logically and treat properly, they need to fully comprehend their patient's situation and concerns. The physician/patient privilege is a legal doctrine that recognizes and protects the confidential nature of communication between patients and their physicians. Discussions between patient and physician can only occur in an atmosphere of trust and confidence.

Therefore, the AAFP has steadfastly supported the privileged and confidential nature of medical information maintained by physicians. The AAFP believes the release of data that is personally identifiable should require explicit patient authorization. Any disclosure of medical record information should be limited to information necessary to accomplish the purpose for which disclosure is made. The AAFP supports practice protocols that include dated written authorization for the release of personal information so that the patient will know for what purpose the information is to be released, to whom, the extent to which secondary release can occur, and include when the authorization will expire. Sensitive or privileged information may always be excluded at the option of the physician unless specific authorization of the patient is given.

This professional obligation to safeguard patient confidences is subject to certain exceptions, which are ethically and legally justified because of overriding social considerations such as public health concerns. Other than this limited exception, every effort must be made by the physician and health plan to utilize appropriate safeguards (e.g., cryptography; message authentication; user verification) to protect both the physician's and patient's privacy.

Conclusion

The Academy is pleased to be able to present its views to the Ways and Means Health Subcommittee. We look forward to working with the subcommittee on health care regulation and quality issues in the months ahead.

AMERICAN COLLEGE OF
OCCUPATIONAL AND
ENVIRONMENTAL MEDICINE

Statement of

Robert S. Rhodes, MD

President

American College of Occupational and Environmental Medicine

before the

House Ways & Means Health Subcommittee

February 26, 1998

Contact: Pat O'Connor
202/223-6222

55 West Seegers Road · Arlington Heights, Illinois 60005-3919
847/228-6850 · FAX: 847/228-1856

Mr. Chairman, on behalf of the American College of Occupational and Environmental Medicine (ACOEM), I thank you for this opportunity to submit the College's comments on the important issue of health care quality.

ACOEM is an international society of 7,000 physicians dedicated to the prevention and management of occupational and environmental injury, illness and disability, and the promotion of health and productivity of workers, their families and communities. ACOEM pursues these goals through preventive medicine, clinical practice, research and education.

ACOEM is the preeminent organization of physicians who champion the health and safety of workers, workplaces and environments. As such, we are greatly concerned with the quality of care provided to our workforce.

Because Americans spend much of their time at work, any assessment of health care quality should examine the quality of care provided injured workers through the workers' compensation system. In particular, the current trend towards providing worker's compensation through managed care entities should be examined both for cost effectiveness and quality of health care delivery.

ACOEM is strongly committed to healthy workers, workplaces and environments. Neither workers nor employers benefit when the quality and availability of medical care is uneven, or when resources are wasted. As a prevention-oriented society, ACOEM believes that one of the best improvements to the workers' compensation system would be to reduce injuries by establishing greater linkages between injury and illness care and prevention programs. Injuries and unnecessary disability are continuing evidence of the failure to implement preventive strategies.

Doctors working in the workers' compensation system should focus on the timely and appropriate return of the employee to modified or full duty and restoration of functional disability. To ensure these goals are met in the managed care setting, occupational management systems will have to be developed by physicians with expertise in occupational medicine. Primary care physicians with training in occupational medicine should have the primary responsibility for managing workers' compensation cases, regardless of whether treatment is provided in a managed care setting or in fee-for-service. The use of occupational physicians in this role will lead to a quicker return to work for the injured worker and greater satisfaction on the part of the employer.

The future is likely to involve the integration of occupational health and workers compensation into managed care plans. The challenge will be the delivery of a quality product to the individual whether in the community or in the workplace. Greater emphasis will need to be placed on ensuring worker satisfaction with care and access to care.

A recent article in the Journal of Occupational and Environmental Medicine studied the use of managed care delivery systems in the workers' compensation program in Washington state. The Washington State Managed Care Pilot Project (MCP) tested the effect of experience-based capitation on medical and disability costs, quality of care, worker satisfaction with medical care and employer satisfaction. The delivery of care in the MCP was changed from the office-based fee-for-service model

to the occupational medicine-based model. Much of the care, and all of the treatment coordination was provided by physicians specialized in occupational medicine and oriented toward timely and appropriate return to work.

The study revealed that "medical costs were reduced by approximately 27%, functional outcomes remained the same, workers were less satisfied with their treatment and access to care initially, and employers were much more satisfied with the quality and speed of the information received from the providers." The authors of the article "believe that it was the occupational medicine-based delivery model, working in conjunction with the method of reimbursement and the cultural context of managed care, that was the most significant innovation leading the MCP successes." In the occupational medicine-based model, care was delivered and coordinated by specialists in occupational medicine or primary care physicians specifically trained and working under the on-site, direct supervision of specialists in occupational medicine. According to the authors, "we believe the outcome of the study would have been quite different if the care had been coordinated by internists and family doctors in the traditional managed care mode." (See: Sparks and Feldstein, *The Success of the Washington Department of Labor and Industries Managed Care Pilot Project: The Occupational Medicine-Based Delivery Model*, Journal of Occupational and Environmental Medicine, pp. 1068-1073, Nov. 1997, vol 39, No. 11). This was due to the fact that the occupational physician knew the workplace, the job requirements, and the potential hazards on the job. With this specialized knowledge in hand, the occupational physician can determine the best course of treatment designed to return the employee to work in the shortest amount of time. In addition, the use of board-certified occupational medicine physicians ensures that the quality of care provided injured workers is high.

Quality of care in the workers' compensation system is a major focus of ACOEM. Attached to my comments is a report prepared by ACOEM containing suggestions on how to improve the current system. Following these guidelines will ensure that both employers and employees are satisfied with the quality of care available to injured workers. Central to this is the use of physicians with expertise in workplace injuries and, more importantly, their prevention.

Thank you for allowing me to present ACOEM's views on this important subject. The College is ready to assist the Committee in any way we can as you continue to examine our health care system.

ATTACHMENT

ACOEM's Eight Best Ideas For Workers' Compensation Reform

The American College of Occupational and Environmental Medicine (ACOEM) is the pre-eminent organization of physicians who champion the health and safety of workers, workplaces and environments. To legislators, regulators and those who are considering ways to streamline and improve workers' compensation systems, the physicians who specialize in taking care of America's injured workers offer a list of eight suggestions. The College suggests taking advantage of certain managed care techniques to improve the quality of both medical services and the flow of health care information. This list of ideas is timely, since the latest chapter in evolving national experiment to improve health care includes the rapid expansion of managed care in workers' compensation.

ACOEM is committed to healthy workers, workplaces and environments. The College strongly advocates that changes be made in the current workers' compensation system. Neither injured workers nor employers benefit when the quality and availability of medical care is uneven, or when resources are wasted. As a prevention-oriented specialty, ACOEM believes that one of the best improvements to the workers' compensation system would be to reduce injuries by establishing greater linkages between injury and illness care and prevention programs. Injuries and unnecessary disability are continuing evidence of the failure to implement preventive strategies. The College offers the skills of its members to help improve the system's effectiveness.

ACOEM also recommends changes in specific regulatory and procedural areas which have made recovery from injuries unnecessarily complicated in the workers' compensation system.

1) Refocus safety programs;
2) Link prevention with injury care;
3) Use health professionals appropriately;
4) Actively involve employers and workers;
5) To manage disability sooner;
6) To standardize the ratings process;
7) To encourage innovation while protecting quality; and
8) To collect new kinds of data to improve decision-making.

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1. **View workplace injuries and illnesses as evidence of prevention failure, and use them to target safety and enforcement programs.**

Every workplace injury and illness is a failure of the prevention system. Thus, prevention services should be a central component of workers' compensation programs. However, prevention is much more than correcting physical or tangible hazards and educating or training people. Prevention requires creating

a workplace culture that searches behind the obvious to the root cause of illness or injury, and uses management practices that effectively protect health.

Information about preventable injuries and illnesses should be analyzed for each worksite, and used to direct employers' workplace health and safety programs, insurers'/payers' loss control consultations, and government compliance inspections.

2. **Require active linkages between injury and illness care services, prevention strategies, and disability reduction programs.**

Organizations set up to provide managed health care for workers' compensation should show connections actively linking injury and illness care, prevention, and disability management. For example, patients with injuries requiring more than a few days away from work should receive disability management. Patients with sentinel conditions which may indicate workplace hazards such as toxic exposures or multiple cases of repetitive strain injury should trigger evaluation of the workplace by health and safety professionals.

3. **Make sure that job-related health decisions are made by health care professionals with appropriate training and expertise.**

Occupational Medicine Physicians specialize in work-related health problems as well as health-related work problems. Such specialists are often the best choice to treat or manage any occupational injury or illness. Since qualified occupational physicians are in short supply, other types of physicians frequently must provide initial care.

Occupational medicine expertise should be required of either treating or consulting physicians when the illness or injury:

1. Is unusual or rare outside the workplace, such as toxic chemical exposures or certain repetitive strain injuries.
2. Involves significant questions about safety or temporary or permanent fitness for work.
3. Is the subject of medical uncertainty or dispute as to work-relatedness.

Case Management: Evaluation, coordination, discretionary authorization or management of any ongoing medical care should be performed by or under the direct supervision of physicians or nurses with expertise in medical care management. However, those who provide prompt assistance to injured workers in accessing appropriate, effective and expedient medical care need not necessarily be health professionals.

Utilization Review: Denial of significant treatment should only be done by a physician. Reliance on treatment protocols or practice guidelines as the sole or final basis for denial without consideration of individual patient circumstances is medically unwise. Appeal procedures should require review by a physician with similar and/or appropriate expertise.

Work-Relatedness Determinations: Physicians who determine work-relatedness in medically complex cases should have appropriate expertise. Additionally, such physicians should be broadly informed, objective, and familiar with pertinent evidence, laws and regulations. Work-relatedness decisions in complex cases usually require:

•A review of pertinent objective clinical facts about the health problem;
•An assessment of applicable scientific evidence; and
•Qualitative and quantitative analysis of documented exposures at work.

4. **Expect active participation by both employers and injured workers.**

Employers must inform their employees about their mutual rights, roles and responsibilities in the workers' compensation system, preferably both at the time of hire and immediately post-injury. Employees should be obligated to mitigate their losses following work-related injury or illness, by cooperating fully with reasonable medical therapy and seeking medically-appropriate temporary transitional work.

5. **Begin management of job and life disruption as soon as disability begins.**

The impact of work-related injury and illness on job and life should be actively managed from the outset, even while medical care is ongoing. Employers should be strongly rewarded for providing both temporary transitional duty and permanent modified duty, both of which have been documented to speed recovery and prevent unnecessary disability.

6. **Use evaluation and ratings systems based on objective, standardized methods as the basis for awards for both physical impairment and vocational disability.**

In order to reduce disputes and variability of results, physicians should be required to use standardized technique in physical impairment evaluations, applying methodology adopted by widely-respected national health professional organizations. Since impairment ratings alone are too often unfair when used as the sole basis for determining awards, a similar objective approach should be adopted for evaluating resultant vocational disability. ACOEM recommends that persons with minor, functionally insignificant physical impairments not receive awards, in order to save resources for those with major vocational disadvantages.

7. **Encourage workers' compensation managed care organizations to innovate; when provider choice is limited, require proof of quality.**

Managed care organizations should be encouraged and given the flexibility to innovate as long as they demonstrate a commitment to collect, track and report indicators of performance in quality and service to appropriate regulatory authorities. Quality accreditation of managed care workers' compensation

services by national organizations with health care expertise is recommended to protect employees.

When injured employees are not free to seek care from whomever they choose, employers or managed care organizations should be obligated to demonstrate that providers they select meet commonly accepted medical quality and customer service standards and that the providers impartially attend to the legitimate needs of both patients and employers.

8. **Demand better and more standardized data, and use it to guide medical care, to direct reforms, and to inform purchasers.**

Expand standard data sets. Traditional claims databases are inadequate to support quality improvement in workers' compensation health care and outcomes. Regulators, payers, employers, and service providers should contribute to a standard set of medical, vocational and financial data for every ill or injured worker, preferably in electronic form. These new data will provide detail now unavailable for use in improving the system. Examples of data to be collected are:

•medical diagnosis (by ICD-9 code, or preferably, more appropriate coding systems);
•medical procedures (by CPT code);
•clinical information such as test results;
•a code to indicate biological severity of injury and illness;
•interval between injury and referral to provider;
•provider type;
•nature of job at time of injury;
•pre- and post-injury functional status; and
•changes in work and disability status over time.

Supply data to improve quality and guide buying decisions. Better "report cards" applicable to workers' compensation are urgently needed. Providers and payers should work together to improve measurement of provider performance, and determine customer satisfaction. Feedback to providers can help identify best practices, track progress and improve quality by reducing unjustified variability. Feedback can also guide buying decisions in occupational health care. Electronic interchange of data between employers, payers and providers will help coordinate efforts and improve both quality and outcomes.

Require more standardization. State-to-state variability in terminology, fee schedules, benefits and procedures hampers improvements to the workers' compensation system by making it difficult to collect, interpret or compare uniform data. Simplifying and standardizing will benefit both workers and employers by making it easier to compare the effect of differences in practices, policies or legislative reforms between states.

Conclusion

By implementing all or most of these eight practical recommendations, legislators will be able to both streamline the existing worker's compensation system and reduce the incidence of work-related injury and illness. The result will be better medical outcomes and reduced cost to employers.

This statement was prepared by the ACOEM Committee on Workers' Compensation through a consensus process under the guidance of Jennifer H. Christian, MD, MPH, Chair.

Committee members contributing to the development of this document include:

Managed Care -- Jennifer H. Christian, MD, MPH;

Residency Program -- Ron Leopold, MD, MBA;

Government -- Kathryn L. Mueller, MD;

Academia - Edward J. Bernacki, MD; Jay Himmelstein, MD; Glenn Pransky, MD; Gregory M. Jewell, MD;

Employers - industry -- Alan L. Engelberg, MD; Dan Gerstenblitt, MD;

Health Care Industry - Ronald R. Loeppke, MD;

Workers' Compensation Insurers -- Deborah Day, MD; Jeffrey S. Harris, MD;

Private Practice -- Norbert T. Belz, MD; Stephen A. Dawkins, MD; John W. Ellis, MD; Charles D. Faverio, Jr., MD; Robert L. Goldberg, MD; Kent W. Peterson, MD; Robert L. Ross III, MD; William S. Shaw, MD; Ronald F. Teichman, MD; Craig A. Vitrano, MD.

This committee consisted of ACOEM member physicians representing the broadest possible spectrum of points of view within the College. Thus, the active committee roster included 22 physicians who work in 17 states and who represent government, employers, private practice, academia, practice management, insurance, and managed care companies.

This statement was approved by the ACOEM Board of Directors in May 1997.

American Society for Quality

ASQ

PRESIDENT
Steven F. Bailey
133 Belmont Drive
Wilmington, DE 19808
DuPont Engineering
302-774-2375
Fax 302-774-2458
baileys@engg.dnet.dupont.com

Commentary of the American Society for Quality on Assessment of Health Care Quality in the United States

submitted to the

House Ways and Means Committee
Subcommittee on Health

March 12, 1998

As the Subcommittee on Health of the House Ways and Means Committee continues to assess health care quality, the American Society for Quality is pleased to offer several observations based on the experiences of the nation's quality practitioners.

There are fundamental limitations in the basic approach to health care quality improvement as it is generally practiced in this country. Perhaps the best way to explain is by way of analogy.

If you wanted a cup of cappuccino, you wouldn't expect to get it from your old percolator. It's simply the wrong machine for the job. Why, then, should we expect excellence from our current systems of health care assessment and quality improvement? The machinery we use for the job is not geared toward excellence. Evaluation of quality has been the province of the accreditation and regulatory organizations, using approaches driven instead by considerations of what is acceptable--minimally acceptable--rather than what is optimal.

Turning up the temperature of the percolator won't produce the desired result, nor will endless fine-tuning or retrofitting it with a foam-making attachment. What is needed is new machinery, a new approach. For health care, a way of interjecting an overarching drive for excellence from all elements of the system.

Do such alternatives exist? Yes.

There are systems and methods that are more in tune with the successful methods in the commercial sectors that have reinvigorated American enterprise and made it the most successful anywhere. Systems designed to aggressively pursue excellence. And to focus on customers as the starting and ending point in quality improvement efforts.

The most widely applied and universally recognized are the approaches spelled out in the ISO 9000 series of international quality systems standards and the Criteria for Performance Excellence of the Malcolm Baldrige National Quality Award. The appeal of these approaches for health care lies in their universality, in their focus on the customer, and in their emphasis on prevention through process management.

Some recent studies have shown that problems in how health care institutions work--rather than problems in how individual health care practitioners do their jobs--lead to mistakes that put patients at risk; nevertheless, because most efforts to find the cause of medical errors seek individuals, many problems do not get fixed. Rather than using inspection-based methods to look for the exceptions and then fix the blame for things gone wrong, the approaches behind Baldrige and ISO 9000 focus on quality management of processes that provide reasonable assurance that things will go right, from the perspective of the customer or patient.

In addition to eliminating errors, this same process management approach is useful in eliminating waste from the system--which is a far more powerful approach than simply wringing cost out of the system.

The merits of these approaches have been tested and proven in American business. ISO 9000 is well known and accepted throughout the world. We know of one hospital that has jettisoned its accreditation process and replaced it with ISO 9000 registration. Whether this becomes a widespread trend remains to be seen, but we do know that many health care institutions are investigating the use of ISO 9000, including federal health care facilities. Certain segments of private industry that are large purchasers of health care services, such as the automotive industry, have come to rely on ISO 9000 and require it of their suppliers. We believe that some of these same businesses will put pressure on their health care suppliers to adopt methods in line with the ISO 9000 approach and the Baldrige criteria. A new revision of the Baldrige Criteria for Performance Excellence has just been published specifically for health care. This follows several years of work that included pilot programs to test the applicability of the widely followed Baldrige criteria in a health care setting. We see many opportunities opening up in the months and years ahead to apply these alternative approaches in health care.

The American Society for Quality encourages the Subcommittee on Health of the House Ways and Means Committee to investigate these options, either as alternatives or as ways to augment and broaden current health care quality assessment approaches.

The 3000-member Health Care Division of the American Society for Quality is actively involved in promoting the wider application of these principles in health care settings. We would be pleased to provide additional information to this Subcommittee.

About the American Society for Quality

The American Society for Quality (ASQ) advances individual and organizational performance excellence worldwide by providing opportunities for learning and knowledge exchange in all facets of quality improvement.

As the leading quality improvement organization in the United Sates for more than 50 years, the Society currently has more than 133,000 individual members and 1,100 corporate sustaining members worldwide. Individual members belong to one of 251 local sections located throughout the United States, Canada, Mexico, and Puerto Rico. ASQ also is organized into 22 Divisions, which are special interest groups organized along the lines of specific industries or technical areas.

The American Society for Quality is a 501(c)3 not-for-profit organization incorporated in the state of New York and headquartered in Milwaukee, Wisconsin.

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AMERICAN SOCIETY OF
PLASTIC AND RECONSTRUCTIVE
SURGEONS

STATEMENT OF THE

AMERICAN SOCIETY OF PLASTIC AND RECONSTRUCTIVE SURGEONS

EXECUTIVE OFFICE
444 EAST ALGONQUIN ROAD
ARLINGTON HEIGHTS, IL 60005
(847) 228-9900
FAX (847) 228-9131

STATEMENT

OF

DENNIS J. LYNCH, MD

PRESIDENT
AMERICAN SOCIETY OF PLASTIC
AND RECONSTRUCTIVE SURGEONS

BEFORE THE

HOUSE COMMITTEE ON WAYS AND MEANS
SUBCOMMITTEE ON HEALTH

February 26, 1998

Contact: Jon Kent
202/223-6222

The American Society of Plastic and Reconstructive Surgeons (ASPRS) wishes to thank the Health Subcommittee of the House Ways and Means Committee for the opportunity to testify on issues of health care quality and accountability.

ASPRS represents 97% of the nearly 5,000 board certified plastic surgeons in the United States. Plastic surgeons provide highly skilled surgical services which improve both the functional capacity and quality of life of our patients. These services include the treatment of congenital deformities, burn injuries, traumatic injuries, and cancer. In treating conditions such as breast cancer or children's deformities, plastic surgeons are usually part of a larger medical team which is called in to provide treatment. For example, with breast cancer patients, plastic surgeons focus on reconstruction of the breast after a mastectomy is performed, in cases where the patient elects reconstruction.

ASPRS applauds efforts to improve the quality of the health care delivery system in this country. Consumer protections, such as a process for appealing denials of care and preventing health plans from interfering with physician communication about treatment options, provide assurances to patients that the health plan they pay for is not sacrificing their health needs in the name of profit. However, more must be done to ensure that patients are able to receive the care they need when they need it the most. All health plans should be required to provide a basic, minimum level of coverage to their beneficiaries and must not be allowed to deny medically necessary services to those patients who need them. Physicians and patients should not have to fight the insurance company at the same time they are fighting a disease.

Our statement focuses on two areas of treatment where we have observed troubling trends of increasing number of denials of insurance coverage. These are breast reconstruction after a mastectomy and children's deformities and congenital defects. In both cases, denials of coverage for necessary medical care threaten vulnerable populations which increasingly bear the brunt of cost-cutting measures by health plans. Further, these procedures were covered by insurance routinely, even as recently as five years ago, but are not any longer.

Breast reconstruction is essential in restoring breast cancer survivors' sense of wholeness and well being. Some insurance companies have decided to deny women coverage for all or part of breast reconstruction on the basis that the surgery is "cosmetic," not reconstructive. ASPRS has been made aware of the problems of obtaining insurance coverage for post-mastectomy breast cancer cases as we have worked long and hard with our patients to obtain the insurance approvals. We have met the resistance expressed in the San Jose, California, *Mercury News* opinion by Joseph Aita, Executive Vice President and Medical Director of LifeGuard, "Looking normal is not medically necessary."

The need for breast reconstruction goes much deeper than looking normal. It is the broad range of psychological problems that one sees in the post-mastectomy patient who is denied reconstructive surgery, which are our concerns. Also, the fear of losing a breast is a leading reason why many women do not participate in early breast cancer detection programs. With breast reconstruction available as an option, more women would not be afraid to detect their cancer at an early stage.

Insurance carriers pay for prosthetic eyes, hips, and nasal reconstructions after tumor incisions. Similarly, breast reconstruction is a reconstructive, not cosmetic procedure. It is performed on abnormal structures to restore them to a more normal state. Insurers should not be allowed to discriminate against the female breast for reconstructive coverage.

To find out how widespread these denials have become, ASPRS surveyed its members recently. The survey revealed that 84% of plastic surgeons across the country reported up to 10 patients each who were denied coverage in a one-year period.

Plastic surgeons have available a number of methods to reconstruct the removed breast or breasts, since some women have both breasts removed for cancer. The methods include the use of tissue expansion and implant, use of flap from the back with an implant, and the use of the patient's own tissue, without an implant, using abdominal or other tissue.

The concept of complete reconstruction is also very important. We create the breast mound, then we add the nipple and areola. Not infrequently, we need to change the opposite breast by surgery in order to obtain symmetrical or equal size breasts so the patient is normal and feels whole again.

Not all post-mastectomy patients desire reconstruction, but for those who do, it is extremely frustrating for the plastic surgeon not to be able to help them. We have numerous letters from patients expressing their frustration and anger over the denial of breast reconstruction by their insurer. In response to the public outcry, twenty-six states have passed laws requiring breast reconstruction coverage after mastectomy, including 13 states just in 1997. However, many Americans receive health insurance benefits through self-funded, federally-regulated ERISA plans which are not covered by state insurance requirements. Federal legislation would guarantee access to breast reconstruction to all women who undergo a mastectomy.

For this reason, ASPRS supports the Women's Health and Cancer Rights Act of 1997 (HR 616 and S 249) introduced by Rep. Sue Kelly (R-NY) and Sen. Alfonse D'Amato (R-NY) and the Breast Reconstructive Surgery Act of 1997 (HR 164 and S 609) introduced by Rep. Anna Eshoo (D-CA) and Sen. Edward Kennedy (D-MA). These bills would require insurance companies that provide coverage for mastectomy to cover breast reconstruction resulting from the mastectomy, including procedures to restore and achieve symmetry on the opposite breast.

Another, even more recent trend, is beginning to be documented in media reports. An increasing number of children face a growing problem of managed care and insurance companies denying insurance coverage for facial deformities and disfigurement, as well as other congenital defects. This fact is confirmed in a recent survey of our members, indicating that over half of plastic surgeons surveyed have had a pediatric patient who in the last two years has been denied or experienced difficulty in obtaining insurance coverage for those procedures.

Children who do not have their facial anomalies repaired face long-term physical and psychological injuries. Surgeons are able to perform the necessary surgeries, but again, some insurance companies claim that these services are "cosmetic" in nature, especially subsequent stage surgeries. Like other forms of reconstruction, surgery to repair facial deformities is reconstructive, being performed on abnormal structures to restore them to a more normal state. The function of the

face is to appear normal. Insurers should not be allowed to discriminate against children born with deformities in this latest attempt to cut costs by denying necessary care.

In December, 1997, the American Medical Association recognized this reality and approved a resolution declaring that treatment of a minor child's congenital or developmental deformity or disorder due to trauma or malignant disease should be covered by all insurers, and such coverage shall include treatment which, in the opinion of the treating physician, is medically necessary to return the patient to a more normal appearance.

We agree with the *American Medical News* editorial of January 26, 1998:

> By now the file of horror stories is pretty thick. Yet some instances of insurer callousness to patient suffering stands out. A case in point is the refusal by some health plans to pay for proper medical treatment of children with physical defects and deformities. ... The dodge that health plans use is to declare surgery designed to create a normal appearance as "cosmetic" and therefore outside the scope of coverage. It is a classic health plan word game ... But this particular variant is among the worst we've encountered, because the biggest losers are children and their frantic parents.

ASPRS appreciates the opportunity to testify before the Subcommittee, and would be pleased to serve a resource as Congress continues its work on health care quality and accountability issues.

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Written Statement of Craig Copeland

Research Associate

Employee Benefit Research Institute

for
The House Ways and Means Subcommittee on Health

Hearing on
"Assessing Health Care Quality"

Washington, D.C.
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The views expressed in this statement are solely those of the author and should not be attributed to the Employee Benefit Research Institute, or the EBRI Education and Research Fund, its officers, trustees, sponsors, or other staff, or to the EBRI-ERF American Savings Education Council. The Employee Benefit Research Institute is a nonprofit, nonpartisan, public policy research organization which does not lobby or take positions on legislative proposals.

STATEMENT SUMMARY

Despite the success attributed to managed care in slowing the increases in medical care costs, managed care has come under intense scrutiny. Physicians, consumer advocates, and some policymakers believe that some of managed care's success in controlling costs has been achieved by denying necessary medical services. However, employers and managed care organizations argue that managed care has eliminated much of the wasteful spending in the health care market while still maintaining the quality of the care provided. In fact, the research thus far shows that managed care plans as a whole provide quality of care equal to that provided in fee-for-service plans.

Once the discussion of health care turns to quality, a question arises concerning what quality is in the health care market. Quality is a multidimensional concept. Even though individuals may agree on its components, they may disagree on their relative importance.

Some individuals equate access with quality. Others would include in their definition of quality how respectfully their providers deal with them, to develop a consumer satisfaction definition of quality. However, an individual's satisfaction may not directly correlate with receiving the most appropriate care for a diagnosis or even a proper diagnosis. Consequently, the outcome of care is widely believed to be an indicator of quality in health care. A high quality episode of health treatment would then involve being treated under the method that restores the individual's health in the shortest amount of time at the lowest level of risk. Even under this definition, there is no clear way to measure quality because different individuals respond to treatments in very different ways. Thus, it is difficult to agree on one definition of quality that fits all circumstances, which makes measuring quality all the more complex.

Studies that attempt to measure quality can be classified into three categories: structure, process, and outcomes. Because quality has many dimensions, a complete measure of quality cannot fall into just one of these dimensions but needs to include all three. A measure of quality based on structure is not worthwhile if it cannot be shown to lead to good outcomes, while an outcome measure is not complete if the process that was used to achieve the outcome is unknown. Consequently, in order to get a clear picture of the quality of health care provided, a measure must evaluate all three dimensions.

Progress has been made toward the goal of measuring the quality of care provided in managed care plans. The Health Plan Employer Data and Information Set (HEDIS) has continued to be refined by the National Committee for Quality Assurance (NCQA) for the purpose of providing multidimensional report card on these plans' quality. HEDIS allows purchasers of health plans to compare managed care plans that are included in this report card. Currently, HEDIS focuses on structure and process measures of quality. However, as advances in outcome measures have been made, HEDIS has expanded its reliance on outcome measures. A significant drawback to HEDIS type-report card measures of quality is that they lead plans or providers to focus resources on the factors that are measured, diverting resources from those that are not measured. Consequently, any report card of this type must balance comprehensiveness against understandability, so that purchasers get an accurate depiction of the quality a certain plan provides in a manner that is easy to understand.

The quality of managed care plans relative to fee-for-service plans has not been demonstrated to be uniformly different in either a positive or a negative way. Thus, HMOs are not low or high providers of quality per se but range from good to poor, with strengths and weaknesses in the care of particular diseases. Therefore, quality measures are needed to evaluate individual health plans for various diseases and conditions rather than for broadly defined categories.

Regulations and mandates for "consumer protections" are not a guarantor of increased quality in the health care market, unless quality is defined as easier access for those with health insurance. However, if quality is defined as successful outcomes of health services provided, the effect of these regulations on quality is in need of further research. However, the regulations will have some impact on the costs of health benefits and insurance. The impact has been estimated to be relatively small to substantial, depending on the interpretation of the mandates and the assumptions derived from that interpretation. Consequently, as studies show, even a small increase in the costs of health insurance could lead to a sizable number of individuals without health insurance, especially employees of small businesses.

STATEMENT

Introduction

In the last decade, substantial changes have occurred in the health care market. Many of these changes were prompted by employers who were no longer able or willing to accept the relatively large annual increases in medical care costs that occurred during the late 1980s and early 1990s. The fee-for-service system of reimbursing health care providers was one of the causes attributed to these substantial increases.[1] Under this system, providers were reimbursed retrospectively for the services they performed. Thus, providers did not have economic incentives to control costs or to perform only services for which the benefits outweighed the costs or risks. In addition, the fee-for-service system tended to focus on the treatment of illnesses as opposed to their prevention. As employers searched for methods to reduce annual health care cost increases to a manageable level, they turned to managed care as their vehicle for providing health benefits to their employees. They embraced managed care because this system provides financial incentives to control costs, e.g., payments to providers are structured to reward an efficient level of care such as a capitated payment (a fixed fee to cover all services provided), salaries, and bonuses. Furthermore, managed care organizations (MCOs) have developed guidelines for the treatment of various illnesses to promote more efficient care. These incentives and guidelines, designed to reduce expenditures for unnecessary utilization, have been the primary factors in the success attributed to managed care. This system in turn has led to significantly smaller increases in medical care costs in recent years. Today, managed care plans have become the overwhelmingly dominant type of health care coverage for the nonelderly population because of their success in controlling costs.

Despite its success in slowing increases in medical care costs, managed care has come under intense scrutiny. Physicians, consumer advocates, and some policymakers believe that part of managed care's success in controlling costs has been achieved by denying necessary medical services. In addition, many consumer advocates contend that employers and health plans are more concerned with reducing costs than with increasing the quality of care provided. Consequently, policymakers have responded by introducing numerous legislative proposals at both the state and federal level to regulate the operation of managed care plans. However, employers and MCOs argue that managed care has maintained health care quality while eliminating much of the wasteful spending in the health care market. In fact, the research thus far shows that managed care plans, as a whole, provide quality of care equal to that provided in fee-for-service plans.[2] Furthermore, employers contend that managed care's success in reducing costs has allowed them to continue to provide health benefits for their employees. Yet, due to managed care opponents' doubts about the quality the system provides, many employers require that managed care plans prove they provide high quality health care. These demands have focused a great deal of attention in the marketplace on the development of quality measures that both employers and consumers will find easy to understand.

This statement looks at quality in the health care market as well as the potential effects of regulations ("consumer protections") on health plans in terms of costs and the number of uninsured. In addition, it discusses the impact of these various regulations on quality in the health care market.

Quality[3]

The perception that health care costs are under control and/or the belief that MCOs reduce costs by denying necessary care has led many health care market observers to question the quality these organizations provide. However, once the discussion of health care turns to quality, a question arises about what defines superior quality in the health care market. Quality is a multidimensional concept. Thus, even though individuals may agree on the components, they may not agree on their relative importance. Therefore, analysts disagree not only on how to measure quality but also on how it is defined. Consequently, policy decisions on health care quality should be based on an evaluation of a particular law's actual effect as opposed to its stated goal or intent. This distinction is important because a law that addresses access or consumer rights does not necessarily address the quality of care a consumer receives. Ultimately, whether a law truly addresses quality will depend in large part on an individual's subjective opinion of what quality entails.

Defining Quality

Some individuals equate access with quality. If they can choose freely among providers, they believe they are receiving quality health care. However, these consumers may not choose the providers who can treat them most effectively, whereas a managed care plan may provide an incentive for the consumer to use providers who are most qualified to treat them. However, the reverse situation could also occur. Other individuals would include in their definition of quality how respectfully their providers deal with them. Here again, an individual's satisfaction may not directly correlate with receiving the most appropriate care

for a diagnosis or even a proper diagnosis. Consequently, the outcome of people's care is widely believed to be the best indicator of quality. A high-quality episode of health treatment would then involve being treated according to a method that restores the individual's health in the shortest amount of time at the lowest level of risk. Even under this definition, there is no clear way to measure quality because different individuals respond to treatments in very different ways. Thus, it is difficult to agree on one definition of quality that fits all circumstances. This in turn makes measuring quality even more complex.

Measuring Quality

Studies that attempt to measure quality can be classified into three categories: (1) structure, (2) process, and (3) outcomes.[4] Structure studies examine the characteristics of the providers or institutions of care such as providers' credentials or hospitals' teaching status. In process studies, the methods that providers use to make treatment decisions are evaluated through, for instance, the investigation of the use of specific protocols or a treatment's appropriateness. Outcome analysis measures the patient's resulting health status or patient satisfaction. However, a complete measure of quality must evaluate all three of these dimensions. A measure of quality based on structure is not worthwhile if it cannot be shown to lead to superior outcomes, while an outcome measure is not complete if the process that was used to achieve the outcome is unknown.

Progress is being made in measuring the quality of care provided in managed care plans. The Health Plan Employer Data and Information Set (HEDIS) has continued to be refined by the National Committee for Quality Assurance (NCQA) to furnish a more multidimensional report card on the quality of care provided by managed care plans. HEDIS allows purchasers of health plans to compare managed care plans that are included in this report card of quality. Currently, HEDIS focuses on structure and process measures of quality. However, as advances in outcome measures have been made, HEDIS has expanded its reliance on outcome measures. These advances are difficult because a large number of factors can affect the outcome of a health care treatment, and there is a need to control for all of the factors that could affect a measure when it is compared across plans or providers. A significant drawback to HEDIS-type report card measures of quality is that they lead plans or providers to focus resources on the factors that are measured, diverting resources from factors that are not measured. Consequently, any report card of this type must balance comprehensiveness against understandability, so that purchasers get an accurate depiction of the quality a certain plan provides in a manner that is easy to understand.

Quality of Managed Care Plans

To date, a comparison of the quality of managed care plans relative to fee-for-service plans has not produced evidence that these two plan types are uniformly different in either a positive or a negative way. A review by Miller and Luft[5] of various studies comparing the quality of HMOs versus fee-for-service plans points out, "HMOs produce better, the same, and worse quality of care, depending on the particular organization and particular disease." Thus, HMOs are not providers of high or low quality per se but range from good to poor, with strengths and weaknesses in the care of particular diseases.[6] Therefore, measures of quality are needed to evaluate individual health plans in terms of various diseases and conditions rather than more broadly defined categories.

It is important to note that the current debate on the quality of care in the health care market is not new to the present managed care era. As Millenson[7] points out, *The New York Times* ran features on the failings of doctors and hospitals in the United States in 1976, and a 1982 President's Commission report concluded that as much as 35 percent of some high-tech hospital care was unnecessary. Thus, Millenson concludes that "deep public dissatisfaction with unfettered doctor and hospital autonomy led to the explosive growth in managed care in the first place."

Quality and Regulations of Health Plans

Proponents of the various regulations of health plans argue that these regulations will increase the quality of health care. However, if these regulations are to be truly considered quality of care measures, they should guarantee that health care consumers will receive a higher quality of health care. The regulations might lower obstacles to access to certain types of care that insured individuals may or may not need. They might also increase insured individuals' satisfaction. In addition, providers of health care would gain protections from various techniques that some MCOs use to limit the way providers practice medicine. Yet, the regulations would do very little to ensure improvement in the outcomes of health care treatments administered by medical providers. Therefore, policymakers need to thoroughly understand the effects of these regulations on the health care market.

Access, consumer satisfaction, and provider protections are important components of the health care market, but improvements in these components would not necessarily improve the overall quality of health care. However, they would increase costs, which could have serious consequences in terms of the number of uninsured individuals. Although estimates of the impact of the cost increases on the number of uninsured

have not been developed for most of these consumer "rights" issues, the Congressional Budget Office (CBO) estimated that for a mental health parity amendment in H.R. 3103 (introduced in 1996) a 4 percent increase in health insurance premiums would lead to 800,000 fewer people having health insurance.[8] In a general analysis of increases in health insurance premiums for employers, The Lewin Group estimates that a one percent increase in employer premiums would lead to an additional 400,000 individuals being uninsured. Thus, if the regulation of health plans has even a relatively small impact on costs, a significant number of people could potentially lose health insurance coverage. Access could be reduced for some in order to increase the satisfaction of those who still have insurance. In addition, health plans and their sponsors contend that these regulations would reduce quality, because plans and sponsors would have limited ability to steer patients to higher quality providers and to enforce protocols for treating various diseases that have proven to be the most effective methods for treating these diseases.

Regulations of Health Care Plans

Managed care's new dominance in the health care market has changed the organization, financing, and delivery of health care. These changes have prompted discussion of the potential need for additional consumer protections or rights within this new structure. Health care consumers are worried about any restrictions on their access to physicians and to various forms of care (e.g., emergency room care, experimental treatments) and about their ability to dispute denied claims or services. In addition, potential limitations on providers, such as so-called "gag rules" and network participation rules, have also come under scrutiny, because they have the potential to undermine the physician/patient relationship.

In response to real or perceived negative reactions to managed care, state lawmakers have proposed and passed many laws or imposed regulations that claim to provide protections for managed care plan participants and to increase the quality of care. These measures are commonly referred to as anti-managed-care legislation by the managed care industry, because they would limit or forbid certain activities that are thought to be used by managed care plans while forcing the plans to perform other new or additional activities. State lawmakers introduced over 1,000 bills relating to health plans by mid-year 1997, of which 20 percent were enacted.[9] Federal lawmakers have also introduced legislation in this area, using either single-issue proposals or comprehensive packages such as the Patient Access to Responsible Care Act (PARCA) (S. 644/H.R. 1415) introduced by Rep. Charles Norwood (R-GA) and Sen. Alfonse D'Amato (R-NY).

Discussion of Regulations of Health Plans

Consumer advocates and some policymakers believe that more regulation and increased liability exposure would increase the quality of care health plans provide. In addition, these groups contend that mandating patients' right to have coverage for the services of any physician they choose would also enhance quality of care. They maintain this opinion because legislation in these areas would greatly reduce any existing barriers to the physician/patient relationship. However, plan sponsors and health plans contend that these measures would increase costs and thus reduce the ability of employers and unions to provide health benefits as well as individuals' ability to afford employer-sponsored health coverage. Consequently, more individuals would become uninsured. Furthermore, health plans argue that an increase in mandates would reduce individuals' choices among plan types. Under the proposed mandates, individuals who may not want a certain benefit would be forced to pay for it if they choose to have any coverage. The same idea would hold true for plan sponsors in their decisions to offer health benefits.

Regulations and mandates for "consumer protections" are not a guarantor of increased quality in the health care market, unless quality is defined as easier access for those with health insurance. However, if quality is defined as successful outcomes resulting from health services provided, these regulations' effect on quality is in need of further research. The regulations would have some impact on the costs of health benefits and insurance. This impact has been estimated to be relatively small to substantial, depending on the interpretation of the mandates and the assumptions based on that interpretation.[10] Despite the wide range of estimates, any increases in the cost of health benefits could have serious implications for the likelihood of small businesses offering health benefits. Feldman et al.[11] estimated that in the state of Minnesota, a $1 increase in monthly premiums would lead to an approximate decrease of 0.017 in the proportion of small establishments (with fewer than 50 employees) offering health insurance. Consequently, if these regulations raise the costs of health insurance significantly, a potentially sizable number of individuals could be without health insurance, especially employees of small businesses.

Conclusion

The health care market has undergone significant change in the last decade. One of the most significant changes has been the huge shift from fee-for-service to managed care for health care coverage. This change was precipitated by the tremendous increases in health care costs. During the shift to managed care, health cost increases have abated. As costs appeared to be under control, many observers began questioning the

quality that was being provided under this new system of managed care. Some have suggested that managed care has brought costs under control by denying necessary care. This belief has led to a tremendous push by consumer advocates for the regulation of MCOs to ensure quality.

The regulations that have been introduced can just as easily be categorized as access measures or provider protections as they can be categorized as quality measures. The determination of whether the regulations discussed in this report actually improve the quality of health care provided depends on one's definition of quality. If a definition only addresses access and consumer satisfaction, these regulations might provide some improvement in quality.[12] However, if the definition of quality refers to the outcome of a health care treatment, these regulations are of questionable value. While they do address consumer rights, it is debatable whether these rights are necessary considering the expense they add to the provision of health care coverage.[13]

While these regulations' effect on quality depends on one's definition of quality, the effect on costs is clear regardless of the definition of quality—an increase. As stated before, any increases in costs will almost certainly increase the number of uninsured. Consequently, these regulations would come at price. Thus, the choice is between regulation that would increase access and consumer "rights" but would be of questionable value in relation to the quality of outcomes versus allowing market forces to improve quality through experimentation. Recent experimentation has led to some competition on quality through the use of such quality indicators as HEDIS, but the level of the quality of care provided still remains a hotly debated topic.

Endnotes

[1] The tremendous growth in technological innovations in health care is another important cause attributed to the increases in medical care costs.
[2] Robert H. Miller, and Harold S. Luft, "Does Managed Care Lead to Better or Worse Quality of Care," *Health Affairs* (September/October, 1997): 7-25; and Robert H. Miller and Harold S. Luft, "Managed Care Plan Performance Since 1980: A Literature Analysis," *Journal of the American Medical Association* (May 18, 1994): 1512-1519.
[3] For a more thorough discussion of quality in the health care market, see William Custer, "Measuring the Quality of Health Care," *EBRI Issue Brief* no. 159 (Employee Benefit Research Institute, March 1995). This section draws from that report.
[4] Avedis Donabedian, "The Quality of Care: How Can It be Assessed?," *Journal of the American Medical Association* (September 23-30, 1988): 1743-1748.
[5] Miller and Luft, *Health Affairs*, 1997.
[6] There appears to be some limited evidence that HMOs provide lower quality of care for chronic physical conditions. However, this has not been universally demonstrated (Miller and Luft, *Health Affairs*, 1997).
[7] Michael L. Millenson, "Beyond the Managed Care Backlash: Medicine in the Information Age," Health Priorities Project Policy Report No. 1 (Washington, DC: Progressive Policy Institute, July 1997).
[8] The CBO has subsequently cautioned that this estimate cannot be generalized to all mandates on health insurance, because people may place different values on other mandates, which would affect the number of employers continuing to offer health insurance and the number of people taking it up.
[9] "1998 Industry Outlook: Quality," *Healthcare Trends Report* (January 1998).
[10] Millman & Robertson conducted an analysis of PARCA, which contains many of these regulations, for Wal-Mart and determined that health insurance premiums would increase between 7 percent and 39 percent. However, they did not examine the health plan liability issue. Muse & Associates also examined PARCA in a study funded by members of the Patient Access to Responsible Care Alliance and determined that health insurance premiums would increase between 0.7 percent and 2.6 percent.
[11] Roger Feldman, Bryan Dowd, Scott Leitz, and Lynn A. Blewett. "The Effect of Premiums on the Small Firm's Decision to Offer Health Insurance," *Journal of Human Resources* (Fall 1997): 635-658.
[12] In Miller and Luft's (*JAMA*, 1994) review of managed care quality studies, they found that HMO enrollees were generally satisfied with their care. However, HMO enrollees appear to be less satisfied with the quality of their care relative to fee-for-service plan enrollees. Yet, in terms of satisfaction with financial aspects of the plan, HMO enrollees were more satisfied than fee-for-service plan enrollees. Thus, some patients appear to be willing to trade some quality satisfaction for lower costs.
[13] A survey by the Kaiser Family Foundation and Harvard University found overwhelming support (72 percent in favor) for the consumer bill of rights endorsed by President Clinton. However, if the bill of rights were to increase monthly premiums by $15 to $20, the support erodes tremendously (only 28 percent would favor) See Kaiser Family Foundation/Harvard University. *National Survey of Americans' Views on Consumer Protections in Managed Care* (The Henry J. Kaiser Family Foundation: January 21, 1998).

National Partnership
for Women & Families

**TESTIMONY OF THE NATIONAL PARTNERSHIP FOR WOMEN & FAMILIES
BEFORE THE SUBCOMMITTEE ON HEALTH
OF THE HOUSE COMMITTEE ON WAYS & MEANS
ON "ASSESSING HEALTH CARE QUALITY"**

February 26, 1998

**Statement of Judith L. Lichtman, President
National Partnership for Women & Families
1875 Connecticut Ave., NW #710
Washington, DC 20009**

The National Partnership for Women & Families is a nonprofit, nonpartisan organization that uses public education and advocacy to promote fairness in the workplace, quality health care, and policies that help women and men meet the dual demands of work and family. A key priority for the National Partnership is to ensure that women enrolled in health insurance plans, particularly "managed" health plans, receive the highest quality care.[1]

Our health care system is undergoing unprecedented changes, most notably the dramatic rise of managed care. These changes will affect every one of us, and women in particular have a tremendous stake in the outcome. Women are the primary consumers of health care services in the country, as well as the majority of managed care enrollees. They are the majority of those on Medicare and the overwhelming majority of adults on Medicaid -- programs that are increasingly turning to managed care. They also make the bulk of health care decisions for their families, including which plan to join, and they spend most of our health care dollars. From making decisions about which health plan will best serve their families' needs, to weighing options about their own health care, women's lives are being dramatically affected by the rise of managed care.

Women have a real stake in how health care services are delivered for other reasons as well. They have unique health care needs that include, but are not limited to, their reproductive capacity. Some diseases (such as osteoporosis and eating disorders) are more prevalent in women, and others (such as heart disease) are too often ignored, misdiagnosed, or mistreated. Moreover,

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[1] Neither I nor the National Partnership for Women & Families, nor the Women's Legal Defense Fund (our name until February 24, 1998) has received any federal grant, contract, subgrant, or subcontract from the federal government during the present or two preceding fiscal years.

women and men with the same underlying disease do not always have the same symptoms, nor do they have the same risk factors. Cutting-edge research continues to shed more light on these gender differences. And finally, differences in social roles and behaviors can have significant implications for women's health. For example, women, much more than men, are the victims of domestic violence in our society. To appropriately diagnose and treat women, health care professionals -- and the health plans that increasingly determine the care they provide -- need to understand the substantial impacts of gender and be specifically trained to provide health care to women.

Managed care has great potential. Its promise is to save money and provide more better quality care through better coordination of services and a strong emphasis on preventive and primary care. Managed care plans are also uniquely positioned to educate millions of women and men about how to get and stay healthy. Women, especially, stand to benefit from managed care done right. A quality managed care plan can make it easier for women to learn about and obtain services such as mammograms, Pap smears, and prenatal care, as well as health-promoting benefits from smoking-cessation classes to discounted health club memberships. In addition, a good relationship with a well-trained primary care provider can give women a chance to get answers to health questions that might otherwise go unasked. But providing quality health care is about much more than just delivering preventive services.

Over the past few years, managed care's potential has been eclipsed by concerns that for some it may do more harm than good. The American public, including America's women, has become increasingly worried that the legitimate interest in controlling costs could compromise the quality of care provided through managed care plans. Drive-through deliveries and outpatient mastectomies may be fine for some women, but as standard operating procedure, they are glaring examples of how women can find themselves at risk if the balance between cost and quality goes awry. Other risks, less dramatic but no less serious, can range from plans not having enough doctors to meet women's needs, to refusing to inform patients about new forms of treatment. Women's health hangs in the balance that managed care plans strike between cost and quality.

Consumer protections now vary widely within states and state-to-state. As a result, where you live and what kind of employer you work for dictate what consumer protections are available. Approximately 40 percent of people enrolled in ERISA plans (about 50 million people) are in *self-insured* ERISA plans that cannot be regulated by state consumer protection laws. So, even though many states have taken tremendous steps in creating protections for health care consumers, many people who live in those states remain virtually unprotected. As a result, to ensure minimum standards for *all* plans, women and their families need *enforceable national standards* -- a federal floor of basic consumer protections for everyone, to which states may add additional levels of protection if they so desire.

We need a comprehensive approach, and one that will tip the balance back in favor of consumers. After all, the goal is -- or should be -- to ensure that consumers get the high-quality, affordable health care services they need, and the time has come for Congress to act.

Requiring all health plans to meet certain standards assures a minimum level of quality. It lets the marketplace compete better *on the basis of actual plan performance* -- not on things that should be "givens" -- such as whether the plan provides access to emergency services under the "prudent layperson" standard. It also helps individual consumers make wise choices for themselves and their families by allowing them to make choices based on their own individual needs. For example, if all plans are required to allow women direct access to obgyn services, a woman will not have to look for a plan that allows this; instead, she can focus on choosing a plan that best serves her personal needs, such as a plan that includes a particular provider who specializes in treating a medical condition she, or a member of her family, may have.

Protections like these, and many others, are already a standard part of many health plans. Good plans have voluntarily stepped up to the plate and demonstrated their commitment to quality. Consumers want value for their health care dollars, and good plans know that value means high quality at an affordable cost.

Government and private purchasers of health care are increasingly demanding value for their dollar. Purchasers remain legitimately concerned about cost, but they also want to provide their employees or beneficiaries a plan that will deliver high quality care. Many plans know that their continued success depends on meeting these expectations.

The National Partnership for Women & Families, in collaboration with other groups concerned about quality health care for women, has developed a set of guiding principles that establish the minimum standards by which health plans should be judged. These "Principles for Quality Health Care" address basic consumer protections and quality standards that are important to women. They can and should be used by advocates, policy-makers, providers, health care purchasers, and the media to further the public policy debate and focus attention on women's health concerns.

We focus here on the consumer protections that are particularly important to women -- mechanisms and processes that all health insurance plans need to adopt to improve the quality of health care specifically for women. In addition to our women-specific principles, there are a host of consumer protections that **all** consumers need.

1. A full range of health care services to meet women's needs.

> Women need access to a full range of health care services -- from preventive care such as osteoporosis screening and family planning services to treatment for acute, chronic, or disabling conditions such as heart disease, cancer, arthritis, and depression. Many plans do not cover prescription contraceptives, even though they cover other prescription drugs.

2. Choice of primary care provider.

Women should be able to choose primary care providers -- the gatekeepers for many managed care plans -- that best fit their current health needs. A woman in her reproductive years may prefer to see an ob-gyn provider for her primary care, while an elderly woman may prefer someone with specific training or expertise in geriatrics. A woman should also be able to choose a pediatrician as the primary care provider for her children. The key is choice and flexibility -- let each woman decide what is best for her and her family.

3. Direct access to ob-gyn services.

Women have unique reproductive health care needs. If a woman's primary care provider is not an ob-gyn, she should be able to see a provider of ob-gyn services without having to get a referral.

4. Access to family planning clinics and other community-based providers.

Women enrolled in managed care plans, especially women who have no choice of what plan to join, should be able to continue receiving certain types of care from providers they have come to rely on and can get to easily. This is especially important when it comes to family planning and other reproductive health services. Young women and teens, for example, may be more comfortable learning about sexually transmitted diseases and pregnancy prevention from community providers they have established relationships with. These community providers are often better able to bridge the cultural, language, and transportation barriers that limit access to care for many low-income and minority women.

5. Continuity of care.

A woman in the middle of treatment should not have to change providers because her provider leaves the health plan or her employer switches health plans. This is especially important for pregnant women (regardless of the stage of pregnancy), women undergoing an intensive course of treatment such as treatment for breast or ovarian cancer, and women with a mental illness, where an established relationship is critical to the treatment's success.

6. Final medical decisions by the patient's provider.

Health care decisions -- including how long patients stay in the hospital -- should be made by trained medical professionals who are in the best position to observe, listen to, and evaluate their patients' needs. Health plans should not be able to override these decisions by imposing arbitrary limits on how services are delivered.

For some women, an outpatient procedure works fine; for others, inpatient surgery is a must. Providers must base their treatment decisions on their patient's individual responses, and therefore, should have the final say in deciding how and where treatment is administered.

7. Respect and nondiscrimination.

Both plan members and health care professionals should be treated with respect and should not be discriminated against on the basis of gender. Plans should not be allowed to refuse women coverage or to limit enrollment of women because they use more health services. Nor should plans discriminate against specific groups of women, such as low-income, older, or seriously ill women. Plans also should not exclude providers that may attract women with costly health problems, including providers with a particular expertise or patient base.

8. Confidentiality.

For many reasons, consumers want the information they share with their health professionals to remain private. Women seeking sensitive services, such as mental health services, substance abuse counseling, or reproductive health care, may be particularly unwilling to seek care unless they are assured confidentiality. Patients need to know that the information they give to their providers and their plans will remain confidential. This confidentiality should extend to information listed in their medical records, communicated through referrals, and used in billing and claims-processing procedures.

9. Access to prescription drugs that the health care provider determines are necessary or appropriate for treatment.

Plans often limit the drugs health care providers can prescribe to those on a plan-approved list, called a formulary. What is and is not on the list can make a big difference for women, especially older women, because they use more prescription drugs than men. Historically, when a drug was tested on men and deemed safe, it was then automatically assumed to be equally safe and effective for women. We now know that men and women respond to some drugs quite differently. By not allowing a provider sufficient flexibility to order the drug that may best meet a woman's needs, health plans jeopardize her health and, in some cases, her life.

10. Access to clinical trials.

Until recently, women and minorities were routinely excluded from participation in clinical trials, and research into diseases that primarily affect women was almost non-existent. Clinical research on women-specific diseases, such as breast and

ovarian cancer, is essential to finding more effective treatments. It is equally critical that clinical research explore the differences in the way common diseases appear in women and men, and the differences in how women and men respond to individual drugs or treatments. Health plans should not stand in the way of advancing research into women's health by prohibiting participation in clinical trials or otherwise discriminating against women who participate in them. Nor should they deny coverage for medical expenses incurred in connection with clinical trials that they would otherwise routinely cover.

11. Affordability.

Because women use more health services and generally have lower incomes than men, affordable care is especially important to them. Women also have higher out-of-pocket costs than men, in part because health plans often do not cover the services women need, such as prescription contraceptives. As employers pass on a greater share of health care costs to employees, an increasing number of the poorest workers are declining health coverage. Health plans should provide health care that is affordable, including reasonable premiums, deductibles, and co-payments.

12. A patient appeals system that is fair, timely, and understandable, and that allows for independent review.

Every day, health plans make decisions about what treatments they will cover for particular patients. All too often, those decisions conflict with the recommendations of the patient's health care provider. As the primary consumers of and decision-makers about health care for their families, women are most likely to be involved in appealing denials of care. Plans must have an appeals procedure that is quick and easy, and gives patients the opportunity to be heard by an independent party who can review the plan's decision.

13. Providers trained specifically to meet women's health care needs.

Many providers still practice medicine based on the traditional male model of biology and disease. Yet, gender plays a leading role in many health issues -- from the types and prevalence of diseases women experience to their symptoms to the treatments that are most appropriate for them. One alarming example points to the need for training in women's health: a 1998 Gallup poll revealed that nearly 2/3 of primary care physicians wrongly believe there is no difference in men's and women's heart disease symptoms. Health plans can play a pivotal role in advancing the practice of gender-based medicine, and they should make sure women have access to both primary care and specialty providers who are trained to meet their particular health care needs.

14. Provider guidelines that are evidence-based and gender-specific.

Health plans use rules known as clinical practice guidelines to direct providers in selecting treatments and to help plans determine what treatments or services to cover. Given gender differences, plans should base decisions about treatment and coverage on gender-specific medical evidence rather than on cookie-cutter rules that best fit the average male's health profile. The plan's clinical practice guidelines should be developed by knowledgeable experts and specialty groups, not the plan's accountants.

15. Quality improvement systems that address women's health issues.

Good health plans should continuously evaluate and strive to improve the quality of care they deliver, and they should make sure the conditions and diseases that affect women are included in what they monitor. They should also track and correct practices that result in unnecessary or inappropriate treatments, such as high rates for hysterectomies or Caesarean section deliveries.

16. Gender-specific data available to consumers.

Women, like all consumers, need to be able to compare plans, and to compare professionals within plans. To do this, they need access to data about performance (by professionals and plans) on conditions and diseases that affect women. Plans should demonstrate their performance in improving women's health by distributing data that help women make the most appropriate health care decisions.

17. Family-friendly policies.

There are many obstacles that make getting health care difficult for women, such as access to transportation, child care, and flexible evening and weekend hours. Plans need to make health care services as accessible as possible to all members. This includes having facilities and providers near public transportation as well as offering extended hours and child care.

In addition to the above consumer protections that are particularly important to women, there are a host of protections that all consumers need:

- ✔Access to emergency services under the prudent layperson standard
- ✔Access to second opinions
- ✔Access to out-of-network providers (at no additional cost) when the plan is unable to provide timely or appropriate services through in-network providers
- ✔Quality improvement system that is periodically reviewed by an independent, external reviewer

- ✔A ban on provider compensation arrangements that may lead to the denial or withholding of medically necessary or appropriate care
- ✔A ban on interference by plans with medical communications between providers and patients
- ✔A ban on compensation arrangements with reviewers that may lead to the denial or withholding of medically necessary or appropriate care
- ✔Full, complete, and readable disclosure of benefits, exclusions, cost-sharing arrangements, and plan structures/processes
- ✔Care that is geographically, culturally, and linguistically accessible
- ✔The ability of consumers to hold health plans accountable for the decisions the plans make
- ✔Consumer ombudsprogram to assist in choosing a plan and addressing problems

As Congress considers new legislation, as the media reports on the public's health care experiences, and as consumers become more aware of the changes in the health care delivery system, these principles should be used to measure how well policy-makers and health plans meet the health needs of women. Their success or failure will determine whether women and their families receive the type and quality of care and services they deserve.