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CONSUMER PROTECTION AND QUALITY ASSURANCE UNDER HEALTH CARE REFORM

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH
FOR FAMILIES AND THE UNINSURED

OF THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED THIRD CONGRESS

SECOND SESSION

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CONSUMER PROTECTION AND QUALITY ASSURANCE UNDER HEALTH CARE REFORM

FRIDAY, APRIL 29, 1994

U.S. SENATE,
COMMITTEE ON FINANCE,
SUBCOMMITTEE ON HEALTH FOR FAMILIES AND THE UNINSURED,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:11 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Donald W. Riegle, Jr., (chairman of the subcommittee) presiding.

[The press release announcing the hearing follows:]

[Press Release No. H–29, April 22, 1994]

FINANCE SUBCOMMITTEE ON HEALTH TO HOLD HEARING ON CONSUMER PROTECTION AND QUALITY ASSURANCE

WASHINGTON, DC.—Senator Donald W. Riegle (D–MI), Chairman of the Committee on Finance Subcommittee on Health for Families and the Uninsured, announced today that the Subcommittee will hold a hearing on consumer protection and quality assurance relating to health care reform.

The hearing is scheduled for *10:00 A.M. on Friday, April 29, 1994,* and will be held in room SD–215 of the Dirksen Senate Office Building.

In announcing the hearing, Senator Riegle stated: "I am holding this hearing to examine the barriers in the health care system that prevent individuals from getting the care they need. Under health care reform, we must structure the health system to make sure that health plans are offering high quality care."

"As we in Congress work on health care, we need to make sure people receive high quality services and have protections within the system against poor treatment."

OPENING STATEMENT OF HON. DONALD W. RIEGLE, JR., A U.S. SENATOR FROM MICHIGAN, CHAIRMAN OF THE SUBCOMMITTEE

Senator RIEGLE. The committee will come to order. Let me welcome all those in attendance this morning. I want to say at the outset this is one of the important hearings in the series of hearings we are having on the health care requirements of people in our country and how they need to be properly addressed in the health care reform action that we will be taking.

I want to thank our witnesses especially, not just for being here, and we appreciate that very much, but also for your long-term leadership on these issues. I appreciate that leadership now and will continue to into the future.

The hearing today will enable us to explore ways to restructure the health care system to eliminate some of the very difficult bar-

riers that now prevent families and individuals from getting the absolutely necessary high quality care that they need.

As we seek to provide universal coverage, we have to recognize that coverage alone does not guarantee that individuals will get the actual health services that they need and must have.

Consumers face a maze of barriers to getting high quality health care. They may not have enough information about plans to choose the one that best meets their needs for services. Or a family could discover that the only plan that they can afford does not include their pediatrician or some other person whose services they need.

Individuals with chronic or special health needs often face arbitrary limits on the number of visits or type of provider that the plan will reimburse. And in the worse case, their health needs are just either not fully addressed or ruled out for coverage.

As health plans attempt to control costs additional barriers are often placed on the people who need health services. Some say these problems exist more in managed care plans.

Since the growth of managed care plans is likely to accelerate under health reform, it is crucial that this committee examine these issues. Managed care offers the possibility of improving the quality of care offered to enrollees by coordinating the services that members need and hopefully by putting more concentration on good, sound preventive care.

But at the same time under managed care plans, plans may face more financial incentives or administrative pressure to under treat people. Traditional indemnity insurance plans are also feeling pressure to control costs and are adding layers of bureaucratic review and oversight to patient care. And all of these gatekeeper functions raise serious questions as to whether in every case people will be allowed to get the care that they may require.

So our desire to contain health care costs must not come at the expense of high quality health services. I think we can do both in health reform. We need to do both to have real access, control health care costs, but at the same time have a high quality system available to everyone.

As we develop a health care reform package, we must look at the issues for the individual and also from a family perspective to make sure that the health system is truly responsive to consumer needs.

We must also understand the needs of health plans and support them in their efforts to create their own systems of quality improvement. As a first step, Senator Bond and I have been working together on a proposal, S. 1494, that develops an infrastructure for information to be used effectively for quality improvement.

So I am very pleased that we are here this morning to learn more from the witnesses about how we can better protect consumers and encourage quality improvements in the health care system itself.

I am going to introduce all four on our first panel and then we will hear from them in that order. Our first witness this morning is Bev McConnell who is here from Trenton, MI. She is here to talk about her experiences and difficulties in obtaining care for her daughter Meredith who has many special health care needs. I especially appreciate your being here. Your 17-year-old son, Neal, is

with you, too, and we welcome both of you and we are pleased that you are here.

Also on our first panel we have a physician and other important noted advocates for consumers. Dr. Jennifer Howse is the president of the March of Dimes and she is here from White Plains, NY.

Mr. Al Chiplin is an attorney with the National Senior Citizens Law Center and is here as a representative of the Coalition for Consumer Protection and Quality in Health Care Reform.

Dr. John Tooker comes to us from Portland, Maine, where he is the Assistant Chief of the Department of Medicine at the Maine Medical Center.

Before you start, Ms. McConnell, let me just say I am very pleased today to have my sister, Dee Ann Riegle—Torres here visiting from Puerto Rico. When she was born my mother was dealing with an Rh blood factor problem we did not really understand that very well. We actually lost a brother that would be between the two of us.

When Dee was born we nearly lost her. But by virtue of God's grace and a wonderfully skilled doctor who happened to be in the right place at the right time they were able to pull her through.

But in our family situation we have seen a great number—perhaps an unusual number—of family health crises. Most recently, my little 1-year-old grandson was on life support and intensive care at the Children's Hospital out in Los Angeles and the doctors held out no hope for his recovery. I am happy to say that he woke up and he is recovering and he is coming back and is out of the hospital. He has a long way to go. We have seen many of these situations in our own family circle and we have seen thousands more in representing the State of Michigan now over these 28 years.

I think unless one deals with a family medical challenge or emergency of a large dimension that they cannot begin to comprehend what is involved here—the heart ache, the difficulty, the expense, the stress, the strain.

If there is one thing our country can do, because we are rich enough and advanced enough, is to make sure that we have a health care system in place that helps individuals and families deal with these problems, we must really live the creed where we say we care about everybody and everybody is equal in the country and we see that people get the chance to come on through these difficult situations.

We understand what that is all about. So we appreciate again especially the leadership of all of you that are testifying today.

So, Ms. McConnell, why do you not start and tell us your story, and about Meredith, and help us understand what we need to do here.

Ms. MCCONNELL. All right.

STATEMENT OF BEVERLY McCONNELL, DIRECTOR, PARENT PARTICIPATION PROGRAM, MICHIGAN DEPARTMENT OF PUBLIC HEALTH, TRENTON, MI

Ms. MCCONNELL. Thank you. First I would like to thank you, Senator Riegle, to appear before the subcommittee and tell you about our story and talk to you about the difficulty that families

of children with special health care needs face in obtaining health services.

My name is Bev McConnell. I live in Trenton, Michigan with my husband, Ray, and three rambunctious teenagers—Neal, Meredith and Emily. Our house with three teenagers is full of loud music and equipment galore. The phone rings constantly. And young people are coming and going all the time.

While our household at first glance may appear to be a typical American scene, a closer look would reveal that the equipment crowding our house is a mixture of footballs and baseball bats, ice skates, wheelchairs, monitors. The music a range from Disney to rap to heavy metal. The phone calls are about both the latest in junior high school gossip and the latest changes in our home nursing schedule for Meredith.

The people who are coming and going are cheerleaders, nurses, other football players and therapists.

My middle child, Meredith, has numerous special health needs. When she was born she was diagnosed with a cleft palate and Pierre Robin syndrome. Ten at 1 month old she was diagnosed with Hydrocephalus and Dandy-Walker syndrome. She also has seizures, apnea, brain stem instability and a cranial nerve defect.

Meredith was admitted to Children's Hospital of Michigan when she was four weeks old for brain surgery. Now this was obviously a very difficult and frightening experience for us and I needed to know more about my daughter's condition.

Although I probably asked every doctor or nurse who entered my daughter's room, no one was able to give me a clear explanation of what Hydrocephalus was and what it would mean for our family. Finally after a few days Dr. Michael Nigro, who is a wonderful pediatric neurologist, came in to examine Meredith.

I asked him again—or actually by this time I demanded—that he tell me what Hydrocephalus was and explain the situation to me. He looked at my frustration and he smiled and sat down with some diagrams to draw out Meredith's anatomy to show me what the blockage, where the implications were and what it would mean.

Now although he, too, was very busy, he recognized my very legitimate need for comprehensive information about my daughter's condition and he took the time to explain that to me in as much detail as I needed. Dr. Nigro was willing to answer my questions without judging them and over the last 14½ years has continued to encourage us to do that.

This hospitalization lasted nearly 2 months. Once it became clear to us that Meredith's health problems were chronic in nature and, you know, we were not going to get a quick fix and everything would be okay, we asked to be taught the complicated procedures that Meredith needed so that we could prepare to take her home and care for her there.

We were shocked and appalled to learn that some hospital staff thought that she should stay there and spend what was essentially expected to be a very short life span in a hospital setting.

I will never forget a young resident who I overheard describing Meredith's condition. He has this real all—knowing kind of—I do not know—God-like voice and he pronounced, "My concern is this.

When, not if, the child dies, the parents will just feel terrible if it happens at home."

I was compelled to point out to him that we are really not very likely to feel good about our daughter's death regardless of where it occurs. The point was that this young physician, who I am sure was very well meaning, took his value system that said a child's death should not occur at home and placed that above our value system that said her life should occur at home, she should live with us. She did end up coming home, by the way.

The bill for that initial hospitalization exceeded the amount of our mortgage balance, which was really shocking to us. We were very relieved though when we learned that our insurance we had through my husband's employer would pay for those bills.

Over the course of the next year, Meredith required five more surgeries, which were very lengthy and equally expensive.

When my husband was laid off from his job the following year, we lost our insurance coverage. Although we had no income and three very young children we had to buy an individual health insurance policy that was very, very expensive. Now we were only able to do this because our parents were able and willing to help us pay those premiums. While Blue Cross/Blue Shield of Michigan was required to sell us an insurance policy, they were not required to make it affordable.

Then when Meredith was 14 months old my daughter, Emily, was born. I required a 7-day stay in the hospital because it was a Caesarean birth. Obviously, I was not able to continue to provide Meredith's special care at home for that week, yet our insurance company would not pay for nursing care for Meredith while I was in the hospital.

We were forced to turn to a public, State and Federal program for children with special health needs to receive enough nursing support to get us through the first month of Emily's life.

Over the years our family has been able to maintain coverage in a fee-for-service arrangement. While this should theoretically give us all of the flexibility necessary to meet our family needs, the complexity of my daughter's overall health makes it difficult to obtain appropriate care.

For example, a few years ago Meredith became ill over a holiday weekend. The pediatrician's office was closed so we took her to a local hospital urgent care center. Because of Meredith's disabilities the physicians in the local hospital were not willing to even fully examine her and they sent us to the emergency room at the pediatric hospital in Detroit.

When we arrived, we were told that we would have a 3-hour wait in the emergency room. Shortly after that I noticed that Meredith was beginning to exhibit some signs of seizure activity and she felt feverish.

I went back to the receptionist and explained Meredith's medical history—that she had a history of seizures, what I was seeing—and asked if we might get bumped up a little bit and get in early. Well, no, a 3-hour wait was a 3-hour wait. Go back and sit down.

We were sitting in one of the finest hospitals in the United States and yet we could not get past a receptionist when our daughter's health condition was deteriorating right before our eyes.

Given Meredith's condition and the way things were heading, we decided to take the chance and drive 40 miles to Ann Arbor to get her into care at a competing children's hospital there, where she was seen immediately, diagnosed with a middle ear infection, and released.

Now a middle ear infection should not require visits to pediatric tertiary centers. But for children with special health needs, even the most routine primary care becomes specialty care.

Another area of concern for children with special needs is coordination of care. When Meredith was hospitalized 2 years ago she required three relatively minor procedures, all of which needed to be done under anesthesia.

The gastrointestinal specialist needed to scope her esophagus. The dental specialist needed to check our her impacted teeth and the surgeons needed to place a central IV line into a main artery.

Because Meredith has had difficulty recovering from anesthesia in the past, it was important to us to coordinate these procedures so that her exposure to anesthesia would be limited. However, we had to force the coordination. It took us 3 days, contacts with every administrator we knew at the hospital, and finally the assistance of a caring pediatric resident who realized the importance of minimizing Meredith's exposure to anesthesia.

We finally accomplished this and everything went real well. But there were two central elements that play here. First, the coordination of services, which was very important; and next, the important information that we had as experts of Meredith McConnell. Families have a tremendous amount of expertise that must be worked into the equation at every level of health care, beginning at the level of individual care.

Our challenges with the health care setting are even more upsetting when I compare what is available to Meredith and what is available to her brother and sister.

For example, late last fall my 17-year-old son, Neal, injured his knee in the last game of a very exciting football season. The injury required surgery and extensive physical therapy. Neal's therapy, which continues, is completely covered by our insurance company.

In contrast, when my husband took Meredith for physical therapy following her injury last year, we received a statement from the insurance company telling us that physical therapy could not be covered because of her pre-existing condition.

That places us in the impossible position of having two children with the same need in a system that will meet my son's needs, but not my daughter's needs.

This line in the sand between habilitative and rehabilitative services sends a message loud and clear that says, for children who start our perfect it is worth our investment. We will spend the money to get you back to where you used to be. But for children like Meredith and thousands of other children like her whose needs are at least as severe and at least as legitimate, the message is, you are not worth our investment. We do not care about you enough to spend the money on what you need.

As their mother, this is a completely unacceptable. I cannot explain this to either one of my children. I wish I could tell you that these are isolated problems and that my family has had a long

string of incredibly bad luck, but the truth is that our family really has had it pretty easy compared to many others.

I am employed by the Michigan Department of Public Health as the Director of the Children's Special Health Care Services Parent Participation Program. In this capacity I serve as a parent consultant to the program, drawing on my personal experience as the parent of a child with extensive special health needs and organizing input from families across the State.

Over the past 6 years the program has been very innovative in developing successful strategies for engaging in genuine partnerships with families that define and direct the course of service delivery. Every day I talk to families who tell me how barriers and health care delivery systems impact their lives.

Like a family in Kalamazoo, both parents hold Masters degrees and are very gifted in their fields. Yet these two gifted people are not considered employable because their son's extensive medical needs have already maxed out the life time million dollar cap on two policies.

A father from Flint called me last week. His 6-month-old son is in the hospital. He has a tracheostomy, a central venous line for nutrition, a gastrostomy and is dependant on a ventilator to sustain his life. His insurance company refused to pay for in-home nursing, which the family wants. It would cost much less than hospitalization.

When the family asked to convert coverage for hospital days into home care, the request was denied and the father was told that the company would no longer pay for hospitalization either because the insurance company's medical experts felt that his son's condition did not require a hospital level of care.

We have heard from a single mother in Ann Arbor who was completing her degree in order to get a good job to support her daughter when her four-year-old's asthma intensified. Her doctor told her that she should buy an individual Blue Cross policy because if her daughter needed to be hospitalized, even for 1 day, the bill could exceed $10,000.

Based on his advice, she bought a policy. But the reality is that this policy did not cover the bulk of this little girl's needs, which included prescription drugs, office calls, and outpatient care. In the end, the child's mother exhausted her life savings by spending $700 per month for a policy that did not meet her needs and she still had to pay out-of-pocket for expensive prescriptions and office calls.

Some suggest that there is no real health care crisis in America. The reality is that every day families in my State and across the nation are faced with barrier after barrier in their quest to care for their children. The future looks very uncertain without universal coverage. Parents are denied the opportunity to explore new careers or more forward in their current careers due to the frustration of job lock.

Families are faced with unclear or obscure definitions of covered services. For children who require highly specialized technical care, the definitions of appropriate providers and medically necessary truly become life and death issues. There is no clearly defined source within systems of care to help translate or coordinate service coverages. There are no formalized roles or provisions for fami-

lies as direct consumers of health services to participate in the ongoing development, implementation and evaluation of services at various levels of service delivery. This is a very real crisis for families of children with special health needs.

I believe that this Nation has an obligation to care for children first. Families will help do this when they are given the tools they need to do the job. These tools are access, choice, coordination, collaboration and accountability.

Access to appropriate, affordable care, to complete and unbiased information about their child's needs, to the necessary recourses to meet those needs including transportation, respite and child care, and to a responsive mechanism for problem resolution and trouble—shooting.

Choice between a set of reasonable options that are consistent with the families values and are affordable.

Coordination between different specialists, programs and facilities.

Collaboration between professionals and family members at every level of our health care system, including National Health Boards, HMO's, hospitals, alliance administrations, et cetera.

And accountability, which includes clearly defined mechanisms for problem resolution with specific time frames and appropriate consequences.

Our family can take most things pretty much in stride when we are protected from needless vulnerability, when we have some clear direction on problem-solving, when we know the parameters of the game. With those things in place, I think our household can typify the standard American scene. We are people who care about one another and who are willing to work a little harder so that all of us can lead optimal lives, live freely and pursue happiness.

Once again, I want to thank you for the opportunity to speak with you today.

[The prepared statement of Mrs. McConnell appears in the appendix.]

Senator RIEGLE. Well, thank you very much. We appreciate your sharing that story with us. I know there is a lot more you could tell us if time could permit. But that is very helpful and I appreciate what you have said.

Dr. Howse, you have certainly seen a lot of situations. We would like to hear from you now.

STATEMENT OF JENNIFER L. HOWSE, PH.D., PRESIDENT, MARCH OF DIMES BIRTH DEFECTS FOUNDATION, WHITE PLAINS, NY

Dr. HOWSE. Thank you, Mr. Chairman. I am Jennifer Howse, President of the March of Dimes Birth Defects Foundation and our mission is to improve the health of babies by preventing birth defects and infant mortality. Thus, we have a very special interest in reducing the barriers to care faced by millions of American families and that you have heard so eloquently stated, I think, by Bev McConnell.

Families deserve to have health security. The March of Dimes is embodied by over 100 Chapters in communities across America, and we represent millions of volunteers who share the widespread

concern about the growing number of families who are uninsured or partially insured who face tremendous barriers and who face overwhelming costs in trying to provide for their children.

Mr. Chairman, we particularly want to commend you for your longstanding interest in the quality of health and we thank you for your dedication to the health of babies in this country. Your committee has an historic opportunity to reshape the health care system of America and the leadership and commitment and expertise that you bring I think can make a world of difference in the future health of our Nation.

Senator RIEGLE. Thank you.

Dr. HOWSE. I am going to just give some excerpts today from the written testimony that I submitted to your committee. I am going to talk about concerns in the current delivery of maternal and infant health services in our country and offer some recommendations about what we feel can be done to improve the health care system, most especially the quality of health care services for mothers and babies.

Let us begin by trying to get 10,000 feet above the planet if we could and talk about the highlights of this health care crisis, which we do, indeed, have. First, the uninsured or under insured—9 million women of childbearing age have no health insurance; 6 million of these women are employed but do not have coverage through their employers; 8.3 million children in America today have no health insurance. And despite some recent and important expansions of the Medicaid program, the number of uninsured children in this country continues to grow. This is in large part because employers are dropping chunks of coverage for dependents.

Also, today pre-existing condition exclusions—a very cruel term—leave many babies with birth defects without health security and leave their families in terrible situations.

I wanted to make a comment about the gaps in benefits for babies with birth defects. We are particularly concerned about these gaps in benefits in our foundation because H.R. 3600, as introduced, appears to exclude certain coverage for babies born with birth defects because the provision for rehabilitative services in that bill is particularly for illness or injury and a birth defect is neither an illness or an injury as commonly understood.

So we are very concerned that particular attention be paid to the crafting of language around rehabilitative and habilitative services to ensure that a baby born with birth defects gets the same standard benefit coverage that all other Americans are entitled to under health care reform.

Senator RIEGLE. Let me just stop you there if I may.

Dr. HOWSE. Yes, sir.

Senator RIEGLE. Excuse me for interrupting. It is a key point and it has been a concern of ours as well. We went back to the administration to ask them what their intent was here because we found it sort of unbelievable that the definition that you gave would be intended to exclude children who have birth defects.

They have indicated to us that it was not their intention. So we intend to change the bill in that area. But it is a key point. And until it is done—signed, sealed and delivered—we cannot count on

its proper resolution. But we have identified that problem and we are moving on that as you suggest.

Dr. HOWSE. Good. Thank you, sir. We are very grateful and we appreciate, of course, the good intentions of the administration. But it has been our experience that it is best for all of us to have it in writing.

Senator RIEGLE. Absolutely. [Laughter.]

Dr. HOWSE. And to be sure that it is crystal clear.

Senator RIEGLE. You are so right. I mean, we are in the law writing business and we want to write it in and not have any other problem with it.

Dr. HOWSE. Thank you, sir.

Let me move then to a problem that we note in lack of preventive care and lack of coordination between preventive, basic specialty and subspecialty services, particularly in the area of maternity and pediatric care. I think we have heard some very particular examples that Bev McConnell has given and I have covered this in detail in my written testimony.

I would like to discuss next some solutions for the problems that I believe all of us commonly recognized. You will probably hear many of the same kinds of solutions proposed by the people who you have invited to testify.

First of all, to make care affordable. I have included in my testimony an example of a wonderful woman named Lynn Morrison. She is from Georgia. She had a nightmare. She suffered terribly during her pregnancy because she was not able to get health insurance when she changed employers. It is very, very important that coverage be guaranteed and portable.

Second, making care available. I have included in testimony an example of a problem of not getting specialty care under a managed care system where a woman with high blood pressure who had a complicated first pregnancy was not able to get a referral in time to the kinds of specialty services that she and others believed would be important and lost the child. This is yet another illustration of how—although managed care theoretically can work—it is very important to make sure we do not sacrifice quality while trying to contain cost.

The third area—making care appropriate. Here I would like to emphasize the importance of standards of care. Again, we apply, if you will, Senator, the notion of "putting it in writing." We want to make sure that, in legislation passed and in the regulations the Secretary is required to issue as a result of legislation, the appropriate standards of care are included. I think that is the best safeguard to making sure that managed care maintains quality while at the same time controlling costs.

We have given an example. We are deeply concerned. New York State Prenatal Care Assistance Program, an excellent program with a track record of resulting in fewer babies born at low birth weight. The standards in that program are proven. They are not being carried over now to Medicaid managed care in the State of New York.

I visited Albany at a large conference, spoke with the chiefs of some of the HMO organizations who all said, do not worry. We care. We will be sure that things are right, but do not put it in

writing because we need flexibility. So we are concerned about that.

Finally, I wanted to give an example of accountability. I think we all agree on what is needed for individual reform. We do need systems reform as well. Regional systems of health care, regional systems of perinatal care, are very, very important, so that we can link up and have coordination and documentation of birth outcomes and children's health needs being met.

There is an excellent model in New Jersey—a perinatal network that they have established through the support of the Robert Wood Johnson Foundation—and, Senator, I would encourage you and your committee to take a look at what they have put into law in New Jersey and some of the early results.

And finally in closing, we want to state that we at the March of Dimes Foundation realize that there are not easy answers to the current crisis in health care. In particular, determining the method of financing health reform is going to be very difficult. But we also believe that our babies are the future of the country.

We believe that our Nation will have the world's healthiest babies, which we certainly do not now, but only when our health care system is reformed. And we believe that the kind of leadership that you have shown during the years, the kind of oversight that your committee is exerting at this time, and the kind of leadership that you are showing will lead us to the health reform that we need.

Thank you very much.

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

Senator RIEGLE. Well, thank you very much. I appreciate your kind personal comments.

But beyond that, I think it is so critical that, as you say, we put it in writing. Systems can become mindless, and the conscience can disappear, and the sensitivity can get lost. I worry about that in managed care. I worry about the squeeze from a financial point of view leading to service delayed, service denied.

The great irony of it all is that it has been my experience that good, high quality health care is the least expensive health care. We avoid all the heart ache and the ocean of tears and sadness and travail that comes from medical situations that could have been avoided or could have been treated with better outcomes.

But so often we seem to insist upon delaying care, denying care and then ending up paying for it with greater cost. So hopefully we will have the clarity of vision in this health care reform process to see that and to avoid that trap. We are going to do everything we can in that area.

I think it is important that you maintain, all of you here, your own lobbying efforts. You do not have the budget to be on television hammering away like some of the other organized points of view. But I think it is very important through the March of Dimes and other organizations that we really get the message across as to what we are talking about here.

The people that think it is not their problem, well, it is their problem, because anybody's problem belongs to all of us in a sense. We all end up paying for it.

I have seen so many cases where people were clicking along and everything was fine. And then low and behold an hour later every-

thing is turned upside down. There is an automobile accident or a motorcycle accident or a sports accident or a birth that does not go the way we had hoped that it would or something else intervenes.

We have to be in a position to deal with those situations and you have given us some very good ideas here today.

Mr. Chiplin, we are pleased to have you and we would like to hear from you now.

STATEMENT OF ALFRED J. CHIPLIN, JR., STAFF ATTORNEY, NATIONAL SENIOR CITIZENS LAW CENTER, WASHINGTON, DC, ON BEHALF OF THE COALITION FOR CONSUMER PROTECTION AND QUALITY IN HEALTH CARE REFORM

Mr. CHIPLIN. Thank you. Thank you, Chairman Riegle, and congratulations on your distinguished record on health care and consumer issues. I am a staff attorney with the National Senior Citizens Law Center. My testimony today is on behalf of the Coalition for Consumer Protection and Quality in Health Care Reform.

The Coalition applauds the President's and Congress's all out effort to reform the health care system. Mr. Chairman, the members of the Coalition know what it is like for health care consumers in our current fragmented system. Consumers are vulnerable to many problems in obtaining health care, including poor information about coverage and options for care. Benefits provided are often inadequate and the means for contesting coverage problems are sometimes obscure or nonexistent.

In addition, consumers often confront insurance companies, practitioners and hospitals that have financial and other incentives that are in direct conflict with consumer needs.

These obstacles to appropriate quality care can be found in various forms in all of the health care scenarios that you will cover—single payer, fee-for-service, managed care or some combination of these.

In other words, consumers need under any health care reform proposal the following: Easy access to unbiased information to help them make meaningful choices between plans, providers and coverage options; an ombudsman program to help them navigate the system and to assist them in resolving complaints; a fair and timely appeals process to address denials, reductions or terminations of benefits and services, including mental health services; and independent and ongoing quality monitoring entities as well as public accountability through licensing and certification systems.

These elements are necessary in any system and it is the responsibility of the Federal Government to assess and monitor the new system and to ensure that quality standards, practice guidelines, data collection and the distribution of health care information is working consistently across the nation.

Consumer due process protections. The Coalition believes that due process rights are essential in any national health care plan and is generally pleased with the appeals process provided in the Health Security Act.

We have also drafted generic language on this topic, which has been included in our written testimony. Most importantly, we believe that as Congress proceeds, it must clarify the circumstances

for providing notice to patients when decisions to deny, reduce or terminate a service or payment have occurred.

For instance, notices should state the specific reasons for the decision to deny, reduce or terminate a service or payment and describe the appropriate appeals process available to the patient.

Notices should be triggered automatically when certain benefits have been denied, reduced or terminated. For example, ongoing treatment, such as hospital care, nursing home care or home health services.

Congress should also clarify that health care providers and plans must substantiate the medical basis for a denial of coverage. Similarly, consumers should have access to second opinions when medical necessity is at issue and health plans should bear those costs as determined by impartial administrative hearing officers.

Consumer information. The success of our new system will depend greatly on the quality of the information provided to consumers. Therefore, we request that you define more precisely the kinds of information that will be available to consumers.

For example, the consumer handbook should include the results of the consumer satisfaction survey conducted by the National Quality Management Council and enrollment and disenrollment figures collected by the Health Care Information System.

Consumers will also need information such as physician certification and repeated disciplinary actions. And they will need condition-specific information to be able to choose between doctors and hospitals where they face major health care needs, including surgery and other complicated care.

Ombudsman. We are pleased that the Health Security Act and others have called for the creation of ombudsman offices. We request, however, that you provide greater detail about this program and about how it can be used by consumers.

For example, the ombudsman program must have a stable source of financing, not only one of voluntary contribution. We strongly believe that corporate enrollees should have the same access to an ombudsman as other enrollees. Also, ombudsman offices must be independent of plans or other purchasing arrangements, including State Government.

Quality improvement and public accountability. The Health Security Act provides an excellent foundation for independent monitoring of quality. However, none of the bills satisfies our basic principle that there must be an external quality review entity independent of payer based and provider based systems in each State.

The Coalition believes that what we call Quality Improvement Foundations (QIFs) should be created in each State through competitive grants. The QIF would be governed by a Consumer Majority Board and include experts in a variety of health and quality research fields.

Each QIF would perform quality monitoring and improvement functions such as development of and support for quality improvement activities, practice guidelines, adherence monitoring, and profiles of the database for low rates of utilization. This will ensure that quality improvement activities are used consistently across the nation. The QIF also will ensure that information regarding provid-

ers of consistently poor care will be forwarded to the appropriate entities.

Consumer representation. Public accountability depends greatly on consumer representation on advisory boards, including health plans, regional and corporate alliances, the National Quality Management Council and State located quality improvement foundations. To enable consumers to fulfill their roles on these various boards, funds must be made available for training and staff.

Licensing and certification. Rigorous professional licensing and accreditation and plan certification is needed to ensure quality care. Licensing boards and other regulatory bodies must sanction those that fail to provide acceptable care.

In conclusion, Chairman Riegle, the Coalition is grateful to you for holding this hearing and we look forward to working with you.

Thank you.

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

Senator RIEGLE. Thank you very much. Thank you, too, for your important service with the National Senior Citizens Law Center.

Dr. Tooker, we are pleased to have you here. I know we all feel greatly encouraged by the decision of your Senator, Senator Mitchell, to forego a stint on the Supreme Court to really give the kind of extraordinary leadership that he gives every day here, but to the health care issue.

I want to tell you something. I have been here a long time—28 years and through 7 Presidents. I have seen in the last 3 weeks with respect to a meeting of Democratic Senators that we had down in Williamsburg, VA and some long meetings during the workday in the last couple of weeks, that George Mitchell has given an extraordinary degree of leadership at this important stage of the development of the health care proposal, way beyond anything that I can recall seeing other times by other comparably situated leaders.

And I tell you that not only because he is from Maine and you have a lot to be proud of, but it is important for everybody in this room and beyond this room who cares about health care to understand that. Because there is no more important leader in our body than the Majority Leader, not to take anything away from anybody else, but I think that he has really greatly improved our prospects of getting a health care bill that will be stronger and better and of the kind that we are all seeking.

So let me invite you to make your remarks now.

STATEMENT OF JOHN P. TOOKER, M.D., F.A.C.P., ASSISTANT CHIEF, DEPARTMENT OF MEDICINE, MAINE MEDICAL CENTER, AND CHAIRMAN, BOARD OF GOVERNORS, AMERICAN COLLEGE OF PHYSICIANS, PORTLAND, ME

Dr. TOOKER. Thank you, Chairman Riegle. We, too, are definitely proud of Senator Mitchell and look forward to working with him as health care reform unfolds. As stated, my name is Dr. John Tooker. I practice internal medicine in Portland, Maine and I am currently the Chairman of the Board of Governors of the American College of Physicians.

The ACP is the nation's largest medical specialty society with more than 81,000 members who practice internal medicine and its subspecialties.

Mr. Chairman, the ACP congratulates you for holding this hearing. While issues such as financing, taxes, and mandates have received extensive national attention, the core issue of ensuring that our patients receive the highest quality of care has received much less attention, hence the importance of this hearing.

The ACP has supported and continues to support comprehensive reform because we believe that our Nation's health delivery system does not work for patients or their physicians. One of the principal failings of our current health system is that patients and physicians have increasingly lost control over treatment decisions as the testimony here today has already indicated.

Insurers, insurance companies and other outside influences have acquired enormous power, creating system that often ignores the physician's recommendations and the needs of the patient.

If I could, I would like to give you a real life example. A 15-year-old girl in rural Maine, truly isolated, was diagnosed with depression and a behavioral disorder that included self-abuse. She struck herself repeatedly in the mouth with a hammer. Her internist attempted to obtain expert care for her. Available to him as a pediatrician who specialized in caring for adolescents in crisis who was both able and willing to see the patient on short notice.

The family's insurer, who had no understanding of the girl's particular problem and her need for immediate help balked at the patient seeing anyone other than a psychiatrist, even though there was no psychiatrist available who could see the child.

Concerned about his patient's safety, this internist spent an entire afternoon on the telephone making over a dozen phone calls to the insurer to obtain authorization for a single visit to this pediatrician. He finally received in frustration authorization by asking the insurance company representative—and I quote—"What do I have to do, let her kill herself before you authorize this treatment?"

Unfortunately, this example is not unique. It is becoming more and more common, particularly as managed care enters the work force, and particularly as managed care is now in transition in many areas of the country.

The ACP believes that the best way to ensure that all Americans receive the highest quality of care is to keep treatment decisions in the hands of patients and their physicians. We must reverse this dangerous trend that has put insurers in charge of the rules and procedures. Often secret insurance companies make decisions about a patient's medical treatment, even over the objections of that patient and his or her physician.

What is particularly appalling to us is that the utilization review process, the criteria by which the decisions are made, are often kept secret from both patients and physicians, are not scientifically based and often focus exclusively on cost, ignoring quality.

In addition to the faulty criteria used, another problem with these reviews is that they are performed on a case-by-case basis, both prospectively and retrospectively.

This intrusion on the doctor/patient relationship wastes time and money since the physician may be forced to justify his or her deci-

sions in the middle of a busy day and most important hurts the quality of care given to the patient.

Mr. Chairman, my colleagues and I became physicians to care for patients, not to go toe-to-toe on a daily basis with insurers. The ACP will insist that health reform legislation contain provisions to ensure that all Americans receive the highest quality of care and the patients and their physicians, not insurers, make decisions about medical treatment.

We also recognize that in addition the need to eliminate these practices in the private sector, the government has also constructively managed patient care by micro managing case-by-case. We cannot substitute excessive government regulation for private sector abuses.

Mr. Chairman, in our view, we need a new approach. We need to develop a quality assurance system that creates an environment that fosters collaboration among patients, physicians, hospitals and health plans to improve quality while simultaneously providing for reasonable external review and when needed disciplinary hearings and proceedings to protect consumers.

Health reform legislation must establish a system of ongoing quality improvement that eliminates case-by-case review, shifting instead to data driven practice profiles of both the process and outcome of the practice of medicine in order to ensure quality.

It must integrate the dual considerations of quality and cost in health care delivery. It must also research the use and development of consumer report cards to ensure that report cards use appropriate data that is clinically relevant.

Finally, we urge you to adopt a requirement that utilization criteria be disclosed to both patients and to physicians, that the criteria be based on reasonable and current medical evidence, that they be consistently applied. In addition, only qualified physicians supervise the review decision, including determinations of the medical appropriateness of any denial as well as the appellate process.

Moreover, mechanisms should be established to evaluate the effectiveness of the utilization review process itself, including provider and patient satisfaction data. We hope to work with you to fully develop recommendations in this area.

In conclusion, we need to create a health system that empowers patients and their physicians. We need to make sure that quality of care is maintained and that the intrusive micro management from external entities, both private and public, be eliminated.

We look forward to working with you to develop legislative solutions to these problems in the weeks to come. Mr. Chairman, thank you for the opportunity to testify on behalf of this critical issue to us and to our patients. I will be happy to answer any questions that you may have.

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

Senator RIEGLE. Thank you very much. I again want to say how much I appreciate the testimony of all four of you.

Let me ask just a couple of questions and then I want to go to our next panel. Before I do, let me say that Senator Grassley was not able to be here today. He very much wanted to be. He has asked me to submit a statement on his behalf. So without objection, I am now going to insert his statement in the record.

This is an issue that he is greatly concerned about and is giving leadership to. I appreciate that and it will help make a difference here.

Let me ask you, and I will just go right down the table, would you all agree that we need to address these issues that you are raising today in both managed care and in fee-for-service plans? Doctor, let us start with you.

Dr. TOOKER. Absolutely. Our view is that the decisions not be based on regulations, but should be based on the education of both the patient and providers, that only through informed patients and providers will there be a reduction in the questions that are raised in the daily practice of medicine and kept out of the regulatory environment of the insurer.

Senator RIEGLE. Dr. Howse?

Dr. HOWSE. We think it is very important to consider a population based medical practice and that the plans, the actual delivery of medical care and the assessment of the quality and outcomes of that care need to be done on a regionalized or population basis. So it does not matter really whether it is fee-for-service or managed care.

The point is to establish a system that is locally or regionally based and takes the needs of all people into consideration.

Senator RIEGLE. Mr. Chiplin?

Mr. CHIPLIN. I would agree and emphasize that with respect to the problems that have been identified here today about coverage and denials of coverage there is a need for due process review procedures in any health care reform package. For this reason we have put together a generic due process review model, pulling from the best of ERISA, Medicare and Medicaid. The model we propose can be inserted in any health care reform package, whether it is fee-for-service, managed care, or some combination.

Senator RIEGLE. Ms. McConnell?

Ms. MCCONNELL. Absolutely. I think both approaches have pros and cons. Fee-for-service arrangements provide a lot of flexibility, but not much coordination. Managed care has a coordination mechanism but the flexibility is lacking at the start of it. You know, about the 15-year-old not being able to get to appropriate specialist is not an uncommon story.

Senator RIEGLE. Let me also ask you this question. I know the problems are somewhat different under each type of delivery system. I am wondering—and again, I would like to go down the table—if you have more concern, generally speaking, about managed care plans than you would have for fee-for-service plans.

Is there anything about the difference between those kinds of systems that would cause us to have to think about them in a different way and perhaps try to respond to a different concern that might be greater in one than the other? Dr. Tooker?

Dr. TOOKER. Not necessarily. We are not necessarily more concerned about managed care. It depends on the controls on the managed care entity and the role of the patients and providers in the plan to ensure the appropriate outcomes. it is when the patient and the provider are blinded and there is an internal management structure that is secret, that controls it, that the outcomes in my view are often times adverse.

Senator RIEGLE. Dr. Howse?

Dr. HOWSE. I think there are more problems at this time in managed care, partially because it is a new concept, but most particularly because there are not clear standards and mechanisms. There is not clear accountability and the emphasis unfortunately at this time has been more on saving money. The drive to put these managed care systems in place has been more about saving money than concerns for the consumer.

I think that the system could be brought into the kind of state that it needs to be effective and workable. But I do not think managed care is there right now. It is more problematic based on current implementation than fee-for-services from a consumer point of view.

Senator RIEGLE. Mr. Chiplin?

Mr. CHIPLIN. I think managed care presents a particular dilemma for the review of claims, particularly how people get information about whether and when a service has been denied, reduced or terminated. The Clinton proposal speaks in terms of a claim based on an indemnity model. It does not address the managed care context. In managed care one is not dealing with a denial of claim as in fee-for-service. Instead, requested services are not provided or are reduced without providing anything in writing to the individual.

Thus, under managed care, there is no particular trigger or entry point that gets into a posture for challenging the initial plan decision to deny, reduce, or terminate service. So, I think we do need to look very closely at the mechanisms that we would use in managed care to assure that people have a mandated review process, including notice, where there are disputes about coverage or service.

Senator RIEGLE. Ms. McConnell?

Ms. MCCONNELL. I am must more concerned about managed care systems because coordination really becomes gatekeeping. Again, for children who have special health needs that access to appropriate providers is really important.

You do not have as much freedom, I guess, to kind of figure out and work through the system and massage it a little bit. If your HMO happens to have a nephrologist but you need a pediatric nephrologist, those are differences. So I have a much higher level of concern there.

And interruption of services—I just heard a story last week about a youngster who is being seen in a rehab clinic who is in the middle of this lengthy process that involves a lot of casting and what not. Insurance coverage changed midstream to a managed care system. And here this kid has a cast on his leg, is in the middle of this process and cannot get the referral from the HMO to continue and follow up that treatment.

Senator RIEGLE. Let me thank you all. We may have other questions for the record from Senator Grassley and others. It has been very helpful to us and I appreciate your contribution today and beyond today. Thank you.

Let me now as this panel is leaving invite our second panel to the table. Once they are down and seated, we will go ahead and introduce them and we will begin.

Let me introduce all three of our witnesses on the second panel and then we will take them in this order. Dr. Kathy Lohr is the Director of the Division of Health Care Services in the Institute of Medicine of the National Academy of Sciences. Margaret O'Kane is the President of the National Committee for Quality Assurance; and Dr. Barry Chaiken joins us from Brookline, MA where he is the Vice President of Clinical Marketing for Medical Intelligence, Inc.

Dr. Lohr, why do we not start with you?

STATEMENT OF KATHLEEN N. LOHR, PH.D., DIRECTOR, DIVISION OF HEALTH CARE SERVICES, INSTITUTE OF MEDICINE, NATIONAL ACADEMY OF SCIENCES, WASHINGTON, DC

Dr. LOHR. Thank you and good morning, Mr. Chairman. I am Kathleen Lohr of the Division of Health Care Services at the Institute of Medicine. I want to thank you today for the opportunity to comment on critical quality of care issues.

As health care reform proceeds, we must keep quality on the national agenda. As you have heard already and so eloquently from your four previous panelists, we must strive to maintain and improve the processes and outcomes of health care services while ensuring that all citizens enjoy equitable access to those services.

We must direct attention to three issues. First, the use of unnecessary or inappropriate care, which is generally agreed to be a significant problem in fee-for-service systems.

Second, underuse of needed, effective, and appropriate care, which is especially critical because managed care systems envisioned by some reform proposals include incentives that may well limit the provision of needed services or referrals—as you have already heard in the discussion.

The third issue is attention to lapses in technical and interpersonal aspects of care.

How can you address these problems as the legislative process goes forward? I suggest four important steps. First of all, ensure that health care organizations establish their own efficient internal systems to protect consumers, improve practitioners' performance, and enhance patients' outcomes. Another step is to provide for external oversight of the means by which we improve and assure the quality of care delivered. A further step is to require public accountability for health care dollars spent. Finally, we must support health professionals in sustaining their ethical commitment to patients and in maintaining their skills and knowledge throughout their careers.

The Institute of Medicine's definition of quality of care may be helpful to your deliberations. It says that "quality of care is the degree to which health services for individuals and populations increases the likelihood of desired health outcomes and are consistent with current professional knowledge."

I want to call your attention especially to four elements of this definition, which is spelled out somewhat more in my written testimony. First, it says the quality of care applies to all health services, not just medical services and not just those relating to physical ailments. Mental disorders are important as well.

Second, it applies to individuals and populations. This means we are concerned not just with the users of care or insured groups. Rather, we should be looking at everyone who lives in a geographic area or is enrolled in a particular health plan. This means we must be concerned with the most vulnerable and frail among us, as we have heard so eloquently already today.

Third, the IOM definition refers to desired health outcomes—that is, health status and functional outcomes that matter to patients and their families.

Fourth, it highlights the responsibility of health professionals to stay abreast of the knowledge base in their fields and to help contribute to the development of, for instance, clinical practice guidelines.

Can we ensure the quality of health in an age of uncertainty about science and an era characterized by rapidly evolving delivery systems? Yes, we can measure the quality of health care. Many experts have been engaged for at least two decades in developing reliable and valid ways to assess the quality of care. I hope that this hearing will help raise the comfort level about this point among the Senators on your committee who are so concerned with health care reform today.

Furthermore, we know that quality can and must be improved. Quality improvement requires several things. For example, standardized measures of health care quality must be developed and used, particularly if we go the route of so-called report cards in the future.

Health plans must be held accountable to the public, sc that the quality of their care and their prudent use of private and public funds can be evaluated. Some plans—integrated systems, hospital networks—today do now try to look at patient functional outcomes and to report on key processes of care for chronic conditions or preventive services.

And we must find ways to disseminate more and better information to providers and to the public. This requires that we appreciate and overcome the barriers to the acquisition, storage, analysis, and release of adequate, unbiased, and useful information. I want to salute your efforts and those of Senator Bond's with respect to Senate 1492 and the national information infrastructure that will be a critical element of successful reform in the future.

Collaboration between the nation's academic health centers and our established quality review organizations exemplified in part by the Medicare peer review organizations that exist today, as perhaps reformulated as quality care improvement foundations or quality health care foundations—as you heard from Mr. Chiplin—will help to move this agenda forward.

Finally, let us remember that health care is about people. Market or consumer-oriented models of health care delivery and the related programs of quality measurement and improvement may serve informed consumers well. But it is unclear how such models

will serve many children, let alone those with special health care needs, or serve the chronically medically ill or the fragile elderly or minority or non-English speaking groups and other populations that are not looked upon as easy or attractive markets to serve.

In closing, to protect quality of care for all people and to promote the objective of universal access to care, both external quality monitoring programs and internal monitoring improvement efforts will be required.

Health care reform offers an unparalleled opportunity to achieve equity and coverage and to set in place institutions that will improve the quality of care through enhanced public accountability and oversight and through enhanced technologies for assessing and changing health care practice for the better.

On behalf of the Institute of Medicine, I look forward to working with you, Mr. Chairman, and other members of the committee on these important matters and I would be pleased to respond to questions. A number of the points that I made are in my written testimony as well.

Thank you.

Senator RIEGLE. Thank you very much.

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

The CHAIRMAN. Ms. O'Kane?

STATEMENT OF MARGARET E. O'KANE, PRESIDENT, NATIONAL COMMITTEE FOR QUALITY ASSURANCE, WASHINGTON, DC

Ms. O'KANE. Good morning. My name is Margaret O'Kane and I am the President of the National Committee for Quality Assurance. We are very pleased to have the opportunity to testify today before the subcommittee on the important topic of consumer protection and quality assurance under health care reform.

To monitor and improve quality under health care reform, we propose a public accountability system using three complimentary efforts. First, entry level standards for all health plans, indemnity and managed care; second, a health plan accreditation process to assure quality care and service; and third, public reporting of performance measures in order to empower consumers.

The goals of such an accountability system should include consumer protection and access to care, continuous improvement and quality, and consume access to information on quality.

National entry standards should determine which health plans are allowed to conduct business in a reformed health care system and should apply to all health plans, no matter what the payment arrangement.

Accreditation assesses how well a licensed health plan has established management structures and processes to monitor the quality of patient care and member service and verifies that those structures and processes are functioning appropriately.

Public reporting of performance measures or report cards will give consumers and purchasers more information on specific aspects of health plan performance and will also provide incentives to plans to continuously improve.

NCQA is committed to empowering consumers and purchasers with information on quality and cost to make informed choices among health plans. This commitment is best illustrated by HEDIS

2.0, a report card developed by NCQA in conjunction with purchasers and health plans and our consumer information project.

In November NCQA released the final version of HEDIS 2.0, a core set of standardized performance measures that were defined by a combined group of major employers and health plans. The components include quality, access, patient satisfaction, utilization and finance.

NCQA is now pilot testing the report card concept with 21 of the nation's largest health plans, using a core set of the HEDIS measures. The pilot project will conclude at the end of this year with a first independently audited national report card released to the public. I would note in referencing that the prior panel, that these measures will be collected on a population basis. We have been very influenced by a lot of the work that Kathy Lohr and the Institute of Medicine have done. We really believe that quality information must be collected on a population basis.

While significant progress has been made in producing detailed information for purchasers such as HEDIS 2.0 much more work remains to be done in exploring the information needs of consumers. Very little is known about the types of quality information that will be compelling to consumers or the best manner in which to present such information.

We launched our consumer information project in 1993 to research these information needs. In addition to the focus groups which we are in the process of conducting, a national survey will be conducted to validate findings and to determine precise consumer priorities.

We will pay particular attention to those groups such as the elderly and chronically ill for whom the choice of a health plan assumes even greater importance. NCQA has also joined in a collaborate effort with the Health Care Financing Administration and the State Medicaid Director's Association on the Medicaid Managed Care Performance Measurement Project.

This 16-month project will focus predominantly on maternal and child health care and determine what data a State Medicaid agency should obtain for managed care contractors in order to monitor their performance in serving some of our most vulnerable populations.

We have also been involved in the Michigan project, a collaborative effort involving 11 Michigan HMOs, the Big 3 autoworkers and the United Autoworkers Union. This project was the first effort to collect standardized comparable data across health plans, including a consumer satisfaction survey and an accreditation review.

For all health plans, NCQA recommends establishing national entry standards and increasing these requirements annually until more demanding accreditation standards can be applied to all plans.

In addition to basic entry standards, NCQA recommends a national set of quality reporting requirements to be used by all health plans. While some health plans have invested significant resources in the development of information systems, others may require more time.

Both the accreditation process and performance measures are critical to ensuring the delivery of quality care and service from li-

censed health plans. Evaluation of the effectiveness of a health plan's internal systems through external review and accreditation provides information on the extent to which a health plan has created an environment supportive of high quality care and the ability of the health plan to continuously improve its performance.

The process also ensures that basic protective and monitoring systems are in place for the problems which do arise. An unfortunate by-product of health care reform could be duplicative and burdensome quality requirements at the federal, State and alliance level.

NCQA already enjoys a relationship with four States and discussions are underway with many others to ensure compatibility between State licensure requirements and accreditation.

By the end of this year nearly half of the HMOs in the country will have been accredited by NCQA. NCQA's accreditation review process includes a structured survey of an organization's quality improvement program, credentialing activities, utilization management system, preventive health services program, medical records and systems for ensuring member rights.

I noted with pleasure that many of the issues that were raised by speakers on the prior panel are addressed in our standards and I would like to submit a copy of the standards for the record.

Our standards are not entry level with only 27 percent of the plans that have gone through the review receiving full accreditation at this time. We do anticipate that that number will grow as more plans have a chance to address the areas where they were initially not in compliance with our standards.

They survey is conducted by a team of highly qualified physicians, all with managed care experience and an administrative reviewer. It is not uncommon for health plans to begin preparing for the accreditation process years in advance to bring themselves into compliance with the standards.

Strengthening QI programs and assuring the opportunity for enrollee input, increased scrutiny of provider credentials, revising member appeal and grievance procedures, ensuring the consistency of utilization management and opening that process up more to physicians, instituting the use of practice guidelines—these are only a few examples of concrete changes that we believe our program has brought about in much of the managed care industry.

We recognize that HEDIS is only the first step towards the development of a system of comparable performance measures on health plan quality. The development of performance measures is an ongoing process. Those measures that already exist have high consensus in the medical community and a strong scientific base. But we do need measure on a broader range of procedures and services.

Based on our experience, NCQA supports a well—researched implementation strategy with realistic goals and a prudent phase-in schedule. Further, whatever the outcome of health care reform, we strongly suggest that advantage be taken of the work that has already been done.

In conclusion, let me just re-emphasize that we are proposing a public/private approach that builds on current work, such as HEDIS 2.0, the accreditation process and the work that we are

doing with consumer information project—a quality and accountability system based on national entry standards, accreditation and public reporting of performance measures, quality requirements for all health plans, both managed and fee-for-service, a reasonable implementation strategy and a medical research system that works to inform what is effective in medical care and how to appropriately measure quality.

We are committed to working with the members of this subcommittee and the entire Congress to ensure that quality and consumer protection are not compromised as a result of health care reform.

Thank you for the opportunity to testify.

Senator RIEGLE. Thank you and thank you for a very detailed presentation.

[The prepared statement of Ms. O'Kane appears in the appendix.]

Senator RIEGLE. Dr. Chaiken, last but not least, we would like to hear from you now.

STATEMENT OF BARRY P. CHAIKEN, M.D., M.P.H., VICE PRESIDENT, CLINICAL MARKETING, MEDICAL INTELLIGENCE, INC./GMIS, BROOKLINE, MA

Dr. CHAIKEN. Thank you, Mr. Chairman, for the opportunity to testify before this committee. My name is Barry Chaiken and I am a Board Certified physician in general preventive medicine and public health, as well as quality assurance and utilization review.

Over the last 10 years I have done research and worked in the field of health care quality assurance. I am Vice President at Medical Intelligence/GMIS, a leading developer of appropriateness protocols, profiling tools and other technology based information systems.

Mr. Chairman, I respectfully request that my submitted written testimony be placed in the record. I will now summarize that testimony.

Senator RIEGLE. Let me just say we will make all statements a part of the record just as a matter of course. They will all be in there.

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

Dr. CHAIKEN. Thank you.

It is with great anticipation I approach this committee today to give testimony on health care issues and the affect new information technologies have on the delivery of care.

Clearly, the swirling debate on how to restructure a health care system has raised the awareness of all Americans to this important issue. The impact of technology on the transfer of information is evident each day on television. Anything that occurs in the world can be almost instantaneously brought to each and everyone's living room.

Surely the fall of communist nations had much to do with the loss of control of information by those authoritarian states. He who controls information has the power to influence and change behavior.

It is through the management of information that we can address some of our health care challenges. We need to use new information technologies to provide physicians, patients, providers and payers with the appropriate relevant information to produce good, acceptable outcomes from appropriate cost effective care.

Criteria, a term often used to describe any medical information summary that assists in the direction or review of care have been in wide use for many years. In the late 1970's and early 1980's many health care providers used criteria such as lengths of stay tables or other checklists to identify gross misuses of resources.

In the 1980's as managed care became more widespread and the interest in quality care increased, organizations developed guidelines and standards to manage quality and utilization of care. Guidelines and standards work well for tests and procedures where the proper plan of care is well known and usually followed.

In instances where this is not the case, appropriateness protocols are useful. This includes procedures of high risk to the patient, high costs and where evidence of inappropriateness exists. In the late 1980's advances in computer technology and information systems research allowed this type of protocol development.

Much attention has been directed to the benefits outcomes research can have on directing good quality care. Outcome measures look at clinical results of treatment, functional health status and patient satisfaction. We no longer think that the surgery was successful if the patient is debilitated or dies.

The development of huge health payment claims databases provide a vast source of mostly untapped physician performance data. Claims data can be used to profile care provided by health care institutions, managed care networks, physician groups and even individual physicians.

Using both software and hardware tools unavailable only a few years ago, organizations can use this claims data to identify patterns of quality and utilization. We are all familiar with the medical databases available to researchers.

Vice President Gore has made popular the phrase "information highway" and we all have heard much about Internet. With the advent of this information highway, medical information and the exploration of medical databases are no longer left solely to clinicians.

Physicians must step forward and take a leadership role in the development of use of these information systems to more efficiently manage high quality care. The medical profession can set the clinical direction for the work on the development of standards, guidelines, protocols and outcomes measures. We have a responsibility to protect the quality and access to care while helping to manage utilization.

Payers have the responsibility to use the best information technologies available to help ensure good quality patient care at a reasonable cost. This commitment must embrace the best tools, not just those tools that they currently use or they feel comfortable with.

Patients too have a serious responsibility for their own care. The advancement of information technology allows non-clinical people access to huge amounts of medical information in a form that they can understand. As patients become more educated about their ill-

nesses and potential treatment options, they must assist their physicians in developing treatment plans that are right for them.

Industry must underwrite innovation through grants and supportive programs that take advantage of new information technologies. Industry can help by encouraging the further development and use of guidelines and protocols, the proper use of profiling systems and the support of outcome studies by their employees. Industry must also recognize the link between quality and cost and not just focus on premiums.

Many commercial organizations embrace the concepts around information technology and quality management. These organizations play a key role in the advancement of medical information technologies through their critical investment in development and maintenance of these technologies.

Consumer groups do much to promote the dissemination of information. Consumer protection organizations collect, package and distribute health care information, thereby allowing people to make more informed choices. With the existing communication and computer networks, none of this information sharing and education could be possible.

Government truly has a role in this information technology explosion. Through the support of research efforts, more can be learned on how to make our information systems better. Although government should not set specific standards of care which can quickly become outdated and unworkable, government can provide general targets that the private sector can work towards.

This includes levels of preventive services, and encouragement of appropriate use of standards, guidelines, profiling and outcomes to monitor the delivery of health care services.

My final advice to the subcommittee is hold tight. The medical information super highway has no speed limit. Thank you. [Laughter.]

Senator RIEGLE. You have given us a lot of very valuable suggestions, all three of you. I appreciate that and we will work with your recommendations. In terms of the most important first one or two steps we should take at the Federal level in terms of encouraging the development of a better system, in terms of quality improvement, what are the things that you think are absolutely critical? Go ahead, Ms. O'Kane.

Ms. O'KANE. Well, I am going to reiterate what I said in my testimony.

Senator RIEGLE. I partly expect that.

Ms. O'KANE. Right.

Senator RIEGLE. But I want you to give me the top of the priority list.

Ms. O'KANE. Well, I think what we need to do is set entry level requirements for plans that are both realistic but ambitious enough and I think it goes beyond what current health plan requirements are or indemnity plans that you can ensure some degree of success.

I think it would be a disaster to have a lot of failures of health plans and massive dissatisfaction just as health care reform is unrolling. So we would be happy to work with you on those requirements.

Second, an accountability system where you start standardizing what is reported so that the information can be collected across all health plans on important aspects of performance, like particularly preventive measures, particular key processes for chronically ill patients and so on.

Dr. CHAIKEN. I would agree with that in the sense that information and collection of information is very useful to be able to identify quality issues, as well as utilization.

One of the problems we have today is that our information systems are really in the childhood stages where data is collected in various types of formats and various types of systems and often is unable to be put together and analyzed. The one way that government can help is to encourage the establishment of some types of broad standards for data collection, similar to the way the computer industry has standardized on the Microsoft disk operating system, so that everybody can work off of a similar platform and then can work from that.

Also, Dr. Tooker earlier talked about having guidelines that are clinically based and that are relevant to clinical matters as opposed to cost. I would like to emphasize my support of that. That is very important for not only protecting patient care but also making sure of the outcomes of good quality.

Dr. LOHR. I would like to suggest two prior broader issues first before mentioning a couple of specifics. One is to encourage you to insist that quality of care be on the national agenda for national health care reform and to pound home the message that reform is not just an issue of access to care, and it is not just an issue of financing and costs. We must keep quality of care in the forefront of our thinking about reform for the next few years or decade.

I want to urge that you and the other members of this subcommittee reinforce the notion that we can define quality of care and that we can measure it. There really is considerable concern, I am afraid, on both sides of the Congress about whether we can do those things. The message that should come through is, yes, we can. It is not necessarily easy. It is not costless. But we can do it and we should be comfortable with that notion so that we do not use the bug-a-boo of "we cannot measure quality" as a means either of not trying it or of stopping reform in its tracks.

Having said that, I think I would mention three particular first steps. One is to understand we need both support for internal quality improvement programs in the health plans however they evolve, whether that is pure managed care systems, existing fee-for-service systems, point-of-service systems, or hybrids that we probably cannot even manage yet.

But in addition, we need strong support for an external quality monitoring program based, I think, probably at the State level with considerable inputs from the private sector—as you have heard, for instance, through groups like NCQA—but with Federal guidance and oversight of the whole process.

My second piece of advice is support for research. Research in the effectiveness of services, in outcomes research, and in the area of quality of care. There is a great deal we do not know yet about report cards, about the way to collect and disseminate information

to consumers or to providers in ways that they will find it useful. We need a considerable amount of work in that area.

The third area that I would underscore is the one that Dr. Chaiken just mentioned, and that is the information infrastructure. I am concerned frankly that with the national information infrastructure, the high performance computing program and so forth, health care may not be getting quite the attention that it should relative to some other sectors of our economy.

I would urge you to consider whether there should not be some real in-depth look at the health care applications of the information infrastructure, and I would be happy to send over a couple of recent reports that the Institute of Medicine has done in the area of databases and computer-based patient records. That may be helpful background.

Senator RIEGLE. Good. We would like to have those.

Let me thank you. We are going to have some additional questions for the record from Senator Grassley and others. You have been very helpful today. This is an issue that is extremely important in the effort to do health reform properly. I again thank you all.

The subcommittee stands in recess.

[Whereupon, at 11:38 a.m., the hearing was recessed.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED

PREPARED STATEMENT OF BARRY P. CHAIKEN

INTRODUCTION

It is with great anticipation I approach this committee today to give testimony on health care issues and the effect new information technologies will have on the delivery of care. Clearly the swirling debate on how to restructure our health care system has raised the awareness of all Americans to this important issue.

A look back at the advancement of modern medicine over the last twenty years is breathtaking. Who could have foreseen the introduction of computer axial tomography or CAT scan imaging, magnetic resonance imaging or MRI, laproscopic surgery with fiber optics, Teflon arterial graphs or the numerous pharmaceutical treatments for previously incurable diseases. The list of these miracles goes on and on, with new miracles introduced each day.

Some claim that these miracles are the cause of our health care costs crisis while others focus on the benefits of these new technologies. I will leave this debate to others, but today will focus on a new technological revolution in health care, that of information management and information systems.

We as Americans have gained so much from the march of technology. In addition to the medical gains already noted, our lives are filled with new reliable devices that provide us with convenience, entertainment and safety. Microwave ovens cook automatically, 35" televisions access 500 channels, and automobiles stop on ice without skidding.

The impact of technology on the transfer of information is evident each day on television. Anything that occurs in the world can be almost instantly brought to each and everyone's living room. Surely, the fall of the communist nations had much to do with the loss of control of information by those authoritarian states. He who controls information has the power to influence and change behavior.

It is through the management of information, in particular its dissemination, that we can address some of our health care challenges. We need to use new information technologies to provide physicians, patients, providers and payors with the appropriate, relevant information to produce good, acceptable outcomes from appropriate cost-effective care.

To understand where we must go, we must look back at what we have already accomplished. Work in the management and distribution of medical information has been going on for some time. Many organizations and individuals have contributed greatly to this effort. With the new technology now available, the challenges have become even greater.

APPROPRIATENESS

Although information technologies could be useful in many areas of health care, laboratory, imaging or pharmaceuticals, I will concentrate on a somewhat broad based issue, appropriateness of care.

Experts have estimated that up to 30% of all medical care is inappropriate or unnecessary. A classic study by Wennberg identified variations in health care in two small towns in Vermont that could not be easily accounted for. Dr. Wennberg looked at the prevalence rate of tonsillectomies in all residents of each town by the age of 20. He discovered in one town a 10% prevalence rate while in the other town a 60% prevalence rate. When he examined the towns for obvious causes of this result, he found that the towns were approximately the same in size, ethnicity, and number and mix of physicians. Dr. Wennberg concluded that practice patterns generated

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these differences in rates. The question arose whether one town received too many tonsillectomies or the other town too few. Either way patients may have received inappropriate care.

Other studies done throughout the 1980s identified inappropriate care for such procedures as pacemaker implantation, coronary artery bypass graft, and hysterectomy, among others. The RAND Health Service Utilization Study (1981–1986) identified varied inappropriateness rates for coronary angiography, carotid endarterectomy and upper GI endoscopy. With such evidence, although we do not know the exact amount of inappropriate care going on in the United States today, we can all agree that there is some degree of inappropriate, unnecessary, and potentially harmful care being delivered. In turn, inappropriate care becomes a quality of care issue that directly impacts costs.

CRITERIA, GUIDELINES, PROTOCOLS

To understand how we might use technology to address this quality of care problem, we need to review some of the information technologies used in the past.

Criteria, a term often used to describe any medical information summary that assists in the direction or review of care, have been in wide use for many years. In the late 1970s and early 1980s many health care providers used criteria such as lengths of stay tables or severity indexing/intensity of service checklists to identify gross misuses of resources. Utilization review companies formed to help providers manage health care resource more effectively. Although many of these systems developed from questionable methodologies, they generally helped reduce resource use. Unfortunately, they failed to adequately address the important issues around quality and appropriateness.

In the 1980s as managed care became more widespread and interest in quality care increased, organizations developed guidelines and standards to manage quality and utilization of care. The Agency for Health Care Policy Research here in Washington contributes greatly to guideline research. The Centers for Disease Control and Prevention provides pediatricians with immunization standards that are used all over the world. The American Cancer Society and other medical societies develop standards for cancer screening. Several commercial guideline efforts produced systems that can identify gross inappropriate care, poor quality, and resource waste.

Guidelines and standards work well for tests and procedures where the proper plan of care is well known and usually followed. In instances where this is not the case, appropriateness protocols are useful. This includes procedures of high risk to the patient, high costs, and where evidence of inappropriateness exists. In the late 1980s, advances in computer technology and information systems research allowed this type of protocol development.

These protocols use both physician and patient information (including patient preference where applicable) to quickly identify appropriate care. These systems are logic based expert systems that attempt to reproduce the clinical thinking that leads to a decision to go ahead with a particular therapy or test. The use of this knowledge engineering process allows the development and testing of expert systems that provide assistance to physicians in making clinical decisions.

Unlike in the 1970s where criteria were developed without rigorous methodologies, appropriateness protocols use accepted research methods that include medical literature review, broad based expert panel selection, and knowledge engineering techniques. Both physicians and their patients now demand protocols that are clinically valid and defensible.

Because these are computer based systems, the inherent logic can quickly be processed resulting in a clinically valid recommendation. Without the use of this technology, the flow chart to capture the internal complexity of the protocol would fill a moderate sized wall, and even then be functionally unusable. In addition to the information itself, the method of delivery of the information is key to its usefulness. Only systems that deliver relevant information at the time that it is needed are truly helpful. It is information physicians strive for, not data.

There are several systems available that use these technologies. Great value, through improved quality of care and reduced costs, can be obtained from using them more actively. In addition, building a trusting and mutually respectful relationship among physicians, patients, providers and payors assists in the use of clinically defensible and respected appropriateness protocols. Their delivery on a technologically sophisticated platform makes them useful.

OUTCOMES

Much attention has been directed to the benefits outcomes research can have on directing good quality care. Research is ongoing at the Agency for Health Care Pol-

icy Research, academic institutions and commercial organizations. Several managed care organizations, hospitals and others use outcomes measures to monitor the benefit their care has provided.

Outcome measures look at clinical results of treatment, functional health status, and patient satisfaction. Presently, my organization is doing short and intermediate term follow-up on patients who have received lower back surgery. Others are developing instruments to measure how patient lives have changed since receiving care. Still others are evaluating how satisfied patients are with their treatment, and measuring their level of improvement in terms that the patient can understand. We no longer think the surgery was successful if the patient is debilitated or dies.

To be sure, outcomes measures are not a magic bullet for our health care quality and cost problems. Methodology challenges exist in outcomes research and there are the additional problems of study costs, study length and changes in medical treatment that make the studies less useful.

These limitations aside, these new research areas take great advantage of the many new information technology tools.

PROFILING

The development of huge health payment claims data bases provide a vast source of mostly untapped physician performance data. Even with its inherent methodology and reliability problems, claims data can be used to profile care provided by health care institutions, managed care networks, physician groups, and even individual physicians. Using both software and hardware tools unavailable only a few years ago, developers can use this claims data to identify patterns of quality and utilization.

Profiling tools often look at episodes of care, the health care process a patient goes through from first becoming ill to finally returning to their baseline health status. In addition, key performance indicators, similar to the standards I mentioned earlier, are used to evaluate physician performance. Standard treatment protocols help monitor resource use for categories of diagnostically equivalent illnesses. With all this, statistical adjustments, using case mix or severity of illness measures, are made to equitably compare physicians using normative data bases in an effort to identify areas where further evaluation is needed.

Notice, I did not use the word outliers or suggest that problem areas are definitively identified. These systems are limited by the data they collect. If properly used, they focus in-depth evaluation on areas that are most likely to identify a problem area. This allows continuous quality improvement to take place as physicians and organizations receive relevant feedback on the care they are providing, while identifying specific areas that require improvement. This improvement can be in the form of education, training and changing of systems (e.g., the way in which things are done.) If improperly used, they incorrectly label some physicians or institutions as problems when in reality they may be treating more difficult patients.

As complicated as these systems are, could anyone imagine doing such sophisticated analysis and evaluation without the use of the latest in information technology?

MEDICAL DATABASES

We are all familiar with the medical data bases available to researchers. Vice President Gore has made popular the phrase "information highway" and we all have heard much about Internet. With the advent of this information highway, medical information and the exploration of medical data bases are no longer left solely to clinicians. Recently I heard the story of a couple where the woman suffered from disruptive sleep patterns and enhanced dreaming. Being familiar with information technology, they used the available professional and consumer data bases to determine the probable diagnosis, testing and treatment of her condition. When they visited a sleep specialist, they were able to provide the treating physician with important information used to further diagnosis and treat her condition. Happily, the woman is doing well, and resting comfortably at night for the first time in years.

This is just one example of how information technology and access to useful relevant information can have a significant affect on the delivery of health care.

CHALLENGES

There is a very big difference between data and information. Whether using criteria, guidelines, protocols, profiles, outcomes or medical data bases, it is the way the data is presented, packaged, and delivered that turns it into information. Information about mycoplasma pneumonia is not very helpful to a physician currently treating someone for Lyme arthritis. Information about Lyme arthritis is equally

unhelpful when the next patient then presents with mycoplasma pneumonia. Data becomes information only when it is relevant to the situation at hand and is available on a real time basis. Our medical system does not lack data, it lacks information. These new information technologies convert data to information. With this there are challenges for all involved.

Physicians

Physicians must step forward and take a leadership role in the development and use of these information systems to more efficiently manage high quality care. The medical profession can set the clinical direction through work on the development of standards, guidelines, protocols and outcome measures. We, as physicians, must accept the fact that utilization is an issue that must be addressed. We have a responsibility to both manage utilization while protecting the quality and access to care. Who better to understand the inherent clinical issues than physicians?

If physicians are to successfully provide leadership, they must embrace the concepts of education and re-training. It should no longer be an embarrassment to physicians to submit to re-training and re-credentialling. When a Navy pilot has trouble landing his fighter on an aircraft carrier, the Navy does not boot the flier out of the Navy. Americans invest millions of dollars training pilots. It would be foolish to cast the pilot off. Instead, the Navy provides retraining to re-certify that flier for aircraft carrier duty. The flier submits to re-training because it is the pilot's duty, and it is part of the normal process of flying a fighter from an aircraft carrier.

Who can deny the huge societal investment in training physicians? There is no physician who can claim to have avoided doing harm to a patient during training. The benefits to society are the contributions physicians makes in healing patients during their entire careers. Does it make sense to use information tools to banish physicians from their craft without the opportunity to re-train? Does it make sense for physicians to resist retraining?

Payors

Payors have the responsibility to use the best information technologies available to help ensure good quality patient care at a reasonable cost. This commitment must embrace the best tools, not just those tools that they currently use or they feel most comfortable. Even though these tools have some limitations, they are constantly improving and their contribution is substantial.

If physicians embrace education and re-training as directed by these information tools, payors must respect physician concerns. Doctors should not be removed from managed care networks solely because of the results of a profiling tool. There must be cooperation between payors and physicians so the information provided by these various tools can be used to improve the quality of care while limiting inappropriate care. Physicians must be given the opportunity to understand their patterns of care, explore the reason for it, and have the opportunity to receive education and re-training, if necessary, to modify that pattern so it is more consistent with what is expected. Payors must truly promote quality of care recognizing that high quality care manages costs. They must encourage innovation in information technology and help physicians to convert data to information to improve quality of care.

Patients

Patients too have a serious responsibility for their own care. As described earlier, the advancement of information technology allows non-clinical people access to huge amounts of medical information in a form that they can understand. Several of the national on-line services, Internet and local computer bulletin boards have forums for patients with similar diseases to share information. As patients become more educated about their illnesses and potential treatment options, they must assist their physicians in developing treatment plans that are right for them. All the responsibility can not be just on the treating physician. Patients need to also embrace preventive services that can significantly impact on their own morbidity and mortality. Finally, they must support the development of new technologies and techniques particularly through their participation in outcomes studies.

Industry

Industry has an important role to play whether their business is in the medical marketplace or not. Industry must underwrite innovation through grants and support of programs that take advantage of new information technologies. Industry can help by encouraging the further development and use of guidelines and protocols, the proper use of profiling systems and the support of outcome studies by their employees. Industry must also recognize the link between quality and cost and not just focus on premiums. With or without managed competition or health care reform, in-

dustry has a leading role to play in reshaping the delivery of health care in America.

OPPORTUNITIES FOR PARTICIPATION

There are many opportunities for clinical and non-clinical people to assist in the development and use of these high technology information tools for quality assurance and appropriate care. For example, the National Association of Managed Care Physicians, located in Glen Allen, VA is a group of 12,000 physicians working to educate physicians for leadership roles in the changing health care delivery system. Its founder, William C. Williams, MD, believes physicians must work to develop the standards, guidelines, protocols and data analysis methodologies so that physicians can provide consistently good quality care. The Association is exploring partnerships with industry to use new information technologies to educate both physicians and patients. The Association's non-profit educational foundation is moving forward with an initiative to train health care professionals in managed care.

The American Board of Quality Assurance and Utilization Review (ABQAURP) located in Tampa, FL, educates and certifies physicians, nurses and other health care professionals in quality assurance and utilization review. Headed by Joseph Murphy, MD, the Board hired the National Board of Medical Examiners to revise and standardize the board certification exam to take into account the changes new technologies have brought to the field of quality management. Regular continuing medical education programs and core body of knowledge courses offer health care professionals the opportunity to learn about the latest advances in quality assurance and utilization management. Recently, ABQAURP formed an educational foundation to promote quality assurance research.

Other organizations that promote quality and cost containment through better use of information include the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Utilization Review Accreditation Commission (UBAC), and the National Committee for Quality Assurance (NCQA). The JCAHO inspects hospitals and other health care institutions while also offering educational sessions to professionals. UBAC accredits organizations that provide utilization review services. NCQA inspects and accredits health maintenance organizations.

Many commercial organizations embrace the concepts around information technology and quality management. These organizations play a key role in the advancement of medical information technologies through their critical investment in development and maintenance of these technologies. An example of one such company is GMIS Inc. Led by its president and chief executive officer Tom Owens, GMIS is spearheading the development of integrated information modules to influence and monitor the delivery of health care. This medical management system model uses appropriateness protocols to identify and limit unnecessary care, unbundling and coding tools to monitor billing practices, and profiling tools to feedback information to physicians so they can improve their own quality and utilization. Medical Intelligence, Inc./GMIS headed by its president Joanne Hilferty, uses physicians and researchers to develop protocols solely based upon clinical information on appropriateness, and outcomes measures focused on patient issues. These and other organizations use the latest in computer, research, and information technology to impact positively on the delivery of health care.

Consumer groups do much to promote the dissemination of information. As noted already, informal illness specific groups have formed to exchange information. More established consumer protection organizations collect, package, and distribute health care information, thereby allowing people to make more informed choices. Without the existing communication and computer networks, none of this information sharing and education could be possible.

Government truly has a role in this information technology explosion. Through the support of research efforts more can be learned on how to make our information systems better. Although government should not set specific standards of care which can quickly become outdated and unworkable, government can provide general targets that the private sector can work towards. This includes levels of preventative services and encouragement of the appropriate use of standards, guidelines and profiling to monitor the delivery of health care services.

CONCLUSION

The information technology revolution is changing the way medical care is delivered. These new tools provide physicians with the opportunity to access relevant clinical information on a real time basis to most likely impact on their patient care. Using standards, guidelines, protocols, and information available from profiling using normative data bases, physicians can obtain useful information on their pat-

terns of care. Patients can obtain understandable information on their disease process, thereby becoming an informed consumer of health care. Organizations exist to educate physicians and other health care professionals in the use of these systems. For-profit firms are developing the tools and making the investment needed to convert data into information.

My final advice to this committee is hold on tight, the medical information superhighway has no speed limit.

PREPARED STATEMENT OF ALFRED CHIPLIN

Mr. Chairman, members of the Committee, my name is Alfred Chiplin. I am a Staff Attorney with the National Senior Citizens Law Center. I focus my attention on cases involving Medicare, home health care and Older Americans Act issues. Suffice it to say, the Center has many years of experience defending the rights of consumer's of health care and other Federal and state entitlements and services.

Today, I am representing the Coalition for Consumer Protection and Quality in Health Care Reform, a coalition of more than 25 consumer groups. We thank you for providing us with the opportunity to testify today, and congratulate you on your excellent record in health care and in protecting the rights of the disadvantaged.

The Coalition applauds the President's and Congress' all-out effort to reform the health care system. Specifically, we are pleased with the Health Security Act's attention to consumer empowerment through an extensive system of data collection, analysis and dissemination. The administration has also demonstrated its concern for patients rights through the establishment of an ombudsman program, an appeals system and the development of grievance procedures.

It is the Coalition's assessment, however, that additional consumer protections are needed to ensure that health care plans provide high quality care. The linchpin of any national health care system is consumer satisfaction. Reform can work, but only with strong consumer protections to ensure that plans do not contain costs by providing less care than is appropriate.

SUMMARY

I would like to outline briefly our vision of consumer protection in the new health care system. This new system relies on competition between health care plans and providers to drive the cost of care down and quality of care up.

Under any new system, consumers will need easy access to unbiased information to help them make meaningful choices between plans, providers, and coverage options. They will need an advocate or ombudsman to help them understand and navigate through the system and assist with resolving complaints. They will need an appeals process to address the denial, reduction, or termination of benefits and services, and quality issues independent and fair. They will want a grievance procedure for other patient complaints.

The system will need independent quality improvement foundations and quality assurance and public accountability through improved licensing, certification, and accreditation systems, and consumer control of governance structures. There must be guaranteed funding for these programs.

These are the elements of a health care system that is sensitized to the basic fact that the system—physicians, nurses, pharmacists, other health care professionals, hospitals, and health care plans—is there to serve those who need care, the consumers.

We do not promote red tape or over regulation, but the burden to ensure consumer protection and prevent poor quality of care falls on the President and Members of Congress. Please do not miss this opportunity to design a consumer- focused system or you will be hearing from your constituents when the system fails.

Today, I would like to address four areas of particular interest to consumers:

I. Consumer Due Process Protections
II. Consumer Information
III. An Independent Ombudsman Program
IV. Quality Improvement and Public Accountability

I. CONSUMER DUE PROCESS PROTECTIONS

Background

The Coalition believes that consumer notice, appeal, and grievance rights—collectively referred to as consumer "due process" rights—are essential in any national health care plan. Under a managed care system, health plans and the utilization

review systems work to keep the cost of care down. In some instances this will be done at the expense of the medical needs of the enrollee. Therefore, access to an independent and timely appeals process is critical to maintaining quality care for consumers.

Medicare beneficiaries enrolled in Medicare participating HMO's do have some, although inadequate, due process protections. Other enrollees in managed care plans have even fewer protections. Even so, the rights of Medicare enrollees to adequate notice and appeals procedures are honored in the breach.

The following case illustrates the necessity for strong consumer due process protections:

> Mrs. G. is a 71 year old resident of Arizona with multiple health problems including Diabetes, High Blood Pressure, Congestive Heart Failure, Anemia, and a Uremic Bladder. She enrolled in a Medicare contracting HMO, which promised to provide her with all of the health services covered by Medicare as well as additional services such as free physical examinations. Mrs. G. has had many problems since.
>
> Last year her right leg was amputated at the knee after her HMO doctor failed to respond to her complaints of pain in her foot. She is now wheelchair bound.
>
> In August, 1993, Mrs. G. was hospitalized with a blood clot. She was discharged by the HMO from the hospital, although she was still quite sick. Her HMO physician was unable to obtain approval from the HMO for rehospitalization and instead sent her to a nursing home.
>
> The HMO sent her home from their nursing home with an indwelling catheter, without making arrangements for home care or instructing her family in the care of the catheter.
>
> Her attorney wrote to the HMO plan demanding home health services. The plan agreed to provide one home health visit per month to change her catheter, but denied any additional services. Later Mrs. G. was hospitalized again with a serious urinary tract infection. After being discharged she was denied HMO-covered home health services needed to assist with her unskilled care needs until her attorney filed a Motion for Preliminary Injunction.
>
> Until her attorney wrote to the HMO and the Health Care Financing Administration, Mrs. G. never received a notice from the HMO stating that care was being denied, explaining the reasons for denying such care, or describing the availability of an appeals process.

Recommendations

A. Appeals Process

We have attached a copy of generic legislative language that we drafted which is applicable to any reform legislation. The primary issues addressed in this language are notice, procedures for independent administrative review (including expedited review), and access to the courts.

However, the Coalition is generally pleased with the review structures envisioned by the Health Security Act, which is consistent with our White Paper that we request be inserted in the record. We suggest that those structures be considered by your Committee. If you choose to use the Health Security Act's approach, the following are recommendations for improvements.

A. Notice of Appeal Rights

Congress must clarify the circumstances for providing notice to patients when decisions to deny, reduce, or terminate a service or payment have occurred. Specifically, the Coalition recommends that notice provisions of the Act be strengthened to include the following:

- Notices should be triggered automatically when certain benefits, such as hospital, in-patient rehabilitation, nursing home and home health care, have been denied, reduced, or terminated;
- Notices should state the specific reasons for the decision and describe the appeals process available to the patient;
- All plans should be required to provide enrollees with periodic notices of their appeal rights and prominently place notices describing appeal rights in provider waiting rooms.

The Health Security Act should clarify that what the Act refers to as a "claim" includes the review of a decision to deny, reduce, or terminate ongoing services. These vital points are also included in our generic legislative language.

2. Need for Independent Expedited Review

Our experience with clients leads us to conclude that without an expedited review system an appeals system is useless in cases of underservice, urgent care situations, or where critical ongoing services are being terminated or reduced. The appeals system takes months at a minimum. Often managed care enrollees denied needed care do not have months to wait for service. Even short delays in the provision of services, such as home health care rehabilitation services, MRIs, specialty care and surgeries can have harmful and permanent effects. The Health Security Act does call for an expedited review system, but one that is not independent of the managed care plans. The Coalition strongly recommends the following additions to the appeals process:

- All managed care enrollees should have available to them an expedited appeals system operating independently of the managed care plans for denials/delays in treatment that could seriously jeopardize their health or well-being.
- An independent monitoring organization should render a decision on all expedited reviews within 24 hours.

3. Shortening of Appeal Time Period

The Health Security Act gives plans 30 days to make a decision of an initial appeal and an additional 30 days to make a second decision on a request for reconsideration. The Health Security Act also requires that all claimants must go through the initial and reconsideration stages prior to referral to a state Complaint Review Office. The Coalition believes Congress should consider the following options to shorten the appeal process:

- The reconsideration stage of the appeal process should be eliminated, allowing enrollees to directly appeal to the Complaint Review Office following a plan denial of the initial appeal; or the time allowed plans to make initial and reconsideration decisions should be shortened to 15 days each.

4. Plan Coverage of Second Opinions

The Clinton Plan places the responsibility and costs of purchasing second opinions on the beneficiary. This places an unacceptable burden of proof on the beneficiary. For low-income individuals in particular, this burden will negate the appeal right. In response to this problem, the Coalition recommends that:

- The Health Security Act should require plans to pay second opinions for specified conditions/procedures, as determined by an administrative law judge where such opinions are necessary for fair resolution of issues or for the development of the record.

5. Point-of-Service Option—Out-of-Network Care

The provision of additional information is not enough to protect HMO enrollees in plans that provide poor quality care. The Health Security Act permits consumers to switch plans only once a year, which a number of our members do not think is often enough. Therefore, it is critical that managed care enrollees retain the option of seeking care outside a managed care plan. Specifically, the Coalition strongly recommends that:

- The Health Security Act's requirement that HMO's offer a "point of service option" be retained, and that low-income individuals and persons with rare diseases and disabilities will pay an appropriately reduced coinsurance for out-of-network care.

Attached is legislative language we have drafted to address this issue.

B. Grievance Process

All certified plans must be required to initiate and maintain a grievance process for patient complaints about problems other than denial, reduction, or termination of service or payment. We believe the grievance process should have the following components:

- Oral and written complaints from patients should be investigated by a patient advocate, who will prepare a written report for the plan and the consumer within 15 days;
- The plan's or insurer's grievance committee should issue a decision within 30 days regarding the patient advocate's report. The written decision should be sent to the grievant.

- Grievants dissatisfied with the grievance committee action should be able to obtain a review by a Complaint Review Office.

II. CONSUMER INFORMATION

Background

Currently, health care consumers lack even the most basic information about the quality of care provided by our health care system. The most common question asked by Medicare beneficiaries considering whether to join an HMO is "which one is best." Unfortunately, we have no answer to this question and Medicare beneficiaries are forced to make their health care choice in a virtual information vacuum.

Moreover, the little consumer information that is collected is of dubious quality. The Health Care Financing Administration (HCFA) and state governments have been extremely lax about HMO data collection in both the Medicare and Medicaid programs. HCFA, for example, collects, but does not analyze Medicare HMO disenrollment data, collects no meaningful utilization or outcome data by plan, and has very loose standards for defining (much less investigating or keeping data regarding) types of complaints received. In short, HCFA collects and provides to the public almost no usable quality of care data.

Further, with few exceptions, the state and federal governments and most HMO's are unwilling to provide consumers and their representatives with any quality of care information. In fact, on April 27th *The Washington Post* ran an article revealing the difficult time that the Federal Government is having in getting health care plans to join a nationwide survey of consumer satisfaction which we believe is a critical element of consumer information. Some plans voiced opposition to an independent surveyor and the choice of questions, and wanted the right to block the release of survey results after reviewing the responses. This is indicative of the need for mandated consumer information.

Recommendations

A. Information

The report card data required in the Health Security Act is an excellent first step toward ensuring that health care consumers have the quality of care information needed to make an informed decision. However, the Coalition believes that additional comparative, plan-specific and condition-specific information should be provided to consumers. The list below is only suggestive of the types of information we believe consumers need. For additional suggestions, I refer you to the Coalition's White Paper submitted for the record.

1. Comparative Information

Congress should require the collection and yearly publication of a number of additional comparative quality of care measures, including:

- Results of the consumer satisfaction survey;
- Plan enrollment and disenrollment figures;
- The ratio of complaints/grievances and appeals to plan enrollees;
- Information on plan providers and costs of out-of-plan use;
- Ratio of primary care practitioners to enrollees and the ratio of board certified physicians to non-board certified physicians;
- Information on plan benefits and any limitations on these benefits;
- Individual plan risk-arrangements (financial incentives under which plan health care providers operate); and
- Plan utilization data for selected services, including hospitalization, home health visits, and psychiatric visits adjusted for age, sex and, when possible, health status.

2. Plan-Specific Information

Plans or health alliances should provide all enrollees, upon request, with the following information to help in the selection of a primary care physician or other plan providers:

- Fact sheets on plan physicians—their training, years of practice, board certification, faculty responsibilities, and confirmed disciplinary actions such as repeated malpractice payments; and
- Fact sheets on individual hospitals, home health agencies, laboratories, pharmacies, and other contracted health providers with lists of services and other details.

3. Condition-Specific Information

Plans should be required to provide age, sex and, when feasible, severity adjusted condition- or treatment-specific information and a comparison with similar information for the region, state or nation. For a particular condition/surgery, this data could include:

- Number of surgeries performed (by hospital and by surgeon);
- Death rates within a specified time period;
- Complication rates for specified surgeries (e. g., surgery for prostate cancer); and
- Hospital infection rates (generally) and readmissions for the same condition within a specified time.

To ensure a better protected and informed public and to promote national consistency in data reporting, the Coalition believes that Congress should add greater specificity to the types of consumer information which must be made available.

B. Plan Marketing Controls

The Health Security Act requires alliances to approve all plan marketing materials. The history of both Medicare and Medicaid HMO's provides ample evidence that HMO marketing activities are open to serious abuse, and we believe some entity must monitor this area.

Consumer report cards with outcome and other measures are critical if consumers are to make informed decisions on which health plan to join. However, if controls on marketing are not adequate, plan marketing activities (including television, radio and print advertisements, celebrity spokespersons, and the actions of individual marketing agents) could undermine the report cards' effectiveness. At a minimum, the Coalition believes that marketing by managed care plans must be carefully scrutinized.

III. AN INDEPENDENT OMBUDSMAN PROGRAM

Background

The Coalition is pleased that the Health Security Act and other health care reform approaches have called for the creation of ombudsman offices to assist consumers with their questions and concerns and to serve as consumer advocates, helping consumers negotiate the system and resolve complaints. It should be noted, however, that as important as an ombudsman program is, it is not a substitute for the appeals process that we have outlined earlier in this testimony.

The Coalition believes, however, that Congress should provide much greater specificity regarding how this program will be designed, and how it can be used by consumers. We also believe that to be truly effective, the program must be adequately financed and operate independently of the plans, alliances, and states.

Recommendations

A. Financing

The Health Security Act includes the option for alliance eligible individuals to designate one dollar of their premium toward an ombudsman program. This approach puts the program in jeopardy from the beginning. Not every enrollee will understand the value of the program until they have a problem and need its services. Further, for the ombudsman program to be effective, it needs a trained, full-time staff supported with steady funding. To ensure an effective ombudsman program, the Coalition recommends that:

- Congress should mandate that a percentage of premiums collected be set aside to cover the costs of the Ombudsman program and other quality improvement and consumer protection systems.

B. Independence

The ombudsman must assist with both plan and alliance-related problems. It is unrealistic to expect the ombudsman to effectively deal with problems that arise within the alliance if it is located there and receives its funding from it. To ensure an effective consumer advocacy ombudsman program, the Coalition recommends that:

- The Ombudsman program be established as a non-profit consumer organization totally separate and independent of alliances, plans, providers, and purchasers.

The attached legislative language provides a framework for this new health care ombudsman.

IV. QUALITY IMPROVEMENT AND PUBLIC ACCOUNTABILITY

Background

The Consumer Coalition believes that consumer information, consumer protection, and quality improvement programs must be accountable to the public, independent of providers and payers of health care, and free of potential conflicts of interest. There has been proposed an excellent foundation for independent monitoring of quality through the establishment and functions of the National Health Board, National Quality Management Program, and National Quality Management Council at the federal level and the alliance quality of care reporting requirements at the state and local level.

Quality of health care is measured in three ways: structure, process, and outcome. All three complement each other and are needed if we are to adequately protect consumers in any managed care plan.

Several proposals provide for information on outcome measures. However, they do not include the establishment of consumer-based independent entities to monitor and improve the quality of care provided by plans. We must also ensure public accountability and adequately define the role of states in ensuring that consumers are protected through strong licensing and certification and enforcement of quality protections.

Recommendations

A. Quality Improvement Foundations

Any health care reform proposal should include an external quality review entity, independent of the payer-based alliances and provider-based plans to monitor and improve quality in each state, but not run by the state itself. For purpose of reference, we call these entities "Quality Improvement Foundations" or QIFs.

The National Quality Management Council would provide competitive grants to create one QIF in each state. Funding would come from the National Health Board through an amount designated from each premium. The QIF would be governed by a consumer majority board, which includes others who are experts in a variety of health and quality research fields.

Each QIF would perform a variety of quality monitoring and improvement functions, including:

- Performance of expedited quality of care reviews:
- Data analysis and data quality testing;
- Dissemination of information on successful quality improvement programs;
- Technical assistance to plans and alliances; Development of and support for quality improvement activities;
- Provision of consumer information beyond the report card;
- Monitoring and feedback to plans on adherence to practice guidelines;
- Analysis of plan utilization measures; and
- Quality assurance by providing:

  —information to consumers

  —feedback to licensing, certification, and accrediting entities and the National Quality Management Council.

B. Medicare Quality Oversight

The Health Security Act proposes the termination of the Medicare Peer Review Organizations. Although the Coalition believes that the functions of these organizations could be strengthened, we oppose their elimination and understand that the Administration no longer supports it either.

C. Consumer Representation

One of the most effective ways to ensure public accountability is to mandate consumer representation on advisory boards. The Coalition is pleased that the Health Security Act recognizes the importance of consumer involvement by providing for consumer representation on some of the boards and advisory councils specified in the bill. However, we believe that the consumer role in the governance of the health care system must be strengthened. Consumers are in a unique position to advocate for a system that delivers high quality care—unlike payers or providers of care, they are immediately affected by any changes in the quality of care delivered and are free from potential conflicts of interest.

The Coalition recommends a stronger consumer role including:

- Consumer control of the boards of any regional health alliances and corporate alliances (the Act currently provides for no consumer representation on corporate alliances.)

- Consumer representation on the National Quality Management Council and the National Long-Term Care Insurance Advisory Council and other boards and commissions established by Congress; and
- Funds to train and provide technical assistance to consumer representatives.

D. State Role and Licensing, Certification and Enforcement

The Coalition supports improving the effectiveness of licensing, certification and accreditation entities. Any reform bill and its implementing regulations should include provisions for strengthening the federal and state roles in licensing, certification, and accreditation, including:

For professional licensing boards (see attached legislative language)—

- Providing incentives through grants to increase the role of consumers on boards to at least 50 percent;
- Mandating that all fees paid by licensees be dedicated to the operation of the board; and
- Publicizing information regarding disciplinary actions.

CONCLUSION

Senators, we believe that proponents of the status quo in our health care system will distort the facts and attempt to scare consumers into believing that quality will suffer under a new health care system. We believe that the mechanisms that we are recommending will protect quality further and provide consumers with the information, advocacy, due process rights, quality improvement, and public accountability that will make this reform better for American consumers of health care.

The Coalition is grateful to Senator Riegle and his staff for holding this hearing and focusing your attention on these critical issues. We look forward to working with you in the future.

DUE PROCESS PROVISIONS FOR HEALTH CARE REFORM

SEC. _____. INDIVIDUAL APPEAL RIGHTS

(a) Appeals Process.-- An appeals process shall be established for patients for whom health care coverage, services, or referrals have been denied, reduced, terminated, or otherwise adversely affected. The appeals process shall include notice, administrative review, and judicial review.

(b) Subsidies and Premium Amounts.-- With respect to the denial, reduction, or termination of a subsidy or of a determination of a premium amount, the Secretary shall develop a notice and appeals procedure that provides the protections available to individuals the same as provided in Title XIX of the Social Security Act.

(c) Notice.-- Written notice must be given to the patient by the insurer or health plan as follows --

(1) promptly after decisions made by physicians and other service providers, as well as plan administrators and insurers, that result in --

(A) denial or termination of a specific service, referral, or coverage requested by the patient verbally or in writing;

(B) termination or reduction of coverage or provision of a course of treatment or ongoing series of services such as nursing home or outpatient therapy services; or,

(C) patient dissatisfaction expressed verbally or in writing with the type or extent of services or coverage being provided.

(2) such notice shall include --

(A) an explanation of the specific facts and law underlying the decision to deny, reduce, terminate or otherwise fail to provide services, coverage, or referral;

(B) a description of the process for appealing such decision sufficient to allow the patient to initiate an appeal and submit evidence in support of his position to the decision-maker.

(d) Administrative Appeals.-- An administrative appeals process shall be made available to the claimant as follows --

(1) an informal review shall --

(A) be held within 5 days of request by a claimant;

(B) be performed by the health plan or insurer;

(C) result in a written decision setting out the basis in fact and law within 10 days of request by the claimant;

(2) an administrative hearing shall --

(A) be held within 30 days of request by a claimant;

(B) be conducted by an independent administrative law judge;

(C) include evidence by an independent medical expert provided for the claimant at the plan's expense when the administrative law judge determines that such medical evidence is necessary for fair resolution of the issues or for development of the record;

(D) provide claimants the right to present supporting evidence, to subpoena and cross-examine adverse witnesses, and to have access to one's medical records;

(E) result in a written decision setting out the judge's findings of fact and conclusions of law within 30 days of the hearing.

(3) an expedited appeal shall --

(A) be available when denial, reduction, delay, or termination of the service, coverage, or referral at issue --

(I) would create a risk of serious or permanent harm to the patient; or

(II) involves an ongoing series of services such as inpatient hospital or nursing home care, therapies, or home health services, such ongoing series of services to be continued through the completion of the expedited appeals process described herein.

(B) include informal review as provided in sub-paragraph (1), above, completed within 24 hours of a request;

(C) provide an administrative hearing decision, as provided in sub-paragraph (2), above, within 3 days of a request.

(4) in order to prevail in an appeal, the health plan or insurer must produce sufficient evidence to justify its decision denying, reducing or terminating the service, coverage, or referral at issue.

(5) failure to complete an administrative decision within the specified time limits will allow the claimant, at his or her option, to proceed immediately to the next stage in the appeals process.

(6) when the claimant prevails in an administrative appeal, the health plan or insurer shall be required to pay the claimant's reasonable costs, and reasonable attorney's and expert's fees.

(e) Judicial Review. -- review of the decisions of the administrative law judge shall be available at the claimant's option in --

(1) an appropriate state court, or

(2) the federal district courts of the United States as follows --

(A) in all cases raising issues as to the validity of statutes, administrative rules, and practices;

(B) in all other cases involving health care coverage, referrals, or services valued at $1,000 or more, except that this jurisdictional amount shall be waived for appeals by indigent claimants;

(3) nothing in this Part shall be construed to require exhaustion of administrative remedies that would be futile or that would create a risk of irreparable injury to the claimant; and

(4) the prevailing claimant shall be entitled to reasonable attorney's fees, reasonable expert witness fees, and other reasonable costs relating to such action.

(f) Pre-emption.-- nothing in this Part shall be construed to pre-empt other consumer rights or remedies available under state or federal law, including common law.

DUE PROCESS AMENDMENTS TO THE HEALTH SECURITY ACT

Subtitle C -- Remedies and Enforcement

PART 1

Amend sec. 5201 to require that notice be given to enrollees whenever hospital, nursing home, and home health services are terminated and whenever a health plan or provider does not prescribe services that are generally prescribed for the enrollee's condition.

Amend sec. 5201 to provide that enrollees are authorized to obtain second opinions from non-plan physicians when their claims have been denied.

Amend sec. 5201 to require notice of disposition of claims for services within 5 days after the date of submission of the claim.

Amend sec. 5201 to state that enrollees whose plans continue to refuse a service without providing timely notice of denial can obtain the service out of plan and require the plan to pay for it.

Amend sec. 5204 to include a 120 day time limit for a hearing decision by the Complaint Review Offices.

Amend sec. 5204 to state that in appeals the burden of proof rests on the plan.

Amend sec. 5206 to specifically state that provisions for civil monetary penalties include a private right of action.

Amend sec. 5216 to require completion of the mediation proceedings for the Early Resolution Program within 60 days.

Amend sec. 5205 to clarify that jurisdiction exists for review of Health Plan Review Board decisions regardless of monetary limitations for cases involving constitutional and statutory interpretation.

PART 2

Amend the Act to include authorization for private enforcement actions against the plans.

Amend sec. 5241 to eliminate the requirement that facial constitutional challenges be brought within one year of enactment.

OUT OF NETWORK COVERAGE AMENDMENT TO THE HEALTH SECURITY ACT

Amend Section 1132, "LOWER COST SHARING," by adding underlined language:

(b) OUT-OF-NETWORK COINSURANCE PERCENTAGE.--

(1) In general. -- The National Health Board shall determine a percentage referred to in subsection (a)(4). The percentage

(A) may not be less than 20 percent; and

(B) shall be the same with respect to all out-of-network items and services that are subject to coinsurance, except as provided in paragraph (2).

(2) Exceptions. --

(A) Higher coinsurance services.-- The ~~National Health Board~~ Secretary may provide for a percentage that is greater than a percentage determined under paragraph (1) in the case of an out-of-network item or service for which, under the higher cost sharing schedule described in section 1133, the coinsurance is greater than 20 percent of the applicable payment rate.

(B) People with special health care needs. -- For families with family adjusted income at or below 250% of the applicable poverty level, based on actual family size, the Secretary shall provide for amounts that do not exceed by more than 25% the amounts such families would pay for in-network services, for individuals who (i) have rare or complex diseases or conditions, as defined by the Secretary, including those described in Sec. 527(a)(2)(A) of the Federal Food Drug, and Cosmetic Act, or (ii) are disabled as defined under Titles II or XVI of the Social Security Act or eligible for benefits as incapacitated under Title IV-A of such Act, during the period when they are determined to be disabled or incapacitated.

(C) Low-income people. -- In the case of approved families (as defined in section 1372(b)(3)), the Secretary shall provide for amounts such families would pay, in addition to the amounts such families would pay for in-network services. Such amounts may distinguish among different groups of approved families, shall assure adequate access to necessary out-of-network services, and shall not exceed those established under subparagraph (B).

(D) General provisions. -- Deductibles and increased premiums shall not apply to individuals described in sub-paragraphs (B) and (C) based on their election of the point of service option.

CONSUMER INFORMATION PROVISIONS FOR HEALTH CARE REFORM

Rename Sec. 5101(a) as Sec. 5101(a)(1).

Insert the following after Sec. 5101(a)(1):

5101(a)(2) Not later than six months after the date of the enactment of this Act, the Secretary shall develop initial guidelines for a "Consumer Guidebook" for plan selection and use, and will mandate specific information to be provided to consumers in the guidebook, which will be readily available to every consumer in an appropriate format to meet the communication needs of individuals. The Consumer Guidebook will include at a minimum:

(i) Plan-Specific Descriptions, presented in a comparative format, including general information about the health care system, benefits package including any limitations on services, how to appeal a health care decision, how to resolve complaints, how to contact a health ombudsman program, risk arrangements within the plan, referral and incentive arrangements and plan financial data.

(ii) Plan-Specific Quality Report Cards, including quality indicators reflecting a common set of performance measures and enrollee satisfaction which compare the plans, providers, and practitioners in a given region and, when appropriate, provide national averages for comparison. At a minimum, the following areas should be included:

Preventive Care
Indicators of undesired or unplanned occurrences
Utilization of services related to service policy
Consumer Satisfaction (obtained from the national consumer satisfaction survey)
Membership statistics

5105(a)(3) Not later than six months after the date of the enactment of this Act, the Secretary shall promulgate regulations defining additional information that shall be available to consumers upon request, including, but not limited to the following:

(i) Provider and Practitioner Specific Descriptive Information to help consumers choose a plan based on the background of specific practitioners or services of a hospital. Information in this section should be written in a standardized format and include at a minimum:

the plan's unique features set apart from items that the plans must contain;
fact sheets on each of the physicians in the plan; and
fact sheets about home health services, hospitals, laboratories, out-patient services, nursing home skilled care and other contracted health facilities.

(ii) Condition-Specific Provider and Practitioner Report Cards, including enrollee surveys to help guide the consumer to the most appropriate specialist or hospital for treatment of a specific condition. Included in this information should at a minimum be hospital and physician specific practice profiles and outcomes data on particular procedures or conditions adjusted for severity.

Amend Sec. 5101(e) by adding the following:

(12) Any information necessary to collect to provide consumers with information described in Sec. 5101(a)(2) of this Act.

OMBUDSMAN PROGRAM PROVISIONS FOR HEALTH CARE REFORM

SEC. ____ DEFINITIONS

As used in this chapter:

(1) OFFICE. -- The term "Office" means the office established in section _____.

(2) OMBUDSMAN. -- The term "Ombudsman" means the individual described in section _____.

(3) LOCAL OMBUDSMAN ENTITY. -- The term "Local Ombudsman entity" means an entity designated under section ____.

(4) PROGRAM. -- The term "program" means the Health Care Ombudsman program established in section ____.

(5) REPRESENTATIVE. -- The term "representative" includes an employee who represents an entity designated under section ____ and who is individually designated by the Ombudsman.

(6) INDIVIDUAL. -- The term "individual" means an individual who participates in the health care system.

SEC. ____ HEALTH CARE OMBUDSMAN

(a) ESTABLISHMENT. --

(1) IN GENERAL. -- In order to be eligible to receive a grant under section ____from funds under section ____, an organization shall, in accordance with this section --

(A) establish and operate an Office of the Health Care Ombudsman; and

(B) carry out through the Office a Health Care Ombudsman Program.

(2) OMBUDSMAN SELECTION DESIGNATION PROCESS.-- Entities shall be selected to serve as an Ombudsman through a competitive grant making process.

(A) The Secretary of Health and Human Services shall designate, confer appropriate authority to, enter into a grant arrangement with an Ombudsman in each state. The Secretary shall negotiate a proposed grant which the Secretary determines will be carried out by such organization in a manner consistent with the efficient and effective administration of this section.

(i) Preference shall be given to private, not-for-profit organizations that represent a broad spectrum of the diverse consumer interests in the state.

(B) The Secretary shall not enter into a grant under this part with any entity which is, or is affiliated with, (through management, ownership, or common, control), a health care facility, managed care organization/network, organizations licensing or certifying health care services, health or corporate alliances, or association of such, within the area served by such entity or which would be served by such entity if entered into a grant with the Secretary under this part.

(C) Each grant with an organization under this section shall provide that --

(i) the organization shall perform the functions set for in this section;

(ii) the Secretary shall have the right to evaluate the quality and effectiveness of the organization in carrying out the functions specified in the grant;

(iii) the grant shall be for an initial term of four years and shall be renewable thereafter based upon favorable performance without reopening the competitive selection process;

(iv) if the Secretary intends not to renew, the organization shall be notified of the decision at least 180 days

prior to the expiration of the grant term, and shall accord the organization an opportunity to present information for the purposes of appeal of the intent by the Secretary not to renew the grant;

(v) the organization may terminate the grant upon 180 days notice to the Secretary;

(vi) the Secretary may terminate the grant prior to the expiration of the grant upon 180 days notice if the Board determines that the organization does not meet the requirements of the section or if the organization fails substantially to carry out the grant. Appropriate appeals mechanisms, including the establishment of a panel of peers, shall be developed by the Secretary to implement this section.

(D) Financing. In determining the amount of money to be allocated to each Ombudsman to carry out the duties defined in subsection (c), consideration shall be given to the establishment of core funding (based on population, geographic considerations, and other factors determined by the Secretary), with additional funds to be awarded to those entities selected on the basis of performance and innovation in the carrying out of their responsibilities.

(3) PERSONNEL.--

(A) The Ombudsman, staff, and other representatives of the Health Care Ombudsman Program shall meet standards for experience, expertise, and training as specified by the Secretary.

(B) The HCOP shall have adequate legal counsel available to --

(i) provide advice and consultation needed to protect the health, safety, welfare and rights of individuals with respect to health care; and

(ii) assist in the performance of the official duties of the HCOP;

(iii) provide representation to any representative of the HCOP against whom suit or other legal action is brought or threatened to be brought in connection with the performance of the official duties of the HCOP; and

(iv) assist in pursuing administrative, legal, and other appropriate remedies on behalf of individuals with respect to health care.

(4) FUNCTIONS. -- The Ombudsman shall serve on a full-time basis, and shall, personally or through representatives of the Office --

(A) identify, investigate, and resolve complaints that --

(i) are made by, or on behalf of, individuals; and

(ii) relate to action, inaction, or decisions of providers of health care services and public or private agencies involved in the delivery, funding, or regulation of health care.

(B) provide information, referral and assistance to individuals about means of obtaining health coverage and services;

(C) identify, investigate, publicize, and promote solutions to practices, policies, laws, or regulations that may adversely affect individuals' access to quality health care, including but not limited to practices relating to:

(i) marketing of health care plans;

(ii) availability of premium subsidies;

(iii) accessibility of services and resources in traditionally underserved areas;

(iv) adequacy of funding to traditionally underserved areas through community rating and risk adjustment

(D) ensure that the individuals have timely access to the services provided through the Office and that the individuals and complainants receive timely responses from representatives of the Office to complaints;

(E) represent the interests of the individuals before governmental agencies and seek administrative, legal, and other remedies to protect the health, safety, welfare, and rights of the individuals;

(F)(i) analyze, comment on, and monitor the development and implementation of Federal, State, and local laws, regulations, and other governmental policies and actions that pertain to the health safety, welfare, and rights of the individuals, with respect to the adequacy of health care facilities and services in the State;

(ii) recommend any changes in such laws, regulations, policies and actions as the Office determines to be appropriate; and

(iii) facilitate public comment on the laws, regulations, policies, and actions;

(G)(i) provide for training representatives of the Office;

(ii) promote the development of citizen organizations, to participate in the program; and

(iii) provide technical support for the development of consumer and citizen organizations to protect the well-being and rights of individuals; and

(H) exercise such other powers and functions as the Secretary determines to be appropriate.

(5) POLICIES AND PROCEDURES.-- The Secretary shall establish policies and procedures for the operation of HCOPs, including but no limited to polices and procedures to --

(A) ensure optimal coordination among HCOPs;

(B) collect and make available nationally uniform and useful data regarding problems and complaints;

(C) ensure that representatives of the HCOP shall have --

(i) access to health care facilities and individuals.

(ii) appropriate access to review the medical and social records of an individual, if the representative has the permission of the individual, or the legal representative of the individual;

(iii) access to the administrative records, policies, and documents, to which the individuals have, or the general public has access, of health care facilities; and

(iv) access to and, on request, copies of all licensing, certification, and data reporting records maintained by the State or Federal government with respect to health care providers.

(D) protect the identity of any complainant or other individual with respect to whom the Program maintains files or records;

(E) ensure that no individual or organization performing functions of the HCOP has --

(i) a direct involvement in the licensing, certification, or accreditation of a health care facility, a health care plan, or a provider of a health care plan, or a provider of a health care service;

(ii) does not have a direct ownership or investment interest in a health care facility, a health care plan, or a health care service;

(iii) is not employed by, or participating in the management of, a health care service, facility, or plan; and

(iv) does not receive, or have the right to receive, directly or indirectly, remuneration (in cash or in kind) under compensation arrangement with an owner or operator of a health care service, facility or plan.

(F) establish and implement minimum qualifications and training requirements for personnel, including volunteers;

(G) promote optimal coordination between the HCOP and other citizens advocacy organizations, legal assistance providers serving low-income persons, the State Long-Term Care Ombudsman Program, and protection and advocacy systems for individuals with disabilities established under --

(i) part A of the Developmental Disabilities Assistance and Bill of Rights Act (42 USC 6001 et. seq.);

(ii) the Protection and Advocacy for Mentally Ill Individuals Act of 1986 (42 USC 10801 et. seq.); and

(iii) the Americans with Disabilities Act.

(6) DESIGNATION OF LOCAL OMBUDSMAN ENTITIES AND REPRESENTATIVES. --

(A) DESIGNATION. -- In carrying out the duties of the Office, the Ombudsman may designate entities as a local Ombudsman entities, and may designate employees to represent the entities.

(B) ELIGIBILITY FOR DESIGNATION. -- Entities eligible to be designated as local Ombudsman entities, and individuals eligible to be designated as representatives of such entities, shall --

(i) have demonstrated capability to carry out the responsibilities of the Office;

(ii) be free from conflicts of interest;

(iii) in the case of the entities, be public or non-profit private entities; and

(iv) meet such additional requirements as the Ombudsman may specify.

(7) CONSULTATION. -- In planning and operating the program, the HCOP shall conduct annual public hearings to get the views of the general public and providers of health care.

(8) ANNUAL REPORT. -- The Secretary shall mandate the collection of information and prepare an annual report --

(A) describing the activities carried out by the HCOPs in the year for which the report is prepared;

(B) containing and analyzing the data collected by the HCOPs;

(C) evaluating the problems experienced by, and the complaints made by or on behalf of, individuals;

(D) containing recommendations for protecting the health, safety, welfare, and rights of individuals with respect to their health care;

(E) analyzing the success of the program and barriers that prevent the optimal operation of the program; and

(F) providing policy, regulatory, and legislative recommendation to solve identified problems.

(9) Analyze, comment on, and monitor the development and implementation of Federal, State, and local laws, regulations, and other government policies and actions that pertain to health care facilities and services, and to the health, safety, welfare, and rights of individuals, in the State, and recommend any changes in such laws, regulations, and policies as the Office determines to be appropriate;

(10) Provide such information as the office determines to be necessary to public and private agencies, legislators and other persons, regarding --

(A) the problems and concerns of individuals; and

(B) recommendations related to the problems and concerns.

(11) LIABILITY.-- No representative of HCOPs shall be liable under State or Federal law for the good faith performance of official duties.

(12) FUNDING.-- The National Health Board will provide funding for the HCOPs by assessing each health care premium an amount to be determined by the National Health Board. The Secretary shall provide the necessary funding to carry out this Section prior to the Board's funding of this Section.

(13) Nothing in this Section shall be construed to limit the rights of individuals to use the grievance and appeals processes in this Act.

HEALTH PROFESSIONAL LICENSING BOARD PROVISIONS

Purpose - It is the purpose of the Congress in this Section to help the states protect the public health and safety by instructing the Secretary of Health and Human Services to award grants-in-aid to health professional licensing boards that conform to the criteria set forth in this title and the implementing regulations promulgated by the Secretary.

Section One -- To be eligible for a grant, a health professional licensing board shall file a plan (certified by the Governor) with the Secretary showing how the board will meet the following criteria:

1. Composition of licensing boards

At least 51% of the members of the licensing board shall be "public" or "consumer" members.

2. Funding

One hundred percent (100%) of the fees paid by licensees to obtain and renew their licenses shall be dedicated exclusively to finance the operation of the board that issues their licenses.

3. Complaint/Report Prioritization and Case Management

The Board must follow a complaint prioritization system that gives the highest priority to allegations of substandard care and that sets reasonable time limits (to be determined by the Secretary) for the investigation of high priority complaints and reports. The board's procedures must ensure that no complaint will be dismissed by the staff without the approval of the board.

4. Timely, Open Disciplinary Proceedings

Disciplinary proceedings shall be completed within a reasonable time frame (to be determined by the Secretary) and shall be conducted in the Sunshine. All voluntary settlements must be approved by the board, in open session.

5. Dissemination of Disciplinary Action Reports

At the time the board determines there is probable cause that a licensee has violated the licensure statue, this information shall become public, including the name of the licensee, the nature of the alleged violation, and the date of the public hearing. All final board actions shall be widely publicized, including the name of the licensee, the nature of the violation, and the nature of the disciplinary action. Boards in professions included in the National Practitioner Data Bank shall report to and query the NPDB as a routine part of the investigative and disciplinary process.

6. Publication and Dissemination of Annual Report

An annual report containing operating statistics and other reasonable information documenting board performance (to be determined by the Secretary) shall be made available at no cost to the public at large.

7. Prohibition on Unjustified Restrictions

No professional licensing board may, through mandate, board rules and regulations, or otherwise, restrict the practice of any class of health professionals beyond what is justified by the skills and training of such professionals.

White Paper on

Minimum Requirements for Consumer Information

Introduction

Consumer information is an important dimension in any reform of the health care system, whether the reform is based on managed competition or a single payer system. Managed competition assumes that well-informed consumers will stimulate plans to provide high quality care at low costs. Under a single payer system, consumer information is important for much the same reason—information about practitioners and providers allows consumers to shop for the best care at reasonable prices. For this to happen, consumers must have access to comprehensive, uniform and comparable information. Under either type of reform, the data collected by the health plans must be verified on an ongoing basis by state entities independent of the health plans, health alliances or other purchasers of care.

A national entity such as a National Health Board should be responsible for 1) establishing uniform data formats, 2) setting standards for collecting and analyzing data and 3) distributing the data on the national, state and plan levels. It is essential that the data and information be accurate, reliable, comparable, timely, and easy-to-understand. It must also be available in different languages and formats for people with special challenges such as the visually or hearing impaired.

With the increase of data collection and dissemination through the electronic media, the protection of consumer confidentiality becomes increasingly important. National standards should be established to protect consumers from unauthorized disclosure of any personal and individually identifiable information.

We want to make it clear, however, that even good consumer information will not eliminate the need for appropriate grievance and appeals procedures, internal and external quality assurance and external, independent quality oversight and monitoring of the health care system.

Summary

We believe that information available to consumers must be more than a "report card." A more appropriate description for what is needed is a "Consumer Guidebook" for plan selection and use. National standards should mandate what specific information will be provided in this guidebook, which should be readily available to every consumer.

The data should also be utilized to assist health care professionals in providing appropriate and effective care and to enable policy makers to fine tune the system to increase quality and reduce costs.

We envision four main categories of information:

1) plan-specific descriptions including general information about the health alliance, the health care system and where to get help

2) plan-specific quality report cards—quality indicators reflecting a common set of performance measures and enrollee satisfaction

3) provider and practitioner-specific descriptions to help discriminating consumers choose a plan based on the background of specific practitioners or services of a hospital

4) condition-specific provider and practitioner quality report cards to help guide the consumer to the best specialist or the best hospital for treatment of a specific condition.

1) Plan-Specific Description Information

If consumers are going to make informed choices, they need good understandable information describing plan configurations, how the health care delivery system works, how to use the consumer guide, how to appeal a health care decision, how to resolve complaints, and how to contact a health ombudsprogram or counseling program. Next, they will need to know the prices, benefits, and services of each plan option. The goal is to enable the consumer to compare health care plans in a given health alliance. The information should include descriptive and practical summaries presented in a comparative format.

Price, benefit and plan operation information could include:

Price Information for individuals and families:

- premiums, deductibles and co-payments
- cost or implications of using services outside the plan
- cost of coverage beyond the basic plan
- premium increase trend

Benefits, Plan Description and Policies:

- benefits covered
- services not covered by the plan
- time in operation
- membership size and percent in certain age groups
- number of practitioners and their areas of specialization
- ratio of membership to primary care physicians
- ratio of physician to non-physician primary care practitioners
- specialists available within the plan; outside the plan
- ratio of board certified physicians to non-board certified
- names of participating hospitals, home health agencies, laboratories, diagnostic facilities, pharmacies
- contractual relations between plans and providers
- plan policy regarding scheduling of routine annual physical exams, pre-natal visits, well-baby visits, immunizations
- plan policy regarding promptness of access for evaluation of symptoms
- plan policy regarding urgent care, hospitalization, length of hospital stays, specialist referrals, diagnostic procedures, mental health services, laboratory services, home health services, prescriptions
- plan policy regarding care management and long-term care
- plan policy regarding second and third opinions
- phone numbers for information specialists who can explain plan details

2) Plan-Specific Quality Report Cards—quality indicators reflecting a common set of performance measures and enrollee satisfaction surveys

The "report card" or quality measures and consumer satisfaction section of the consumer guidebook should compare the plans, providers, and practitioners in a given health alliance and, when appropriate, provide national averages for comparison. Areas that should be covered include enrollee access to care, quality of care, appropriate use of medical care,

utilization rates, and the effectiveness of specific treatments and patient outcomes by diagnosis or procedure. Information about where to get assistance in interpreting the information and data should be provided to the consumer.

Performance Measures

Use of a common set of performance measures will not only provide consumers with good decision-making information, it will also enable health plans and providers to identify the best practices. The national health board created to oversee the new health care system should also use the quality measures in the development and dissemination of clinical practice guidelines, the updating of the benefit packages, and the analysis of the cost-effectiveness of the health care provided.

It is expected that quality and its indicators will improve and evolve based on information from outcomes research. Required reporting of patient care encounters (presenting problem, diagnosis and treatment), and uniform patient identifiers to allow longitudinal records, should be considered. In addition, reporting of complications and hospital acquired injuries in the clinical record should be required. Clinical information will provide far more useful data than data extracted from billing codes (notably not available from managed care programs). Outcomes research studies should be conducted to evaluate patients' health status after specific treatments, including physiological measurements, functional status, and well-being/quality of life. This information should be made available to consumers, providers, and policy makers. These measures are essential for competition to succeed in improving and/or maintaining quality of health services.

The following types of information could be included in this section of the guidebook:

Preventive Care

Percentage of enrollees of certain age groups for whom appropriately timed preventive measures were provided or recommended, such as:

- health history interview and record
- annual physical and functional status assessment; urinalysis; blood hemoglobin, cholesterol (adult)
- childhood immunizations and boosters
- seniors: flu vaccination annually; pneumococcal vaccination one-time; boosters for tetanus and diphteria
- hepatitis b vaccine (for those with high exposure risk)
- tuberculosis screening
- colorectal screening
- mammogram screening
- gynecological exam and Pap smear annually (adult and/or sexually active females)
- prenatal care during 1st, 2nd, 3rd trimesters
- routine eye exams for seniors and diabetics

Indicators of undesired or unplanned occurrences, such as:

- inappropriate use of medications
- re-admissions within 30 days of post-surgery hospital discharge
- location-of-service acquired infections
- pressure ulcers occurring in patients confined to bed.
- injuries sustained at location-of-service: e.g., fractures, muscle contractures, harmful medication and treatment errors

Utilization of services related to service policy, such as:

- average time between first report of acute illness and examination
- average time between diagnosis and treatment of acute illness
- percent follow-up visit or phone call after acute illness
- average length of hospital stay: surgery, normal delivery, C-section, rehabilitation, mental health acute care
- number of referrals to specialists per primary practitioner
- number of referrals for diagnostic procedures
- average time between diagnosis and various kinds of elective procedures

Consumer Satisfaction

A standard survey should be developed that will measure satisfaction among health plan participants. It could have some regional or otherwise appropriate individualized characteristics, but the main body of the survey should be consistent across the country so that it can be used for national comparisons. The survey should be short and clear and contain questions related to acceptability, availability and accessibility. It could include:

- overall satisfaction with care received
- degree to which questions were answered
- adequacy of treatment information
- did treatment alleviate symptoms
- convenience of location of doctors and hospitals
- number of specialists from which to choose
- number of primary care physicians from which to choose
- ease of obtaining desired referral
- degree to which plan follows through on referrals to medical services
- attitude of staff and of physician
- length of time between making appointment and visit for symptoms or for preventive care
- length of time "on hold" before getting through to the plan
- length of time spent in the waiting room
- length of time spent with practitioner
- length of time between diagnosis and treatment
- availability of advice over the phone
- excessive paperwork or bureaucratic hassles
- willingness to recommend this plan to a friend

It should be mentioned that the New England Medical Center, Health Institute has developed an "Employee Health Care Value Survey" as part of the Health Plan Employer Data and Information Set, HEDIS, which looks promising.

Membership statistics

Membership statistics can also be indicative of consumer satisfaction and should be listed:

- number of new enrollees and dis-enrollees per year
- number of enrollee complaints

3) Provider and Practitioner-Specific Descriptive Information

Further details on plans and their health care professionals should be provided on a per request basis. For example, if a consumer is trying to decide between Plan A and Plan B, he or she may want to review the detailed plan descriptions, which would be written in a standardized format with the plan's unique features set apart from items that the plans must contain.

Information such as fact sheets on each of the physicians in the plan, their training, years of practice, board certification, faculty responsibilities, and documented disciplinary actions, including repeated malpractice payments, should be provided in this documentation. Fact sheets about home health services, hospitals, laboratories and other contracted health facilities could also be developed. The health alliances or individual plans could supply this information under supervision and monitoring of the state quality assurance entity.

Hospitals

Types of services provided, bed capacity and nursing services staffing of each type of unit:

- emergency department
- intensive care unit
- cardiac care unit
- general medicine and specialty units
- rehabilitation therapies
- surgery general and specialties
- obstetrics: delivery room, birthing room, operative procedures
- newborn care: normal newborn and intensive care nurseries
- radiology treatment and diagnostic capacity
- laboratory
- social services and discharge planning

Home Health Services

- skilled nursing and rehabilitative care
- hospice care services
- personal care aides
- home care equipment (e.g. oxygen, suction, special beds)

Out-patient Services

- urgent care
- di[illegible]nc and follow-up care
- p[illegible]macy services
- laboratory services

Nursing home skilled care

- routine practitioner visits
- diagnostic services

4) Condition-Specific Provider and Practitioner Report Cards including Enrollee Surveys

Condition or treatment specific information is important to the person who faces a major operation or health care decision and should be available upon request. This information is different from the plan specific report card in that it includes both hospital and physician specific practice profiles and outcomes data on a particular procedure or condition.

For example, a consumer may want to know which hospital in the region (or the country) has the most experience in kidney transplants; which surgeon has the lowest mortality rate within that particular hospital or within a region; which hospital has the lowest mortality rate; which has the lowest post-surgery complication rates, and other factors. This is similar to what has been done for coronary artery bypass graft surgery in both

Pennsylvania and New York. The information could be presented either on a nation-wide or a region-wide basis and could be available from the national health board or its designees. The data should be appropriately adjusted for severity to avoid skewing outcomes for surgeons and hospitals serving more vulnerable populations. Also, health counselors should be available for answering questions regarding this and other consumer information.

Information obtained through the enrollee satisfaction surveys which address condition-specific provider and practitioner quality and outcomes should also be available as part of this report card.

Confidentiality of Personal Information

With more emphasis on data collection and improved electronic data interchange, the risk of violating a person's right to privacy increases. Health care information often contains very personal information about physical and mental medical history, conditions and treatments.

The collection, storage, handling, and transmission of individually identifiable health care data should in no way infringe upon a person s right to privacy and to keep certain information confidential. National uniform standards should delineate very specifically what type of individually identifiable information may or may not be released without the person's authorization. Such standards should also delineate to whom confidential data may be released and for what purposes it may be used.

Conclusion

Consumer information must be developed with consumers' needs in mind and with active consumer participation. Information should be available in written, verbal and electronic forms, and in Braille and other languages to reach all populations. The success of health care reform is largely dependent on the ability of consumers to make wise choices and influence the quality and cost of health care. Therefore, the plan must provide the consumer with the necessary tools for good decision-making. Consumers need to know which provider offers the best services at the least costs, which practitioners have the most success with which treatments, and which hospitals are most likely to send the patient home without further complication. They also need protection against misuse of their personal records; and information about how to file complaints, appeal decisions or get outside assistance by a health ombudsprogram or counselor. This will require resources, but it will cost a small fraction of the cost of not implementing an effective health care monitoring and reporting system from the start. Good information and decisions alone will not ensure quality care. Quality assurance measures, grievance and appeals procedures, and independent, external entities must be in place to monitor quality and enforce standards.

White Paper On
Consumer Due Process Protections

November 30, 1993

Executive Summary

This white paper identifies and examines key consumer notice, appeal, and grievance rights -- collectively referred to as consumer "due process" rights -- essential in any national health care legislation and consistent with the Clinton Health Bill. Section I, the Executive Summary, provides an outline of these rights. Section II is an analysis of the key principles arising under federal statute, case law, and constitutional law that a impact on the nature and scope of due process in the delivery of health care services.

I. **EXECUTIVE SUMMARY: Outline of Necessary Due Process and Consumer Protection Elements In National Health Care Reform**

A. **Broad Societal Interests In An Appeals Process That Is:**

- - **Fair**

- - **Accountable**

- - **Timely**

B. **Specific Due Process and Consumer Protection Elements**

1. Appeals Process. An appeals process shall be established for patients for whom health care services or payments have been denied, reduced, or terminated. The appeals process shall have the following components:

o Written notice shall be given to the patient by the insurer or health plan for:

a) any decision to deny or reduce requested services;

b) all terminations of institutional care, such as hospital, nursing home, home health care;

c) failure to provide specified services, such as rehabilitation services and home health services for the improvement/or prevention of deterioration of a patient's condition.

[Regulations should be developed to specify the circumstances under which written notice of appeal rights is required and the relevant time periods for the receipt of notice.]

o Posted Notice of the right to appeal denials, reductions, and terminations of coverage are to be appropriately displayed in public areas of all health plan facilities.

o A "Plain Language" Explanation of appeal rights shall be provided to individuals upon enrollment in health plans.

o Expedited review of the correctness of the denial, reduction, or termination of urgently needed services must be available as follows --

a) the patient attests that services are urgently needed and the failure to provide them promptly or the failure to continue them may impair or retard improvement or cause deterioration of the patient's health status.

b) expedited review must be performed by an independent hearing officer, as defined below, who shall issue a written decision to the patient within two (2) days of the request for review.

c) services or payment by the insurer or plan must continue until an expedited review decision has been issued.

- Review by an independent hearing officer for all other services shall be governed by the following administrative process --

  a) review of its denial, reduction, or termination decision must be provided by the insurer or health plan, which shall issue a written decision within 15 days of the request for review.

  b) hearing by an independent hearing officer must be available with 30 days of a review decision. An independent hearing officer is an individual who is not an employee or designee of the insurer or health plan;

  c) written decision setting out the hearing officer's rulings on issues of fact and law must be issued within 30 days of the hearing;

  d) beneficiary coverage of services in place before the insurer's or health plan's initial adverse decision shall continue pending a hearing decision when requested by the beneficiary, unless the continuation would be harmful to the beneficiary as documented in writing by the treating physician;

  e) beneficiaries shall have the right to present favorable evidence, including out-of-plan second opinions in cases challenging plans' service denials, the right to review and present information from their medical records, and the right to compel the attendance at hearings of decision-makers whose actions are under challenge;

  f) hearing officers shall have a duty to assist claimants in developing the factual record, including ordering out-of-plan second opinions.

- Judicial review shall be available in state or federal court in cases involving at least a specified threshold amount of charges, including the aggregation of claims to meet the threshold amount. Such threshold requirements can be waived for low-income persons at the discretion of the courts. Relief for prevailing consumer-claimants should include reasonable costs and fees.

- A Private Right of Enforcement shall be available to plan enrollees to maintain an action for damages and for any other relief, including injunctive and declaratory relief, for acts or omissions of a Health Plan, Health Alliance, State, or Federal Government which deprive such an enrollee of any right or benefit created or established to implement the provisions of the Act.

- Penalties should be set by a national health board for plans and alliances that do not meet appeal rights standards and time-lines.

2. Grievance Process. A grievance procedure shall be established within each health plan for the resolution of complaints of individuals about problems other than denial, reduction, or termination of service or payment, including, but not limited

to, delays in scheduling appointments, rude or undignified treatment at health plan facilities, the physical conditions of facilities, or enrollment and disenrollment disputes. The components of the grievance process are as follows --

- o The right to complain orally or in writing to a Patient Advocate or other independent ombudsman who shall investigate the facts, seek to resolve the problem in a way suitable to the patient, and prepare a written report for the individual and for the plan within 15 days.

- o The right to have the complaint referred to a Grievance Committee of the health plan that will recommend action in response to the complaint and report to the individual and to the plan within 30 days.

- o The right to have still unresolved grievances reviewed by Health Alliances or other independent monitoring entities authorized to investigate and respond with a full range of sanctions including corrective action, civil monetary penalties, and termination of health plan status.

- o Penalties should be set by the national health board for plans and alliances that do not meet grievance procedure standards and time-lines.

C. Health Plan Governance. Individual health plan beneficiaries shall have the right to substantial and meaningful participation as consumers of care in all levels of governance and decision-making in the operation of health plans, health alliances, and state and federal oversight organizations.

D. Protection of Existing Rights. Rights afforded under any Federal health reform plan should not invalidate or limit any other federal or state law or any law of any political subdivision of any state that provides greater protection for the rights of beneficiaries under health plans.

E. Alternative Dispute Resolution (ADR), Including Mediation. The use of ADR under appropriately defined circumstances can augment an appeals process. We stress, however, that ADR is not effective in situations where the only solution is "yes" or no," or in a determination of which side wins.[1] Disputes

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[1]. See, L. Singer, M. Lewis, A. Houseman, E. Singer, "Alternative Dispute Resolution and the Poor Part II: Dealing with Problems in Using ADR and Choosing a Process, " 26 Clearinghouse Review 288, 290 (July 1992).

over whether a particular service is covered under the plan, whether a participant meets the eligibility criteria for particular services (such as long-term care or home health services) would not be appropriate for ADR.

There is also a concern about the unequal bargaining power of the parties to ADR and that ADR not become a vehicle for delay. Plans are likely to control the review forum, its location and setting, as well as medical and other information relevant to decision-making. In addition, ADR can have the harmful affect of deflecting consumer energy -- making them give up -- and in the process, consuming time and financial resources that could be used more appropriately.

ADR works where multiple outcomes are possible, where the parties want to maintain an on-going relationship, and where the parties want to help develop a settlement. Grievances concerning service, such as long waits, difficulties in getting appointments, rudeness and undignified treatment, may lend themselves to ADR.

II. STATUTORY DUE PROCESS PRINCIPLES AND PRECEDENTS

The Medicare and Medicaid programs[2] have served as the primary laboratories of experience in shaping due process rights in government sponsored health care programs. Because Medicare has followed a social insurance model, it offers a useful analog to the types of national health plans under consideration. In 1982, the Congress changed the structure of Medicare payments to allow and encourage Health Maintenance Organizations (HMOs) to enroll Medicare beneficiaries. HMOs receive a monthly capitated at-risk payment for each Medicare enrollee. By 1992, Medicare enrollment in HMOs had climbed to about 1.5 million persons, or about three (3) percent of total Medicare enrollees.[3] This growing segment of the Medicare program represents an even closer analog to the models of managed competition being considered for national health reform.

The Medicaid program likewise provides a useful analog, although in a different respect. Medicaid represents a Federal/State collaborative program with substantial state control

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[2]. 42 U.S.C. §1395 et seq. (Medicare); 42 U.S.C. 1396 et seq. (Medicaid). Medicare eligibility is not based on an applicant's financial status. See, 42 U.S.C. §1395c. Eligibility for Medicaid, however, is based on state income and resource requirements and status, i.e., disability. 42 U.S.C §1396a.

[3]. Nancy De Lew, et al., "Special Report: A Layman's Guide to the U.S. Health Care System," 14 Health Care Financing Review 151, 162 (Fall 1992).

over specifics of the program within federal standards. The principle of Federal/State collaboration and State flexibility are characteristic of national health reform proposals to date.

Finally, the Employee Retirement Income Security Act (ERISA) establishes federal statutory protections for participants in private employer-sponsored group health plans.[4] Due process rights under ERISA are not as extensive as the rights under Medicare and Medicaid. National health reform proposal based on the current model of employer-provided health insurance may, however, look to ERISA as the underpinning for its due process provisions.

A. Medicare Hearing Rights

With respect to denials, terminations, or reductions of services, due process for Medicare beneficiaries has been approached primarily from a constitutional protection model as outlined originally in the 1970 Supreme Court case, Goldberg v. Kelly.[5] In Goldberg, the opportunity to be heard is identified as the fundamental requisite of due process.[6] Due process is further defined as including the right to adequate notice;[7] to appear personally (with or without counsel) before an impartial decision maker; to present evidence; and to confront or cross-examine adverse witnesses.[8] Courts have recognized at least three public policy interests that favor due process hearings to mediate claims and disputes with respect to entitlements: "the desire for accuracy, the need for accountability, and the necessity for a decision making procedure which is perceived as "fair" by the citizens."[9]

Due process principles also underlie the concept of

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4. The primary focus of ERISA is on pension plans. However, its disclosure and fiduciary duty rules, as well as its causes of action, are applicable to all employee benefit plans, including health plans.

5. Goldberg v. Kelly, 397 U.S. 254 (1970).

6. Id., at 267.

7. David v. Heckler, 591 F. Supp. 1033 (E.D.N.Y. 1984).

8. Id., at 268-69. See also, Bowen v. Michigan Academy of Family Physicians, 476 U.S. 667 (1986); Kraemer v. Heckler, 737 F.2d 214 (2nd Cir. 1984).

9. Gray Panthers v. Schweiker, 652 F.2d 146, 161-162 (D.C.Cir. 1986) (Gray Panthers I). The court reiterated this position in Gray Panthers II, 716 F.2d 23 (D.C.Cir. 1993), at 28.

pre-termination review. As the Court noted in Goldberg, "termination of aid pending resolution of a controversy over eligibility may deprive an eligible recipient of the very means by which to live while he waits."[10] Unfortunately, with respect to the Medicare program, pre-termination review as a legal concept is not uniformly developed. Pre-termination review, however, has been recognized to some extent in the areas of Medicare covered home health, and skilled nursing facility (SNF) care, and hospital care.[11] Even there, the precise nature and scope of pre-termination review is not established.

The Supreme Court, in Morrissey v. Brewer, noted, "[D]ue process is flexible and calls for such procedural protections as the particular situation demands."[12] In Matthews v. Eldridge, the Supreme Court established a three-pronged balancing test for evaluating whether a hearing procedure meets due process standards for Social Security Act cases:

> First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.[13]

Medicare hearing rights are codified at 42 U.S.C. §1395ff. The Hearing is to provide the same procedural rights as provided to Social Security Title II beneficiaries. 42 U.S.C. §1395ff(b)(1). Title II hearing rights, including review in the federal district courts, codified at 42 U.S.C. §405(b)-(g), require reasonable

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10. 397 U.S. at 264.

11. See, Martinez v. Sullivan, 874 F.2d 751 (10th Cir. 1989); Kraemer v. Heckler, 737 F.2d 214 (2d Cir. 1984); Martinez v. Richardson, 472 F.2d 1121 (10th Cir. 1972); Martinez v. Bowen, 655 F. Supp. 95 (D.N.M. 1986). See also, Sarrassat v. Sullivan, (N.D. Calif. 1989) [1990] Medicare and Medicaid Guide, ¶38,504)(Skilled nursing facilities must use uniform denial notices to inform residents of their right to request facilities to submit claims to the intermediary for initial decision. The notice must also state that a facility cannot bill the resident until the intermediary makes a formal determination).

12. Morrissey v. Brewer, 408 U.S. 471, 481.

13. Matthews v. Eldridge, 424 U.S. 319, 334-35.

notice and opportunity for a hearing. These hearings are non-adversarial.[16] Attorneys fees are available pursuant to 42 U.S.C §405(g) and through the Equal Access to Justice Act (EAJA), 42 U.S.C. §2412 et seq., (federal district court review).

Medicare beneficiary hearing and appeals rights are further defined in 42 C.F.R. §405, Subpart G (Reconsiderations and Appeals Under Medicare Part A); 42 C.F.R. §473, Subpart B (Peer Review Organizations Reconsiderations and Appeals); 42 C.F.R. §405, Subpart H (Review and Hearing Under the Supplementary Medical Insurance Program -- Part B); 42 C.F.R. §417, Subpart C HMO/CMP Beneficiary Appeals). While these appeals procedures vary in specifics, they all include, at a minimum: (1) an initial review and/or "reconsideration" by the original decision-making entity or someone else; (2) review in the form of a hearing before an independent hearing officer; and (3) recourse to the judicial system if a threshold amount of money remains in controversy. Medicare beneficiaries who have been successful in judicial appeals can recover their attorneys' fees under two provisions of the law.[13]

Circumstances requiring expedited appeals are illustrated by the Peer Review Organization (or PRO) hearing procedures. These apply, for example, when a Medicare beneficiary is a hospital inpatient and the doctor and hospital agree that the patient should be discharged. If the patient requests PRO review before noon of the first working day after the denial notice was delivered to the inpatient, then the hospital must provide the patient's record to the PRO by the close of that first working day. The PRO must issue a review decision within one full working day after the date the PRO received the review request and the records. In such cases, the hospital may not charge the patient for any charges incurred before noon of the day following the day on which the PRO review decision is received by the patient. If the patient is still dissatisfied with the decision, the regular process of reconsideration, hearing, and judicial review remain available.

Due process rights have been the subject of beneficiary litigation involving HMOs. For example, Medicare beneficiaries who use HMOs have claimed that they have been denied due process because HMO appeals procedures were not clearly defined and made known to them. Problems have included the lack of notice or a clearly defined procedure for review (including timely review by the HMO and access to external review such as Administrative Law

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[16]. See, e.g., Richardson v. Perales, 402 U.S. 389, 403 (1971).

[13]. 42 U.S.C. §405(g) (concerning judicial review of the Secretary's decisions under the Social Security Act); and the Equal Access to Justice Act, 28 U.S.C. §2412.

Judge and court review).[14] Empirical studies of Medicare HMO operations by the General Accounting Office and Medicare advocacy groups have confirmed the existence of substantial problems in claims approval and payment, processing beneficiary appeals, and quality assurance systems.[15]

Experience with statutory changes in Medicare Part B appeals highlights the need for Congress to act with clarity in writing review and adjudicatory rights into statutes. In extending Part B benefits to Medicare beneficiaries in the Omnibus Budget Reconciliation Act of 1986, Congress did not make explicit the procedural steps leading to administrative law judge review.[16] This resulted in additional layers of claims review and considerable delays in obtaining relief for beneficiaries. The experience further led to Congressional studies of the problems created and to protracted litigation.[17]

B. Medicaid Hearing Rights

Medicaid hearing rights are found in federal law at 42 U.S.C. §1396a(a)(3) and in the regulations at 42 C.F.R. §431, Subpart E, as mandated by Goldberg v. Kelly and its progeny.[18] They include an opportunity for an appeal of any action or inaction harmful to the Medicaid beneficiary. Notice and hearing protections are triggered by a broad range of adverse actions, including denials of

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[14]. See, e.g., Levy v. Sullivan, (C.D. Calif. 1989) [1989-2] Medicare and Medicaid Guide ¶37,809 (Settlement calling for the processing of HMO reconsideration requests pursuant to a 30-day timeliness standard and the issuance of a new HMO manual setting out a 30-60 day standard for the HMO stage of reconsideration decision-making.)

[15]. General Accounting Office, HCFA Needs to Take Stronger Actions Against HMOs Violating Federal Standards, HRD-92-11 (November 12, 1991); Medicare Advocacy Project, Inc., Medicare Risk-Contract HMOs in California: A Study of Marketing, Quality, and Due Process Rights (January 1993); E. Hallowell, Challenging the HMO System of Incentives. Philadelphia Inquirer, (March 28, 1989).

[16]. Omnibus Budget Reconciliation Act of 1986, §9341, codified at 42 U.S.C. §1395ff

[17]. See, Isaacs v. Bowen, 865 F.2d 468 (2nd Cir. 1989); Abbey v. Sullivan, 785 F.Supp. 165 (S.D. N.Y. 1992).

[18]. Goldberg, supra note 2.

eligibility [19] or services;[20] claim denials for "technical reasons," such as form errors;[21] and imposition of copayments.[22] Related rights include the requirements that the agency issue and publicize its hearing procedures; that applicants and recipients receive notice of an adverse agency action, generally in advance of the action (with aid and services continued pending the appeal); and that applicants and recipients have the right to see case files, to review documents used by the state, to present witnesses, to cross-examine adverse witnesses, and to receive a decision on the record within a specified time.

Medicaid recipients must receive notice from the Medicaid agency of provider claims that have been denied. The agency must provide recipients with written certification that they are not liable for denied claims,[23] and recipients are entitled to limited notice and hearing rights regarding denied provider claims.[24]

Under Medicaid, consumers may sue in federal court to vindicate their rights, without jurisdictional dollar minimums.[25] Attorneys' fees and experts' fees are available to consumers who prevail.[26] Jurisdiction is also available in many state courts.[27]

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[19]. See, e.g., Phillips v. Noot, 728 F.2d 1175 (8th Cir. 1984).

[20]. See, e.g., Eder v. Beal, 609 F.2d 1175 (8th Cir. 1984).

[21]. See, e.g., Easley v. Arkansas Dep't of Human Services, 645 F. Supp. 1535 (E.D. Ark. 1986).

[22]. See, e.g., Claus v. Smith, 519 F. Supp. 829 (N.D. Ind. 1981); Becker v. Blum, 464 F. Supp. 152, 155-57, 156-57 n. 5 (S.D.N.Y. 1978).

[23]. Easley v. Arkansas Depart. of Human Services, 645 F. Supp. 1535 (E.D. Ark. 1986).

[24]. Daniels v. Tennessee Depart of Health and Environment, (M.D. Tenn. 1985)[1985] Medicare and Medicaid Guide, ¶34,562.

[25]. 42 U.S.C. §1988; and see also, Suter v. Artist M., 112 S.Ct. 1360, 60 U.S.L.W. 4251 (March 25, 1992), raising questions about the standing of consumers under current law.

[26]. 42 U.S.C. §1988.

[27]. One example of a discrete issue in the Medicaid program is Medicaid estate recoveries. Numerous state court decisions have shaped the development of this law. See, e.g., Estate of Burke, 443 N.Y.S.2d 1003, 111 Misc. 2d 196 (N.Y. Surr. Ct. 1981), aff'd,

c. ERISA Consumer Experience

ERISA was enacted to safeguard the rights of workers and beneficiaries in employee benefit plans, including employer provider health insurance. Nonetheless, the protections available under ERISA are much less extensive than those available under Medicare and Medicaid. In fact, in some instances the limited appeals provisions of ERISA actually cause harm to individuals.

ERISA explicitly provides that "disclosure be made and safeguards be provided with respect to the establishment, operation, and administration of [employee benefit] plans."[28] The disclosure provisions are especially important for participants and beneficiaries in employer-sponsored group health plans. The required disclosure documents explain eligibility to participate in health plans, coverage amounts, co-payments and deductibles, and describe grievance and appeal rights. Congress felt so strongly about the need to provide information to participants and beneficiaries that it established a cause of action and penalty for plan administrators who fail to comply with a request for documents within thirty days.[29]

In addition to the disclosure requirements, ERISA and its implementing regulations and case law establish a notice and review process for any participant or beneficiary whose claim for benefits has been denied.[30] Adequate written notice must be provided in language calculated to be understood. The notice must contain the specific reasons for the denial, reference to the health plan provisions upon which the denial is based, a description of any additional information needed to perfect the claim and the reasons why the information is necessary, and an explanation of the steps for submitting the claim for review.[31]

Failure to comply with the notice provisions can result in liability to the health plan. Thus, a health maintenance organization whose notice did not adequately inform the participant of the reasons for denial of coverage and of the need to obtain a second opinion was required to reimburse the participant for the

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57 N.Y.S.2d 382, 456 N.Y.S.2d 716 (1982); In re Estate of Hanson, 451 N.W.2d 364 (Minn. Ct. App. 1990); Shelton v. Fresno Community Hosp., 174 Cal. App. 3d 39, 219 Cal. Rptr. 722 (1985).

[28]. 29 U.S.C. §1001(a).

[29]. 29 U.S.C. §§1132(a)(1)(A), (c).

[30]. 29 U.S.C. §1133.

[31]. 29 C.F.R. §2560.503-1(f).

medical expenses he incurred.[32] A plan whose denial notice was not specific enough about reasons for the denial of benefits and about the appeals process could not claim that the participant's appeal was untimely filed, and was required to pay the participant's attorneys fees.[33]

Participants whose claims have been denied must be given a reasonable opportunity for a "full and fair review by the appropriate named fiduciary of the decision denying the claim."[34] Although ERISA does not require claimants to pursue remedies through the plan's internal appeals procedure, courts have established a federal common law requirement that participants exhaust plan remedies before going to court.[35] An exception may be made and exhaustion not required in cases where serious procedural violations are shown or where exhaustion would be futile.[36]

Each health plan must establish a time period during which a claimant may file a request for review of a denied claim. Department of Labor regulations require that decisions on review be made "promptly," generally within 60 days. Plans may extend the time period for response to 120 days after receipt of the request for review if there are special circumstances, such as the need to hold a hearing or to wait for a meeting of the board of trustees. A request for review that is not acted upon within 120 days is deemed to be denied, and the claimant may seek judicial review.[37]

Participants and beneficiaries have hurt by the restrictions in the ERISA claims procedure. Unfortunately, many plans do not comply with the regulatory time frames, and some do not respond to requests for review. Claimants who have received inadequate notice concerning the appeals procedure have literally spent years waiting for the plan to act on their appeals.

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[32]. Bellanger v. Health Plan of Nevada, 814 F.Supp. 918 (D.Nev. 1993).

[33]. White v. Jacobs Engineering Group, 896 F.2d 334 (9th Cir. 1989).

[34]. 29 U.S.C. §1133(2).

[35]. See, e.g., Amato v. Bernard, 618 F.2d 559 (9th Cir. 1980).

[36]. See, e.g., Schwartz v. Interfaith Medical Center, 715 F.Supp. 1190 (E.D.N.Y. 1989); Gavalik v. Continental Can Co., 812 F.2d 834 (3d Cir. 1987).

[37]. 29 C.F.R. §2560.530-1.

The Department of Labor regulatory time frame also is problematic. A health plan participant can be made to wait four months for a decision whether a plan will cover needed medical treatment, thus delaying the treatment or the payment of expenses already incurred. There is no provision for expedited review in emergency situations; the most that the claimant can hope for is that a court will agree to waive the exhaustion requirement. Finally, too many plans view the claims procedure as a rubber stamp of the initial determination. There may be no independent evaluation of the dispute; the review is performed by the same person who made the initial determination.

Unlike Medicaid, and unlike Medicare to a certain extent, there is no right under ERISA to pre-termination review. Coverage under a private employer-sponsored group health plan is not an entitlement. Nothing in ERISA requires employers to offer health insurance to their employees and retirees, or to continue providing benefits at a constant level of coverage. Rather, ERISA gives employers and plan sponsors flexibility to create, alter, or terminate a health plan. Courts have cited the voluntary nature of ERISA health plans in upholding the right of plan sponsors to reduce coverage for a specific illness such as AIDS.[38] If, however, an employer has promised employees or retirees a specific level of benefits or benefits for a specific amount of time, courts may under a contract analysis require the employer to provide the health benefits that were promised.[39] While the court case is pending, however, the claimant is not entitled to the medical benefits in question.

An on-going case exemplifies the difficulties with ERISA. An insurance company notified a beneficiary, who uses both a gastrostomy tube and a jejunal tube, that it would no longer cover the nursing services he requires in order to reside at home. Coverage will terminate before the ERISA appeals process is complete, and there is no requirement that benefits continue pending appeal. Thus, even if the beneficiary receives a favorable decision from the claims process, his condition may deteriorate so much during the period in which his nursing needs are not covered that he will be forced into a nursing home anyway.

III. CONSTITUTIONAL UNDERPINNINGS OF HEALTH CARE ACCESS AND DUE PROCESS

A review of the constitutional underpinnings of health care access starts with the question of whether a "fundamental right" to

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[38]. McGann v. H & H Music, 946 F.2d 401 (5th Cir. 1991); Owens v. Storehouse, 984 F.2d 394 (11th Cir. 1993).

[39]. See, e.g., International Union v. Yardman, 716 F.2d 1476 (6th Cir. 1983); Owens v. Storehouse, supra at 398.

health care exists in this country. This question is at the heart of constitutional equal protection analysis. As will be shown below, the absence of a firm positive answer to the fundamental right/equal protection question shifts the epicenter of constitutional analysis to the principles of procedural due process under the Fifth and Fourteenth Amendments.

A. A "Fundamental Right" To Health Care?

Legal commentators have frequently acknowledged the sad fact that the United States Constitution neither mandates nor creates a general or universally applicable "fundamental" right to health care.[40] Such a right has been recognized only in circumstances involving incarceration or commitment. For example, courts have reasoned that to put someone in prison where he or she is stripped of the ability to have access to care, and subsequently not to provide care, can result in "cruel and unusual" punishment which the Eighth Amendment prohibits. Inmates, therefore, have a right to care, and correctional officials have a duty to provide care that does not manifest a "deliberate indifference to the serious medical needs" of inmates.[41] Similarly, persons with mental retardation who are involuntarily committed possess a constitutional right to liberty, which includes rights to adequate food, shelter, clothing, and medical care:

> When a person is institutionalized-- and wholly dependent on the State[,] ... a duty to provide certain services and care does exit.[42]

The Supreme Court has refrained from explicitly recognizing a general right to treatment for all institutionalized persons. However, numerous lower courts and state legislatures have formalized this basic entitlement.[43] For the public at large, however, the lack of a recognized fundamental right to health care virtually eliminates a key constitutional avenue in advocacy for health care-- that of "equal protection."

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[40]. See, e.g., Nancy N. Dubler & Charles P. Sabatino, "Age-Based Rationing and the Law: An Exploration," in Too Old For Health Care? - Controversies in Medicine, Law, Economics, and Ethics (Robert H. Binstock & Stephen G. Post eds., 1991).

[41]. Estelle v. Gamble, 429. U.S. 97,106 (1976).

[42]. Youngberg v. Romero, 457 U.S. 307, 317 (1982); see also, DeShaney v. Winnebago County Department of Social Services, 109 489 U.S. 189 (1989).

[43]. Barbara A. Weiner, "Treatment Rights," in The Mentally Disabled and the Law (S.J. Brakel, J. Parry, & B.A. Weiner, 1985).

B. Equal Protection Analysis

The Fourteenth Amendment provides that "no State shall ... deny to any person within its jurisdiction the equal protection of the laws." While this clause is not applicable to the federal government, it has been held that most acts by the federal government that would deny equal protection constitute a "deprivation of liberty" within the Fifth Amendment's due process clause.[44]

Generally, equal protection analysis has been used to determine the validity of classifications used in legislation. Most legislation imposes responsibilities on, or grants or denies benefits to, some classes of people-- whether they be taxpayers, parents, sport fishermen, pickle producers, employees, older persons, low income persons, high income persons, able bodied persons, or persons with disabilities. Normally, any such classifications will be upheld by the courts if "rationally related" to a proper state interest.[45] This test is highly deferential to legislative discretion. However, a higher standard -- a "strict scrutiny" test -- will apply if either of two conditions are met: (a) the legislative classification interferes with the exercise of a fundamental right, or (b) the classification operates to the particular disadvantage of a "suspect class".[46] Under this more rigorous test, a classification will be held to violate equal protection unless found to be necessary to promote a "compelling" state interest. Challenges to legislative classifications have a relatively high likelihood of success under the strict scrutiny test. While some justices have argued regularly for intermediate versions of this test, the dichotomous approach remains the official analytic approach of the Supreme Court. A right of the public at large cannot, of course, rely on a "suspect class" claim. Consequently, the non-recognition of a fundamental right to health care extinguishes viable constitutional claims based on equal protection.

Despite the lack of a general and legally enforceable right to health care in the United States, there may be some notion of a "right to life-sustaining care," based, paradoxically, on two growing bodies of cases: one establishing the right to refuse

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44. Bolling v. Sharpe, 347 U.S. 497 (1954).

45. Ronald D. Rotunda, et al., 2 Treatise on Constitutional Law: Substantive and Procedure, (1986).

46. See, e.g., Massachusetts Board of Retirement v. Murgia, 427 U.S. 307, 312 (1976).

life-sustaining treatment or a so-called "right to die,"[47] and the other addressing the concept of a "right to life," first popularized in the abortion debate. These lines of cases acknowledge a state's "interest in the protection and preservation of human life" in the case of treatment refusals,[48] and the state's "interest in protecting potential human life" in the abortion cases.[49] The policy consequences of these two lines of cases have led some commentators to conclude, wryly, that the federal government is interested in children "from conception to birth" and in adults "from sickness to death," but only if life itself is imperiled.

Unfortunately, even within these limited contexts, the existence of a state interest in protecting and preserving human life has not led to the recognition of a fundamental constitutional right to life-sustaining health care. Therefore, equal protection analysis in this context ultimately fails. Instead, these cases focus on an analytically different but related constitutional principle, that of procedural "due process" under the Fifth and Fourteenth Amendments.

C. Procedural Due Process Analysis - The Constitutional Cornerstone

Applied to the federal and state governments, respectively, the Fifth and Fourteenth Amendments mandate that no person shall be deprived "of life, liberty, or property, without due process of law." As stated earlier, equal protection analysis is used to determine the constitutional validity of legislative classifications. In contrast, due process analysis is most relevant in adjudicating alleged deprivations of existing property or liberty interests. Of key importance is the fact that the existing liberty or property interests do not have to be constitutionally created. They may be rights created by statute or those recognized in the common law.

The due process clause is essentially a "limitation on the

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[47]. The line of cases starting with In re Quinlan, 355 A.2d 64, 70 N.J. 10 (1976), cert. denied, 454 U.S. 858 (1976) eventually led to the U.S. Supreme Court's first decision on the right to refuse life-sustaining treatment in Cruzan v. Director, Missouri Department of Health, 497 U.S. 261 (1990).

[48]. Cruzan, supra note 47, at 261.

[49]. Webster v. Missouri, 492 U.S. 490, 519 (1989).

State's power to act."[50] It was intended to secure the individual from the arbitrary exercise of the powers of government and to prevent "unwarranted government interference,"[51] but it does not create an affirmative general obligation upon the government to provide any particular form of aid. The Supreme Court has been quite clear on this point, particularly in abortion cases, most recently reaffirming this proposition in Webster v. Missouri where it stated:

> ...the Due Process Clauses generally confer no affirmative right to government aid, even where such aid may be necessary to secure life, liberty or property interests of which the government may not deprive the individual.[52]

The Court applied similar reasoning in a case contemporaneous to Webster, holding that the due process clause imposed no duty on the state of Wisconsin to provide adequate child protective services.[53]

Even though the due process clause provides no affirmative assurance of health care access, its procedural implications are, nevertheless, extremely significant for any national system of health care in two respects. First, to the extent that health reform legislation creates or controls statutory entitlements to benefits, procedural due process protections against deprivations of these benefits will apply. Statutory entitlement to a benefit is a property interest to which due process rights attach.[54] For example, state statutes establishing Medicaid and other indigent

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50. DeShaney v. Winnebago County Department of Social Services, 489 U.S. 189, 195 (1989).

51. Id., at 196; see also, Parratt v.Taylor, 451 U.S. 527, 549 (1981).

52. Webster, supra note 49, 492 U.S. at 507; see also, Harris v. McRae, 448 U.S. 297, 316 (1980), in which the Court said: "Regardless of whether the freedom of a woman to choose to terminate her pregnancy for health reasons lies at the core or the periphery of the due process liberty recognized in Roe v. Wade, 410 U.S. 113 (1973), it simply does not follow that a woman's freedom of choice carries with it a constitutional entitlement to the financial resources to avail herself of the full range of protected choices."

53. DeShaney, supra note 50.

54. See, e. g., Atkins v. Parker, 472 U.S. 115 (1985); Logan v. Zimmerman Brush Co., 455 U.S. 422 (1982).

care programs have been held to engender property interests protected under procedural due process.[55]

Second, any rationing of care under such a system will likewise be scrutinized under principles of due process, since rationing may be functionally equivalent to a deprivation for those groups adversely affected. The following sections examine the nature and extent of procedural protections that may be constitutionally necessary in any government mandated or sponsored universal health care system. The rationing of health care is not addressed in this paper.

IV. QUALITY ASSURANCE AND CONSUMER PROTECTION

The duty to provide an adequate level of quality in the provision of health care is deeply rooted both in common law principles of tort and contract and in manifold state and federal administrative laws regulating health care providers. For certain vulnerable populations, such as those involuntarily institutionalized, poor quality of care may also result in a deprivations of a patient's constitutional rights.[56]

All states license individual and institutional health care providers, setting standards for practice and services. States commonly set additional standards for state-funded health and long-term care services. On top of all this, Medicare and Medicaid set extensive standards, primarily through "conditions of participation," on all participating providers.[57]

The central role of the individual with respect to his or her own health care is rooted in the common law right of self determination. In the oft-quoted 1914 case of Schloendorff v. N.Y. Hospital, Justice Cardozo succinctly articulates this right:

> Every human being of adult years and sound mind has the right to determine what shall be done with his own body.[58]

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[55]. See, e.g., Daniels v. Woodbury County, 742 F.2d 1128 (8th Cir. 1984); Griffeth v. Detrich, 603 F.2d 118 (9th Cir. 1979); Eder v. Beal, supra; Kimble v. Solomon, 599 F.2d 599 (4th Cir. 1979); Jones v. Blinziner, 536 F. Supp. 1189 (N.D. Ind. 1982).

[56]. Estelle v. Gamble, supra note 41; Youngberg v. Romero, supra note 42, 457 U.S. at 317.

[57]. See, generally, Medicare & Medicaid Guide, ¶12,305 (CCH).

[58]. Schloendorff v. Society of New York Hosp., 105 N.E. 92, 93 (N.Y. 1914).

The other common law root of consumer control arises from the common law offense of battery which made any offensive, unwanted touching an actionable wrong. From this common law action evolved the right of "informed consent" and the corollary right to refuse treatment. A constitutional basis for personal control over health decisions is now well established in a substantial line of cases from the 1976 Karen Ann Quinlan (recognizing a privacy interest)[59] decision to the Supreme Court's opinion in Cruzan v. Director, Missouri Department of Health (recognizing a liberty interest).[60]

From these foundations has developed a body of patient/client rights and protections concepts that have been articulated most extensively in the area of nursing home care pursuant to the 1987 nursing home reform amendments.[61] While the depth and breadth and detail of these rights is specific to a targeted, highly vulnerable group of patients, they are, nevertheless, instructive as a high water mark of patient/client rights and as an affirmation of basic consumer protection elements establishing: the right to notice and information necessary to make informed decisions; the right to protections against abuse; the right to complain through effective grievance mechanisms without fear of retaliation; and the right to personal preferences and privacy.

V. The Administrative Procedures Act (APA) (5 U.S.C. §§554-557)

The formal adjudication sections of the APA apply to cases which by statute must be reviewed on the record after a hearing. While not directly applying to Medicare or Medicaid beneficiary appeals, these adjudicatory sections, consistent with constitutional norms of due process, provide the following:

1. A clear statement (notice) of the right to a hearing. Generally, this includes a statement that a hearing is available, the applicable time periods for requesting the hearings, and the steps necessary to obtain that hearing. §554(b).

2. An opportunity to participate in the hearing. This includes the right to be physically present at the hearing. §554(c).

3. An opportunity to appear before an impartial hearing officer. The hearing officer should be free to make an independent judgment of the facts at issue. §554(d) and 556(b).

4. The right of parties to be represented by counsel at hearings. Parties should be free to have either a lawyer or other representative present at hearings. §555(b)

5. The right to present oral and written evidence and to conduct cross-examination. This includes the right to see and examine all relevant documents prior to the hearing. §556(d).

6. The right to submit proposed findings of fact, conclusions of law, or to note exceptions. This includes the right of parties to submit oral and written legal arguments in support of their respective positions. §557(c).

7. The right to a written record or transcript of the hearing. This includes the right to have access to the transcript of the proceedings in a timely fashion and at affordable costs. §556(3).

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[59]. In re Quinlan, 355 A.2d 647, cert. denied sub nom. Garger v. New Jersey, 429 U.S. 922 (1976).

[60]. Cruzan, supra note 47.

[61]. Omnibus Budget Reconciliation Act of 1987 (OBRA), Pub. L. No. 100-203, Title IV, Subtitle C, §§4201-4206, 4211-4216, 42 U.S.C. §§1395i-3(a)-(h), 1396r(a)-(h), Medicare and Medicaid, respectively.

PREPARED STATEMENT OF SENATOR CHARLES E. GRASSLEY

Mr. Chairman, thank you very much for holding this hearing. I think that it is very important to bring into focus the concern for consumer protection that must be one of the central concerns of our health care reform project.

This concern for consumer protection has been a thread in evidence through several of our hearings: This concern is animated by fear that underservice will be the core problem of a reformed system in which health care providers and payers bear most of the financial risk of providing care and "manage" care so as to reduce cost.

It was expressed as early as last year before the full Finance Committee by Karen Davis and Stuart Altman, both of whom stressed the importance of maintaining a viable fee-for-service element in any reformed health care system.

It has been expressed by others before this committee. Those representing individuals who provide care to people needing expensive care rendered by specialists—the Federal cancer centers, for instance—are concerned that their patients may have difficulty in gaining access to specialized care. It was expressed also by some witnesses who care for the low income or the culturally different.

As I implied earlier, Mr. Chairman, although this concern has run through testimony at several of our hearings, yours is the first hearing to bring it into clear focus.

It seems to me that this committee has to build into whatever reform legislation we pass substantial consumer protections. I am not completely sure yet how we should do this.

But there might be several ways to approach this problem. Certainly more and better information about the quality of services will help consumers better understand how well their health plans are serving them. Your witnesses today provide some useful suggestions about what might be needed in the way of quality assessment systems.

Overall system design can also have an important bearing on the need for more specific consumer protections. For instance, as Stuart Altman and Karen Davis suggested, continuation of a viable fee-for-service element in any reformed system will enable individual consumers to "vote with their feet" if they are displeased with managed care plans.

Perhaps we should consider requiring health plans to have reinsurance to protect them against the consequences of catastrophic costs associated with treating expensive health care problems of enrollees. In that way, some of the pressure to cut corners on care that seems to me potentially inherent in requiring health care providers or health plans to bear the financial risk of treatment will be mitigated.

We should also consider making the rules established by health plans completely "transparent" so that individual consumers, and organizations representing consumers, will understand just what the rules are that might have a bearing on treatment.

Mr. Chairman, thank you once again for holding this important hearing. I look forward to working with you and your staff on this aspect of health care reform.

PREPARED STATEMENT OF JENNIFER L. HOWSE

Mr. Chairman and Senators of the Committee, I am Dr. Jennifer L. Howse, president of the March of Dimes Birth Defects Foundation. Our mission is to improve the health of babies by preventing birth defects and infant mortality. Thus, we have a special interest in reducing the barriers to care faced by millions of American families who want to have healthy babies. These families deserve to have health security. The March of Dimes, embodied by our 100 chapters and over one million volunteers, also shares widespread concern about the growing number of uninsured and the increasing cost of health care in America.

Mr. Chairman, we want to commend you for your interest in the quality of health care and thank you for your dedication to the health of babies in this country. This committee has an historic opportunity to reshape the health care system. The leadership and expertise you bring to these issues can make a world of difference in the future health of our nation.

I appreciate the opportunity to be here with you today to discuss concerns about the delivery of maternal and infant health services, how these problems illustrate larger problems, and what can be done to improve the health care system, including specifically the quality of care for mothers and babies.

I. PROBLEMS IN THE HEALTH CARE SYSTEM CAN BE ILLUSTRATED BY FAILURES IN DELIVERING MATERNITY AND INFANT CARE

The health care system does not encourage use of preventive services

Prenatal care is a good example. While prenatal care has been found to be effective and cost effective—saving $3 for every $1 invested—the nation has failed to ensure access for all pregnant women. Each year, one-quarter of all pregnant women receive no prenatal care in the critical first three months of pregnancy. Nearly 90,000 babies are born to mothers who arrive at the hospital having received no prenatal care—with no medical records, no plan for care at birth, and no regular provider. Two major reasons for gaps in prenatal care use are lack of insurance coverage and a health care delivery system that is not user friendly.

As the number of uninsured has grown in recent years, women and children were among those most likely to lose coverage

Despite recent expansions of Medicaid, the number of uninsured children and women of childbearing age grew during recent years. Loss of dependent coverage for working families is a major factor in this erosion. Many employers and families could not afford increasing premiums for dependent coverage. As a result:

- Each year 400,000 pregnant women have no health insurance, public or private.[1]
- Nearly 9 million women of childbearing age (18-44 years) have no health insurance—this figure includes 6 million women who work.[2]
- More than 8 million children have no health coverage throughout the year.[3]

Many of the sickest populations have been left behind

Our Foundation is particularly concerned about the exclusion of children with birth defects. Because birth defects are often considered "pre-existing conditions," infants with birth defects are then excluded from insurance plans. Those infants who survive may have no coverage for services to prevent or limit disabilities. Unless major reforms to the health care system are enacted, these children with birth defects and millions of others who have serious health conditions will be permanently denied health coverage.

We need a health care system

Today, our health care delivery approach is often fragmented and haphazard. A good illustration is care for women who want to have a healthy baby. Most women of childbearing age often do not receive preventive services before they become pregnant—when much could be done to prevent birth defects and infant mortality. Prenatal care may be broken into a physical exam here, lab tests there, and smoking cessation somewhere else. At the time of birth, prenatal records may be missing. After the baby is born—and, if healthy, typically leaves the hospital within 24 hours after birth—the family may have no provider for pediatric care. Poor coordination continues despite our knowledge of what to do and why maternity and infant care is important.

We do not invest our resources wisely

A recent study (sponsored by the March of Dimes and conducted by RAND[4]) found that only a small fraction of total health costs are spent on maternity and infant care—$27.8 billion or less than 5 percent of total health care spending. Over $2 billion of this amount is uncompensated care—a loss or pay-back after the baby is born and many opportunities to address risks have passed. Much of today's costs are for care of sick babies, rather than for an investment in health. Refocusing our spending on prevention will reduce health care costs and infant mortality.

II. WHAT CAN BE DONE TO IMPROVE THE HEALTH CARE SYSTEM?

The March of Dimes believes that any health care reform proposal should ensure that care is affordable, available, and appropriate. These are the core components of access.

Make care affordable through guaranteed, universal coverage

Our principles support health care reform that includes universal coverage for pregnant women and infants. American families need guaranteed coverage. This change is fundamental to improving access and the health of our babies.

Last November, Lynn Morrison, a mother from Georgia and March of Dimes volunteer, testified before the Senate Labor Committee about the challenge of finding coverage for her last pregnancy. She reported that:

"I am an average working person . . . This year, money was a little tight, even though we [she and her husband] both were working. When I learned I was pregnant I had just changed jobs. . . but my new job did not offer employee health insurance . . . I tried to get on my husband's health insurance plan through his work. We learned that they had been taking monthly payments from his paycheck as if he had a family plan, but I was never really enrolled. When he tried to enroll me, I was denied coverage because my pregnancy was considered a "pre-existing condition." I really wanted this baby to have a healthy start . . . I went to the welfare office and got a temporary Medicaid care. I called several doctors, but no one would see me . . . Then the welfare office told me my family income was too high for Medicaid . . . [Staff at a hot-line] gave me the name of a hospital that has a package maternity plan for uninsured women. The charge was $3000 for prenatal care and my hospital delivery and newborn costs . . . I knew it would be hard for us to pay this . . . We worked out a payment schedule that we could afford. In my fifth month of pregnancy, I got to see a doctor, finally. A month later, I went into premature labor . . . but with help I was able to carry Deseree to term . . . All of this not only put my baby at risk, but we were afraid of losing our house and our marriage. I am here to urge you to change the health system so that no other women, children and families will have to go through the ordeals and financial stress we went through to have a baby."

Make providers available

The supply and distribution of providers should be improved. Short-term strategies include scholarship and loan repayment programs and financial incentives to establish or maintain a practice, particularly in rural and urban areas. A long-range approach requires development of a national health workforce plan, with reforms in medical education and medical liability.

Providers should be organized into networks that are related to the needs of the population, that provide the full range of care. Experts in maternity and infant care agree that basic, specialty, and subspecialty care must be available as needed.[5] Networks and plans that do not have relationships with subspecialty providers place families at risk. Families who want to have a healthy baby should have access to a range of providers who can handle complications.

Health care reform should include strategies to increase the supply of primary care providers, but new policies should not overlook the important role of specialists and subspecialists. For a pregnant woman with diabetes or a premature newborn, specialty or subspecialty care can save a life or prevent disability. In fact, the major declines in infant mortality of the past 20 years have largely been the result of better access to appropriate care for high risk mothers and newborns, especially access to subspecialty care at perinatal centers with neonatal intensive care units (NICU).[6] Most children who leave an NICU grow up with no health problems.[7] These gains in infant survival and child health should be protected under a reformed health system by ensuring access to a range of providers.

At a town meeting in St. Louis, Missouri—one of five such meetings convened by the March of Dimes to study perinatal care issues—health professionals from Barnes Hospital and Washington University reported that:

"A young women was referred to our center for prepregnancy counseling and high risk prenatal care. She had a history of hypertension that had led to a renal transplant. Following prepregnancy counseling, she accepted the risk of a pregnancy and was very compliant with her therapy plan. She successfully delivered a 5.5 pound, full-term baby girl without complications. Two years later, at the time of her second pregnancy, her coverage had changed to a private managed care plan. The plan required her to see a generalist in the field of obstetrics, with only limited access (once per trimester) for specialty consultation. At 18 weeks gestation [four and one half months into the pregnancy], this patient presented at a primary hospital with symptoms suggestive of an infection. After several complications, she developed preterm labor leading to delivery of a "previable" infant that could not survive. The woman was hospitalized for several days after this and treated for significant anemia and complications from the infection. Fortunately, she did not have permanent damage. This patient represents a person who will never be convinced that lack of access to the specialty care she had in her first pregnancy didn't link to her loss."

Make care appropriate through adequate benefits and quality assurance

Any health reform proposal should require a standard, minimum benefit package that includes the range of services needed by pregnant women and children. In light of rapidly changing technology and therapies, there also should be an ongoing process to update the standard benefit package.

Monitoring quality is essential to consumer protection and cost containment. Standards of care, based on research and clinical experience, should be used to measure performance. Information from quality monitoring should be shared with consumers in language that is easy to understand and reflects standards of care.

In the case of prenatal care, we know what is important,[8] and we know we can improve outcomes.[9] Studies have shown that good results can be achieved—even for the low-income, high-risk women.[10] Yet as some states move to implement Medicaid managed care programs or state health care reform plans, proven standards have been dropped.

- In New York State, state officials created an enhanced prenatal benefits for low income pregnant women who receive Medicaid. Known as the Prenatal Care Assistance Program (PCAP), it provides comprehensive prenatal care and encourages providers to see women early and throughout pregnancy. The program has proven effective. Data from 1991 show a significant reduction in low-birthweight (7.5% for PCAP versus 10.4% for Medicaid recipient women not using PCAP providers). PCAP participants also were less likely to have premature babies. Groups traditionally at highest risk for poor birth outcomes—including African-American, Hispanic-American, teenaged pregnant women—showed the greatest and most consistent benefits from PCAP.[11] Despite this demonstrated success, PCAP standards are not being applied to the growing number of Medicaid managed care plans in New York.

Accountability for communities, not just individual patients

Any health care reform plan should provide for accountability—whether ensured through a local board, a regional alliance, or a state health agency. While each individual patient wants a trusting relationship with their health provider, more is needed. Accountability for the whole population—of a city, region, or state—is essential to containing costs, improving outcomes, and ensuring quality.

Mechanisms are needed to gather information that will be needed for planning and for educating consumers about their choices. Without data on the total population of an area, it will be impossible to compare the performance of various plans and providers. To monitor outcomes, population-based information and accountability mechanisms are essential.

In some areas of the country, health delivery systems are supported by planning and care coordination, involving both the private and public sectors.

- In New Jersey, the private and public sectors have built a model for accountability and coordination in maternal and child health. In 1992, the New Jersey Department of Health implemented the maternal and child health chapter of the State Health Plan by establishing and licensing a maternal child health consortium (MCHC) in each region. The MCHC was defined by the state to mean a nonprofit organization consisting of all perinatal and pediatric providers. In each region, the MCHC is required to: develop a system plan, coordinate and monitor perinatal and child health care, provide or coordinate professional education, and establish a program for quality assurance. Qualified professional staff administer the program. Any hospital in New Jersey providing obstetrical, neonatal and pediatric services must participate and contribute to support of the MCHC. The annual cost for seven regional MCHCs is estimated to be $4.8 million or approximately $40 per birth. The program is based on a voluntary initiative that began with support from the Robert Wood Johnson Foundation. In the two year demonstration phase, the proportion of woman in New Jersey receiving early prenatal care rose from 73% to 81%. The state's infant mortality rate declined from 9.8 to 8.9 per 1,000, despite concurrent epidemics of drug abuse and HIV infection.

CONCLUSION

We recognize that there are no easy answers to the current crisis in health care. However, as the nation's third largest voluntary health organization, we urge you to act thoughtfully and expeditiously to ensure affordable, available and appropriate health care for all Americans. The nation cannot afford to delay health care reform. We also urge you to remember mothers and babies. Any major changes in the health care financing system will have an impact on the health of the 4 million babies born

each year. Every day 11,000 babies are born—800 have low birthweight, 410 have a birth defect, and over 100 die.[12] Most American women experience pregnancy during their lives, with nearly 7 percent of women of childbearing age giving birth each year. Our nation cannot have the world's healthiest babies until our health care system provides access for every woman and baby.

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PREPARED STATEMENT OF KATHLEEN N. LOHR

Good morning, Mr. Chairman and members of the Subcommittee. I am Kathleen Lohr, Director of the Division of Health Care Services at the Institute of Medicine (IOM), National Academy of Sciences. The Institute of Medicine was chartered in 1970 by the National Academy of Sciences to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public. In this the Institute acts under both the Academy's 1863 congressional charter responsibility to be an advisor to the federal government and its own initiative in identifying issues of medical care, research, and education. I welcome the opportunity this morning to comment on critical quality-of-care issues in health care reform, drawing where appropriate on recent IOM work.

ENSURING QUALITY OF CARE AND THE GOALS OF HEALTH CARE REFORM

The diverse goals and incentives of reform, as they relate to the quality of health care, must be clear. We must maintain and improve the processes and outcomes of health care services, while ensuring that all our citizenry enjoy equitable access to those services. A reformed health care system must be able to address three issues. The first is use of unnecessary or inappropriate care, which is generally agreed to be a significant problem in fee-for-service systems; the second is underuse of needed, effective, and appropriate care, which is an especially critical issue because managed care systems favored by health care reform include incentives to limit care that may affect needed as well as unneeded services; and the third are lapses in technical and interpersonal aspects of care.

One IOM report explained these three problems as follows (pp. 35–36):[1]

- "too much care"—the unnecessary or inappropriate care provided in this country costs money that could be put to more productive use and makes patients vulnerable to harmful side effects;

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[1] Institute of Medicine. *Assessing Health Care Reform.* M.J. Field, K.N. Lohr, and K.D. Yordy, editors. Washington, DC: National Academy Press, 1992 ("Assuring the Quality of Care," pp. 33–44).

- "too little care"—necessary and appropriate services are often unused or unavailable, not only when people lacking health insurance delay seeking care or receive no care at all but also when even those with insurance face geographic, cultural, attitudinal, or other barriers that limit their abilities to receive, for example, proper well-baby or well-child care, prenatal care, ongoing care for chronic illnesses, emergency care, rehabilitative services or palliative care; and
- "inferior care"—health care professionals are expected to be able to diagnose and treat our ailments with competence and compassion, but not all clinicians have full mastery of their specialties, and not all can communicate with their patients with grace and empathy; these problems remain significant challenges to quality assurance and improvement efforts.

In attempting to restructure health care, we must take four steps to transform the nation's approach to health care delivery to overcome these problems and accomplish those ends:

- ensure that health care organizations establish efficient systems to protect consumers and to enable practitioners to improve their performance and their patients' outcomes;
- provide external oversight of the means by which we improve and assure the quality of care delivered;
- require public accountability for health care dollars spent; and
- support health professionals in sustaining their ethical commitment to their patients and in maintaining their skills and knowledge throughout their careers.

DEFINING QUALITY OF CARE

The Institute of Medicine's definition of quality of care may be helpful in these deliberations. It says that "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."[2] Note especially the following characteristics of that definition.

First, *designating the core as health services* means that quality of care applies to a broad range of services, not just medical services, and not just those relating to physical ailments. Furthermore, it applies to many types of health care professionals (physicians certainly, but also nurses, dentists, therapists, and various other health professionals), and all settings of care (from hospitals and nursing homes to physician offices and even private homes).

Second, *specifying populations as well as individual patients* means that concerns about quality of care are not restricted just to users of care or to insured groups. Rather, we must be concerned with all groups, who might be defined by geography (such as a state or region), cultural heritage, diagnosis, or sociodemographic characteristics, and these groups will include the most vulnerable and frail among us. Moreover, it implies an emphasis on access to health care, covers other potential problems of the underuse of care, and suggests that the perspectives of both individuals and society are important.

Third, *stipulating desired health outcomes* is especially important because it draws attention to a link between the processes of health care and outcomes of that care. It also means we must be mindful of patient well-being and welfare and of the importance of patients and their families being well-informed about alternative health care interventions and their related expected outcomes. Finally, it requires health care professionals to take their patients' preferences and values into account.

Finally, *emphasizing current professional knowledge* underscores the need for health professionals to stay abreast of a dynamic knowledge base in health care and to take responsibility for clarifying for their patients the processes and expected outcomes of care.

A word about patient outcomes is in order, because this concept must be understood as encompassing a broad range of health-related quality of life measures. These include aspects of physical functioning, mental and emotional well-being, cognitive functioning, functioning in usual social roles appropriate for one's age and other characteristics, levels of energy and vitality, and pain, as well as one's general perceptions about one's health. Several fine instruments to measure these aspects of health and well-being are available and being used in quality improvement or quality management programs in this country today.

Physicians and other health professionals are more familiar with other measures: survival or life expectancy, presence of disease or flare-up of a chronic illness, complications of an operative procedure, need for hospitalization, and biophysical and

[2] Institute of Medicine. *Medicare: A Strategy for Quality Assurance.* Vols. I and II. K.N. Lohr, editor. Washington, DC: National Academy Press, 1990.

laboratory measures. These are indeed important factors, but they do not sufficiently reflect the kinds of outcomes that matter to patients. Rather, in quality assurance and quality improvement, an effort must be made to reflect functional outcomes and aspects of well-being beyond those that physicians or nurses have traditionally used. In addition, we must draw the patient actively into decisionmaking—decisionmaking grounded in a good understanding among all concerned parties of the expected outcomes of different care processes.

MEASURING AND IMPROVING QUALITY OF CARE: ESSENTIAL AND DOABLE

Can we accomplish all this? Can we ensure the quality of health care in an age of uncertainty about science and an era characterized by rapidly evolving health care delivery systems?

We **can** measure the quality of health care. Many experts have been engaged, for at least two decades, in the development of reliable and valid ways to assess the quality of care in both inpatient and ambulatory settings. More recently, we have seen the advent of rigorous clinical practice guidelines (which can be used to establish medical review criteria, consumer information guides, and similar quality-related tools).[3] Such quality review methods and guidelines relate to such aspects of health care as: preventive care (for example, immunizations and prenatal care); acute and chronic diseases (such as asthma, diabetes, high blood pressure, and myocardial infarction); outcomes of major surgery (for instance, hip replacement or coronary artery bypass graft); and consumer satisfaction with services.

We also **can—and must**—improve the quality of health care. "Quality improvement" as America's health care system is transformed, will require applying standardized measures of health care quality, making health plans accountable to the public, eliciting cooperation from patients and consumers, and disseminating more and better information to providers and to the public. A "science" of systems and management exists that will help us describe, comprehend, and influence positively the systems, organizations, and settings through which we receive health care. Proponents of the continuous improvement approaches to quality of care cite the need to expand our knowledge base about systems as a whole, variation and statistics, psychology (such as group process, conflict resolution, motivation, creativity, human factors engineering, and behavioral decision theory), and learning. These concepts and tools are not yet familiar to clinicians or health administrators. Thus, linking them to more customary or newly emerging disciplines and approaches in health, such as technology assessment, clinical evaluation, and medical decisionmaking, will be crucial.[4]

Collaboration between the nation's academic health centers and our established quality review organizations, perhaps reformulated as health care quality foundations, will help to move this agenda forward. The elements of a successful review organization include quality improvement monitoring, analysis of data about variations in existing practice patterns, feedback of information to providers and practitioners, traditional external review and reporting responsibilities, assistance to facilities and health plans with their own internal quality improvement programs, and outreach to consumers. These activities can be harnessed to the research and education/training capabilities of academic institutions in a partnership likely to benefit all parties.

Such quality foundations might be seen as private, not-for-profit, state-based alliances of health professionals, consumers, purchasers, and payers. They would undertake quality review and improvement activities for all patients, care settings, and types of services. The new directions being set in motion for the nation's peer

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[3] The IOM defines clinical practice guidelines as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (Institute of Medicine. *Guidelines for Clinical Practice: From Development to Use.* M.J. Field and K.N. Lohr, editors. Washington, DC: National Academy Press, 1992). Implicit in this statement are certain emphases: (1) rigorous, science-based procedures for development; (2) decisionmaking about health care that involves both clinicians and patients; (3) a focus on specific clinical circumstances, including the full range of clinical conditions and problems with which primary care physicians deal, rather than simply individual technologies or procedures; and (4) an assumption that guidelines will be practical, explicit, working documents, not just lengthy compilations of the literature.

[4] P.B. Batalden and P.K. Stoltz. "A Framework for the Continual Improvement of Health Care: Building and Applying Professional and Improvement Knowledge to Test Changes in Daily Work." *Journal of Quality Improvement* 19 (10):424–447, 1993; D.M. Berwick. "Do We Really Need a Framework in order to Improve?" *Journal of Quality Improvement* 19 (10):449–450, 1993; D.M. Berwick. "Improving as Science." Paper presented at 1993 Robert Wood Johnson Conference and submitted for publication. Boston, MA: Institute for Healthcare Improvement, 1993.

review organizations, in collaboration with academic centers with strong capacity-building resources, hold much promise for a systematic approach to external and internal quality improvement and quality management programs that can take us well into health reform and the 21st century.

GATHERING AND DISSEMINATING INFORMATION

To improve the performance of the nation's health system and the health status and well-being of all its citizens—the crucial impetus for reform efforts—we clearly need better health data. In addition, major work to establish comprehensive, computer-based patient records as the standard in both inpatient and outpatient settings, will be needed.[5] The purposes to which more and better data might be put were recently catalogued by an IOM committee on "health data in the information age" as follows (p. 1):[6]

> to assess the health of the public and patterns of illness and injury; identify unmet regional health needs; document patterns of health care expenditures on inappropriate, wasteful, or potentially harmful services; identify cost-effective care providers; and provide information to improve the quality of care in hospitals, practitioners' offices, clinics, and other health care settings.

As noted further in that IOM report, these purposes call forth proposals for the creation and upkeep of comprehensive, population-based databases, and the success of health care reform in the long run may depend critically on the availability of reliable and valid data in such computer-based data files. Several difficulties must be addressed, however, in bringing the health care system into the information age.

One hurdle is the quality of the information in such databases; the information must be dependable, accurate, complete, and appropriate for the purposes to which it will be put. Another challenge involves disclosure of information about facilities, providers, plans, and individual practitioners. This subject relates directly to the call for "report cards" and similar information dissemination techniques that is often heard in the health care reform context, particularly for proposals based on notions of competition.[7]

The IOM committee on health data concluded that "[p]ublic disclosure is acceptable only when it: (1) involves information and analytic results that come from studies that have been well conducted (2) is based on data that can be shown to be reliable and valid for the purposes at hand, and (3) is accompanied by appropriate educational material" (p. 11). That committee further noted that virtually no systematic examination of the effects of information disclosure to the public is available. Thus, no conclusive intelligence is at hand to indicate whether public disclosure can materially influence individuals' decisionmaking about health plans or providers or demonstrably affect quality improvement programs.

No one should underestimate the barriers to the acquisition, storage, analysis, and release of adequate, unbiased, and useful information of this sort. Among the questions for which answers must still be sought:

- How useful are existing data resources for the clinical evaluative sciences?
- How well can the usual data elements of existing or planned databases, including "core data elements," reflect relevant patient outcomes?
- How well in hand are technical and methods issues in data collection and analysis? (These include linking data and databases over time and across institutions and facilitating flexibility and supplementation of databases built around uniform core content.)
- What are the critical "human: interface" issues in data collection, particularly as they involve clinicians?
- What are key political and practical issues, as well as barriers to and incentives for change?

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[5] For a review of computer-based medical records, see Institute of Medicine. *The Computer-based Patient Record. An Essential Technology for Health Care.* R.S. Dick and E.B. Steen, editors. Washington, DC: National Academy Press, 1991.

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[7] For prescient commentary about quality and competition, see R.H. Brook and J.B. Kosecoff. "Competition and Quality." *Health Affairs* 7:150–161, Summer 1988.

- Will health care reform be an opportunity for significant advances in developing databases, in solving privacy, confidentiality and security problems, and in addressing legal, financial, and governance issues?
- Can "continuous quality improvement" be applied to health care database development, especially with respect to ensuring reliability, accuracy, and validity of data and to devising standard definitions and usages for major data elements (including coding)?
- What research is needed into measures and instruments, survey approaches, and the appropriateness and effectiveness of technologies and procedures, and can sufficient public and private resources be marshalled to support that research?

In short, significant investment and research in the national information infrastructure are imperative. Great care must be taken not to expect—or promise—too much, too early, from information dissemination about quality of care to the public at large, even though preliminary steps to make information available will be important in encouraging patients and families, payers and purchasers, and consumers broadly defined to take responsibility for decisions about their health and health care.

Another important factor involves the new kinds of managed, structured plans that may emerge in coming years (with or without health care reform). A distinction between traditional fee-for-service plans and integrated plans may be telling, because the latter are (presumed) to manage the entire health care process and the former are not. The data needs and likely sources of information to evaluate quality, well as the potential measures, may well differ. Furthermore, so-called point-of-service options cut across these extremes, posing the need to be able to track what may be considerable out-of-plan use of certain types or for selected family members. It will be imperative that our consumer protection and quality improvement programs be able to deal in a fair and unbiased way with all these models of health care delivery.[8]

Indeed, a significant goal of quality improvement and management as health care reform proceeds is to create a seamless mechanism for monitoring performance and tracking outcomes over time and through all settings of care. These are major challenges for data systems now, and the difficulties become greater when and if we contemplate relying on report cards as part of our health care decisionmaking.

CONCLUDING STATEMENT

Finally, let us remember that health care is about *people*. Market- or consumer-oriented models of health care delivery may serve informed customers well, but it is unclear how such models will serve children, the chronically mentally ill, the fragile elderly, minority or non-English-speaking groups, and other populations that are not looked upon as easy or attractive markets to serve. Innovative programs of quality improvement may be predicated on, and often succeed for, the insured middle class for whom those market-oriented models are designed, but those programs may offer little to underserved or at-risk populations or the providers who care for them.

Therefore, I would emphasize the following point: To protect quality of care for all people, and to promote the objective of universal access to care, both external quality monitoring programs and internal quality improvement efforts will be required. Health care reform offers an unparalleled opportunity to achieve equity in coverage and, at the same time, to set in place institutions that will improve the quality of care through enhanced public accountability and oversight and through enhanced technologies for assessing and changing health care practice for the better. On behalf of the Institute of Medicine, I look forward to working with you, Mr. Chairman, and other members of the Senate on these important matters.

PREPARED STATEMENT OF BEV MCCONNELL

Good Morning. I would like to thank Senator Riegle, as Chairman of the Subcommittee on Health for Families and the Uninsured along with the other members of the subcommittee and the Finance Committee for the opportunity to talk with you today about the difficulties that families face in obtaining health services. My remarks will focus particularly on families who have children with special health care needs, the essential components they require in health care systems, and why they must not be forgotten in designing new approaches to health care delivery.

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[8] See A.L. Siu, E.A McGlynn, H. Morgenstern, and R.H. Brook. "A Fair Approach to Comparing Quality of Care." *Health Affairs* 10:62–75, Spring 1991.

My name is Bev McConnell. I live in Trenton, Michigan, with my husband Ray and three rambunctious teenagers: Neal, Meredith, and Emily. Our house is full of loud music and equipment galore. The phone rings constantly and young people are coming and going all of the time. While our household at first glance may appear to be a typical American scene, a closer look would reveal that the equipment crowding our house is a mixture of football pads, baseball bats, ice skates, wheelchairs, and monitors. The music includes Disney, Rap and Heavy Metal. The phone calls are about the latest Jr. High School gossip and the latest changes in our home nursing schedule. The people coming and going are cheerleaders, nurses, football players, and therapists.

My middle child, Meredith, has numerous special health needs. At birth, she was diagnosed with a cleft palate and Pierre Robin syndrome. She was diagnosed at age one month with Hydrocephalus and Dandy-Walker syndrome. She also has seizures, apnea, brain stem instability, and a cranial nerve defect. Meredith was admitted to Children's Hospital of Michigan when she was four weeks old for brain surgery. This was obviously very difficult and frightening for us, I needed to know more about my daughter's condition. Although I probably asked every doctor or nurse who entered my daughter's room, no one gave me a clear explanation of what hydrocephalus was. Finally after a few days, Dr. Michael Nigro, a pediatric neurologist came in to examine Meredith. Again I asked, or by this time demanded that he explain this diagnosis to me. He looked at my frustration, smiled, and sat down to draw a diagram of Meredith's anatomy. Although he too, was very busy, he recognized my very legitimate need for comprehensive information about my daughter's condition, and took the time to explain it to me in as much detail as I needed. Dr. Nigro was willing to answer my questions without judging them, and encouraged me to ask more if I needed to.

My daughter's hospitalization lasted nearly two months. Once it became clear to us that Meredith's health problems were chronic in nature and would not be completely resolved, we asked to learn the complicated procedures she needed so that we could take her home. It was appalling to learn that some hospital staff thought she should stay there and essentially spend what was expected to be a very short life in a hospital setting.

I will never forget the young resident who I overheard describing my daughter's situation. In his all-knowing voice he pronounced that "My concern is this. When, not if, this child dies, the parents will feel terrible if it happens at home." I was compelled to point out to him that we were not likely to feel good about our daughter's death regardless of where it occurred. The point here is that this young, and probably well meaning physician put his value system which said that a child's death should not occur at home, and placed it above our value system which said that her life should occur at home.

We were shocked to learn that the bill for that initial hospitalization exceeded the amount of our mortgage balance. We were relieved to learn that the insurance we had through my husband's employer would pay the bill. Over the course of the next year, Meredith required five more surgeries which were very lengthy and equally expensive.

When my husband was laid off from his job the following year, we lost our insurance coverage. Although we had no income, and three young children, we had to buy an individual health insurance policy that was very, very expensive. We were only able to do this because our parents were able and willing to help us pay the premiums. While Blue Cross/Blue Shield of Michigan was required to sell us an insurance policy, they were not required to make it affordable.

When Meredith was 14 months old, my daughter Emily was born. I required 7 days in the hospital due to a Cesarian birth. Obviously, I was not able to continue to provide Meredith's special care at home for that week. Yet, our insurance would not pay for nursing care at home for Meredith. We were forced to turn to a public state/federal program for Children With Special Health Needs to receive enough nursing support to get us through the first month of Emily's life.

Over the years, our family has been able to maintain coverage in a fee for service plan. While this should theoretically give us all of the flexibility necessary to meet our family's needs, the complexity of my daughter's overall health makes it difficult to obtain appropriate care.

For example, a few years ago, Meredith became ill over the weekend. The pediatrician's office was closed so we took her to a local hospital urgent care center. Because of Meredith's disabilities, the local hospital would not even fully examine her and sent us to the emergency room at the pediatric hospital in Detroit. When we arrived, we were told that we would have a three hour wait. Shortly after, I noticed that Meredith was beginning to exhibit some seizure activity. I went back to the receptionist, explained Meredith's medical history which included seizures, ex-

plained that she was running a fever, and asked if we might be seen sooner. Nope, a three hour wait was a three hour wait. We were sitting in one of the finest hospitals in the nation and we could not get past a receptionist though our child's health was declining before our very eyes. Given the way Meredith's condition was progressing, we decided to take a chance, drive 40 miles to Ann Arbor and get her into care at a competing children's hospital where she was seen immediately, diagnosed with a middle ear infection, treated, and released.

A middle ear infection should not require visits to two pediatric tertiary hospitals. This is an example of how, for children with special health needs, even the most routine primary care becomes specialty care.

Another area of concern for children with special needs is coordination of care. When Meredith was hospitalized two years ago, she required three relatively minor procedures, all of which needed to be done under anesthesia. The gastrointestinal specialists needed to scope her esophagus, the dental specialists needed to examine her impacted teeth, and the surgeons needed to place a central IV line into a main artery. Because Meredith has had difficulty recovering from anesthesia in the past, it was important to us to coordinate these procedures so that her exposure to anesthesia would be limited. However, we had to force the coordination. It took us three days, contacts with every administrator we knew at the hospital, and the assistance of a caring pediatric resident who realized the importance of minimizing Meredith's exposure to anesthesia.

We finally accomplished this and all went well. There were two essential elements at play here. First, the coordination of services and, next, the important information that we had as experts on Meredith McConnell. Families have a tremendous amount of expertise that must be worked in to the equation at every level of health care, beginning at the level of individual care.

Our challenges with the health care system are even more upsetting when I compare what's available to Meredith and what's available to her brother and sister. For example, late last fall, my 17 year old son Neal injured his knee in the last game of a very exciting football season. The injury required surgery and extensive Physical Therapy. Neal's therapy is completely covered by our insurance company.

In contrast, when my husband took Meredith for Physical Therapy following her injury last year, we received a statement from the insurance company telling us that Physical Therapy could not be covered because of her pre-existing condition. That places us in the impossible position of having two children with the same need in a system which will meet my son's needs but not my daughter's.

The "line in the sand" between Habilitative and Rehabilitative services provides comprehensive services to children who started out perfect. If we can get them back to being A-OK, that's considered a worthwhile investment. But for Meredith, and thousands of other children like her the message is loud and clear. "If you can't be perfect, you're not worth our investment." As their mother, this is completely unacceptable.

I wish that I could tell you that these are isolated problems and that my family has had a long string of incredibly bad luck but I can't. The truth is that my family has had it pretty easy compared to many others.

I am employed by the Michigan Department of Public Health as the Director of the Children's Special Health Care Services Parent Participation Program. In this capacity, I serve as a Parent Consultant to the program drawing on my personal experience as the parent of a child with extensive special health needs and organizing input from other families across Michigan. Over the past six years, the program has been very innovative in developing successful strategies for engaging in genuine partnerships with families that define and direct the course of service delivery.

Every day I talk to families who tell me how barriers in health care delivery systems impact their lives.

Like a family in Kalamazoo. Both parents hold masters degrees and are very gifted in their fields yet they are not considered employable because their son's extensive medical needs already have maxed out the lifetime million dollar cap on two policies.

A father from Flint called last week. His six-month-old son is in the hospital with a tracheostomy, a central venous line for nutrition, a gastrostomy, and is dependant on a ventilator to sustain his life. His insurance company refused to pay for in-home nursing, which the family wants and would cost less than hospitalization. And when the family asked to convert coverage for hospital days into home care, the request was denied and the father was told that the company would no longer pay for hospitalization either because the insurance company's medical experts felt that his son's condition did not require hospital care.

We've heard from a single mother in Ann Arbor who was completing her degree in order to get a good job to support her daughter when her 4 year old's asthma

intensified. Her doctor told her that she should buy an individual Blue Cross policy because if her daughter needed to be hospitalized, the bill for one day could exceed $10,000. Based on his advice, she bought a policy. But the reality is that the policy did not cover the bulk of this child's needs which included prescription drugs, office calls, and other out patient care. In the end, the child's mother exhausted her life savings by paying $700 per month for a policy that did not meet her needs, and still had to pay out of pocket for expensive prescriptions and office calls.

Some suggest that there is no real health care crisis in America. The reality is that every day families in my state, and across the nation, are faced with barrier after barrier in their quest to care for their children. The future looks very uncertain without Universal coverage. Parents are denied the opportunity to explore new careers or move forward in their current careers due to the frustration of job-lock. Families are faced with unclear or obscure definitions of covered services. For children who require highly specialized, technical care, the definitions of appropriate providers and medically necessary care become life and death issues. There is no clearly defined source within systems of care to help translate or coordinate service coverages. There are no formalized roles or provisions for families as direct consumers of health services to participate in the ongoing development, implementation and evaluation of services at various levels of service delivery.

This is a very real crisis for families of children with special health care needs.

I believe that this nation has an obligation to care for children first. Families will help do this when they are given the tools they need to do the job. These tools are access, choice, coordination, collaboration, and accountability:

ACCESS:

To appropriate, affordable care.

To complete and unbiased information about their child's needs.

To the necessary resources to meet those needs including transportation respite and child care.

To a responsive mechanism for problem resolution, and trouble-shooting.

CHOICE:

Between a set of reasonable options that are consistent with the families values and are affordable.

COORDINATION:

Between different specialists, programs, and facilities.

COLLABORATION:

Between professionals and family members at every level of our health care system including National Health Boards, HMO's, Hospitals, Alliance Administrations, etc.

ACCOUNTABILITY:

Which includes clearly defined mechanisms for problem resolution with specific timeframes, and appropriate consequences.

Our family can take most things pretty much in stride when we are protected from needless vulnerability, when we have some clear direction in problem solving, when we know the parameters of the game. With those things in place, I think our household *can* typify the standard American scene. We are people who care about one another and who are willing to work a little harder so that all of us can lead optimal lives, live freely, and pursue happiness.

Thank you once again for the opportunity to speak with you today.

PREPARED STATEMENT OF MARGARET O'KANE

Good morning. My name is Margaret O'Kane and I am the President of the National Committee for Quality Assurance (NCQA) We are pleased to have the opportunity to testify today before the Subcommittee on the important topic of consumer protection and quality assurance under health care reform.

NCQA promotes improvements in the quality of patient care provided by managed health care plans through the development and application of detailed standards for continuous quality improvement *and* measures of performance for health plans. NCQA is committed to providing information on quality to consumers, purchasers, health plans, federal and state governments. Governed by a Board of Directors of

purchasers, managed-care executives, union and consumer representatives, and independent quality experts, NCQA represents a unique partnership to implement effective mechanisms to monitor and improve the quality of care and services.

To monitor and improve quality under health care reform, NCQA proposes a public accountability system using three complementary efforts.

1. National entry level standards for all health plans
2. Health plan accreditation to assure quality care and service
3. Public reporting of performance measures to empower consumers

The goals of such an accountability system should include:

- Consumer protection and access to care
- Continuous improvement in quality
- Consumer access to information on quality

Such a system is consistent with the Physician Payment Review Commission's 1994 Report to Congress. In addition, the three major reform proposals now before the Senate all embody a number of the principles NCQA believes are necessary for a strong quality component in a health care reform environment. All three proposals make an important and crucial change by moving away from the punitive approach and towards a systematic, performance-based system for measuring and encouraging improvement in quality.

National entry standards should determine which health plans are allowed to conduct business in a reformed health care system, and should apply to all health plans no matter what the payment arrangement. Accreditation assesses how well a licensed health plan has established management structures and processes to monitor and continuously improve the quality of patient care and member service, and verifies that those structures and processes are functioning properly. Public reporting of performance measures or "report cards" will give consumers and purchasers more information on specific aspects of health plan performance in order to make informed choices about health plans. This information will also give policymakers the means to gauge progress towards public health priorities. Implementation of performance measures should be continuous, with measures added as medical research supports their validity, and as health plans develop the information systems needed to produce the data. NCQA is now pilot testing the report card concept with 21 of the nation's largest health plans using a core set of the Health Plan Employer Data and Information Set (HEDIS 2.0) measures. The pilot project will conclude at the end of this year with the first independently audited national report card released to the public.

NCQA believes the combination of national entry standards, health plan accreditation and publicly reported performance measures is critical to ensuring the delivery of quality care and service. Let me discuss these points in more detail and describe NCQA's involvement in these areas.

CONSUMER NEEDS

NCQA is committed to empowering consumers and purchasers with information on quality and cost to make informed choices among health plans. This commitment is best illustrated by HEDIS 2.0—a report card developed by NCQA in conjunction with purchasers and health plans—and the Consumer Information Project. While significant progress has been made in producing detailed information for purchasers, such as HEDIS 2.0, much more work remains to be done in exploring the information needs of consumers. Very little is known about the types of quality information that will be compelling to consumers or the best manner in which to present such information. With support from the Commonwealth Fund, NCQA launched the Consumer Information Project earlier this year. The planning stage of the project is nearing completion, and shortly we will begin convening a series of focus groups. In addition to the focus groups, a national survey will be conducted to validate findings and determine precise consumer priorities. This information will better enable NCQA to produce meaningful information on health plan quality to aid consumers in their selection of health plan. We will pay particular attention to those groups, such as the elderly and chronically ill, for whom the choice of a health plan assumes even greater importance.

In addition to the Consumer Information Project, NCQA has joined in a collaborative effort with HCFA and the State Medicaid Directors Association on the Medicaid Managed Care Performance Measurement Project. Funding for the project has been provided by the David and Lucile Packard Foundation. The goals of the 16 month project, which will focus predominantly on maternal and child health care, are to determine:

- What data should State Medicaid agencies obtain from managed care contractors to monitor the performance of the managed health care plans serving the Medicaid population?
- How should the performance measures be defined so as to attain reliable and comparable data from diverse manage care providers?
- How can the needs of State Medicaid agencies be coordinated with other purchasers?

NCQA is also conducting focused quality reviews of Medicaid managed care providers in the state of Massachusetts, with a focus on special needs populations.

REQUIREMENTS FOR ALL HEALTH PLAN STRUCTURES

NCQA strongly believes that all health plans, regardless of their financing and delivery structure, should be accountable with minimum quality elements in place to monitor all services and medical delivery. At a minimum, less structured delivery systems such as indemnity plans should be required to: credential their providers; monitor both insurance and health delivery complaints and grievances; implement standards for utilization management; and provide data about member satisfaction and clinical performance. All health plans must be required to provide data on quality performance, or those more structured plans which have invested in information systems could be placed at a disadvantage in the marketplace.

NCQA recommends establishing national "entry" standards for all health plans, both indemnity and managed, and increasing these requirements annually until the more demanding "accreditation" standards can be applied to all plans. In addition to basic "entry" standards, NCQA recommends a national set of quality reporting requirements to be used by all health plans. These requirements must be phased in gradually to allow health plans to develop the necessary internal information system capabilities. The implementation of information systems in health plans to collect the data needed to produce performance measures is an ongoing process. While some health plans have invested significant resources in the development of information systems, others may require years to establish such systems.

Policy makers must strike a balance between the desired types of quality measurement and the ability of health plans to meet these requirements. If the requirements are too minimal, quality will be compromised. However, quality requirements that lack practical applicability may undermine a reformed systems's likelihood of success.

NCQA believes that effective quality oversight systems and measures will drive health plan behavior. Therefore, it is essential to carefully consider the incentives in potential monitoring strategies in order to make successful quality performance consonant with public health priorities. Performance requirements should hold health plans responsible for appropriate care to their entire population. Quality requirements should be based on indicators that emerge from the efficient functioning of effective delivery systems.

As previously mentioned, NCQA believes that to monitor and ensure quality under any reformed health care system, there must be a public accountability system using three complementary efforts: national entry level standards, rigorous health plan accreditation, and public reporting of performance measures. We are concerned, however, that some proposals appear silent on the role of accreditation.

Both the accreditation process and performance measures are critical to ensuring the delivery of quality care and service. As the Physician Payment Review Commission wrote, "information from report cards alone may not drive plans that provide inferior quality out of the market; external monitoring and controls may be necessary." Accreditation is vital to ensuring that a given health plan thoroughly investigates its providers, is responsive to member grievances, has a system that ensures appropriateness of care and performs other critical functions.

THE ACCREDITATION PROCESS

Evaluation of the effectiveness of a health plan's internal systems, through external review and accreditation, provides information on the extent to which a health plan has created an environment supportive of high quality patient care, and the ability of the health plan to continuously improve its performance. The process also ensures that basic protective and monitoring systems are in place for the problems which do arise. Such information is crucial as consumers and purchasers make choices among competing health plans.

Another important goal of the accreditation program is the consolidation of multiple review processes which health plans must often undergo. Eliminating the duplication of these repetitive external reviews will free time and resources at the health plan for quality improvement activities. An unfortunate byproduct of health

care reform could be duplicative and burdensome quality requirements at the federal, state and alliance level. NCQA already enjoys a relationship with the states of Pennsylvania, Florida, Kansas, and Oklahoma, and discussions are underway with many others to assure compatibility between state licensure requirements and accreditation. Earlier, I described our work with HCFA and the State Medicaid Director's Association to develop performance measures for Medicaid plans, and the overall importance of compatibility between public and private sector efforts.

NCQA's accreditation review process includes a structured survey of an organization's quality improvement program, credentialing activities, utilization management, preventive health services, medical records, and systems for ensuring member rights. The accreditation process also includes physician review of medical records in order to assess the quality of care being delivered by the health plan. Our standards are not "entry level. " The survey is conducted by a team of highly qualified physicians, all with managed-care experience, and an administrative reviewer. Upon successful completion of the NCQA accreditation program, a managed-care organization receives a three-year accreditation. Alternatively, a plan which receives provisional accreditation is reviewed again within one year. NCQA provides detailed recommendations to provisionally accredited plans to help them move to full accreditation. Approximately 77 percent of the health plans reviewed to date received provisional status, 18 percent have been fully accredited, and five percent were denied. It is not uncommon for health plans to begin preparing for the accreditation process years in advance by making substantive changes in the way the health plan operates to comply with the standards. Changes such as strengthening QI programs and assuring the opportunity for enrollee input, increasing scrutiny of provider credentials, revising member appeal and grievance procedures, ensuring the consistency of utilization management procedures, and instituting the use of practice guidelines for preventive services are only a few examples of the concrete changes occurring as a result of accreditation.

At present, a number of major national employers require NCQA accreditation for all the HMOs they offer, including Allied-Signal, Ameritech, GE, GTE, Pepsico, Procter & Gamble, UPS, and Xerox. Many other employers like General Electric, IBM, Mercantile Stores, and USAir strongly recommend that their health plans become NCQA accredited. At the end of 1993 NCQA had completed accreditation reviews of over 150 managed care organizations nationally, and by the end of 1994 nearly half the HMOs in the country will have been accredited by NCQA.

PERFORMANCE MEASURES

In addition to an accreditation program, a framework for assuring the accountability of health plans should include the public reporting of comparable data on various aspects of performance. Such a system will serve to: (1) provide health plans with "benchmarking" information to identify areas of improvement; and (2) provide consumers, purchasers and regulators with information to assess health plan performance.

It is important to note that the development of such measures is an ongoing process. The performance measures that already exist, such as those for most preventive health services, have high consensus in the medical community and a strong scientific base. However, measures of a range of other procedures and services have not yet achieved the level of validity and consensus which should be attained before being included as national standards for performance. Quality indicators for cardiac care are one example. Implementing comprehensive measures of quality for a broad array of acute and chronic conditions is a goal for the next several years. We expect to see an increased focus on outcomes measures as medical research establishes more linkages between the delivery of care and its outcomes.

Let me describe NCQA activities in this area. In November, NCQA released the final version of HEDIS 2.0, a core set of performance measures that were defined by a combined group of major employers and health plans. This effort began in 1992, when NCQA was asked to coordinate the project.

Specific components within HEDIS 2.0 are:

- Quality—measuring the health plan's performance in the delivery of certain selected services. These include:
    1. Preventive Services
    2. Prenatal Care
    3. Acute and Chronic Disease
    4. Mental Health
- Access and Patient Satisfaction—measuring performance in member access to care and satisfying members;

- Membership and Utilization—measuring performance regarding membership stability and demographics as well as resource allocation within the plan; and
- Finance—measuring performance in achieving financial stability.

As HEDIS 2.0 gains widespread acceptance, it will assist health plans in their quest for a common set of reporting standards that will satisfy the needs of multiple users. Standardized definitions and specific methodologies for deriving performance measures, as outlined in HEDIS 2.0, will enable plans and employers and others to accurately trend health plan performance, and as the measures are refined, use them in a comparative manner.

HEDIS is only the first step toward the development of a system of comparable performance measures on health plan quality. As future improvements in methodologies and underlying data systems are made, plan data will become more reliable, and more measures will be developed for report cards on health plans.

We have also been involved in the Michigan Project, a collaborative effort involving Ford, GM, Chrysler, the United Auto Workers' Union, nine southeastern Michigan HMOs, and NCQA. This project is the first effort to collect standardized, comparable data, use a consumer satisfaction survey and accreditation. The data includes information on mammography, pre-natal care, childhood immunizations and access. The project's goal is to produce comparable performance data on each participating HMO for use by external customers such as the auto companies and the United Auto Workers. The auto companies and the union will use the information to ascertain the quality of care and service delivered by their participating managed- care organizations. The information will be used to establish baseline data and benchmarks for HMO quality improvement, allowing HMOs to demonstrate to their major employer groups their successes in improving the quality of their care and service.

As we have discussed, the whole area of quality measurement is relatively new and certainly dynamic. While NCQA is on the cutting edge in terms of managed care organizations, even our projects with HEDIS 2.0 and the Michigan Project are relatively new. Based on our experience with these projects, which involve a modest numbers of health plans, NCQA supports a well researched implementation strategy with realistic goals and a prudent phase-in schedule. Further, whatever the outcome of health care reform, we strongly suggest that advantage be taken of the work already done.

CONCLUSION

The three major reform proposals now before the Senate all take the important and necessary step of moving to a systematic performance-based system with national standards. However, we are concerned that some of the timetables discussed for implementing such a system may be unrealistic. The first goal of the quality component should be to protect consumers. As mentioned, whatever federal body is ultimately responsible for establishing a quality management program, it should look at work already done such as HEDIS 2.0, the accreditation process, and the Consumer Information Project. There exists the potential for a burdensome quality program with conflicting or duplicative quality requirements, the result of which could be resources diverted unnecessarily from the delivery of services.

We recommend the following:

- A public/private approach that builds on current work
- A quality and accountability system based on national entry standards, accreditation and public reporting of performance measures
- Quality requirements for all health plans—managed care and fee-for-service indemnity plans
- A carefully structured implementation strategy with reasonable short term goals, and a prioritized phase in period for long term goals
- A system that is built around compatibility, and avoids duplication resulting from multiple sets of requirements.
- A medical research system that works to inform what is effective in medical care and how to appropriately measure quality

NCQA is committed to working with Congress and the Administration to assure that the quality component of any reform proposal meets the goals that we all agree on—assuring quality, continuous quality improvement, and accountability.

PREPARED STATEMENT OF JOHN TOOKER

Good morning. My name is Dr. John Tooker. I practice internal medicine in Portland, Maine and I am Chairman of the Board of Governors of the American College of Physicians. The ACP is the nation's largest medical specialty society, with more than 80,000 members who practice internal medicine and its subspecialties.

Mr. Chairman, the ACP would like to express its appreciation to you for holding this hearing. We are troubled that issues such as financing, budgets, and mandates have received extensive discussion and media coverage, while the issue of how to make sure our patients receive the highest quality of care has been virtually ignored.

The ACP supports comprehensive reform because we believe that our nation's health system does not work—for physicians or their patients. One of the principal failings of our current health system is that physicians and their patients have increasingly lost control over treatment decisions. Outside influences—particularly insurers—have become increasingly strong, creating a system that often ignores a physician's recommendations and the patient's needs.

Let me give you a real-life example of how this works. A 15-year old girl in rural Maine was diagnosed with depression and a behavioral disorder that included self-abuse—she struck herself in the mouth with a hammer. Her internist attempted to obtain expert help for her. He spoke with a pediatrician specializing in caring for children in crisis, who was willing to see the patient on short notice. The family's insurer, who had no understanding of the girl's particular problem and her need for immediate help, balked at the patient seeing anyone other than a psychiatrist—even though no psychiatrist practiced nearby who could see the child right away. The internist was concerned about his patient's safety, and spent an entire afternoon on the phone, making over a dozen phone calls to the insurer to obtain authorization for a visit to the pediatrician. He finally received authorization by asking the insurance company representative "What do you want to do, let her kill herself before you'll authorize this treatment?"

Mr. Chairman, in order to ensure that all Americans receive the highest quality of care, it is critical to keep treatment decisions in the hands of patients and their physicians. Unfortunately, in today's health care system, insurance companies have acquired enormous power. Through their rules and procedures, they often make decisions about a patient's medical treatment. What is particularly appalling is that the so-called "utilization review" criteria by which these decisions are made are often kept secret from doctors and patients, vary by company or payer, are not scientifically based, and often focus exclusively on cost and ignore issues of quality.

In addition to the faulty criteria used, another problem with these reviews is that they are performed on a case-by-case basis. They focus on an individual patient cared for by a particular physician. This intrudes on the doctor-patient relationship, wastes time and money since the physician may be forced to justify his or her decisions, and most importantly, can hurt the quality care provided to the patient.

Since these practices are becoming more and more common, the ACP believes it is critical that health reform legislation address this problem. We agree with the President and the First Lady who have stated that in a newly reformed health system, clinical responsibility should be restored to practitioners and that the current system of "checkers checking checkers" should be eliminated.

The ACP will insist that any final version of health reform legislation contain provisions to ensure that all Americans receive the highest quality care, and that patients and their physicians make decisions about medical treatment—not insurance companies.

In addition, it is important to remember that while we need to eliminate these practices in the private sector, the government also engages in micromanagement of patient care. We cannot substitute excessive government regulation for private sector abuses.

Mr. Chairman, we need a new approach. We need to adopt health reform legislation that ends case-by-case reviews, and instead establishes a quality assurance system that uses data from practice profiles—of processes and outcomes—to measure quality. Moreover, health reform legislation should promote development of a system of ongoing quality improvement, that integrates considerations of both quality and cost.

Quality in medical care derives primarily from professional and institutional imperatives to achieve excellence. Such excellence comes from within individuals and organizations; it cannot be imposed by an external authority. The challenge in health reform is to develop a quality assurance system that creates an environment that fosters collaboration among physicians, hospitals, and health plans to improve

quality, while simultaneously provides for reasonable external review, and when needed, disciplinary proceedings to protect consumers.

The ACP recognizes a role for external oversight and regulation. Licensure, certification, periodic inspections and examinations are important societal mechanisms to assure the public that professionals and institutions have achieved and continue to maintain an adequate level of competence. In addition, the PROs have authority to sanction physicians for care judged inadequate in quality.

While incompetence or malfeasance should be addressed by formal mechanisms which are apart from medical practice such as licensing and PRO reviews, as well as mechanisms that are a part of medical practice such as credentialing by hospitals, they have little positive effect on the striving for excellence or on continuous quality improvement. Further, an environment choked with threats of discipline and severe sanction will erode the impulse to strive for excellence. Consequently, disciplinary and regulatory activities must be kept separate from the quality improvement environment.

Our recommendations for a new quality assurance system are:

- All health plans should have a quality improvement program and participate in the national effort to develop measures of quality. The legislation should explicitly recognize that the principal responsibility for quality rests on health professionals and institutions.
- There should be no individual case review performed on a routine basis. The task of external oversight should be the profiling of care at the local, state and national levels. The organization which carries out this function should not have any disciplinary or regulatory authority. This will allow practitioners to work in conjunction with individuals who are doing the profiling. Practitioners should come to view these persons as colleagues and not as police.
- Because utilization of services, quality, and cost are interrelated, profiling these different but complementary aspects of care should be the responsibility of one entity. Separation of responsibility can lead to an undue focus on cost with potential compromise in quality. It can also leave considerations of quality unrestrained by the reality of finite resources.
- The profiling function could be located within a new entity or it could be housed at an existing institution and overseen by a representative council made up of practitioner and patient or consumer interests.
- When the profiling indicates a possible lapse in quality, the entity should work with the relevant health plan to investigate the cause of the data variation, and improve the quality performance of the plan.
- When a profile of an individual, an institution, or a community suggests a potential serious problem with quality, that information should be forwarded to appropriate credentialing or licensing authorities. Findings from review of worrisome profiles must be made public in a timely manner by the authority charged with the review.
- In so far as is practical, profiling should be based on reviews from outcomes as well as well-developed practice guidelines.
- The licensing of health professionals, hospitals, and health plans should remain the responsibility of state government. The credentialing function should be the responsibility of hospitals and health plans.
- Increased research and development is needed on practice guidelines, profiling, and health plan report cards. The latter would include health plan performance measures and consumer satisfaction surveys. We must ensure that information provided on report cards is clinically relevant and appropriate. The impact of report cards on consumer choice of health plan also requires careful study.

These principles should form the basis of a new quality assurance system. I want to make clear however, that it may be several years before the new quality system is in place. Therefore, it is critical that we provide relief for practitioners and their patients from case-by-case utilization review activities that are occurring now, and may occur during the transition period.

We urge you to adopt a requirement that utilization review criteria be disclosed to physicians and patients, that the criteria be based on reasonable, timely medical evidence, and that they be consistently applied. In addition, physicians should supervise the review decisions, including determinations of the medical appropriateness of any denial, as well as an appeals process. Finally, mechanisms should be established to evaluate the effects of the utilization review program—including provider and patient satisfaction data. We would like to work with you to more fully develop recommendations in this area.

CONCLUSION

Mr. Chairman, we need to create a health system that empowers physicians and their patients. We need to make sure that quality of care is maintained, and micromanagement from external entities—private and public—is eliminated. We look forward to working with you to develop legislative solutions to this problem in the upcoming weeks.

Thank you for the opportunity to testify on this issue of critical importance.

COMMUNICATIONS

STATEMENT OF ACCREDITATION ASSOCIATION FOR AMBULATORY HEALTH CARE (AAAHC)

I. ABOUT AAAHC

The Accreditation Association for Ambulatory Health Care ("AAAHC") is the primary accreditation organization dedicated to the accreditation of ambulatory care facilities. AAAHC maintains published standards of ambulatory health care, conducts on-site surveys using volunteer peer-based reviewers to serve as fact-finders with respect to the standards, and confers accreditation on ambulatory care organizations that are in substantial compliance with those standards. AAAHC's governing body includes representatives of 13 national ambulatory health care associations which have come together as a consortium to sponsor this voluntary accreditation activity.

AAAHC accredits a wide range of ambulatory care facilities including, for example, health maintenance organizations ("HMOs") and other prepaid or managed care systems; ambulatory surgery centers ("ASCs"); office-based surgery practices; medical group practices and clinics; college and university health services; community health centers; dental group practices; and post-surgical recovery centers. Currently, there are approximately 425 organizations that are accredited by AAAHC in 48 states and the District of Columbia.

The Administration's health care reform proposal is expected to increase managed care. AAAHC's managed care review experience, which goes back 13 years, has included work in reviewing all three types of HMO models, including staff models, group models and IPA models. More specifically, AAAHC has conducted HMO surveys on behalf of the Arizona Health Care Cost Containment System ("AHCCCS"), and the Hawaii Medicaid program. AAAHC was also selected to survey and accredit all of CIGNA's staff and medical group/IPA model health plans in the United States, and is designated as an approved external HMO review entity in the states of Pennsylvania, Oklahoma, Kansas, and Florida. Moreover, organizations accredited by AAAHC serve more than 100 different HMOs throughout the country, providing services to over 2,000,000 enrollees through more than 6,000 physicians. As a result of this past and ongoing HMO review experience, AAAHC has a working understanding of the quality-of-care issues involved in developing and operating managed care plans.

Because of the quality of AAAHC's standards and the thoroughness of its surveys, AAAHC has been recognized and accepted by all types of third party payors (Blue Cross and Blue Shield plans, commercial carriers, HMOs, CHAMPUS, and other governmental agencies) as meeting their conditions of participation and reimbursement programs. In addition, a number of professional liability carriers extend premium discounts to surgical facilities and medical group practices accredited by AAAHC. Thus, since its founding, AAAHC's accreditation program has gained acceptance and recognition from the health care community, government, and the general public.

II. BACKGROUND: QUALITY OF CARE-RELATED PROVISIONS OF THE ADMINISTRATION'S HEALTH CARE REFORM PROPOSAL

In light of its dedication to promoting high quality care, AAAHC is extremely interested in those provisions of any health care reform legislation that pertain to quality of care. While AAAHC recognizes that the Administration's health care plan is by no means the only major one under consideration, AAAHC believes that it is likely that the Administration's proposal will serve as the primary "starting point" for the debate. Moreover, a number of the quality of care-related provisions of the Administration's proposal are also reflected in H.R. 3222 (the "Cooper bill") and S.

1770 (the "Chafee bill"), the two major alternative health care reform proposals under consideration by Congress. For these reasons, this testimony focuses primarily on the Administration's plan.

The Administration's health care reform plan includes a number of provisions relating to the quality of care. First, each health plan would be required to, among other things: verify the credentials of practitioners and facilities; ensure that all providers participating in the plan meet applicable State licensing and certification standards; oversee the quality and performance of participating providers, consistent with certain specified quality assurance requirements; and investigate and resolve consumer complaints against participating providers. (S. 1757, §1411).

Second, not later than one year after the date of the enactment of health care reform legislation, a new National Health Board would be required to establish and oversee a "performance-based program" of quality management and improvements designed to enhance the quality, appropriateness, and effectiveness of health care services (the "National Quality Management Program"). This program would be administered by the "National Quality Management Council," which would be required to develop a set of "national measures of quality performance," to be used to assess the provision of health care services and access by plans and by significant contract providers within the plan. (S. 1757, §5001 *et seq.*) National measures of quality performance would provide information on access to, appropriateness of, and outcomes of health care services and procedures, as well as health promotion, disease prevention, and consumer satisfaction. The Administration's plan includes detailed criteria to be used in developing and selecting national measures of quality performance; however, these criteria make no reference to accreditation, nor are accreditation agencies included among those to be consulted in developing and selecting national measures of quality performance.

Third, each health plan would be required to, among other things, measure and disclose performance with respect to quality measures used by the National Quality Management Council, regional and corporate alliances, and participating states. In addition, each health plan would be required to "provide such other reports and information on the quality of care delivered by health care providers who are members of a provider network as may be required" and maintain "quality management systems" that, among other things, measure the quality of care furnished by providers that are members of the plan's network. S. 1757, §5013.

Fourth, each health alliance would be required to annually publish and make available to the public a performance report outlining in a standard format the performance of each health plan with respect to the criteria developed by the Council.

Fifth, not later than three years after the enactment of health care reform legislation, the National Health Board would be required to develop "demonstration standards for the licensing of health care institutions" that address "essential performance requirements related to patient care." The standards would be applicable to health care providers (as opposed to health plans). The standards would be required to be developed in a manner that permits them to be applied uniformly to all health care institutions, except in the areas of fire safety, sanitation, and patient rights. (Thus, the standards may be developed in a manner that does not appropriately recognize differences between hospital and freestanding settings, or differences among different types of freestanding providers.) By January 1, 1996, the National Quality Management Council would be required to complete demonstration projects for the newly developed licensing standards, to evaluate the impact of the standards in ensuring quality of care, reducing costs, and reducing burdens on health care providers. Any standard developed by the Council would preempt state licensure standards. The National Quality Management Council would:

> *Undertake research efforts designed to develop a system for carrying out through grant or contract a single, consolidated annual audit and inspection of each health care institution and health care provider for the combined purposes of federal, state, local, and private licensure, accreditation, and certification.*

S. 1757, §5011(d) (Emphasis added).

III. IMPLICATIONS OF THE ADMINISTRATION'S HEALTH CARE REFORM PROPOSAL FOR AAAHC

A number of these provisions, if enacted, could have an extremely significant impact on AAAHC and its members. First, under the Administration's proposal, the quality standards that health plans will be required to meet will be specified primarily by the National Quality Management Council and by the regional alliances. It can be anticipated that federal standards will likely be established regarding each

health plan's administration and management, its operating experience, its range and quality of services, its financial health, and its compliance with discrimination and "redlining" rules. *While nothing in the proposal would restrict the ability of a state to require private accreditation of health plans, the Administration's current proposal includes no specified role for accreditation agencies in the certification process for health plans, nor does the Administration's plan implicitly or explicitly authorize alliances to delegate some or all of the responsibility for certifying health plans to private accreditation agencies.*

Second, it is unclear whether, and to what extent, particular providers would continue to have an incentive to become accredited if the Administration's proposal is enacted. While the Administration's plan does require health plans to measure the quality of care provided by health care providers that are members of the plan's provider network, it is unclear whether health plans will consider whether or not a particular provider is accredited in evaluating quality. In the absence of legislation requiring health plans to consider accreditation as a factor in the quality evaluation process, health plans may focus primarily on the costs of care provided and on "report card" criteria that are unrelated to accreditation standards.

Third, the Administration's proposal calls for the establishment of uniform national licensing standards for health care providers. While this provision of the Administration's plan would likely take some considerable time to implement, such national licensing standards could effectively displace private accreditation standards for health care providers, once the standards are developed and implemented. Moreover, the Administration plan, as currently drafted, could be read to require the development of standards that do not recognize the differences between freestanding and hospital facilities or the differences among different types of freestanding providers.

In short, the Administration's health care plan, as proposed, does not provide any substantial role for private accreditation organizations in ensuring the quality of care provided by health care institutions in the future. Rather, "quality" would be assured through the adoption of national practice guidelines, the dissemination of information concerning health plans' compliance with certain quality measures established by the National Quality Management Council, the adoption of uniform licensing and certification standards for health care providers, the expansion of health care outcomes research, and other means. While health plans would be required to establish quality management systems that measure the quality of health care furnished by participating providers, the Administration's plan neither implicitly nor explicitly requires health plans to consider accreditation in the process of evaluating participating providers.

IV. AAAHC'S POSITION WITH REGARD TO HEALTH CARE REFORM

AAAHC firmly believes that any health care reform plan that is enacted by Congress should be structured to ensure that quality is not sacrificed in the effort to contain health care costs. As the primary accreditation organization for ambulatory care facilities in the United States, AAAHC believes that private accreditation of health care facilities can serve an important role in ensuring quality. More specifically, AAAHC believes that minimum federal and state standards should be established for health plans and that AAAHC and other private accreditation organizations should be authorized to play a role in reviewing health plan compliance with such standards. AAAHC also believes that the health care reform legislation should include appropriate incentives for health plans to use accredited providers by, at a minimum, requiring health plans to disseminate information concerning which of its providers are accredited. Finally, AAAHC believes that private accreditation organizations should be formally included in at least an advisory capacity on the council, commission or other body dedicated to the formulation of quality standards.

AAAHC would be delighted to work with the Subcommittee to further define the role that private accreditation organizations can play in assuring quality under the new system. If you have any questions concerning AAAHC's position with respect to these issues, please do not hesitate to call AAAHC's Executive Director, Christopher Damon, at (708) 676–9610 or AAAHC's Washington counsel, Diane S. Millman, at (202) 778–8021.

STATEMENT OF ASSOCIATION FOR PROFESSIONALS IN INFECTION CONTROL AND EPIDEMIOLOGY, INC.

THE ISSUE

Health care reform is focused on providing *quality* health care to all Americans. APIC's concern is the lack of scientifically validated and widely accepted mechanisms for defining *quality* in health care.

BACKGROUND

In a study recently published through the Kellogg Graduate School of Management, 69% of 3,303 hospitals surveyed stated that they have launched sophisticated quality improvement programs, most in the last two years. Concurrently, the private sector has spearheaded a variety of projects designed to provide the consumer with a "report card" on the quality of their health care system. In addition, several states, such as New York, Pennsylvania, and Maryland, have established a system requiring providers to furnish selected indicators of the quality of their care. Reform plans, for instance the Health Security Act, would replace the existing quality system controlled chiefly by the Medicare Peer Review Organizations, with a massive new program aiming at continual quality improvement.

A number of legislative initiatives are being entertained to reform the way health care is provided in an effort to guarantee all Americans access to affordable basic health care. In the main, these health care reforms focus on three goals: security, choice and savings offered through a variety of standardized health care benefits packages, including managed care and individual or employer-based health insurance alliances. Achievement of these goals, most notably cost savings, depends on a favorable risk mix in the populations served to include pre-existing conditions, age and other factors affecting use of health care services. Such risk adjustment is an immature science when applied to health care and not yet armed with scientifically proven methodologies. Adequate risk adjustment is central to the success of the Health Security Act and a component of most other reform plans. Health plans are paid the same amount per person and therefore have a financial incentive not to enroll individuals expected to exceed the baseline costs. Conversely, health plans have an incentive to compete in wasteful ways, to attract the "good risk" persons not expected to consume. The literature on risk adjustment tells us that currently 1 % of the population accounts for 25% of health care costs; 5% of persons account for 50%. In addition, a Commonwealth Fund (New York City) study of health care expenses by older workers showed that costs to employers of working men ages 55–64 are 5.5 times as high as for working men 18-24. For working women, the spending levels were highest in childbearing years, then tapered off in the 55-64 age bracket. Attempts to define a workable risk adjustment formula to this point have not been successful. The real risk is to shift the high cost consumer out of plan coverage. At risk in this scenario are the populations universal coverage is designed to protect, namely the elderly, the medically underserved, the chronically ill, and the major consumers of healthcare services.

All of the reform plans in some manner depend on existing statistics to project future impact and savings. Many economists including Duncan and Gross (*Statistics for the 21st Century: Proposals for Improving Statistics for Better Decision Making,* 1993) suggest that baseline data does not exist for 25% or better of the proposed policy objectives. Congressional Budget Office Director, Robert Reischauer, has cautioned that there is great uncertainty about the cost estimates surrounding such a large systemic reform initiative due to changes in behavior of providers and consumers, altered incentives becoming available, and especially the time necessary for such consequences to be fully played out. Such experts caution us that making a directional link between cost and outcomes is the largest and most complex task in health care statistics. What is needed are better systems for classifying and coding information on a large number of variables, including sites and settings of care; data on the types of care, with specific information on procedures, drugs, diagnostic tests, and other technologies; and better cost data. These deficits must be addressed immediately in order to evaluate the effect of any reform plan.

In anticipation of reform, health care providers have been attempting to address increasing demands from regulatory agencies, insurance providers, and consumers for assessment and accountability as well as evidence of quality in day to day medical practices. This has been described as a national preoccupation with measurement of clinical performance. The relationship between quality health care and cost is a delicate one best measured with epidemiologic methods. Cost reductions will most certainly effect care quality and will need to be measured with precision to assess clinical importance. These measurements, using quality indicators, will be

made locally and data developed for internal and external comparison. In fact, all of the reform proposals call for national data collection efforts including outcomes and most call for measurement of performance against standards. To be useful and at the very least not detrimental, such data must be collected using careful, scientifically sound epidemiologic methods (e. g. randomized clinical trials or case control studies) and analyzed within the constraints of its appropriate context. In the current reform proposals, there is significant concern that quality improvement initiatives fail to specify any role for private accreditation or independent voluntary quality review but rather leave these issues up to the states.

Proposals building a standardized benefits package to be offered to America must include assessment of cost and effectiveness. APIC concurs with the Office of Technology Assessment report "Benefit Design in Health Care Reform: Report #1—Clinical Preventive Services, September 1993. Many clinical preventive services have not been evaluated in terms of efficacy or cost effectiveness, thus their value is unknown. Other screening services have been shown to be effective in reducing or delaying the incidence or burden of disease for some but few show a net savings in medical costs when applied to populations facing only an average risk of disease.

The growing emphasis on primary and preventive care delivery shifted from episodic, high-cost healthcare is consistent with APIC's previously stated goals. While we support and applaud the major principles and tenets of many of the health care reform plans being considered, namely universal access, simplicity, savings, choice, quality and consumer protection, we are concerned about several basic issues that remain underdefined and unclear. Of particular concern is the development and application of outcomes and performance measurement criteria.

In many of the reform proposals, managed care has been equated with cost containment. According to the CBO, by 1990 the percentage of employees in one form of managed care or another, including fee for service plans with utilization review, increased from 59% to 95%. A study by the GAO in October 1993, "found little empiric evidence" that managed care cut costs although it appears to have cut base costs. APIC registers concern about launching a universal health care concept based on the assumption that federalizing healthcare will decrease the cost of care delivery of uncertain value and the possibility of such unproven change is frought with potential for adverse effect on the quality of medical care.

IMPLICATIONS FOR HEALTHCARE

APIC is concerned with the failures and short comings of the nation's current healthcare system. Quality measurement and improvement must remain a central focus of healthcare reform and its product must be relevant to health care settings and providers. It must be locally driven and standardized across all types of health plans. Finally, and perhaps most important, there should be incentives for improvement of accuracy and adjustment of requirements as the field changes.

One of the tenets of reform is the development and application of practice standards. Implicit in the success of these efforts is effective peer review based on accurate outcome data. Healthcare reform must strive to enhance conditions that support peer supervision: (a) a collective sense of responsibility and accountability among medical professionals, (b) a sense of local autonomy and empowerment, and (c) institutional, legal and financial support for peer supervision at the local level.

Incentives for cost containment vary among the proposals. Health Security Act relies solely on employer incentives rather than pressuring providers to reduce costs. This strategy desensitizes employers and more importantly individual consumers to health care costs and, without individual commitment, is unlikely to provide the long term results expected.

Health Care Research, described by some as the surest route to wellness, cost control and a stronger trade balance is at risk by proposed imposition of price caps on new "breakthrough" drugs, by leaving decisions of support for clinical trials of new drugs up to local health plans and projected funding decreases for academic medical centers. APIC concurs with its esteemed colleagues in equating medical research with future investments that save lives, reduce long term medical care costs, increase worker productivity and safety, and provide the U.S. with a strong export capability. Currently the U.S. spends less than 2% of its total healthcare budget to the study of disease. We support the proposal that a fixed portion of all health premiums be placed in a fund dedicated to supplementing existing NIH appropriations. The effect of this would be to provide an additional $5 billion annually and raise the NIH grant success rate to 33 percent.

APIC remains available to dialogue on any of the issues discussed and to collaborate with other professional organizations in an effort to support the actualization of the goals of increased access to quality health care for all Americans.

SPECIAL REPORT

Interim report of the Quality Indicator Study Group

William E. Scheckler, MD, Chair

BACKGROUND

There currently is an increasing interest, from a variety of sources, in the use of "quality indicators": measures whose deviation from accepted standards signals the possible existence of a quality problem. Examples of quality indicators might include the clean surgical wound infection rate, the rate of unplanned return to the operating room, the rate of patient falls, and so on.

The Quality Indicator Study Group was formed in early 1993, at the suggestion of several members of the Society for Hospital Epidemiology of America (SHEA) and the Association for Professionals in Infection Control and Epidemiology (APIC), in order to evaluate the validity, utility, and reliability of quality indicators proposed for interhospital comparisons. The study group consists of representatives from SHEA, APIC, and the Surgical Infection Society (SIS) (see Table 1 for membership and affiliations), and has been charged by the boards of those societies to:

1. review quality indicators that are in use or in development and that are intended for interhospital comparisons of the outcome of care among acute care hospitals in the U.S.;
2. describe scientific and epidemiologic criteria that may be used to evaluate these quality indicators, with a focus on outcome indicators for nosocomial infection; and
3. apply these criteria to existing and planned quality indicators in order to prepare a state-of-the-art position paper for publication in the journals of the study group participants.

To date, the study group has held four telephone conference meetings and two discussion sessions. A substantial amount of relevant material concerning the use of various nosocomial infection rates as quality indicators for the outcome of care in hospitals has been reviewed. The study group

From the Quality Indicator Study Group of the Society for Hospital Epidemiology of America, the Association for Professionals in Infection Control and Epidemiology, Inc, and the Surgical Infection Society

This article is also being published in *Infection Control and Hospital Epidemiology*

Address reprint requests to William E. Scheckler, MD, University of Wisconsin Medical School, Department of Family Medicine, 777 S. Mills St., Madison, WI 53715

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Table 1. Sponsoring organizations and membership of Quality Indicator Study Group

Sponsor	Member	Location	Comment
SHEA	William E. Scheckler, MD	Madison, WI	Chair
	Robert Weinstein, MD	Chicago, IL	Liaison to AHA
	Peter Gross, MD	Hackensack, NJ	Liaison to JCAHO
	Walter Hierholzer Jr., MD	New Haven, CT	Liaison to HICPAC
	Robert Gaynes, MD	Atlanta, GA	Liaison to CDC
APIC	Ona Baker, RN, MSHA, CIC	Amarillo, TX	
	Jacalyn Bryan, RN, BSN, CIC	Fairfax Station VA	Until 2/1/94
	Terrie Lee, RN, MS, CIC	Charleston WV	
	Emily Rhinehart, RN, BSN, CIC	Boston, MA	After 2/1/94
SIS	James Lee, MD, PhD	Minneapolis, MN	

SHEA, Society for Hospital Epidemiology of America; *AHA*, American Hospital Association; *JCAHO*, Joint Commission on the Accreditation of Healthcare Organizations; *HICPAC*, Hospital Infection Control Practices Advisory Committee; *CDC*, Centers for Disease Control and Prevention; *APIC*, Association for Professionals in Infection Control and Epidemiology; *SIS*, Surgical Infection Society

has made an effort to contact the various organizations and agencies involved in using and developing nosocomial infection indicators.

The study group believes it is in the best interest of our patients, healthcare colleagues, hospital administrators, and public policymakers that important issues involved in the use of quality indicators be identified. We also believe there is some urgency to make initial recommendations while we continue the work of preparing a formal paper about quality indicators.

GROUPS CURRENTLY USING NOSOCOMIAL INFECTION INDICATORS

Several quality indicators that include nosocomial infection rates currently are used by a number of organizations:

Overall nosocomial infection rates and surgical site infection (SSI) rate by class

- Maryland Hospital Association
- Greater Cleveland Health Quality Choice (overall rates only)
- South Carolina Hospital Association
- North Carolina Hospital Association
- Indiana Hospital Association
- Georgia Hospital Association

Intensive care unit nosocomial infection rates and surgical site infection rates by risk index

- Joint Commission on Accreditation of Healthcare Organizations
- Centers for Disease Control and Prevention (CDC)/National Nosocomial Infections Surveillance (NNIS) System

Overall nosocomial pneumonia and primary nosocomial bloodstream infection rates

- Maryland Hospital Association (added in 1989)

Groups already using nosocomial infection rates as quality indicators are developing or are contemplating development of additional such indicators. Medical Management Planning Inc of California is working with 12 children's hospitals to establish nosocomial infection indicators. Other groups are discussing establishing their own indicators. If you are aware of any other groups using nosocomial infection rates as quality indicators, please provide the specific information to the study group chair.

IMPORTANT ISSUES

The following issues are viewed by the study group as crucial when evaluating indicators of healthcare outcomes, particularly when looking at the use of nosocomial infection rates as indicators:

1. *Evaluation of quality—outcome or process:*
   Issues of definable events, seen as the outcome of care, are designated frequently as "quality" indicators. Note that processes of care also can be used for evaluation.
2. *Selection of "quality indicators"—key questions:*
   What are the best criteria by which to decide which indicators to use? Is the indicator an accurate measure of quality? If a process indicator is used, is there a link to outcome? As you improve the measure, do you improve care? Who decides?
3. *Definition of an indicator—the numerator.*
   Clear definitions are essential. Measures should be valid and reproducible.
4. *Definition of an indicator—the denominator.*
   The population and its characteristics must be defined for a rate calculation.
5. *Reliability of data collection—key questions:*
   Can the data be collected reliably and be reproducible? Is the sample size large enough for a valid rate calculation?
6. *Completeness of data collection—key questions:*
   What are the mechanisms of data collection? What assurances of thoroughness exist?

7. *Training – key question:*
   Is adequate training/discussion in all aspects of data collection, analysis, interpretation, and uses of reports provided to all pertinent staff?
8. *Feasibility and ease of data collection:*
   Some systems are based on ease and accessibility of collection of data, whereas others are very complex and go for thoroughness. Key questions: What are the advantages and disadvantages of these differing approaches? What is the cost of the data collection system versus the value of the system? What are the relative cost advantages of these different approaches?
9. *Comparability of populations – severity and case mix realities:*
   For any interhospital comparisons, the mechanism for ensuring similarity among the populations being compared must be scientifically sound.
10. *Internal tracking versus external comparisons:*
    The use of the indicator must be reviewed at the beginning. An indicator that might prove satisfactory for internal review could be totally inappropriate for comparison with other institutions.
11. *Use of "benchmarks" – "standard of care" – key questions:*
    If external comparisons are used to assure quality, are they valid and appropriate to your institution and your patient populations? What is the source of the benchmark or standard of care? There is a paucity of good risk-adjusted data for nosocomial infection rates.
12. *Confidentiality versus marketing/contracts:*
    Some managed care plans require an institution to reveal certain quality indicator data and rates, including nosocomial infection rates, without any consideration of the issues defined here.
13. *Relationship to "continuous quality improvement":*
    Accurate indicator data might well serve as a critical component needed to continuously improve care/organizational performance using the Continuous Quality Improvement (CQI/TQM) paradigm.
14. *Timeliness of data collection and reports:*
    Data are most useful when there is a fast "turnaround" between collection and availability for review.
15. *Sharing methods and data in the medical literature:*
    Quality and outcome indicators should be defined in peer-reviewed articles, and their use should be subjected to valid scientific study.
16. *The future – "informatics":*
    Newer methods of collecting, editing, storing, and sharing data will become more widespread in the future, as computer networks, CD-ROM, and other technologies become available.

PROVISIONAL RECOMMENDATIONS

With these issues in mind, the study group believes the following provisional recommendations are in order at this time for members of SHEA, APIC, and the SIS:

1. Look for a "scientific package insert" with every quality indicator. The answers to the above key questions should constitute a useful scientific package insert, such as is required for every drug.
2. Look for a "warning label" on every quality indicator used to compare hospitals. Significant caution, with respect to the issues above, needs to be exercised in using any indicator for comparison between and among hospitals.
3. Educate yourself about what constitutes good epidemiology and good science for a quality indicator.
4. Educate your quality assurance/quality improvement staff in basic epidemiology – then discuss selection of quality indicators.
5. Educate the decisionmakers in your institution, hospital group, and/or state hospital association regarding good epidemiology and good science for a quality indicator. You should be part of the decisionmaking process and should alert your administrators about what will be coming from accrediting organizations.
6. Develop networks through APIC, SHEA, or other groups to discuss quality indicators.
7. Be sure nosocomial infection indicators are valid *before* they are introduced to your hospital.
8. If you currently are participating in a data-aggregating consortium, such as those groups listed previously, use nosocomial infection indicators only if and when they are shown to be valid, reliable, and to meet the other parameters outlined above. The study group has serious reservations about any aggregating system currently in use that focuses on overall nosocomial infection rates and/or surgical site infections stratified only by surgical "class" (e.g., "clean", "clean-contaminated")

9. Be aware that there are no scientific data to support using nosocomial infection rates of any type for interhospital comparison for hospitals of less than 100 beds.
10. The CDC's NNIS program is interested in comparability of data among hospitals and is involved in efforts to develop risk adjustment indices. Be alert to developments that, when validated, might serve as paradigms for good indicators of nosocomial infections.
11. Beware of inadequate nosocomial infection indicators being used in:
    a. Managed care contracts
    b State law mandates
    c. Hospital advertising
    Be ready to advise your colleagues about this.
12. Provide any useful information you have to the SHEA, APIC, SIS Quality Indicator Study Group.

SHEA
William E. Scheckler, MD
University of Wisconsin
Department of Family Medicine
777 South Mills St.
Madison, WI 53715

APIC
Terrie Lee, RN, MS, CIC
Charleston Area Medical Center
3200 McCorkle Ave. S.E.
Charleston, WV 25304

RECENT DEVELOPMENTS

The Maryland Hospital Association Quality Indicator Project (MHAQIP) invited a group of its users and a group of experts in infection control epidemiology to meet on February 17, 1994, to discuss the current MHAQIP indicators for infection control and to make recommendations for improvement. Representatives of the Quality Indicator Study Group (Terrie Lee, Walter Hierholzer, and Robert Gaynes) were included in this meeting. Infection control practitioners, hospital epidemiologists, hospital administrators, system analysts who represented user hospitals, and the Maryland Hospital Association were present at the meeting as well.

The meeting facilitated the exchange of information and formulation of broad plans for making the MHAQIP indicators for infection control more epidemiologically sound and useful. Specific recommendations included methods for improved risk adjustment of such indicators and potential ways to improve the accuracy of the data. The MHAQIP representatives at the meeting reported that they will meet with their user group representatives to discuss these plans and promised to inform the Quality Indicator Study Group of various steps taken through this improvement process.

Suggested reading

The following sources are relevant to the forgo ing discussion and are recommended if you wisl to review these matters further.

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   For copies: IMCARE
   1101 Vermont Ave. N.W., Suite 500
   Washington, DC 20005
   (202) 289-1700
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STATEMENT OF THE GROUP HEALTH ASSOCIATION

The Group Health Association of America (GHAA) is pleased to submit testimony on consumer protection and quality assurance to the Health for Families and the Uninsured Finance Subcommittee of the Senate Committee of the U.S. Senate. GHAA represents 350 health maintenance organizations (HMOs) with 33 million members who account for about 75 percent of total HMO enrollment nationwide.

BACKGROUND

HMOs provide integrated, coordinated high-quality health care at predictable cost to consumers, who consistently give HMOs positive reviews. Consumers' positive attitudes towards HMOs are reflected in increasing enrollment and high renewal rates. HMO enrollment has quadrupled during the past decade alone. Today about 45 million people roughly one out of every five Americans who have health insurance—are enrolled in HMOs, and GHAA estimates that HMO enrollment will exceed 50 million by the end of 1994. This increase in enrollment is representative of consumer satisfaction with HMO plan. Many national surveys have found high levels of satisfaction among HMO members and studies consistently find equal or better satisfaction among consumers enrolled in managed care organizations when compared to those in the fee-for-service sector.[1]

Comprehensive Benefits

HMOs provide comprehensive benefits, usually with no deductibles and with minimal copayments. HMOs emphasize primary and preventive care services: 93 percent of HMO enrollees are covered for routine physical exams, compared to 43 percent of fee-for-service plan participants; more than 90 percent of HMO enrollees are in plans covering well baby care, compared to less than 60 percent of fee-for-service participants. HMO coverage for illness is similarly comprehensive: 90 percent of HMO enrollees are covered for skilled nursing and hospice care, for example, compared to 80 percent of fee-for-service participants.

Many HMOs contract with centers of excellence or single-service providers. Three-quarters of HMOs contract with home health centers and transplant centers. Nearly as many contract with mental health centers. About 60% of HMOs contract with tertiary care centers, cardiac care centers, diagnostic imaging centers, surgical centers, and vision care centers.

Preventive and Primary Health Care

As part of their integrated approach to health care, HMOs offer a continuing program of preventive and primary health care services, for example comprehensive maternity and well- baby care, family planning and reproductive health services, smoking cessation, mammography screening, and case management practices that encourage early intervention. A Rand Corporation study published January 15, 1994, showed that HMOs were rated above the national average in the delivery of key prenatal services. All of these contribute to both quality and cost containment; indeed, improved quality of care and long-term cost containment are virtually inseparable in this context.

Quality Assessment and Improvement Systems

HMOs quality assessment and improvement systems include careful selection of well-qualified providers who will work well within a coordinated care system. Eighty-five percent of HMO physicians are board-certified, compared to 60 percent of physicians nationwide. And, unlike the fee-for-service sector, HMOs routinely monitor and analyze clinical practices and patient outcomes. They use this information to improve the quality and cost-effectiveness of care. Such high-quality, cost-effective care requires active coordination of services, active attention to detail, and active consumer education.

CURRENT PROTECTIONS FOR HMO CONSUMERS

Consumers in HMOs have the benefit of a variety of consumer protections as a result of the integrated HMO delivery systems as well as public and private standards and regulations. The organizational structure of the HMO itself supplies pro-

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[1] A Kaiser Family Foundation and the Commonwealth Fund study (December 1993) found that 85% of HMO members are either very satisfied or somewhat satisfied with their health care coverage. 87% of HMO members reported having a regular doctor, compared with 80% of non-members, and 83 % of HMO members reported being satisfied with their choice of doctors, compared with 79% of non-members. Similar results were found by Novalis Corp in September 19993, the *Boston Globe* and Harvard School of Public Health the same month, and National Research Corp. and *Consumer Reports* in 1992.

tection because integrated, coordinated care is inherently more accountable than uncoordinated fee-for-service medicine. Each patient's primary care physician takes responsibility for coordinating needed care. If the patient is unsatisfied with his or her primary care physician, the patient may choose another. HMOs also have internal quality programs designed to identify and design strategies to address areas that can be improved. HMOs also have internal patient grievance procedures, which are a formal mechanisms that allows patients to voice complaints about coverage or administrative procedures. Many HMOs now are being accredited by the independent National Committee for Quality Assurance, whose accreditation standards are widely accepted and exceed customary performance standards. Finally, many state and federal agencies oversee HMOs. All told, this adds up to protection well beyond that available to most health care consumers.

CONSUMER PROTECTION UNDER REFORM

GHAA believes that the most important components of consumer protection under reform are national health plan standards and consumer choice. It is critical that all health plans meet uniform standards regardless of their structure and that consumers are offered a periodic choice among health plans to allow them to "vote with their feet" if dissatisfied with their plan.

National Health Plan Standards

We believe that national health care reform should include uniform, national standards for health plans as part of a strategy for protecting patients and providers. Without such standards, the regulatory climate will vary from state to state, potentially creating problems and uncertainties for consumers as well as for providers of care. In recognition of the importance of national standards, GHAA has been working with our member plans to develop health plan standards that we believe will provide a uniform level of protection for consumers throughout the United States.

From a consumer protection standpoint, it is critical that **all** health plans meet uniform standards—and this will become even more important as health care reform evolves. That standards apply to the full spectrum of health plans that offer coverage ranging from traditional HMO coverage to traditional indemnity coverage. Key elements of these standards are described below:

Health care delivery system standards include requirements: that plans with delivery systems of participating providers provide access to all covered benefits; that enrollees have the opportunity to select a primary care physician of their choice within the plan and change physicians if desired; and that service area boundaries are drawn in a nondiscriminatory manner.

Quality assurance system standards will require all plans with delivery systems to meet requirements for internal quality assurance and improvement systems. In addition, all health plans should report performance measures annually to allow consumers to compare and make informed choices among competing plans.

Patient privacy must be protected by all health plans. The standards provide that the confidentiality of patient-specific information must be maintained as required by applicable law.

Marketing standards for all health plans should include requirements that all plans must provide written descriptions of their benefits, services, and procedures that clearly and fully describe any and all limitations of coverage. All advertising materials must be factually accurate and must be responsive to the needs of diverse populations.

Administrative standards should ensure that enrollees and physicians are fully informed of plan policies and procedures. In addition, GHAA believes that established internal dispute resolution procedures should be available to enrollees, when disputes arise between health plans and enrollees.

Capitalization standards, based on standards developed by the National Association of Insurance Commissioners' Model HMO Act and NAIC insurance company standards, maximize the likelihood that all health plans will have the financial capability to provide promised health care benefits. Consumers must have confidence in the viability of the health plan serving them and must have protection against interruptions in continuity of care due to the failure of a plan.

Consumers must be protected in the event of insolvency. GHAA supports federal laws that mandate that health plan enrollees must be held harmless from incurring liability for the payment of any fees that are the legal obligation of the health plan.

Consumer Choice

Consumer choice also should be a key component of health care reform. GHAA and its member plans long have advocated that consumers be offered the right to consider a variety of health plans, including HMOs and other managed care plans as well as fee-for-service (FFS) plans. Furthermore, enrollees should be given periodic opportunities to consider alternative health plans. Aside from the fact that consumers deserve this protection, it simply makes good sense to ensure that enrollment in HMOs is truly voluntary and firmly based on understanding how HMOs work.

Consumers have various HMO models to choose from. In staff or group model HMOs, physicians and outpatient services usually are provided in the HMO's own facilities. In independent practice association (IPA) model and network model HMOs, patients see physicians in their own offices. Increasingly, consumers also can choose plans offering a point-of-service (POS) option that allows them, at additional cost, to select unaffiliated physicians, although only a small percentage of HMO enrollees are currently enrolled under this option.

GHAA also supports the concept of "report cards" embodied in President Clinton's health plan to strengthen consumer choice. In cooperation with the independent National Committee for Quality Assurance, GHAA member plans have been working for some time on developing and refining such a system. Report cards will provide comparative information with will permit consumers to make informed choices among health plans.

The development and refinement of meaningful report cards requires standardized data collection and analysis, and it will take time for all plans to develop the capability to meet this need. But we are confident that within a few years report cards will become not only a major consumer education tool but will encourage competition among health plans on the basis of quality as well as price, an environment in which HMOs expect to do well.

Legal Reforms

The different reform proposals that have been introduced contain a number of legal changes. Changes to the legal system that should be designed to benefit consumers and facilitate competition. Antitrust laws are designed to protect consumers by ensuring a sufficient level of market competition to maximize consumer choice, and to keep prices down and quality high. These laws have been critical to allowing innovation in the health care marketplace by preventing providers from working together to block the development of HMOs and other managed care organizations. Current antitrust policies allow ample opportunity for new provider-sponsored health plans and joint ventures without permitting monopolistic practices that would result in a less competitive environment. Therefore, GHAA strongly supports maintaining current antitrust protections and opposes new exemptions for such purposes as collective negotiations of fees by providers. As safe harbors currently exist which permit the vertical integration of the health care system, any further antitrust relief would impact on health care costs and potentially reduce existing consumer protection guidelines.

Three-quarters of HMOs contract with home health centers and transplant centers. Nearly as many contract with mental health centers. About 60% of HMOs contract with tertiary care centers, cardiac care centers, diagnostic imaging centers, surgical centers, and vision care centers.

CONCLUSION

In conclusion, GHAA would like to reiterate our support for uniform, national standards for health plans and for a system that allows all consumers to choose between fee-for-service, HMOs or other managed care plans. We urge you to consider carefully the standards GHAA has developed. Consumers are entitled to the peace of mind of knowing that all health plans are adequately capitalized and financially sound; that health plans are able to provide the full range of services that they commit themselves to offer; that quality of care is continually reviewed and enhanced; and that health plans have the freedom to select participating providers based on clearly established credentials, including cost-effectiveness.

STATEMENT OF THE JOINT COMMISSION ON ACCREDITATION OF HEALTH ORGANIZATIONS

We are submitting this testimony to be part of the hearing record on consumer protection under health care reform. We appreciate the opportunity to provide the Subcommittee with our viewpoint on quality issues under health care reform. I am

Dennis O'Leary, President of the Joint Commission on Accreditation of HealthCare Organizations, the nation's largest and oldest private sector healthcare accrediting body. Quality measurement is our business, and has been for over 75 years. We are nationally and internationally recognized as a leader in developing standards and performance measures for health care delivery.

Health care reform poses new, but exciting challenges for quality oversight, particularly in providing accurate and useful information to consumers and in ensuring appropriate accountability for complex, managed networks of care. The Joint Commission is poised for these challenges as a result of both its seven-year Agenda for Change, which is now concluding, and its new evaluation and accreditation program for health care networks (a.k.a. health plans). We believe that both of these futuristic Joint Commission initiatives can serve as models for the federal government during its debate over the proper structure for quality oversight of health plans.

We seek to shape your legislative perspective by suggesting the addition of three specific items to the health care reform legislation that you mark-up. These suggestions would, we believe, strengthen oversight, maintain public confidence in the new system, and promote continuous improvement in the delivery of health care services.

Our first recommendation addresses the basic framework necessary to ensure constructive oversight of the diverse array of health plans that are emerging in response both to current changes in the health care environment and to anticipated health care reform initiatives. Quite simply, we recommend that:

Congress insist on the inclusion of a core set of national quality standards for health plans as part of health care reform legislation.

In this regard, it is important to recognize that there are two types of quality measures which are integral to the structure for any sound national health care quality management program— standards and performance measures. Both are vital, and each is complementary to the other. Performance measures are a description and quantification of past events; while standards are designed to predict future performance based on an assessment of current organizational function.

We are all aware that performance measures are currently in vogue and viewed by many as the primary substrate for Report Cards. We take no issue with that basic premise. The federal government should require that health plans measure performance outcomes and report those results. However, we are deeply concerned that there is an apparent propensity to discount the need for national quality standards. I specifically allude to the Health Security Act which makes no provision for national quality standards for participating health plans. To construct a national quality management program without national standards would be to roll the dice on patient outcomes and provide only for after-the-fact review of substandard health plans. Further, the absence of standards would effectively eliminate the availability of critical information needed to evaluate the effects of health care reform on quality of care.

Standards for health care organizations have been around a long time, and are widely credited with significantly raising the level of quality care in the United States. This has in turn provided assurances and comfort to consumers, purchasers, and the government alike. As early as 1918, standards for hospitals were published by the American College of Surgeons, thus forming the basis of the College's Hospital Standardization Program—the predecessor to the Joint Commission. The Joint Commission was formally established in 1951 to measure hospital compliance with standards related to quality of care. Today, we evaluate and accredit over 9000 health care organizations that include not only hospitals, but also those providing home care, nursing home care, mental health care and ambulatory care.

In the landmark Social Security Amendments of 1966, Congress established requirements for standards that would apply to hospitals wishing to participate in Medicare, and embraced a partnership between the private sector and the federal government in order to assure substantive oversight of hospital performance. Since then, the federal government has relied upon the Joint Commission to determine the performance eligibility of hospitals and other health care organizations to receive Medicare and Medicaid reimbursement.

The standards-based approach has stood the test of time, and it remains the foundation of any future quality oversight program. Application of state-of-the-art standards has steadily raised the level of quality of United States health care to the finest in the world. President Clinton acknowledged in his September 22nd speech to the nation on health care, that superior quality is now a hallmark of the American healthcare system. The President said, "We are blessed with the best health care professionals on earth, the finest health care institutions, the best medical research, the most sophisticated technology." In his recent State-of-the-Union address, he reiterated this theme by saying that we have " . . . the world's best health care profes-

sionals, cutting edge research and wonderful research institutions, Medicare for older Americans. None of this—none of it should be put at risk."

We agree with the President's characterization of America's health care, but I respectfully submit that we must continue to do well what we have done well in the past. If we fail to set standards for rapidly changing configurations of health services delivery, we may jeopardize our nation's citizens and this country's leadership in quality. With the opportunity to reconfigure our nation's health care delivery system comes the solemn obligation to effectively oversee the quality of care provided through this new delivery system.

Recognizing that integrated networks are increasing in number and are a prominent feature of the reform landscape, the Joint Commission began a pioneering venture last year to develop an evaluation and accreditation program tailored to the characteristics of these new entities. Developing meaningful standards for health plans presents a more complex and unusual challenge than does the process for creating, say, home care standards. For instance, standards will need to assess factors that relate to the integration of many types of services and their accountability. These include attention to continuity of services, access to and use of patient care information, and health plan management, among others.

We should expect similar state-of-the-art, standards for any national quality oversight program. We understand the concerns that some have about previous overzealous efforts in developing federal regulations for health care facilities, but that need not, and should not, be a blueprint for the future. The art of standard-setting has now evolved to a point where it is quite feasible to design a comprehensive standards framework consisting of simple, patient-centered performance objectives for any type of organization, including a health plan or network, We know this is feasible, because we have done precisely this type of standard-setting as part of our Agenda for Change and our new evaluation program for health care networks.

We finally note that there are those who support the establishment of individual state certification programs for health plans or networks, as in the Health Security Act. Given limited resources and expertise across the states to establish such programs, this requirement would simply become another unfunded mandate.

Further, and more importantly, this would in essence create 50 different state quality programs, thereby subverting the interests of multi-state employers, multi-state providers, and consumers who, sometimes of necessity, shop across state lines for health care. To the point, 50 different certification programs for quality would render any meaningful comparisons between or among states impossible. We therefore believe that national standards are in the best interest of all affected parties, including the states which will be expected to actually administer the quality oversight activities within their jurisdictions.

A second important challenge of health care reform will be the provision of performance information about health plans that is understandable to consumers and helpful to them in making judgments about quality and in committing to important purchasing decisions. Report Cards are being widely touted as the linchpin for effective health care reform and as the vehicle for empowering consumers. Expectations are high for the role they will play in educating the public and in leveraging consumer purchasing power, while giving providers comparative information for quality improvement activities. We are deeply concerned, however, that Report Cards as currently conceptualized will not serve those purposes. Rather, they run the real risk of containing incomplete and noncomparable information that will eventually frustrate those who try to use them. This in turn undermines public confidence in the new delivery system. To avoid these serious but unnecessary risks, we urge that:

> *Congress enhance the concept of Report Cards to require that (1) the federal government standardize all of the measures to be used for Report Cards and, (2) require that these Report Cards include information on health plan compliance with national standards.*

The Joint Commission is firmly on record in support of providing useful information about provider performance to the public. We commend the President for introducing the concept of routine collection and dissemination of performance data as part of the Health Security Act. Such information is integral, as well, to the promotion of accountability for sound quality management. The availability of standardized information on specific quality parameters would give plans the ability to compare their performance with others and use this information in their internal quality improvement activities. Yet, we cannot ignore the reality that Report Cards as currently conceptualized, would generally be self-reported data against a limited number of variables, few of which may be sensitive measures of quality.

We believe it important that the following specific cautions about the contemplated Report Cards be raised:

- Self-reported data are easily misreported and sometimes purposefully engineered to reflect favorable performance. Such propensities can be curtailed through on-site evaluations and other screening mechanisms.
- Report Cards solely containing performance measures quantify the performance of a health care organization on a relatively small number of important variables (approximately 50, per the health Security Act) that would be measured.
- Most performance measures presently being suggested for Report Cards focus on process and access issues, and few on clinical or functional outcomes. This reality is unlikely to change in the near term. Thus, it is essential that Report Cards contain information about standards compliance to obtain a full picture of a plan's ability to deliver high quality care.
- Report cards solely containing performance measures will only provide consumers with a picture of past performance, and will not predict the future performance of the organizations which the consumer-turned-patient must choose among for care.

The Joint Commission has had a long and unique experience in the development and use of performance measures. We are quite cognizant of the potential value that can be gained from the routine collection of performance measurement data, but we are also aware of the limitations of outcomes data when used as the lone measures of quality. As part of our initiative to modernize the accreditation process—the Agenda for Change—we began the development of a new outcomes-based performance measurement system called the Indicator Measurement System (IMSystem.) This effort has placed the Joint Commission at the forefront of developing clinical performance measures. The IMSystem will continuously collect objective data on indicators—our name for performance measures—which can be used to assess each organization's performance on important governance, managerial, clinical, and support functions in the context of a national database.

We have learned several important lessons from this ambitious, pioneering effort that are germane to the concept of Report Cards. I would like to share these with you. First, choosing what to measure is not a simple task. Each measure should have real impact on, or be a direct measure of, an important patient outcome. Determining relevance and importance is a matter of combining consumer priorities and clinician knowledge with a realistic assessment of the ability to collect the desired data. Second, we need to keep the system simple and focused. Data should not be collected as an end in itself, nor for purposes that are to be defined at a later date. If we fail on this point, we will undermine the credibility of the system with those who must provide the data, and we will have created another expensive albatross. Third, we must link performance data to improved outcomes through a cyclical process of continuous quality improvement. That is the ultimate objective of this activity. Fourth, indicators (performance measures) are an effective complement to standards, but cannot supplant them. Documentation of bad outcomes, if they occur, is an after-the-fact reality that may guide future consumer choice, but offers little solace to those already affected. Documentation of failed standards compliance creates the opportunity to make changes before bad outcomes occur. And lastly, self-reported data must be monitored for accuracy. If we design our quality measurement program with these specifications mind, we will create a system that is relevant to the needs of consumers, purchasers, providers, and policymakers.

We would hope that the Congress will not create a large new bureaucracy to relearn the private sector's years of experience with measuring performance. Rather, Congress should insist that any federal Council, Commission, or Board given oversight responsibilities with regard to Report Cards, have the explicit charge of ensuring that Report Cards contain standardized measures of care—for both performance measures and standards—that will produce comparable, useful information for consumers. Any such oversight group should borrow heavily from private sector experience and growing array of new measurement tools, in order that there be an effective transfer of knowledge on quality measurement issues and efficient use of federal resources.

Our third suggestion relates specifically to the need for a meaningful better public/private sector partnership concerning national quality management activities. Simply stated, it is important that the right expertise be at the table during the design of a national quality measurement and management system. We therefore believe that Congress should require that:

Any national quality management group created in legislation, such as the proposed National Quality Management Council, be required to include representation from among those entities having expertise in direct quality evaluation.

Such expertise is necessary to the creation of an efficient and sound system of performance measurement. We suggest that those of us who have labored to create and implement national quality monitoring programs have a special perspective and set of skills that could constructively be brought to bear on creating the architecture for and making operational the goals of a national quality measurement system. We do understand first-hand the technical issues and difficulties that attend such a formidable undertaking.

One of the major challenges that such a group would face is selecting and refining measures that will produce useful performance information across health plans. Comparable, risk-adjusted, accurate and understandable information products also will be essential if we are to expect providers of care to take the Report Cards seriously and commit themselves to improvement against these measures.

It is also important that the right type of expertise be immediately available to address important data issues such as standardization of data elements. The tasks of identifying appropriate performance measures that truly reflect significant patient outcomes; testing these measures for validity and reliability; and developing data specifications to ensure comparability of findings, dictate that organizations with this experience be part of any national quality committee such as the Health Security Act's National Quality Management Council.

I would like to conclude with the observation that change, particularly change of this potential magnitude in an area as sensitive and personal as health care, will inevitably create major public anxieties. For the public, quality is every bit as major an issue as cost and access, and any reform initiative that may inadvertently infuse negative incentives for quality in the delivery system, must have a sound balancing process to address that concern. Therefore, Congress must address more than structural provisions for health care reform. It must also provide credible quality measurement and oversight processes that provide ready public access to relevant information and offer assurances that attention is indeed being directed to improving health care services. At issue is the priority which Congress must give to quality maintenance and enhancement, and how best to achieve the excellence in medical care which the American people clearly desire. The Joint Commission, together with others in the private sector, stand ready to assist you in this endeavor.

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