

EXECUTIVE OFFICE OF THE PRESIDENT

27-Oct-1993 12:31pm

TO: (See Below)

FROM: Jeffrey L. Eller
Office of Media Affairs

SUBJECT: President and First Lady Remarks on 10/27

THE WHITE HOUSE
Office of the Press Secretary
For Immediate Release
October 27, 1993
REMARKS BY THE PRESIDENT

AND THE FIRST LADY
ON DELIVERING THE "HEALTH SECURITY ACT OF 1993"
TO CONGRESS
Statuary Hall
U.S. Capitol
Washington, D.C.

11:25 A.M. EDT

MRS. CLINTON: Thank you very much, Mr. Speaker. I come to the podium really to thank all of you. I want to thank the Speaker and Majority Leader Gephardt, Minority Leader Michel. I want to thank Majority Leader Mitchell and Minority Leader Dole. I want to thank all of the members in both Houses and their staffs for an extraordinary amount of work,

advice and counsel. And I appreciate beyond being able to express the strong commitment that so many of you bring to this debate.

This will be, for the next months, an opportunity for all of us to work together, to go beyond politics as usual, to make it clear to the American people that this President and this Congress hear them and are committed to solving their problems in a very real way.

This bill is the result of literally thousands of people, many of whom are in this room and represented here; but many who are not, who are all over this country who have shared their stories, who have written letters, who have button-holed their members of Congress or a Cabinet secretary to talk about what needed to be done.

What we have attempted in this bill is to put in one place comprehensively the pieces of the health care plan. If we had attempted to merely

repeal pieces of other legislation or make amendments to them, or if we had decided that we would not include in this such matters as public health, which are critical to a reformed health care plan, we would have been able, of course, to produce a smaller bill that would not had quite as many pages, but would not have had in one place everything that you will have to consider as you move forward.

We have also made decisions that some matters belong in this bill, such as the benefits package. Others who have alternatives have determined that that is something that should be left to a later day and a body other than this Congress. We've put it into this bill. I don't know how many thousands of pages would be replaced or repealed with the passage of a bill with these features covered in it, but it would go into the tens of thousands. We are trying to have a document with the presentation of this bill that will give us a framework off of which to work.

I especially want to thank the members of the Cabinet who are here and their extraordinary staff for the analytical work that has been done to prepare this bill. And we offer the services as would be obvious to work with members of Congress and committees to analyze other bills and alternatives with the same level of analytical dimension and economic analysis as has been brought to this bill, because if we are to have the kind of honest and open debate that we know we need, we have to hold every possible proposal and plan to the highest level of scrutiny to determine what it would really mean and how it would really work in the lives of Americans.

That's what we owe the American people. That's what we have attempted to do in this bill, knowing we have literally no pride of authorship on many of the details and technical aspects of it. That we leave to the legislative process with whom we look forward to working. But we do have an historic opportunity.

Many of you, Republicans and Democrats, who have worked and worried over health care for years, have told me that the one thing that stood in the way of your being able to do whatever it is you thought was best was you did not have a President committed to seeing that through. I can tell you we have a President committed to seeing that through. (Applause.)

And what this President and I and all who have worked on this look forward to is a vigorous, honest debate that sheds light and not just heat, and which is rooted in what is really happening in our country. And I am absolutely confident that if we do that, then in this Congress, in this next year, we will meet again to sign the kind of bill that the majority of us will be proud to have been a part of.

Thank you very much. (Applause.)

SPEAKER FOLEY: Long before he made the decision to seek the high office which he now holds,

the President emphasized the importance of health care reform for the American people. From the time of the campaign to the inauguration, and every week and month since then, the President has reiterated time and time again how central the solution of this problem is to the welfare and economic, as well as personal and social, of the American people. He has provided the leadership clear and unfailing to bring this legislation to the Congress. He will provide the leadership in the coming months to see it enacted until, as many have said, that happy day arrives when the Health Security Act of 1994 is signed by the President of the United States, William Jefferson Clinton.

I'm proud to present you now the President. (Applause.)

THE PRESIDENT: Thank you very much. Thank you, Mr. Speaker, Senator Mitchell, Senator Dole, Congressman Gephardt, Congressman Michel. To all the distinguished members of the Congress from

both Houses and both parties who are here today, I thank you for your presence and your continuing interests. I thank you for giving Hillary and me the opportunity to come here to Statuary Hall.

This has been a remarkable process. I can never remember a time in which so many members of Congress from both parties and both Houses had so consistent and abiding commitment to finding an answer to a problem that has alluded the country and the Congress for a very long time.

I want to thank the hundreds, indeed thousands, of people who have worked on this process which has led to the bill. I want to thank the literally hundreds of members of Congress who attended the health care university recently -- an astonishing act of outreach by a bipartisan majority of the United States Congress to try to just come to grips with the enormous complexity and challenge of this issue.

I believe the Health Security Act, which I am here to deliver, holds the promise of a new era of security for every American and is an important building block in trying to restore the kind of self-confidence that our country needs to face the future, to embrace the changes of the global economy, and to turn our nation around. A nation which does not guarantee all of its people health care security at a time when the average 18-year-old will change jobs eight times in a lifetime, and when the global economy is emerging in patterns yet to be defined can hardly have the confidence it needs to proceed forward.

If our nation does that, I believe we will do as we approach the 21st century what we have always done -- we will find a way to adapt to the changes of this time; we will find a way to compete and win; we will find a way to make strength out of all of our diversity.

This legislation, therefore, literally

holds the key to a new era for our economy -- an era in which we can get our health care costs under control; free our businesses to compete better in the global economy; and make sure that the men and women who show up for work every day are more productive because they're more secure, and they feel that they can do two important jobs at once: be good members of their family, be good parents, and good children and well as good workers.

This is a test for all of us -- a test of whether the leaders of this country can serve the people who sent us here and can actually take action on an issue that, as tough and complex as it is, is still absolutely central to moving us forward. And it is a test that I believe we can all pass.

And so I have today just one simple request. I ask that before the Congress finishes its work next year you pass and I sign a bill that will actually guarantee health security to every citizen of this great country of ours. (Applause.)

The plan that we present today, as embodied in this book as well as the bill, is very specific, it is very detailed, and it is very responsible. And though we will debate many points -- and we should debate many points -- let me just make clear to you the central element of this plan that is most important to me. It guarantees every single American a comprehensive package of health benefits. And that, to me, is the most important thing. A comprehensive package of health care benefits that are always there and they can never be taken away. That is the bill I want to sign. That is my bottom line. I will not support or sign a bill that does not meet that criteria. That is what we owe the American people. (Applause.)

Now, as we enter this debate, which I very much look forward to, I ask that we keep some things in mind. First of all, when we debate something that the administration recommends or something some of you recommend, and it seem bewildering in its

complexity, I ask that it be compared against what we have now, because none of us could devise a system more complex, more burdensome, more administratively costly than the one we have now. Let us all judge ourselves against, after all, what it is we are attempting to change.

Secondly, I ask that we follow the admonition that Senator Dole laid for us -- let us all ask ourselves as clearly as we can, who wins, who loses, why is the society better off, and how much does it cost or save. And if we know, let us say. And if don't know, let us frankly admit that we may not know the answer to every question.

We have gotten in a lot of trouble as a nation, I think -- and I see Senator Domenici, one of our great budget experts nodding his head --pretending that we could know the answer to some things that we don't know the answer to. We have tried to be as conservative as we could here in making sure that we have not overclaimed for cost

savings or overestimated how small the cost of things will be. Therefore, I think we have in our plan put more money in than it will cost to implement this plan -- but better to be wrong on that side than the other side. We have really worked hard here. And I think we must all do that.

Thirdly, I think we should all say what are the principles that animate this debate. For us, the principles are simple -- they're the ones I outlined in my address to Congress, but let me briefly state them again. They are security, over and above everything; simplicity -- the system we create must be simpler than the one we have; savings -- we cannot continue to spend for what we have 40 percent more than any other country and much more than that over and above what our major competitors, Germany and Japan, spend to cover fewer people; quality -- we must not ask any American to give up the quality of health care; choice -- people have to have choice in the private system of health care. Our plan would provide more choices to most Americans

and fewer choices to none. And there must be responsibility -- to pretend that we can control the costs and take this system where it ought to go without asking more Americans to assume more personal responsibility is not realistic. We have too many choices -- costs in our system that are the direct result of personal decisions made by the American people that lead to rampant inflation based on personal irresponsibility. And we have to tell the American people that and be willing to honestly and forthrightly debate it.

Now, our plan guarantees comprehensive benefits and focuses on keeping people healthy as well as treating them when they're sick by providing primary and preventive care. It reduces paperwork by simplifying the forms that have to be dealt with by doctors, by hospitals, by people with insurance. And that's important. We know -- every one of us can agree on at least this: that the paperwork in this system costs at least a dime on the dollar more than any of our major competitors pay. We must deal with

this. That's a dime on a dollar on a \$900-billion health care system. We can't justify that. It has nothing to do with keeping people well or helping them when they are sick.

We have to crack down on fraud. We know our system today is so complex we waste tens of billions of dollars in fraudulent medical expenses that we can change.

We ought to help small and medium-sized businesses, self-employed people and family farmers to have access to the same market power in holding their costs down that big business and government have today.

I agree with Senator Dole or whoever it was that said this term "alliance" sounds foreboding, but an alliance is basically a group of small and medium-sized businesses and self-employed people and farmers designed to give them the same bargaining power in the health care market that only the

government and big business has today. We must do that. We cannot expect people to be at that kind of disadvantage, especially since many of them are creating most of the new jobs for the American economy.

We should, and we do, protect our cherished right to choose our doctors. Indeed, we try to increase choices for most Americans. Most workers insured in the workplace have now not very many choices about what kind of health care they receive -- only about one in three have choices. Under our plan, all workers would have more choices in the kind of health care they receive, without charging their employers more for the workers having the option to make that choice.

We preserve and strengthen Medicare. We give small businesses a discount on the cost of insurance. We invest more in medical research and high-quality care. We must never sacrifice that. That's something we want America to spend more on

than any other country. We get something for it. It's an important part of our economy and an important part of our security. We should continue to do that.

Our plan rejects broad-based taxes, but does ask everyone not paying into the system that is still there for them when they need it to pay in accordance with their ability to pay. Two-thirds of the funds that finance this entire system come from asking people who can access the system today, who have money but don't pay a nickel for it, to pay their fair share. And I think we ought to do that. It's not right for people to avoid their responsibility and then access the system that the rest of the American people pay for, and they pay too much because too many people don't pay anything at all.

So these are the fundamental elements of our plan, of this bill. But above all, it guarantees true health care security. It means if you lose your

job, you're covered; if you move, you're covered; if you leave your job to start a small business, you're covered. It means if you or a member of your family get sick, you're covered, even if it's a life-threatening illness. It means if you develop a long-term illness, because you will be in broad-based community rating systems, you will still be able to work. It means that the disabled community in America, full of people, millions of them, who could be in the work force today, will now be able to work and contribute and earn money and pay taxes because they will be in a health care system that will not burden their employers or put their employers at undue risk.

That's what security means. It means that we will, in other words, be able to make the most of the potential of every working American who wishes to work during the time they can work. It is a huge, huge economic benefit in that sense.

Every nation with which we compete has

achieved this. Only the United States has failed to do so. We are now going to be given a chance to do it. And I think we must; and I think we will.
(Applause.)

I want to reiterate what I have said so many times. I have no pride of authorship, nor do I wish this to be a partisan endeavor or victory. We have tried to draw on the best ideas put forth over the last 60 years by both Democrats and Republicans. This bill reflects the sense of responsibility that President Roosevelt tried to put forward when he asked if the Social Security program includes health care. It reflects the vision of Harry Truman, the first President to put forward a plan for national health care reform. It reflects the pragmatic approach that President Nixon took in 1972 when he asked all American employers to take responsibility for providing health care for their employees.

It embodies the ideas, the commitment of generations of congressional leaders who fought to

build a health care system that honors our nation's responsibilities, and who have tried to learn to how we might use the mechanisms of the marketplace and the competition forces that have helped us in so many other areas to work in the health care arena.

This is a uniquely American solution. It builds on the existing private sector system. It responds to market forces. It attempts to do what I think we should all be asking ourselves whether we're doing -- it attempts to fix what's wrong and keep what's right. And that ought to be our guiding star, all of us, as we enter this debate.

I think by guaranteeing comprehensive benefits and high quality, and allowing most people to get their coverage the way they do now, leaving important personal decisions about health care where they belong -- between patients and doctors -- we have done what we can to do keep what is right.

I think by asking people who don't pay now

to be responsible by simplifying the system, by cracking down on fraud, by making sure we minimize regulations, we are taking a long step toward doing what is necessary to fix what is wrong, to improve quality and hold down costs.

All of the alternatives that will be debated, I ask only what I have already said. Let us measure ourselves against the present system and the cost of doing nothing. Let us honestly compare our ideas with one another and ask who wins, who loses, and how much does it cost. And let us see whether we are meeting the guiding principles which ought to drive this process.

But when it is over, we must have achieved comprehensive health care security for all Americans, or the endeavor will not have been worth the effort. That is what we owe the American people. And let me say again, the most expensive thing we can do is nothing. The present system we have is the most complex, the most bureaucratic, the most mind-

boggling system imposed on any people on the face of the earth. The present system we have has the highest rate of inflation with the lowest rate of return. The present system we have is hemorrhaging, losing 100,000 people a month permanently from the health insurance system; two million people every month newly become uninsured, the rest of them get it back. They are never secure.

The present system we have has an indefinable impact on workers in the workplace, wondering what will happen if they lose their health insurance. What does that do to their productivity, to their self-confidence, to their family life?

The present system we have is eating up the wage increases that would otherwise flow to millions of American workers every year because money has to go to pay more for the same health care. The present system we have, I would remind you, my fellow Democrats and Republicans, is largely responsible for the impasse we had over the last budget, and the

fights we had.

Look what we did. We diminished defense as much as we should, and some of us are worried about whether we did a little more than we should. We froze domestic spending, discretionary spending for five years, when all of us know we should be spending more in certain investment areas to help us convert from a defense to a domestic economy and put people back to work in our cities and our distressed urban areas. We froze it. (Applause.)

We raised a good bit of taxes. And even though over 99 percent of the money came from people at the highest income group, nobody in this Congress wanted to raise as much money as we did. Why? Because we passed a budget, after doing all of that, in which Medicaid is going up at 16 percent a year next year, declining --declining to an increase of 11 percent a year in the fifth year; Medicare is going up at 11 percent a year next year, declining to nine percent a year in the fifth year of our budget.

That's why we did that. We could have had a bipartisan solution, lickety-split, giving the American people a plan that would have reduced the deficit and increased investment in putting the American people back to work if we were not choking on a health care system that is not working. (Applause.)

Now, I don't know about you, but I don't ever want us to go through that again. That is not good for the Congress, it is not good for the country, it is not good for the public interest. And the most important thing is we can't give the American people what they need. They want to be rewarded for their work. They want to know if they're asked to go back to school, if they're asked to embrace the challenges of expanded trade, if they're asked to compete and win in a global marketplace -- that if they do what they're supposed to do, they'll be rewarded. They want to know that they can be good parents and good workers. They want

to know if they get sick, but they're still health enough to work, they won't have to quit because of the insurance system. They want to know if they're disabled physically or if they have had a bout with mental illness or they've dealt with any other thing that can be managed, that they can still be productive citizens. And the bizarre thing is that we could do all this and still have a system that is more efficient and wastes less than the one we've got.

So I ask you, let's start with this bill and start with this plan, and give the American people what they deserve --comprehensive universal coverage. That's what we got hired to do --to solve the problems of the people and to take this country into the 21st century.

Thank you very much. (Applause.)

END11:52 A.M. EDT

Distribution:

sent
9/23/93

THE WHITE HOUSE

23 September 1993

Justin -

Thank you, thank you for the
great health reform endorsement
letter!

Carol W. Rasco

JUSTIN DART, JR.



P6/(b)(6)

CC HRC
MACE
RABCO
Bar Boorstin
Mack Gorman
D. Gergen

SEP 22 REC'D

health.s20

September 21, 1993

Dear Mr. Podesta:

Enclosed is a copy of my letter endorsing the President's health care reform plan. I will send it by fax and mail today to more than 3,000 leaders of the disability community in all fifty states. I attempt to promote united support for the great positives of the plan, while at the same time being sensitive to the concerns of many colleagues that the proposal would not achieve all the legitimate health care goals of people with disabilities.

I believe that only through the dynamic leadership of the President and Mrs. Clinton have we focussed the attention of the nation on long overdue health care reform. It is vital that all Americans support his efforts to implement equitable, affordable universal health services.

I will cooperate in any way possible.


Justin Dart

JUSTIN DART, JR.

P6/(b)(6)

September 21, 1993

Dear Colleagues:

As you know, on Wednesday evening President Clinton will present to the nation his plan for health care reform. America's health care system is the most expensive in the world. Millions of people are not covered by health insurance, and we die younger than the people of many other nations. Millions of people with disabilities are condemned to unemployment and poverty because that is the only practical way they can get health care.

I enclose the response of the Consortium for Citizens with Disabilities to the President's plan. As you see, CCD applauds the President's effort to achieve responsible health care, and pledges to support and to strengthen the initiative.

President Clinton is calling for quality, affordable health services that will be guaranteed for life to every American, regardless of disability, economic status or employment. Conscience demands that I give my full personal support to the President's leadership for equitable, universal health care and to the position of CCD.

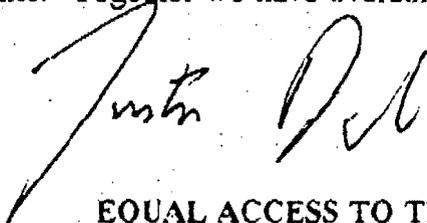
The President's plan would not – and possibly could not, in the present economic and political reality – achieve all of the legitimate health care goals of people with disabilities. However, its enactment would be a giant step forward. We would at long last be guaranteed inclusion in basic health care programs, and many of our special needs would begin to be addressed.

Having established the principle of inclusion, we will be in a stronger position to advocate for complete equity. And we will have a special advantage that we have not had in years past because, to an unprecedented extent, President Clinton has made us partners in the decision making process. Let us cultivate and expand that partnership.

I agree completely with CCD and other colleague advocates that we of the disability community must work with the Administration and the Congress to improve the plan in the areas of our concern, and that we must vigorously oppose efforts to maintain the status quo or to enact only marginal reforms. I believe that we must unite to ensure health care that fulfills the principles of ADA. I believe that we must unite to support the President's effort to achieve guarantees of quality health care for every single person, because anything less is a betrayal of the American dream and of the sacred value of human life.

Colleagues, America cannot win this historic struggle without your personal leadership. Yoshiko and I will be advocating with you on every issue of equity and empowerment. We must unite. Together we have overcome. Together we shall overcome.

Justin Dart

**EQUAL ACCESS TO THE AMERICAN DREAM**

THE WHITE HOUSE

WASHINGTON

MEMORANDUM TO CAROL H. RASCO

FROM: Stanley S. Herr

SUBJ: Growing Unified Disability Community Support for the
President's Health-Care Reform

DATE: Dec. 28, 1993

I am pleased to enclose Justin Dart's Dec. 20th memorandum and CCD action alert that reflects a new sense of unity in the disability community to give forceful support to President Clinton's drive for universal rights to health care. Several of us have been working to get such a strong message out to keep universal coverage and long-term care as the focus and rallying point.

The "strengths" and "concerns" analysis that Alan Bergman has marshalled is far more balanced than prior documents that we have previously seen coming from UCP. The concern on the outpatient rehabilitation benefit is also reasonably stated, and the First Lady's recent letters on revisiting that issue offer some hope of a principled equal access to physical therapy and related essential therapies to avoid regression and more costly treatment down the road. I am receiving information from several sources that such therapies are often in existing insurance plans now.

Let me close with best wishes to you, Mary-Margaret and Hamp for a happy and healthy New Year!

OFFICE OF DOMESTIC POLICY

THE WHITE HOUSE

DEC 28 REC'D

FROM THE OFFICE OF:

CAROL H. RASCO
ASSISTANT TO THE PRESIDENT
FOR DOMESTIC POLICY

DEC 28 REC'D

TO: Roy

DRAFT RESPONSE FOR CHR BY: _____

PLEASE REPLY (COPY TO CHR): _____

PLEASE ADVISE BY: _____

LET'S DISCUSS: _____

FOR YOUR INFORMATION: _____

REPLY USING FORM CODE: _____

FILE: _____

RETURN ORIGINAL TO CHR: _____

SCHEDULE: _____

REMARKS:

I need to meet w/ Stam
during 1st 2 weeks in Jan.
Put this in meeting folder.
CHR - fyd - School to work

JUSTIN DART, JR.

P6/(b)(6)

hcccd.d20

December 20, 1993

To: Debbie Fine, Stan Herr, Heather Booth, Bob Sevigny

From: Justin Dart

I enclose the most recent materials by CCD on the health care reform issues. These are particularly significant because they include a unified position statement developed by a committee of disability rights advocates - including myself - with diverse points of view. The committee is chaired by Allan Bergman of UCPA.

You will note that the unity statement concludes with the sentence: "The one message we must all say loud and clear is to support the President's commitment to make health care a right for all Americans!!!"

I deeply appreciate your leadership for universal health care.

HEALTH CARE FOR ALL AMERICANS NOW

Consortium for Citizens with Disabilities

TO: ALL CCD MEMBER ORGANIZATIONS AND OTHER MEMBERS OF THE
DISABILITY COMMUNITY

FROM: ALLAN I. BERGMAN, CHAIRPERSON, AD-HOC TASK FORCE ON
GRASSROOTS ORGANIZING ON HEALTH CARE REFORM

RE: UNIFIED DISABILITY MESSAGE AND LOCAL/STATE GRASSROOTS
ACTION DURING THE CONGRESSIONAL RECESS

DATE: DECEMBER 17, 1993

We need your immediate dissemination of the enclosed packet to your affiliates, chapters, members, board members and other people attached to your organization.

Health care reform represents a historic moment in American society; one which may not recur for twenty or more years. Children and adults with disabilities and their families cannot wait that long for lifetime security regarding health care coverage. Thanks to the leadership of President Bill Clinton and the First Lady, Hillary Rodham Clinton, we have the opportunity to convince Members of the United States Congress to establish a federally guaranteed right to health care for each American child and adult regardless of age, pre-existing condition, current health status, employment status or income.

Unfortunately, many of the special interests in this \$939 billion sector of the country's economy (one-seventh of the gross domestic product) want to maintain the status quo and are expending millions of dollars to try to convince the public and Members of Congress that we do not need major health care reform and that we cannot afford it. This is a fascinating conclusion since the United States now spends more dollars per capita on health care than any other country and is the only country in the free world that does not have a national right to health care.

We must begin to act today in a united disability voice in order to help Congress develop the "political will" to vote for legislation that guarantees a national right to comprehensive health care for all Americans. The enclosed packet is the first set of materials to assist us in this process. We urge you to send out these CCD materials with a cover letter on your organization's letterhead to your network(s) immediately so that Members of Congress can be barraged by members of the disability community from January 3 through January 24, 1994.

The materials in the packet are as follows:

1. CCD Action Alert with immediate action steps;
2. Talking Points for Health Care Reform from a Disability Perspective and the CCD Principles for Health Care Reform
3. CCD Key Issues for People with Disabilities in Health Care Reform
4. List of Members of Congress on the key Senate and House Committees of jurisdiction by state.
5. In addition, we encourage you to enclose a one pager on lobbying, a one pager on meetings with Members of Congress and a one pager on letter writing. If you do not have these materials we are enclosing UCPA's for your use if you desire.

We expect to have a second packet of unified CCD materials to distribute at the end of January. If you have any questions about this initiative or any of the materials, please call either Kathy McGinley of the ARC at (202) 785-3388 or me at (202) 842-1266. I also would like to thank the following members of the task force for their assistance: Justin Dart, Robert Demichelis, Marty Ford, Becky Ogle, and Denise Rozell.

P.S. If you would like any of the materials on disc, UCPA will be pleased to provide that for you if you will provide us with a clean 3.5 inch IBM formatted disc. Our materials are in Word Perfect 5.1. Please call Susanna Gorton at (202) 842-1266 for any information on obtaining the materials on disc.

Consortium for Citizens with Disabilities

**ACTION
ALERT!**

TO: The Collective Disability Community

FROM: Your National Disability Advocates

DATE: December 17, 1993

RE: *Unified Disability Grass Roots Action on Health Care Reform Needed During Congressional Recess and throughout 1994*

The playing field for health care reform has now shifted from the White House to all 535 members of the United States Congress. The President's Health Security Act was officially introduced in November and is S. 1757 and H.R. 3600. All other bills which have been introduced, except for the President's plan and the Single Payer plans (S. 491 and H.R. 1200) are dangerous to children and adults with disabilities. YOUR ACTION is needed NOW to ensure that the issues affecting people with disabilities are properly addressed as Congress begins to work on these bills. This is a historic opportunity in which we must be victorious.

Health Care Reform for children and adults with disabilities and their families is the most CRITICAL issue that Congress will address in 1994 that will directly impact the life of every child and adult with a disability in this nation. *We in the disability community must convince the Congress and the nation that we will not accept and in fact, will vigorously oppose, tinkering, band-aid solutions masquerading as health care reform. We will accept nothing less than comprehensive, lifetime health care and security that is guaranteed by law to every single child and adult in America.*

Every American with a disability, their family, friends, advocates and providers in every local community must get engaged in the health care reform debate immediately. Members of Congress must get the information and be pressured to enact comprehensive health care reform that will establish a right to health care in the United States. Your national disability advocates cannot compete with the multi-million dollar budgets of the health insurance, hospital, physician, pharmaceutical, and nursing home industries, their lobbyists and their well funded political action committees (PACs). YOUR action today can and will change this! Health care reform from a disability perspective will only be won in the trenches because, as is often said, "ALL POLITICS IS LOCAL".

Time is of the essence! Some Congressional subcommittees are planning to complete their work on the bills as early as the end of February in preparation for eventual House and Senate floor action. For now, Congress has adjourned and will not reconvene until January 24, 1994. Members will be spending a great deal of time at home over this lengthy recess and YOU must take advantage of this wonderful window of opportunity. YOU, as a voting constituent, must tell YOUR Members of Congress that YOU expect them to vote for health care reform that meets the needs of people with disabilities. Members must hear from YOU about YOUR personal/family experiences and YOUR expectations of them for health care reform from a disability perspective. People with disabilities and their families must convince Members of Congress that long term services reform is an essential part of health care reform. Throughout this process, we all must work to protect, strengthen and improve the provisions of the bills as they effect children and adults with disabilities and their families. Without establishing the right to health care it will not matter what is included in the comprehensive benefit package. *The one message we must all say loud and clear is to support the President's commitment to make health care a right for all Americans!!!*

IMMEDIATE ACTION STEPS:

I. Public Forums:

Identify the dates and locations of public meetings, town hall meetings and forums scheduled by your Members of Congress and *be sure that the disability community is well represented at each of these public events*. Contact the local/regional district office of the Senator or Representative to obtain this information and establish a working relationship with the staff.

II. Meetings with Members:

- A. *Schedule specific meetings with your Members of Congress for individuals with disabilities and parents of children with disabilities to tell their stories and why we must have a right to health care for all Americans.*
- B. Review the attached list of Members of Congress from your state who are members of one of the five key committees with jurisdiction over health care legislation: Senate Finance Committee; Senate Labor & Human Resources Committee; House Education & Labor Committee; House Energy & Commerce Committee; and House Ways & Means Committee. *Establish a core group liaison from the disability community to constantly maintain communication with these members of Congress and their staffs.* None of them can be ignored.

III. Disability Message:

- A. Review the attached list of talking points for Health Care Reform and the two key questions you need to ask every Member of Congress.
- B. Hold briefing meetings and provide information to individuals with disabilities, their families, friends and advocates about health care reform and what is at stake. Please read the information we send you.
- C. Make copies and share this Action Alert, the Talking Points, the CCD Principles, and the Key Issues for People with Disabilities in Health Care Reform with as many people as you can.
- D. Prepare personal stories about the importance of health care and long term services reform using real examples such as:
 - horror stories about non-treatment of health conditions or about discrimination in the present health care system;
 - the result of impoverished or other severe financial circumstances which stem from costly health insurance, high medical expenses, or unfair existing insurance practices;
 - work disincentives resulting in continued unwanted dependency on public assistance;
 - the "institutional bias" in the current long term care system.

IV. Follow-up:

- A. Please call, FAX or mail us reports of any public forums or meetings with Members of Congress or their staff.
- B. Please mail or FAX us any copies of letters you write and responses you receive.

TALKING POINTS FOR HEALTH CARE REFORM FROM A DISABILITY PERSPECTIVE

1. **HEALTH CARE IN AMERICA IS IN A CRISIS:**
 - All of us are vulnerable even if we have good plans today
 - Millions of people are being refused and losing coverage annually
 - Costs for health care are out of control
2. **WE NEED COMPREHENSIVE REFORM NOW; WE WILL VIGOROUSLY OPPOSE TINKERING, BAND-AID SOLUTIONS MASQUERADING AS REFORM**
3. **WE COMMEND PRESIDENT CLINTON FOR HIS BOLD INITIATIVES AND SUPPORT HIS COMMITMENT TO UNIVERSAL COVERAGE AND HEALTH CARE AS A RIGHT FOR ALL AMERICANS REGARDLESS OF AGE, INCOME, HEALTH OR EMPLOYMENT STATUS**
4. **DISABILITY IS A NATURAL PART OF THE HUMAN EXPERIENCE AND NOT ANOTHER SPECIAL INTEREST GROUP**
5. **HEALTH CARE REFORM MUST BE BASED ON THE CCD PRINCIPLES FOR HEALTH CARE REFORM (over) AND MUST, BY FEDERAL LAW:**
 - **ESTABLISH AN ABSOLUTE RIGHT TO HEALTH CARE OF EVERY AMERICAN CHILD AND ADULT**
 - **ASSURE UNIVERSAL COVERAGE BASED ON**
 - no exclusions for pre-existing conditions
 - continuity of benefits even if you move, change or loose your job
 - no lifetime cap on benefits
 - affordable deductibles, co-payments and out of pocket limits
 - community rating-underwriting that includes everyone in setting premiums
 - choice of providers with a recognition that the primary care physicians for individuals with disabilities and chronic health conditions often are specialists
 - comprehensive benefits based on individual need and choice, including rehabilitation therapies (physical and occupational therapies, speech/language pathology services), durable medical equipment, home health services, mental health and substance abuse services without arbitrary limits and regardless of age of onset or cause of disability
 - consumer involvement in system planning, implementation and oversight
 - quality assurance and timely, impartial appeal mechanisms to ensure that children and adults with disabilities receive the services that they need
 - **ENSURE THAT NO ONE LOSES ANY COVERAGE THEY NOW HAVE**
 - **BE CONSISTENT WITH THE PRINCIPLES OF SELF DETERMINATION AND INCLUSION EMBODIED IN THE AMERICANS WITH DISABILITIES ACT.**
6. **LONG TERM CARE (services and supports) REFORM INCLUDING PERSONAL ASSISTANCE SERVICES AND FAMILY SUPPORTS MUST BE AN INTEGRAL PART OF HEALTH CARE REFORM AND MUST ENSURE THAT :**
 - children and adults of all ages with all types of disabilities are eligible
 - services and supports are appropriate to the individual's/family's choices and preferences
 - the emphasis is on family, home and community services and supports
 - affordable caps on co-payments are established
7. **KEY QUESTIONS TO ASK MEMBERS OF CONGRESS: (in person or in your letters):**
 - Will you go on the record today that you will vote for legislation that provides a lifetime guarantee to every American by January 1, 1998 of comprehensive, affordable health care, regardless of pre-existing condition, economic or employment status?
 - Will you go on the record today as supporting legislation that makes a firm commitment to the development of services and supports that truly meet the health care needs of children and adults with disabilities - including long term services, personal assistance and mental health services, rehabilitation for all, assistive technology, and prescription drugs?

DISABILITY PERSPECTIVE ON HEALTH CARE REFORM

Non-Discrimination People with disabilities of all ages and their families must have access to health care which:

- prohibits pre-existing condition exclusions;
- prohibits rating practices that discriminate against higher users of health care;
- ensures that all persons, regardless of income or health status, have access to all needed health-related services; and
- ensures continuity and portability of coverage.

Comprehensiveness In addition to acute care hospital and physician services, comprehensive health-related services include:

- preventive services, including services to prevent the worsening of a disability;
- health promotion/education services;
- diagnostic services;
- long and short term home and community-based services;
- prescription drugs, biologicals and medical foods;
- mental health, counseling and substance abuse services;
- rehabilitation services, including audiology, occupational therapy, physical therapy, psycho-social services, respiratory therapy, speech-language pathology services, cognitive, vision and behavioral therapies, and therapeutic recreation;
- personal assistance services and independent living services; and
- durable medical equipment and other assistive devices, equipment, and related services.

Appropriateness Services must be provided to persons with disabilities on the basis of individual need, preference and choice which:

- ensures consumer choice in relation to services and provider;
- ensures a range of service settings through an integrated delivery system;
- ensures appropriate amount, scope and duration of services; and
- ensures the availability of trained personnel

Equity People with disabilities and their families must be ensured equitable participation in the nation's health care system and not burdened with disproportionate costs. An equitable system:

- limits out-of-pocket expenses and cost sharing requirements for participants;
- provides access to services based on health care need, not income level or employment status; and
- ensures adequate reimbursement for service.

Efficiency The health care system should provide maximum appropriate effective quality services with minimum administrative waste. An efficient system:

- reduces administrative complexity and minimizes administrative costs;
- allocates resources in a more balanced way between preventive services, acute care, rehabilitation and chronic care management;
- maintains effective cost controls so that all people can get the health care services which they need.

Consortium for Citizens with Disabilities

Bob Griss (202) 842-1266
Janet O'Keeffe (202) 336-5934
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KEY ISSUES FOR PEOPLE WITH DISABILITIES IN HEALTH CARE REFORM

The 43 million Americans with disabilities have an enormous stake in the current health care reform debate. People with disabilities include individuals with physical and mental impairments, conditions, or disorders, and severe, acute, or chronic illnesses which limit or impede their ability to function. Following is a brief review of the strengths and potential concerns about the Clinton health care reform proposal from the perspective of people with disabilities.

STRENGTHS

Universal coverage.

- o All legal residents of the United States would be covered by 1998.
- o Health care coverage would not be dependent upon employment.

Non-Discrimination.

- o All federal civil rights laws, including Section 504 and the Americans with Disabilities Act, apply to system entities (e.g. health alliances, health plans, National Health Board, providers).
- o Elimination of pre-existing condition exclusions.
- o Mandatory community rating.
- o No lifetime caps on medically necessary or appropriate covered services (except orthodontia).
- o Protection against catastrophic out-of-pocket costs. Limits on out-of-pocket costs for deductibles and co-payments are \$1500 for an individual and \$3000 for a family. No balance billing allowed.
- o Recognition of the importance of cost-sharing discounts for low-income persons.

Comprehensive Benefits Package.

- o Coverage of inpatient and outpatient rehabilitation.
- o Durable medical equipment benefit includes coverage of accessories and supplies necessary for repair and maintenance of such equipment; fitting and training; and replacements of prosthetic devices due to change in a person's physical condition.
- o Coverage of outpatient prescription drugs.
- o Mandatory coverage of medical services associated with approved clinical trials.
- o Preventive services.
- o Recognition that long-term services are crucial components of health care for persons of all ages with disabilities. Also, the introduction of important new initiatives in this area, including new funding for home and community-based services, tax credits for personal assistance services for working persons with disabilities, and provisions which emphasize consumer choice and control.

Medicaid.

- o Movement away from two-tiered health care system by integration of acute care portion of Medicaid into new system.

Cost Containment.

- o Medicare prescription drug rebates and review of new drug pricing.
- o Standardization of health insurance forms will reduce administrative costs.

System Design.

- o Consumer protections guarantee consumers due process rights (including notice of benefits determinations, grievance procedures, and access to judicial review), confidentiality of medical records, and open access to regulatory proceedings and non-patient identifying records and data.
- o Establishment of regional health care alliances will increase the negotiating power of consumers.
- o Allows for consumer choice among plans, and includes an "out-of-plan" services option.
- o Allows for ability to enroll in and disenroll from plans during "open season" and for "cause."
- o Role for consumers in the governance and administration of the health alliances.
- o Recognition of the need for quality assurance mechanisms.
- o New funding of health research would focus on prevention research and research on chronic conditions. Priority areas include child and adolescent health, birth defects, chronic disease and conditions, mental health, environmental health, and substance abuse.

Transition to New System.

- o There are a number of provisions designed to ensure maintenance of current health care coverage and benefits during the transition period. These include: requirements which help preserve current coverage, restrictions on premium increases, limit on duration of pre-existing condition exclusions, and a national transitional health insurance risk pool.

CONCERNS

Non-Discrimination.

- o There should be assurances of non-discrimination against people with disabilities in all aspects of the reformed health care system.
- o Choice of insurance plan will be based on ability to pay, and a person who wants or needs greater choice of providers will be required to pay more. In addition, access to benefits beyond the federally guaranteed minimum will depend on ability to pay.
- o Discounts on cost-sharing should be adequate to ensure freedom of choice of provider.
- o Risk adjustments payable to health plans must be set at an adequate level to remove economic incentives for providers to underserve people with disabilities and to guarantee that the amount, duration, scope, and quality of services to people with disabilities are appropriately based on medical need.

Benefits Package.

- o Services for maintaining function and preventing deterioration for persons with disabilities are not included in the preventive services package and are limited in the acute care benefit.
- o Limitations on outpatient rehabilitation benefit would provide coverage only for therapies that "restore functional capacity or minimize limitations on physical and cognitive functions as a result of an illness or injury." These restrictions severely limit access for many people with congenital, developmental, or other disabilities that are not the result of an illness or injury. In addition, the limitations ignore the importance of access to therapies and other services that maintain function or prevent deterioration. Respiratory care services are limited in scope, site, and duration.
- o Durable medical equipment is tied to acute care-oriented Medicare definition.
- o Mental health and substance abuse services are limited in scope and duration.
- o Overly restrictive prescription drug formularies could have a detrimental effect on the quality of care for some persons with special medication needs. In addition, for certain conditions, mandatory substitution of generic drugs without the informed consent of the consumer and the treating physician could compromise quality of care.
- o The need for supplemental coverage plans demonstrates the lack of comprehensiveness of the federally guaranteed core benefits package for many individuals with special needs.
- o Any new program to provide long-term services and supports must include eligibility criteria that are appropriate for the diverse range of physical and mental disabilities, and must assure that the full array of necessary services and supports are available to all eligible persons.
- o Any new long-term services program, or changes to existing programs, must not exacerbate the institutional bias in the system.
- o Persons currently receiving long-term services through the Medicaid program must continue to receive these services. The financing requirements for any new program must not lead to a reduction in the levels or types of services currently provided to those most in need: low-income persons with disabilities.

Access to Special Services under Managed Care Systems.

- o Managed care systems contain strong financial incentives to restrict appropriate access to specialists. Capitated managed care systems must have the flexibility to permit primary care physicians to refer participants with disabilities to specialists without being penalized financially. Additionally, managed care systems should offer people with disabilities and special health care needs the option of having a specialist at their "gatekeeper" in the system.
- o Access to specialized treatment centers must be ensured. The Clinton bill says that a state "may" require alliances to ensure that at least one accountable health plan has a contract with a "center of excellence." This provision does not adequately address the issue.

Medicaid.

- o Medicaid beneficiaries who become part of the alliances should have access to the full range of health plans. In addition, Medicaid beneficiaries who now receive additional, optional services may lose these benefits. Of particular concern is continued access to the Medicaid Early, Periodic, Screening, Diagnosis and Treatment (EPSDT) program for children. The plan includes an undefined program for children who currently receive EPSDT services.

System Design.

- o **The plan only makes vague reference to a "public health initiative" in which the states would have much flexibility. Therefore, there are concerns as to what would happen to existing programs under the Centers for Disease Control and Prevention and other entities within the Department of Health and Human Services. Examples include the CDC Disabilities Prevention Program, Maternal and Child Health Block Grant programs, and substance abuse prevention and treatment programs.**
- o **An Advisory committee addressing the needs of people with disabilities should be established under the auspices of the National Health Board.**
- o **There should be significant consumer input into development of the health care "report cards."**

THE WHITE HOUSE
OFFICE OF DOMESTIC POLICY

CAROL H. RASCO
Assistant to the President for Domestic Policy

To: _____

Draft response for POTUS
and forward to CHR by: _____

Draft response for CHR by: _____

Please reply directly to the writer
(copy to CHR) by: _____

Please advise by: _____

Let's discuss: _____

For your information: _____

Reply using form code: _____

File: Health Reform

Send copy to (original to CHR): _____

Schedule ? : Accept Pending Regret

Designee to attend: _____

Remarks: *This arrived today although
we've cancelled - thought you
might want to review.*
RZ



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October, 1994

Dear Colleague:

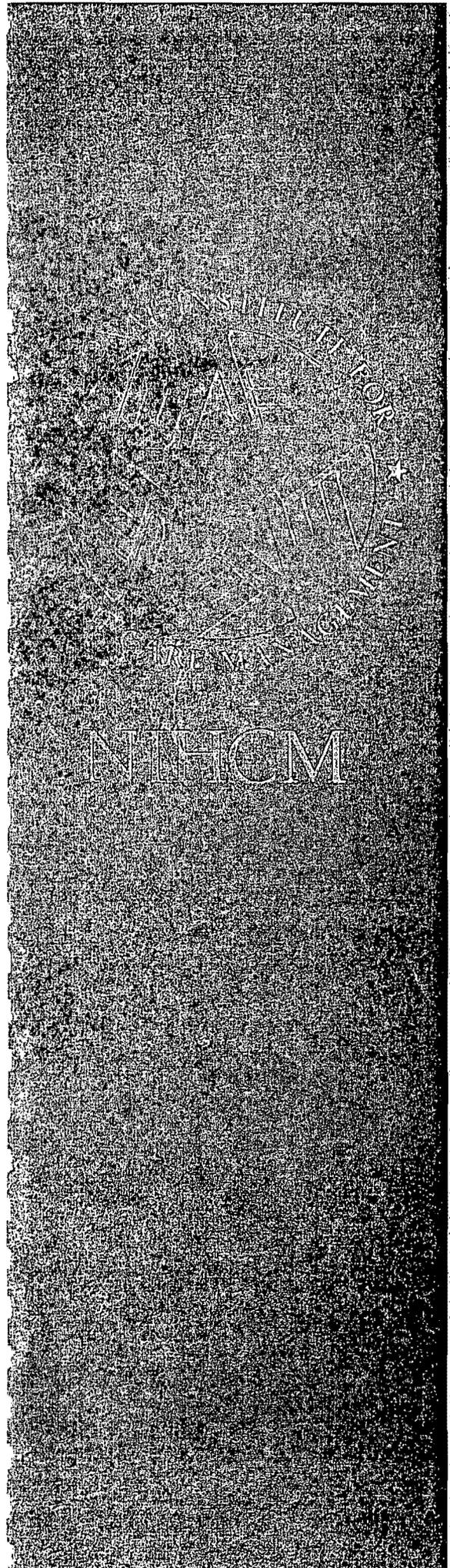
The National Institute for Health Care Management (NIHCM) is pleased to provide to you the enclosed paper, "*Medical Necessity, Experimental Treatment and Coverage Determinations: Lessons From National Health Care Reform.*" The paper was authored by Dr. Linda Bergthold and Dr. William Sage, under a grant from NIHCM.

The paper offers: 1) a thoughtful discussion of the issue set in context of a changing marketplace; 2) a summary of "medical necessity" language from public programs and private plans; and, 3) language from the major reform bills considered by Congress in 1994.

NIHCM brings together public sector and private sector experts to find solutions to health care problems through practical forums and unbiased, nonpartisan research.

Sincerely,

Nancy Chockley
Executive Director



**NATIONAL INSTITUTE FOR
HEALTH CARE MANAGEMENT**

**"MEDICAL NECESSITY,
EXPERIMENTAL TREATMENT AND
COVERAGE DETERMINATIONS:
LESSONS FROM NATIONAL
HEALTH CARE REFORM"**

WHITE PAPER ON REFORM ISSUES

October, 1994

**NATIONAL INSTITUTE FOR
HEALTH CARE MANAGEMENT**

**"MEDICAL NECESSITY, EXPERIMENTAL TREATMENT
AND COVERAGE DETERMINATIONS: LESSONS
FROM NATIONAL HEALTH CARE REFORM"**

Linda A. Bergthold, Ph.D.
William M. Mercer, Incorporated

William M. Sage, M.D., J.D.
O'Melveny & Myers



NIHCM

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EXECUTIVE SUMMARY

The structure of health insurance benefits seldom makes headlines, but has important consequences for consumers, employers, providers and payers. Recent efforts to craft federal reform legislation, although unsuccessful, nonetheless provide important lessons that can be applied in the private insurance marketplace, in state legislatures and in Congress when the health reform debate resumes next year. Notably, federal legislation considered during 1994 contained standards for "medical necessity" and procedures for making decisions and resolving disputes that did not adequately account for recent changes in health care delivery and the limitations of the judicial system.

A striking feature of legislation considered in the 103rd Congress, including proposals for "incremental" reform, was its tendency to standardize the benefits that might be offered by health plans. These provisions would have the most dramatic impact on self-insured employee benefit plans currently protected from substantive regulation of benefits by ERISA. **With limited exceptions, federal legislation proposed during 1993:**

- **Mandated coverage using relatively inflexible definitions of medically necessary care and requiring health plans to pay many costs of investigational treatment;**
- **Limited financial incentives and regulated care management practices to ensure that coverage decisions are open, uniform and unbiased;**
- **Established extensive appeals rights, specified detailed dispute resolution mechanisms and expanded access to judicial review; and**
- **Restricted the ability of health plans and consumers to vary coverage and dispute resolution procedures by agreement.**

Coverage provisions of reform legislation considered during 1994 also raised the possibility that Medicare standards poorly suited to a managed care environment would be extended to private health plans. In addition, proposed federal legislation would have significantly affected coverage of specific benefit categories, such as mental illness, disability, preventive medicine, reproductive care and the services of non-physician health professionals.

A major shortcoming of proposed federal legislation was its failure to address current changes in health care financing and delivery. **To be successful, coverage standards and procedures must be compatible with:**

- **New relationships among insurers, providers and health professionals in integrated health care delivery systems;**
- **Changing roles of purchasers, consumers and patients; and**

- **The tension between innovation and expense in the development of advanced medical technologies.**

The other principal drawback of most reform legislation considered in 1994 was its continued reliance on private litigation to resolve disputes over coverage. **Experience has shown that courts are likely to have limited success resolving disputes over coverage because of the following:**

- **The complexity of clinical problems leads to results-oriented decisions;**
- **The need for urgent resolution weighs in favor of coverage;**
- **The judicial system is not well-equipped to balance individual and social needs as will be required in a future health care system that is able to expand access only by promoting cost-effectiveness; and**
- **Wasteful litigation and excessive awards are likely to increase as large organizations take greater responsibility for health care delivery.**

Considering the complexity of coverage determinations and the lessons of the recent Congressional debate, **we offer the following recommendations to federal and state policymakers for future health care legislation:**

1. **Define required benefits according to broad categories, not specific details.**
2. **Avoid value-laden terms such as "medically necessary" and "medically appropriate" to determine coverage of specific services within the established benefits categories.**
3. **Allow health plans or the regulatory process to define coverage in terms of meaningful benefit, acceptable risk and cost-effectiveness, each supported by sufficient evidence.**
4. **Do not use benefits requirements to force private health plans to expand their responsibilities beyond health insurance and health care.**
5. **Do not base future standards and procedures on current Medicare practice.**
6. **Require adequate disclosure of coverage practices to consumers instead of imposing extensive regulation.**
7. **Establish an expert board or commission to make public recommendations regarding coverage issues, including technology assessment.**
8. **Consider specific legislation to streamline or guide judicial review of coverage decisions and available remedies.**

INTRODUCTION

America's population is aging, its demand for health care is growing, and its capacity to meet that demand with expensive medical technologies and other services is keeping pace. As annual health care spending approaches one trillion dollars, the high cost of covering treatments that are not necessary or appropriate, or that are still experimental or unproven, has implications for individual consumers, private health plans, government budgets and society as a whole.

This Issues Paper explores an important aspect of health care reform: the need to define coverage and resolve disputes in ways that make sense for future health care financing and delivery. It identifies key issues affecting determinations of necessity or appropriateness of medical treatment, using legislation considered by the 103rd Congress to illustrate the pros and cons of various approaches.¹ Its intent is not to provide definitive answers but to raise the critical questions. Only enlightened debate regarding this complicated and emotionally charged subject can prevent unintended and unwanted effects of health reform legislation and facilitate the transition to an improved and restructured health care system.

Three features of today's health care system add particular urgency to the task of developing standards for determining what is "medically necessary" or "medically appropriate" and for handling disputes over coverage.

- States and the federal government will continue to pursue reform legislation intended to control cost and expand coverage, including benefits language that may have sweeping consequences, both intended and unintended, for private plans and providers.
- Integrated health plans that receive capitated premiums to serve defined populations using networks of affiliated providers are replacing unaffiliated hospitals and physicians paid on a fee-for-service basis, increasing cost-based competition and blurring traditional distinctions between insurers and providers.
- No parallel change has occurred in the way that the judicial system approaches coverage disputes, with courts often making results-oriented judgments in complex medical situations and entrepreneurial counsel championing individual "rights" that may contrast sharply with health plan finances, community priorities and clinical and economic realities.

POLICY ISSUES IN COVERAGE DETERMINATIONS

Setting the boundaries of health care coverage is an important test of our ability to craft a more rational health care system. Currently, the principal impetus for rationality is cost. In a world of limited resources, a prerequisite to expanding access to health care is reducing the use of unnecessary, ineffective and unproven services. Evidence exists that informed consumers and well-organized managed care plans can contain costs while maintaining or improving quality. This is the primary reason to develop sound standards for determining coverage.

In addition to being rational, an effective system for coverage decisions must be accountable. In other words, it must acceptably balance individual rights with the need for the

system to run smoothly. This is the principal justification for devoting considerable attention to the processes used to make decisions and resolve controversies. Occasionally, these processes will reveal initial determinations that were mistaken or ill-motivated. More often, they will offer reassurance of the basic fairness of the system without imposing excessive cost. As has been observed, "it is virtually inevitable that a rational and decent system of care will disappoint patients' and subscribers' expectations at critical and disputed points."²

An ideal system for defining benefits and resolving disputes should:

- Empower consumers and patients by ensuring informed consent to proposed treatment and providing "due process" rights to participate in and seek review of decisions regarding coverage;
- Reflect the current state of clinical knowledge and professional ethics by encouraging physicians and other health professionals to provide objective evidence for their recommendations and ensuring that this evidence will be accorded appropriate weight;
- Promote efficiency on a system-wide basis by allowing health plans to structure delivery systems that provide cost-effective services to their enrolled populations;
- Recognize the inevitability of conflict between emotionally vulnerable patients and any economically rational health system by anticipating common disputes, tempering expectations with clear rules and implementing timely, efficient dispute resolution mechanisms.

Achieving these goals requires addressing three issues: (1) identifying usable legislative or contractual standards for coverage, (2) describing reasonable procedures for applying these standards to specific cases and for resolving disputes, and (3) assigning responsibility for developing and implementing these standards and procedures to the appropriate private or public entities. The Appendix to the Issues Paper summarizes the approaches to these issues taken by federal Medicare and state Medicaid programs and by private health plans, as well as by recent federal reform proposals. As described in this section, addressing these issues raises a variety of important questions. The remainder of the Issues Paper considers these questions in the context of specific challenges confronting today's rapidly changing health care system.

How To Define Coverage

The scope of covered benefits can be defined in insurance contracts or health care legislation either by developing a comprehensive list of included services, or by identifying broad categories of covered care such as physician services, hospitalization, prescription drugs, and subjecting them to specific exclusions. Several issues arise with respect to the use of lists. To what extent does the technical nature of health care render lists incomprehensible to consumers? Should lists be developed individually by health plans or based on consensus standards? How should lists be re-evaluated and updated? Should lists be enforceable even if they do not match patients' reasonable expectations of coverage? Do lists perpetuate a fee-for-service rather than outcome-based view of health care?

For the most part, health plans have not used exhaustive lists of covered benefits in order to avoid intruding on the authority of physicians. Instead, health plans have relied primarily on specific exclusions (which also raise many of the above questions) and on general standards of medical necessity. Language limiting coverage should be precise, readily understandable to consumers, and capable of guiding internal decisions as well as administrative or judicial review in appropriate instances. Currently, terms such as "medically necessary," "medically appropriate," "experimental" and "investigational" are often undefined or ambiguous, leading to unpredictable and inconsistent results. Many questions must be addressed by consumers, providers and insurers. Should definitions include concepts of safety? Of efficacy? Of cost-effectiveness? Should coverage depend on the setting in which the service is provided or the qualifications of the provider?

How To Make Coverage Decisions and Resolve Disputes

Sound procedures for gathering and evaluating information are necessary to support decisions applying legislative or contractual coverage standards to specific situations. What evidence should be considered? Prevailing practice? Published research? FDA or other government approvals? Findings of professional societies or other expert bodies? Should decisions be made by plan administrators or by independent panels? To what extent might financial relationships or incentives raise conflicts of interest? At what point should the patient participate in the process? Should any of the process be public?

Equally important is the appeals mechanism available to patients who are dissatisfied with a decision. How can this process be both timely and fair? Should special procedures apply to life-threatening situations? Is informal mediation worthwhile? What "due process" rights should patients have? Should there be mandatory dispute resolution within the health plan, by an independent administrative officer, or by a non-judicial body such as a board that includes health plan, health professional and consumer interests? Should non-judicial dispute resolution be binding? Should purchasers and payers participate? Under what circumstances should litigation be available, and how should it be conducted? What remedies should be available?

How to Apportion Responsibility

Many parties share interests in, and authority over, coverage determinations. These include health plans, their constituent providers, enrollees as consumers and as patients, employers and other payers, and state and national government. An appropriate division of responsibility based on the capacity of various actors to make fair, informed decisions could greatly increase the effectiveness of any system of coverage. Which contract terms and procedures should be left to negotiation between individual health plans and consumers? What is the proper role of employers, purchasing groups and other payers? Should physicians and other health care providers act on behalf of the health plans with which they are affiliated, or should they have independent obligations? Should trade and professional organizations develop consensus standards? What rules should be established by government?

An important issue is whether or not to place legal restrictions on the ability of private parties to contract freely for health coverage. What would be the effect of disturbing current contractual arrangements? Would limiting contractual freedom protect consumers from

unfair arrangements? Would it reduce confusion and improve competition based on price and quality? Or would it lessen competition by discouraging negotiation? Could it relieve them of unpredictable and potentially excessive legal liability? Might it provide security by insulating parties from ethical issues involving cost and the use of scarce resources?

Even where decisions are made by government, important tensions exist because society is not homogeneous and government is not monolithic. To what extent should standards reflect national priorities as opposed to prevailing practice patterns and available resources in local communities? Should a menu of permissible options be available? Should only particularly problematic coverage practices be prohibited? Should government act through legislation or through the regulatory process? Should the federal government limit itself to basic standards and traditionally national issues, with residual jurisdiction left to the states, or should federal law predominate? Should government seek advice from national or state health boards or non-political, expert bodies? Should particular decisions be delegated to these entities?

LESSONS FROM FEDERAL REFORM PROPOSALS

During 1994, Congress discussed a variety of health reform proposals intended to protect the interests of consumers and patients, restructure the incentives governing markets for health insurance and health care, and expand access to health coverage. Nearly all of the reform bills, from the most "incremental" to the most sweeping, placed requirements and restrictions on coverage under private health plan contracts as well as through public health insurance programs. These provisions tended to share certain principles, but expressed those principles in highly variable and often inconsistent detail. Three bills in particular -- the two proposals introduced by the Democratic leadership in the House and Senate based on the recommendations of the appropriate committees and the so-called "Mainstream Proposal" drafted by moderate Senators of both parties -- illustrate the complexity defining coverage through legislation and the important effects, both intended and inadvertent, that such provisions may exert on the U.S. health care system.

An analysis of the approaches taken by these three bills can offer important lessons to policymakers for future legislative and private sector initiatives. Next year, the 104th Congress will undoubtedly consider new proposals affecting health care benefits and insurance practices, and may also reopen debate on comprehensive national health reform legislation. In addition, the lack of progress at the federal level has added urgency to state legislation enacting insurance reforms and other measures to expand access and contain health care costs. The marketplace will also continue to modify medical underwriting practices and to restructure the benefits available through private insurance, particularly as large purchasers and purchasing pools in both the public and private sectors force health plans to compete more aggressively. These trends will affect the scope and terms of coverage and the consequences of adopting particular approaches to coverage standards and procedures.

Standardization of Benefits

Some advocates of market-based health reform favor a relatively comprehensive, standardized health care benefit package. They argue that subtle variations in benefits promote risk selection, while standardization facilitates more effective price and quality comparisons by

consumers. Following this approach, all three recent federal reform bills -- the House and Senate leadership bills and the "Mainstream" proposal -- standardized benefits for private insurance plans, including self-insured plans previously protected from regulation by ERISA. Even less sweeping federal bills, as well as most recent state reform proposals, contain some degree of benefits standardization. At the same time, the insurance and managed care industries have revised their benefit packages in response to market forces and the possibility of state and federal reform.

Mandated Scope of Coverage

Standardization does not necessarily imply that all health plans must offer only one package of benefits. Nonetheless, both Democratic leadership proposals set forth a single "guaranteed" package and limited variations to the manner of delivery and associated cost-sharing -- fee-for-service, point-of-service or closed panel -- rather than the scope of coverage. The Mainstream bill included three packages: "standard" (comprehensive), "catastrophic" (higher cost-sharing) and "basic" (fewer categories of covered benefits). An important tension therefore arose in each proposal between standardization to facilitate comparison shopping by consumers, and mere expansiveness of benefits that might add to cost and decrease opportunities for price competition.

All three proposals defined the required scope of coverage according to broad categories of services (e.g., hospital or professional care), with the House leadership bill essentially using Medicare standards. As a result, the cost to plans of providing these benefits depended on how concepts of "medical necessity" and similar exclusions were defined and applied. However, none of the proposals allowed health plans to continue their current practices for setting these standards. Neither did any proposal expressly allow health plans to include provisions in their insurance contracts reserving discretion to assess necessity, a factor often given substantial weight by courts when determinations are challenged.

Instead, all three proposals relied on federal law to specifically define the boundaries of coverage. The Senate leadership bill and the Mainstream proposal required health plans to provide all "medically necessary or appropriate" treatment within the required categories of services. The Senate leadership bill defined "necessary or appropriate" as "intended to maintain or improve the biological, psychological or functional condition of a health plan enrollee or to prevent or mitigate an adverse health outcome to an enrollee." The Mainstream bill defined the concept as "for treatment of a medical condition, safe and effective, and medically appropriate for the enrollee," with each term subject to further definition in the statute.³ The House leadership proposal did not contain a new definition of "necessity," but extended Medicare's definition ("reasonable and necessary" care) to all health plans while apparently applying a new standard of "appropriateness" to services not traditionally within Medicare. All three bills also expressly required health plans to cover costs related to certain "investigational" treatments.⁴

Because of ambiguities in terminology and new categories of covered benefits (e.g., investigational treatments), these bills tended to expand the scope of coverage and therefore would have increased health plans' costs and the premiums they must charge. This was particularly true for the House leadership proposal, which used Medicare standards that up to now have been limited to consideration of safety and effectiveness, have relied on community

standards of practice and have been applied inconsistently by fiscal intermediaries and carriers. For example, Medicare standards (unlike state Medicaid policies) have not been interpreted to allow cost-effectiveness judgments, although limited concepts of cost-effectiveness were included in the Health Care Financing Administration's 1989 proposed rule on coverage determinations, which has never been finalized.

Standards for Coverage Decisions

Proposed federal legislation would also have affected the manner in which health plans conduct claims review. For example, the House bill established strict standards for utilization review, including prohibitions on direct financial incentives for claims denials, limitation of decision-making to clinically qualified personnel, uniform application of standards based on the most currently available medical evidence, and provider participation in development of the review process. The Senate leadership bill and Mainstream proposal were somewhat less prescriptive in their "patient protection" provisions. The Senate bill, for example, required disclosure to enrollees, providers and government of treatment guidelines, utilization protocols and general coverage determinations, and limited financial incentives to those permitted for "competitive medical plans" (Medicare HMOs).

In addition, all three bills required claims approvals or denials to be made within a set period of time (usually 30 days), and to be accompanied by a clear explanation of the action taken. The House leadership bill specifically required that denials of treatments as not medically necessary or appropriate, as experimental or investigational, or as inconsistent with practice guidelines, include the medical basis for the determination, the guidelines used (if any) and a description of the decision-making process. Both Democratic leadership bills also included expedited approval requirements for preauthorized services.

The effect that these requirements would have had on current law and common business practices is uncertain. Some features of the bills parallel developing case law and industry practice, such as an emphasis on openness and uniformity, rather than an irregularly applied "black box" process, and the elimination of certain financial incentives. On the other hand, terms such as "clinically qualified" and "most currently available evidence," which appeared in the House leadership bill, contain inherent ambiguities and would be unlikely to help courts make consistent, objective decisions.

Required Appeals and Dispute Resolution

Legislative changes to the processes used by health plans for appeals and dispute resolution may have even greater effects on health plans than changes in substantive standards. For example, the Democratic leadership proposals contained extensive procedures to be followed by patients and private health plans in the event that claims are denied. Each health plan would be required to provide timely review, which must be conducted by an individual who did not initially deny the claim and must include the participation of a qualified physician.⁵ Individuals whose claims are again denied would be able to challenge the decision in a state complaint review office. Each level of appeal would have to be exhausted before moving to a higher level or to court, except that the House leadership bill allowed immediate judicial review of refusals to

preauthorize services. In addition, the Senate leadership proposal gave complainants the option of binding resolution by the complaint review board, including an award of attorney fees and "other appropriate relief" if the complainant prevails, or proceeding to court.

The probable effect of the Democratic leadership proposals would be to increase greatly the cost of private health plan coverage decisions.⁶ The two most problematic aspects of the proposed procedures are the requirement that determinations of medical necessity be made de novo in each individual case (especially if by a broadly constituted appeals board as in the House proposal), and the failure to make any level of non-judicial review both mandatory and binding. The first provision would reduce the ability of plans to develop and rely on guidelines or other prospective standards. The second would add layers of expensive process without offering the predictability and cost-savings of avoiding litigation.⁷

On the other hand, the Senate Mainstream proposal emphasized efficiency in resolving coverage disputes, providing for federal administrative review (appealable to the federal courts) of claims still contested after internal review has occurred, and allowing health plans to establish a mandatory, binding arbitration system as an alternative. Claims coming before the federal administrative process would be reviewed de novo only if they involved preauthorization; post-treatment payment decisions are accorded deference. Remedies would be limited to the service or claim, with costs and attorney fees to a prevailing complainant.⁸ The Mainstream proposal also established a separate federal cause of action for failure to use reasonable care in utilization review (based on a federal standard), but required administrative remedies to be exhausted and decided in the complainant's favor, and limited recovery to economic damages plus an equal amount of non-economic damages, in any case not to exceed \$100,000.

Varying Coverage by Agreement

An important and perhaps unintended consequence of the coverage determination provisions in all three major proposals considered by the 103rd Congress was to impose uniformity on the structure of health insurance benefits. Despite the clear advantages of standardization, it seems clear that complete equivalency can never be achieved among health plans, nor might it be desirable. The key question is the extent to which individual or group purchasers should be free to contract for various levels of coverage. Some degree of flexibility in the structure of benefits can help meet the need of diverse populations, allow more price-conscious purchasing, and promote competition. Potential trade-offs include allowing plans to cherry-pick healthy individuals using customized benefits and increasing the risk that plans will misrepresent the scope of coverage.

For example, most policymakers agree that consumers should be allowed to buy additional services as part of a supplemental package that is regulated adequately to prevent fraud. Following this approach, the leading Congressional proposals all permitted health plans to offer benefits beyond those required.⁹ At the same time, however, the proposals appeared to preclude health plans from establishing varying standards for "appropriateness," even if those standards are clearly disclosed and result in savings to consumers who elected them. For example, health plans might construct cost-effectiveness standards for coverage that offered reduced premiums in exchange for excluding certain high-cost, low-benefit treatments.

A related question is whether consumers should be allowed to contract for specific processes to resolve coverage disputes -- for example, to limit their right to challenge coverage decisions in court or their potential remedies if a challenge is successful. Many health plans and providers currently include requirements for binding arbitration in their contracts with patients. These provisions have generally been upheld by courts. However, the House leadership proposal specifically prohibited health plans from requiring consumers to waive any procedural rights as a condition of claim approval. This suggests that mandatory, binding arbitration would no longer be an option, despite its potential to reduce costs and premiums. (The Mainstream proposal, on the other hand, expressly allows health plans to impose binding arbitration.)¹⁰

Effect on Existing Federal and State Regulatory Schemes

Federal reform legislation, if enacted, would also affect existing regulations and programs, including employee benefit plans governed by ERISA, Medicare and Medicaid.

Self-Funded Health Plans (ERISA Plans)

Employer-sponsored health plans are regulated by federal benefits law (ERISA). ERISA contains reporting and disclosure requirements for benefit plans and imposes fiduciary duties on plan administrators, but leaves the design and content of self-insured benefits to employers.¹¹ For self-funded plans, ERISA also broadly preempts state insurance laws and other state laws mandating benefits (insured plans provided by employers are protected from many state law claims and remedies, but remain subject to insurance regulation). Although ERISA has been criticized for allowing self-insured employers to limit the benefits they provide, it has also given the private sector the freedom to design innovative, cost-effective health plans that have increased employees' access to health coverage.

Because of ERISA's broad preemptive effect, disputes over the scope of coverage of ERISA plans, including cases involving medical necessity or experimental treatment, have followed a different course, and have often resulted in different outcomes, than cases with similar issues arising in the traditional insurance arena. Courts may not make an independent assessment of the evidence in cases involving ERISA plans that have reserved discretion to their administrators to determine the scope of coverage, but may only judge whether that discretion was abused.¹² Punitive damages are not available under ERISA, and the majority of courts have held that compensatory damages (even for allegations of malpractice) are precluded as well, protecting self-insured plans from the multi-million dollar judgments that are becoming increasingly common in state courts. Recently judicial decisions also allow ERISA plans to compel binding arbitration of coverage claims.

Much of this protection from litigation would have vanished if the leading Congressional reform proposals had been enacted. All three bills required self-insured plans to offer the nationally guaranteed benefit package and to follow the grievance and appeals procedures discussed above.¹³ An argument can be made that the widely disparate handling of claims resulting from the happenstance of an individual being enrolled in an ERISA plan or commercial insurance plan is unjustifiable. However, dramatically changing the rules of the game for ERISA plans would have a significant cost, especially given that employers are not required to provide coverage. If an employer has taken on the financial risk of providing and paying for

health insurance for employees, shouldn't that employer enjoy some degree of flexibility in benefits design? Subjecting self-funded plans to potentially expensive requirements and exposing them to new legal risks is likely to affect adversely their willingness to provide benefits in the first place.

Medicare and Medicaid

Services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" are excluded from Medicare coverage (special provision is made for coverage of preventive care and certain other services). Individual coverage decisions are generally made by contract carriers, fiscal intermediaries and professional review organizations (PROs). The Health Care Financing Administration has also issued over 200 "national coverage decisions" relating to specific treatments or technologies, generally based on the recommendations of the Office of Health Technology Assessment (OHTA) of the Agency for Health Care Policy and Research. Medicare beneficiaries are entitled to a hearing to contest a denied claim and to written notice of the final decision. Judicial review is generally restricted to whether the administrative action was unreasonable.¹⁴

Unlike Medicare, federal Medicaid law does not expressly address medical necessity except through its general intent that states provide "necessary medical services" to indigent citizens. As a result, each state has crafted its own coverage rules, many of which are found in practice manuals and internal memoranda rather than formal regulations. Using the more lenient standard of review applicable to administrative decisions affecting government programs, courts have generally upheld these state standards and procedures as reasonable, often looking to Medicare law to guide interpretation of medical necessity under Medicaid. Several states, including Florida, Minnesota and South Dakota, have Medicaid policies that include concepts of cost-effectiveness, although these limitations have seldom been applied or litigated. As more states attempt to move their Medicaid populations into managed care systems, potential ambiguities and other legal questions raised by these standards may be tested.

Federal reform proposals have generally maintained Medicare as a separate program, and have nominally eliminated Medicaid while converting federal contributions to new subsidies for low-income individuals and requiring state maintenance of effort.¹⁵ The House leadership bill would have had the additional effect of imposing Medicare's interpretation of medical necessity on private health plans, while making available far more liberal administrative and judicial review of contested decisions than are now available under Medicare, including those currently applicable to Medicare HMOs.

The main problem with this approach is that Medicare coverage standards are unlikely to be well suited to managed care plans that receive capitated payments, structure provider networks, and reduce costs through network design, practice guidelines and prospective control of services. Medicare is basically a system of unmanaged fee-for-service care in which government exerts strict control over reimbursement rates through retrospective claims review with limited rights to administrative appeals. For example, the Medicare statute disclaims interference with physician judgment and therefore avoids preauthorization of treatment or other forms of prospective or concurrent utilization review. In addition, Medicare's coverage standards are designed specifically for an elderly population, and have not been applied to other groups.

For example, the restriction of medical necessity to "illness and injury" largely ignores restorative and preventive care, except for certain enumerated services.¹⁶

Specific Areas of Health Coverage

Over the past thirty years, public and private benefit packages have converged over coverage standards for hospitalization, outpatient care and professional services. However, considerable variation in coverage remains in some areas, such as preventive services, mental illness/substance abuse services, reproductive services, chronic illness and rehabilitation services, and with respect to the role of specific providers in delivering care.

Mental Illness and Substance Abuse

Coverage standards and procedures for handling claims disputes will be extremely important in the case of benefits, such as care for mental illness, for which potential demand is high but objective criteria establishing necessity and benefit are often unavailable. All three Congressional proposals would have expanded mental health and substance abuse coverage to some degree, but none explicitly based coverage on a case-management model without preset limits on hospitalizations, physician visits or other specific services, although the Senate leadership bill and the Mainstream proposal directed the national benefits board or commission to do so to the extent possible. This leaves unanswered how "parity" between treatment of mental and physical illness can be accomplished without fiscal irresponsibility. Mental illness coverage rules also raise issues relating to patient protection. How can patients with mental illness best make informed choices of coverage and of care? How should their interests be represented in coverage decisions and disputes?

Chronic Illness and Disability Services

Chronic illness and disability account for a growing proportion of health care spending. As the population ages, demand for long-term care and supportive services will continue to increase, and coverage disputes involving these services are likely to arise more frequently. Coverage standards are therefore of considerable concern to affected patients and their representatives, as well as to government and private actuaries. Existing Medicare law, for example, focuses on "illness or injury" and "malformation of a body member," which excludes many disabilities.

All three Congressional proposals made some effort to expand coverage for these services, notably home care and personal assistance with activities of daily living. An issue of major importance to the future health care system is whether long-term care can be defined so as to be economically supportable, or whether ambiguous coverage standards may unintentionally encompass an even broader array of social services. If health coverage is expected to meet all the social needs resulting from a medical condition, that expectation must be made clear and appropriate resources devoted to meeting it.

Preventive Services

The HMO Act of 1973 expanded and promoted consistency in the provision of preventive services within HMOs. However, indemnity plans often continue to exclude

preventive services or subject them to the same deductibles as hospitalization, which has been shown to reduce their utilization excessively. All three Congressional bills mandated coverage of preventive services such as child immunizations and some screening tests which have been shown to improve health through early detection of disease. Even if overall coverage remains voluntary, national standard of this type would increase the use of preventive services. However, extending Medicare standards as in the House leadership proposal might limit covered preventive services to those enumerated in legislation or regulation. On the other hand, extensive procedural remedies such as those in the Senate leadership bill might encourage legal claims, including class actions, asserting rights to preventive services other than those specifically required.

Reproductive Health Care Services

As anticipated, abortion has occupied center stage in the national debate over reproductive health care. All three Congressional bills would have explicitly covered family planning and pregnancy-related services. However, none specifically covered abortion, and each contained a "conscience clause" allowing individual health professionals and facilities to decline to provide it.¹⁷ Given existing prohibitions on federal funding of abortion services, this type of coverage standard could lead to challenges against health plans that elected to provide abortion as part of the standard benefit package. In particular, Medicare's standard of medical necessity based on illness or injury has been interpreted narrowly as applied to reproductive services. For this reason, some policymakers advocate using a broader term, such as "medically appropriate," that would take into account other physical and psychological conditions.

Important issues regarding medical necessity also arise on the other end of the reproductive health spectrum. Demand is increasing for newly available services to diagnose infertility and assist fertility. The associated cost of this care is extremely high. No Congressional proposal has explicitly addressed this issue, although the Senate leadership bill required the National Health Benefits Board to study the potential inclusion of in vitro fertilization in the guaranteed benefit package.¹⁸ One difficulty with determining coverage using general standards of necessity or appropriateness is whether a distinction can be drawn between "normal" or "abnormal" infertility, and whether this distinction will blur as older people have children using newly discovered methods.

Specific Categories of Providers

Historically, covering a greater variety of providers has tended to increase cost.¹⁹ Virtually every category of licensed health care professional has lobbied for coverage of the services they provide in state or national reform legislation, either through mandated benefits or through "any willing provider" provisions. To reduce interest group politics and in recognition of the need for flexibility in order to improve cost-effectiveness, both Democratic leadership proposals refrained from specifying classes of health professionals whose services would be included in the guaranteed benefit package. The Mainstream proposal also followed this approach, specifically prohibiting the national benefits commission from basing coverage on class of provider.²⁰

Groups who are unsuccessful in the legislative arena may also elect to pursue reimbursement in court based on the coverage standards in federal legislation. A legitimate concern of some health professionals about the application of the term "medical necessity" to

coverage decisions is that services will be confined to the traditional medical model. "Medically appropriate" may be more broadly interpreted, although HCFA uses the term to indicate that services are provided by qualified personnel in a setting commensurate with the patient's medical needs. The ultimate cost impact of expanding coverage to a variety of health professionals through definitions of necessity or appropriateness that are not provider-specific is unknown.

IMPLICATIONS FOR REFORM: HEALTH CARE DELIVERY

Recent changes in health care delivery, such as the proliferation of HMOs and other forms of managed care, have important implications for coverage determinations as consumers, providers and insurers adapt to new roles and relationships. Coverage standards established in federal or state legislation must be attuned to today's rapidly integrating health care industry, and should not rely on increasingly outdated assumptions derived from an indemnity payment model of health insurance. This is particularly important if reform legislation expands access to a comprehensive package of services, increasing the need to contain costs through careful management.

Integrated Health Care Systems

The dominant trend in many areas of the U.S. is the integration and consolidation of insurers, health facilities and professional groups into corporate organizations and contractual networks that deliver a comprehensive package of covered services in exchange for a prepaid capitated premium. Coverage standards for these systems must balance potentially conflicting considerations. On the one hand, patients in closed networks require protection against underservice and rapid, accessible routes to appeal denials of benefits. On the other hand, health plans must be able to estimate utilization and administer claims predictably and efficiently in order to structure networks, work with providers and manage expenditures to meet the expectations of employers and other payers.

The leading federal reform proposals considered during 1994 would have imposed considerably more detailed coverage requirements on HMOs than do existing federal and state laws, including Medicare's "at-risk" program. Notably, the Congressional bills made few distinctions with respect to coverage standards and procedures between managed care and "fee-for-service" plans. By contrast, current HMO regulatory schemes generally require health plans to maintain grievance mechanisms and appeals processes, but do not specifically define the scope of coverage, largely because a private payer rather than government is responsible for approving or denying individual claims for payment. For example, the Federal HMO Act and state laws based on it, such as California's Knox-Keene Health Care Service Plan Act, require only that HMOs provide at least "basic health care services," subject to general principles of "medical necessity." For several reasons, the more intrusive approach taken by recent reform proposals might encounter difficulties.

The Convergence of Coverage and Care

Although federal reform proposals have relied on managed care to reduce waste and control costs, a related phenomenon -- that the line between coverage and care is blurring -- has gone largely unrecognized. In traditional fee-for-service medicine, care was determined entirely by individual physicians, leaving payment as the sole province of insurers. If disputes

over medical necessity or experimental treatment arose, clinical and financial issues were similarly separated. By contrast, mature managed care systems tend to merge health care financing and delivery, using common organizational structures and capitated financial incentives to involve payers in the structure of provider networks and physicians in the cost-conscious use of resources. As a result, the dynamic of coverage decisions and dispute resolution is changing.

A fundamental question is whether an integrated system can set parameters for coverage without affecting physician decision-making and the standard of care. For example, retrospective denial of claims is likely to become less common, except for out-of-network utilization in "point-of-service" plans. However, prospective decisions constitute actual barriers to care and must be made both in a timely manner and in accordance with principles of informed consent. A related issue is whether coverage denials in an integrated system can be monitored. Many *de facto* coverage decisions may not be identified as such because they are made by individual network physicians responding to new financial and organizational incentives rather than by a centralized utilization review process. There may also be a tension between the established law of informed consent and plans' and providers' desire to foster reasonable consumer expectations regarding coverage.

An important aspect of this trend that was ignored in the Democratic leadership bills is the potential for coverage litigation and malpractice litigation to arise from the same incident, increasing overall litigation risk for health plans and their affiliated providers.²¹ For example, failure to diagnose cancer can arguably be attributed to health plan guidelines for "necessary" screening, or a cancer treatment failure can be alleged to have resulted from a denial of access to "appropriate" providers or services. Although the Senate leadership bill included tort reform provisions, neither Democratic leadership bill dealt explicitly with potential malpractice claims against health plans, restricted coverage litigation, or considered the continued viability of ERISA's limitations on remedies. The Senate Mainstream proposal, on the other hand, limited remedies both for traditional malpractice claims and for allegations of negligent utilization review as well as for coverage denials, which would have helped discourage "claim shopping" by attorneys.

Health Professionals and Coverage Decisions

In a traditional fee-for-service environment based on third-party payment, decisions over whether a particular treatment was "appropriate" or "experimental" generally involve physicians advocating treatment and insurers defending contractual integrity. Congressional proposals have tended to follow this paradigm and have assumed a dialogue between the treating physician and administrative review staff. However, the demands on integrated health systems and their organizational structures may alter to some degree the relationship between patients and their physicians or other health professionals in coverage decisions and disputes.

Even with restrictions on financial incentives, which were included in all three Congressional bills, health professionals in managed care systems will tend to favor cost-effective care over leaving no stone unturned regardless of marginal cost or benefit. Dissatisfied patients may challenge their physicians' recommendations, and may seek support from unaffiliated practitioners with variable motives and incentives. Regulation of coverage decisions and appeals

will need to provide for the changing roles of individual health professionals and institutional processes in conveying information and avoiding or resolving disputes.

Purchasers, Consumers and Patients

The success of integrated health care delivery depends in large part on sophisticated purchasers and informed consumers making intelligent decisions about coverage and utilizing services efficiently. Coverage standards must accommodate this need and the changes it will produce in the relationships among participants in the health care system.

Active Health Care Purchasing

Whether as self-funded ERISA plans or as members of cooperative purchasing groups, employers and other sponsor organizations are evolving from relatively passive purchasers to active partners with health plans in integrated systems. As purchasers increase in power and sophistication, they will influence coverage standards and procedures through negotiation with health plans or by structuring provider networks. For example, the California Public Employees Retirement System (CalPERS) requires participating health plans to offer standardized benefits and co-payments.

Nearly all federal reform proposals considered during 1994 relied on employers to become more active purchasers and encouraged the voluntary formation of purchasing cooperatives (health alliances) to negotiate coverage on behalf of smaller companies and individuals. As discussed above, each of the three leading Congressional bills would have also specified the benefits to be provided. However, the usefulness of uniform coverage standards and procedures to facilitate comparison shopping may be outweighed for sophisticated purchasers by the reduced ability to customize benefits to their needs and financial resources. A second issue is reconciling the potentially conflicting incentives confronting large purchasers with respect to the beneficiaries they represent as individuals and as a group, especially for employers whose own funds are at stake. For example, recent litigation has begun to address the question of whether ERISA plan administrators designing benefits and making coverage decisions have a financial interest in aggregate cost-efficiency that conflicts with their fiduciary duty to individual beneficiaries.

Changing Patterns of Demand

The changing nature of demand for health care services will affect standards for coverage and procedures for resolving disputes. Over the last thirty years, coverage disputes have moved from the fringes of American medicine, involving "alternative" therapies and providers, to its high-technology heart. Different issues may arise in the future. As the population ages, for example, demand is certain to increase for care of chronic diseases and disabilities and for long-term supportive and social services. Determinations of necessity or appropriateness must adapt to these trends. Even the nature of "investigational" treatments may change somewhat as population-based health management takes on added importance and expensive research focuses on long-term effects of prevention or early treatment of large groups in addition to cutting-edge therapy for acutely ill individuals.

The benefits structures of the Congressional bills are conservative in the sense that they reflect current health insurance practices and clinical priorities. The Senate leadership bill in addition provided a mechanism for revision and adjustment through the National Health Benefits Board (the Mainstream bill authorized a benefits commission to recommend changes but not to impose them). One limitation of the Democratic leadership bills is that their procedural remedies appear to have been designed to deal with individual disputes over "big-ticket," high-technology therapies, which would occur relatively rarely. In the future, high-stakes disputes may arise over coverage of support services, preventive care or health promotion (such as education, diet and fitness) with less visibility and lower per-service costs but much greater potential utilization. New procedures may be required to ensure adequate coverage while avoiding burdensome class action litigation.

Health Plan Disclosure and Informed Consent

Individuals receiving care from integrated health systems require information in order to make effective enrollment and treatment decisions. In keeping with this, Congressional proposals have tended to require extensive consumer disclosure, including explanation of utilization review processes and grievance and appeal mechanisms. However, apart from general provisions in the Democratic leadership bills allowing enrollees to contest a health plan's compliance with law, it is not clear how administrative reviewers and courts would have interpreted these disclosure requirements, especially in relation to specific coverage denials. Another issue that may arise in integrated, closed-panel health plans is the relationship between disclosure of coverage standards and information given to patients as informed consent to treatment. Unless these questions are answered, it may be difficult for health plans to balance comprehensiveness of information with promotion of reasonable patient expectations and cost-effectiveness.

Controlling Expensive Technologies

At present, the majority of significant coverage disputes concern technology-intensive services such as high-dose chemotherapy with autologous bone marrow transplantation (HDC-ABMT). If primary and preventive care continue their ascendancy, and demand increases for quality more than length of life, coverage disputes may eventually focus on chronic care and social services instead of technology. However, as long as technologically sophisticated treatments retain their current mystique, disputes will continue to arise between patients and health plans as to whether or not "appropriate" means "cost-effective." Legislative standards and procedures may therefore need to address the use of expensive technology more directly.

Untested "Breakthrough" Therapies

A major challenge for health reform is to introduce the concept of cost-effectiveness into health care in a way that is ethically and economically acceptable. Cost-effective coverage standards are easier to appreciate in cases that allow comparisons to be made between alternative treatments. However, the most visible coverage disputes often relate to untested breakthrough treatments to which no arguably beneficial alternative exists, but which may offer a glimmer of hope for otherwise terminal conditions. Health plans have generally

found courts unsympathetic to their attempts to dispute the appropriateness of these treatments except in cases where a contract clearly excludes the specific service at issue.

Following current industry practice, recent Congressional proposals have not distinguished between these possible "breakthrough" therapies and other services except through comparatively vague definitions of "investigational" treatments. Because the bills mandated uniform benefit packages (including expansive requirements for coverage of costs associated with certain investigational treatments), left ambiguous the role of cost-effectiveness and offered extensive procedural recourse to patients, health plans probably would have an even harder time denying coverage of untested "breakthrough" therapies. Eventually, it may prove necessary to separate cases involving untested "breakthrough" therapies from other coverage determinations, and either to subject them to centralized approval or to devise ethically acceptable coverage standards based on the likelihood of achieving certain goals with respect to length and quality of life.

Technology Assessments and Clinical Practice Guidelines

Many health plans and other organizations are conducting scientific assessments of new technologies and developing protocols for clinical practice. These determinations may underlie definitions of necessity or appropriateness, or may be used as evidence when making individual coverage decisions. This trend has been incompletely recognized in proposed reform legislation. For example, neither Democratic leadership bill established an explicit link between technology assessments or practice guidelines and individual coverage decisions, although both bills assumed that health plans would establish and use guidelines.²² In fact, both proposals alternated between promoting the use of practice guidelines and technology assessments by expanding federal research funding, and protecting the rights of individuals who have claims denied by requiring extensive review of individual circumstances.²³

Only the Senate Mainstream bill dealt explicitly with the coverage aspects of practice guidelines, expanding the role of the Agency for Health Care Policy and Research in establishing guidelines, relating those guidelines to coverage recommendations by the National Health Benefits and Coverage Commission, and regulating the use of internal guidelines by health plans. However, neither the Mainstream bill nor the Democratic leadership proposals allowed reliance on practice guidelines or technology assessments to constitute a defense to coverage litigation or malpractice liability, which may prove necessary to promote cost-effectiveness and avoid litigation.

Moreover, technology assessment and guideline development are expensive, and consensus practice is hard to define for most health services. Additional legislation or regulation may ultimately be required to develop guidelines and perform assessments efficiently and to avoid inconsistency. However, to the extent that guidelines and assessments are established by government only for the most controversial and costly treatments, and are used to determine the scope of standardized, mandated coverage, ethical questions of rationing are likely to be raised.

Clinical Research and Academic Health Centers

Many disputes over the coverage of expensive technologies involve patients who, on their own or following their physicians' recommendations, seek specialized treatment at

academic medical centers, often as part of clinical research trials. These institutions are generally at the forefront of medical training and research, and exert considerable influence over policymakers, practitioners and the public. Moreover, as "centers of excellence" they may remain apart from, or maintain multiple affiliations with, integrated health care systems. In addition, direct government funding of clinical research at these institutions has declined substantially over the last decade because of federal spending cuts, making them more sensitive to the effects of cost-containment in the private sector. Recognizing these pressures, both Democratic leadership proposals and the Mainstream bill provided direct educational funding for academic health centers, and also indirectly endorsed their activities by requiring coverage of at least the routine medical costs associated with qualified testing of investigational treatments.

Adequate support for basic and applied clinical research will be indispensable to maintaining innovation in the health care system, and clinical trials are essential to the proper assessment of new treatments. However, it would be disingenuous to expect academic centers to base the extent and direction of their activities on "objective" factors unrelated to available funding. Requiring health plans to cover costs of clinical trials is certain to increase the number of treatments investigated and the scope of testing. In the final analysis, it may be very difficult to balance the need to test new therapies carefully with the cost implications of mandated coverage and the specter of rationing if government specifies both the treatments to be tested and the extent of testing. Also at issue is the degree to which academic health centers should continue to pioneer specialized technologies as opposed to devising new ways to manage the basic health of populations.

IMPLICATIONS FOR REFORM: THE LEGAL SYSTEM

Although many disputes over coverage are resolved informally, the most contentious claims eventually reach the judicial system. Coverage litigation is currently one of the most troubling business risks for health plans, as rapid changes in health care delivery to meet pressures for cost and access encounter a skeptical, entrepreneurial and individually focused legal system. This volatile mixture exploded in late 1993 in *Fox v. HealthNet*,²⁴ when a California jury awarded \$89 million in compensatory and punitive damages to the family of a woman who had been denied coverage of HDC-ABMT for breast cancer.

Experience has shown that courts are imperfect decision-makers with respect to medical necessity, experimental treatment and other coverage issues. As legislation is enacted expanding rights to health coverage, and as large organizations become more involved in health care delivery, the demands on the legal system and the consequences of its judgments are certain to increase. High-profile, emotional controversies such as the HealthNet case may reflect public discomfort with corporate decisions that are seen as having life-or-death consequences. Changes in dispute resolution that parallel other legal and structural trends in the health care system will be necessary to promote predictability and administrative efficiency while still assuring fairness.

Results Orientation of Judicial Review

The judicial process is accustomed to performing three functions: determining the law, assessing the facts and reaching a decision. In coverage cases (with the possible exception of those relating to ERISA plans), courts generally rely less on legal distinctions and more on factual medical evidence. Unfortunately, this evidence is often highly technical, requires the testimony

of competing experts, and may be beyond the timely understanding of judges and juries. The judicial process has therefore tended to search out support for the "right" result, often a humanitarian decision in favor of a needy patient.

If anything, the dispute resolution processes in the Democratic leadership proposals would have exacerbated these tendencies. Although the bills provided mandatory avenues of non-judicial redress, access to the courts was never foreclosed. In addition, each reviewing body would have been required to assess the circumstances *de novo*, providing additional opportunities to select evidence that supports the desired outcome. The Senate Mainstream proposal, on the other hand, provided for binding arbitration and judicial deference to federal administrative review except for cases involving preauthorization.

Urgency of Resolution

One factor that makes coverage determinations particularly difficult for courts is weighing an individual's urgent need for health care against an institution's long-term financial interest. The supposed "life and death" nature of certain treatments and the need for expedited review in the case of prospective denials by insurers add to courts' tendencies to make fact-specific decisions that err on the side of the patient. As a result, courts asked for injunctive relief nearly always require services to be provided, and leave the dispute over payment to be resolved afterward.

All three Congressional proposals required health plans to make timely initial decisions and reviews on appeal. The bills also made administrative mechanisms readily available. Unfortunately, the lack of binding effect granted these determinations in the two Democratic leadership bills would likely have increased the amount of hasty judicial review, which might well have succumbed to the temptations described above. For example, the House proposal explicitly permitted patients immediate access to the courts without exhausting administrative remedies if a claims denial could reasonably be expected to result in placing the claimant's health in serious jeopardy, serious impairment to bodily functions or serious dysfunction of any bodily organ or part. If courts continued their current practice of granting injunctions in most cases, prospective utilization review activities that are essential to managed care could have been seriously impaired.

Balancing Individual and Social Needs

Successful integrated systems will customize their services to suit defined populations in specific geographic markets. Assessments of community needs will influence construction of facilities, acquisition of equipment and affiliation with health professionals having particular specialties and skills. Contractual provisions governing coverage may be based on information regarding likelihood of benefit and cost-effectiveness in the population served as well as the circumstances of individual cases.

In order for health plans to promote this population-based view of necessity or cost-effectiveness, courts must uphold decisions made by consumers at the point of enrollment as well as decisions made by patients at the point of service. The key question is whether consumers can be adequately informed to choose a "system of care," possibly including limits on coverage and a non-judicial framework for resolving disputes, in advance of their need for

services. In the past, courts have often been reluctant to deny coverage even if, as a consumer weighing the risks of requiring care, a patient had made a rational decision to accept limited benefits.

As described above, none of the leading Congressional reform proposals allowed consumers to accept more limited coverage or abbreviated remedies in exchange for lower cost. In fact, courts applying those standards might have been particularly likely to overturn practice guidelines and technology assessments developed by health plans on the grounds that disclosure was inadequate or that health plans exceeded their authority to vary the guaranteed benefit package. This could have further impaired the cost-effectiveness efforts of health plans.

Liability and Damages for Large Organizations

Fox v. HealthNet and similar cases demonstrate that an effective framework for addressing coverage determinations in an environment increasingly characterized by large, integrated health plans must include issues of legal liability and, specifically, the availability and extent of money damages. Juries frequently increase the size of awards when corporate "deep pockets" are available, and have tended to express their distrust of insurers and suspicion of managed care in the severity of their judgments. Under current law, however, these cases tend to be brought only against plans not sponsored by employers. The fact that ERISA claimants are entitled only to the benefit at issue and not to compensatory or punitive damages, as well as ERISA's broad preemption of related state causes of action, greatly reduce the incentives for plaintiffs and their counsel to bring suit.

Reform legislation similar to the bills considered during 1994 may worsen the risk of unfounded suits and excessive awards. Neither Democratic leadership proposal explicitly limited damages otherwise available under state or federal law, and even the Senate leadership bill failed to cap awards in medical malpractice cases. Only the Senate Mainstream proposal curtailed damages in both medical malpractice and coverage suits. In addition, none of the bills provided a specific defense for coverage decisions made in reliance on established guidelines or technology assessments. All three bills, particularly the Democratic leadership bills, also raised the possibility that causes of action previously unavailable against ERISA plans will be permitted under federal health reform.²⁵ Provisions of this sort could accelerate current trends assessing huge damages against large managed care organizations, adding to cost and discouraging new entry.

RECOMMENDATIONS

The terminology and processes used for making coverage decisions in health plans will become increasingly important and contentious in the private marketplace and in the debate over state and national health reform. In the past, most coverage disputes were isolated incidents resolved through narrow contractual interpretation and deference to individual physician judgment. By contrast, the coverage standards that apply to tomorrow's integrated health care systems will have far-reaching consequences for our ability to provide universal access to high-quality, affordable health care.

Several critical questions currently confront state and federal policymakers, and the health care industry, with respect to standards for coverage and procedures for reaching decisions and resolving disputes. This Issues Paper has discussed several aspects of this complicated subject, illustrated by a description of the leading federal reform proposals considered during 1994. Based on this experience, and recognizing that these issues cannot be resolved overnight, we recommend the following approach to coverage issues in state or federal reform legislation:

Recommendation #1:

Health care reform legislation should define broad categories of health services for the minimum guaranteed benefit package instead of attempting to mandate details of coverage.

- Report language can describe what those categories of services mean and what limitations there might be on their scope.
- Health plans would be permitted, but not required, to provide additional services.

Recommendation #2:

Reform legislation should describe benefits simply as "covered services," defined by specific criteria, but avoiding value-laden terms such as "medically necessary" and "medically appropriate."

- Terms such as "medically necessary" and "medically appropriate" carry excessive baggage from prior usage in Medicare and private insurance plans.
- "Medically necessary" may be overly restrictive with respect to services such as health maintenance and promotion, while "medically appropriate" might be interpreted too expansively.

Recommendation #3:

Specific criteria defining "covered service," whether left to health plans or set forth in regulation, should be phrased in terms of meaningful benefit, acceptable risk and cost-effectiveness, each supported by sufficient evidence.

- These definitions must be crafted carefully and deliberately. The State of Oregon spent over a year educating the public and scientific constituencies, yet controversy remains.
- A prerequisite to effective legislation is building consensus within the scientific, policy, business and advocacy communities about how to define these terms and what criteria to use. Improperly devised standards could adversely affect the ability of managed care plans to deliver high-quality, cost-effective care.

Recommendation #4:

Benefits legislation should avoid expanding the responsibilities of private health plans beyond health insurance and health care (e.g., provision of social services or allocation of resources to meet community rather than individual needs).

- Many services not traditionally considered "health care" are undoubtedly beneficial to health. Unfortunately, coverage standards such as "appropriateness" may generate excessive and unexpected cost if applied to social or custodial services, unless they are clearly excluded from categories of required coverage or otherwise limited.
- Health plans may appropriately consider cost-effectiveness with respect to individual beneficiaries. However, specific government guidance will be necessary in order to balance individual with community needs or to identify services that should be available only on a limited basis.

Recommendation #5:

Current Medicare standards and procedures, although relatively well established, should not form the basis of coverage determinations for the future.

- Medicare's standards are based on government reimbursement of services provided on a fee-for-service basis. In the future, most health care will be delivered within organized systems receiving capitated payments.
- The inadequacies and fragmented nature of the current Medicare package and its "illness or injury" based definition of medical necessity make the extension of Medicare to new populations a problematic policy issue.
- Although there is a strong policy argument for consistency among the various health insurance plans under national reform, it will eventually prove easier to move Medicare's standards toward those of private plans than vice versa.

Recommendation #6:

Legislation to protect consumers should emphasize disclosure rather than compliance with uniform, specified processes for coverage determinations.

- Competitive forces will not improve the health care system unless individuals have both the economic incentive and the ability to make informed choices.
- Health plans currently use a variety of methods to make decisions and resolve disputes efficiently, many of which have been specifically upheld by courts.

Recommendation #7:

A health board or benefits commission composed of objective experts should be established to advise health plans, courts, and government with respect to scope of coverage and related issues, such as technology assessment. Case-by-case decisions, of course, should be made by individual plans.

- Every health insurance plan in the country defines and makes decisions with respect to coverage differently. Without some guidance from a public body expert in health care, courts reviewing private decisions are likely to reach fact-specific, inconsistent conclusions.
- More consistent and enduring terminology is likely to result from a slower, more deliberate process that is relatively sheltered from political pressure and can therefore address difficult issues such as cost-effectiveness.

Recommendation #8:

Additional legislation will be needed to streamline or guide the judicial process and prevent unreasonable awards while still adequately protecting the rights of individuals.

- Regardless of the care taken to define medical necessity and related terms, any government-endorsed benefit structure will create new issues to be disputed in the courts.
- The judicial system has not demonstrated an ability to resolve coverage disputes consistently, nor has it considered itself well qualified to make clinical judgments.
- The increasing involvement of large organizations in delivering health services predisposes to excessive litigation if unlimited remedies are available.

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SELECTED REFERENCES

Boren, Stephen D., Sounding Board: I Had a Tough Day Today, Hillary. *New England Journal of Medicine* 1994, Vol. 330, No. 7, pp. 500-502.

Eccles, Robert N. and David E. Gordon, Adams Case Illustrates the Confusion and Complexity of Determining Whether Medical Expenses Are "Experimental." *ERISA Litigation Reporter*, Vol. 1, No. 3, July-August 1991, pp. 2-7.

Hall, Mark A. and Gerard F. Anderson, Health Insurers' Assessment of Medical Necessity. *Univ. of Penn. Law Review* 1992, Vol. 140, pp. 1637-1712.

Harris, John M., Jr. and Douglas A. Schur, Insurance Law and Managed Care. *Internal Medicine World Report* 1994 (in press).

Havighurst, Clark C., Prospective Self-Denial: Can Consumers Contract Today to Accept Health Care Rationing Tomorrow? *Univ. of Penn. Law Review* 1992, Vol. 140, pp. 1755-1808.

Institute of Medicine, Committee for Evaluating Medical Technologies in Clinical Use, *Assessing Medical Technologies*. Washington, D.C.: National Academy Press, 1985.

Peters, William P. and Mark C. Rogers, Variation in Approval by Insurance Companies of Coverage for Autologous Bone Marrow Transplantation for Breast Cancer. *New England Journal of Medicine* 1994, Vol. 330, No. 7, pp. 473-477.

Physician Payment Review Commission, "Coverage Decisions and Technology Assessment," in *Annual Report to Congress* 1994, pp. 219-236.

U.S. Department of Health and Human Services, Health Care Financing Administration, Proposed Rule: Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions That Relate to Health Care Technology. *Federal Register*, Vol. 54, No. 18, January 30, 1989, pp. 4302-4318.

U.S. Department of Health and Human Services, Public Health Service, Process for Health Care Technology Assessments and Recommendations for Coverage. *Federal Register*, Vol. 58, No. 231, December 3, 1993, pp. 63988-63991.

U.S. General Accounting Office, Medicare Part B: Inconsistent Denial Rates for Medical Necessity Across Six Carriers, March 29, 1994 (T-PEMD-94-17).

NOTES

¹ The Issues Paper analyzes in detail the three proposals that survived in Congress the longest: the Democratic leadership bill introduced in the House of Representatives by Rep. Gephardt (Guaranteed Health Insurance Act of 1994, H.R. 3600, introduced July 29, 1994), the Democratic leadership bill introduced in the Senate by Sen. Mitchell (Health Security Act, S. 1757, introduced August 2, 1994), and the "Mainstream" bill being drafted for introduction in the Senate by a bipartisan coalition (draft of September 16, 1994).

² Paul T. Menzel, *Consumer Expectations and Access to Health Care: A Commentary*, Univ. of Penn. Law Review 1992, Vol. 140, pp. 1919-1922.

³ While the Senate leadership bill empowered a "National Health Benefits Board" to establish criteria and procedures for determining necessity or appropriateness and to promulgate regulations and guidelines with respect to particular services, the Mainstream proposal limited the authority of its "National Health Benefits and Coverage Commission" to making recommendations and establishing temporary policies pending issuance of formal treatment guidelines by other agencies.

⁴ The Senate leadership bill specifically required health plans to cover investigational treatments provided as part of a qualified research program. The House leadership bill and the Mainstream proposal did not force health plans to cover the investigational treatments themselves, but required coverage of associated patient care costs when research is conducted in "approved" or "qualified" trials.

⁵ For managed care plans (including point-of-service plans), the House leadership bill even requires that reviews be conducted, and determinations of medical necessity or appropriateness be made, by a formal board of appeals consisting of representatives of the health plan (including physicians, plan administrators and individual enrollees), individual consumers not enrolled in the plan and physicians with expertise directly related to the facts of the appeal.

⁶ Under all three bills, Medicare's processes -- basically a right to appeal and to receive notice of a decision -- remain unchanged, and would be extended to enrollees in the House leadership bill's new Medicare Part C.

⁷ It is also unclear that any pattern of decisions in preliminary, non-judicial forums would constitute binding precedent or even evidence to support a decision in a subsequent case. The Mainstream proposal, by contrast, provided for reporting of arbitration decisions to the Department of Labor in order to build a body of consistent precedent.

⁸ Under the Mainstream proposal, the Department of Labor, but not private plaintiffs, would be permitted to assess civil monetary penalties if there is a pattern of bad-faith claims denial.

⁹ Supplemental coverage might therefore include treatments that had been excluded from the guaranteed package as "investigational" or "inappropriate." For example, some consumers might desire access to certain transplantation techniques or cutting-edge reproductive health services

that are not included in the basic package. Some might prefer the services of alternative practitioners such as chiropractors or acupuncturists. Others might be particularly interested in a broader array of services for specific diseases such as breast cancer.

¹⁰ One question that might arise, however, if appeals or remedies were substantially restricted is whether Constitutional "due process" requirements were implicated.

¹¹ McGann v. H&H Music Co., 946 F.2d 401 (5th Cir. 1991).

¹² Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101 (1989).

¹³ The House leadership proposal imposed current Medicare requirements on self-insured plans, precludes binding arbitration of ERISA claims, overturned current limits on de novo judicial review and potentially allowed actions to be brought under federal law against self-insured plans for compensatory and punitive damages. By contrast, the Mainstream proposal retained most ERISA standards and in essence extended them to non-ERISA health plans, with the exception of subjecting ERISA plans to suit for negligent utilization review as a new federal cause of action.

¹⁴ Another reason why Medicare rulings are seldom controversial may be that program beneficiaries frequently rely on private supplemental coverage to make up gaps in coverage, and is often a secondary payer if other sources of coverage are available.

¹⁵ A principal feature of the House leadership proposal was a new Medicare Part C, which would have extended a version of Medicare to the uninsured.

¹⁶ The availability of de novo judicial review of contested claims (as required by the House leadership proposal) may also foster expensive litigation based on traditional interpretations of Medicare law that yields results incompatible with managed care. At the same time, current Medicare beneficiaries, including those enrolled in health plans offered by the same managed care organizations, would under both Democratic leadership proposals have much more limited rights and remedies than private plan members if care is denied.

¹⁷ By comparison, recent studies have shown that two-thirds of private insurance plans cover abortion routinely, with an additional fifteen percent of plans covering abortion subject to some limitations such as evidence of rape, incest, or danger to the life of the mother.

¹⁸ Apart from this provision, the Senate leadership bill left specific decisions to the national benefits board, the Mainstream bill relied on administrative and judicial interpretations of its coverage definitions, and the House leadership bill retained Medicare-based coverage standards of necessity, appropriateness and investigational treatments.

¹⁹ As health care delivery moves from a fee-for-service to a managed care model, however, a broader array of health professionals may be able to offer improved care at reduced cost.

20 Nonetheless, the House leadership bill expands coverage of certain chiropractic services, the Senate leadership bill increases opportunities for advanced practice nurses and amends Medicare to reimburse them to a greater extent, and the Mainstream proposal includes provisions specific to Christian Science.

21 A major issue is whether state law malpractice claims might be recharacterized as coverage claims under federal health reform laws to avoid potential ERISA preemption. A skillful attorney might also use procedures designed for one type of claim to build a record for the other.

22 The Medicare basis of the House proposal also suggested that OHTA and HCFA would continue to release national coverage decisions.

23 The House bill, for example, would have weakened incentives for private plans to develop and apply guidelines for investigational treatments or medical necessity because any conclusion drawn from those guidelines would have been subject to re-evaluation in each case by the plan's required board of appeals, which would likely have been prohibited from considering cost-effectiveness.

24 No. 219692 (Cal. Sup. Ct. Dec. 28, 1993). The case was subsequently settled for an undisclosed but substantially smaller sum.

25 For example, both leadership bills allowed private challenges to health plans' compliance with required standards and procedures, the Senate leadership bill directed claims review officers to award the benefit at issue, costs, attorney fees and "other appropriate relief" to successful claimants, and the Senate Mainstream bill set forth a new federal cause of action for negligent utilization review for which limited non-economic damages are available.

APPENDIX: COVERAGE DEFINITIONS

MEDICAL NECESSITY

DEFINITIONS OF MEDICAL NECESSITY IN LEGISLATION AND PRIVATE PLANS

LINDA A. BERGTHOLD, Ph.D.

(10/1/94)

I. DEFINITIONS IN EXISTING LEGISLATION

A. MEDICARE

Section 1862(2)(1)(A) of the Social Security Act: Prohibits Medicare payment for services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." The act specifically excludes certain services from coverage (e.g. cosmetic surgery and routine dental care), but it does not provide a comprehensive list of services and equipment that are either covered or excluded. The Act gives the Secretary of Health and Human Services the discretionary authority to identify medical services that are not medically reasonable and necessary for the treatment of illness or injury. (42 U.S.C. § 1395y(a)(1) (1988).

B. MEDICAID

The Medicaid statute has been construed similarly to require states to cover all "medically necessary services".

Examples of state definitions of medically necessary:

Florida: Covered outpatient services must be medically necessary, preventive, diagnostic, therapeutic or palliative services (Fla Admin. Code Ann. r. 10C-7.040(1992)). Requested service must be reasonably calculated to prevent, diagnose, correct, cure, alleviate, or prevent the worsening of conditions that threaten life, cause suffering or pain, result in illness or infirmity, or threaten to cause or aggravate a handicap, physical deformity, or malfunction, and there is no equally effective, more conservative or less costly course of treatment available.

Minnesota: Covered services must "(A) be determined by prevailing community standards or customary practice and usage to: (1) be medically necessary; (2) be appropriate and effective for the medical needs of the recipient; (3) meet quality and timeliness standards; (4) be the most cost effective health service available for the medical needs of the recipient; (B) represent an effective and appropriate use of medical assistance funds." (Minn. R. 9505.0210)

South Dakota: To be medically necessary, the covered service must meet the following conditions: (1) It is consistent with the recipient's symptoms, diagnosis, condition, or injury; (2) It is recognized as the prevailing standard and is consistent with generally accepted professional medical standards of the provider's peer group; (3) It is provided in response to a life-threatening condition; to treat pain, injury, illness or infection; to treat a condition that could result in physical or mental disability; or to achieve a level of physical or mental function consistent with prevailing community standards for diagnosis or condition; (4) It is not furnished primarily for the convenience of the recipient or the provider; and (5) There is no other equally effective course of treatment available or suitable for the recipient requesting the service which is more conservative or substantially less costly. (S.D. Admin. R. 67:16:01:06.02)

C. FEDERAL EMPLOYEES HEALTH BENEFIT PROGRAM (FEHBP) "PROTOTYPE" DEFINITION OF MEDICAL NECESSITY

Plans can negotiate a different definition.

Medical necessity means that services, supplies, or equipment provided by a hospital or provider of health care services associated with a particular plan:

1. are appropriate to the diagnosis or treatment of a patient's condition, illness or injury;
2. are consistent with the standards of good medical practice in the United States;
3. are not primarily for the personal comfort or convenience of the patient, family, or provider;
4. are not a part of or associated with scholastic education or vocational training of the patient;
5. in the case of inpatient care, cannot be provided safely on an outpatient basis.

The fact that a covered provider has prescribed, recommended or approved a service, supply, or equipment, does not, in itself, make it medically necessary.

II. TREATMENT OF MEDICAL NECESSITY IN PROPOSED LEGISLATION (1994)

A. LEGISLATION IN WHICH MEDICAL NECESSITY IS DEFINED SPECIFICALLY:

1. COOPER/BREAUX HR 3222

Sec.1302 SPECIFICATION OF UNIFORM SET OF EFFECTIVE BENEFITS

(a)(2) SPECIFICATION OF ALL MEDICALLY APPROPRIATE TREATMENTS

(a) **MEDICALLY APPROPRIATE TREATMENTS** -- The uniform set of effective benefits submitted under paragraph (1) shall include such categories of health care services that the Commission determines will provide for the delivery of medically appropriate treatment by the AHP.

(D) **ADDITIONAL COVERAGE** - Nothing in this paragraph shall be construed as preventing a plan from providing coverage of treatment that has not been determined (under subsection (b)) by the Commission to be medically appropriate for the purposes of this paragraph.

(b) **CRITERIA FOR DETERMINATION OF MEDICALLY APPROPRIATENESS FOR BENEFIT COVERAGE**

(1) **IN GENERAL** - An AHP is required to provide for coverage of the uniform set of effective benefits only for treatments and diagnostic procedures that are medically appropriate... a treatment (as defined in paragraph (6) (A) or diagnostic procedure is considered to be "medically appropriate" if the following criteria are met (as interpreted by the Commission):

(A) **TREATMENT OR DIAGNOSIS OF MEDICAL CONDITION**

(i) **IN GENERAL** - The treatment or diagnostic procedure is for a medical condition.

(ii) **MEDICAL CONDITION DEFINED** - The Term "medical condition" means a disease, illness, injury, or biological or psychological condition or status for which treatment is indicated to improve, maintain, or stabilize a health outcome (as defined in paragraph (6) (B)), or which, in the absence of treatment could lead to an adverse change in health outcome.

(iii) **ADVERSE CHANGE IN HEALTH OUTCOME DEFINED** - In clause (ii), an adverse change in a health outcome occurs if there is a biological or psychological decremental change in a health status or if the original endowment for a feature lies outside the normal range.

(B) **NOT INVESTIGATIONAL** - There must be sufficient evidence on which to base conclusions about the existence and magnitude of the change in health outcome resulting from the treatment or diagnostic procedure compared with the best available alternative (or with no treatment or diagnostic procedure if no alternative treatment or procedure is available).

(C) **EFFECTIVE AND SAFE** - The evidence must demonstrate that the treatment or diagnostic procedure can reasonably be expected to produce the intended health result or provide intended health information and is safe and the treatment or diagnostic procedure provides a clinically meaningful benefit with respect to safety and effectiveness in comparison to other available alternatives.

(2) **TREATMENT OR DIAGNOSTIC PROCEDURE CONSISTENT WITH PRACTICE GUIDELINES** - A treatment or diagnostic procedure that is provided consistent with a practice guideline established under Section 1309 (or its predecessor) is deemed to be medically appropriate.

2. CHAFEE/THOMAS - S.1770

Sec. 1301 - OFFERING OF BENEFIT PACKAGES

(b) **Covered Items and Services** - Subject to the procedures for clarification and modification described in Part II, covered items and services consist of the following items and services, but only when the provision of the item or service is **medically necessary or appropriate**.

(d) CRITERIA FOR DETERMINATION OF MEDICAL NECESSITY AND APPROPRIATENESS

SAME AS COOPER/BREAUX except for the introduction of the phrase "medically necessary or appropriate."

(1) **IN GENERAL** - A qualified health plan shall provide for coverage of the items and services described in subsection 9(b) only for treatments and diagnostic procedures that are medically necessary or appropriate. In the case of a dispute concerning a determination of medical necessity or appropriateness and subject to the succeeding provisions of this subsection, for purposes of this title, a treatment, (as defined in subparagraph (6)(A) or diagnostic procedure shall be considered to be medically necessary or appropriate if the following criteria are met

PART II - BENEFITS COMMISSION

Allows the Commission to develop and submit to Congress the clarification of covered items and services under Section 1301(b) - the Commission may propose to eliminate a category of items or services, but may not specify particular treatments or procedures to be covered.

Chafee version also introduces section (f) "Freedom to Offer Benefits " - Nothing in this section shall be construed to prohibit a health plan that is not a qualified health plan from offering any health care benefits.

3. ALTERNATIVE PROPOSALS IN WHICH THE TERMS ARE DEFINED:

A. MAINSTREAM COALITION (SENATE FINANCE) (6/27/94):

E4 - BENEFIT PACKAGES - MEDICALLY NECESSARY OR APPROPRIATE

"A Qualified Health Plan shall provide for coverage of the categories of benefits described in this section for treatment and diagnostic procedures that are **medically necessary or appropriate**.

An item or service is "**medically necessary or appropriate**" if, consistent with prevailing medical standards, it is:

- a. For treatment of a medical condition;
- b. Safe and effective (i.e., there is sufficient evidence to demonstrate that the item can reasonably be expected to produce the intended health outcome or provide the intended information).
- c. Medically appropriate for a specific patient (i.e., it can reasonably be expected to provide a clinically meaningful benefit if furnished in a setting commensurate with the patient's needs).

Criteria for determination of medically necessary or appropriateness are set forth. QHPs shall make all coverage decisions under these criteria. The Commission can, in limited circumstances, issue interim coverage recommendations.

B. THE MAINSTREAM PROPOSAL (9/16/94 - LAST VERSION RELEASED BEFORE THE OCTOBER RECESS)

SUBTITLE B - BENEFITS

Sec. 1106 - MEDICAL NECESSITY OR APPROPRIATENESS

(a) **IN GENERAL** - Health care interventions in the categories of covered benefits shall be covered by a certified health plan when medically necessary or appropriate. A health plan may, but is not required to, exclude health care interventions that are not medically necessary or appropriate.

(b) DEFINITION. A health care intervention shall be considered to be medically necessary or appropriate if:

(1) MEDICAL CONDITION

(A) IN GENERAL - The health care intervention is for a medical condition.

(B) MEDICAL CONDITION DEFINED - The term "medical condition" means a disease, illness, injury, congenital defect, or biological or psychological condition or status for which health care intervention is indicated to improve, maintain, restore, or stabilize a health outcome (as defined in section (1101) or which, in the absence of such intervention, could lead to an adverse change in health outcome or a deterioration.

(C) ADVERSE CHANGE IN HEALTH OUTCOME DEFINED - In paragraph (B), an adverse change in health outcome occurs if there is a biological, psychological or functional decremental change in a health status.

(2) SAFETY AND EFFECTIVENESS --

(A) IN GENERAL - The health care intervention is safe and effective.

(B) WHEN SAFE AND EFFECTIVE - A health care intervention is safe and effective if there is sufficient basis to support conclusions that such health care intervention can reasonably be expected to produce the intended health outcome and if the expected benefit for the enrollees of the health care intervention outweighs any expected harm.

(3) INDICATED FOR SPECIFIC ENROLLEE -

(A) IN GENERAL - The health care intervention is indicated for the specific enrollee.

(B) WHEN INDICATED - A health care intervention is indicated for a specific enrollee if, with respect to that enrollee's medical condition (and age), and in consideration with other available options, the health care intervention is appropriate and can reasonably be expected to provide a clinically meaningful benefit for the enrollee.

(C.) BASIS FOR DETERMINATIONS -

(1) IN GENERAL - Determinations pursuant to subsection (b) shall be supportable by evidence that includes one or more of the following --

(A) published peer-reviewed medical literature;

(B) opinions of medical specialty groups;

(C) general acceptance in the medical community; and

(D) recommendation of the Commission pursuant to this section.

2. PRESUMPTIONS - The following presumptions shall apply with respect to determinations under subsection (b):

(A) FDA-APPROVED DRUGS AND BIOLOGICS - A drug or biologic which is approved for marketing by the Food and Drug Administration is deemed to be safe and effective if such drug or biologic is furnished for treatment of a medically accepted indication (as defined in section 1927(k)(6) of the Social Security Act).

(B) FDA-APPROVED DEVICES - a medical device that has been cleared for marketing by the Food and Drug Administration is deemed safe and effective when used for the conditions, purposes, or uses prescribed, recommended, or suggested in the labeling of the device.

(C) PRACTICE GUIDELINES - A health care intervention furnished to an enrollee consistent with a practice guideline developed or certified by the Agency for Health Care Policy and Research under Section 912 of the Public Health Service Act is deemed to be safe and effective, but the omission of an item or procedure from a practice guideline does not give rise to a presumption that an item or procedure is not safe and effective.

Sec. 1101- DEFINITIONS. For purposes of this subtitle:

(4) HEALTH CARE INTERVENTION - The term "health care intervention" means any health-related item or service provided, with respect to a specific indication, to diagnose, improve, maintain, restore, or stabilize a health outcome or to prevent or mitigate an adverse change in a health outcome.

(5) HEALTH OUTCOME - The term "health outcome" means an outcome that affects the length or quality of an enrollee's life. Quality of life includes ability to perform activities of daily living, ability to work, relief from discomfort or pain, alleviation of fatigue, and cognitive, social, or emotional functioning and wellbeing, taking into account both the functional capacity of the individual and those functional capacities that are appropriate for individuals of the same age.

(6) HEALTH PROFESSIONAL SERVICES - ...professional services that are lawfully provided by a physician or another health professional who is legally authorized to provide such services in the State in which the services are provided.

(7) QUALIFIED INVESTIGATIONAL TREATMENT - ...an investigational treatment that is part of a peer-reviewed and approved research program (as defined by the Secretary) or research trials approved by the Secretary. A research trial is deemed to be approved for purposes of this paragraph if such trial is approved by one or more of the following: The NIH, the FDA..., the Department of Veterans Affairs, the Department of Defense, or by a qualified nongovernmental research entity as defined in guidelines issued by one or more of the NIH, including guidelines for cancer center support grants designated by the National Cancer Institute.

C. THE CHAIRMAN'S MARK OF THE SENATE FINANCE COMMITTEE (6/29/94)

IV. BENEFITS AND THE NATIONAL HEALTH BENEFITS BOARD

B. "Health plans would be required to offer a standardized set of covered services. Categories of covered services would be specified in statute. A National Health Benefits Board would be directed to refine covered services by reference to standards of medical necessity or appropriateness. **Medically necessary or appropriate treatments** would be defined by law as those intended to maintain or improve the biological or psychological condition of the enrollee or to prevent or mitigate an adverse health outcome to the enrollee."

AS AMENDED 7/3/94: "Qualified health plans would provide coverage for categories of services that are medically necessary or appropriate for the enrollee. Criteria for determination of medically necessary or appropriate treatments would be set forth (by the National Health Benefits Board)." (Term now used but not defined)

16. Investigational treatments, including routine care provided in research trials by the Secretary of HHS, the Directors of the National Institutes of Health, the Commissioner of the Food and Drug Administration, the Secretary of Veterans Affairs, the Secretary of Defense, or a qualified nongovernmental research entity as defined in guidelines of the NIH, including guidelines for National Cancer Institute-designated cancer center support grants; or a peer-reviewed and approved research program as defined by the Secretary of HHS.

B. PROPOSED LEGISLATION IN WHICH THE TERMS WERE USED BUT NOT DEFINED

1. CLINTON - S.1757

PART 4 - EXCLUSIONS

Sec. 1141 - EXCLUSIONS

(A) MEDICAL NECESSITY - The comprehensive benefit package does not include -

(1) an item or services that is not medically necessary or appropriate; or

(2) an item or service that the National Health Board may determine is not medically necessary or

appropriate in a regulation promulgated under Section 1154.

2. CHAIRMAN OF SENATE LABOR AND HUMAN RESOURCES COMMITTEE EDWARD KENNEDY'S MARK

(Same as Clinton language)

Part 4 - EXCLUSIONS

Section 1141. EXCLUSIONS

(a) **MEDICAL NECESSITY** - The comprehensive benefit package does not include -

(1) an item or services that is **not medically necessary or appropriate**; or

(2) an item or service that the National Health Board may determine is not medically necessary or appropriate in a regulation promulgated under Section 1154.

3. NICKLES - S.1743

Sec. 112. Family Security Benefits Package

(a) **IN GENERAL** - The requirements of this section are met, if the health insurance plan --

(1) provides coverage for **all medically necessary acute medical care** described in subsection (b),

(2) does not exclude coverage for selected illnesses or selected treatments if consistent with medically accepted practices, and

(3) meets the patient cost sharing requirements of subsection (c).

Nickles specifically excludes abortion services.

4. MCDERMOTT - H.R. 1200

Sec. 201 - COMPREHENSIVE BENEFITS

(a) **IN GENERAL** - subject to the succeeding provisions of this title, individuals enrolled for benefits under this Act are entitled to have payment made under a State health security program for the following items and services **if medically necessary and appropriate** for the maintenance of health or for the diagnosis, treatment or rehabilitation of a health condition.

5. ROWLAND - H.R. 3955

(3) **EXCEPTIONS** - Paragraph (1) shall not be construed as requiring a plan to include payment for--

(A) items and services that are **not essential and medically necessary**;

(B) routine physical examinations or preventive care (other than care and services described in subparagraph (D) of paragraph (1)); or

(C) experimental services and procedures.

6. MICHEL- H.R. 3080

SEC. 1102 - PLAN DEFINED

(a)(1)(B) the plan includes **only essential and medically necessary services**, including medical, surgical, hospital, and preventive services; except that no specific procedure or treatment, or classes thereof, is required to be covered in such a plan, by this act or through regulations.

7. SENATORS DOLE AND PACKWOOD S.2374 (8/9/94)

SUBTITLE B - STANDARDS FOR REFORM

PART II - INSURANCE REFORM STANDARDS APPLICABLE TO HEALTH PLANS

Sec. 21115- BENEFITS OFFERED (related to FEDMED benefits package)

(3) Medical Necessity or Appropriateness

(A) DETERMINATIONS BY HEALTH PLANS

(i) **IN GENERAL** - The determination of medical necessity or appropriateness of specific treatments or procedures shall be made by individual health plans with reference to criteria established under subparagraph (B).

(ii) **NEW PROCEDURES AND TECHNOLOGIES** - Health plans may make coverage decisions regarding new procedures and technologies with reference to the criteria established by the Secretary under subparagraph (B).

(B) **CRITERIA ESTABLISHED** - The Secretary shall establish general criteria for determining whether an item or service specified by the Secretary under paragraph (2)(B) is medically necessary or appropriate.

III. TREATMENT OF MEDICAL NECESSITY IN PRIVATE PLANS (Five examples)

1. **"Medically necessary"** means services or supplies, provided by a Provider Facility or Provider Individual, which are required for treatment of illness, injury, diseased condition, or impairment, (one plan includes **"pregnancy related condition"** in this list) and are:

- a. consistent with the patient's diagnosis or symptoms, and
- b. appropriate treatment according to generally accepted standards of medical practice, and
- c. not provided only as a convenience to the patient or Provider, and
- d. not investigational or unproven, and
- e. not excessive in scope, duration, or intensity to provide safe, adequate, and appropriate treatment to the insured. Any service or supply provided at a Provider Facility will not be considered Medically Necessary if the Insured's symptoms or condition indicate that it would be safe to provide the service or supply in a less comprehensive setting.

2. "Medically Necessary" means services or supplies (the Plan) determines to be:

- a. appropriate and necessary for the symptoms, diagnosis or treatment of a medical condition, and
- b. provided for the diagnosis or direct care and treatment of the medical condition, and
- c. within standards of good medical practice within the organized medical community, and
- d. not primarily for the convenience of the patient, the patient's physician or another provider, and
- e. the most appropriate supply or level of service which can safely be provided.

3. "Medically Necessary" means that, according to generally accepted medical practice, the service or supply must be:

- a. consistent with and appropriate for the treatment of the member's symptoms, illness, or injury;
- b. **of proven value or usefulness;**
- c. the most appropriate and cost effective level of service or supply which can safely be provided to the member as determined by the plan.
- d. not primarily for the convenience of the member, his or her family, or the provider.

4. "Medically Necessary" means that a procedure, service or supply is all of the following:

- a. appropriate and necessary for the diagnosis and treatment of your illness or injury;
- b. consistent with professionally recognized standards of health care determined within the State and given at the right time and in the right setting.
- c. **not more costly than alternative services that would be effective for the diagnosis and treatment of your condition.**
- d. enables a patient to make reasonable progress in treatment.

5. A service is considered "medically necessary" if it is:

- a. appropriate and consistent with the diagnosis and **could not have been omitted without adversely affecting the patient's condition or the quality of medical care rendered;**
- b. compatible with the standards of accepted medical practice in the United States;
- c. provided not solely for your convenience or the convenience of the doctor or hospital;
- d. not primarily **custodial care;** and
- e. the **least costly** level of service that can be safely provided.

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