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PHOTOCOPY
PRESERVATION

WHITE HOUSE COMMISSION
on
COMPLEMENTARY and ALTERNATIVE MEDICINE POLICY

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Meeting Topic I:
CAM: Understanding Coverage and Reimbursement

and

Meeting Topic II:
CAM: Research Challenges

+ + +

Volume I

+ + +

Monday, May 14 2001

8:15 a.m.

Academy for Educational Development
1825 Connecticut Avenue, N.W.
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Washington, D.C.

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C O N T E N T S

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PROCEEDINGS

[8:20 a.m.]

Opening Remarks

DR. GORDON: Good morning to the Commissioners. It is great to see everybody back. Good morning, everybody. I am Jim Gordon, and I am the chair of the White House Commission on Complementary and Alternative Medicine Policy. David Bresler will not be here, but the rest are here. So welcome everybody.

We have three days of hearings, and we are going to begin in a moment, but first I would like everybody just to sit quietly for a moment.

[Moment of silence observed.]

DR. GORDON: Before we start, I want to say a few words. We have a somewhat complex agenda these next couple of days. In fact, we are really doing two and a half agendas. We have the Understanding Coverage and Reimbursement, which will be the first topic we will cover for the next day and a half, and this afternoon, we are returning, for an hour or so, to discussions of Access and Delivery.

Everybody should have received the information,

the summaries, of the Access and Delivery packet from last fall. Did everybody get those that Joe, with Jim Swyers' help, put together?

So we will be working on Coverage and Reimbursement. We will also, then, be going back to Access and Delivery, and then tomorrow, finishing up with Coverage and Reimbursement in small group discussions. So there will be three different small group discussions, the first on Access and Delivery, then Coverage and Reimbursement, and then midday tomorrow, we will be moving into the final day and a half on Research.

The task here is to assimilate the information and the perspectives of the panelists who will be coming to talk with us, and also to really come up with a number of focused recommendations. So that is going to be the task of the small groups in each of these three meetings, and each of the small groups bringing those recommendations back to the larger group.

We are moving swiftly toward the Interim Report. This will be the last meeting before the Interim Report, at which we are going to be hearing people coming to us and giving us their perspectives. The July 2nd and

3rd meeting is going to be a time when we will be taking a look at all the recommendations that we have come up with, and most particularly of a kind of focused list of recommendations, and discussing those.

So, is everybody clear on what we are going to be looking for? Again, we have a wide array of speakers. People who are deeply versed in the issues will be coming before us the next three days. It is up to us to take in the information and to digest and assimilate it, and then to produce recommendations, to use a biological metaphor.

This morning, there is a good deal of material. Does everybody know Maureen, who has been enormously helpful to us, who has put together the panelists and a lot of background information for us?

So we are going to be working with an area that some of you are quite familiar with, that others of us are not nearly as familiar. Especially, the next day and a half, we are really going to have to sit back and assimilate.

I want to remind everybody, as if anybody needed reminding, this is really the time for us to be asking the hard questions. As Dean and others have

pointed out many times, coverage and reimbursement is indeed the bottom line, and if we are going to figure out how we address that bottom line, this is the time for us to do it, not only in listening but in really trying to understand and trying to ask the experts who are coming before us this next day and a half, how complementary and alternative medicine can best adapt itself to that bottom line, and how that bottom line can open up to include and encompass complementary, alternative and integrative approaches.

So Steve has a few words he wants to say about what we are up to, and then we will begin with the first panel.

DR. GROFT: Thank you very much, Jim, and good morning to everyone.

This is a very special meeting for the staff. This signifies the end of the issue-specific meetings. From here on out, the Commission members will be doing a lot of discussing and formulation of recommendations and plans for later on. So it will be extremely busy.

As Jim mentioned, we will have these breakout sessions, and while members of the public are invited to

attend those sessions, your participation will be restricted at that point. We really need the Commission members to discuss the issues. If you have any comments, members of the public, if you have any comments or suggestions, or even recommendations, there will be a staff person from the Commission staff present in the meeting. Please write them down and hand them to that staff person.

The schedule is so tight, I don't think it really will permit public participation. So this is one of the ways. As we have done all along, the staff is available whenever you would like to talk with us. If you would like to come in for a meeting, we are available, just call.

You can see our new address, same phone number. We have been working under very tight quarters. Like this meeting, where we are moving into the recommendation and report development stage, I think the new work environment will be conducive to the staff members starting to write and prepare the reports. So we are looking forward to the new quarters.

I also would like to encourage everyone to look

at the website for whatever you may need relating to the Commission. We now have all of the transcripts, the agendas, the Federal Register announcements, available on the website. We finally got that straightened out, and everything is quickly available.

After this meeting, usually we get the transcripts back within two weeks, and it goes up almost immediately. So whatever we talked about is available through the website.

As Jim mentioned, the next meeting will be July 2nd and 3rd, and we hope to get everyone out at a decent hour on the 3rd. We thank all of the families, the mothers, the wives, the friends, who permitted everyone to travel yesterday to get here. Give everybody a big hug when you get home.

Thank you very much.

MS. CHANG: Our first speaker, Dr. Michael O'Grady from Project Hope, Center for Health Affairs. Speakers, if you will, make sure that you speak directly into the mike for our transcriber. We will be timing you so that we keep on schedule ourselves, and if you will notice there is a little box on the table. Thank you.

Panel I: Overview of Health Care Financing in the United States

DR. GORDON: Good morning, Dr. O'Grady, and thank you for coming to give us this overview, to take on this daunting task.

Presenter: Michael O'Grady, Ph.D.

DR. O'GRADY: Does everyone have the slides in front of them from your briefing material? Okay, good.

I would like to talk to you this morning a little bit about the logic of health insurance, coverage, different benefit design to a certain degree, and the different ways that they have evolved over the last decade or so, because there have been a number of different changes that have gone on.

I want to start, briefly, with the logic of insurance, the role of insurance, beyond health insurance. When we think of what insurance really does, the key underlying principle is this idea of replacing an unpredictable and potentially catastrophic financial situation, and that is important in some sense. There is the other, catastrophic, but a financial situation that can occur, and replacing that with something that is

quite predictable and manageable as a financial situation.

So when we think of not only a catastrophic health event, your house burning down, stepping in front of a bus, something else going on, no matter what that happens to be, that is the underlying logic, the death of the main worker in a family. That is the underlying logic, to not face yourself with something that will bankrupt you, and you can't predict when it is going to happen.

That $2,000 premium that comes every year, year in and year out, for all its down side, does make sure you don't face that million-dollar bill, suddenly, one time when you don't know it is coming. Even if you did know it was coming, the million-dollar bill would probably wipe you out anyway.

Now, health insurance is a hybrid of what we normally think of as classical insurance because it also has this budgeting component. We normally don't think of going to our homeowner's every time we want to replace a window or clean the gutters. In health insurance, for a number of historical reasons having to do with things as

unrelated as wage and price controls during World War II, it has evolved into something that actually covers much more than simply catastrophic health events, the same way your homeowner's covers catastrophic homeowner events.

So we now have this situation where we are really paying for what would normally be thought of as routine expenses, which is sort of odd and unique in health insurance.

Now, on the next slide, it is certainly not limited to these four, but these are the four big ones in terms of when you think about the way health insurance is typically provided in this country. The traditional way is fee-for-service medicine, which, I will go into a little more detail, but that is pretty much what most people are familiar with. You submit a bill. You are reimbursed; reasonable and customary. An insurer is making an estimate of what is a reasonable payment and paying some percentage of that, with the beneficiary paying the rest.

Health maintenance organizations arrived on the scene a good 30, maybe pushing 40 years ago now, in terms of a different form, a capitated payment. There is no

longer an insurer, in the traditional sense, holding the risk. There is an organization of physicians and hospitals that has banded together to form a health maintenance organization.

Now, there are two new forms that are starting to pick up their popularity. The one I am about to mention has really become quite popular in terms of this response to both fee-for-service medicine on the one hand, and HMOs on the other.

The one is the Preferred Provider Organization. That is when you hear statistics quoted about 80 percent of Americans are now in managed care. To a certain degree, don't be misled to think they are all going to their Kaiser-Permanente group of 100 docs practicing in one building downtown. Much of that growth has been in these PPOs or Preferred Provider Organizations, which are a response from fee-for-service to some of the price and savings that you see in HMOs.

The fourth one that I would like to talk briefly about is the point-of-service plan, and this, again, is a response from HMOs moving more towards fee-for-service in order to offer people more choice, because

often the complaint in a traditional HMO is the lack of choice of a specialty provider.

Now, taking it a little deeper into each of these, the key characteristics, the essentials in a traditional fee-for-service plan, and there are certainly tons of them. This is what we typically think of Blue Cross Blue Shield, at least Blue Cross Blue Shield 10 years ago, Medicare, the traditional government-run program, not the private plans. This is what we normally think of as traditional fee-for-service.

Now, there is really, in effect, I say here, limited or no management by insurers. In the last five to six years, anyway, the Blues and some of the other fee-for-services have attempted to say that they at least do some minimal management. There is at least a passing of the data.

Well, here is a typical example I will give you of what they would do in terms of a notion of management in this context. You take a look at various physicians operating in a particular hospital, and you take a look at who is the most expensive, who is costing you the most. Let's say it is six people. Then you go back and

you dig, and you see who they are.

Well, you find that three of them are doing the hardest burn cases, the hardest cancers; they are really taking the toughest cases. Then you see three really don't have a particularly tougher caseload than anyone else, but they are just ordering more tests; they are bringing their patients back in that much more frequently.

That is the sort of thing that, in this environment, they are going to at least start to ask some questions about how that practice is going. That is normally referred to as physician profile.

Now, one of the less managed aspects of this, and a key thing in terms of thinking about the economics of what is going on, is, there is a payment per procedure, so you do it; you send the bill in later; they pay you. The more procedures you do, the more you are paid. So there is clearly an incentive set up, or at least there is no disincentive to continue to do more and more and more.

Certainly, this is quite limited in terms of its cost efficiency, and just in the competition that

goes on between different health plans, these sorts of plans have not been very competitive, especially in recent years, with HMOs and with these other hybrid forms that I will talk about in a second. Their premiums have gone up faster. They are not managing the benefit; they are not being careful.

The incentives for the providers, if there is anything, there is incentive to do more, not less. That has both its advantages and disadvantages, but at least in terms of, if you are in a situation where you are competing with other insurers to not have the highest premiums in town, that is not a great situation to be in.

Now, any financial risk here is held by the insurance company. It is important to keep that in mind here. One of the common themes will be, who is holding the financial risk. If somebody miscalculates in how much it is going to cost one year to the next in terms of this, who is left holding the bag?

In this case, the beneficiaries who have actually subscribed for this kind of coverage, they and their employers, as is typical, have shared the cost here, perhaps 80 percent employer, 20 percent being paid

by the worker. If that premium isn't enough to cover the costs that come in at the end of the year, they are not willing to come back to the insurance company and say, would you like us to give you another $1,000 for this year. It doesn't work that way. The insurer is on the hook.

If you would like to get into later, there are different models that have grown up that are a little different in terms of where employers actually hold the risk and let insurance companies simply manage the benefit, but I was trying to stay with key principles at this point.

Now, when we think of HMOs, the main thing going on there, the distinction is, the notion of a capitated payment, that in effect the HMO is acting like the insurance company. They are given a capitated payment, normally by an employer or whoever is purchasing the coverage. They are given that amount.

That gives them a certain freedom to do whatever they think is the right mix of benefits, services, providers, in order to offer coverage that will be satisfactory to the beneficiary, but it also means

that, with that, they hold the risk that if they miscalculate in what that premium is, they are left holding the bag, they are the ones who will go bankrupt, not the insurance company.

Certainly, there are very strong incentives, and it is a design for cost efficiency. Many people have said that they have gone overboard, that there is a question of quality. Now it is a situation when you have a capitated payment, it is the exact flip side of what we saw with fee-for-service.

You are, in effect, financially in a situation where you have greater incentives to do less, not to do more, in terms of, you have a set pot of money. If you use it all up on various services and bringing them in for more and more visits, that cuts into what is available for providers' salaries and other profits of the HMO.

So one of the things, rather than stay very general, to start thinking of some of the concerns that you folks might have, is, the HMOs have, in a sense, been more open than we normally see, certainly than some of the government programs like Medicare. They have been

more open to the idea of alternatives.

Now, to a certain degree, it is good medicine; to a certain degree, it is bottom line. They are certainly open to the idea of cost efficient alternatives: do you really need a physician to see this person in a traditional setting. You have a good group of diabetics. You are trying to tighten up their control. What can you do with a diabetes educator; what can you do with a nurse practitioner; what can you do with a dietician.

So that notion of an openness to something other than somebody with an M.D. at the end of their name, constantly seeing this person every time, or, certainly open, in terms of a cost sense, to people having an alternative to going to a hospital. It is quite clear to HMOs that the way that costs them the most money is when people are hospitalized. Hospitals going at $1,500 or so per day, certainly, avoiding a day or two of hospitalization, you have saved yourself a fair amount of money, given that that is roughly the amount that people are paying in their annual premium for the whole time.

So they certainly have been, at least historically, more open to alternatives. We will have to see how that continues in the future.

The Preferred Provider Organizations, I would like to talk to you a little bit about them for a second because they are sometimes thought of as managed care lite. They are the fee-for-service industry's response to what is going on in terms of the rise of managed care. What I have talked about so far has mostly been the financial incentive for providers.

What they also realized in most of the writing on fee-for-service medicine, is that one of the problems is that the beneficiaries have very little incentives themselves to be cost efficient. They basically cover their deductible, now typically maybe $250 for the year. They do have a certain amount that they pay, but they are paying probably at most 20 to 25 percent of any particular bill.

What a PPO design offers them, is, it offers them an option to go to a lower cost, for them, alternative. They can go to a provider for a $10 co-pay rather than a 25 percent co-insurance. They can see

different people, but they have to choose from the list of providers who have agreed to offer the insurer a price discount.

Now, some of your other witnesses can talk about how those contracts work. Let's say I am -- and I don't want to keep picking on Blue Cross Blue Shield -- so, Aetna or somebody, and you are coming in and you are dealing with a hospital in particular, and you take a look at this hospital and you say, my god; from our analysis of the bills and the claims and whatnot, it looks like we must be 35, 40 percent of these people's business. Well, we certainly are a very good customer.

So, at a minimum, you go to that hospital and you say, we know that at this point maybe 10 to 15 percent of your people are uninsured, and that is, in effect, to you, bad debt. Your prices are that much higher in order to cover that bad debt. Well, we know that if you come in and somebody has got our card, there is no bad debt; you will be paid. You may be squabble with us about whether it is the right amount you are paid, but you will not have bad debt if that person has an Aetna or a Blue Cross Blue Shield card.

So right off the bat, we really don't expect to be charged that extra 10 or 15 percent that you are charging everyone else who might be presenting a bad debt situation for you.

That is right off the bat, they are going to ask for some sort of a discount. As they said, they are going to look, and they will say, it looks to us like we are a good 30 or 40 percent of your business. Now, in any other business that is out there, if I am 30 or 40 percent of your business, don't I get some sort of volume discount. If you were an airline and we were buying that many tickets on your plane, we would expect some sort of a price break. Those are the initial rounds of things, as you can see in the economics of how you negotiate these things, you would want to do.

Now, PPOs even go a step beyond that. What they are asking -- normally, you will see it on both the physician and the hospital side, but I think we normally see it on the physician side -- is the notion where they are asking you to come forward and offer them a price discount. There are certain things in the contract that will also protect them against you, simply upping your

volume. If you used to see patients normally twice a year, you give them a 10, 15 percent discount and see them three and four times a year. So there are some protections in there. At least, the smarter insurers put those kind of protections in there.

What they are saying to you is that we would like a price break, and for that price break, what we will do is we will make it very easy for our people to come to you. Rather than facing the deductible and the 25 percent co-insurance, they will only face $10.

That certainly, at least in an emotional sense, can annoy quite a few providers, to have, all of a sudden, somebody come in; they used to charge $50 a visit, and now somebody says, we want you to charge our people $35. They are annoyed at that.

Well, the dynamic that is going on there is this situation, especially in areas where you see an over-supply of providers, and it is particularly true in specialists. So you are a cardiac practice, and you have got five or six guys; you have got a payroll to meet; you have got to pay for that very expensive equipment, and your waiting room is only 50 percent full; your

physicians are only seeing people, maybe, five and a half, six hours a day.

You have to figure out some way to fill up that waiting room. So if someone comes to you and says, yes, I know it is not $50 per person that you see; it is only $35, but here is an opportunity to fill up those extra two or three hours, especially if you are a young provider, just out, who hasn't built up much of a practice. This can be an attractive offer, especially if the alternative is to continue to only work, effectively, half or two-thirds time and have a big, empty waiting room, and have the durable medical equipment people coming by to talk to you about when they are going to be paid.

So that is the dynamic that is being offered here. It is traditional insurance in some sense. It is not a situation where these providers are on payroll the way we think of a traditional HMO, but at the same time, there is a negotiation based on price and there is also a set of incentives provided to the subscribers, to the beneficiaries, to the actual people who come and see you that will be given a price break on this if they come to

the providers that have agreed to this discount.

So the beneficiary saves money and the insurer saves money. It simply is an economic calculation on the provider side: Is this a deal that is worth making.

The one little point I wanted to make here, also, is what we talked about before. To digress quickly for a second, what you will see is, you will see amazing variation across the country in terms of what it costs to practice medicine, things that certainly drives the Medicare program crazy in terms of why it is costing their people $700 a month in Dade County, and $300 a month in rural Iowa.

They know that one is too high. One is probably too low. It is not like Iowa is the gold standard. Those people are having access problems and other things like that. But this sort of variation drives them crazy. As I said, in fee-for-services where you have an over-supply, especially, and if people are paid more the more procedures they do, part of those areas that are very, very high cost areas that have an over-supply.

As I say, sometimes of hospitals, sometimes of

specialists, there is not too many of them. So this, in effect, switches some of that incentive around from the insurer's point of view. From the insurer's point of view, an over-supply of physicians in a traditional fee-for-service is going to drive their costs up. In this sort of situation where you are asking providers to offer you a discount, and they are in fairly fierce competition with their colleagues, an over-supply of physicians drives costs down, or at least has the potential to, depending on how they negotiate.

Now, the fourth type of plan I would like to talk to you briefly about is the point-of-service plan. This is a response, the same way that PPO was a response from traditional fee-for-service to try and move towards some of the things they thought they could do that managed care was able to do: negotiating discounts; offering some price incentives for people; offering some sort of a break.

The point-of-service plan is the traditional HMO moving, to a certain degree, in the direction of fee-for-service. The main complaint there being the lack of choice of provider. This allows, in the sense you can

think that fee-for-service built an in-network benefit when they moved to a PPO, and an HMO as building an out-of-network benefit for themselves, to be able to say, if people are traveling or if people really have a particular provider that they were really very, very loyal to, that they could continue to see them, but come into their HMO and see the HMO physicians for the rest of their care.

It, in many, many ways, looks like a PPO in terms of, you see these differences between an in-network and out-of-network design. You go in-network, it is $10, no matter what the visit is. If you go out-of-network, it is a percentage, 25, 30 percent of the reasonable and customary charge.

Now, the key distinction between a PPO and a point-of-service plan is the notion of, do you need a referral. It is coming out of the HMO world, and therefore, if you go out-of-network, still there is a strong connection there of a gatekeeper and some notion.

Certainly, different plans have been diluting this down considerably over the last few years, but when you see people in either your own practices, if you are

providers, or when you sit in the waiting room and you hear someone say, well, I am in, whatever; I am in Kaiser, or I am in CareFirst, or whatever. Then you hear the receptionist say something about, do you have a referral.

Now, they are being careful. They are simply to be assured that they will get paid eventually, or they need to know that that person is really coming in and has agreed in effect, whether they know it or not, to pay 100 percent out of pocket for that care.

The thing that sometimes is missed on the beneficiaries is, none of these organizations are saying you can't go to another provider. They are just saying you will have to pay for it if you go to another provider.

So part of what is going on now, the PPOs and the point-of-service, within the last 10, maybe 15 years -- I think Abby could speak better to exactly when we first started to see them on scene -- it sets up a trade-off here, and it is a trade-off being offered to the beneficiaries; do they want to maximize choice of provider. They certainly can do that, but for that

greater choice, they almost always have to pay more.

Certainly, in recent years, it has been they pay more in premiums, but they also pay more in terms of the obvious out-of-pocket costs. That is where they are going to be paying a percentage of a charge.

In some of the more traditional plans, if the provider charges more than the insurance company is willing to pay, there is also the chance that the beneficiary, the subscriber, will be paying what we call balanced billing. It is a $100 charge. The insurer says, we don't think so; we only think it is worth $80 when we look at reasonable and customary in your area. So the beneficiary is charged 25 percent of the $80, and then the additional $20 difference between what the insurance company is going to pay and what the provider feels that they should be paid.

So certainly in that situation, for the beneficiary, for the subscriber, maximum choice, but also maximum financial out-of-pocket exposure. As we come down, you can save some more money if you go to a PPO, you can save even more on point-of-service, and eventually you are in the tightest control and the least

choice of provider in what we think of as a traditional HMO.

Now, what do we tend to see in terms of this? I don't know of anything systematic. We know some anecdotal sorts of things where what you will see, especially in the PPOs, is, you will see something where someone will have their longtime provider that they see, whether that is a general practitioner or someone. They will stay with them whether they are in-network or out-of-network, but then when they have something come up, they need to see an ophthalmologist, if they don't have a longtime ophthalmologist they have always seen, they turn to this, what is the network providers.

They certainly, at that point, can go back to old Doc Jones that they have loved and worked with for the last 20 years and say, are there two or three guys here on this list that you are comfortable with me seeing for ophthalmology?

And so, you can see this mixed pattern. There may be different things where they will stay with an out-of-network, more traditional provider that they have had for a long time to maintain that relationship, and pay

more for it, but if it is somebody that they don't have that long-term relationship with and the guy that they do trust has said, oh, yes, Charlie and Joe are just fine, they will save the money and go to the guy on the in-network list.

I wanted to talk a little bit in terms of the logic of why different things get covered and don't get covered. Correct me if I'm wrong, but certainly the medicine of it, you guys don't need me to tell you anything about, but this is more to think of the economics of it and, as Dr. Gordon mentioned, the business side of these things.

If a new benefit actually is going to increase costs, and the kind of people who are normally doing this kind of work are actuaries and benefit design people, and whatnot. There is, perhaps, a slight bias based on experience that normally new benefits do increase costs. No matter what they were presented as, over time they tend to increase cost.

Let's just say for a minute, you are looking at something that you know will increase cost, I mean, that certainly can be done, but it has to be done in such a

sense that you know that the people who are your bottom line clients, whether that is employers or individuals, workers and retirees, et cetera, et cetera, are going to value that.

The best example I can think of is prescription drugs. We are now in a situation, with the Medicare program, where there certainly is quite a debate going on about prescription drugs. Of the Medicare beneficiaries right now, if any of them think they are going to get prescription drugs without having to pay more, I don't think they have been paying attention to the news. They almost undoubtedly will be heavily subsidized. They won't pay dollar for dollar. They may pay 50 cents on the dollar, and the taxpayers will pick up the other 50.

For the most part, is that still a popular benefit? Sure. They are very interested in being able to expand and pick up this extra benefit of prescription drug coverage, even though they know that it will cost them more, because they value that benefit more than they feel they will probably be charged. That is quite true of any of these sorts of things.

So if there really is a compelling case, and

the insurer knows that the people are not going to flinch at whatever the premium difference is going to be by the new benefit being covered, that is not anywhere near as controversial a move as it might be otherwise. If it is something that they are going to start to cover but there will be quite a concern about the premium effects, and it is liable to make them uncompetitive in this often very competitive market, there certainly is going to be quite a bit of hesitation.

Now, the second situation is if it is basically cost-neutral, and we certainly have seen a couple of these. In terms of offering alternatives, that is certainly what is often put forward as the presentation of what you can do. It certainly is true if it is not going to cost anything more to the insurer, they have the option to remain agnostic on this. It is mostly in terms of when their actuaries go over it, is there some unpredictable cost that is hidden here.

The examples I have given are things that are treatment-specific. If you have coverage and you know you have got X number of diabetics, you have got 5,000 diabetics out of 100,000 people that you insure, and you

are deciding whether you are going to cover insulin pumps or not, well, you are pretty sure that somehow your exposure is not going to grow much beyond 5,000.

It is not something where all of a sudden, there is going to be an off-label use for insulin pumps. You basically know what you are getting into. You can work that out. You can say: insulin pumps; 5,000 people; $5,000 a pump; what do we think we are going to reduce in terms of hospitalizations; what do we think we are going to reduce in terms of other sorts of complications of these people; and what is it going to mean long-term.

Now, as I said, in terms of the weigh-off, if you decide that even if those pumps are better but they are still going to cost you a little bit of money, they may go forward and do it anyway as long as they don't think there will be too much of a push back from the employers or the beneficiaries.

Certainly, if you can look at it, know that it is contained, know that you are not suddenly going to find that people are coming out of the woodwork to ask for insulin pumps, you can know what you are getting into. That is basically it.

Now, capitated payments, the example I would give this is the debate that went on over mental health parity over the last five to six years -- well, I guess longer than that, because it certainly started around the time of the Clinton health care reform. This was a situation, especially in the managed behavioral health, where they came in and they said, at a minimum, we can guarantee you that this won't cost you any more. We can expand the kind of coverage we are doing for mental health. We can offer more, and because we manage it so well, it is not going to cost a dime. We will basically take the efficiencies out of managing it, and use that to expand benefits.

Not an atypical insurer response was, fine, and we will give you the capitated payment that we currently spend on mental health, and you will be responsible for these new expanded benefits. That way, if you can do it, more power to you; but if you can't, don't come back to us for more money.

So that, certainly, is another way. Is an insurer willing to move into a new area? Yes, if someone else holds the risk for them. That certainly lightens up

their decision-making process quite a bit.

The third one I just wanted to mention is, there are some that are really lucky when an insurer hits it, where you have something that adds value and doesn't add cost. The example, in terms of discussing with actuaries over the last decade or so, and this certainly is not true for the elderly -- this is not true for the Medicare population -- but for the non-elderly population, the addition of home health benefits was viewed as a great thing, because it was clearly a trade-off.

It didn't cost them anything more, but those workers, those employees, who suddenly saw they had this option to not sit in a hospital, to be able to go home, to have a visiting nurse, to have that sort of service, it increased the value of the benefit package to them. They saw it as more valuable and it cost the insurer, it cost their employer, no more money.

So that certainly was a great situation for them to be in. As I say, in the elderly, that is quite a bit different. It cost quite a bit of money.

Now, covering a new benefit. If it decreases

cost, everybody is happy; win-win; adds value; reduces premium; and also helps in terms of, you are offering more to the beneficiaries in terms of choice. You are offering them more benefits, in effect, and you are in a better price situation in terms of your competition.

If it something that you are really pretty sure is not going to increase your premiums, and there are not really decreasing premiums in this world, but there is slowing the growth of premiums, that is a situation where certainly they are quite open-minded to the idea.

MS. CHANG: Just to let you know, you have three minutes.

DR. O'GRADY: Sure. Don't even need it.

A couple of final points, just to think about. Clearly, much of insurance and much of when we think of coverage and what is going on, is based on incentives. There are incentives for the beneficiary, for the subscriber of the insurance, for the individual that is out there. There are incentives for the insurance company. There are incentives for providers.

To a certain degree, people often get very frustrated with that, especially with the insurance

companies. You can certainly get frustrated with them, but it is not the most productive thing if they are responding to the incentives that they are confronted with. So that is the dilemma in terms of thinking about this; do you want to try and think about how to respond to those incentives, or do you want to try and change those incentives, a tougher task. But, right or wrong, that i what is out there, is the only thing that I would, hopefully, leave you with.

The other thing to keep in mind here, when different decisions are being made on coverage and whatnot, that the final decision, whether it appears this way or whether it is even in the short-term, this answer, really does stay with the person who holds the long-term financial risk.

For example, let's take the very lean and mean squeeze-down of HMOs over the last five to eight years. Now, was that the HMOs just deciding that this was a better way to practice medicine, to deny care the way that they were, and to really question a lot more? No. They were basically receiving pressure from the employers, who are their major clients, their major

customers, that said that premium growth was getting out of hand, and that if this HMO could not keep premium growth down, they would go to another and they would take their business elsewhere.

And so, in times of very high premiums, they were receiving pressure from employers and other purchasers in order to keep it down. Now, did they go overboard? Sure. Some did, some didn't.

Just to keep in mind, when we talk about things like Medicare, Medicaid, we are talking the government, for the most part, and when we are talking about private sector, we are normally talking employers. If we are talking within an HMO environment, we have this mix of a number. To a certain degree, they have these outside clients with employers in the government, and at the same time, they also have their internal notions of what they need to do to meet the bottom line.

Thank you.

Panel Discussion

DR. GORDON: Thank you very much.

I just want to check with people in the audience. Can you hear okay? Can everybody hear okay?

Great.

Tom and Dean, Joe and George.

MR. CHAPPELL: Thank you, Dr. O'Grady. To the question of managing the risk for the insurer, I have two scenarios to ask you about. Would the insurer find acceptable a notion of the government providing reinsurance the same way reinsurance is provided in casualty lines when risk goes beyond the calculated?

That is my first question. My second question is, you were describing two types of insurance, the catastrophic, and then the budgeted. The budgeted example I think of is the industry's example to fund a dental hygiene checkup; no injury, no illness, just preventative maintenance.

Many of the CAM services fit into that preventative or potentially budgeted program. In your opinion, do you think the insurers could entertain either a reinsurance concept and/or a continuation of the concept of the budgeting approach for CAM services?

DR. O'GRADY: To take your second first, if that is okay. Assuming on the notion of budgeted versus long-term catastrophic there has been a logic there that

tries to be flexible, although it may not appear that way to the outside, in terms of that if there are things that you normally wouldn't cover, but that if it appears cost effective in that it is going to avoid something you do cover that is liable to be much more expensive, there is certainly a notion to a certain degree, depending on the insurer, kind of extra contractual agreements that are done, but it is also the idea of are you willing to cover certain things that might avoid a hospitalization down the line, which is always sort of the big ticket item that you are trying to avoid.

So I think that in terms of are they willing to pick up certain things that you would think of as being routine to avoid -- I think your example about the dental is fine, we don't normally think if dental hygiene as avoiding a hospitalization -- but are there other things that you could do. That is why they tend to be very generous sometimes on things, on immunizations, things that you know, if you get the kids the shots, you are going to avoid a lot of big, expensive trouble for those kids, sort of lose/lose; they-are-real-sick and you-are-out-a-lot-of-money situations.

So I think that there is more this idea of, if there is some notion of something that they do cover that is liable to have a cost effect, are they willing to be more flexible in terms of how they do that.

Different insurers look at that differently. The government is particularly poor at that, in that the government is not very flexible in terms of its ability to change its benefits. Let me draw a distinction because it is not fair to one of the next speakers. The Medicare program is not very flexible in doing it. FEHBP is not bad at all in terms of evolving their benefits and taking a look and being more flexible like that.

I am not sure that a reinsurance mechanism in some question like that, of, what is going on. Certainly, if there is a need for a reinsurance mechanism, it would be more on the catastrophic.

What we normally see on that in some of the things that have come up about covering the uninsured, where there is a subpopulation out there that has not had health insurance coverage, the insurers, the private market, is just nervous, it is just unpredictable. They don't know those folks. They don't know, given the same

age, sex, part of the country, whether they will be someone who will cost the same amount as people who currently have insurance.

Therefore, they are looking for someone to share their risk with, and the government is certainly a prime candidate for that sort of thing.

Now, you also had a question about reinsurance. In terms of? I'm sorry, I forgot your first question.

MR. CHAPPELL: The entities you have described are the beneficiary, the doctor, as far as discounts are concerned, and then the insurance, the private insurer.

I am simply suggesting that the government could be a fourth party in the system.

DR. O'GRADY: It could, yes.

MR. CHAPPELL: But insofar as we are trying to increase choice for consumers, the industry loses leverage on price. So the government can be an additional entity in that system as a concept.

DR. O'GRADY: It is, right. It can be. It can be in two ways.

There are two types of reinsurance that we normally think of in this sort of situation. Is

everybody comfortable with the notion of what reinsurance is? Okay.

There are those where smaller insurers band together, the private insurers. What they do is they band together. They know they pay into a certain pool and they spread the risk for costs over, whatever, $100,000, any cases, whatever.

The other one that has been brought up recently has to do with Medicare prescription drug benefit, where insurers will be responsible for costs up to a certain amount, but then in effect government-provided reinsurance picks up after that. The House Republican proposal last year had I think it was at somewhere around $7,000 or so, after that then the government would cover 80 percent of the cost over $7,000.

That certainly is a mechanism that does throw you into the same mix here of everyone else who is competing for budget money. That is not an inexpensive way to go, and that will be tax money and then subsidy from the taxpayers. So that then puts you in that whole political mix.

To a certain degree, I am glad you brought that

up, because there are two ways to go here. One way is the idea of thinking about this market, thinking about the insurers, how that sort of goes. The other way is to go the government route.

Now, that doesn't have quite the economic incentives that you face in terms of dealing with the insurance companies and employers and whatnot, but that puts you then in a different kind competition with people like the AMA and the AHA and other folks like that, which certainly can be done, but that is, in many ways, as tough a competition as the market competition.

DR. GORDON: Thank you.

Dean?

DR. ORNISH: Well, first I want to thank you. I thought that was a really great overview, and I appreciate it, very clear.

A couple questions. One of the things that you said very clearly was how financial incentives determine medical practice to a large degree, and that the idea behind HMOs and other iterations of managed care was to try to change the incentives for doing, say, procedures, and to look at cardiology, for example bypass surgery and

angioplasty, and yet if you look at managed organizations, you really don't find that kind of decrease in those kinds of procedures, nor do you really find the corollary to that, which would be an increase in preventive approaches or wellness or health education or CAM.

My first question is why do you see neither the reduction in procedures nor the increase in alternative approaches or preventive approaches when the incentives are supposed to be encouraging those two things?

DR. O'GRADY: I don't know that I can answer that. I'm not sure why you wouldn't. Are you sure that it is across the board that all HMOs don't? As I look at different HMOs, I find that their practices do tend to very and that there are those that simply are called HMOs but they certainly spend most of their time just negotiating discounts with providers.

DR. ORNISH: Right.

DR. O'GRADY: And I don't see the kind of behavior. There are others that we see that certainly have tried to do different things, certainly some of the disease-management programs, some of the things in end-

stage renal disease where the HMOs have been pretty effective. That is something again where they would want a very strong financial protection because those are very expensive cases, but they have been fairly effective in terms of managing them in a more coordinated sense, in terms of putting the team together and making sure that there is not this sort of sometimes disjointed care that you can get in a traditional fee-for-service environment.

I don't want to sound overly cynical about them in terms of that they are only out to make money. They are certainly not out to go bankrupt, that is quite clear.

DR. ORNISH: My question, though, is the whole point of HMOs and other managed care was to try to change the incentives. In a fee-for-service, as you said, the more procedures you do, the more money you make. In an HMO, it is supposed to be opposite.

DR. O'GRADY: Right.

DR. ORNISH: In practice, you don't find that. Likewise, there should be more of an emphasis, an economic incentive for preventive approaches, for wellness, for alterative interventions in a capitated

environment, but you don't see that either.

My question is I'm just curious why you might speculate that that is the case.

DR. O'GRADY: To speculate would be that some of the things we have seen from them are things where the cost effectives are clearly nailed down, and if they had some doubts about the cost effectiveness. I mean, certainly what we see is when you see the sort of cost effectiveness studies that are done by some of the large pharmaceutical companies, now those are very expensive to do, the use of ase inhibitors as a prophylactic against kidney disease among diabetics, something like that, but that is a very hard --

DR. ORNISH: That kind of begs the question, because if we again focus on things like angioplasty and bypass surgery, those have been covered since inception and yet those kinds of cost effectiveness studies have not been done. They don't prolong life. They don't reduce cardiac events for most patients, and yet those have been covered. Even now, there are no randomized control trial data showing, for example, that angioplasty prolongs life or prevents cardiac events.

So, I'm just curious, again, what is going on here?

DR. O'GRADY: I don't know.

DR. ORNISH: It is just the corollary to my question. Until we first understand why these aren't being done, it is hard to understand how we change that.

I mean, it certainly made sense to think that changing the economic incentives would change that, but it really hasn't, by and large, on either side, in part because I think there is a certain inherent conflict of interest that the same cardiologists who are deciding if you need an angioplasty are the ones who personally benefit, or for that matter a bypass, if you have the procedure, but still there are no checks and balances from the payment side.

As Jim is saying, part of our charge is to make recommendations, and to the degree that complementary and alternative medicine interventions are not affected by economic incentives, then what would affect that?

DR. O'GRADY: I don't know that I can accept your first premise here, that the economic incentives are not in play here.

DR. ORNISH: Certainly they are in cardiology.

DR. O'GRADY: All I'm saying is if they are not convinced that it is a cost effective alternative, whether you are dealing with a built-up momentum of a particular way of practicing over the years, certainly that is a tough nut to crack, and I don't have any particularly good advice on that one.

But the idea that these folks are certainly in fairly tight competition with each other to keep their premiums down, it may be a question of convincing them that this is something that actually will both provide better treatment and save them money. But if they are not convinced, they are not going to do it.

DR. ORNISH: This will be the last thing I say, but just without belaboring the point, but that presumes that the conventional interventions have been shown to be cost effective, and, by and large, certainly things like angioplasty, bypass surgery have not made that same test.

So the question is why is there a double standard, what can be done, and how if economic incentives are not really determining that, what are the factors?

DR. O'GRADY: I would say that certainly what you say is true on the idea that what has traditionally been done has not had to go over the hurdles that we are talking about here.

I would say that in terms of demonstrating cost effectiveness, that is the control case, and if you can demonstrate that you come in at a more cost effective manner than the traditional way of doing things, you have in effect demonstrated that the traditional way is not -- I don't know whether you want to say not competitive, but is not necessarily the preferred route, compare both in terms of medical outcomes and in terms of how much it costs, but I don't know quite else what to tell you.

DR. PIZZORNO: I have about four questions. First, how do *-- [off mike].

DR. O'GRADY: Some of those I can't answer, like the percentage that goes to billing, but I certainly can take a crack at a couple of them.

Certainly medical savings accounts is one that I have done a fair amount of work on, both in terms of thinking about for the general population and the not-very-long-lived Medicare version of medical savings

accounts. I listed the big four here. Medical savings accounts and probably physician sponsored organizations, PSOs, are five and six, neither of which has picked up very much market share in terms of enrollees, but are interesting alternatives.

Medical savings accounts are certainly the idea, and normally it is not just a medical savings account, it is an account that looks like a health IRA in some sort of a sense, linked with a high deductible plan. The idea, again, is to go to beneficiaries and give them a strong financial incentive to be prudent consumers of their own health care.

So the idea is that they typically have a $250 deductible, they now have a $2,500 deductible. Really, it is moving the insurance back to that more classic model of, it is there for catastrophic events to occur, the idea being that if you move someone from a $250 deductible to a $2,500 deductible, their premiums should come down. You are not covering that much more of the expenses that go on.

How do you then share those savings back with the beneficiary? The idea is that the premium reduction

there is put into an account that gains interest, that has certain tax advantages to it if you leave it there and let it roll over, the same way it would in an IRA.

If you have a particularly bad year and have $2,500, you can use that account to pay your $2,500. If you don't and it accrues over time, you can get it out the same way you could get out an IRA, or you can use it for long-term care expenses and continue to have the tax advantages.

A couple of years ago, maybe more than a couple now, four or five, this was presented very strongly to Congress by a number of large insurers as a great new idea. It was probably oversold to a certain degree. They were, at that point, pushing that it could reduce premiums in half. Most of the independent estimates were more like 25 percent, but reducing health insurance premiums 25 percent is nothing to sneeze at. That is really quite substantial.

The opponents thought that it was going to come in and be just terrible, that it meant a lot of people were not going to get needed care, et cetera, et cetera. The bottom line is that, what it has worked out to be is,

in effect, a sort of targeted product.

It works very well for people who are fairly high-income, who work in small firms; architects, lawyers, physicians, those sorts, where you have five or six partners who are in some sort of an operation that $2,500 deductibles are not going to stop them from getting needed care, they are making $75-, $100,000 or more, a year. So it doesn't have the negative sides. Those folks can now get a lower premium.

It is very hard to get insurance -- I don't know how many are in this boat -- if you really are in a firm of 10 or 12 people or less. So this allows them a break on that.

It has turned out to be something, at this point anyway, of a niche product and served that particular niche quite well. Some of the analysts who have looked at it view it as sort of an income-related deductible, that you have basically talked higher income people into taking a higher deductible, and you share the savings with them. It works fine for 5 to 10 percent of the population. It hasn't really caught on in other than that particular 5 or 10 percent of the population.

Physician-sponsored organizations, the other one, is the idea of physicians actually banding together to form their own insurance company, in some sense. That has not taken off, that I am aware of, while there are a few. In 1997, there was a change in law that allowed them to form. How they significantly differ from a physician-owned HMO? Not totally clear what the big distinction is there between them.

Like I say, they were an idea that was thought would really catch on. I think that doing the insurance side of the business, in many ways, is a lot harder than some providers think when they get into it. They are not actuaries. This idea of, what is the right premium to charge people, is a pretty tough calculation to make and to do it well. So that is the MSA side.

Certainly, I have no idea what physicians now spend in terms of their expenses. There is this idea, in terms of when you look at this sort of continuum of HMOs, point-of-service, PPOs, there is some idea there of different providers, and it is almost a generational effect.

Who is it that can afford to still have a full

waiting room and not have to consider offering discounts, or not have to wonder whether it is time to simply give up trying to have this whole business side of things and just go work for the HMO and take that salary?

The correlation tends to be that that tends to be older, more established providers who can continue to do that and operate in a more traditional way. The younger guys feel a certain financial pressure to either offer price discounts or to just say I can go down to Kaiser, they will pay me $120 a year and I can go home at 5:00.

DR. GORDON: Joe, I want to move on because there are two more.

DR. PIZZORNO: The other question was of these four plans, which tend to be more receptive to inclusion of CAM providers?

DR. O'GRADY: Until Dr. Ornish said what he said, I would have said the HMOs because they tend to be more open to alternatives that will save them money, but he doesn't seem to feel that they are very open.

So, in that sense, I think it is back to the idea of what my final point was, to a certain degree

whether things are going to be covered or not is going to go back to the people who pay in the end, whether it is the employers or the beneficiaries themselves who push for these kinds of benefits to be covered, which is where, to the earlier example, where coverage of things like dental came in.

There was a push for it, the beneficiaries wanted it, and where people had choice, they chose the plans that offered dental coverage and they moved out of plans that didn't. So, again, it was a market response to say I better offer some dental coverage here or I'm going to lose customers.

DR. GORDON: George?

MR. DEVRIES: Dr. O'Grady, thank you for your overview and introduction to third-party reimbursement systems. My question, two of them, really are along what are some practical steps that are happening related to introduction of CAM benefits into third-party reimbursement benefit plans?

I am speaking of, specifically, one thing we are seeing out there is a health plan, an HMO may not cover chiropractic or acupuncture or massage therapy or

naturopathy for all their members as a mandated benefit, but they might do a supplemental benefit rider, much like they do dental, vision, behavioral health, or pharmacy. Blue Cross Blue Shield of South Carolina is going to testify today. They are rolling out this type of program.

So your comments on that kind of incremental approach to at least starting inclusion of CAM benefits within health plans.

Then, secondly, maybe some overview from you related to you had mentioned the concept of behavioral health care management firms, and we see that happening a lot in the CAM side, where there are basically specialty vendors that work with the health plan, much like pharmacy, dental, vision, organizations also do. So maybe some comment there, maybe drilling down a little bit and giving us your thoughts in terms of how some of the inclusion of CAM into health plan can practically be achieved?

DR. O'GRADY: First of all, to think about the idea offering as kind of supplemental rider in some sense, the one thing you want to be careful of there is

that much of insurance is spreading risk over large numbers of people, some who will use the benefits, some who won't.

I guess my advice would be you would have to offer a variety of different benefits bundled together. Where we have seen individual riders at times, they can be very expensive because the only people who sign up for them are those who have a pretty good likelihood that they are going to use them.

MR. DEVRIES: Just a comment.

DR. O'GRADY: Yes?

MR. DEVRIES: Being offered as group riders, not individual riders.

DR. O'GRADY: Yes. And that gets back to the earlier point about the idea of if there is enough of a push from the employees in a particular firm, that they are asking their benefits people and it is sliding back up that what our people are looking for is this kind of benefit to be added, the same way, like I said, dental before or I guess even bigger would be when prescription drug first came in 10, 15, 20 years ago, that it is a perceived demand for it.

Also I guess I would say that the idea of saying that you have the ability to sort of pop it in, pop it out, depending on what that is, that they don't have to change every piece of insurance that they offer in a particular state to include it has got to be more attractive than all of a sudden they find that it is a state-mandated benefit and if they want to operate in their state, they have to do it. Yes, that is much more attractive.

On the carve-out notion, I think again, like with the mental health, the idea is that if there is some way to carve out and there was some notion that someone other than the insurer is at least sharing in the risk, if not accepting it outright, again, that tends to make things look more attractive. So the behavioral, mental health people, I didn't want to leave you with the impression that tons of those behavioral, mental health folks necessarily came forward and said, yes, we will take all risks, that was sort of the put-up or shut-up sort of point in those discussions that I could see, at least in terms of whether there would be federal benefit change. If these guys are so sure it is going to save

money, then let it be their money.

DR. GORDON: Joe Fins.

DR. FINS: Thank you for your comments. Your last line talks about the insurers responding. We can't blame them for responding rationally. But another way of looking at it is that they are responding entrepreneurially in offering low-cost, relatively low-cost CAM benefits that will increase market share. We have heard that from previous witnesses.

So, is it rational or is it entrepreneurial, and what should the standards be, and how do we regulate it so that patients and buyers get the best set of products that enhance health, not the ones that increase margin?

DR. O'GRADY: The question is how do you overlap those two? How do you make it quite clear?

That is, I guess, without sounding like a broken record, is back to the idea of convincing the employers and the beneficiaries themselves that this is something that is of value to them, that they ask the insurer to do it.

I don't want to discount the notion of

convincing insurers that it is a cost-effective alternative, because that certainly lowers whatever other hurdles there are, but if you are going to make an argument that even if this does cost more money, it is just better medicine and it should be covered, that is certainly a reasonable argument to make. Then it is back to the idea of can you demonstrate that it is worth it.

DR. FINS: What I'm asking, though, are there different sets of standards that if the industry has an economic advantage by offering a product that costs relatively less compared to other items, say we can increase our cherry picking in this context, get well people who are into health promotion, who have good lifestyles, who will cost us less, that not only is it going to cost less, it is less filling.

DR. O'GRADY: Right.

DR. FINS: So, how do we not create another set of perverse incentives and graft on to the incentives that are already problematic in offering, if we do offer, a set of CAM benefits or consider that?

DR. O'GRADY: The alternative to simply convincing them on a cost-effectiveness basis or on that

this will be, as you put it, the entrepreneurial attractiveness of it is to certainly -- and we have seen this in other sorts of benefits in the past -- is to take a more public point of view in terms of either state legislatures or coming to Congress and saying this really needs to be a covered benefit, even if it costs more, even if it is not to the market advantage of particular private firms, it needs to be done.

That is certainly another discussion in terms of the incentives there and who you are in competition with for that limited budget or just simply saying that this is. It is certainly not unusual to see at the state level something of these are the benefits if you want to offer coverage in this state that you need to be able to cover as a minimum. Certainly the Medicare benefit package is quite clearly laid out of what is covered and what is not expected to be covered, acute care, and it is laid out in the statute. That certainly is another way to go.

It is a question of, certainly, is if it is viewed as something that will not raise cost significantly, or let's go with your entrepreneurial

notion again, disproportionately. If everybody knows that because something is going to happen, their premiums are going to go up 2 percent, but their competitors premiums are going to go up 2 percent, entrepreneurial they are not disadvantaged by that. But that normally does mean a more public-policy sort of response, which is what we have seen the mental health providers doing, they are pushing for parity.

DR. GORDON: Charlotte?

MS. KERR: Thank you, Dr. O'Grady. I'm looking at your bio, and I see that your present work is focusing on Medicare reform issues, and I would assume certainly a part of that is the prescription drug coverage.

DR. O'GRADY: Yes, it is.

MS. KERR: Some people, including some of us, would probably think when you look at how to meet the needs of, in this case, Medicare, the elderly, that things like botanicals and perhaps homeopathy might meet some of those needs. What I am wondering is have there been steps to investigate the use of these alternatives in your process in planning in Medicare, and, if not, why not, not from a point of view of blame, but what would

you need, for example, to be able to consider these alternatives in a rational way? Do you have representatives, for example, of CAM in your planning teams? You have got the point of my question, take it from there.

DR. O'GRADY: Sure. I don't think anybody has drilled down enough to say what you would list out on a particular proposal of what would be covered and what wouldn't.

What they have done, to a certain degree, and there is certainly an ongoing debate about how much choice you allow and how much variation you allow. Part of it is the concern that was mentioned before, the idea that to a certain degree there is a certain school of health economists, and certainly, the actuaries who tend to look at that, that you don't want tons of variation.

Now, that has to do with, simply, if you have five different insurers that are offering something, the best way to be sure that people are the prudent consumers that they want to be is if they offer the exact same benefits. And so, you know the real difference is your perceived quality of what you are getting and what you

are paying for it. That makes the transaction as clean as possible.

The alternative is one that says, well, no, really you would like to be able to have different people sort of try and meet the needs of different groups. Now, they know that anyone has to be careful. You want to be very careful about the idea of the cherry-picking that was mentioned before, that you simply pick off the healthiest people, and you have a very low premium because you have people who never reach their deductible, much less have any hospitalizations. Therefore, you are manipulating the game rather than being a cost-efficient provider of care.

So, long way around, in terms of thinking about this and thinking about the options, it comes down to this dilemma, in terms of an option, to a certain degree those proposals that talked about there being one provider in a particular region, the government list of what is offered -- not the government -- for the most part, they would contract out to a pharmaceutical benefit manager.

The Clinton plan had this design. The country

would be split into X number of regions. HCFA would give the contract to a particular provider, who then would negotiate with all the drug companies and work up what would be offered.

That has certain large-volume buying advantages in terms of, you are buying for all the Medicare beneficiaries in these four states or whatever. It has certain disadvantages in terms of, that does not allow tons of variation. Now, if you happen to get your stuff on the list, you are made in the shade, but if you are not, if you are an alternative, that is a little iffier.

The House Republicans had another proposal that had its own warts in different ways, but it did have more of the idea that you would have multiple different coverage in a particular geographic area, so that if someone decided they wanted to offer X or Y, there would be some allowance of variation.

Now, most of the variation in that, I have to say, was being discussed, more, the idea that we know that with people like the Medicare population, there is a wide variety in terms of their incomes. So that, the same way we see this, in who chooses HMOs versus who

chooses fee-for-service, that for lower-income people, they are willing to give up some choice to reduce their expenses, and that higher-income people do not.

No one that I am aware of has gotten to anything that has said anything, one way or another, about what would be included, how tight formularies would be, those sorts of questions.

MS. KERR: My question gets back to something Dean Ornish was speaking to, and I am actually asking a question in a way that I wonder if there is something you need for us to help in with this kind of problem solving.

For example, is it the research? Is it the body that actually gets in the room? We happen to know a particular program our colleague has in cardiovascular work -- I don't know the proper name, Dean, of what you call your program -- but, there is data there to say that this may be more successful than angioplasty. That is a good question, why isn't that there?

In the same way, you may not have the data that the pharmaceuticals have given you -- I can't think of any drugs at the moment -- for homeopathy or botanicals. I am asking a very simple question. Is that so? Is it,

the data is not there? Is the person, the body, not in the room to bring up the conversation? Or, can you say yourself, and you are an expert -- just reflect a little more, now or later -- what would be an intervention? Where would the needle go to bring about a new conversation, speaking as an acupuncturist?

DR. O'GRADY: I guess at this point, in terms of, if you are talking about various treatments or procedures, or whatever, that are not part of the status quo, it is hard for me to see that, under a model that has one plan for the entire region, that you are going to do better than one that allows there to be four or five of them to be in competition with each other.

I certainly may be wrong on that. It may be that there is some race to the bottom, quickly, among the four or five to not offer anything other than generics. I have not seen plans that look like that. Again, it comes down to what is perhaps the overall dilemma here, is it a market-based approach to expand coverage or is it a government-based; I guess, who do you want to lobby, insurers or Congress.

DR. GORDON: Thank you very much. We really

very much appreciate your testimony.

DR. O'GRADY: Thank you.

DR. GORDON: One of the things we would like to do, if this is okay with you, is to give you a transcript of your testimony, and if there is anything you would like to add to it, on reflection --

DR. O'GRADY: It depends on how open you make that offer.

DR. GORDON: That would be great.

DR. O'GRADY: Thank you.

DR. GORDON: One thing I want say to the Commissioners before the next panel comes up is, we went 10 minutes over time on this panel. I am trying to think of ground rules that will make things move along. I think we should begin with just asking one question each, and then we can come back if there is more time.

The other thing is, I am going to ask all the panelists who are coming forward to answer as succinctly and as to the point as possible. That way, we will be able to have more back-and-forth dialogue. Thank you.

Panel II: Federal Purchasers

MS. CHANG: Panel Session II. If Dr. John

Whyte and Abby Block would come up from the Health Care Financing Administration and the U.S. Office of Personnel Management. Thank you.

Again, I will remind the speakers to speak directly into the microphone. I will give you a three-minute warning, just so you know when to sum up.

Presenter: John Whyte, M.D.

DR. WHYTE: Good morning. I think you have a copy of most of what I'm going to say in front of you. I'm John Whyte, and I'm a general internist by training. Presently, I am the Acting Director of the Division of Items and Devices at the Health Care Financing Administration.

I want to thank Maureen Miller and Steve Groft for inviting me to speak today. Steve, Maureen, I think Joe Kaczmarczyk, and I, had a very good meeting about two months ago at HCFA, and I am delighted that we are able to come here to continue to build upon that relationship and really create a dialogue, and to exchange information.

We have had several meetings with the National Center for Complementary and Alternative Medicine. I

will be here most of today and others from HCFA will be here some of the other days to answer any questions you might have, because we really look at this as a dialogue and not as a single point in time.

As most of you know, the Health Care Financing Administration, HCFA, is the federal agency that administers the Medicare program. In the program we have 39 million beneficiaries, 32 million of those beneficiaries are over the age of 65. We also have about 7 million beneficiaries who are under the age of 65. Five hundred thousand patients participate in the end-stage renal disease program, and about six and a half million people are covered by Medicare because of disability.

I am going to give you a brief overview of the coverage process at HCFA, as well as the payment policies. Within that discussion, I am going to answer some of the questions that were posed to HCFA by the Commission.

So, on your first slide you have basically the overall structure of the Health Care Financing Administration. The head of the Agency is known as the

administrator. This person is appointed by the President and confirmed by the Senate. Presently, we have an administrator designee, who is Tom Scully from the Federation of American Hospitals.

The centers or the offices that you would primarily be interested in are the Center for Health Plans and Providers, which we refer to as CHIP, because they deal with the physician fee schedule, some of the scope of practice issues, our payment policies relating to durable medical equipment and other policies of that nature.

Two other centers or offices would be the Center for Medicaid and State Operations, CMSO. I know many of you have had questions about Medicaid coverage policies, and that would be the office that would primarily deal with Medicaid issues.

The office that I am a part of is the Office of Clinical Standards and Quality. Within that office, we have a Coverage and Analysis Group. On your next slide, you will see that there are basically three divisions. There is a Division of Operations. There is a Division of Medical and Surgical Services, and then there is the

Division of Medical Items and Devices that I am a part of. The devices that I deal with are non-implantable devises. Those devices are in the Division of Medical and Surgical Services.

I refer you to our website, which is www.hcfa.gov, which is a great source of information. Much of what I say today is available on that website.

So, whenever we talk about coverage in the Medicare program, I have to refer to certain statutes. I guess you learn that you become somewhat a government person when you are able to quote statutes off the top of your head, and say Section 1862(a)(1)(A) of the Social Security Act, which I'm going to refer to, says that no payment may be made or expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

There are two points about that, and you really have to keep the statute in mind when you think about complementary and alternative medicine. The first is that the statute is phrased in the negative, that we shall not pay. So, the premise that a device, a service, or a procedure might be of some benefit to some patient

under some circumstance is not a criterion in which the Medicare program can base coverage decisions on.

Now, I can empathize as a physician, as a provider when people come to HCFA to talk to us about if only Medicare would cover something, then we would be able to collect the information to know that this is a good coverage policy. What I have to tell you is we have to start at square one, where we must know that there is data demonstrating effectiveness, because that is the way the statute is phrased.

The second point is that preventive services are not mentioned here. So, we talk about the diagnosis or treatment of illness or injury. So, in general, the Medicare program does not cover preventive benefits. I am going to come back to that, but, in general, we don't cover preventive medicine.

The other issue relating to the Social Security Act, it also defines providers and the scopes of services that some of them can provide. Now, I am going to come back to that a little later, because some of the issues relating to complementary and alternative medicine, there are providers that may not necessarily be recognized by

Medicare in order to be paid.

So, although you may feel that massage therapists may offer certain services, if they are not recognized as a provider by Medicare, we wouldn't have to authority to pay for those services by those types of providers.

Now, there are three general methods by which coverage decisions are made in the Medicare programs, and this is one of the most misunderstood concepts of the program. The first is that our Medicare contractors, and there is a contractor in every state and some contractors cover more than one state, there is not actually 50 carriers, there is approximately 43. The reason I say approximately is because sometimes they change, so in the course of a week, it might be 42 or 44. So, approximately 43 contractors develop local medical review policies, which we refer to LMRPs.

Basically they consult with a group of practicing providers, beneficiaries, and others in their community as a part of a carrier advisory committee. Then they publish in their bulletin what a draft policy is, and then it becomes effective within a certain period

of time.

A great source of information on these LMRPs, local medical review policies, can be found at www.lmrp.net.

Now, HCFA also develops national coverage policies, and that is where I spend 100 percent of my time, looking at national coverage policies; but the reality is that in 35 years, 36 years in the Medicare program there are 250 to 300 national coverage policies. There are 6,000 local medical review policies.

So, the point I'm trying to make for you is that although everyone thinks of Medicare as a national program, and, indeed, it is a national program, there is a significant amount of carrier variation. This discretion on the part of carriers sometimes does cause disparity and beneficiaries will often be very concerned, and members of Congress will be concerned for their beneficiaries when they find that you can get a certain device or procedure or perhaps transurethral needle ablation of the prostrate for BPH in a state like Texas, but if you looked in Arkansas, you might not be able to. People can't really understand that, because they think

of it as a national program.

Yet, at the same time, many people from the medical device industry, which predominately are small companies, not the typical large pharmaceutical company, they often contract or work with a group of local physicians, their local academic medical community, and with 43 carriers, they may be able to get a few carriers to cover it for a period of time and, therefore, they can have some diffusion of technology.

So, there are both strengths and weaknesses of care or discretion. Sometimes it causes disparity, but at the same time, it can also have diffusion of technology.

Other important points there are that local medical review policies are subject to greater appeal. Beneficiaries will often appeal to administrative law judge if claims are denied, whereas national coverage policies have less ability to be appealed. There are going to be some changes in some recent congressional action. But the point I'm trying to make to you is that there may be opportunities for all of you to work with our local carriers to think about coverage policies for

some of your therapies. Everything does not always have to be done at the national level.

So, if you leave with one thing from my talk, you should remember that there is local carrier discretion, and that might be something that you want to explore within the context of Section 1862(a)(1)(A) of the Social Security Act.

The next slide talks about that Medicare is a defined-benefit program. This is also important for you to know. There are approximately 55 statutorily defined benefit categories, and you must fit into a benefit category as a first step towards coverage.

They are very broad categories, physician services, physical therapy, occupational therapy, durable medical equipment. But the point is, Congress defines what these benefit categories are. The Health Care Financing Administration does not have the ability or authority to create a new benefit category.

Two points about this, I talked to you about preventive benefits, that in general the statute doesn't allow us, and you might want to say in your question session, but, Dr. Whyte, don't you cover Pap smears,

don't you cover mammography, don't you cover colo-rectal screening, they are all screening benefits, and you are right, they are. What I can tell you is that Congress has mandated each of those benefits and has written into statute, line by line, that the Medicare program shall cover those screening services, and that is because we don't have the authority to cover preventive benefits. So that is something for you to keep in mind.

In some questions that you posed to HCFA prior to this meeting, you asked me about the benefit category for chiropractic, and basically that is Section 1861(r), which basically refers to subluxation.

Now, after you fall into a benefit category, you then have to satisfy our process for what is medically necessary and reasonable. Another important point for you to remember -- so, now you know that we have local carrier discretion -- is the issue of FDA approval or FDA clearance, because a lot of people will come to us and say, but it is been approved by the FDA, so what is the holdup with Medicare, why isn't Medicare paying for it.

What we say is that FDA approval or more often

FDA clearance is a prerequisite but it is not a guarantee for coverage. The statutory language of the FDA is that something is safe and effective. Our statutory language is that it is medically necessary and reasonable, as I just referred to.

So, in many ways you could use the analogy of a supermarket, that FDA approval puts something on the shelf. Then HCFA has to come around as a prudent purchaser and decide what to put in that care. Hopefully, none of you would assert that everything that is on the shelf we have to buy. There needs to be some criteria, and I'm going to talk to you about what some of those criteria are that we use to determine what we are going to buy.

Basically, we have a process which relies upon authoritative evidence in demonstrated medical effectiveness. We want to see that benefits outweigh reasonably anticipated risks. We want to see evidence of improved health outcomes. Again, we want to know that something complies with our regulatory requirements.

The next slide, which is on Page 5 of your handout, is our process, basically in a schematic. I

know you can't really see it, it is not relevant for you to be able to read the writing. I see Dr. Ornish is looking very closely at it with its small print. But the point is for you to see that the process actually does flow, that there is some reason to what HCFA does, and there is an orderly process, and I'm going to go through that.

Basically, it all starts with a request. The reason why I am going over this for you is because at the end of the day in your ultimate deliberations later, you might want to talk about Medicare covering certain alternative medicine and complementary medicine policies, so you need to know what our process is, because I think that will give your recommendations greater weight.

It basically all starts with a request. It can either be internal, meaning that HCFA decides to do it, or it could be external. Our Federal Register Notice in April of 1999, which is on our website, explains this process. It must be in writing. It must identify the request as a request for national coverage determination. Then there needs to be some supporting documentation.

What we say as part of this process is that we

will get back to you within 90 days with some type of decision. I will explain what those decisions could be. But in terms of the supporting documentation, and this goes to some of the questions raised in the earlier discussion, we want to see a full description of the service in question, including the benefit category, because, remember, something has to fall into a benefit category.

We want to see a compilation of medical and scientific information currently available, because, remember, we say this is an evidence-based decision-making process, so there needs to be some body of evidence.

We want to know about description of clinical trials underway. We also want to know about the status of FDA activity.

So, when we talk about supporting documentation, I want to talk about some of the evidence that we look at. An important point here is that there is a continuum. There is randomized clinical trials. There is controlled case series. There is case reports. There is consensus statements.

The important point is that we look at everything. One of the criticisms of the new process is that we only look at randomized clinical trials. We have never said that, and if you look at our recent coverage decisions, and there is approximately 30 of them, we talk to the fact that there is a hierarchy of evidence and that really we need to look at everything. Randomized clinical trials are not always possible. There is some argument they may not always be ethical. But the point is there are other ways to do analytic studies, and that is the important point.

One of the previous questioners asked about does there need to be a body of literature. The answer, of course there needs to be a body of literature. For us, at least in our Division of Items and Devices, what we say is that we need to hold the same standards, both to conventional therapies, as well as some alternative therapies. Maureen, Steve, and I have talked about that maybe alternative is not the best word, because an intervention is an intervention is an intervention. Really, what we are trying to do is determine the body of evidence behind that intervention, to know that it works.

I think Dean Ornish is a very good example of what has been done in terms of trying to use the scientific method that has answered questions. What I have seen from Dr. Ornish is not simply assertions that his constellation of services works, but rather he has asked the appropriate analytic questions. He has designed an appropriate scientific study. He has used statistical methods to analyze that data. Then he has published it in peer-reviewed scientific literature in very well-respected journals.

So, when you talk about body of literature, I would urge you to look at the example of Dr. Ornish and what he has done to really try to show that there is evidence of effectiveness. I am sure he will tell you how much difficulty he still had with that approach, even though that is the preferred approach.

So, it is something that I really want to emphasize, that there does need to be a body of literature. Everything doesn't have to be a randomized clinical trial. But I think at times, sometimes the field of alternative medicine has not benefitted from some of the supporters and advocates who really don't

want to have a scientific literature base. I'm using it in a very broad sense, because clinical consensus and other opinions are important as well.

As part of the process, we often order technology assessments, and this goes to the whole body of literature, and it is just something for you to know, that there are 13 evidence-based practice centers of the Agency for Health, Research, and Quality, which we often use to do technology assessments.

We also have a Medicare Coverage Advisory Committee. Presently there are six panels, medical, surgical, drugs -- biologic, therapeutic -- laboratory, medical devices, durable medical equipment and diagnostic imaging.

An important point here is that we presently are soliciting new nominees. We have about 100 members, and they are on a rotating -- not rotating, I'm blanking on the word -- but a third are expiring this year. So, we are looking for new members. Nominations are due by May 30th. On our website it describes how you can apply to be a member of the Medicare Coverage Advisory Committee.

So, I suggest that you look at that, because some of you might be interested in that. We do accept self-nominations, although it is always good to be nominated by someone, but we do accept self-nominations.

Earlier, I talked about a formal request, which I think all of you should consider for some of your therapies, what we say is we will get back in 90 days. What are some of the decisions that we can make in those 90 days? That also assumes that we might have ordered a technology assessment or referred something to Advisory Committee, which obviously would take longer than 90 days.

There could be national non-coverage, meaning that we forbid the carriers to cover it under any circumstance. There could be no national decision, and essentially we will leave it to carrier discretion, where most policies are done. There could be national coverage decision with limitations. An example of that, someone referred to the insulin pump earlier, we presently only cover the continuous subcutaneous insulin infusion pump for type one diabetics. There could be national coverage decision without limitations.

So, that is something for you also to think about, because some people will come to HCFA and ask coverage for everyone. That may not necessarily be wrong, but at the same time, when we talk about an evidence-based approach, there may be more appropriate patient populations that would benefit from a therapy, and sometimes coverage policies have to be incremental. You first look to see where the greatest body of the literature is and look at that patient population first. So, that is something that I would encourage you to look at, as well.

Basically, when we make a coverage decision, there still is some time lag until a decision is implemented. So, I wouldn't want you to get all excited and think that you are going to submit a national coverage request and then in 90 days it will be able to be covered. That is not necessarily true.

What we say is that in some ways it is like a law. Not all laws take effect at day one. What we say is that within 180 days from the next full calendar quarter we hope that payment is effected. We actually have been doing better in recent months, and we continue

to strive to do better, but that is just something that I want to alert you all to.

Two other points that I want to touch very briefly upon, because I anticipated that you all would have a lot of questions, so I want to be able to be sure that you are able to ask those, is that we do have a clinical trial policy, presently issued in the Executive Memorandum earlier last year, basically telling us that we would cover the routine patient care costs for clinical trials.

I'm not going to go into it in this discussion, because most of the information is available on our website, and I encourage you to look at it.

The only other point I wanted to touch upon are two demonstrations that we are doing, which I think all of you are very familiar with. I have enclosed information on those in your packet. The first is the Dean Ornish program for reversing heart disease and the second is the cardiac wellness extended program by Dr. Herbert Benson, involving up to 1,800 patients in each of those programs. Basically, it will extend from October '99 to November 2003. The handout that I have enclosed

basically provides most of the information.

Some other attachments that I have included is more specific information on our payment policies and basically how we determine how much providers are paid for various services.

That is mostly what I am going to say. I have my contact information and phone number at the end of my slides. I realize that HCFA can be a confusing place at times. I know very well, I know Maureen knows that HCFA can be confusing, as well.

Certainly, you should feel free to contact me directly if you have questions or concerns. As I said, I will be here most of today. Other people from my division will be here later in the week. I encourage you to continue the dialogue, which I think will be very productive. I look forward to working with all of you. Thank you.

DR. GORDON: Thank you very much. Thank you for the clarity and directness of the presentation.

The next presenter will be Abby Block from the U.S. Office of Personnel Management.

MS. BLOCK: Good morning. I'm Abby Block. I

am the Assistant Director for Insurance Programs at the United States Office of Personnel Management. I thank you for inviting me here this morning to talk with you about the Federal Employees Health Benefits Program.

You asked for some background information about the program. President Eisenhower in February of 1954 called for a health program for federal employees in line with the best practices of progressive private employers and indicated that a health insurance program should be part of a well-rounded personnel program.

Public Law 86382, the Federal Employees Health Benefits Act of 1959 was enacted on September 28th of 1959. The program actually became up and running in July of 1960. So, it has been around for some time now, as you can see. There have been very few changes to that initial legislation over the years. Basically, what was enacted in 1959 is very much in place today, with very small changes.

The reason that that is possible is that the statute was very much a framework statute, giving a lot of flexibility, so that we have been able to accommodate all of the changes in health care that have taken place

over these many years and still operate within that initial enabling legislation.

The legislation gave the Civil Service Commission, which is now OPM, the authority to contract with certain types of health benefits plans for a broad range of services, including hospital benefits, surgical benefits, ambulatory patient benefits, pharmaceuticals, other medical supplies and services. But the law is very, very general in terms of coverage. It really simply states that there has to be a comprehensive benefits package.

It specified that those eligible for coverage are employees, and we cover 2.2 million active employees, retirees, and we cover 1.9 million retirees at this time. Of those, the retirees with Medicare, there is 1.3 million of those. Under our program, retirees who are Medicare-eligible continue to be eligible for FEHB coverage. They pay the same premium as active employees and receive the same benefit package, but the Medicare program is their primary payer.

That is sort of an interesting construct, because Medicare, as you know, was enacted after the

Federal Employees Health Benefits Program and no change was made to the program to date to try to integrate those two programs. So, we work through a coordination of benefits process, and it works reasonably well.

We cover 4.6 million family members, and that includes spouses, children, and former spouses. The law also specifies the method of determining the government contribution for the program.

The legislation did not specify benefit levels for that range of services. While it talks about a range of services, it makes no mention of the level at which coverage will be provided.

OPM provides direction to the carriers through an annual call letter, through regular carrier letter mailings. We hold an annual health plan conference each year, and our health benefit specialists, our contract specialists, have day-to-day interaction with the carriers.

There are several types of plans in the FEHB program. We have a group of open-fee-for-service plans. Those include plans like the Blue Cross Blue Shield Service Benefit Plan, the GEHA Plan, the Mail Handlers

Plan. Those are open to all on a nationwide basis. They cover 5.7 million lives, 1.3 million employees and 1.5 million retirees, of which 1.1 million are Medicare enrollees, and family members, 2.9 million family members.

We also have a group of so-called closed-fee-for-service plans. Those plans are limited to people who either work for a certain agency or belong to a certain association, such as the Secret Service, the Foreign Service. Those are open to specific groups nationwide. They cover 209,000 lives, of which 42,000 are employees, 59,000 are retirees, and 34,000 of those retirees are Medicare covered. They also cover 108,000 family members.

The other type of plan that we have in the program are the HMOs, Kaiser, Pacific Care, Aetna, US Healthcare, those types of plans. As you know, they serve particular geographic areas.

We have 2.7 million lives covered under the HMOs, 879,000 employees, 307,000 retirees, of which 161,000 are Medicare eligible, and 1.6 million family members.

That breaks down, by the way, I don't know that we gave you the percentages here, but the breakdown is approximately 70 percent in the fee-for-service type plans, 30 percent in the health maintenance organizations.

In terms of the number of plans available, wherever a federal employee or retiree happens to live, they have a minimum of seven plans available to them. Those would be those national open-to-all fee-for-service plans. In some geographic areas, because of the HMO penetration, a person could have as many as 31 health plans available to choose from.

The definitions are very broad and flexible. As I said earlier, the law gave us a lot of flexibility, which is why we can still operate under it even though it was enacted in 1959. The government-wide plans and employer organization plans now have a very strong PPO component, so that we don't contract with PPOs, per se, all of those fee-for-service plans are in fact PPO organizations.

In-network services are the services most often used by consumers. The reason for that really is the way

we structured the PPO networks when they were introduced in the 80s, we did not have a penalty for going out of network, but we offered a real financial incentive for using network providers. That is, the in-network benefit is a richer benefit than the out-of-network benefit.

The out-of-network benefit is the standard benefit, it is the benefit that was in place before the PPOs came into being, but when the PPOs were introduced, the carriers actually improved the benefits that were available if a person elected to use a PPO provider.

We contract bilaterally with each plan on an annual basis. We are just getting to the point of beginning annual benefit and rate negotiations. Actually, the benefit rate proposals from the health plans are due to use by regulation on May 31st each year, so we are getting very close to that May 31st deadline. Then, bang, beginning June 1st, negotiations start, and I will talk a little later about the time frames for that process.

Each plan must contain detailed statement of the benefits which it includes, including its maximums, its limitations, its exclusions, and other definitions of